Factors that Influence the Recognition, Reporting, and Resolution of Incidents Related to Medical Devices and an Investigation of the Continuous Quality Improvement Data Automatically Reported by Wireless Smart Infusion Pumps

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Thesis submitted to the
Faculty of Graduate and Postdoctoral Studies
in partial fulfillment of the requirements
for the Doctorate in Philosophy degree in Epidemiology

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CO-AUTHORSHIP

The content in this thesis were designed, analyzed and interpreted by the author of this dissertation, Julie Polisena, as part of her doctoral work. Three manuscripts based on Chapters 2, 3, and 4, were co-authored by Tammy Clifford, Anna Gagliardi, David Urbach, Hal Hilfi, Mario Bédard, Rana Chreyh, and Michelle Fiander. These aforementioned authors provided conceptual, editorial, and interpretive assistance for the studies.

ACKNOWLEDGEMENTS

I would like to extend my sincere gratitude to all those who gave me the opportunity to complete my doctoral thesis. Firstly, I wish to thank my thesis supervisor, Dr. Tammy Clifford. I am especially grateful for her constant encouragement in my doctoral studies and career advice. I look forward to our continued work together and her mentorship. Secondly, I wish to thank members of my thesis advisory committee, Drs. Anna Gagliardi, Adam Elshaug, and Craig Mitton, for sharing their valuable insights. Notably, the systematic review and telephone interviews would not have been possible without Anna's guidance and expertise. There are several individuals who provided some assistance during my thesis. I would like to acknowledge Mike Tierney, Hal Hilfi, Mario Bédard, Rana Chreyh, Felipe Castro, Drs. David Urbach, Anthony Easty, and Alan Forster. Thank you to my colleagues, Andra Morrison, Jeannette Smith, Michelle Mujoomdar, and the Information Specialists at the CADTH. A special thank you goes to the surgeons and registered nurses who participated in the telephone interviews despite their busy schedules. Lastly, I would like to thank my remarkable parents, family members, and friends, notably Jim Ramuglam and Ray Banks, for their support and genuine interest in my doctoral studies.

ABSTRACT

Medical devices are used to diagnose, treat, or prevent a disease or abnormal physical condition without any chemical action in the body. They can also result in unintended incidents and other errors. This thesis was divided into three chapters: i) a systematic review on the recognition, reporting and resolution of incidents related to medical devices and other health technologies; ii) telephone interviews with physicians and registered nurses (RNs) to solicit information on the resolution, reporting and resolution of medical device-related incidents based on their professional experience; and iii) a case study to review the continuous quality improvement (CQI) data retrieved from the wireless smart infusion pump system at The Ottawa Hospital (TOH) and to propose a CQI data analysis process. The systematic review included 30 studies on factors that influence the recognition, reporting and resolution of incidents in hospitals and interventions to improve patient safety. Central themes that emerged for incident reporting were personal attitudes, awareness and perception of incident reporting systems, organizational culture, and feedback to healthcare professionals. In our telephone interviews, physicians and RNs attributed incident recognition to devices not operating based on the manufacturer's instructions, and to the hospital staff's knowledge of and professional experience with the use of the medical device, and clinical manifestations of patients. Suggestions to improve medical device safety surveillance centered on education and training to ensure that the staff is able to use the medical device properly and know what would be considered an error, and how to report these errors. The results of the systematic review and interviews helped to inform the design of a medical device surveillance framework in a hospital setting. Our case study assessed the Dose Error Reduction Software compliance and frequency of soft and hard limit alerts with wireless smart infusion pump systems over a one year period. A CQI data analysis process to monitor the

performance of wireless smart infusion pumps is proposed. The findings of this doctoral thesis can contribute to the development of a medical device surveillance system that would help to improve health care delivery and patient safety in a health care institution.

KEYWORDS: medical devices, health technology, post-market surveillance, incidents, medication errors, infusion pumps, continuous quality improvement, patient safety, hospital

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Chapter 1

1.0 BACKGROUND AND RATIONALE

The US Food and Drug Administration (FDA) defines a medical device as an instrument used to diagnose, treat or prevent a disease or abnormal physical condition without any chemical action in the body.[1] Medical devices are used to monitor, replace or modify anatomy or physiological processes. They enable effective diagnosis and treatment, use less invasive techniques in many instances, and improve health care delivery and patient outcomes.

The Medical Device Lifecycle

The medical device lifecycle can be presented in four main phases: development, regulatory approval, health technology assessment (HTA), and post-market surveillance (PMS). The development of a medical device is an iterative process that consists of prototypes, quality assurance, product improvements, re-testing and continuous modifications until optimal performance has been achieved. After the device is on the market, modifications can continue based on the user experience and product evaluations.[2]

Medical devices are categorized according to the potential risk that they pose to the patient.[3,4] These categories determine the evidence necessary for regulatory approval. Although randomized controlled trials (RCTs) are considered to be the "gold standard" in the evidence hierarchy, they are not required to demonstrate the clinical effectiveness and safety compared with drug therapies.[5] Clinical data to demonstrate both the efficacy and safety of new class III

medical devices are required in the US. In contrast, the European regulatory authorities are concerned principally with the safety of the medical devices.[6] Although industry is required to conduct studies on human subjects, there are no guidelines on the sample size, design, or follow-up period.[4,7] Health Canada assesses all medical devices for their clinical effectiveness, safety, and quality for licence approval in Canada.[8] The regulatory body categorizes medical devices as class I, II, III, or IV. For class II and above, manufacturers require a licence issued by Health Canada before they can be sold or advertised in Canada, and these licences must be renewed annually. Exceptions to the application process are investigational testing in human clinical trials and the special access program.[9]

The International Network of Agencies for Health Technology Assessment defines HTA as a multidisciplinary field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology.[10] The results and recommendations of a HTA support informed decision making on the use of specific health technologies, such as drug therapies, medical devices, screening and diagnostic tests, and surgical and non-surgical procedures, in clinical practice. The current HTA methodological framework may not capture the complexities of the design and application of medical devices on patients. An European initiative, the MedtecHTA project, aims to address the shortcomings of the existing HTA framework and to develop a tool that will provide an evidence-informed approach for decisions the effectiveness and safety on complex health technologies.[11]

Stronger PMS represents a feasible method to lower the risk of device-related adverse events. The data collected can enable us to address the risks of device-related adverse events sooner via

the earlier detection that is facilitated by structured surveillance systems. It can monitor safety and effectiveness without impeding access to innovative devices; identify and communicate incident data to avoid further events; guide the development of training, organizational process improvement, or other patient safety interventions; direct decision-making about funding or replacement by purchasers and policy-makers; and potentially even inform the total product lifecycle by manufacturers.

Medical device licensing differs from the requirements for drug therapies. There is little evidence supporting the safety and effectiveness of most medical devices. As a result, medical device problems can surface years later after they have been used or implanted in thousands of patients. We argue that major changes to the device approval process are unlikely, and policies intended to detect and reduce harms of medical devices must instead target the PMS space.

Medical Devices and Determinants of Device-related Incidents

Incidents among medical devices have garnered widespread attention through frequent media reports of injuries, recalls, and class-action lawsuits. Such devices include catheters, infusion systems, surgical instruments, and implantable devices, including surgical mesh, pacemakers, stents, defibrillators, and artificial joints.[12,13] Research to date consists of small observational studies that describe incident rates but have not investigated the type and number of and reasons for device recalls.[14-20] For example, audit of the UK National Patient Safety Agency over seven months found that 1,021 of 12,084 incidents were due to devices, but reports lacked specificity about the devices, their associated procedures, and outcomes.[13] More information is needed to

identify devices associated with incidents and the nature of those incidents to establish a baseline description of the problem.

Data on the type, rate and reasons for medical device warnings or recalls, and the quantity and quality of evidence supporting licensed devices would help us to understand how device surveillance could be improved. Information on current hospital surveillance systems for reporting device incidents, or factors that influence incident recognition, reporting and resolution is lacking. Studies in this area are required to understand how PMS for devices could be improved.

Infusion pumps are examples of a medical device that are used to administer fluids, nutrients and medications into a patient's body in a controlled manner.[21] They are affiliated with medication errors that can lead to severe harm or death in patients and increased costs to the health care system.[22] Drug dosages and concentrations are programmed manually in traditional infusion pumps, so they are at greater risk for errors of incorrect dose and infusion. Smart infusion pumps are automated technologies that incorporate dosage limits, alerts to the user when dosage limits are exceeded, configurable settings by patient type, and clinical care area and access to patterns of use. They have the capacity to collect data that can provide some insight to the soft limits exceeded, hard limits attempted, and rate advisory changes, and identify quality improvement opportunities by reviewing current practices.[23] Subsequently, these data are presented in continuous quality improvement (CQI) reports for review by the institution. Drug library parameters are programmed by the hospital pharmacy with input from multidisciplinary teams across the institution and can be revised for correction purposes or to reflect clinical practice.

More studies on the effectiveness of smart pumps versus traditional pumps on medical errors are merited.[24]

1.1 THESIS OVERVIEW

Previous studies developed frameworks on factors that contribute to patient safety incidents[12,25] and on barriers and motivators to incident reporting.[26] Results of these studies found that factors related to active failure in performance or behaviour, user, team, institution, system, culture, training, accountability and patient safety or incident reporting. To date, most studies focused on incident rates and not on the appropriate design of a hospital medical device surveillance system.[14,15,17,19,20,27] More information on current surveillance systems, and a deeper understanding on factors that influence incident recognition, reporting, and resolution, therefore, would help to enhance existing or develop new surveillance systems.

This thesis aimed to investigate factors that influence the recognition, reporting, and resolution of medical device-related incidents by health care professionals related to the use of medical devices in hospitalized patients and to review interventions to improve medical device surveillance in a hospital facility. These objectives were assessed through a systematic review of the medical and grey literature related to health care technologies (Chapter 2). As most of the literature was not specific to medical devices and focused on incident reporting, sixteen physicians (n=12) and registered nurses (n=4) at two teaching hospitals in Ontario, Canada were interviewed to discuss their professional experiences with the use of medical devices in their local setting. They also were solicited to share their suggestions or interventions to improve medical device surveillance to mitigate potential device incidents. The findings of the systematic

review and qualitative research help to inform the design of a conceptual framework for a hospital medical device surveillance system (Chapter 3). Finally, a case study was conducted to review the CQI data collected by the infusion pumps over a one year period. A formal CQI data analysis process was designed to monitor the impact of the wireless, smart infusion pumps on the Drug Error Reduction Software compliance and frequency of hard limits attempted (Chapter 4). All three studies were exploratory in design, but they provide some comprehension on the design and development of an effective surveillance system to improve patient care and health services delivery in a hospital setting.

1.2 MANUSCRIPTS

Four manuscripts were prepared based on chapters 2, 3, and 4 of this thesis.

The first manuscript, "*Factors that Influence the Recognition, Reporting, and Resolution of Incidents Related to Medical Devices and Other Healthcare Technologies: A Systematic Review*", was based on Chapter 2 of the thesis and has been published in Systematic Reviews (*Systematic Reviews* 2015, 4:37). Julie Polisena led the systematic review and preparation of the manuscript. Anna Gagliardi, David Urbach, and Tammy Clifford contributed to and reviewed the draft version of the manuscript. Michelle Fiander developed and ran the literature search and reviewed the draft versions of the manuscript. All authors read and approved the final manuscript.

The second manuscript, "*Factors that Influence the Recognition, Reporting, and Resolution of Medical Device-Related Incidents in Hospitals: A Qualitative Study of Physicians and*

Registered Nurses", was based on Chapter 3 of the thesis and has been published in the BMC Health Services Research (*BMC Health Services Research* 2015, 15:220). Julie Polisena led the qualitative research and preparation of the manuscript. Anna Gagliardi participated in the qualitative study and contributed to and reviewed the draft version of the manuscript. Tammy Clifford contributed to and reviewed the draft versions of the manuscript. All authors read and approved the final manuscript. A third manuscript, "A Proposed Framework to Improve the Safety of Medical Devices in a Canadian Hospital Context" was published in *Medical Devices (Auckland, NZ)*. 2014;7:139-147. Julie Polisena led the design of the framework and preparation of the manuscript. Jeff Jutai and Rana Chreyh contributed to and reviewed the draft versions of the manuscript. All authors read and approved the final manuscript.

A draft manuscript, *"Continuous Quality Improvement Data Reported by Wireless, Smart Infusion Pumps: A Case Study"* was based on Chapter 4 of the thesis and will be submitted to the *American Journal of Health System Pharmacy*. Julie Polisena led the case study and the manuscript preparation. Hal Hilfi, Rana Chreyh, Mario Bédard, and Anthony Easty contributed to and are reviewing draft versions of the manuscript.

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Chapter 2

Factors that Influence the Recognition, Reporting, and Resolution of Incidents Related to Medical Devices and Other Healthcare Technologies: A Systematic Review

2.0 ABSTRACT

Background

Medical devices have improved treatment of many medical conditions. The use of devices can lead to unintended incidents, potentially resulting in unnecessary harm, injury, or complications to the patient, a complaint, loss, or damage.

Objectives

Our research objectives were two-fold: i) to explore factors that influence device-related incident recognition, reporting and resolution; and ii) to investigate interventions or strategies to improve the recognition, reporting and resolution of medical device-related incidents.

Methods

We searched the bibliographic databases: MEDLINE, Embase, the Cochrane Central Register of Controlled Trials, and Pubmed. Grey literature (literature that is not commercially available) to locate studies on devices frequently identified hospital incident reporting systems, the nature of those incidents, and factors that influence incident recognition, reporting and resolution published from 2003 to 2014.

Results

Thirty studies were included. The results indicated that fear of punishment, uncertainty of what should be reported and how incident reports were used and time constraints to incident reporting are common barriers to incident recognition and reporting. Relevant studies on the resolution of incidents or impact of interventions or strategies to improve the recognition, reporting and resolution of device-related incidents were not found.

Conclusions

The available evidence on factors influencing incident recognition, reporting, and resolution by health care professionals suggest various theories can inform data collection and analysis in future studies. Further research should investigate the impact of human, system, organizational, and education factors on the development and implementation of local medical device surveillance systems.

2.1 BACKGROUND

The US Food and Drug Administration (FDA) defines a medical device as an instrument used to diagnose, treat or prevent a disease or abnormal physical condition without any chemical action in the body.[1] Devices may be used to monitor, replace or modify anatomy or physiological processes, and have improved care delivery and associated outcomes for many conditions. Studies, however, have found that devices were involved in up to 62% of all unintended incidents in general health care systems.[2-8] Incidents can be defined as an event or circumstance that could have, or did lead to unintended or unnecessary harm to person, a complaint, loss or damage.[9,10]

Widespread concern about device-related incidents has prompted numerous calls for enhanced monitoring as evidenced by many editorials in prominent international medical journals.[11-13] It is a great challenge to claim any marketed product as risk-free. Since research to date has been largely limited to describing incident rates, the optimal design of a surveillance system in a hospital context remains unclear.[3-8] Post-market surveillance (PMS), therefore, represents a crucial approach to prevent and mitigate potential harm associated with the use of devices. PMS would monitor safety and effectiveness without impeding access to innovative devices, identify and communicate incident data to avoid further events, and guide the development of training, organizational process improvement, or other patient safety interventions, direct decision-making about funding or replacement by purchasers and policy-makers, and potentially even inform device improvement by manufacturers. Several limitations of post-market device surveillance were identified. For instance, an audit of the UK National Patient Safety Agency over seven months found that 1,021 of 12,084 patient safety incidents were due to devices,[6] but lacked

details about the device, procedure, outcomes, and factors causing the incident. The UK National Patient Safety Agency audit found that device-related incidents were caused by device failure (43.8%), inappropriate use (29.3%), lack of training (12.3%), and inadequate maintenance (1.5%). The cause could not be determined for 13.1% of cases.[7] In addition to these factors, another review identified user error, environmental controls, and support system failure as determinants of device-related incidents.[2]

Medical Device Regulation and Classification Systems

Medical devices are categorized into different groups based on the potential risk that they pose to the patient, where class I poses the lowest risk.[14,15] The risk categories also determine the testing and evidence required for the approval process. Differences in the clinical testing and regulatory process between the US and Europe will impact the approval and introduction of a medical device to clinical practice. In the US, clinical data to demonstrate the efficacy and safety of new class III medical devices are required, while the European regulatory authorities focus on the safety of the medical devices. Subsequently, there is usually a one- to three-year delay in the introduction of a medical device to the US market compared with the European market.[16]

The regulatory processes in North America and Europe for new drugs necessitate the conduct of phases II and III randomized controlled trials (RCTs) in order to develop evidence on the efficacy and safety of the drug.[17] Unlike drug therapies, the approval process for class III medical devices typically does not require clinical effectiveness and safety data derived from a RCT.[18] On the other hand, manufacturers must perform studies on human subjects, but there are no standards on the sample size, design, or follow-up period.[15,17]

In Canada, the federal government assesses all medical devices for their clinical effectiveness, safety, and quality prior to sales authorization.[19] Most medical devices require a licence before they can be sold or advertised in Canada. Health Canada classifies medical devices as class I, II, III, or IV, where class I represents the lowest risk category and does not require a licence.[20] For class II and above, manufacturers require a licence issued by Health Canada that must be renewed annually.[20] Exceptions to the application process are investigational testing in human clinical trials and the special access program.[20] Applications for approval are submitted to and assessed by Health Canada.

Although thousands of medical device applications are submitted each year in the US, fewer than 100 that are considered to be high-risk devices go through a premarket approval (PMA). Instead, the majority of applications undergo a 510(k), where safety and effectiveness data are not always mandatory.[18] As a result, equivalent clinical evidence would unlikely be available across all medical devices, rendering product comparisons nearly impossible.[21] One study reviewed the scientific evidence in the FDA database of 50 implants that must be cleared through the 501(k) process between 2008 and 2012. The authors found that the legal requirement make available the scientific evidence of the substantial equivalence, safety, or effectiveness of these implants was not enforced.[22] Another study reviewed the clinical evidence generated for 28 high-risk therapeutic devices over the total product life cycle. These devices received initial market approval (i.e., pre-market approval pathway) between 2010 and 2011. The authors found a variation in the volume and quality of pre- and post-market studies, and 13% of initiated post-market studies were completed between three to five years following FDA approval.[23]

Once a medical device has been implemented, the manufacturer must report all deaths and serious adverse events and device-malfunctions experienced in clinical practice to the Medical Device Reporting program overseen by the FDA.[24,25] As part of the PMS phase, hospitals and other health care facilities also are required to report serious medical device-related injuries to the manufacturer, and deaths to both the manufacturer and FDA.[1] Depending on the data reported, the FDA may issue an investigation on the medical device in the form of a literature review, clinical trial, an analysis of complaint information, or a mandated registry.[1] Moreover, investigators may perform field inspections at the manufacturer site, or the regulatory authority may issue a public health advisory for a potential risk or a safety alert for an identified risk.[1]

In the European Union, regulatory authorities in each member state must report serious adverse events to a centralized European database, EUDAMED.[25]

In 1992, a voluntary collaboration of national regulatory authorities in the US, Canada, Europe, Australia, and Japan, called the Global Harmonization Task Force (GHTF), was formed.[15] This group intends to discuss and compare their approaches to the regulation and control of medical devices, as well as to establish uniform medical device regulatory requirements among the participating countries. As of 2011, the organization and membership of GHTF is under review to ensure a uniform implementation of the GHFT regulatory model.[26]

Medical device classification systems can facilitate the organization and sharing of information in an explicit manner. Such systems include nomenclatures (i.e., a system of labels, definitions, and codes to identify groups of medical devices for specific purposes), taxonomies (i.e.,

hierarchy of nomenclatures), and coding systems.[27] A medical device nomenclature or taxonomy defines the objective and scope of the terminology included and facilitate the coding, capturing and retrieval of information in a consistent way.[28] White et al. defined the key elements of a taxonomy or nomenclature for medical devices and diagnostics as follows: i) explicit terminology and a detailed description of each health technology; ii) comprehensive list of new and innovative medical devices; iii) hierarchical and structured system with some flexibility; iv) a coding system that facilitates communication, data manipulationand removal of linguistic barriers; v) appropriate number of categories and subcategories and level of information; and vi) interoperability with other systems used by providers and stakeholders.[27]

Several medical device nomenclatures are used globally to increase the transparency and traceability of medical devices. The common ones are the Global Medical Device Nomenclature (GMDN), the Universal Medical Device Nomenclature System (UMDNS), Unique Device Identification (UDI) System, and Systemized Nomenclature of Medicines-Clinical Terms (SNOMED CT).

The GMDN is a system that provides standardized descriptors for medical devices and diagnostic tests.[27] It aims is to provide health authorities and regulators, health care providers, medical device manufacturers and suppliers, regulators, and others with a naming system that will support patient safety. The structure of a GMDN preferred term for medical devices includes a five-digit code, term name, and a definition. The system is used for data and information exchange among manufacturers, regulators and healthcare authorities and to support inventory control, purchasing and supply chain management in hospitals.[27,29]

The Universal Medical Device Nomenclature System (UMDNS) is another classification system for medical devices and supplies, clinical laboratory equipment and in vitro diagnostics, genetic tests, medical software related to devices, selected hospital furniture, systems and test equipment, as well as personal and assistive devices that been in use over several decades and is managed by the ECRI Institute. The system aims to facilitate the identification, processing, filing, storing, retrieval, transfer and communication of data on medical devices.[29] Similar to the GMDN System, UMDNS terms are generic, and they are assigned a five-digit code.

The objective of the Unique Device Identification (UDI) System is to assign a unique identifier to medical devices in a globally accepted standard format. A UDI system was part of the FDA's strategy post-market surveillance for medical devices, and it became law under the FDA Act of 2007.[30] UDIs can allow hospitals to trace the devices and track of the number of devices in use, facilitate a more rapid identification of devices involved in adverse events, improve field service corrective actions, and help to reduce the risk of medical errors for physicians and patients by better integration of information on device use into medical records. The UDI format consists of a set of numeric or alphanumeric characters created by a coding system and UDIs are stored in the FDA's Global Unique Device Identification Database.[29,31] UDIs will be implemented in phases. For example, implantable, life-supporting, and life-sustaining devices are required to have a UDI number. To optimize the intended benefits of UDIs, they must be linked to a patient's medical records or insurance claims.[32]

SNOMED CT is a comprehensives system that maintains clinical health terminology and is owned by The International Health Terminology Standards Development Organisation. The objective is to provide common clinical terms in a health care setting.[27] The SNOMED CT International Medical Devices Project incorporate terms for medical devices and its content are derived from the GMDN database.[33]

Medical Literature on Patient Safety Incidents

We conducted a literature review on published and unpublished studies on patient safety incidents in hospitals. Lawton et al. developed a "contributory factors framework" from the published literature on factors that add to patient safety incidents in a hospital context. The authors found that two main contributory factors related to patient safety incidents were active failures (i.e., any failure in performance by the end-user) and individual factors (i.e., characteristics of the person delivering the care that may contribute in some way to active failures).[2,34] In addition, Pfeiffer et al. proposed a framework on barriers and motivators for incident reporting. They concluded that individual, organizational, and incident reporting systems factors impacted reporting behaviour.[35] While not specific to devices, a systematic review identified 1,676 factors contributing to patient safety incidents in 83 eligible studies, and categorized factors into 20 domains including active failure in performance or behaviour, clinician, team, institution, system, culture, training, accountability, and patient factors.[8]

Based on the results of our literature review, we were unable to identify studies on incidents associated with the use of health technologies have examined theoretical perspectives, such as human factors, cognitive psychology or sociology, which would reveal how systems, technology,

and human beliefs and behaviour influence device use, and incident identification and reporting.[36-38] Multiple interacting factors may influence the recognition, reporting, and resolution of device incidents, but we did not find any studies that have examined theoretical perspectives, such as human factors (i.e., how people use technology), cognitive psychology, or sociology, which would reveal how systems, technology, and human beliefs and behaviour influence device use, and incident identification and reporting.[36-39] To design optimal surveillance systems for use in a hospital facility, reporting mechanisms and incentives, and provider or organizational quality improvement interventions, and multi-disciplinary theory-driven information are needed to confirm and further understand these contributing factors.

Identifying Optimal Postmarket Surveillance Strategies for Medical Devices

In 2011, a one-day meeting was organized to discuss and prioritize the elements of a surveillance system. The participants represented different professions and perspectives and included researchers, clinicians, surgeons, government regulators, industry, and patient advocacy groups. Their recommendations identified research priorities for PMS systems to improve the implementation, monitoring, and use of medical devices. One of their recommendations centered on factors, such as barriers and facilitators, that influence reporting among patients, providers, and facilities.[40]

The World Health Organization published a 2011 report that highlighted the principles of operations, reported problems, use and maintenance for core medical equipment. They defined core medical equipment as, "technologies that are commonly considered as important or necessary for specific preventive, diagnostic, treatment or rehabilitation procedures carried out in

most health care facilities".[41] The majority of these devices were used in a hospital setting. More information on the nature of hospital-based surveillance systems, and the factors that influence incident recognition, reporting, and resolution, therefore, could be used to improve current, or develop new surveillance systems.

Objectives

To prevent or mitigate the impact of device-related incidents, a greater understanding of how to support recognition, reporting, and resolution of incidents is needed. This information could be used to inform the components and associated strategies of a PMS. The purpose of this study was to systematically review the literature and synthesize what is known about factors that influence recognition, reporting, and resolution of incidents, and the ideal features of hospital monitoring systems. Our study objectives were twofold:

1. To explore factors that influence device-related incident recognition, reporting, and resolution;
2. To investigate interventions or strategies intended to improve the recognition, reporting, and resolution of medical device-related incidents by health care professionals.

2.2 METHODS

Approach

The medical and grey literature (i.e., literature that is not commercially available) was searched systematically to identify and describe studies on factors that influence the recognition,

reporting, and recognition of the medical device-related incidents in a hospital. After preliminary searches, an insufficient amount of evidence specific to medical devices was identified. As our study objectives were focused on factors that influence the recognition, reporting, and resolution of medical device-related incidents and was not exclusive to the functionality of devices, we expanded the search to include other health technologies to include drugs, diagnostic and screening tests, and surgical and non-surgical procedures. We identified, categorized and analyzed the factors into various themes, and the results are presented according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) reporting guidelines.[42]

Literature Search Strategy

The literature search was performed by an information specialist using a peer-reviewed search strategy (Appendix 1).

Peer reviewed literature searches were conducted for the systematic review. The following bibliographic databases were searched: MEDLINE (1996-) with in-process records & daily updates via Ovid; Embase (1980-) via Ovid; the Cochrane Central Register of Controlled Trials via Wiley; PsycINFO database, and PubMed. The search strategy consisted of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were medical errors, post-marketing product surveillance, medical device recalls, and safety-based medical device withdrawals combined with prostheses and implants, adverse events, and medical errors. The final search strategy was determined after three test searches from which the authors selected potentially relevant citations. The potentially

relevant citations were used to validate the final search strategies. Systematic reviews were sought with the objective of providing investigators with potentially relevant syntheses from which studies not identified by the search strategy might be culled. The initial search was completed on December 31, 2013, and periodic searches were conducted until July 31, 2014.

Grey literature was identified by searching relevant sections of the Grey Matters checklist (http://www.cadth.ca/resources/grey-matters), which includes the websites of regulatory agencies, health technology assessment agencies, clinical trial registries, and professional associations. These searches were supplemented by hand-searching such as reviewing the bibliographies of key papers and through contacts with appropriate experts.

Eligibility and Selection

Selection Criteria

The literature search strategy did not specify a timeframe as we were concerned about the dearth of evidence on the topic. Upon reviewing the literature search results, we decided to include empirical quantitative and qualitative studies published from 2003 to 2014 that identified factors associated with medical device-related incidents in a hospital setting and were more representative of current practice. Although the initial study objectives focused medical device-related incidents, other health technologies, such as drug therapies, diagnostic and screening tests, vaccines, and surgical and non-surgical procedures, were eligible for inclusion given the dearth of evidence on this topic. The authors expanded the scope to ensure the comprehensiveness of the appropriate literature identified. The complete eligibility criteria in terms of subject matter and study design are outlined in Appendix 2.

Exclusion Criteria

In addition to not meeting the aforementioned selection criteria, articles that reported the nature or number of adverse events or incidents associated with the use of a health care technology without examining factors that influence their recognition, or reporting or how they were addressed were excluded. Studies that involved primarily trainees, such as medical students, interns or residents, were not relevant to this systematic review. Ineligible articles also included studies on automated surveillance systems using administrative data or medical records, automated adverse event or incident reporting by the health care technology itself, and advisories, warnings or recalls by manufacturers or regulators. Regional or national surveillance systems, even when the data are contributed by the hospitals, were not eligible. If a systematic review with literature search from 2003 to 2014 was eligible for inclusion, the individual studies were excluded so as to avoid double counting. Articles or outcome measurements in selected studies on contributory factors to or cause, frequency, rate, or type of errors, incidents or adverse events in a hospital facility also were excluded. Finally, articles in the form of abstracts, letters, commentaries, newsletter articles, or editorials were excluded.

Article Selection

The principal investigator (JP) and a research assistant (SM) independently reviewed the titles and abstracts of search results and selected articles for inclusion based on the eligibility criteria. Rather than resolving selection differences at this stage, all those selected for inclusion by at least one reviewer were retrieved in full-text since ultimate judgment about inclusion must often be reserved until the full text was examined. If more than one publication described a single

study and presented the same study results, the most recent paper was included. The full-text articles were reviewed independently by the principal investigator and the research assistant.

Data Extraction

A data extraction form was developed based on the published literature to collect information on study design and findings including factors, such as device features, failure or malfunction, clinician or institutional characteristics, system or patient factors, and types and severity of adverse events (Appendix 3). The principal investigator extracted data from all eligible studies. Data were reviewed independently by a research assistant. Any disagreements between the reviewers were discussed until a consensus was reached.

Quality Assessment

The main intent of our systematic review was to identify factors that influence the recognition, reporting, and resolution of medical device-related incidents and interventions and strategies to improve the recognition, reporting, and resolution of these incidents. The instrument used to assess the quality of the included studies varied by their design. There is no agreed-upon quality assessment tool for qualitative studies. We checked for the appropriateness of the research design, recruitment strategy and data collection, potential researcher bias, ethical considerations, data analysis, and reporting of study findings was reviewed for each study.[43] For comparative studies, the SIGN50 checklists for cohort and case-control were applied.[44,45] In general, the studies were assessed on their appropriateness of design to answer the research questions, potential risk of biases and confounding, as well as relevance of findings to our scope. One reviewer wrote the comments for each question in the quality assessment tool for individual

studies, and another reviewer verified the responses. The strengths and limitations of the individual studies were described.

Data Analysis

The extracted data were tabulated by the principle investigator and verified by the research assistant, noting differences between independently extracted information for the same article, and resolving those through discussion. Tabulated findings were examined to assess the quantity, design, and quality of studies. The factors contributing to incident recognition, reporting, and resolution, and interventions or strategies for their improvement were described.

2.3 RESULTS

Quantity of Research Available

The literature search identified 4,730 citations. From these, 81 potentially relevant full-text articles were retrieved for further scrutiny, and five potential articles were identified through hand-searching of full-text articles. Fifty-six studies were excluded if they focused on the cause, frequency, rate or type of incident, did not describe the incident reporting system, described a national surveillance system, or had an inappropriate study context, design or population. Two studies were excluded since they were published in languages not spoken by anyone on the research team. Thirty studies were selected for inclusion. The PRISMA flowchart in Appendix 4 details the process of study selection.

Summary of Study Characteristics

Study Characteristics

The publication years ranged from 2004 to 2013. Nine studies were published in the US,[46-54] five in the UK,[55-59] four in Australia,[60-63] three in Canada,[64-66] two each in Italy,[67,68] and in Korea,[69,70] and one each in Turkey,[71] China,[72] Pakistan,[73] France,[74] and the Netherlands.[75] Two studies examined incidents associated with the use of medical equipment or devices,[72,74] and one Canadian study investigated the barriers and facilitators to medication error reporting in four community hospitals.[64] The remaining studies did not focus on incidents related to the use of any specific health care technologies. Appendix 5 presents the main purpose of the studies and the corresponding frequency. Half of the selected studies (n=15) focused on the attitudes toward, barriers to, experience in, facilitators to, and/or perceptions of adverse event, error and incident reporting. Most studies were surveys (n=15)[46,48,49,52,54,57,60,63,65,67,68,70,71,73,74], six were interviews[51,56,58,59,66,69] and three were descriptive[50,55,72] and three involved focus groups.[47,53,62] Other studies were a review of patient records,[75] non-equivalent clinical trial,[61] and a mix methodology of interviews and focus groups.[64] The complete study characteristics of the included studies are outlined in Appendix 6.

Summary of Quality Assessment

The research objectives across all studies were explicit. Where applicable, a verbal or signed informed participant consent was obtained for most studies.[39,51,64,71,76] Three studies did not involve any participants,[52,55,72] but numerous studies described how participants were selected randomly to obtain various perspectives from health care providers.[51,64,71,74,76] None of the studies reported any potential biases as a result of the interactions and relationship between the researchers and participants, and Bodur et al. stated that participants completed the surveys in

silence and without any discussion.[71] To reduce the risk of researcher bias, Hwang et al. removed any survey questions that would influence the participants' responses.[71] Although many studies described the statistical analyses, where appropriate and presented them in detail, most did not discuss in great detail the contribution of study findings in relation to current practice or policy (Appendix 7). Overall, the studies were explicit in their objectives and description of study design and participant recruitment strategies. In most studies, however, the relationship between the researcher and study participant was unclear, and the potential impact of the study findings in the hospital setting was not mentioned, or the potential impact of the study findings on patient safety culture in hospitals was not discussed in many studies.

Summary of Findings

Details on the study findings are found in Appendix 8.

Factors that Influence the Recognition of Incidents by Health Care Professionals

Health Technology Features

In one study on the local medical equipment management system, attributes of manufactured products or their composed parts influenced occurrence and recognition of device incidents reports.[72] For example, the panel module and battery were common errors identified related to the portable physiological monitor. In the same study, sensors, probes, and cuffs were perceived to influence the recognition of errors due to pulling and tension by the patient.[72]

Factors that Influence the Reporting of Incidents by Health Care Professionals

Personal Attitude of Healthcare Professionals

Personal attitudes of healthcare professionals towards incident reporting were presented in 16 studies.[46,52-54,58-60,62-66,68,69,71,73] In a survey conducted in three public hospitals in Turkey, over 20% of respondents felt that error reporting was non-punitive, but a similar proportion were concerned that reported errors were recorded in their personnel file.[71] In another study, an increased number of staff were satisfied with newly implemented safety measures and had less fear of punishment in reporting a medical error.[52] Respondents in a Canadian study performed in four community hospitals listed patient and provider protection and professional compliance as incentives to report medical errors within their facility.[64] A survey of anaesthesiologists in Australia found that fear of blame and litigation and perceived lack of support from colleagues were common barriers to adverse event reporting.[60] Focus groups in three public hospitals in Adelaide, Australia felt that culture of blame, lack of knowledge about the process and what constitutes an incident, time constraints and complexity of reporting forms, lack of feedback, or lack of legal privilege afforded to the reporting process were barriers to incident reporting.[62]

Additional reasons cited in numerous studies for not reporting errors include not knowing what and how to report, fear of repercussion and punishment, mistrust and lack of confidentiality, organizational support, time and easy systems for reporting and follow-up.[53,54,63,66,68,69,73] Fear of blame, rejection of bureaucracy and managerial scrutiny, administrative sanctions, legal penalties, or perception that incident reporting does not improve patient safety were other reasons why physicians did not always report errors.[58,59,68,69,71,73] A Canadian survey of 125

radiotherapists, nurses, dosimetrists, doctors, and other staff in an academic cancer centre responded that lack of organization support, perception that the incident was not enough to report, concerns about personal reputation, and desire to avoid work interruption and just continue with their job, were common barriers to not reporting to an incident.[65] Based on the results of one survey, a greater percentage of physicians were less likely to report an error versus risk managers if the patient was unaware of it (24% versus 9%) or did not think that the patient would want to know about the error (32% versus 19%).[46]

Organizational Culture

The impact of organizational culture on error reporting was presented in four studies.[51,70,71,77] The findings of a US survey conducted in rural hospitals indicated that 71% of staff found their organizational culture supported error reporting, where blame was not associated with persons reporting medical errors.[51] One survey that assessed physicians' and nurses' perceptions of patient safety across three hospitals in Turkey found that the frequency of reporting errors ranged from 13% to 18%.[71] In another survey, 71% of health professionals did not believe that there was a culture of blame in their hospital.[51] A survey of over 850 nurses in eight hospitals in Korea was conducted to investigate their perception of patient safety culture at their institution. Over 30% responded that they worked on "crisis mode" where they tried to complete many tasks in a short amount of time. While 15.6% felt that patient safety was never sacrificed at their hospital, 12.2% felt that a patient safety problem existed.[70] Over 40% of members of pediatric cardiac teams in three academic hospitals found that their operating room (OR) culture was conducive to learning from their colleagues' mistakes, but over 60% found it a challenge to discuss mistakes when they occur in the OR.[77]

Awareness of Incident Reporting System

Four surveys evaluated hospital staff awareness of a local surveillance or reporting system.[49,52,63,74] In a survey of hospital staff knowledge of the medical device surveillance system in a Paris hospital, there were no statistically significant differences among the percentage of physicians, head nurses and nurses, other caregivers, and administrative staff in the correct identification of errors captured by the hospital device surveillance. A greater proportion of full-time and temporary nurses and other caregivers reported that they correctly knew whom to identify if faced with an incident compared with physicians and administrative staff.[74] In contrast, a larger proportion of doctors and nurses correctly identified medical device-related incidental situations that required the local surveillance system compared with other caregivers and administrative staff.[74] Among 120 internists surveyed in the US, 41% were not familiar with the safety process at their institution, and 33% knew how to report an adverse event or a near miss event that could have an adverse patient consequence but did not.[49] Another survey reported an increase in the staff awareness of the importance of patient safety and willingness to report safety errors one year after the patient safety program was implemented.[52] In a survey of doctors and nurses in hospitals in South Australia, over 90% of physicians and nurses were aware of the hospital incident reporting system.[63]

Perception of Incident Reporting System

Five studies explored the perception of health care professionals on their local incident reporting system.[46,51,57,63,77] In one survey, over a third of doctors were uncertain whose responsibility it was to write a report, did not see the relevance of reporting a near miss, or found the Australian

Incident Monitoring System (AIMS) and form too complicated and cumbersome to complete. Nurse responses, on the other hand, were more varied for the same questions. In the same survey, over 50% of doctors felt that the incident form was too time-consuming to complete or that the incident was too trivial to report compared with over 40% of nurses, who felt the same way.[63] One survey of 30 health care providers and administrators in eight rural hospitals expressed challenges associated with the transition from a manual to an electronic reporting system related to the training time and implementation and maintenance costs.[51] A web-based survey assessed the familiarity with reporting, reporting behaviour, and perceived obstacles to reporting in a general surgical setting. The responses indicated that nurses were significantly more likely than doctors to know where to find and to complete a form. In general, nurses also were three times as likely to report no-harm events compared with doctors. Factors that would impact the likelihood of reporting an adverse event for both nurses and doctors were level of harm, incident type, and profession.[57] Compared with physicians, a greater percentage of risk managers felt that current systems for physicians to report patient safety problems were adequate (57% versus 29%) and current mechanisms to inform physicians about errors that occur in their institutions in one US study.[46] Similarly, 57% of pediatric cardiac members reported that they knew the process for questions with regards to patient safety in their hospital department.[77]

Feedback to Health Professionals

Two studies described the health care professionals' perception on the feedback provided after an error was reported.[63,71] A study set in three public hospitals in Turkey found that at least 30% of hospital staff felt that the feedback on and communication about medical errors was open, received feedback informing staff about changes to practice or procedure based on reported

errors, were informed of errors that occur in their hospital units, were encouraged to discuss strategies to prevent future errors, and were comfortable in "speaking up" if they saw something that may negatively affect resident care. In the same survey, 47% of respondents were afraid to ask questions if something did not seem right.[71] A survey conducted in six hospitals in Australia indicated that over half of doctors and nurses felt that they did not receive any feedback following error reporting, nor were they able to determine if the reports led to actions or changes.[63]

Incentives to Incident Reporting

Respondents in a Canadian study performed in four community hospitals listed patient and provider protection and professional compliance as incentives to report medical errors within their facility.[64] Other incentives identified were to obtain immediate help for the patient, to learn from mistakes, and to develop a system to minimize repetition of incidents.[73]

Factors that Influence the Resolution of Incidents by Health Care Professionals

We did not identify any relevant studies on factors that influence the resolution of incidents by health care professionals. For our study, a resolution was defined as an intervention to reduce the risk of medical device-related incidents from occurring in the future.

Summary of Factors that Influence Recognition, Reporting and Resolution of Medical Device-Related Incidents

According to the findings in one study, a factor that influenced the recognition of incidents was related to health technology features. Personal attitudes of health professionals, including

perceived barriers, organizational culture, perception of incident reporting systems, education and training, as well as lack of feedback on error reports and action taken, influenced the health care professional's decision to report an error. Awareness and complexity of the surveillance system, knowing who the person responsible is, and an understanding of patient safety also had an impact on reporting. These factors may be linked to the promotion and training efforts from the hospitals for the participants in the selected studies. Relevant studies on the resolution of incidents were not identified (Appendix 9).

Interventions or Strategies that are meant to improve the Recognition, Reporting and Resolution of Incidents by Health Care Professionals

Eleven studies reported on interventions or strategies intended to enhance the recognition, reporting, and resolution of incidents by health care professionals.[49,60,61,67,69,73,75]

Interventions or Strategies for Recognition of Incidents by Health Care Professionals

One study measured the feasibility and utility of a 36-item real-time safety auditing during routine clinical work in the intensive care unit. Although there were some concerns with the amount of time required to complete the patient safety audit or potential impact on patient care flow, hospital staff generally support the audit initiative to detect errors and safety defects in clinical practice.[50]

Interventions or Strategies for Reporting of Incidents by Health Care Professionals

An anonymous survey revealed that 75% of anaesthesiologists in Australia agreed or strongly agreed that feedback, role models, legislated protection, ability to report anonymously, and clear guidelines are effective strategies to improve adverse event reporting.[60] In another study,

physicians stated that continuous monitoring of data quality based on prespecified standards and assessment of a health professional's performance by one or more individuals in the same field, evaluation of the current behaviours on safety and training and an improvement in procedures were potential strategies to improve adverse event reporting.[75] A non-equivalent group controlled trial measured the effectiveness of an intervention to improve incident reporting rates and the types incidents reported in two regional hospitals in Australia. The intervention incorporated education, various reporting options, change in report management and enhanced feedback. The results showed a significant improvement in reporting rates for both nurses and doctors in numerous hospital departments.[61] Another study explored measures to overcome barriers to incident reporting among 42 nurses across 42 general hospitals in Korea. The most frequently reported measures were the introduction of a reward system, improvement of reporting system, recruitment more staff for patient safety incident management, enhancement of safety culture, and education and training opportunities.[69]

Responses to interviews with 30 health care providers and administrators in eight US rural hospitals indicated that an electronic reporting system would be useful and can reduce the reaction time after the error had been reported. Moreover, some features in a reporting system that would increase acceptance and utilization by hospital staff members include user-friendly features, fast, minimal training requirements, accessibility, and provide statistics upon report.[51] In an anonymous survey of 120 physicians, over 50% of respondents felt that electronic and anonymous reporting and clarification on what constitutes adverse events or near misses and the reporting mechanism would very likely increase incident reporting.[49] In another study of 217 participants, 60.5% of doctors (n=69/114) and 80.5% of nurses (n=83/103) felt that reporting

would be easier if reports were addressed to the head of the hospital department.[73] Jeffe et al.'s study identified numerous facilitators to error reporting. They were as follows clear guidelines, clarification of reporting mechanisms and training of health care providers, nonaccusatory environment, anonymous reporting mechanisms, sufficient personnel and efficient reporting tools, and routine follow-up of error reports.[53]

Interventions or Strategies for Resolution of Incidents by Health Care Professionals

Henneman et al. conducted focus groups to explore error-recovery strategies used by critical care nurses. Participants indicated that knowing all aspects of the patient, other patients in the unit, the plan of care, and referring to critical care policies and procedures, hospital accreditation, and unit-based and other standards as examples of effective strategies to identify or correct errors.[78] One hospital in the UK introduced several changes in clinical practice as a result of device incidents reported for vitreoretinal surgery to reduce the risk of similar errors from reoccurring.[55] A survey of over 600 physicians (n=696) in hospitals across Italy investigated their attitudes about preventing and managing medical errors. Over 85% of respondents agreed to discuss with colleagues about medical errors (n=98.4%), increase information seeking to reduce recurrence of medical errors (n=96.8%), and report medical errors to their institution to improve the quality of care (n=87.6%).[67]

2.4 DISCUSSION

Summary of Evidence

Our systematic review identified 30 studies on factors that influence whether and how incidents

are recognized and reported by hospital staff and strategies to improve their recognition, reporting, and resolution. The majority of studies in this review focused on factors that influence error reporting. While health technology features was identified as a factor in the recognition of incidents in one study, the central themes identified for the reporting of incidents were personal attitudes, awareness, and perception of incident reporting systems, organizational culture, and feedback to healthcare professionals. More specifically, awareness of current local surveillance system or to whom to report the incident and the complexity of the surveillance system or database were discussed by health care professionals across numerous studies. Fear of punishment, lack of trust and lack of familiarity with local reporting systems and processes, however, were common barriers to medical error or incident reporting. The study participants indicated that they would report errors more frequently if reporting were easier, they were educated about what to report and how, and received timely feedback on actions taken based on reported data. Subsequently, incidents may be under-reported due to failure to recognize or report them, and lack of, or poorly designed systems.

Incident reporting systems are intended to protect the health and safety of patients, users and others by reducing the hospital's risk of adverse events and incidents.[79,80] ECRI Institute's guide for setting up an effective program to adequately address medical device safety recommended that a hospital facility develop and document explicit policies and procedures for collecting information, such as hazards, risks and where the system is breaking down, and informing the appropriate staff members about it. According to the guide, the manufacturer should define and outline the severity of the problem and appropriate actions required to rectify it.[81] Authors of one study reported that they plan to use the findings from the focus groups to continue to remove

barriers to medication error reporting in order to encourage patient safety in the hospital facilities.[64]

One systematic review on institutional medical incident reporting systems found that incident reporting alone is insufficient to reduce the risk of medical errors in a hospital. The authors suggested that successful management of medical risk in hospital facilities occurs in three phases: i) risk identification by reviewing the reporting systems and incident and near-misses reports; ii) risk analysis through root cause analysis; and iii) risk control by implementing system changes and improvements.[80] The evidence in the systematic review by Lawton et al. revealed that the majority of contributory factors were active failures (for example, errors, mistakes, violations, slips, lapses, mistakes, deviations from policy) and individual factors (for example, fatigue and inexperience). This observation suggests that many studies in the review did not go beyond the immediate cause of incidents, including immediate behaviour, performance or skills of individuals, who were deemed as responsible for the incident. Several uses of this framework would be to improve root cause analyses, systematically collect data about contributory factors on patient safety incidents by redesigning existing reporting systems, and assist clinicians and administrators to guide risk management of poor safety performance at the organizational level.[34]

To increase the patient safety of medical device use in a hospital, Hinrichs et al. recommended a holistic system among stakeholders, who were responsible for their purchasing process. Their study findings based on observational work, participatory workshop and semi-structured qualitative interviews in five UK hospitals found that decisions among health care stakeholders typically were made in isolation across the hospitals. The authors concluded that this occurrence

would result in knowledge and training gaps and would have a negative impact on patient care.[82] A prospective cohort study of adult inpatients admitted to a 40-day medical ward at a teaching hospital in the US reported that many adverse events identified by inpatients were not captured by the hospital incident reporting system or medical record. Subsequently, the authors recommended the engagement of inpatients to work closely with clinicians in the identification and prevention of medical errors were needed to improve patient safety in the institution.[83]

Limitations

We were unable to identify relevant literature on factors that influence the resolution of medical device-related incidents. Although the grey literature was searched to ensure the comprehensiveness of this report, there is a dearth of evidence in this area. We also recognize that in-hospital research on incident recognition, reporting, or resolution does occur but is not always published due to the hospital's mandate or sensitive nature of the topic.

We excluded two studies that published in languages not spoken by anyone on the research team. The literature, therefore, was restricted to studies published in languages spoken by the authors, including English, French, Italian, and Spanish; however, Morrison et al. found no systematic bias when English-language restrictions were imposed in systematic reviews.[84]

Most studies in our review were not specific to medical device-related incidents, but some of the findings can be extrapolated to medical devices surveillance systems or incident reporting databases.

Direction for Future Research

Following this review, general, orthopedic and vascular surgeons, cardiologists, and interventional radiologists and nurses in two teaching Canadian hospitals were interviewed to explore factors that influence medical device-related incident recognition, reporting, and resolution. The same interviews also solicited information about the nature of their hospital-based device incident reporting systems and suggestions for improvement. The results of this systematic review helped to guide the interview questions. To contribute to the design and development of a medical device surveillance system, an investigation of other sectors that involve the design, development, and use of a technology, such as transport, and machinery and equipment, may be warranted to understand their mechanisms in place to recognize, report, resolve, and reduce the risk of errors and malfunctions associated with its use. This exercise also would incorporate the feasibility and appropriateness of these mechanisms to a device surveillance system in a hospital facility.

A 2013 study explored a core set of organizational and cultural attributes to achieve success and sustainability in quality improvement methods and innovations in health care organizations. The authors recommended that organizations focus on people, processes, and perspectives when planning, adapting, and enhancing initiatives and interventions to improve quality of care in their organizations.[85] An investigation on the relevance of these recommendations for initiatives to improve medical device surveillance in hospitals may be warranted.

In addition, a 2012 Cochrane Systematic Review measured the impact of audit and feedback on the practice of healthcare professionals and patients. The findings indicated that they may

provide incremental but important improvements in professional practice. Feedback is more effective when baseline performance is low, the source is a supervisor or colleague, it is given more than once both verbally and in writing, and definitive goals and an action plan are specified. The authors suggest that future studies can compare and contrast different approaches to deliver feedback to health care professionals.[86]

2.5 CONCLUSIONS

This report included 30 studies describing factors that influence the recognition and reporting of incidents in a hospital setting were included. Findings in these studies suggest four main barriers to error reporting: fear of punishment or censure, uncertainty regarding what should be reported, uncertainty as to how incident reports will be used, and the lack of time. Potential strategies to improve incident reporting include accessible electronic error reporting systems, training about what to report and how, and feedback on actions taken based on error reported. Although we were interested in relevant studies describing the resolution of incidents by health care professionals, we identified none.

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APPENDIX 1: LITERATURE SEARCH STRATEGY

OVERVIEW	
Interface:	OvidSP
Databases:	Embase <1980 to 2013 Week 52> Ovid Medline <1996 to Week 52 2013> Ovid Medline In-Process & Other Non-Indexed Citations < December 31, 2013> **Note:** Subject headings have been customized for each database. Duplicates between databases were removed in Reference Manager.
Date of Search:	December 31, 2013
Alerts:	Search updates began April 14, 2013 and are ongoing at monthly intervals.
Study Types:	Systematic reviews; meta-analyses; technology assessments; randomized controlled trials; controlled clinical trials; multicenter studies; cohort studies; cross-over studies; case control studies; comparative studies.
Limits:	Humans

SYNTAX GUIDE	
/	At the end of a phrase, searches the phrase as a subject heading
.sh	At the end of a phrase, searches the phrase as a subject heading
MeSH	Medical Subject Heading
fs	Floating subheading
exp	Explode a subject heading
*	Before a word, indicates that the marked subject heading is a primary topic; or, after a word, a truncation symbol (wildcard) to retrieve plurals or varying endings
#	Truncation symbol for one character
?	Truncation symbol for one or no characters only
ADJ	Requires words are adjacent to each other (in any order)
ADJ#	Adjacency within # number of words (in any order)
.ti	Title
.ab	Abstract
.hw	Heading Word; usually includes subject headings and controlled vocabulary
.pt	Publication type

Medline Strategy

1 *Medical Errors/ (8708)

2 incident? reporting.ti. (269)

3 exp food/ (1077970)

4 p?ediatric$.ti,ab,hw. or (child$ or neonat$ or neo-nat$ or infant? or perinat$ or peri-natal$ or "in vivo" or "in vitro").ti,ab,hw,pt. (4032684)

5 exp Child/ (1568825)

6 (aa or dt).fs. (2238128)

7 placebo?.ti,ab,hw. (185191)

8 drug safety.ti,ab. (2638)

9 ((safety and efficacy) or (safety and effectiveness) or treatment or versus).ti. (982749)

10 or/3-9 [Concepts to exclude] (7203868)

11 (equipment failure/ or equipment failure analysis/ or prosthesis failure/ or equipment safety/) and ((new or newer or newly) adj2 (device or devices or product?)).ti,ab. (534)

12 (equipment failure/ or equipment failure analysis/ or prosthesis failure/ or equipment safety/) and surveillance.ti,hw. (738)

13 (equipment design/ or orthodontic appliance design/ or prosthesis design/) and (Safety Management/ or Risk Management/) (468)

14 "Equipment and Supplies"/ and medical errors/ (53)

15 (Failure adj4 ((new or newer or newly or medical) adj2 (device or devices or equipment or product?))).ti,ab. (95)

16 (device? failure or equipment failure or product? failure).ti,ab. (912)

17 Product Surveillance, Postmarketing/ and ae.fs. (3184)

18 (exp "prostheses and implants"/ or stents/ or drug-eluting stents/ or suburethral slings/ or suture anchors/ or urinary sphincter, artificial/ or visual prosthesis/ or defibrillators, implantable/ or exp electrodes, implanted/ or exp pacemaker, artificial/ or cardiac resynchronization therapy devices/ or exp catheters/ or infusion pumps/ or infusion pumps, implantable/) and (surveillance and (device or devices or product? or post-market$ postmarket$ or market$)).ti,ab. (389)

19 (exp "prostheses and implants"/ or stents/ or drug-eluting stents/ or suburethral slings/ or suture anchors/ or urinary sphincter, artificial/ or visual prosthesis/ or defibrillators, implantable/ or exp electrodes, implanted/ or exp pacemaker, artificial/ or cardiac resynchronization therapy devices/ or exp catheters/ or infusion pumps/ or infusion pumps, implantable/) and medical errors/ (321)

20 (exp "prostheses and implants"/ or stents/ or drug-eluting stents/ or suburethral slings/ or suture anchors/ or urinary sphincter, artificial/ or visual prosthesis/ or defibrillators, implantable/ or exp electrodes, implanted/ or exp pacemaker, artificial/ or cardiac resynchronization therapy devices/ or exp catheters/ or infusion pumps/ or infusion pumps, implantable/) and (regulatory or government? or policy mak$ or decision mak? or (regulation? adj3 (device? or product?))).ti. (137)

21 ((medical device? or medical product?) and (surveillance or monitoring or reporting or detecting or safety or postmarket$ or post-market$ or after market)).ti. (284)

22 ((medical device? or medical product?) adj2 adverse event?).ti,ab. (34)

23 (exp "prostheses and implants"/ae or stents/ae or drug-eluting stents/ae or suburethral slings/ae or suture anchors/ae or urinary sphincter, artificial/ae or visual prosthesis/ae or defibrillators, implantable/ae or exp electrodes, implanted/ae or exp pacemaker, artificial/ae or cardiac resynchronization therapy devices/ae or exp catheters/ae or infusion pumps/ae or infusion pumps, implantable/ae) and ((reporting or detection or detecting or identifying).ti. or ((report$ or detect$ or identif$ or tracking or track?) adj3 (system? or process or processes or model? or guideline?)).ab.) (546)

24 (exp "prostheses and implants"/ or stents/ or drug-eluting stents/ or suburethral slings/ or suture anchors/ or urinary sphincter, artificial/ or visual prosthesis/ or defibrillators, implantable/ or exp electrodes, implanted/ or exp pacemaker, artificial/ or cardiac resynchronization therapy devices/ or exp catheters/ or infusion pumps/ or infusion pumps, implantable/) and Consumer Product Safety/ (147)

25 Consumer Product Safety/ and MEdical errors/ (10)

26 (Government Regulation/ and medical device?.ti.) or device regulation?.ti. (137)

27 "product recalls and withdrawals"/ or medical device recalls/ or safety-based medical device withdrawals/ (188)

28 (or/11-27) not 10 [Set 1] (5108)

29 Product Surveillance, Postmarketing/ (5763)

30 29 not (or/3-5,7-8,28) [Set 2] (2465)

31 (medical device? or medical product?).ti,ab. (8890)

32 exp Quality Assurance, Health Care/ or Quality of health care/ (309183)

33 (and/31-32) not (or/10,28,30) [Set 3] (452)

34 (randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or placebo.ab. or clinical trials as topic.sh. or randomly.ab. or trial.ti. (946983)

35 exp animals/ not humans.sh. (4091851)

36 34 not 35 [Cochrane RCT Filter 6.4.d Sens/Precision Maximizing] (875433)

37 multicenter study/ or clinical trial/ (641413)

38 ("research support american recovery and reinvestment act" or research support nih extramural or research support nih intramural or research support non us govt or research support us govt non phs or research support us govt phs).pt. (7622594)

39 congresses.pt. (61515)

40 comparative study/ or evaluation studies/ or retrospective studies/ (2281040)

41 case reports.pt. (1698354)

42 case-control studies/ or cohort studies/ or longitudinal studies/ or follow-up studies/ or prospective studies/ or cross-sectional studies/ (1317381)

43 ((systematic adj2 review) or meta-analysis).ti. or Meta-Analysis.pt. or overview.ti. or (literature adj2 review).ti. (134074)

44 or/28,30,33 [Sets 1-3 combine with filters/study designs] (8025)

45 (44 and 36) not 43 [RCT sets 1-3] (759)

46 (44 and (37 not 35)) not (or/43,45) [Multicentre Sets 1-3] (353)

47 (44 and (38 not 35)) not (or/43,45-46) [Research Support pub types Sets 1-3] (1069)

48 (44 and (40 not 35)) not (or/43,45-47) [Comparative/Evaulation/Retro Sets 1-3] (590)

49 (44 and (42 not 35)) not (or/43,45-48) [Longitudinal, Cohort, Cross Sectional Sets 1-3] (269)

50 (44 and (41 not 35)) not (or/43,45-49) [Case Reports Sets 1-3] (366)

51 (44 and (39 not 35)) not (or/43,45-50) [Congresses Sets 1-3] (14)

52 (and/43-44) not (or/45-51) [Reveiws] (94)

53 (2003$ or 2004$ or 2005$ or 2006$ or 2007$ or 2008$ or 2009$ or 2010$ or 2011$ or 2012$ or 2013$).ed,ep,yr. (10693386)

54 (comment or editorial or letter).pt. or placebo?.ti,ab,hw. (1514226)

55 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 (3514)

56 (55 and 53) not 54 [Results 2003 forward excluding pub types requested by authors] (2338)

57 55 and 2013$.ed,ep,yr. [Jan 1-2014 update results] (295)

58 ("20661930" or "21821515" or "19342525" or "20142403").ui. [exemplar studies suggested by peer reviewers] (4)

59 ((1 and (or/36-38)) not (or/35,56)) and 53 [MedErrors & Filters new terms Jan 2014] (1223)

60 (2 not (or/35,56,59)) and 53 [Results incident reporting title screen all-Jan 2014] (185)

EMBASE Strategy

1 medical device recalls/ or safety-based medical device withdrawals/ (187)

2 ((medical device? or medical product?) and (surveillance or safety or postmarket$ or post-market$ or after market or premarket or pre-market)).ti. (286)

3 (((cardiovascular$ or high risk or Class 3 or "class III" or implant$) adj2 device?) and (surveillance or monitoring or reporting or detecting or safety or postmarket$ or post-market$ or after market)).ti. (172)

4 (device? and (surveillance or postmarket$ or post-market$ or after market or premarket or pre-market)).ti. (232)

5 ((medical device? or medical product? or implant$ device?) adj2 adverse event?).ti,ab. (49)

6 (Fault? adj4 ((new or newer or newly or medical) adj2 (device or devices or equipment or product?))).ti,ab. (9)

7 exp *devices/ and *medical error/ (313)

8 exp devices/ and postmarketing surveillance/ (1046)

9 Postmarketing surveillance/ and (device or devices).ti. (377)

10 Postmarketing surveillance/ and (device or devices).ab. (410)

11 exp devices/ and (postmarket$ or post-market$).ti,ab. (603)

12 exp *devices/ and reporting.ti. (477)

13 exp *devices/ and (surveillance adj2 (method? or process$ or program? or progammes or scheme or schemes or model?)).ti,ab. (262)

14 exp devices/ and ((adverse event? or error? or failure) adj4 (reporting or detection or detecting or identifying)).ti,ab. (1193)

15 (device? adj5 ((adverse event? or error? or failure) adj4 (reporting or detection or detecting or identifying or identification))).ti,ab. (57)

16 exp *devices/ and "safe use".ti,ab. (364)

17 "product development"/ and *feedback system/ (3)

18 exp *devices/ and (error? or adverse event?).ti. and (report? or reporting or identification? or identify or detect? or process or procedure or programme or programmes).ti,ab. (382)

19 exp *devices/ and *feedback system/ and (report? or reporting or identification? or identify or detect? or process or procedure or programme or programmes).ti,ab. (88)

20 exp devices/ and adverse event? reporting.ti,ab. (84)

21 or/1-20 (5235)

22 exp drug/ and (safety or efficacy).ti. (19338)

23 exp food/ (626689)

24 (child or children or infant? or neonat$ or baby or p?ediatric$ or "in vitro" or newborn?).ti. or in vitro study/ or child/ or newborn/ (2786015)

25 pediatric ward/ or pediatrician/ or exp pediatrics/ (84364)

26 placebo?.ti,ab,hw. or placebo/ (315818)

27 or/22-26 [Terms to exclude] (3658400)

28 21 not 27 (4783)

29 (2003$ or 2004$ or 2005$ or 2006$ or 2007$ or 2008$ or 2009$ or 2010$ or 2011$ or 2012$ or 2013$).em,yr. (11122438)

30 28 and 29 (3449)

31 demonstration project?.ti,ab. (2223)

32 (time points adj3 (over or multiple or three or four or five or six or seven or eight or nine or ten or eleven or twelve or month$ or hour? or day? or "more than")).ab. (12071)

33 pilot.ti. or (pilot adj (project? or study or trial)).ab. (86766)

34 (multicentre or multicenter or multi-centre or multi-center).ti. (39789)

35 random$.ti,ab. or controlled.ti. (919687)

36 (control adj3 (area or cohort? or compare? or condition or design or group? or intervention? or participant? or study)).ab. (595904)

37 *experimental design/ or *pilot study/ or quasi experimental study/ (7022)

38 ("quasi-experiment$" or quasiexperiment$ or "quasi random$" or quasirandom$ or "quasi control$" or quasicontrol$ or ((quasi$ or experimental) adj3 (method$ or study or trial or design$))).ti,ab. (114503)

39 ("time series" adj2 interrupt$).ti,ab. (1162)

40 (rat or rats or cow or cows or chicken? or horse or horses or mice or mouse or bovine or animal?).ti. (1429559)

41 (exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/) and (human/ or normal human/ or human cell/) (15119370)

42 (exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/) not 41 (5221479)

43 (or/31-39) not (or/40,42) [Filter to find non-rct designs] (1259586)

44 30 and 43 (353)

45 controlled clinical trial/ or controlled study/ or randomized controlled trial/ [EM] (4282465)

46 randomi?ed.ti. or ((random$ or control) adj3 (group? or cohort? or patient? or hospital$ or department?)).ab. or (controlled adj2 (study or trial)).ti. (675203)

47 (random sampl$ or random digit$ or random effect$ or random survey or random regression).ti,ab. not randomized controlled trial/ [Per BMJ Clinical Evidence filter] (53480)

48 (exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/) and (human/ or normal human/ or human cell/) (15119370)

49 (exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/) not 48 (5221479)

50 (or/45-46) not (or/47,49) [RCT Filter for EMBASE] (2899361)

51 30 and 50 (410)

52 or/44,51 (616)

53 ((or/4,9) not (or/27,49,52)) and 29 [Unfiltered results from "high value" search concepts] (285)

54 *medical error/ (6707)

55 (report$ or prevent$ or cause or causes or causal or strateg$).ti,ab. (5261297)

56 54 and 55 (2353)

57 incident reporting.ti. (330)

58 (((or/56-57) and (or/43,50)) not (or/40,42)) and 29 [Terms added Jan 2014] (263)

59 (52 or 53) and 2013$.em,yr. [Jan 2014 update results] (161)[Original Strategy]

60 58 not 59 [New terms results Jan 2014] (262) [New Strategy Dec 2013]

OTHER DATABASES	
PubMed	The PubMed strategy was a focussed, truncated search on the most useful concept, namely, medical device recalls.
Cochrane Library, all sections Issue 4, 2013	Same MeSH, keywords, as per MEDLINE search, excluding study types and Human restrictions. Syntax adjusted for Cochrane Library databases.
PsycINFO	1806 to December Week 4 2013

Cochrane Library (Wiley)

ID Search Hits

1 ((prosthes$ or ventilat$ or device or catheter?) adj3 infection?).ti,ab,tw,kw. (720)

2 (Catheteri?ation or (Intubation adj Intratracheal) or (Ventilator? adj2 Mechanical) or (Device? adj2 Remov$) or (ventilator? adj2 Wean$) or Catheter?).ti,ab,tw,kw. (9980)

3 (((mechanical or device or artificial or assist$ or wean$) adj2 ventilat$) or (artificial adj respirat$)).ti,ab,tw,kw. (3392)

4 indwelling device?.ti,ab,tw,kw. (4)

5 or/2-4 [Devices] (12996)

6 (sepsis or septic?em$ or bacteremia or fungemia or nosocomial$ or Hospital acquired or (equipment adj2 contamination) or infection? or (ventilator? adj2 pneumonia)).ti,ab,tw,kw. (36029)

7 ((pathway? or protocol? or algorithm?) adj2 (clinical or treatment? or diagnos$ or management or infection? or infectious? or antibiotic?)).ti,ab,tw,kw. (4019)

8 critical pathway?.ti,ab. (33)

9 guidance.ti,ab. (1563)

10 (quality adj2 (improv$ or manag$ or care or healthcare)).ti,ab. (6708)

11 (guideline? adj4 (adher$ or antibiotic? or applicat$ or apply$ or clinical or complian$ or concord$ or deploy$ or diagnos$ or effect$ or efficacy or evidence or experiment$ or impact or implement$ or infectious? or infection? or introduc$ or management or pilot$ or study or treatment? or trial? or utili?ation or utili?ing or utili?e?)).ti,ab,kw,tw. (3655)

12 (protocol? adj3 (adher$ or antibiotic? or applicat$ or apply$ or clinical or complian$ or concord$ or deploy$ or diagnos$ or effect$ or efficacy or evidence or experiment$ or impact or implement$ or infectious? or infection? or introduc$ or management or pilot$ or study or treatment? or trial? or utili?ation or utili?ing or utili?e?)).ti,ab,tw,hw. (10615)

13 (pathway? or guidance or algorithm? or (quality adj2 (improv$ or manag$ or care or healthcare))).ti,ab,tw,kw. (15529)

14 or/7-13 [GL] (28465)

15 and/5-6,14 (172)

16 medical errors.mp. [mp=ti, ot, ab, sh, hw, kw, tx] (105)

17 "2013".yr. and 15 (5)

18 ("2003" or "2004" or "2005" or "2006" or "2007" or "2008" or "2009" or 201$).yr. and 16 [New terms added Jan 2014] (93)

19 or/17-18 (98)

20 from 19 keep 1-76 (76) [Cochrane Central Database of Controlled Trials]

21 from 19 keep 77-93 (17) [CDSR]

22 from 19 keep 77-92 (16)[HTA]

23 from 19 keep 93-98 (6) [EED]

PubMed

Search	Query	Items found
#11	Search "Root Cause Analysis"[Mesh]	66
#17	Search "Medical Device Recalls"[Mesh] OR ("medical device" AND faulty) OR ("medical device" AND error) OR ("medical device" AND recall)	147 *[Original Dec 2013 strategy]*
#20	Search "Medical Errors"[Majr]	23687
#21	Search ("report"[tiab] or "reporting"[tiab] or prevent*[tiab] or cause[tiab] or causes[tiab] or causal[tiab] or strateg*[tiab])	3307433
#22	Search (#20 AND (#21 OR #11))	7162
#23	Search (#20 AND (#21 OR #11)) Filters: Clinical Trial	276

PSYCINFO

Search	Query	Items found
1	incident reporting.ti. (31)	
2	medical error?.ti. (96)	
3	or/1-2 [Set 2] (127)	

Grey Literature	
Dates for Search:	*Feb 6th and 8th 2013*
Keywords:	*device or devices AND surveillance (e.g. on medical device sites) or postmarket* post-market AND device AND safety..*
Limits:	Publication years 1996-present

The following sections of the CADTH grey literature checklist, "Grey matters: a practical tool for evidence-based searching" (http://www.cadth.ca/resources/grey-matters) were searched:

- Health Technology Assessment Agencies
- Databases (free)

APPENDIX 2: SELECTION CRITERIA

Articles that focus on surveillance programs, reporting systems and databases for incidents and adverse events related to the use health care technologies in a hospital setting are eligible for inclusion.

Identify factors that influence whether and how incidents/adverse events related to the use of health care technologies are recognized, reported and resolved in a surveillance program, reporting system or database by health care professionals.

Factors include by are not limited to:

- device features
- clinician characteristics
- team characteristics
- institutional characteristics
- system factors
- user interface factors
- patient factors
- type of adverse event
- frequency of adverse event

OR

Develop, implement or evaluate the impact of interventions/strategies that are meant to improve the patient safety, recognition, reporting, and resolution of incidents/adverse events related to the use of health care technologies in a surveillance program, reporting system or database by health care professionals. **Interventions include but are not limited to:**

- modifying characteristics of the surveillance program, reporting system or database
- organizational culture or readiness for change specifically meant to improve incident reporting
- education or training on how to identify/report incidents
- role of quality managers or other individuals who function as change agents
- providing feedback to health professionals on rates or types of incidents
- incentives such as mandatory reporting or financial incentives/accountability agreements

- marketing/promotional strategies to raise awareness of surveillance program, reporting system or database

Clinical indications:

There are no limitations.

Patient population:

Adult or pediatric patients who are hospitalized.

Health care professionals:

- general physicians
- medical specialists
- surgeons
- nurses practitioners
- physicians' assistants
- biomedical engineers
- hospital administrators or managers
- risk managers
- quality control officers
- patient safety consultants
- procurement specialists, agents or managers

Health care technologies:

- medical or surgical devices
- drugs
- diagnostic or screening tests
- vaccines
- surgical or non-surgical procedures

Note: Studies that do not specify any health care technologies but focus on the recognition, reporting, or resolution of adverse events, incidents, near misses, or medical errors in a hospital setting are eligible for inclusion.

Study setting:

Studies conducted in any type of single hospital or a hospital network (e.g., University Health Network) are eligible. The setting is not limited to any specific ward or department in the hospital.

Timeframe:

Studies published from 2003 and onwards are eligible.

Publication type:

Meta-analyses

Systematic reviews

Randomized trials

Non-randomized studies

Surveys

Interviews

Focus groups

Glossary:

Adverse event[9]: an unintended injury caused by medical management rather than by a disease process.

Near miss[9]: potential adverse event that could have harmed the patient but did not do so as a result of chance.

Error[9]: a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot attribute to the intervention of some change agency. Failure of planned actions to achieve their desired end—without the intervention of some unforeseeable event.

Incident[9]: an event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage.

Post-Market Surveillance Program[87]: Involves the collection, monitoring and assessment of adverse reactions to marketed health products and other data, as well as standard market intervention and communication procedures, along with associated policy development and business transformation activities.

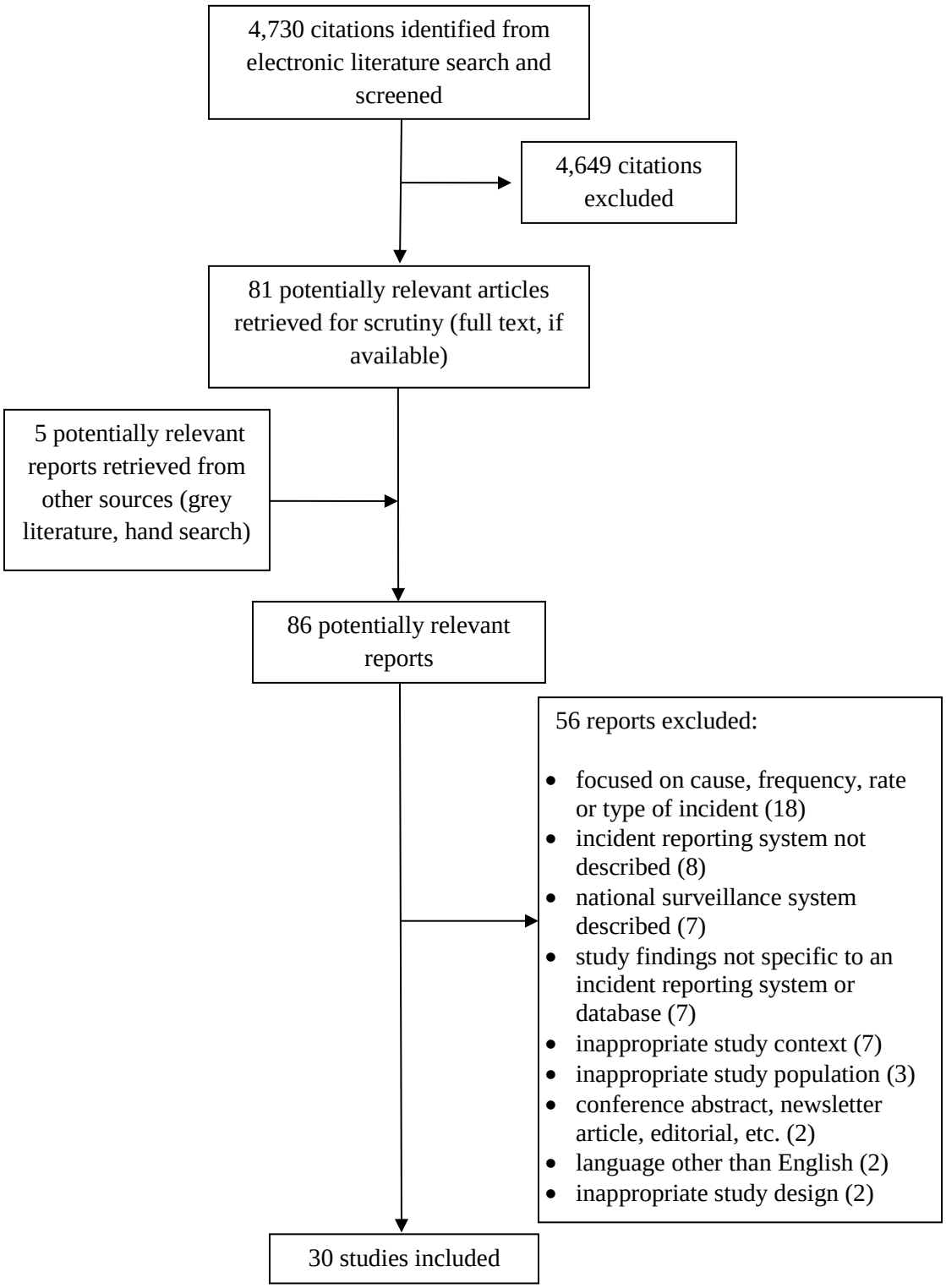
APPENDIX 3: DATA EXTRACTION TEMPLATE

Author:		**Year:**	
Country of first author:		**Journal:**	
Study setting:			
Study sponsor:			
Study design:			
₃ syst review (incl meta-analysis)	₃ randomized trial	₃ observational	
₃ before/after intervention	₃ survey	₃ interviews/focus group	₃ other:
Study details:			
Number of sites			
Number of participants, adverse events or errors			
Intervention			
Data collection and analysis			
Objective(s)			
Clinical category:			
₃ general surgery	₃ orthopedic surgery	₃ cardiothoracic surgery	
₃ anesthesiology	₃ cardiology	₃ interventional radiology	
₃ not specified			
Surveillance/alert database names:			
Type of device (name):		**Clinical procedure (name):**	
Nature of incident (describe):			
Adverse event Frequency			
Timing			
Patient outcome			
Other			
Factors that influence incident recognition, reporting, and recognition (describe):			
₃ device failure or malfunction			
₃ inappropriate use			
₃ provider			
₃ team			
₃ institution			

▪ patient	
▪ other	
Factors that influence whether and how device-related incidents are identified by health care professionals (describe):	
▪ device features	
▪ clinician characteristics	
▪ team characteristics	
▪ institutional characteristics	
▪ system factors	
▪ user interface factors	
▪ patient factors	
▪ type and severity of adverse event	
▪ other	
Interventions or strategies to improve the identification/recognition of device-related incidents by health care professionals (describe):	
▪ characteristics of the reporting system	
▪ organizational culture or readiness for change specifically meant to improve incident reporting	
▪ education or training on how to identify/report incidents and associated costs	
▪ role of quality managers or other individuals	
▪ providing feedback to health professionals on rates or types of incidents	
▪ incentives such as mandatory reporting or financial incentives/accountability agreements	

▪ awareness of reporting system	
▪ other types of interventions not identified here	

APPENDIX 4: PRISMA FLOWCHART



APPENDIX 5: MAIN PURPOSE OF INCLUDED STUDIES AND THEIR CORRESPONDING FREQUENCY

Main purpose	Number of studies
Attitudes toward, barriers to, experience in, facilitators to, and/or perceptions of adverse event, error and incident reporting	16 [55]
Description of causes and health consequences and/or effectiveness of prevention strategies for adverse events	3 [55]
Hospital staff's attitude towards, knowledge of, and/or behaviour in medical errors	3 [55]
Perception of patient safety culture among hospital staff	3 [55]
Error recovery strategies by health care providers	2 [55]
Impact of incident reporting system in surgery	1 [55]
Perceived effectiveness of incident reporting in mental health and acute care hospitals	1 [55]
Effectiveness of real and potential medical errors on health care providers	1 [55]
Effectiveness of improvement incident reporting strategies	1 [55]

APPENDIX 6: STUDY CHARACTERISTICS OF INCLUDED STUDIES

First author; country; year	Number of centres; number of participants (errors); sponsor	Study objective(s) (verbatim)	Study design and duration; clinical category(ies)
Wong[55]; UK; 2013	1 ophthalmic facility; 579 incidents; no funding sources	To examine the impact of patient safety incident reporting on errors during vitreoretinal surgery.	Descriptive; January 1997 to December 2009; vitreoretinal surgery
Anderson[56]; UK, 2012	2 large, teaching hospitals; 62 health care practitioners (e.g., doctors, nurses and managers); government	To examine the perceived effectiveness of incident reporting in improving safety in mental health and acute hospital settings.	Documentary analysis and semi-structured interviews; NR; mental health and acute care
Flotta[67]; Italy; 2012	Hospitals across 20 Italian regions; 696 physicians; none	To investigate physicians' knowledge about evidence-based patient safety practices, their attitudes on preventing and managing medical errors and to explore physicians' behaviour when facing medical errors.	Survey; NR; general medicine, general surgery, medical specialities, ICU/ED
Hartnell[64]; Canada, 2012	Four community hospitals; 30 participants (pharmacists, physicians, nurses); government	1. To identify incentives barriers and facilitators to encourage medication error reporting as perceived by front-line hospital staff; 2. To understand why certain factors serve as barriers; 3. To explore how some hospitals have successfully removed barriers.	Key informant interviews and focus groups; NR; NR
Heard[60]; Australia; 2012	The Australian and New Zealand College of Anaesthetists; 327 consultant anaesthesiologists and 103	To explore the attitudes and barriers of anaesthesiologists to reporting adverse events and errors.	Anonymous, self-administered survey; NR; anesthesiology

First author; country; year	Number of centres; number of participants (errors); sponsor	Study objective(s) (verbatim)	Study design and duration; clinical category(ies)
	anesthesia residents, NR		
Hwang[69]; Korea; 2012	42 general hospitals; 42 nurses; government	To explore the barriers to and factors facilitating the operation of patient safety incident reporting systems.	Interviews and emails; July 2010 to April 2011; NR
Albolino[68]; Italy; 2010	14 hospitals; 820 health care workers; government	To assess workers' experience of patient safety incidents and their expectations on incident reporting	Written survey; April/May 2006 to January 2007; surgery, medicine, obstetrics & gynaecology, intensive care, radiology & laboratory, rehabilitation, and other
Bodur[71]; Turkey; 2010	1 general hospital, 1 teaching hospital, and 1 university hospital; 309 participants (physicians and nurses); NR	1. To determine the validity and reliability of the Hospital Survey on Patient Safety Culture; 2. To evaluate physicians' and nurses' perceptions of patient safety in Turkish hospitals; 3. To compare the findings with US hospital settings.	Cross-sectional survey; not specified
Chien[72]; China; 2010	1 2,300-bed university hospital; NR; NR	To present information framework to build and to enhance the CED on the medical equipment management capabilities with an example for portable physiological monitors used in nursing department.	Descriptive; NR; NR
Espin[66]; Canada; 2010	3 hospitals (1 urban academic tertiary hospital, 1 community hospital, 1 academic paediatric hospital); 37 nurses;	To explore emergent factors influencing nurse' error reporting preferences, scenarios were developed to probe reporting situations in the ICU	Semi-structured interviews; NR; ICU

First author; country; year	Number of centres; number of participants (errors); sponsor	Study objective(s) (verbatim)	Study design and duration; clinical category(ies)
	government and academic		
Henneman[47]; US; 2010	2 urban university medical centers and 2 community hospitals; 20 nurses; non-profit organization	To describe error-recovery strategies used by critical care nurses.	Focus groups; NR; critical care units
Loren[46]; US, 2010	NR; 1,673health care facility-based risk managers; government and academic	To conduct a national survey of risk managers' attitudes regarding patient safety and error disclosure and to compare the results with a previously published survey of medical physicians.	Survey; November 2004 to March 2005; NR
Malik[73]; Pakistan, 2010	600- bed tertiary care facility; 114 doctors 103 and nurses; NR	To determine the attitudes and perceived barriers toward incident reporting tertiary care health professionals in Pakistan.	Survey; NR; medicine (non-surgical), ICU, surgery, anesthesia, gynecology & obstetrics, paediatrics, ER, and others
Smits[75]; Netherlands, 2010	21 hospitals (4 university, 6 tertiary teaching, and 11 hospitals); 744 AEs identified in 7,926 patient records and 55 physicians reviewed patient records; government	To gain more insight into: 1. The causes of AEs; 2. The relationship between the causes of AEs and the preventability and health consequences of the AEs; 3. Potential prevention strategies to prevent AEs; and 4. The relevance of the prevention strategies for each main causal factor type.	Retrospective patient record review; August 2005 to October 2006; excluded admissions of psychiatry, obstetrics and children <1 year old
Kreckler[57];	General surgical department in teaching	To evaluate the process of incident reporting in a surgical setting. In particular, the influence of event outcome on reporting behaviour; staff perception of surgical	Anonymous web-based questionnaire survey; January to

First author; country; year	Number of centres; number of participants (errors); sponsor	Study objective(s) (verbatim)	Study design and duration; clinical category(ies)
UK; 2009	hospital; 55 doctors and 82 nurses; NR	complications as reportable events	March 2007; general surgery
Kroll[58]; UK; 2008	10 hospitals; 38 junior doctors; none	To investigate experiences of and responses to medical error amongst junior doctors and to examine challenges junior doctors face and the support they receive	Semi-structured interviews; NR; NR
Hohenhaus[54]; US; 2008	2 US states; 173 nurses; government	To evaluate current practice of reporting medical error among nurses in the emergency department	Survey; April to June 2005; emergency medicine
Bognár[48]; US; 2007	3 academic hospitals; 61 PCS team members; non-profit organization	To explore the impact of real and potential medical errors on PCS team members.	Survey; NR; pediatric cardiac surgery
Cooke[65]; Canada; 2007	1 academic cancer care centre; 125 radiotherapists, nurses, dosimetrists, doctors and other staff	To motivate improvements in an organisational system by measuring staff perceptions of the organisation's ability to learn from incidents and by analysing their personal experience of incidents.	Survey, NR; oncology
Evans[61]; Australia; 2007	2 regional hospitals; 14 doctors and 19 nurses; government	To assess the effectiveness of an intervention package comprising intense education, a range of reporting options, changes in report management and enhanced feedback, in order to improve incident-reporting rates and change the types of incidents reported.	Non-equivalent group controlled clinical trial (10 intervention and 10 control units); June to August 2003; medical units, surgical units, ICUs, EDs, neurology, cardiology, and gastrointestinal surgery
Kim[70];	8 university hospitals; 886	1. To describe the frequency of error reporting for near misses and harmless but potentially harmful errors	Survey; NR; internal medicine,

First author; country; year	Number of centres; number of participants (errors); sponsor	Study objective(s) (verbatim)	Study design and duration; clinical category(ies)
Korea; 2007	nurses; government	2. To describe nurses' perceptions of patient safety culture in their working unit and hospital, their supervisors' attitudes toward patient safety issues, communication channels, and processes regarding patient safety 3. To examine whether nurses's perceptions were significantly associated with their work experience, work position, type of unit, age, and working hours	ICU, surgical unit, ER, OR, obstetrics unit, other
Evans[63]; Australia; 2006	3 principle referral hospitals, 1 major referral hospital, and two major rural base hospitals; 773 participants (physicians and nurses); NR	To investigate by profession: 1. Awareness and use of current incident reporting system; 2. The types of incidents staff are more likely to report and believe should be reported; 3. The barriers to reporting.	Cross sectional survey; November 2001 and June 2003; NR
Schectman[49]; US; 2006	1 academic medical center; 120 physicians; NR	To assess the safety reporting behaviour and witnessed AEs or near misses	Anonymous survey; spring 2005; internal medicine
Urspung[50]; US; 2005	20-bed tertiary care medical-surgical NICU; 338 errors; government	To conduct a pilot study to determine the feasibility (whether audits were completed each day they were attempted and whether staff disclosed errors during routine daily work) and utility (whether the safety questions audited detected important errors) of 36-item real-time safety auditing during routine clinical work in the ICU.	Descriptive; January 28-March 4 , 2003; NICU
Cohen[52]; US; 2004	489-bed non-teaching suburban community hospital; NR; NR	To determine comprehensive patient safety program's impact on two specific putative measures of the safety culture: event-reporting rates and surveys of staff opinion.	Survey; January 2000-March 2003 in 3 phases; NR

First author; country; year	Number of centres; number of participants (errors); sponsor	Study objective(s) (verbatim)	Study design and duration; clinical category(ies)
Demiris[51]; US; 2004	8 rural hospitals in Missouri; 30 participants (administrators, physicians, and nurses); NR	1. To investigate rural healthcare providers' and administrators' attitudes towards patient safety and their attitudes towards and expectations of an adverse event reporting system; 2. To provide insight into the organizational culture and level of readiness as well as to identify critical issues pertaining to the rural context that needs to inform the design of such strategies.	Interviews; NR; NR
Jeffe[53]; US; 2004	20 academic and community hospitals; 49 staff nurses, 10 nurse managers, 30 physicians; government	To gain insight into workers' perspectives about key concepts and issues regarding medical error reporting in hospitals.	Focus groups; May to June 2002; NR
Kingston[62]; Australia, 2004	5 units across 3 tertiary metropolitan public hospitals; 33 participants (medical and nursing staff; NR	1. To examine attitudes of medical and nursing staff towards reporting incidents; 2. To identify measures to facilitate incident reporting.	Focus groups; March 21-22, 2002; NR
Mazeau[74]; France; 2004	2 hospitals; 216 participants (physicians paid on hourly basis, head nurses, nurses, other caregivers, and administrative personnel); NR	1. To evaluate staff knowledge of hospital medical device surveillances and to describe potential determining factors of this knowledge; 2. To design a method suitable for any evaluation of hospital staff knowledge about what must be indisputably known by a large part of the staff.	Cross-sectional survey; December. 3, 2001-January 15, 2002; NR

First author; country; year	Number of centres; number of participants (errors); sponsor	Study objective(s) (verbatim)	Study design and duration; clinical category(ies)
Waring[59]; UK; 2004	1 medium-sized district general hospital; 28 interviews with 3 senior medical representatives and 25 specialist physicians; NR	The attitudes of medical physicians towards adverse incident reporting in health care, with particular focus on the inhibiting factors or barriers to participation are explored.	Interviews; 2001 to 2003; anaesthesia, acute medicine, obstetrics, rehabilitation and surgery

AE=adverse event; AMDE=adverse medical device event; CED=clinical engineering department; ED=emergency department; ER=emergency department; ICD=International Classification of Diseases; ICU=intensive care unit; NA=not applicable; NICU=neonatal intensive care unit; NR=not reported; OR=operating room; PCS=pediatric surgical team; UK=United Kingdom

APPENDIX 7: STRENGTHS AND LIMITATIONS OF INCLUDED STUDIES

First author	Strengths	Limitations
Wong[55]	• The study objectives were explicit. • An analysis of consecutive vitreoretinal patient safety incidents reported over a specified period at the hospital was conducted. • Data analysis was described. • Study results were described. • Ethics approval from the research ethics committee was obtained.	• How the study findings would be used to further improve incident reporting at the institution was not described in detail.
Anderson[56]	• The study objectives were explicit. • The study design was informed by the perspective of systems theory to conceptualize incident reporting to assess and improve system performance. • Participants were health care practitioners recruited from different divisions at two large teaching hospitals; one that specializes in acute care and a second one in mental health. Participants were knowledgeable of the incident reporting system. • Semi-structured interviews were conducted in private rooms. • Input from risk managers was sought to ensure that the questions were appropriate and relevant. • Participants provided written consent to participate.	• The authors did not describe their role in the analysis phase. • How the study findings would be used to improve incident reporting in hospitals was not described in detail.

First author	Strengths	Limitations
	• Ethical approval from research ethics committee was obtained. • Interviews were transcribed verbatim and analysed using framework analysis. • Themes were supported by interview data and interviews results were explicit.	
Hartnell[64]	• The study objectives were explicit. • The study design was informed and guided by a theoretical framework that recognizes the role of individual, organizational and cultural factors on overall safety of organization. • Participants were selected from four community hospitals of comparable size and demographics with varied scores on the Safe Medication Practices Canada Hospital Medication Safety Self-Assessment tool. • Focus groups and in-depth interviews were conducted to learn the perspectives on barriers to medication error reporting from front-line hospital workers. • The interviews and focus groups were audiotaped and transcribed by an independent third-party. • Ethics approval was granted from Dalhousie University Health Sciences Human Research Ethics Board and from the research board at all four hospitals. • Each participant signed an informed consent statement.	• Limited data was presented to support the major themes described. • The authors did not describe their role in the analysis phase and potential biases.

First author	Strengths	Limitations
	• The analysis process was described and how major themes were derived. • The major themes based on responses by health care professionals were listed. • The authors indicate that the study findings could be used to encourage medication error reporting in a hospital setting to improve patient safety.	
Heard[60]	• The study objectives were explicit. • An anonymous, self-administered study of anaesthesiologists and anaesthesiology residents was conducted. • Patients were recruited from the Australian and New Zealand College of Anaesthetists. • Survey questions and data analysis were described. • Survey results were described.	• Ethics approval status was not reported. • How the study findings would be used to improve the incident reporting among in anaesthesiology was described in detail.
Flotta[67]	• The study objectives were explicit. • National cross-sectional survey was conducted to represent Italian hospital physician's characteristics. • Survey questions were described and pilot-tested. • Ethical approval from research ethics committee was obtained. • Data analysis was described. • Survey findings were described.	• Authors provided limited detail on how study findings can be used to impact patient care.
Hwang[69]	• The study objectives were explicit.	• Authors provided limited detail on how study findings can be used to

First author	Strengths	Limitations
	• Qualitative study was conducted where data were collected via interview or email. • Participants were hospital employees with expertise in patient safety incident reporting systems in hospitals. • Questions that could reflect researcher's prejudice and lead to participants' induced responses for the purpose of the study. • Ethical approval from research ethics committee was obtained. • Data analysis was conducted using qualitative content analysis. • Study findings were described.	impact patient care.
Bodur[71]	• The study objectives were explicit. • The survey was based on questions developed by the Agency for Healthcare Research and Quality and is considered to be a valid, reliable and efficient tool for patient safety culture. • Authors selected one hospital of each type available in Konya, Turkey and to include health care providers who have direct contact with patients. • A pilot test was conducted to ensure the comprehensibility of the survey. • Verbal consent was given by each participant and ethics approval was obtained. • Participants completed the survey without any discussion.	• How the study findings would be used to improve the patient safety culture in hospitals was not explicit.

First author	Strengths	Limitations
	• The data analyses were described in detail, and the survey findings were reported.	
Chien[72]	• The study objectives were explicit. • The authors indicated that the medical equipment management system was sufficient for the clinical engineering department.	• No study participants were involved. • Study findings were descriptive, so no data analyses were conducted.
Loren[46]	• The study objectives were explicit. • Risk manager survey on disclosure of medical errors was conducted and results were compared with those from a previous physician survey. • Ethics approval from research ethics committee was obtained. • Survey content was described. • Data analysis was described. • Survey results were described.	• How the study findings would be used to improve disclosure of medical errors in hospitals was not explicit.
Malik[73]	• The study objectives were explicit. • Survey was conducted in a teaching hospital. • Questionnaire was based on a modified version by Agency of Health Related Quality and other researchers. • Content of questionnaire was described. • Ethics approval from research ethics committee was obtained. • Data analysis was described • Study findings were described.	• How the study findings would be used to improve the patient safety culture in hospitals was not explicit.
Smits[75]	• The study objectives were explicit.	• No study participants were

First author	Strengths	Limitations
	• A retrospective patient record review study was conducted to examine adverse events in 21 hospitals. • 55 trained physicians reviewed medical, nursing and outpatient records. • Data analysis was described. • Study findings were described. • Impact of study findings in clinical practice was described.	involved. • Strategies to mitigate or prevent review bias were not described.
Espin[66]	• The study objectives were explicit. • Semi-structured interviewed were conducted with nurses across 3 hospitals. • The interviews were transcribed verbatim and all identifying features were removed. • Ethics approval was in each institution and written consent was provided from all study participants. • Interview script was provided. • Data analysis was described. • Study findings were described.	• The authors did not describe their role in the analysis phase and potential biases. • Impact of study findings in clinical practice was not described.
Henneman[47]	• The study objectives were explicit. • Focus groups were conducted with critical care nurses to explore strategies used to identify, interrupt and correct errors. • Participants signed a consent form. • Focus groups were audiorecorded and recording were transcribed verbatim. • Data analysis was described.	• Ethics approval status was not reported. • Study limitations and suggestions for future research were provided, but the impact of study findings on clinical practice was not described.

First author	Strengths	Limitations
	• Study findings were described.	
Albolino[68]	• The study objectives were explicit. • 2 questionnaires were conducted to evaluate hospital workers' opinions and perceptions of patient safety incidents and incident reporting systems. • Surveys were based on Agency Healthcare Research Quality's Patient Safety Culture Survey and the Safety Attitude Questionnaire. • Data analysis was described. • Survey results were described.	• Ethics approval status was not reported. • Study limitations and suggestions for future research were provided, but the impact of study findings on incident reporting systems was not described.
Kreckler[57]	• The study objectives were explicit. • Survey questionnaire was conducted in 4 wards responsible for elective and emergency general surgical admissions in a teaching hospital. • Questionnaire structure was described. • Data analysis was described. • Survey results were described.	• Ethics approval status was not reported. • Contributions of the study findings to clinical practice were not described.
Kroll[58]	• The study objectives were explicit. • Semi-structured interviews were conducted with junior doctors across 10 hospitals to explore a range of experiences with medical errors. • Written consent was obtained from study participants. • All interviews were audio-recorded and field notes were made by the interviewer. • Data analysis was described.	• Ethics approval status was not reported. • Contributions of the study findings to clinical practice were not described.

First author	Strengths	Limitations
	• Study findings were described.	
Hohenhaus[54]	• The study objectives were explicit. • Survey was conducted to ask nurses about their experiences with medical errors that have been made in the clinical setting. • Questionnaire was based on one from researchers at the University of Chapel Hill that explored the medical error reporting practices of a diverse group of emergency department healthcare providers. • Ethics approval from research ethics committee was obtained. • Survey findings were described.	• Data analysis was not described. • Impact of the study findings to clinical practice, study limitations and directions for future research were not reported.
Cooke[65]	• The study objectives were explicit. • Survey with hospital staff was conducted to explore the components of the organization's incident learning system from both a personal and organizational perspective. • Survey questionnaire was described. • Data analysis was described. • Survey results were described.	• Ethics approval status was not reported. • Study limitations and direction for future research were provided, but the impact of the study findings on clinical practice was not described.
Kim[70]	• The study objectives were explicit. • A Korean version of the Agency for Healthcare Research Quality questionnaire for patient safety culture was used to survey nurses at 8 hospitals. • Ethics approval from research ethics committee was obtained. • Data analysis was described.	• Study findings, directions for future research, and impact of the study findings to clinical practice were not reported.

First author	Strengths	Limitations
	• Survey findings were described.	
Bognár[48]	• The study objectives were explicit. • A complex survey methodology was used to increase the study validity. • Ethics approval from research ethics committee at each institution and written informed consent was obtained from each participating pediatric cardiac surgical member. • Survey content was described. • Data analysis was described. • Survey findings were presented in detail.	• Impact of the study findings to clinical practice was not reported.
Evans[61]	• The study objectives were explicit. • Focus groups and surveys were conducted to compare incident reporting rates and types of reported generated between i) baseline and study period and between ii) control and intervention units among nurses and doctors across 4 hospitals • Survey validation and focus group methods used were described elsewhere. • Data analysis was described. • Study findings were described.	• Ethics approval status was not reported. • Study limitations were discussed but the impact of study findings to clinical practice was not reported.
Evans[63]	• The study objectives were explicit. • The anonymous survey methods used was described. • Ethics committee approval was obtained from each participating hospital. • Study findings were presented in detail.	• Directions for future research were discussed but contributions of the study findings to existing knowledge or understanding were not reported.

First author	Strengths	Limitations
Schectman[49]	• The study objectives were explicit. • Survey was conducted for housestaff active clinical faculty physicians at university hospital • Survey instrument was described and was based on components of Agency for Healthcare Research Quality questionnaire on patient safety culture. • Data analysis was described. • Survey findings were described.	• Ethics approval status was not reported. • Study limitations were discussed but the impact of study findings on clinical practice was not described.
Urspung[50]	• The study objectives were explicit. • The 36-item patient safety audit was described in detail and tested to help develop a real-time random patient safety audit for clinicians in a hospital setting. • Institutional Review Board approval and informed consent was not required. • All health care provider and patient identifiers were deleted before the study findings were presented. • Study findings were presented in detail. • In addition, to using study findings to help develop a random safety audit tool, studies are underway with clinical staff performing daily audits.	• Relationship between authors and participants and potential biases was not reported. • Study findings were descriptive, so data analyses were not conducted.
Mazeau[74]	• The study objectives were explicit. • The sampling frames and how participants were selected was explicit. • Interviews were conducted via telephone using a structured	• Rationale for survey was not reported. • Relationship between authors and survey respondents and potential biases was not reported. • Ethics approval status was not

First author	Strengths	Limitations
	questionnaire. • Data analyses of responses were described. • Study findings were presented.	reported. • Contributions of the study findings to existing knowledge or understanding were not reported.
Demiris[51]	• The study objectives were explicit. • Interviews were conducted to investigate rural health care providers' and administrators' attitudes towards and expectations of an adverse event reporting system. • CEOs of the hospitals were contacted to identify administrators and health care providers for the interviews, and a convenience sample of rural hospitals was used. • The interview protocols were approved by the University of Missouri's institutional board. • Each participant provided consent. • The study findings were presented in detail. • The study provided some insight on the patient safety culture in rural hospitals, such as the need for a medical error reporting system.	• The researcher and participant relationship was not reported. • Study findings were descriptive, so data analyses were not conducted.
Cohen[52]	• The study objectives were explicit. • Authors described the implementation of a patient safety culture program in a hospital. • Authors described the data analysis process.	• The researcher and participant relationship was not reported. • Ethics approval for the study was not reported.

First author	Strengths	Limitations
	• The study findings were presented in detail. • Authors mention the development of methodology to accurate and objectively measure harm without a manual chart review as next steps.	
Kingston[62]	• The study objectives were explicit. • Authors described the data analysis process. • Researchers did not participate in focus groups. • Ethics approval was granted from each participating organization. • Contributions of study findings to existing knowledge or understanding were discussed.	• Study findings were mainly descriptive, so no data analyses methods were no described.
Waring[59]	• The study objectives were explicit. • Interviews were the predominant method of data collection and were conducted with medical and managerial staff from across the hospital. • All interviews were recorded electronically and transcribed verbatim. • The coding process and data analysis were described. • The interview findings were described.	• The researcher and participant relationship was not reported. • Ethics approval for the study was not reported. • Description of contributions of the study findings to existing knowledge or understanding was limited.
Jeffe[53]	• The study objectives were explicit. • Focus groups of nurses and physicians from various specialties and with	• Potential biases of researcher and participant relationship was not reported.

First author	Strengths	Limitations
	different levels of experience in both academic and community hospitals were conducted. • Questions were developed based on a literature review and a series of interviews with local internists, surgeons, and nurses to identify error reporting issues of importance. • Focus groups were facilitated by two co-authors, who has some experience in conducting focus groups. • Focus groups were audiotaped and tapes were transcribed verbatim. • Data analysis process was described. • Study findings were described. • Brief description of contributions of the study findings was provided.	• Ethics approval for the study was not reported.

APPENDIX 8: STUDY FINDINGS ON FACTORS THAT INFLUENCE THE RECOGNITION, REPORTING AND RESOLUTION OF INCIDENTS BY HEALTH CARE PROFESSIONALS

First author	Outcome measurement	Main study findings (verbatim)		
Wong[55]	Change in clinical practice as a result of device incident reported	Device-Related Incident	Description	Change in Practice
		Hypotony	Disconnection of air tubing from machine causing hypotony due to loose connection	Theatre staff specifically trained to check connections more carefully
		Hypotony	Hypotony on initiation of vitrectomy: vitrector found to be connected to wrong (pneumatic scissors) port on machine	Stopper installed at unused pneumatic scissors port
		Device: instrumentation disconnection	High pressure cannula disconnection from syringe during injection of viscoelastic into anterior chamber resulting in vitreous haemorrhage	Syringes with leur lock tips introduced to ensure cannula firmly locked to syringe during use
		Device: foot petal failure	During pars plana vitrectomy, failure of foot pedal occurred resulting in vitreous incarceration and iatrogenic retinal break	Foot pedals specifically checked at the start of each operating list
		Device: inconet microscrope filter	During endolaser, the surgeon noticed excessive backscatter, attributed	Clearer labelling of laser and filters implemented

First author	Outcome measurement	Main study findings (verbatim)		
			to the placement of an incorrect filter for the wavelength of laser being used	
		Misplaced infusion port	During vitrectomy procedure, pars plana infusion port placed in choroidal space, instead of in vitreous cavity	Weekly consultant-led teaching session for Fellows and Residents introduced
Anderson[56]	Challenges faced by hospital staff in implementing an effective incident reporting system	• Acceptance of incident reporting and blame: lack of willingness or experience using system; fair blame was necessary, balance the need for accountability and a no blame culture was sometimes a challenge. • Investigation of incidents: lack of dedicated time and resources; difficulties in identifying the causes of incidents and in determining the appropriate actions to prevent a similar of occurring again. • Implementation of changes: poor quality of recommendations made in investigation reports. • Evaluation of changes: reliance mainly on informal methods of evaluation, such as team discussions, management oversight and spot checks; formal methods, such as audits and scorecards. • Feedback to staff: feedback about incident reports and related outcomes; lack of knowledge on how the system operated; difficulties of communicating this information in an effective way.		
Hartnell[64]	Organizational culture or readiness for change to improve incident reporting	Organizational factors identified as barriers to medical error reporting: • Ineffective reporting system • Lack of trust about how error reports will be used • Reporting is the responsibility of someone else		

First author	Outcome measurement	Main study findings (verbatim)
	Incentives such as mandatory reporting or financial incentives/accountability agreements	Incentives for medical error reporting: Patient protection • Improved care/improved patient safety • To prevent patient from receiving wrong medication Provider protection • Provides immunity/protection from legal action • Fear of censure (harsh criticism or blame) Professional compliance • Perceived severity of error (more severe errors are more likely to be reported because a report will be expected) • Follow the rules or policies • Ensures accountability
Heard[60]	Attitudes and emotional factors influencing reporting an unspecified adverse event caused by an error	Barriers (n=430 respondents): There were no significant differences between Error and No Error groups in terms of agreeing or strongly agreeing: Doctors who make errors are blamed by their colleagues: 46% (CI: 42%-51%): agreed or strongly agreed 26% (CI: 22%-30%): disagreed or strongly disagreed 27% (CI: 23%-32%): neutral Participants in the Error group were more likely to agree or strongly agree with the following barriers versus the No Error group: • I am worried about litigation • I don't want to get into trouble

First author	Outcome measurement	Main study findings (verbatim)			
		• My colleagues may be unsupportive • I am worried about disciplinary action • I may be blamed unfairly for the event • I do not want the case discussed in meetings There were no significant differences between Error and No Error groups in terms of disagreeing or strongly disagreeing: Adverse even reporting makes little contribution to quality of care: 93% (CI: 90%-95%): disagreed or strongly disagreed I don't know whose responsibility it is to make a report: 86% (CI: 83%-90%): disagreed or strongly disagreed A good outcome of the case makes reporting unnecessary: 86% (CI: 83%-90%): disagreed or strongly disagreed I don't know which adverse events should be reported: 73% (CI: 68%-77%): disagreed or strongly disagreed More than 75% (lower confidence limit) of respondents agreed or strongly agreed with 7 assistive strategies about: • Feedback • Role models • Legislated protection • Ability to report anonymously • Clear guidelines The majority of respondents disagreed or strongly agreed with the following strategy: 'Payment for time taken to report'			
Flotta[67]	When a medical error occurs,		% Agree	% Uncertain	% Disagree

First author	Outcome measurement	Main study findings (verbatim)			
	physicians should:	Conceal medical errors occurred during clinical management	1.2	8.6	90.2
		Avoid similar patients or analogous circumstance	18.4	19.5	62.1
		Increase information seeking to reduce recurrence of medical errors	96.8	1.9	1.3
		Discuss with colleagues about medical error during clinical management	98.4	1.2	0.4
		Report medical errors to their own institution to improve the quality of care	87.6	13.9	1.5
		Discuss with the involved patient	44.5	44.1	11.4

First author	Outcome measurement	Main study findings (verbatim)			
		about medical error occurred during clinical management			
Hwang[69]	Barriers in the operation of incident reporting systems	Barriers			No. (%)
		Mainly organizational factors			43 (44.8)
		Constraints of incident reporting systems (e.g. no assurance of anonymity, no integrated , dual reporting systems, lack of system accessibility, usability problem; difficult to report multi-department involved incidents)			10 (10.4)
		Weak safety culture (e.g., blame and punishment for person involved in the incident: blame for department involved in the incident)			6 (6.3)
		Inter-department conflict and lack of cooperation (e.g., lack of cooperation from clinical departments unavailable department-specific incident cases; conflict due to which department are responsible for the incident)			6 (6.3)
		Limited reporting (e.g., lack of reporting by the other department except nursing department; reporting only incidents due to external factors such as caregivers)			6 (6.3)
		Intractable cases within time and financial constraints			6 (6.3)
		Absence of fulltime patient safety officers			5 (5.2)
		Delayed feedback			2 (2.1)
		Absence of education and training opportunities on patient safety and incident reporting			2 (2.1)
		Mainly individual factors			53 (55.2)
		Low reporting rate			13 (13.5)
		Middle-level managers lack of patient safety leadership (e.g., lack of awareness of the importance of patient safety incident reporting lack of knowledge and skills of patient safety and incident reporting,			10 (10.4)

First author	Outcome measurement	Main study findings (verbatim)	
		fear of blame)	
		Lack of physician's reporting and participation	7 (7.3)
		Top-level managers: lack of patient safety leadership	6 (6.3)
		Staff: lack of knowledge and skill related to incident reporting (e.g., use of tools such as root cause analysis and failure mode and effect analysis what should be reported and how to report)	6 (6.3)
		Lack of staff awareness of the importance of patient safety incident reporting	5 (5.2)
		Late reporting	3 (3.1)
		Fear of blame, stress	2 (2.1)
		Insufficient knowledge and skills related to incident reporting of risk managers	1 (1.0)
	Measures to resolve or overcome barriers	External • Need for education and training programs provided by academic society • Enforcement of patient safety standards in the Healthcare Accreditation Program • Establishment of a national institute to support hospitals' patient safety activity	3 (2.9)
		Internal	101 (97.1)
		Organizational	81 (77.9)
		Introducing a rewarding system (e.g., rewarding for near misses, department-level rewarding link to individual performance appraisal)	16 (15.4)
		Enhancing incident reporting systems (e.g., a variety of reporting channel: computer, paper, email, telephone use of data from different sources such as patient complaints and malpractice claims improving system accessibility using various platform in computers assurance of anonymity and confidentiality, improving reporting forms integrate, unified reporting systems with existing hospital information systems)	12 (11.5)
		Enhancing safety culture	11 (10.6)

First author	Outcome measurement	Main study findings (verbatim)	
		Providing education and training opportunities	11 (10.6)
		Improving staffing for patient safety incident reporting management	9 (8.7)
		Visualizing and sharing successful results/outcomes	7 (6.7)
		Promotional activities (e.g., patient safety day ceremony, poster display)	5 (4.8)
		Providing feedback	3 (2.9)
		Designation of patient safety facilitators at the department level	2 (1.9)
		Monitoring and surveying safety culture	1 (1.0)
		Monitoring and surveying staff perception of patient safety	1 (1.0)
		Non-punitive policy	1 (1.0)
		Hospital-wide efforts to improve patient safety	1 (1.0)
		Creating a formal committee dealing with incident reports	1 (1.0)
		Individual	20 (19.2)
		Improving staff's awareness of patient safety and incident reporting	9 (8.7)
		Strengthening patient safety leadership from top-level managers	7 (6.7)
		Strengthening patient safety leadership from middle-level managers	4 (3.8)
Bodur[71]	Organizational culture or readiness for change to improve incident reporting	Frequency of events reported received the lowest score: 15% (4SD) Frequency of reporting a mistake but is caught and corrected before affecting the resident: 13% (2 SD) Frequency of reporting a mistake, but has no potential to harm the resident: 14% (3 SD) Frequency of reporting a mistake that could harm the resident, but does not: 18% (4 SD) Outcome is lower among physicians versus nurses ($p < 0.05$)	
	Feedback provided to health professionals on rates and types of incidents	Feedback and communication openness about error: 38% (6 SD) Lower among staff working 50 hours or more per week and in staff working in	

First author	Outcome measurement	Main study findings (verbatim)			
		emergency/ICU/OR (p<0.05) Feedback given to staff about changes put into place based on event reports: 30% (4 SD) In staff working in emergency/ICU/OR (p<0.05) Staff are informed about errors that happen in the units: 47% (9 SD) Approached to prevent errors from happening again are discussed: 42% (6 SD) In staff working in emergency/ICU/OR (p<0.05)			
	Incentives such as mandatory reporting or financial incentives/accountability agreements	Non-punitive response to error: 24% (4 SD) Staff feel like their mistakes are held against them: 14% (1 SD) When an event is reported, it feels like the person is being written up, not the problem: 19% (1 SD) Mistakes have led to positive changes here: 42% (11 SD) Staff worry that mistakes they make are kept in the personnel file: 23% (4 SD)			
Chien[72]	Device features that influence the identification of incidents by health care professionals	Panel module and battery are errors encountered frequently that are related to the machine.			
	Patient factors that influence the identification of incidents by health care professionals	Sensors, probe and cuff account for the most frequent number of errors and are connected usually to patients, which can be damaged due to pulling and tension.			
Loren[46]	Risk managers' and physicians' general attitudes about patient		Risk Managers (n=1,472) %	Medical physicians (n=1,311)	P-value

First author	Outcome measurement	Main study findings (verbatim)			
	safety and error reporting			%	
		Medical errors are one of most serious problems in health care (agree)	83	65	<0.001
		Medical errors are usually caused by system failures (agree)	84	58	<0.001
		Does you hospital/health care organization have an error reporting system for physicians to use to improve patient safety?			
		Yes	15	16	0.370
		No	81	39	<0.001
		Don't know	4	45	<0.001
		Current systems for physicians to report patient safety problems are adequate (yes)	57	29	<0.001
		At my hospital or healthcare organization, system changes to improve patient safety occur after errors are reported (agree)	94	75	<0.001
		Current mechanisms to inform physicians about errors that occur in their hospitals or health care organizations are adequate (agree)	51	17	<0.001
	Risk managers' and physicians'	Near misses should be disclosed	19	32	<0.001

First author	Outcome measurement	Main study findings (verbatim)			
	attitudes about error disclosure	(agree/strongly agree)			
		Minor errors should be disclosed (agree/strongly agree)	75	77	0.118
		Serious errors should be disclosed (agree/strongly agree)	98	98	
		Serious errors should be disclosed (strongly agree)	70	49	<0.001
		Physicians are opposed to disclosing serious errors to patients (agree/strongly agree)	39	NA	NA
		Physicians are opposed to disclosing serious errors to patients (agree)	73	NA	NA
		Disclosure would make it LESS likely that the patient would sue (agree/strongly agree)	58	69	<0.001
	Risk managers' and physicians' perceived barriers to disclosure (LESS likely to recommend disclosure (RM) or disclose (MD) a serious error to a patient (yes))	Patient unaware of the error	9	24	<0.001
		If I think the patient would not want to know about the error	19	32	<0.001
		If I think the patient would become angry	2	13	<0.001
		If the physician did not know the	1	20	<0.001

First author	Outcome measurement	Main study findings (verbatim)				
		patient very well				
		If I think the physician might get sued	3		27	<0.001
		If I think the patient would not understand the information	47		61	<0.001
Malik[73]			Doctors N=114 (%)	Nurses N=103 (%)	OR (95% CI)	P-value
	Reason to report:	To get immediate help for patient	25 (22)	25 (24)	0.87 (0.46, 1.64)	0.68
		To learn from mistakes	48 (42.1)	13 (12.6)	5.035 (2.52, 10.04)	<0.001
		To develop a system to minimize repetition of incident	91 (79.8)	87 (84.4)	0.727 (0.36, 1.46)	0.37
	Reporting would be easy if reports were made to:	Colleague	22 (19.2)	15 (14.5)	1.402 (0.68, 2.87)	0.35
		Senior faculty member	20 (17.5)	17 (16.5)	1.076 (0.52, 2.18)	0.84
		Head of the department	69 (60.5)	83 (80.5)	0.37 (0.19, 0.68)	0.001
		Administration	22 (19.2)	10 (9.7)	2.22 (0.99, 4.95)	0.04
	Barriers to incident reporting:	Non-supportive environment,	26 (22.8)	12 (11.6)	2.24	0.03

First author	Outcome measurement	Main study findings (verbatim)				
		culture of shame and blame			(1.06, 4.71)	
		Loss of prestige among colleagues	18 (15.7)	9 (8.7)	1.95 (0.83, 4.57)	0.11
		Legal and financial penalties	28 (24.5)	27 (26.2)	0.91 (0.49, 1.69)	0.77
		Administrative sanctions	79 (69.2)	70 (67.9)	1.06 (0.59, 1.88)	0.84
		Lack of feedback	101 (8.5)	87 (84.4)	1.42 (0.65, 3.13)	0.37
Smits[75]	Potential prevention strategies for AEs	Percentage (%) of physicians who selected the following prevention strategies for all preventable AEs: Quality assurance/peer review (continuously monitoring of data quality based on prespecified standards and assessment of a health professional's performance by one or more individuals in the same field): 65% Evaluation (evaluating the current way of behaving regarding safety): 53% Training (improving (re)training programmes for skills needed): 50% Procedures (completing or improving formal or informal procedures): 40% Percentage (%) of physicians who selected the following prevention strategies for AEs with human-related causes: Quality assurance/peer review: 68 % Percentage (%) of physicians who selected the following prevention strategies for AEs with patient-related causes: Quality assurance/peer review: 78 %				

First author	Outcome measurement	Main study findings (verbatim)
		Percentage (%) of physicians who selected the following prevention strategies for AEs caused by organizational factors: Procedures: 67 %
Espin[66]	Error perception	• Deviation from standards of practice • Breaks/breaches in protocol • Negative outcomes to the patient • Repeated offenses • Scope of practice
	Formal reporting	• Patient negligence • Actual and potential harm • Advocacy • Learning opportunities
	Informal reporting	• Patient care issues • Harm and learning experience • Means to clarify or validate their opinions or concerns regarding patient care with managers and colleagues
	Non-reporting	• Lack of harm to the patient • Lack of time • Fear of reprisal • Lack of management response in justifying their choices to not report
Henneman[47]	Strategies to identify errors	• Knowing all aspects of the patient • Knowing other patients in the unit • Knowing the plan of care or recognizing the lack of a comprehensive plan • Systematically assessing patients by scanning the patient and the patient's immediate environment • Awareness of the unit's policies and procedures • Double-checking physicians' orders or interventions with other nurses

First author	Outcome measurement	Main study findings (verbatim)		
		• Using policy- and unit-based system processes • Questioning novice nurses or physicians during change-of-shift report or multidisciplinary rounds to prompt them to discuss their decision or actions in more detail		
	Strategies to interrupt errors	• Offering assistance in a nonthreatening and supportive manner • Clarifying the plan of care or the appropriateness of a plan of care		
	Strategies to correct errors	• Persevering which often involved phone calls or pages to the patient's physician • Being physically present • Knowing the plan of care and its rationale • Offering options enabled nurses to care for patients without embarrassing or disrespecting another team member • Refer to critical care policies, hospital accreditation agencies and unit-based or other standards • Asking senior clinicians for assistance or clarification		
Albolino[68]	Personal experience with patient safety issue	• Almost 90% of workers who participated in a formal incident investigation agreed on the effectiveness of this activity with respect to a positive change on patient safety. • 10% of interviewees had never been informed of a patient safety incident that occurred to a colleague. • 90% declared that they received information at least once in their careers.		
	Barriers to reporting in case of never reporting of adverse events		Hospital setting without IRS (n=215)	Hospital setting with IRS (n=160)
		Fear of mistrust of colleagues	14.4%	5.6%
		It is not considered a priority	12.6%	11.9%
		Fear of punishment	4.2%	4.4%
		Does not help to improve safety	4.2%	2.5%
		Lack of time	2.8%	2.5%
Kreckler [57]	Familiarity with reporting, reporting behaviour and perceived	1 nurse and 6 doctors did not know of local reporting system		

First author	Outcome measurement	Main study findings (verbatim)
	obstacles to reporting	Nurses were significantly more likely than doctors to know where to find a form: (98% vs. 43%, p<0.001) Doctors were significantly less likely to have ever completed a form: (15% vs. 65%, p<0.001) Nurses who completed between 2 and 4 incidents reports in the last year: 45% Doctors who did not complete any incident reports: 69% Factors that would significantly affect the likelihood of reporting: Level of harm (F(1.8, 246) = 254.2, p<0.001) Incident type (F(1.9, 258) = 64.4, p<0.001) Profession (F(1, 135) = 20.7, p<0.001) Nurses were almost more 3 times as likely to always report no-harm events vs. doctors Surgical complications were far less likely to be reported than the fall, allergy and group and save incidents, regardless of profession Lack of time, feedback, and understanding about what constitutes a patient safety incident were important barriers compared with fear, regardless of profession
Kroll[58]	A norm of selective disclosure	• Majority of participants considered their mistakes to have been minor, but there were reports of some serious errors • Most participants said they had discussed their errors informally with team members • 5 accounts described disclosure and apology to a patient • Formal reporting appeared to be selective
	Effects of the team	• Many interviewees, especially those in 'medical' jobs, reported receiving 'good' practice supervision and support from seniors. • Juniors recognized that colleagues were crucial in preventing and minimising harm

First author	Outcome measurement	Main study findings (verbatim)
	Individualized blame and responsibility	• Individuals expressed a range of attitudes to error, including that it: should be avoided, should be put in perspective; had limited impact and provided a useful learning experience. • There was recurrent mention of blame, either self-blame or blame directed at others. • Explanations for error were largely focused on the individual, thereby potentially impeding these trainees from seeking advice or reflecting on other possible contributory factors.
	Learning moment	• Many potentially valuable learning opportunities were missed, either because the senior's response was inappropriate or because juniors did not access help. • Most learning seems to have occurred where the situation was discussed and feedback was constructive and supportive.
Hohenhaus[54]	Reporting errors	• 42% indicated "nothing" happened when they had reported an error • 22% reported that they were "disciplined by a supervisor" • 20% indicated that they had never made a medical error in their entire nursing careers • 33% stated that they had been afraid to report a medical error they had made • 66% said they had not been afraid to report • 33% had been afraid to report an error made by someone else • 51% stated they might not report if there was no harm to the patient and the error was recognized quickly • 16% wrote that they would always report an error, regardless of who made or what the circumstances were • 9% reported they might not report if a physician told them not to report the error • 7% would not report if their supervisor told them not to • 99% reported they would always report an error that resulted in harm to a patient • 25% would report any error made by a novice nurse • 77% felt that they were provided with adequate resources when faced with the decision to report a medical error

First author	Outcome measurement	Main study findings (verbatim)				
		• 84% felt supported by other healthcare professional colleagues and administrators when faced with reporting a medical error • 77% felt that they had been provided with adequate information and training regarding the reporting of medical errors				
Cooke[65]	Reasons why a respondent would not respond to an incident		Quite, very or extremely important , % (n/N)	Not at all important, % (n/N)		
		Lack of organizational support	22.9 (27/118)	43.2 (51/118)		
		I didn't think the incident was enough to report	18.6 (22/118)	47.5 (56/118)		
		Concern about my reputation: I don't want to be seen as "accident-prone"	15.0 (18/120)	44.2 (53/120)		
		Desire to avoid work interruption and just carry on with the job	15.0 (18/120)	57.5 (69/120)		
		Too busy	13.7 (16/117)	53.0 (62/117)		
		Because reporting an incident would be "telling on" my colleagues	12.7 (15/118)	50.0 (59/118)		
		Fear of discipline	11.7 (14/120)	48.3 (58/120)		
		Desire not to have my name on an incident report	10.1 (12/119)	59.7 (71/119)		
		Concerns about the reputation of the organization	9.2 (11/120)	64.2 (721/120)		
		Avoidance of "red tape" associated with incident reports and investigations	5.9 (7/118)	57.6 (71/118)		
Kim[70]	Nurses' perception of patient safety culture and cooperation climate	Selected perceptions	Mean	Strongly disagree (%)	Neither (%)	Strongly agree (%)
		Perception of overall patient safety				

First author	Outcome measurement	Main study findings (verbatim)				
	within units and across units	It is by chance that more serious errors don't happen here	4.0	6.1	11.4	82.5
		We work in "crisis mode" trying to do too much, too quickly	2.8	32.8	44.3	22.9
		Patient safety is never sacrificed	3.4	15.6	34.7	49.7
		We have a patient safety problem here	3.5	12.2	35.4	52.4
		Our systems are good at preventing errors	3.2	11.7	55.2	33.1
		Unit is doing everything possible to ensure patient safety	4.0	2.4	20.0	77.5
		Teamwork within units				
		Staff members support one another	4.1	0.9.3	16.3	82.6
		Staff members treat one another with respect	3.7	4.6	33.4	62.1
		Physicians and nurses work well together as a team	3.0	26.7	43.2	30.1
		When a lot of work needs to be done quickly, we work together as a team	3.8	4.28	26.4	69.1
		When one gets busy, others help out	3.9	7.7	15.7	76.6
		Difficult to speak to physicians when there is a problem	3.5	14.2	29.5	56.3
		Hospital units				
		Don't coordinate well with one another	3.4	10.3	42.5	47.1

First author	Outcome measurement	Main study findings (verbatim)				
		Good cooperation among them	3.3	10.5	50.7	38.8
		Often unpleasant to work with staff from other units	3.4	15.3	35.3	49.5
		Work well together to provide the best care	3.3	8.3	52.4	39.3
Bognár[48]	Factor analysis of selected safety attitudes domain	Safety Climate	N	% Agreed	Mean (SEM)	Factor loading
		Debriefing after errors occur is common	48	29	2.92 (0.14)	0.68
		The culture in our OR makes it easy to learn from mistakes of others	51	43	2.68 (0.13)	0.65
		I received appropriate feedback about my performance	55	62	2.20 (0.13)	0.49
		It is difficult to discuss mistakes when they occur in the OR	52	60	2.42 (0.14)	0.41
	Factor analysis of selected error burden domain	Error management				
		My department provides adequate, timely information about events in the hospital that might affect my work	59	68	2.10 (0.14)	0.82
		I am encouraged by my colleagues to report any patient safety concerns	59	78	1.94 (0.13)	0.74
		I know the proper channels to direct questions regarding patient safety in my department or work area	57	95	1.51 (0.09)	0.67
		Our levels of staffing are sufficient to handle the	52	31	2.79 (0.12)	0.55

First author	Outcome measurement	Main study findings (verbatim)				
		number patients				
		Trainees in my discipline (e.g., nurses, residents) are adequately supervised	53	79	1.83 (0.11)	0.53
		I have used the hospital's reporting system for documenting medical errors	51	61	2.23 (0.19)	0.52
		Decision making in our OR should include more input from others OR staff than it does now	50	74	1.96 (0.11)	0.51
		Disruptions in continuity of patient care can be detrimental to patient safety	58	93	1.48 (0.08)	0.48
		Problems with equipment are frequent in the OR	52	69	2.17 (0.14)	0.46
		We have a confidential reporting system for documenting medical errors	47	85	1.65 (0.13)	0.42
		When medical errors occur they are handled appropriately	53	85	1.77 (0.11)	0.42
		Risk Modification				
		I am properly trained to use and existing equipment in the OR	55	95	1.71 (0.11)	0.77
		Errors because of lack of skill are rare in the OR	52	58	2.23 (0.13)	0.75
		The OR equipment in our hospital is adequate	53	47	2.58 (0.15)	0.72
		Errors because of lack of knowledge are rare in the OR	54	59	2.24 (0.13)	0.70
		I would feel perfectly safe as	59	64	2.09	0.66

First author	Outcome measurement	Main study findings (verbatim)				
		a patient in our OR			(0.14)	
		I am afraid to report adverse events as I might be punished or lose my job	60	12	3.57 (0.10)	0.53
		I am reluctant to report adverse events as I might get a colleague or friend in trouble	60	15	3.45 (0.09)	0.52
		I expect to be consulted on matters that affect the performance of my duties	55	95	1.29 (0.08)	0.40
Evans[61]		Control reports	Intervention reports	Rate ratio (95% CI)	Absolute difference (SEM)	
	Reporting rates/10,000 OBDs: ICU	17.0 (7/4,107)	118.2 (153/12,943)	0.1 (0 to 0.3)	34.0 (31.7)	
	Reporting rates/10,000 OBDs: Surgical	71.9 (140/19,458)	150.8 (165/10,940)	0.5 (0.4 to 0.6)	76.3 (29.7)	
	Reporting rates/10,000 OBDs: Medical	141.0 (313/22,197)	243.1 (612/25,178)	0.6 (0.5 to 0.7)	84.5 (30.4)	
	Reporting rates/10,000 OBDs: Total inpatient reporting	101.0 (462/45,762)	189.6 (930/49,061)	0.5 (0.5 to 0.6)	60.3 (18.4)	
	Reporting rates/10,000 ED attendance	22.2 (86/38,760)	46.5 (181/28,888)	0.4 (0.3 to 0.5)	39.5 (11.5)	
	Reporting rates/10,000 OBDs: Doctors	0.7 (3/45,762)	6.3 (31/49,061)	0.1 (0 to 0.3)	5.2 (3.6)	
	Reporting rates/10,000 OBDs:	88.5 (405/45,762)	177.3 (870/49,061)	0.5 (0.4 to 0.6)	59.0 (17.9)	

First author	Outcome measurement	Main study findings (verbatim)			
	Nurses				
	Reporting rates/10,000 ED attendances: Doctors	0.3 (1/38,760)	9.0 (26/28,888)	0.03 (0 to 0.2)	9.5 (3.7)
	Reporting rates/10,000 ED attendances: Nurses	19.3 (75/38,760)	31.2 (90/28,888)	0.6 (0.5 to 0.8)	24.8 (9.2)
Evans[63]	Awareness and use of the incident reporting system	Doctors (93.6%; 174/186) vs. nurses (99.8%; 586/587): RR=1.01 (95% CI: 0.99 to 1.03)			
	Ever completed an incident report	Doctors (64.6%; 115/186) vs. nurses (89.2%; 520/587): RR=1.38 (95% CI: 1.19 to 1.61)			
	Know how to located/access an incident form	Doctors (43.0%; 77/186) vs. nurses (88.3%; 515/587): RR=2.05 (95% CI: 1.61 to 2.63)			
	Know what to do with a completed incident form	Doctors (49.7%; 89/186) vs. nurses (81.9%; 476/587): RR=1.65 (95% CI: 1.27 to 2.13)			
	Staff self-perception of reporting of incidents	Incident	Doctors (n=186; %)	Nurses (n=576; %)	P-value
		Patient falls should always be reported	75.8	97.0	NR
		Drug error near misses should ways be reported	42.1	41.9	NR
	Self-perceived barriers to reporting (percentage who agree with the	I never get any feedback on what action is taken:	57.7	61.8	0.371

First author	Outcome measurement	Main study findings (verbatim)			
	statement)	The incident form takes too long to fill out and I just don't have the time	54.2	44.1	0.022
		The incident was too trivial	51.2	41.2	0.027
		When the ward is busy I forget to make a report	47.3	48.1	0.930
		I don't know whose responsibility it is to make a report	37.9	10.8	<0.001
		When it is a near miss, I don't see any point in reporting it	36.0	49.0	0.003
		The AIMS+form us too complicated and required too much detail	31.9	35.0	0.512
		Junior staff are often blamed unfairly	31.0	25.6	0.169
		Adverse incident reporting is unlikely to lead to system changes	28.6	29.9	0.775
		I wonder about who else is privy to the information that I disclose	27.1	33.8	0.112
		If I discuss the case with the	24.9	11.5	<0.001

First author	Outcome measurement	Main study findings (verbatim)			
		person involved nothing else needs to be done			
		I don't feel confident the form is kept anonymous	22.6	30.0	0.065
		I am worried about litigation	20.7	20.6	1.000
		It's not my responsibility to report somebody else's mistakes	17.2	16.4	0.814
		My co-workers may be unsupportive	13.8	20.8	0.045
		I don't want to get into trouble	10.6	18.6	0.014
		Even if I don't give my details, I'm sure that they'll track me down	8.4	17.0	0.006
		I am worried about disciplinary action	8.3	18.1	0.002
		I don't want the case discussed in meetings	7.2	15.5	0.005
Schectman[49]	Reporting behaviour	• 49 physicians (41% of 120 respondents) were not familiar with the safety process • 12 physicians (10% of 120 respondents) were very familiar with the safety process • 39 physicians (33% of 119 respondents) knew how to report an AE or a near miss			

First author	Outcome measurement	Main study findings (verbatim)			
		• 55 physicians (46% of 120 respondents) were aware of QI initiatives at the hospital that were based on the safety and quality monitoring systems			
	Barriers	Reason	Not Important	Somewhat Important	Very Important
		Unsure of reporting mechanism	29% (35)	41% (49)	29% (35)
		No actual harm came to patient	32% (38)	45% (54)	23% (27)
		Reporting too difficult or time-consuming	32% (38)	42% (49)	26% (31)
		Unsure whose responsibility to report	34% (41)	48% (57)	18% (21)
		Unsure of what is considered AE/NM	36% (43)	48% (57)	16% (19)
		Inadequate M.D. participation in system	36% (43)	40% (48)	24% (28)
		Concern about consequences of reporting other's error	44% (52)	42% (50)	14% (16)
		Reporting makes no difference (nothing will change)	45% (54)	42% (50)	13% (15)
		Concern about being blamed or judged less competent	64% (76)	26% (31)	9% (11)
	Ways to increase incident reporting	Item	Unlikely	Somewhat Unlikely	Very Likely
		Allow electronic reporting of AEs/NMs	2% (2)	27% (32)	71% (84)
		Clarify reporting mechanism	5% (6)	42% (50)	53% (62)
		Clarify what constitutes an AE/NM	8% (10)	39% (46)	53% (62)
		Allow anonymous reporting	8% (9)	38% (45)	54% (63)
		Increase physician involvement in QI process	14% (16)	51% (59)	35% (41)
		Provide feedback on QI projects arising from reports	15% (17)	55% (64)	31% (36)

First author	Outcome measurement	Main study findings (verbatim)			
		Provide individual feedback following report	17% (20)	56% (66)	27% (32)
		Provide summary feedback on a regular basis	21% (24)	53% (61)	27% (31)
		Make reporting mandatory	38% (45)	35% (41)	26% (31)
Ursprung[50]	Frequency of errors detected by safety audits	• 338 errors • Most errors were detected at bedside, allowing for immediate feedback to clinical staff (data not provided)			
	Policy changes and educational initiatives resulting from information obtained via patient safety audits	• Development of a pulse oximeter saturation guideline. • Education of the clinical staff as to optimal oxygen saturation targets for various clinical conditions. • Change in the patient identification system used in the NICU. • Education of the nursing staff as to the hospital policy concerning identification bands. • Nursing leadership participation in a follow up safety audit study: revision of safety audit questions, creation of new safety audit questions; staff emails concerning findings of the study. • An intermediate care unit in the hospital learned of the audits and started their own unit based safety audit system			
	Feedback on use of patient safety audits in clinical practice	• Only one concern of auditing was reported to the research nurse or to NICU leadership. • Several clinical staff members reported that auditing 5–7 questions per patient during the work rounds was time consuming, occasionally disrupting the flow of rounds. • Many staff expressed enthusiasm for continued auditing during work rounds provided that only one or two safety questions were addressed per patient. • Many clinicians (nurses, nurse practitioners, and physicians) expressed interest in being a ‘‘safety auditor’’.			
Mazeau[74]	Feedback provided to health professionals on rates and types of incidents	Higher percentage of head nurses and nurses (100) and other caregivers (89) correctly knew whom to alert if faced with a hospital incident versus physicians (74) and administrative staff (82) ($p<0.001$)			

First author	Outcome measurement	Main study findings (verbatim)
		No statistically significant difference among physicians (39), head nurses and nurses (59), other caregivers (54) and administrative staff (35) in correct identification of hospital device surveillance correspondent in their hospital (p=0.076)
	Awareness of a reporting/surveillance system	Higher percentage of physicians (88), head nurses and nurses (95) correctly responded to medical device definition versus other caregivers (64) and administrative staff (65) (p<0.001) Higher percentage of physicians (77), head nurses and nurses (69) correctly identified medical devices versus other caregivers (53) and administrative staff (41) (p=0.004) No statistically significant difference among physicians (55), head nurses and nurses (53), other caregivers (50) and administrative staff (41) in correct identification of incidents listed in survey that concern hospital device surveillance (p=0.75) Higher percentage of physicians (90), head nurses and nurses (95) correctly identified incidental situations that required hospital device surveillance procedure versus other caregivers (83) and administrative staff (71) (p=0.03)
Demiris[51]	System factors that influence the identification of incidents by health	Health care providers stated that an electronic reporting system would be useful and could have potential to shorten the reaction time after an event has been

First author	Outcome measurement	Main study findings (verbatim)	
	care professionals	reported (data not provided) Features a reporting system should have in order to be accepted and utilized by care providers: • Easy to use • Fast • Require minimal training • Accessible • Provide statistics	
	Incentives such as mandatory reporting or financial incentives/accountability agreements	Percentage of providers believed that there was no culture of blame that was regularly placed on individuals involved in medical errors: 71% (n=10/14)	
	Education or training on how to identify/report incident and associated costs	Potential challenges associated with transition to an electronic reporting system: • Training time and cost • Implementation and maintenance costs	
Cohen[52]	Incentives such as mandatory reporting or financial incentives/accountability agreements	Results showed an increase in staff satisfaction with the safety measures in place and less fear of punishment or retribution for reporting medical error (data not reported)	
	Awareness of a reporting/surveillance system	Results demonstrated an increase in staff's awareness of the importance of patient safety and willingness to report safety events ($p<0.001$)	
Kingston[62]	Barriers to incident reporting	Barriers to incident reporting	Suggested strategies
		Lack of knowledge about	• Education at orientation

First author	Outcome measurement	Main study findings (verbatim)	
		the process and what constitutes an incident	• Ongoing education and use of case studies to highlight reportable events at departmental forums • Ability to access a reference manual about what to report
		"Nursing Forum" by association	• Rename/redesign the form to make it more relevant to medical staff
		Time constraints and complexity of reporting form	• Simplify the reporting process-one page being the optimal length • Option of quicker reporting processes (e.g., telephone reporting, online submission)
		Lack of feedback when report generated	• Risk-assessment tool to prioritize action for follow-up • Type and timing of feedback given dependent on severity of incident or degree of risk to the organization. • Staff informed of follow-up processes
		Lack of legal privilege afforded to the reporting process	• Education to explain current legal privilege afforded through Australian federal legislation • Confidentiality guaranteed • Increased confidentiality and security of the reporting process to prevent access to information by unauthorized personnel
		Culture blame	• Option to report anonymously to an independent body, without fear of being identified and with the option to omit identifiers if either self and/or organization • Education
		No value	• Individual/group feedback of action taken
Waring[59]	Cultural Barriers to Reporting	The fear of blame and the fear of reporting	• All doctors involved in the research made reference to the 'blame thing' or a 'blame culture' when expressing their apprehensions

First author	Outcome measurement	Main study findings (verbatim)	
			about incident reporting.
		The inevitability of error and the purpose of reporting	• This research revealed that from working on the premise of 'perfection' (Leapre, 1999), doctors regarded errors as an inevitable and sometimes beneficial dimension of their work. • It was found that the majority of physicians believed all human activity was prone to error. • In consequence, the doctors tended to regard incident reporting as a managerial exercise and questioned its contribution to service quality.
		Rejection of bureaucracy and managerial scrutiny	• A prominent theme that characterised the views of doctors and emerged from the issues raised above was a strong revulsion of what was often termed 'bureaucracy', 'red tape', 'admin', and management. • The doctors were particularly concerned that the growing number of bureaucratic hospital procedures would reduce their capacity for 'real' medical work.
		Divergent occupational responsibilities and expertise	• In the light of the above findings, one of the most interesting themes in the interviews was the sentiment that incident reporting was designed and operated primarily for other occupational groups that were more suited to bureaucratic procedures, especially 'nursing'. • Doctors often claimed that incident reporting grew out of the nursing profession because its culture was familiar with 'form filling' and 'paper work' and more amenable to managerial control.
Jeffe[53]	Barriers to Error Reporting	• Not knowing what to report • Not knowing how to report	

First author	Outcome measurement	Main study findings (verbatim)
		• Fear of repercussions (culture of blame) • Lack of confidentiality • Lack of time and easy systems for reporting • Lack of follow-up
	Facilitators to Error Reporting	• Clear guidelines • Clarify reporting mechanisms and train health care providers (especially physicians) to use them • Nonaccusatory, mentoring • Nonaccusatory, mentoring/collegial environment • Anonymous reporting mechanisms • Sufficient personnel and efficient reporting tools • Routine follow-up of error reports for educational purposes and to show them that hospital will act on error reports

AE: adverse event; Adverse medical device event= the adverse medical device event; AIMS=Australian Incident Monitoring System; CI=confidence interval; CUSA=cavitron ultrasonic surgical aspirator; CVA=cardiovascular accident; ED=emergency department; ICD=international classification of diseases; ICU=intensive care unit; LOS: length of stay; IRS=incident reporting system; MD=medical doctor; NICU=neonatal intensive care unit; NM=near miss; OBD=occupied day bed; OR=odds ratio; OR=operating room; PSI=patient safety incident; QI=quality improvement; RM=risk manager; RR=relative risk; SD=standard deviation; SEM=standard error of the mean; VR=vitreoretinal

APPENDIX 9: FACTORS INFLUENCING THE RECOGNITION, REPORTING AND RESOLUTION OF MEDICAL DEVICE-RELATED INCIDENTS

Factor	**Number of studies**
Recognition	
Health technology features	1 study[59]
Reporting	
Personal attitudes of health care professionals	16 studies[46,52-54,58-60,62-66,68,69,71,73]
Organizational culture	4 studies[51,70,71,77]
Awareness of incident reporting system	4 studies[49,52,63,74]
Perception of incident reporting system	5 studies[46,51,57,63,77]
Incentives to incident reporting	2 studies[64,73]
Feedback to healthcare professionals	2 studies[63,71]
Resolution	
None of the studies reported on the resolution of medical device-related incidents	

Chapter 3

Factors that Influence the Recognition, Reporting and Resolution of Medical Device-Related Incidents in Hospitals: A Qualitative Study of Physicians and Registered Nurses

3.0 ABSTRACT

Background

Medical devices are used to monitor, replace or modify anatomy or physiological processes. Despite their benefits, they can also be associated with adverse events, placing patients at risk and leading to their withdrawal from market. No previous research has thoroughly examined factors that impact their behaviours associated with medical device incidents. The main objectives for this qualitative study were to explore factors that influence and to identify initiatives underway to improve the recognition, reporting, and resolution of device-related incidents.

Methods

Semi-structured telephone interviews with physicians and registered nurses (RNs) in two tertiary care hospitals were conducted using a grounded qualitative approach. Purposive and snowball sampling was used to identify potential study participants. Transcribed interviews were read independently by one individual to identify, define and organize themes and were verified by another reviewer.

Results

Twelve physicians and four RNs were interviewed. Central themes related to the recognition of device incidents were associated with the hospital staff's knowledge and professional experience, medical device performance, and clinical manifestations of patients, while incident reporting was influenced by error severity, personal attitudes of the health care professional, and feedback received on the error reported. Furthermore, physicians tended to discontinue using medical devices or equipment if they malfunctioned, and the problem was not resolved. Education and training and the implementation of large-scale registries were discussed as important initiatives or suggestions to improve medical device surveillance in clinical practice.

Conclusions

Based on the findings of our review, "Factors that Influence the Recognition, Reporting, and Resolution of Incidents Related to Medical Devices and Other Healthcare Technologies: A Systematic Review", ours is the first study to publish interview responses solicited from physicians and RNs on factors that influence the recognition, reporting, and resolution of medical device incidents and improvement strategies in a Canadian hospital context. Results from the telephone interviews suggested that multiple factors that influence participation in the medical devices surveillance activities were consistent with results for medical errors as reported in the systematic reviews discussed in the Background section. The study results highlighted important considerations in the design and development of a hospital medical device surveillance system that would enhance health care delivery and patient safety. In addition, we presented a framework to improve the safety of medical devices in a Canadian hospital context.

3.1 BACKGROUND

Medical Devices and Determinants of Device-related Incidents

Medical devices are defined commonly as instruments used to diagnose, treat, or prevent a disease or abnormal physical condition without any chemical action in the body.[1] Despite their benefits associated with health care delivery and improved patient outcomes, medical devices can lead to unintended incidents and other errors if they malfunction or are used improperly. Incidents are defined as an event or circumstance that could, or did lead to unintended or unnecessary harm to person, a complaint, loss or damage. Devices can be defined as technology for monitoring, examining, replacing, or modifying anatomy or a physiological process.[2,3]

According to a UK audit, device-related incidents were caused by device failure (43.8%), inappropriate use (29.3%), lack of training (12.3%), and poor maintenance (1.5%).[3] While not specific to devices, a systematic review identified 1,676 factors contributing to patient safety incidents in 83 eligible studies that were categorized into 20 domains including active failure in performance or behaviour, clinician, team, institution, system, culture, training, accountability, and patient factors.[4] An exploratory study of errors reported by surgeons found they were caused by multiple systems (for example, communication, workload, staffing, protocols, ergonomics) and cognitive (for example, judgment, memory, vigilance) factors.[5] These studies suggested that many incidents may be caused by device failure or malfunction, while many others were caused by one or more issues unrelated to the product. A 2013 systematic review of surgical technology and operating-room safety failures found that equipment-related failures were involved in a large proportion of all-cause errors.[6] The total and mean equipment-related error rates was greater

among six cardiac surgical sites compared with error rates in five general surgical sites ((total mean error rate, cardiac surgery: 18.45 [range 9.5-32.8] versus general surgery: 2.0 [0-5.9]) and (mean equipment error rate, cardiac surgery: 2.99 [1.7-4.1] versus general surgery: 0.79 [0.7-0.86])). The authors recommended that a generic checklist system that addresses the availability, configuration and settings, malfunctioning or failure be developed and incorporated with the World Health Organization Surgical Safety Checklist. Furthermore, the authors recommended that surgical teams be trained to work with the technology and user-friendly systems that allow the technology to be integrated in the operating theatre be developed.[6]

Reducing the Risk of Device-related Adverse Events: Pre-market Solution?

Unlike drug approvals, which require evidence from clinical trials involving thousands of patients, the clinical behaviour of devices is purportedly more predictable than chemical compounds, so they are often licensed (i.e., approved for market use) based on limited data.[7] Kramer examined data submitted to the US Food and Drug Administration (FDA) in all cardiovascular device license applications in the year 2000 and found that studies did not report safety and effectiveness end points or loss to follow-up.[8] Numerous medical devices were recalled due to problems that surfaced only once the devices were in widespread use. In 2003, the FDA approved Enteryx, a polymer injected into the esophageal wall to treat chronic gastro-esophageal reflux disease based on a single uncontrolled study of 85 patients.[9] Two years later Boston Scientific issued a recall following multiple reports of death and serious injury.[10] The FDA's 510(k) process allows licensing of high-risk devices if the applicant demonstrates they are "substantially equivalent" to previously licensed products.[7] Manufacturers can also seek market approval through the "supplement" process that is used for modified devices that

received pre-market approval (PMA). The supplement process does not require clinical testing of the device for approval. This approach suggests that preclinical testing is deemed to be superior to clinical testing. It, however, should be noted that results of laboratory testing, engineering, and in-vitro studies do not predict the long-term impact of medical device use in the targeted patient population. Goodman et al. recommended that additional evidence be required to assess the validity of clinical data for supplement PMA applications.[11]

In the US, devices that do not pose an unreasonable patient safety risk, their benefits likely outweigh their risks and comparable devices must not have received approval through another FDA approval process, are eligible for the humanitarian device exemption approval. This exemption serves as an incentive for manufacturers to develop devices for patient population with fewer than 1,000 individuals per year and eligible devices do not require evidence of their effectiveness. In one case, the Wingspan intracranial stent system received market approval via the humanitarian device exemption process, but evidence from a randomized controlled trial (RCT) raised safety concerns with its use. Despite the study results, the device remains on the market. The authors suggested that data from RCTs prior to a humanitarian device use approval would reduce the risk of PMA of potentially unsafe devices and public availability of post-market surveillance (PMS) data would raise public awareness on the effectiveness and safety of medical devices.[12]

There are several reasons why evidence requirements for device licensing will not change significantly in the foreseeable future. First, unlike drugs that are protected for many years by patents that allow manufacturers to recover R&D costs, devices undergo frequent modifications

based on user feedback, and do not provide manufacturers with prolonged market exclusivity. As devices can be licensed without strong evidence, there is no natural sponsor for device trials. In 2005, Health Canada processed 63 New Drug Submissions. In same year, it reviewed New Medical Device License Applications for 2,598 Class II devices, 664 Class III devices, and 112 Class IV devices; 1,577 Amendment Applications for Class II to IV devices; and 5,895 Faxback Amendment Applications for Class II to IV devices.[13] Second, stronger pre-market regulation will not necessarily prevent all device-related incidents. For many devices, problems may not occur or be recognized for several years. Furthermore, device incidents are under-reported to national regulators. An Auditor General's report found the rate of voluntary reporting of device-related incidents in Canada was 33 events per million, compared with 510 in the US and 148 in the UK, all of which substantially underestimate actual rates.[14] A 2011 Auditor General's report found an increase of 4,867 device incident reports submitted to Health Canada in the 2009/2010 fiscal year compared with 1,000 incident reports in the 2001/2002, an increase of 387 percent. This increase in incident reports may be due in part by the establishment of the Canadian Medical Device Sentinel Network, where initially 10 health care facilities across Canada were involved.[15]

Benefits and Reality of Post-market Device Surveillance

PMS is used to collect data on adverse events associated with the use of medical devices, and it enables us to address the risks of device-related adverse events sooner via the earlier detection that is facilitated by structures surveillance systems. This approach would prospectively monitor safety and effectiveness through the data collection without impeding access to innovative devices, more rapidly identify and communicate incident data to avoid further events, guide the

development of training, organizational process improvement or other patient safety interventions, direct decision-making about funding or replacement by purchasers and policymakers, and potentially even inform the total product lifecycle by manufacturers. Such an approach was successful in Sweden which established a hip implant registry in 1979 and reduced its national revision rate to 10%, one of the lowest in the world.[16] Monitoring enabled comparative assessment to identify the best performing hip implants. As a result, the number of different types of implants used is far less than in other countries. Costs for hip arthroplasty in the U.S. are expected to rise to $24 billion by 2015, but if the revision rate were reduced to 10% as observed in Sweden, $2 billion in total costs could be avoided.[16]

Literature on Factors that Influence the Recognition, Reporting and Resolution of Medical Device-Related Incidents in Hospitals

To date, we have been unable to identify empirical studies of device incidents that examined theoretical perspectives, such as human factors, cognitive psychology, or sociology, which would reveal how systems, technology, and human beliefs and behaviour influence device use and incident identification and reporting.[5,17-19] Each of these areas possesses numerous possible sub-theories, models or frameworks. For example, sociological theories identify social, political, and economic factors that influence human behaviour. Polisena et al. conducted a systematic review on factors that influence device-related incident recognition, reporting, and resolution, as well as interventions or strategies to improve the recognition, reporting, and resolution of device-related incidents.[20] The authors expanded the scope to include other health care technologies, such as drug therapies, diagnostic and screening tests, vaccines, and surgical and non-surgical procedures, to ensure the comprehensiveness of the relevant literature found. Thirty studies on

factors that influenced the recognition and reporting of incidents by health care professionals were identified. Most of the studies focused on factors that influence incident reporting. One study indicated that health technology features influenced the recognition of incidents by health care professionals in a hospital facility.[20] Central themes on incident reporting that emerged from the systematic review were personal attitudes of the health care professionals, such as perceived barriers, organization culture, perception of incident reporting systems, education and training, and lack of feedback or action taken. None of the studies discussed resolutions to reduce the risk of future incidents. Moreover, some interventions or strategies intended to improve the recognition, reporting and resolution of device incidents included checklists, education, enhanced feedback, a no blame environment, an electronic and anonymous reporting system, and understanding the patient, plan of care, and hospital policies and procedures.[20] It remains unknown what is the most effective medical device surveillance that will improve patient safety in a hospital setting. Elements that contribute to the recognition, reporting, and resolution for the design and development interventions and strategies to reduce the frequency of device incidents merit an exploration.

Objectives

The study objectives were to:

1. Identify common medical device-related incidents reported by physicians and registered nurses (RNs) in the hospital incident reporting system, and for these;
2. Explore factors that influence device-related incident recognition, reporting, and resolution;

3. Identify and describe barriers for recognition, reporting, and resolving device-related incidents;
4. Identify and describe initiatives to improve the recognition, reporting, and resolution of device-related incidents; and
5. Propose a framework to improve the safety of medical devices in a Canadian hospital context.

The study findings are intended to help improve or design strategies that enable incident identification and reporting, analysis and interpretation, and sharing of data to guide decision-making about medical device purchase, use, training, process improvement, and reassessment in a Canadian hospital context. For our study, resolution was defined as interventions used to reduce the risk of similar medical device-related incidents from reoccurring.

3.2 METHODS

Approach

To address the research objectives, physicians and RNs, who work in a tertiary care hospital, were interviewed to identify the type of devices giving rise to incidents and the nature of those incidents, explore factors that influence and barriers to device incident recognition, reporting and resolution. The same interviews also solicited information about initiatives or strategies to improve the recognition, reporting, and resolution of device-related incidents using a grounded qualitative approach.

A systematic review of the medical and grey literature (i.e., literature that is not commercially available) on factors that influence common device incidents and their recognition, reporting, and resolution to help guide the interview questions.[20] Telephone interviews were conducted between September and December 2013 in two Canadian teaching hospitals with over 1,500 hospital beds combined. Ethics approval was sought and received by the ethics board at each hospital, and each study participant signed a consent form prior to the telephone interview. In our invitation to the prospective study participants, we assured them that their individual identity and the name of their organization would not be published to maintain their anonymity.

The grounded theory research method was used to elicit views and insights for a rich understanding of phenomena.[21,22] Grounded theory seeks to develop theoretical models extracted from the data, where study participants have experienced the process that contributes to this theory. Subsequently, this theory provides direction on what and how to examine it. It uses an inductive approach that begins with open questions (for example, what are some factors that influence the recognition of these incidents?), and involves a set of rigorous research procedures leading to the emergence of concepts. Grounded theory is a systematic approach to thematic analysis that involves interpretation from the researchers. We followed the Strauss and Corbin approach that emphasizes the systematic development of a theory to explain the process, action and interaction on a topic (for example, the recognition, reporting, and resolution of medical device-related incidents in a hospital setting).[23,24]

Our study employed a purposive sampling strategy to invite prospective interviewees with experience and knowledge central to study topic (for example, physicians and RNs with

various specialties, who regularly use medical devices in a hospital). We would have asked the same questions in the face-to-face or telephone interviews, but opted for telephone interviews to allow for a sample of participants in multiple cities and for flexibility in the physicians' and RNs' schedules.[25] The critical incident interviewing technique, which asks respondents to provide detail about particularly relevant experiences, also was employed.[22]

Based on the grounded theory approach, data analyses were conducted alongside the data collection process, and open coding occurred in the initial study phase to identify distinct themes in the data. Many themes were generated with open coding, and the constant comparative method compared the data collected with the emerging themes. We then applied the axial coding process to ensure that the themes accurately represented the interview responses and to explain how the themes were related via a combination of inductive (i.e., "bottom up") and deductive thinking (i.e., "top-down").[23-25]

Although focus groups are a recognized form of data collection in qualitative research, our study objective was not to achieve consensus or have a debate on medical device-related incidents. We sought to explore individual experiences and detailed perceptions without the group influence factor. Interviews ensured anonymity and permitted further probing on a sensitive topic that the participants may not have felt comfortable sharing with their colleagues.

Sample Selection and Recruitment

Physicians and RNs were identified by research team members to collect information from individuals at a hospital in two metropolitan cities in Ontario, Canada, who varied by health

profession sampling criteria (purposive sampling). To reduce the risk of skewed interview responses, we recruited six physicians from each hospital who varied by specialization and therefore exposure to and use of different devices (two general surgeons, two orthopedic surgeons, two vascular surgeons, two cardiologists, two cardiac surgeons, two interventional radiologists). In addition, four registered nurses (two nurses from each hospital) with experience in intensive care units or operating rooms (ORs) were recruited. Snowball sampling was applied to identify potential RNs to participate in the study as we found it a challenge to recruit them to our study. Prospective interviewees were invited by electronic mail and asked to sign and return a signed consent form. Information from representative, rather than a large number of participants is needed in qualitative research. It is not meant to produce generalizable results but to provide an in-depth exploration of issues. Sampling was concurrent with data collection and analysis and proceeded until no further unique themes emerged.

Thematic saturation, where the categories were explained adequately and new categories did not emerge, was assessed upon review of codes derived based on responses for each interview question. If no new themes emerged related to factors that influence incident recognition, reporting, and resolution, as well as recommendations to improve medical device surveillance, the authors deemed that additional interviews with physicians and RNs would not add new insights to the current responses. As the interview questions were specific to medical device-related incidents in two teaching hospitals in the same jurisdiction, thematic saturation was achieved after 16 interviews, where no new information was obtained and some redundancy was observed in the thematic categories in subsequent interviews.

Data Collection

Data collection and analysis followed the principles of grounded qualitative research.[21,22] Since no previous studies have examined theoretical factors influencing the recognition, reporting, or resolution of incidents, this method enabled induction, or the drawing of ideas from information conveyed by participants, because it did not rigidly adhere to pre-existing constructs derived from established models or theories.[26] As previously mentioned, the critical incident technique was used to prompt interviewees to reflect upon significant or impactful events and provide a detailed description of the scenario. It has been used by others to explore medical equipment failures.[22,27] An interview guide was developed (Appendix 1) to ask users to provide an example of a medical device-related incident in order to describe how they recognized, reported and resolved it. We also asked them to provide suggestions or indicate initiatives underway to improve device surveillance in their local setting.

One reviewer (JP) conducted the interviews. The interview guide was pilot-tested with one vascular surgeon and interventional radiologist to refine the wording and flow of questions. During the pilot-test, a second reviewer (ARG) reviewed the transcription to provide suggestions on appropriate prompts to ensure a thorough exploration on the topic with the study participants. Interviews of approximately 30 minutes were conducted by telephone and audio-recorded to accommodate the busy schedules of physicians and nurses and to minimize research costs since participants were geographically dispersed. Interviews were audio-recorded and transcribed verbatim by a professional transcriptionist.

Data Analysis

Qualitative analysis identified unique themes in an inductive manner.[28,29] Transcribed interviews were read independently by one reviewer (JP) to identify, define, and organize themes. Thematic analyses involve interpretation from the investigators. A second reviewer (ARG) also independently read the transcriptions and developed themes. Qualitative studies are inherently more subjective than quantitative studies. To minimize bias, both reviewers then compared their findings and achieved consensus through discussion. Detailed notes that explained the rationale for the selection of codes for particular responses were documented. Moreover, a log was maintained of emerging codes, their definition, and sample narrative illustrating application of that code (open coding). The narrative was reviewed using the constant comparative technique to identify all instances of the coding framework and items not matching the framework, to determine how to expand or merge thematic codes (axial coding). Coded text was tabulated by research objective to compare and interpret results, and MS Excel was used to organize the data. One reviewer (JP) reviewed the text repeatedly to ensure consistency in the interpretation of the transcripts. Major themes emerged from the code schemes and patterns identified in the data helped to inform the development of a conceptual framework to improve the safety of medical devices in Canadian hospitals. The code dictionary is found in Appendix 2.

3.3 RESULTS

Number of Interviews Conducted

Telephone interviews were conducted with 12 physicians and four RNs at two teaching hospitals. One cardiac surgeon, cardiologist, general surgeon, orthopaedic surgeon, interventional radiologist, vascular surgeon, and two RNs from each hospital participated in the study. Health

care professionals, with years of practice that ranged between two and 39 years and from various specialities, were selected from two separate institutions to represent unique perspectives on medical device-related incidents. Their characteristics are presented in Appendix 3. Additional interviews were not conducted as thematic saturation was achieved, where the categories were explained adequately and new categories did not emerge. No new data, therefore, were necessary.[30]

Medical Device-Related Incident Examples

Medical Devices Prone to Incidents

Types of medical devices commonly associated with incidents range from dialysis and extra corporeal life support machines and infusion pumps to implantable devices, such as catheters, stents, and inferior vena cava filters (Appendix 4). Staplers also were mentioned by both clinicians and nurses as prone to incidents during a clinical procedure. One cardiologist responded that new medical devices were more prone to errors as a result of a learning curve associated with its use.

Cause of Incidents

The common causes of incidents were device malfunctions and human errors. Other causes included inadequate training on the device, programming errors, inappropriate use of device among ineligible patients, or the patient did not have access to the proper medical device. In one interview, the respondent was unable to determine the cause of incidents.

Impact on Patient Care

In our study, patient care refers to the services provided by the health care professional to benefit the patient's well-being. One clinician indicated that several colleagues had patients who suffered catastrophic haemorrhages or death from defibrillator malfunctions, and another patient bled when a device became detached during a cardiac surgery and subsequently died. Some complications observed by the hospital staff include increased bleeding in the liver, skin burns and stinging, and a linear endoscopic stapler stuck inside a patient. In one instance, the patient's condition deteriorated during the clinical procedure but the individual recovered. Device malfunctions typically involved delays in the surgical procedure or the same procedure had to be performed twice.

Problem Solving

One RN mentioned that she and her team would monitor errors experienced with an electrical generator through incident reports and challenged the manufacturer's responses. As a result, the company's research and development department improved one of the disposable components for the equipment. One cardiac surgeon expressed that there were challenges with determining the cause of the incident; it can be difficult to determine if the incident was caused by a device malfunction or user error. To reduce the risk of an adverse event in the OR, the surgeon would repeat the same procedure on the same patient or conducted an emergency procedure.

Factors that Influence Recognition of Medical Device-Related Incidents

Interviewees were asked to discuss factors that they thought influenced the recognition of medical device-related incidents and to provide an example of how they recognized a device-related incident that occurred with a patient. Themes related to incident recognition included

education and training, hospital staff knowledge and experience, performance of medical device, and warnings or advisories (Appendix 5).

Education and Training

One cardiologist indicated that the staff was aware of the mechanism to deal with errors at his institution.

Hospital Staff Knowledge and Experience

Telephone responses revealed that the recognition of a medical device-related incident or malfunction was related to the clinician's past experience with the use and knowledge of device. An orthopedic surgeon commented, "*And frankly, the surgeon is most responsible for that. I mean, the team is there, at the time of the case, and obviously is there to help. But, once the patient leaves the procedure, the operating room, it's on the surgeon to monitor the progress and follow it. So it's surgeon experience and diligence, really"* (AOS1). Another surgeon sometimes recognized an incident based on a patient's clinical manifestation.

Performance of Medical Device

Issues with medical devices can be recognized if they did not operate according to the manufacturer instructions. Specific medical device features alerted the hospital staff if an error had occurred. The performance of medical devices was sometimes linked to their off-label use on patients with complex problems or conducting an experimental treatment.

Warnings or Advisories

Warnings or notifications issued by manufacturers alerted the hospital staff through a letter of notice on the potential risk of malfunctions associated with a specific medical device. Regulators also published warnings or advisories on medical devices problems observed at other institutions.

Factors that Influence Reporting of Medical Device-Related Incidents

Interviewees were asked to discuss factors that they thought influenced the reporting of medical device-related incidents and to provide an example of how they reported or what prompted them to report a device-related incident that occurred with a patient. Themes related to incident reporting included error reporting compliance, ethics, feedback on how reported information is used, information sharing, incentive for error reporting, institutional and professional cultures, and reporting system and process to hospitals, manufacturers, and regulators (Appendix 6).

Clinician Communication with Patient

Physicians informed patients or family members of a medical device-related incident that occurred during the hospital stay. They also advised them or asked consent about the potential risks involved with a novel clinical procedure. They include off-label use of the device occurred in the patient, or any warnings or advisories issues from the regulators or manufacturers to allow the patient to make an informed decision about their preference.

Feedback on How Reported Information is Used

One physician stated that his hospital quality committee gave feedback to the department or manufacturer to resolve the incident labelled as severe or critical. Based on the experience by a

cardiologist, information on a medical device incident was to provide the manufacturer a better understanding of the cause of the medical device problem.

Incentives for Error Reporting

It is not surprising that physicians did not want to work with medical devices that did not function according the manufacturer's instructions, especially if the incident was complex, and wanted to notify other potential users about their safety issues to reduce the risk of incidents with the specific device. Furthermore, one cardiologist reported incidents to better understand why the device malfunctioned – "*It's also the nature of, certainly, the nature of the clinician who wants to understand why the device has malfunctioned, and that's one of the major impetus to also report an incident, so that you get an understanding of how to improve the device and to ensure an incident like this doesn't happen again"* (BCA1). A cardiac surgeon felt that it was the clinician's responsibility to educate and inform others of any medical device issues experienced. Furthermore, hospitals were eligible for a reimbursement from the manufacturer if a device part was replaced as a result of a malfunction or breakage.

Information Sharing

It was common practice for physicians to share their experiences or express their opinions with each other or exchange information at local and international meetings to learn if their colleagues experienced similar incidents or malfunctions with a specific device.

Organizational Culture

In our study, organizational culture refers to the general attitude of the hospital towards incidents that occur in the organization. A few respondents felt that they were either encouraged or required to report incidents, malfunctions, near misses, or anything that could lead to an error. They also observed that hospitals have become less punitive over time when an incident was reported, and adopted more of learning culture instead, where incidents were used as an education opportunity for the hospital staff. One physician felt that the staff was monitored closely by their institution. According to another physician, the hospital quality of care committee oversaw OR issues and insisted that incident reports be submitted regularly, "*And the quality of care committee at our hospital has become more insistent and demanding for regular reports, as an example, from radiology, where traditionally, interventional radiology wasn't in the habit of tracking as closely their complications or results*" (BVS1 and BIR1). One cardiac surgeon and a RN from the same institution commented that their hospital wanted to maintain a high standard of care for their patients.

Reporting System and Process

According to the interview responses, physicians, nurse managers, or the hospital inventory suppliers reported device failures and malfunctions directly to the manufacturer and, in some instances, returned defective parts to the company. In instances where a physician was unaware of the reporting system and process, he or she would ask the RN to report the incident on his or her behalf. The Biomedical Engineering Department also received reports about the device incident. If a hospital error reporting system or process existed, device incidents, malfunctions, or near misses were documented in an operative or incident report, error database, or a patient's chart. In some cases, a RN included the manager in biomedical engineering in the hospital

incident form or reported the error to the purchasing department. The same RN indicated that clinicians or the Biomedical Engineering Department reported recurring or life-threatening problems with medical devices to the regulator and the ECRI Institute. The ECRI Institute is an independent, non-for-profit organization that evaluates approaches that will improve the safety, quality, and cost-effectiveness of patient care.[31] One physician commented that device incidents, which occurred within a research study, also were reported to the regulator. Another physician indicated that a hospital employee conducted the quality assurance of current reporting processes.

An internal registry was used to track the results of vascular surgeries in one hospital, but this type of system was not available in all clinical areas, including interventional radiology. The same hospital also participated in a global vascular qualitative initiative that allowed vascular surgeons to submit data about preoperative patient and the procedure performed. The database was not focused on devices but was centered on clinical outcomes, such as mortality, complications, limb ischaemia, and length of hospital stay. Another surgeon stated that a system was in place within his hospital, where malfunctioned devices were registered for tracking purposes, along with the actual malfunction, and surgical team involved. The respondent did not elaborate on how the data were used by the hospital. In one hospital, RNs reported problems or complications with patient care in a patient safety and learning system. A cardiologist stated that an online error reporting system at his hospital classified the error severity from mild to critical. For example, any irregularity observed in the patient's care was graded by severity level in the incident reports. One physician followed the regulatory guidelines and completed the necessary

paperwork for complex procedures performed to ensure personal protection against any potential legal consequences.

Factors that Influence Resolution of Medical Device-Related Incidents

Physicians and RNs were asked to share factors that they thought influenced the resolution of medical device-related incidents and to provide an example of how they resolved a device-related incident that occurred with a patient. Themes related to the resolution of incidents included education and training, future use of medical device, information sharing, organizational culture, medical device procurement process, and preventive actions (Appendix 7).

Education and Training

It was common practice for physicians to organize morbidity and mortality rounds in their department to discuss medical device-related incidents as part of the quality improvement process for patient care. Clinicians also participated in interdepartmental formal rounds to learn from colleagues and discuss potential solutions to the medical device problem. Some interviewees felt that adequate training by the hospital and manufacturers on the use of a current or new medical device for new staff and continuous education on how to operate a medical device helped the end-user to understand the medical device functionality and to recognize potential errors and malfunctions. Adequate training for new devices and continuous education for devices already in use by the hospital staff were recommended as strategies to reduce the risk of the same incident or malfunction from reoccurring in the future and to increase awareness of device incident recognition, reporting, and resolution. One example included nurse educators

updating RNs on safety tools, medical device features, and equipment programming. Training on error reporting systems and processes also benefited the hospital staff.

Future Use of Medical Device

For malfunctioning devices, one respondent stated that the hospital returned equipment to manufacturer and requested a refund. In addition, hospitals ensured the availability of devices in stock to avoid delays in a clinical procedure, replace old equipment with a newer version, and contact the manufacturer for in-servicing. The most common decision among respondents related to a device malfunction was its disinvestment or discontinued use in clinical procedures. As one surgeon stated, "*So if there's a product of concern, we remove that product from the hospital*" (BOS1). Devices also were discontinued temporarily until the manufacturer provided a solution to the problem. If an alternative therapy was not available for the patient, one cardiac surgeon responded that she and her colleagues continued to use the device.

Information Sharing

In addition to notifying their colleagues of medical device-related incidents, physicians consulted with them on resolutions with novel clinical procedures.

Organizational Culture

A cardiologist and a cardiac surgeon from the same institution indicated that staff members were quick to resolve a medical device-related incident as it can negatively impact the clinical procedure execution, and their patient's clinical outcomes.

Medical Device Procurement Process

Several respondents felt that it was important for their hospital purchasing department to review the contractual obligations with the manufacturers and incorporate the appropriate clauses to help ensure that they adequately addressed performance issues observed in their medical devices. Device incidents and malfunctions reported by the hospital staff were used to negotiate terms and agreements with manufacturers in future contracts. One orthopaedic surgeon revealed that his hospital checked the medical devices, such as x-ray and tourniquet machines, and kept a record of when they were last tested. Moreover, the biomedical engineering group conducted a quality assurance of the equipment and verified its safety with proper international document prior to a purchase decision.

Preventive Actions

Preventive actions were carried out, such as modifications to future surgical procedures. Respondents also described proactive measures that were in place in their department. They included safety checklists to mitigate and manage incidents, planning for the off-label use of a device in a specific case in a multidisciplinary team and how to address a similar case in the future, and a clinical review of manufacturer instructions to determine they are appropriate. A physician described a strategy to prevent similar incidents from reoccurring as follows, "*And then we either plan for how to deal with the case in the future, if that's the case, or what we do is we discuss the case and see how the problem might be prevented in the future. Basically, we're learning, hopefully, we're all learning from a single person's mistake or whatever outcome there was, to try to prevent the same thing from happening in the future*" (AIR1). Nurse educators

recommended that RNs conduct independent checks of the equipment programming although it is unknown if they were compliant.

Barriers to Recognition, Reporting and Resolution of Medical Device-Related Incidents

Study participants were prompted to discuss common barriers to recognition, reporting, and resolution of medical device-related incidents based on their experience. Themes related to barriers included conflicts of interest, education and training, error reporting compliance, feedback on how reported information is used, hospital staff knowledge and experience, impact on patient care, liability, medical device procurement process, performance of medical device, personal attitude of health care professional, problem solving, professional culture, and response from manufacturers (Appendix 8).

Conflicts of Interest

According to a response, conflicts of interest may be present with a physician due to a vested interest with a manufacturer. For example, a case was reported in 2014 where the US Department of Justice fined Carefusion, a manufacturer, $US 40 million with allegations that it paid a physician, Dr. Charles Denham, over $US11 million to influence the decisions by a "safe practices" committee of the National Quality Forum (NQF). The NQF is a non-profit membership organization based in the US that promotes patient safety and healthcare quality.[32] This conflict of interest was not present among the RNs in our study sample.

Education and Training

A lack of awareness of implications among hospital staff on patient care if errors were not reported and how to report a medical device-related incident or malfunction were common barriers cited by numerous respondents. One cardiologist did not think that there were any barriers to device incident recognition, reporting, and resolution in his hospital.

Error Reporting Compliance

Error reporting was not always consistent across hospital staff and departments, especially if reporting medical device-related incidents was voluntary or was a human error. For instance, one physician admitted to not report errors that he did not deemed to be serious. This response speaks to the need for nomenclature and enhanced training on patient safety and medical device-related incidents.

Feedback on How Reported Information is used

One RN and one cardiac surgeon from the same institution were discouraged by the lack of follow-up from the hospital when an incident or a malfunction was reported and felt that nothing happens. Conversely, it was reported that the manufacturer used the information reported by the hospital to improve the design and functionality of the medical device in one instance.

Hospital Staff Knowledge and Experience

Hospital staff members, who know how to operate the device, were not always present during the operation; thus, delaying the recognition or resolution of potential incidents and malfunctions. A high turnover with the use of some medical devices rendered it a challenge for staff members to gain experience with them and, thus, understand the nuances of the medical

device performance. One interventional radiologist found it demanding at times to interpret imaging information performed in another institution and indicated that clinicians who transferred patients with complex profiles to a tertiary care hospital did not always have the capacity to recognize medical device-related problems. One general surgeon suggested that the success of the clinical procedure also depended on the proper set up of instruments by the nurse. An interventional radiologist stated that he is only made aware of an incident with a patient by the referring service. If a medical device incident was infrequent, some hospital staff members were less aware of the error report system and, subsequently, did not report the event.

A general surgeon expressed some frustration when the nursing staff in the OR had limited knowledge on the proper use of the device, so delays occurred during the clinical procedure. One RN acknowledged that the nursing staff did not always have the expertise to troubleshoot problems observed with a medical device, and found it a challenge to differentiate between an incident and a near miss.

Impact on Patient Care

Monitoring and capturing long-term follow-up information from patients, who were transferred from institutions outside of the tertiary hospital catchment area, can pose a problem for clinicians. There also is a lack of ownership among hospital staff members for patients who are transferred to the hospital from an external jurisdiction.

Liability

Error reporting potentially posed a risk to the reputation of the health care professional, institution, and manufacturer.

Medical Device Procurement Process

One respondent expressed a concern with being responsible for a probable severed relationship between the hospital and manufacturer if the hospital discontinued the use of their medical device due to an error reported by her.

Performance of Medical Device

Some medical devices were a challenge to use if the individual components were assembled from different systems produced by the same manufacturer. For newer devices, their long-term function and impact on patient care were unknown. Moreover, signals displayed by new medical devices can be misinterpreted by hospital staff.

Personal Attitude of Health Care Professional

Some respondents were intimidated by punishment and potential legal consequences and feared a loss of credentials or privileges at their institution if they reported a device incident. Others also felt that error reporting to the hospital was complicated and time-consuming – "*...knowledge of how to complain and time factors, like, not knowing how to make a complaints or lodge a complaint and you know, often what happens is you troubleshoot it enough that you kind of get through the case and then you can't be bothered, you know, you don't have time and you can't be bothered putting a complaint in. You know, you get busy and you move on to the next case*" (BGS1). Both physicians and RNs were concerned about their professional reputation if they

reported an error, regardless if it was a device malfunction or human error. A few hospital staff members did not think that there were any barriers to recognizing, reporting, and resolving medical device-related incidents in their area of practice.

Problem Solving

In terms of resolving a device incident, challenges arose in troubleshooting a unique circumstance in real-time even when the manufacturer representative was present in the OR. It is unclear if manufacturers frequently had difficulties troubleshooting device incidents. As well, conflicts between the hospital and manufacturer can occur as both parties are interested in the first right to inspect a medical device to understand the cause of the malfunction.

Professional Culture

Hospital staff did not always want to discuss each other's complications with the use of medical devices, but some felt that they had a professional obligation to report a device incident or malfunction to the hospital. One RN suspected that there was a lack of compliance among her colleagues in conducting independent checks in the programming of the medical equipment.

Response from Manufacturers

Both physicians and RNs expressed their frustration with manufacturers or distributors when they provided limited information about the device incident or malfunction reported by the hospital – "*So, you know, it becomes a bit frustrating when we do everything the way we're taught, and then, we get the same response from the vendors all the time"* (BRN1). An inadequate response, therefore, hindered the hospital staff from resolving the problem.

Initiatives or Suggestions to Improve Recognition, Reporting and Resolution of Medical Device-Related Incidents

Study participants were asked if they were aware of any initiatives in their institution and to provide suggestions to improve the recognition, reporting, and resolution of medical device-related incidents (Appendix 9). Themes that emerged from their responses included education and training, organizational and professional cultures, and reporting systems and processes.

Education and Training

Hospitals must ensure that their staff receives adequate training on the use of new medical devices and existing error reporting systems and how to report device incidents and malfunctions to ensure consistency in clinical practice. One surgeon suggested as follows, "*I think more immediate feedback maybe about particular incidences, and it's more education for me, because there's probably a lot of the times, and maybe the majority of times, where it's a lack of knowledge that I have, about using it, rather than the product necessarily being faulty"* (BGS1). Several physicians and RNs were unaware of any initiatives underway in their hospitals for device incident recognition, reporting, and resolution.

Organizational Culture

Although post-market surveillance (PMS) systems for devices, such as the FDA Manufacturer and User Facility Device Experience (MAUDE) database, exist and error reports are available in the public domain, one physician felt that there should be increased collaboration among hospital facilities to track the performance of medical devices. Collaborations exist for the purchase of

medical supplies and equipment, so he wondered why a similar one had not been established yet for medical device-related incidents and malfunctions. The respondent did not comment on existing PMS systems, so his thoughts on their effectiveness to improve the safety of medical devices are uncertain. One respondent observed an expansion of processes and practices over time, such as morbidity and mortality, from vascular surgery to interventional radiology.

Professional Culture

One RN suggested that RNs play a more active role in refusing to use a medical device that did not perform as intended and allow frontline staff, who used the medical device in practice, to test and understand how it works. As well, the same respondent felt that RNs should be more empowered and be allowed to refuse to use defective medical equipment.

Reporting System and Process

One surgeon indicated that a provincial-wide vascular database would be implemented in his hospital. It was intended to capture all vascular procedures prospectively, but was not limited to device incidents. This database, however, was not mentioned by the other vascular surgeon in our sample. A couple of physicians suggested setting up an infrastructure to facilitate the automation of reporting medical device-related incidents and malfunctions. This approach would reduce the occurrence of device problems going unnoticed – "*... certain big university hospitals, they all have processes in place, is to create an infrastructure or a process that automatically kicks in, regardless of what the surgeon says, regardless of what the nurse says. There's an automatic – it can't be swept under the rug"* (AGS1). Some respondents felt that hospitals should collaborate to develop and adopt a global registry that captures the performance of medical

devices used in their institutions. Such a registry would help to determine more accurately the denominator in the number of procedures associated with specific medical devices. The same surgeon also recommended mandating a review or debriefing of surgical cases among the operating staff on a regular basis to learn from their occurrence.

Interpretation

Even though the literature identified the performance of a health technology as a factor that influenced the recognition of incidents, numerous respondents attributed the recognition of incidents to devices not operating based on the manufacturer's instructions, and to the hospital staff's knowledge and professional experience on both medical device performance and clinical manifestations of patients (Appendix 10). When a device incident had occurred, patients and their families were notified, manufacturers were contacted, and hospital incident forms were completed. If the device incident was deemed to be serious by the physician, the regulators also were advised. The interviewees suggested that it was a challenge to discern if the error reporting to various parties was consistent. Conversely, errors not deemed to be serious by the physician or RN or near misses were not always reported to the hospital.

Several participants felt that the manufacturer's response to a device incident provided insufficient information to resolve the problem, and they were reluctant or adverse to reuse the medical device in future clinical procedures. Some, therefore, recommended that the hospital purchasing department incorporate appropriate clauses in new or renewed contracts with the manufacturer.

The telephone interviews also revealed that physicians discontinued using a specific device if it malfunctioned and the problem was not resolved and the risk, therefore, of a similar incident reoccurring continued to exist. Should an alternative therapy not be available, then risk mitigation strategies developed by the hospital department were planned for future clinical procedures. A systematic review on case studies that illustrate disinvestment and resource allocation decision making process revealed that six of the 14 studies examined the safety and adverse event evidence of the health care technologies and services proposed for disinvestment. It was unclear, however, the impact of the evidence during the decision process.[33]

Respondents indicated that a medical device surveillance program that incorporated a medical device registry, increased education and training, and an open communication and feedback strategy with hospital administrators and managers to encourage information sharing and increase incident reporting would contribute to increased patient safety in a hospital facility. More specifically, education and training programs on the incident recognition and appropriate use of new medical devices to enhance their performance on patient care, greater awareness on error reporting and its significance, increased feedback from management to staff about reported errors, and modifications to the medical device purchase process to increase the manufacturer's accountability to device incidents that occur would ameliorate medical device surveillance in a hospital facility.

A Proposed Medical Device Surveillance Framework

The results of our systematic review and telephone interviews were used to propose a conceptual framework on medical device surveillance in a Canadian hospital context.[34]

Assumptions

The medical device surveillance system framework was developed under the following assumptions:

• The framework for the medical device surveillance system was drafted from a tertiary academic hospital perspective in a Canadian setting. The hospital had an established Centre for Patient Safety with a mandate to provide safe patient care to both inpatients and outpatients through continuous research, education, and evaluation methods.

• The centre employed three to four staff members.

• The hospital provided biomedical engineering services, whose primary responsibility was to test and implement new devices, maintain medical equipment, and act as advisors to the selection of medical equipment.

• A medical device surveillance system currently did not exist at the hospital.

Appendix 11 presents the proposed surveillance system for a hospital that intends to reduce barriers to improve the safety of medical devices. An effective medical device surveillance system would incorporate multiple components that accurately document and assess the appropriate actions to reduce the risk of incidents, adverse events, and patient harm. An adverse medical device event (AMDE) database and medical/equipment library, an open communication and feedback strategy, as well as an education and training program would be developed to increase the hospital staff members' awareness and understanding of the purpose and objectives of the surveillance system.[35]

AMDE Database

The AMDE database would detect signals of previously unidentified AMDEs or near misses and identify any trends on AMDEs.[35] Data from the volunteer incident reports submitted by the health care providers would enable the hospital staff to:

• Detect rare or unexpected AMDEs;

• Detect problems that occur in clinical practice;

• Access complete information on AMDEs, including the specific nature of the device, brand, and model number;

• Appreciate the public health burden imposed by AMDEs of specific types or related to specific device types; and

• Identify appropriate resolutions to minimize risk of AMDEs or near misses for specific devices.

The data collected in the AMDE database would accurately represent the incident and allow the health care providers to describe the error from their perspective.[35]

Open Communication and Feedback Strategy

Our systematic review on factors that influence incident recognition, reporting, and resolution found that communication and feedback had an impact on error reporting by health care professionals.[20] Based on responses from physicians and nurses in three public hospitals in Turkey, 38% (6 standard deviation [SD]) felt that the feedback on and communication about medical errors was open, as well as feedback provided to staff about any changes based on event reports (30%; 4 SD). Only 15% (4 SD) of errors, however, were reported.[36] Forty-seven percent (9 SD) of hospital staff indicated that they are informed of errors that occur in their hospital

units, and 42% (6 SD) are approached to discuss strategies to prevent future errors.[36] In another survey, over 50% of doctors and nurses indicated they did not receive feedback on their reported errors and were unaware they resulted in any changes.[37] Furthermore, our telephone interviews revealed some frustration among frontline clinicians with the lack of feedback from their institution when they reported a medical device-related incident.

Benn et al. proposed a safety feedback loop for safety incidents at the organizational level. The cycle consists of the following major steps: 1) receipt, screening, and archiving of incoming reports; 2) analysis of trends in aggregated incident data and investigation in root causality for incidents is essential to focus corrective efforts on repeating issues; and 3) development and implementation of system improvements to prevent recurrence and address system vulnerabilities.[38] Examples of outcomes collected from the safety-feedback loop include alerts about new hazards based on incident reports, trends, and best practices identified from surveillance systems.[38] Individual adverse events or incidents can be monitored closely to determine an appropriate resolution and potential weakness in the safety surveillance system.

Follow-up with health care professionals on the outcome of their reported error or incident would help to increase the frequency of errors reported.[20] Some examples of successful feedback mechanisms previously employed involve safety committee processes, publications, electronic dissemination, staff bulletins, manuals, and conferences. In one study, newsletter distribution and information dissemination at monthly departmental meetings resulted in increased incident reporting rates.[38] Mahajan acknowledged that additional evidence is required to understand the impact of these techniques on the safety of medical devices and patient care in general.[39]

Integration of Medical Devices with Information Systems

The installation and maintenance of radio frequency identifier/real-time location systems are important to identify, track, and manage the location of equipment, monitor temperature and sterilization, track consumables and manage inventory, and track staff and patients in health care institutions.[40] In addition, medical device connectivity is a technology that links medical devices with information systems to reduce the risk of human error in entering clinical data.[41]

Canadian Medical Devices Sentinel Network

The Canadian Medical Devices Sentinel Network (CMDSNet) involves a group of dedicated and trained representatives from at least ten acute or community-based health care facilities within Canada. These representatives report adverse events associated with the use of medical devices to the Marketed Pharmaceutical and Medical Devices Bureau of Health Canada. The reports sent help regulators to better characterize how hospital facilities use devices, how problems are perceived and reported, and which aspects of the system contribute to a particular event, potentially mitigating risk at an earlier stage. Hospitals benefit from timely new safety information to make informed decisions concerning the appropriate use of medical devices due to more comprehensive incident data and earlier regulatory interventions.[42]

As a participating member of the CMDSNet, a hospital would benefit from the following outcomes:[42]

• Increased awareness by hospital frontline users about the benefits of reporting incidents and knowledge of safe medical device usage;

• Establishment of a direct communication link between the hospital and Health Canada

• Access to early warnings and signal detection;

• Development of a sense of community among CMDSNet users, through an information sharing forum; and

• Creation of a feedback loop within the network.

In addition to signing a confidentiality agreement with Health Canada, the involvement of participating hospital facilities is as follows:

• Establish internal processes to increase awareness of error reports via CMDSNet;

• Identify two to four main reporters in the hospital as official representatives to CMDSNet;

• Respond to questions from Health Canada about submitted reports;

• Respond to "ad hoc" adverse event questions;

• Receive and disseminate information from the monthly CMDSNet Bulletin; and

• Participate in a monthly teleconference with members of CMDSNet.

Although CMDSNet is exclusive to Canada, similar networks or initiatives in other jurisdictions to monitor incidents, adverse events, or malfunctions associated with the use of medical devices in a hospital context would also be applicable to the proposed framework. For instance, the Medical Product Safety Network in the United States is a device surveillance network of approximately 280 hospitals that was established to monitor device use and adverse events associated with their use.[43]

Important Considerations for Medical Device Surveillance Systems

Cost Items of Proposed Medical Device Surveillance System

Individual cost items associated with the proposed medical device surveillance system framework are not readily available. Appendix 12 highlights the main direct cost items associated with the development, operations, maintenance, and upgrades with the proposed medical device surveillance system. Direct costs are costs that are directly linked to the production and services of the surveillance system, and they can be further divided into fixed and variable costs. Examples of fixed costs include equipment and software purchases, while variable costs vary with the volume of activity.[44] Development costs involve mostly fixed costs, such as equipment and software purchases. Personnel, operating, and maintenance costs are associated with daily system maintenance and data collection and are comprised primarily of variable costs. Upgrade and enhancement costs are related to any system improvements and upgrades.[44]

Potential Benefits and Economic Value of Proposed Medical Device Surveillance System

The potential benefits of the proposed medical device surveillance system from patient, health care professional, and institutional perspectives are highlighted in Appendix 13. The post-market medical device surveillance will be strengthened with the proposed system. Also, the surveillance data can lead to the development of a conceptual framework of factors that influence device incident occurrence, recognition, reporting, and resolution, thus leading to enhanced patient safety and improved clinical outcomes. In addition to understanding the benefits and risks of medical devices in practice, a surveillance system can inform future device modifications in design and functionality, market potential of a new device, and impact on efficiencies in hospital practice such as time spent on a procedure and resource use.[45] In summary, the proposed surveillance system would facilitate the monitoring of device-related incidents and reduce the

risk of adverse events or device malfunctions, leading to cost savings such as reduced hospital stays, improved patient care and decreased risk of health professional and institutional liabilities.

Implementation of Proposed Medical Device Surveillance System

The surveillance system should be pilot tested for a predetermined time frame to a select group of hospital decision-makers and health care professionals prior to its release on a broader scale. These individuals would represent the demographics of intended users. Items to be tested include data to be collected by the surveillance system, such as the data sources and collection methods, and procedures on data handling. The pilot test will not only collect feedback about the value of data collected and ease of use, but identify and correct any possible weaknesses in the system. To ensure a smooth transition in the hospital, the implementation phase would be divided into numerous sub-phases, where the surveillance system would be installed in one hospital ward at a time (for example, cardiac care and cancer care) to further identify and resolve any potential glitches in the system. Information technology staff would be on-call throughout the implementation phase to resolve any potential errors or answer questions from the intended users in order to ensure a seamless surveillance system launch.

Critical Incident Analysis

During the critical incident analysis phase, assigned hospital staff members from clinical, biomedical engineering, infection control, and other relevant departments must understand what happened, how and why the incidents occurred, and identify appropriate actions to resolve each situation. Following the implementation of these actions, their impact must be monitored, evaluated, and shared with all parties involved.[46] Vincent et al. proposed a critical incident

analysis framework based on evidence in the published literature. The framework provides investigators with a structured approach on how to perform a comprehensive critical incident analysis by outlining the main factors and related contributory factors for consideration. It is important to note that errors that do not result in patient adverse events (i.e., near misses) are not excluded from the analysis process.[47]

Evaluation of Proposed Medical Device Surveillance System

Surveillance systems are dynamic and require acceptance from intended users to render them successful. Moreover, they must be flexible enough to incorporate changes to ensure their relevance over time. It is important to understand how hospital decision-makers and health care providers plan to use the surveillance data. Data quality, timeliness, credibility, leadership, and persistence in data feedback processes were identified as additional important factors to surveillance systems that will improve patient safety.[38]

Once the surveillance system has been in operation for a predetermined time frame, a comprehensive evaluation should be conducted to measure its utility in and impact on the reduction of barriers to reporting AMDEs, incidents, and device malfunctions by health care professionals. Health care providers and hospital administrators would be asked to complete anonymized surveys, as well as participate in individual interviews or focus groups to solicit feedback on the communication strategies, education and training program, and overall user experience with the surveillance system. The evaluation would determine whether the surveillance system met its objectives. Questions might be, “Was the data collected in the system relevant and timely?”, “Was it useful for hospital administrators and health care providers?”,

"Was the system easy to use?", "Would the hospital administrators and health care providers continue to use the system?", "Are there opportunities to further enhance the attributes of the system?".

The surveillance system also would be evaluated to measure its impact on reducing the risk of patient complications, length of hospital stay, plus morbidity and mortality based on the surveillance data and patient records. Periodic evaluations, both from functional and technical perspectives, are necessary to determine effective actions to maintain the relevance of the surveillance system.[48] For example, if surveillance data revealed that defibrillators failed to deploy repeatedly due to human factors, then a training program on the appropriate use of the device would help to reduce this type of incident in a measurable way. Conversely, if the root cause of the same issue was uncharged batteries, then a program that ensures that defibrillators stay plugged-in could reduce this type of incident and be beneficial.

3.3 DISCUSSION

Summary of Results

Sixteen interviews with physicians and RNs were conducted to identify medical devices that gave rise to incidents and to explore factors that influence recognition, reporting, and resolution of device incidents. The participants also were asked to identify barriers to and suggest areas for improvement for medical device safety surveillance. Depending on the respondents' speciality and professional role, their experience with incidents involved implantable and compressing devices, surgical instruments, and machines commonly caused by human error or malfunctions. Participants were asked to provide examples as prompts to describe factors that influence device

incident recognition, reporting, and resolution according to their experience. Appendix 4 is not meant to represent a comprehensive list of medical devices that give rise to incidents but rather to highlight some examples provided by the interviewees.

Similar to the published literature, common barriers to the recognition, reporting, and resolution of medical device-related incidents were associated with lack of awareness on how and what to report in the local error reporting system, and the perception that error report was time-consuming. Hospital staff knowledge and experience also posed as a barrier, in some instances, to recognizing and resolving a device incident or malfunction. As reported in previous studies, respondents mentioned fear of punishment, especially if the incident was associated with an off-label use of the device, legal consequences and negative impact on one's reputation as additional barriers to incident reporting. Some cardiologists and cardiac surgeons did not perceive any significant barriers to recognition, reporting, and resolution of device incidents. Suggestions to improve medical device safety surveillance centered on education and training to ensure that the staff were able to use the medical device properly and know what and how to report errors.

The recognition, reporting, and resolution of medical device-related incidents also can be influenced by issues of information privacy and security associated with the use wireless devices. These devices can be implantable, worn on the body or for other external applications and can be used in hospitals, homes, clinics, laboratories, and blood establishments. Although not legally enforceable, the FDA issued guidance documents in 2013 on wireless medical devices that outline considerations for the selection of wireless technology, quality of service, coexistence and electromagnetic compatibility and standards for cyber-security, including wireless signals

and data. As wireless technologies are becoming more widely used in hospitals, staff also must review their network devices and take appropriate measures to protect patient sensitive data, including developing a security strategy for health care delivery via mobile devices.[49,50] The guidance also presents recommendations on premarket submission for manufacturers. They relate to product description, a risk-based approach to verification and validation, summaries of test data, and information of the product labeling.[51]

During one interview, a RN felt that nurses should play a bigger role in medical device selection for use in clinical practice. In many instances, current PMS systems failed to detect device defects before they were used in large patient populations. Physicians felt that large-scale registries would permit a more accurate and comprehensive understanding of the frequency of use of specific medical devices in clinical practice and their performance. Clinical registries and remote registering databases lend themselves to data collection and information sharing that would provide health care professionals with a more accurate confidence of the device reliability and would lead ultimately to improved patient care.[52,53] Kramer et al. compared and contrasted postmarket surveillance systems of medical devices in the United States, European Union, Japan, and China. The authors noted that all systems relied on passive adverse event collection, but differed in their allocation of stakeholder responsibilities and methods to evaluate the performance and safety of marketed devices. They recommended a more active approach to medical device surveillance and better coordination among regulators, manufacturers, clinicians, and patients to protect patients from ineffective or harmful devices while still maintaining access to new devices.[54]

One physician in the interview indicated that safety checklists were employed as preventive measures for incidents. A before-and-after observational study on the effectiveness of surgical safety checklists was conducted across all acute care hospitals in Ontario. The findings indicated that the checklists did not significantly improve patient outcomes, such as operative mortality, after their implementation unlike the results in previous studies. It is possible that any significant improvements previously reported in previous studies were dependent on the study settings, or a formal training and closer monitoring of compliance would have greater impact on enhanced patient outcomes.[55] Even though Polisena et al.'s systematic review encompassed a variety of health care technologies or hospital patient safety, factors described in the studies on error recognition and reporting and strategies for improvement are aligned with those related to medical device incidents according to the interview results.[20]

We proposed a framework to improve the safety of medical devices used in a Canadian hospital facility based on evidence in the literature and interview responses on factors that influence the recognition, reporting, and resolution of device-related incidents. Our assessment suggested that a medical device surveillance program that combines an AMDE database, education and training program, medical device and equipment library, and open communication and feedback strategy would be instrumental to improve patient care. We advised that direct costs of the surveillance system be calculated both in the planning and implementation phases of the initiatives, while the benefits would be assessed in the implementation phase in order to evaluate the impact of the safety of medical devices in the hospital. A partial or complete implementation of the proposed framework in a Canadian hospital facility would enable an assessment of its effectiveness in patient safety enhancement. Furthermore, data collected on the clinical outcomes and quality of

care can contribute to cost-effectiveness studies of a new medical device compared with the standard care.[52]

A 2012 systematic review developed a "contributory factors framework" from the published literature on factors that add to patient safety incidents in a hospital context. Among the 95 empirical studies that were included, 30 were conducted in an intensive care unit (ICU) and 16 in a surgical department. Active failures (i.e., any failure in performance or behaviour of the health care professional), individual factors (i.e., characteristics of health care providers), communication systems (i.e., effectiveness of the processes and systems in place for the exchange and sharing of information between staff, patients, groups, departments and services, equipment and supplies, and management of staff and staffing levels) were most frequently identified as contributory factor domains in both settings. On the other hand, training and education were identified less frequently in both the ICU (n=8; 2.1%) and surgery (n=3; 0.89%).[4,7]

To help hospital staff learn from a medical device-related incident, Amoore and Ingram developed an anonymous feedback framework that included a description of the incident and its cause, lessons to be learnt, action taken to correct the incident, and interventions to help prevent errors.[56] Although not specific to a hospital setting, Maisel argued for a staged notification if a patient's medical device was recalled, where physicians were notified first by the manufacturer. In turn, they notified the patients. This approach facilitates shared decision making between the physician and patient on the appropriate course of action. Since the use of medical devices in clinical practice continues to expand, rigorous monitoring for medical device performance,

greater awareness of device malfunctions, the introduction of unique device identifiers on devices to improve their traceability in the United States and Europe, and demand for increased reliability of medical devices are warranted.[57,58]

The Normalization Process Theory can provide further insight on factors that influence the recognition, reporting, and resolution of medical device-related incidents in a hospital facility. Also, it can be used to describe factors that influence the implementation and integration of medical devices in a hospital setting.[59] This theory incorporates four constructs that describe how processes are used to operationalize new health technologies or interventions in routine practice and ensure their sustainability. They include coherence (i.e., participants' capacity to cooperate and coordinate their actions to implement a new medical device), cognitive participation (i.e., participants' commitment to operationalize the medical device in their setting), collective action (i.e., how participants operationalize a new medical device), and reflexive monitoring (i.e., how participants appraise the ways that a new medical device impacts them and their surroundings). The toolkit helps us to understand the human processes involved in the implementation, embedment, and integration of new medical devices in routine practice.[59]

Even though previous studies developed a framework on incident reporting to improve patient safety in a hospital context,[60,61] we did not identify relevant studies on factors that influence the recognition, reporting, and resolution of medical device incidents and improvement strategies. Our interview responses suggested that factors that influence the recognition and reporting of device incidents were consistent with results for medical errors or incidents as reported in previous systematic reviews.[4,20,60,61] A qualitative study design allowed for an in-depth analysis

that may not be feasible with a quantitative study. Semi-structured telephone interviews allowed interviewees to feel comfortable enough to discuss their experience and concerns related to medical device-related incidents without feeling intimated by their peers or superiors. In addition, the interviewees were assured that neither they nor their organization would be identified in the study results. The interview responses provided some insight on strategies to ameliorate the recognition, reporting, and resolution of medical device-related incidents. Responses from the telephone interviews related to barriers to reporting and suggestions to improve the surveillance of incidents were aligned with the results of a previous systematic review.[20]

Limitations

Interpretation and application of the findings may be influenced by several limitations. As our study was exploratory, we limited the setting to two academic hospitals. Responses from the telephone interviews may not be transferable to community care hospitals or other health care settings as tertiary care institutions differ in terms of clinical procedures performed, medical devices used, and hospital policies, processes and procedures.

Purposive sampling was employed, so participants were not randomly selected but were invited to participate to provide diverse perspectives according to years of practice and specialty areas. There was a potential for responder bias, where physicians and RNs, who are more interested in medical device-related incidents compared with their colleagues, agreed to be interviewed, influencing the responses. For example, we attempted to recruit more RNs from each hospital, but they indicated that they were unable to participate due to their schedules. We, however,

ensured that at least one RN in the OR and ICU participated in our study and our analysis of their responses suggested similarities in their perspectives and experiences in medical device incidents in hospitals.

The authors were unable to ascertain if the device incidents occurred due to the device malfunction, user error or insufficient knowledge on their proper use, as well as the severity of device incidents.

As telephone interviews were conducted for practical reasons, the interviewer was unable to see interviewee's physical gestures or nuances that can been seen in person. Instead, she relied on the interviewees' audio cues.

Directions for Future Research

Our exploratory study sought feedback from physicians and RNs about their experiences with medical device-related incidents in a hospital context. Interviews with physicians with other specializations, hospital administration staff, the Biomedical Engineering Department, and manufacturers would provide additional information on factors that influence the recognition, reporting, and resolution of device incidents and can serve as a counterpoint to the interview responses in the current study. In addition, interview responses from health care professionals in a community hospital setting can be compared and contrasted with responses in the current study to identify potential trends, similarities, and differences. Future research can further investigate the device malfunctions cited by the interview respondents by reviewing any existing hospital records, and compare them to reports of recalls to assess their prevalence and severity in clinical

practice. In addition, follow-up interviews to review how device malfunctions were handled after they reported errors to the hospital and compare the results to their written policies and procedures that explicitly states the principals and course of actions merits an investigation.

Since numerous respondents indicated that an active role of these other health care professionals is paramount to reduce the risk of device incidents, their insights could help to create a comprehensive framework that outlines components of an ideal surveillance system. The data collected from this system can then contribute to design improvements for medical devices and training programs to reduce the risk of user error.

Recent initiatives are developing innovative study designs to improve the reliability of premarket assessment on the use of medical devices in "real-world" settings.[62,63] New paradigms propose hierarchical modeling that combines premarket and postmarket data to illustrate the effectiveness and safety of a medical device throughout the total product lifecycle.[64] Continued research in this area can be used to inform recommendations to strengthen post-market device surveillance, as well as integration with pre-market data.

The telephone interviews in our study illustrate some of the perceptions of physicians and nurses related the recognition, reporting, and resolution of medical device-related incidents. Further investigation is required to understand the causes and rationale behind their thought processes and behaviours. For instance, follow-up interviews would provide some insights on the physician and RN perceptions of devices the risk they pose to their patients, as well as elucidate why

physicians and RNs are concerned about their professional reputation if it is their obligation to deliver health care to and ensure the safety of their patients.

An exploration of exemplar Canadian and international medical device surveillance systems and their features and their application in a hospital setting can lead to the development of a minimum data set for incident reporting. These developments warrant further evaluation as they will help to ameliorate patient care outcomes and health care delivery. Future research can further investigate the device malfunctions cited by the respondents and compare them to reports of recalls to assess their prevalence and severity in clinical practice.

3.4 CONCLUSIONS

Sixteen interviews were conducted among physicians and RNs in two teaching hospitals. They were asked to describe factors that influence the recognition, reporting, and resolution of medical device-related incidents and their improvement strategies. The hospital staff's knowledge and experience, as well as the patient's clinical characteristics and device performance were important factors in incident recognition. Incident severity, awareness and ease of use of reporting systems and processes, as well as organizational culture and personal attitudes and perceptions of responses contributed to the frequency of reporting incidents to the hospital, regulators, and manufacturers. The discontinued use or disinvestment of a medical device or equipment was the most common resolution to prevent the reoccurrence of a similar error. Suggested strategies for improvement were associated with education and training, institutional and professional cultures, and improved reporting systems and processes. Future research can investigate the experiences of other health care professionals, regulators, and manufacturers on

medical device-related incidents and the integration of premarket and post-market data to enhance medical device surveillance systems and improve patient outcomes. The proposed medical device surveillance system incorporated multiple components to accurately document and assess the appropriate actions to reduce the risk of incidents, adverse events, and patient harm.

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APPENDIX 1: INTERVIEW GUIDE

Identify Common Medical Device-Related Incidents; Explore Factors Influencing their Recognition, Reporting, and Resolution; and Describe Local Incident Surveillance Systems or Process

Dial: <*insert dial-in number*>

Participant Code: <*insert code*> Moderator code: <*insert code*> <*insert number*> to start recording

OPENING REMARKS

Introduce yourself:

- Hello, my name is Julie Polisena.
- I'm a PhD candidate in the Department of Epidemiology at the University of Ottawa.
- This interview is part of my doctoral thesis, "*Medical Device-Related Incidents: Factors that Influence their Recognition, Reporting, and Resolution and a Taxonomy of Mitigation and Prevention Strategies"*.

Objective:

- I am going to ask you a few questions about the types of devices that give rise to incidents, based on your experience, as well as the nature of those incidents. I would also like to explore factors with you that influence incident recognition, reporting and resolution and discuss the nature of device incident reporting systems in your hospital, if it exists.
- The interview will require about 30 minutes. You will be audiorecorded, but your responses will remain anonymous, and neither you nor your organization will be identified.
- Before we begin, do you have any questions*?*

PROFESSIONAL ROLE

First, I have a few simple questions so that we understand your professional role.

- *For nurses only*: What is your speciality (e.g. intensive care unit, cardiac care, emergency medicine, operating room, etc.)?
- *For all interviewees*: How long have you been practising your profession?

MEDICAL DEVICE-RELATED INCIDENTS

Now we'll explore the factors common to medical devices prone to incidents and the nature of these incidents.

Definitions:

Medical devices: (henceforth called devices): For this study, devices are defined as technology for monitoring, investigating, replacing or modifying the anatomy or a physiological process. They are classified internationally as high-risk, and in several studies were highly associated with incidents.

Incident: an event or circumstance which could have, or did lead to unintended and/or unnecessary harm to a person, and/or a complaint, loss or damage.

Adverse event: an unintended injury caused by medical management rather than by a disease process.

Common device-related incidents

- In your area of practice, please identify the types of devices more commonly associated with incidents.
- Please recall a particular incident that resulted in an adverse event, and describe:
    - Incident
    - Clinical procedure
    - Timeframe of when the incident occurred
    - Frequency of incident occurred
    - How it was identified
    - Who was involved (including different departments, hospitals, clinics, clinicians, etc.)
    - Whether and how it was reported
    - How it was managed or resolved
    - Outcome

Factors Influencing Recognition

- What are some factors that influence the recognition of these incidents?
    - Device features

- Clinician / Team / Institution / System
- Patient
- Reporting system availability and features (hospital-based or manufacturers)
- Professional culture/image
- Education/guidance for recognition and reporting
- Feedback on how reported information is used
- Motivation/incentives/risks for reporting

Prompt: Can you provide an example of how you recognized a medical device-related incident that occurred with a patient?

Factors Influencing Reporting

- What are some factors that influence the reporting of these incidents?
  - Device features
  - Clinician / Team / Institution / System
  - Patient
  - Reporting system availability and features (hospital-based or manufacturers)
  - Professional culture/image
  - Education/guidance for recognition and reporting
  - Feedback on how reported information is used
  - Motivation/incentives/risks for reporting

Prompt: Can you provide an example of how you reported or what prompted you to report a medical device-related incident that occurred with a patient?

Factors Influencing Resolution

- What are some factors that influence the resolution of these incidents?
  - Device features
  - Clinician / Team / Institution / System
  - Patient
  - Reporting system availability and features (hospital-based or manufacturers)
  - Professional culture/image
  - Education/guidance for recognition and reporting
  - Feedback on how reported information is used

- Motivation/incentives/risks for reporting

Prompt: Can you provide an example of how you resolved a medical device-related incident that occurred with a patient?

Repeat this process for a different type of device, and for different types of incidents, medical errors and near misses.

Definitions:

Near miss: potential adverse event that could have harmed the patient but did not do so as a result of chance.

Error: a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot attribute to the intervention of some change agency. Failure of planned actions to achieve their desired end—without the intervention of some unforeseeable event.

Local Surveillance Systems

Now we'll discuss the surveillance systems or processes for medical-device related incidents.

Definition:

Post-Market Surveillance Program: Involves the collection, monitoring and assessment of adverse reactions to marketed health products and other data, as well as standard market intervention and communication procedures, along with associated policy development and business transformation activities.

- Please describe your local processes and systems for recognition, reporting and resolving device-related incidents.

Prompt: Are you aware of any initiatives underway at your hospital to improve the recognition, reporting and resolution of device-related incidents?

Prompt: What are some of the factors that create barriers to the recognition, reporting, and resolution of incidents?

Prompt: Apart from what you have already told me, how can we improve the recognition, reporting and resolution of device-related incidents?

CONCLUSIONS

Is there anything else you would like to add?

Do you have any questions for me?

Before we conclude, we could use your help in identifying <*insert profession*> at your primary place of practice, and other sites where you practice so that we can invite them to participate in a similar interview.

Thank you for taking the time to speak with me.

APPENDIX 2: CODE DICTIONARY

Theme	Code	Definition	Example
Clinician communication with patient	Clinician informs patient and/or family of potential problem medical device	Patients and family members are informed of potential problem with medical device	~Our hospital decided, probably a little prematurely, to notify every single patient we operated on in that time period. So, there was phone calls left right and centre, panic.
Clinician communication with patient	Clinician informs patient and/or family of risks involved with off-label use of device in patient	Patients and family members are informed of off-label use of medical device	~we will present that also in our discussion to the patient and their family, you know, that this plan has been subjected to a multidisciplinary review
Clinician communication with patient	Clinician informs patient and/or family of risks involved with novel clinical procedure	Patients and family members are informed of novel clinical procedure with medical device	~And we're all very concerned that if there's an incident, that it's not related to patient selection. But when we're discussing the procedure and getting consent for the procedure from the patients, we are very careful to relay our previous experience and we're anxious for them to understand, 'You're about to undergo something novel -'
Clinician communication with patient	Clinician informs patient and/or family of medical device-related incident	Patients and family members are informed of potential problem with medical device	~the incident was disclosed to the family and the patient when the patient was awake. So it was an internal management of the problem.
Clinician communication with patient	Clinician informs patient and/or family of manufacturer advisory	Patients and family members are informed of manufacturer advisory for medical device	~so the company knows who's got it. So the company notifies them and the hospital notifies them. So when a patient comes in, they know what, it's on advisory. Then we recommend the treatment.
Clinician communication with patient	Clinician informs patient and/or family of incident with medical device	Patients and family members are informed of potential problem with medical device	~We have a responsibility to tell the patient.

Theme	Code	Definition	Example
Clinician communication with patient	Clinician gives full disclosure to patient and/or family of risks involved with clinical procedure	Patients/family are provided full disclosure by the hospital on potential risks associated with clinical procedure	~whenever I do things off label, I open myself to the risks of liability later. So, we have a culture of honesty and trying to be as upfront with the patient. And there've been instances where we've offered patients something novel, and they've declined, because of our description. I: Right. Or the risks involved. And so you – er, sorry, please. I'm interrupting - P: Um, or the lack of knowledge around the risks involved
Clinician communication with patient	Clinician informs patients/families of novel clinical procedure	Clinicians discuss novel clinical procedures with patients/families to help them to understand the risks involved and to obtain their consent	~But when we're discussing the procedure and getting consent for the procedure from the patients, we are very careful to relay our previous experience and we're anxious for them to understand, 'You're about to undergo something novel -' I: Right. P: 'that we don't know the ten year consequences for this.
Conflicts of interest	Clinicians have more vested interest in manufacturer versus nurses	Clinicians have a more vested interested in a medical device compared with nurses	~nurses will be easier cause they have no vested, sort of biased interest one way or another, where the surgeons will be harder to convince
Education and training	Hospital staff is aware of medical error or incident reporting mechanism	The hospital staff is aware of the medical error or incident reporting mechanism in their institution	~there's definitely a mechanism to deal with it, sure, and there's an awareness of it, I think. There's an awareness of medical error and that, for sure, in our, I think we have a culture of looking for that here.

Theme	Code	Definition	Example
Education and training	Manufacturer provides training for new staff	Manufacturer provides additional training on the use of medical devices to new hospital staff	~where we have new fellows who are learning. We'd show them how to do it; we're work with them. And then they're still having trouble. So we got the company to come in and give them like a day long symposium kind of, on it. So, I think we're pretty proactive about trying to make sure that everybody understands how to use the equipment properly.
Education and training	Nurse educator provides continuous education on equipment programming to hospital staff	Nurse educator provides continuous education and sessions on equipment programming (e.g., infusion pumps) to hospital staff	~I: Okay. Okay. All right. Thank you. And I just, you mentioned earlier, continuous education efforts. So would that imply a nurse educator having a session or some sort of, um, education rounds, related to, for instance, programming of infusion pumps or would it also involve a manufacturer representative coming to the hospital and providing some in-servicing or an education session? P: There've been both.
Education and training	Update hospital staff with in-services on safety tools and on medical device features	Hospital staff are updated with in-services on safety tools and to understand medical device features	~We actually do in-services, weekly in-services as well, just to update people on all of the, sort of some of the tools that we use and anything that's knew or maybe alert someone to, you know, 'If it doesn't turn on, maybe this is what, you know, the tourniquet has a safety feature so that you can't accidentally turn it off during the surgery.' So definitely teaching.
Education and training	Report and discuss medical device-related incident at morbidity and mortality rounds	Clinicians participate in morbidity and mortality rounds where medical device-related incidents are discussed	~Other instances, if we've had several events, we have continuous quality improvement process, where we're having morbidity and mortality rounds on a monthly basis.

Theme	Code	Definition	Example
Education and training	Report and discuss incidents with colleagues at quality review rounds/case conferences	Clinicians participate in quality review rounds/case conference where medical device-related incidents are discussed	~If there was no other kind of, good chance, again, I would, usually the same people at the morbidity and mortality review are a head of our case conference, where we would, are also present at our pre-operative case conferences. And I would present the plan again. We'd discuss the previous event, and say 'Look, is there another way? Is there a different device? Any other suggestions?' So, I don't think I'd be worried about any personal consequences.
Education and training	Clinician participates in interdepartmental formal rounds	Clinicians participate in formal rounds with multiple hospital departments	~And then we hold, do our formalized rounds both within ourselves, interventional radiology and with vascular surgery and with radiology, the department of medical imaging as well.
Education and training	Manufacturer provides training for new staff	Manufacturer provides additional training on the use of medical devices to new hospital staff	~where we have new fellows who are learning. We'd show them how to do it; we're work with them. And then they're still having trouble. So we got the company to come in and give them like a day long symposium kind of, on it. So, I think we're pretty proactive about trying to make sure that everybody understands how to use the equipment properly.
Education and training	Hospital interaction with manufacturer on education	Hospital is in regular contact with manufacturer for educational purposes	~We're in contact with manufacturers quite frequently, for educational purposes. And they often do come in the operating room, because they're, if we're doing a complicated case, and they may want, we may want their help. So, they certainly are intricately involved.
Education and training	Nurse educator provides continuous education on equipment programming to hospital staff	Nurse educator provides continuous education and sessions on equipment programming (e.g., infusion pumps) to hospital staff	~I: Okay. Okay. All right. Thank you. And I just, you mentioned earlier, continuous education efforts. So would that imply a nurse educator having a session or some sort of, um, education rounds, related to, for instance, programming of infusion pumps or would it also involve a manufacturer representative coming to the hospital and providing some in-servicing or an education session? P: There've been both.

Theme	Code	Definition	Example
Education and training	Lack of awareness of implications of not reporting errors	Hospital staff are unaware of implications of not reporting an error or incident	~But it surprises me that the person that may be reporting it to me, or that I see, you know, involved in it, doesn't realize that that level of implication. And I say "Well, first, you have to document it."
Education and training	Lack of knowledge of ownership for device incident or malfunction	There is a lack of knowledge of ownership for medical device-related incident or malfunction	~But so, I'm not sure so that it's a professional image. To some extent, it is a medical legal issue. If you, like, who, if a device has malfunctioned, was it because of how it was implanted or whether it was a fundamental problem with the device. So I think there is some fear of a medical legal problem, and who has ownership of that.
Education and training	Lack of knowledge of how to report an error	There is a lack of knowledge of how to report a medical device-related incident or malfunction	~ knowledge of how to complain and time factors, like, not knowing how to make a complaints or lodge a complaint and you know, often what happens is you troubleshoot it enough that you kind of get through the case and then you can't be bothered, you know, you don't have time and you can't be bothered putting a complaint in. You know, you get busy and you move on to the next case.
Education and training	Clinician is unaware of hospital database for medical device-related incidents	Clinician is not aware of a hospital database specific to medical device-related incidents	~There is no database, as far as I know, where we actually report at the hospital, where we do report complications for medical device ~But I'm not aware of any that exist just for complications and device failures.
Education and training	Clinician is unaware of hospital initiatives to improve recognition, reporting and resolution of incidents	Clinician is not aware of any initiatives in the hospital to improve recognition, reporting and resolution of incidents	~And are you aware, (name), of any initiatives underway at your hospital to improve the recognition, reporting and resolution of device related incidents. P: No.

Theme	Code	Definition	Example
Education and training	Clinician is unaware of barriers for device incident recognition, reporting and resolution	Clinician is not aware of any barriers for medical device-related incidents recognition, reporting and resolution in his institution	~I don't, I haven't, I don't think there are. In our institution, I don't believe there are barriers in terms of reporting or resolving these issues. I think the reporting system is a very, is accurate. It's fairly robust. In terms of resolution of the incident, I think we have a process to resolve the incident, whether it be through hospital means; through working with the companies to understand why the device malfunctioned. I think there are a number of processes in place that we are able to resolve the incidents in an effective manner. ~In our hospital, again, our recognition of adverse events, reporting adverse events, and with technology devices, I think again, is very, is a good process. We have a very good process for that. And, again, resolving them in our institution, I don't know what everyone else does, but I can tell you, at our institution, I mean, we, again, we work through a process. And until people are comfortable the adverse event is resolved, then it, you know, it doesn't get closed. Again, if the adverse event is a minor adverse event and everyone tends to agree that this is something that's minor and if it was related to a device malfunction, again, we recognize that and we work through it to understand why the device didn't work. Now, that may not be through the hospital; it may be through the manufacturer. So again, I don't think we have a major problem with that at our hospital. Devices do malfunction, (inaudible 23:45). So, but in terms of resolving them, and the process, in terms of reporting, I don't have any problems with that.
Education and training	Lack of knowledge of ownership of error	Some RNs do not always report errors because they should take ownership	~But so, I'm not sure so that it's a professional image. To some extent, it is a medical legal issue. If you, like, who, if a device has malfunctioned, was it because of how it was implanted or whether it was a fundamental problem with the device. So I think there is some fear of a medical legal problem, and who has ownership of that.

Theme	Code	Definition	Example
Education and training	Ensure hospital staff receives adequate training on device	Hospital staff must be adequate on the use of a medical device	~I think more immediate feedback maybe about particular incidences, and it's more education for me, because there's probably a lot of the times, and maybe the majority of times, where it's a lack of knowledge that I have, about using it, rather than the product necessarily being faulty.
Education and training	Provide continuous education to hospital staff on how to operate a medical device	Hospital staff should receive continuous education on how to operate a medical device in order to reduce the risk of human error	~Well, I think the human errors in reprogramming the infusion pumps, I don't know, continuous education; reminding people they have to be very careful when they do this.

Theme	Code	Definition	Example
Education and training	Adequate training on medical device should be provided as patient care responsibilities are shifted from one health care profession to another	As responsibilities related to patient care are transitioned from one health care professional to another, adequate training on the use of medical devices for staff members with new responsibilities	~Dialysis nurses are given, I think it's like a six week training program on how to run these machines, when the responsibility for running the machines transitioned to the bedside nurse, we were given eight hours. So there's a definite education component to that. The same thing is happening with ECLS, the extra corporeal life support machines. For year, it was perfusionists who were at the bedside and ran the machines. Perfusionists do an eighteen month course to do that. And again, we were given an eight hour training session and the perfusionists leave now. And so, I think errors are happening because we're getting short tracked on training with some of these devices. I: Okay. Okay. So more training and perhaps continuous training on these types of devices, you feel would help to reduce the risk of human errors when using these specific medical devices? P: Absolutely. And again, these are responsibilities that are being transitioned from different healthcare professionals in, onto the bedside nurse.

Theme	Code	Definition	Example
Education and training	Have adequate training for staff on use of new device	Hospital staff must be adequate trained on the use of a new medical device	~Or more commonly, was the learning curve just too steep and was the training not adequate enough, to avoid the problem? And most companies are quite good about training courses. And some of them make the training courses mandatory before you use new devices. But it's, you know, it's still somewhat flexible. I mean, surgeons are on their own accord, so to speak or left to their own, to achieve a comfort level with an implement, whether it's an old one or particularly a new one that they're going to try. And so they've gotta be, they have to adopt a certain comfort measure on their own, before trying it. Now, is that standard and uniform? No, people are different. And so, you may have people who are a little more cavalier and others who are extremely cautious. And so, I'm sure there's a bell curve as to where those individuals fall. But, mitigating the problems are usually, mostly have to do with training and technique of the surgeon.
Education and training	Clinician is unaware of hospital initiatives to improve recognition, reporting and resolution of incidents	Clinician is not aware of any initiatives in the hospital to improve recognition, reporting and resolution of incidents	~And are you aware, (name), of any initiatives underway at your hospital to improve the recognition, reporting and resolution of device related incidents. P: No.
Education and training	Training to increase awareness of reporting system to hospital staff	Training should be provided to hospital staff to increase their awareness of existing reporting system	~, I think the availability of the systems, and education about the systems. So if there was something in place already, it would be certainly nice to have somebody let us know about it
Education and training	Training on how to report errors	Training should be provided to hospital staff to on how to report errors	~and how it works.

Theme	Code	Definition	Example
Education and training	Provide continuous education to hospital staff on how to operate a medical device	Hospital staff should receive continuous education on how to operate a medical device in order to reduce the risk of human error	~Well, I think the human errors in reprogramming the infusion pumps, I don't know, continuous education; reminding people they have to be very careful when they do this.
Education and training	Adequate training on medical device should be provided as patient care responsibilities are shifted from one health care profession to another	As responsibilities related to patient care are transitioned from one health care professional to another, adequate training on the use of medical devices for staff members with new responsibilities	~Dialysis nurses are given, I think it's like a six week training program on how to run these machines, when the responsibility for running the machines transitioned to the bedside nurse, we were given eight hours. So there's a definite education component to that. The same thing is happening with ECLS, the extra corporeal life support machines. For year, it was perfusionists who were at the bedside and ran the machines. Perfusionists do an eighteen month course to do that. And again, we were given an eight hour training session and the perfusionists leave now. And so, I think errors are happening because we're getting short tracked on training with some of these devices. I: Okay. Okay. So more training and perhaps continuous training on these types of devices, you feel would help to reduce the risk of human errors when using these specific medical devices? P: Absolutely. And again, these are responsibilities that are being transitioned from different healthcare professionals in, onto the bedside nurse.

Theme	Code	Definition	Example
Education and training	Clinician is unaware of barriers for device incident recognition, reporting and resolution	The clinician is unaware of any barriers for medical device-related incident recognition, reporting and resolution in his institution	~I don't, I haven't, I don't think there are. In our institution, I don't believe there are barriers in terms of reporting or resolving these issues. I think the reporting system is a very, is accurate. It's fairly robust. In terms of resolution of the incident, I think we have a process to resolve the incident, whether it be through hospital means; through working with the companies to understand why the device malfunctioned. I think there are a number of processes in place that we are able to resolve the incidents in an effective manner. ~In our hospital, again, our recognition of adverse events, reporting adverse events, and with technology devices, I think again, is very, is a good process. We have a very good process for that. And, again, resolving them in our institution, I don't know what everyone else does, but I can tell you, at our institution, I mean, we, again, we work through a process. And until people are comfortable the adverse event is resolved, then it, you know, it doesn't get closed. Again, if the adverse event is a minor adverse event and everyone tends to agree that this is something that's minor and if it was related to a device malfunction, again, we recognize that and we work through it to understand why the device didn't work. Now, that may not be through the hospital; it may be through the manufacturer. So again, I don't think we have a major problem with that at our hospital. Devices do malfunction, (inaudible 23:45). So, but in terms of resolving them, and the process, in terms of reporting, I don't have any problems with that.
Education and training	Lack of knowledge of ownership of error	Some RNs do not always report errors because they should take ownership	~But so, I'm not sure so that it's a professional image. To some extent, it is a medical legal issue. If you, like, who, if a device has malfunctioned, was it because of how it was implanted or whether it was a fundamental problem with the device. So I think there is some fear of a medical legal problem, and who has ownership of that.

Theme	Code	Definition	Example
Error reporting compliance	Reporting not always consistent	Hospital staff do not report incidents consistently	~So in those, in both those instances, whether or not a report gets made by the actual nurse who might have come across that is questionable. They may pass it on to somebody. But I see events like this take place on, I don't want to say a regular basis, but I see them take place on a, (sigh) certainly the occurrences I would say, are at least a few times a year, where the implications of what happened were life threatening.
Error reporting compliance	Clinician doesn't report isolated incidents that aren't deemed to be serious	If the medical device-related incident is not perceived to be serious, the clinician won't report the error	~Like, you know, if it was a one off, one device where there's an issue, we probably wouldn't report that. And again, it would depend on the magnitude.
Error reporting compliance	Reporting of medical device-related incident is voluntary, so compliance is low	Compliance is low among hospital staff for voluntary incident reporting	~The other reporting requirement is as I described earlier, which is the operating room requirement, with the debrief at the end of the case. So that always gets recorded in writing, based on a verbal discussion about how the case went. Did it go according to plan or not? If it didn't, then the issues that were surrounding that get discussed.
Error reporting compliance	Nurse is unlikely to report human errors to hospital	If human error is the cause of the medical device problem, it will unlikely be reported to the hospital	~ There have been incidences where it's been a human error in the programming of the machine. And I don't think that incident reports get completed for that.
Error reporting compliance	Reporting not always consistent among RNs	RNs don't report errors consistently	~So in those, in both those instances, whether or not a report gets made by the actual nurse who might have come across that is questionable. They may pass it on to somebody. But I see events like this take place on, I don't want to say a regular basis, but I see them take place on a, (sigh) certainly the occurrences I would say, are at least a few times a year, where the implications of what happened were life threatening.

Theme	Code	Definition	Example
Error reporting compliance	Reporting of medical device-related incident is voluntary, so compliance is low	If device incident is voluntary, reporting compliance is low	~The other reporting requirement is as I described earlier, which is the operating room requirement, with the debrief at the end of the case. So that always gets recorded in writing, based on a verbal discussion about how the case went. Did it go according to plan or not? If it didn't, then the issues that were surrounding that get discussed.
Error reporting compliance	RN does not report isolated incident with stapler	RN doesn't report isolated incidents with stapler and gets a replacement instead	~So if the first one fails, then they get a replacement.
Error reporting compliance	Clinician doesn't report isolated incidents that aren't deemed to be serious	Incidents that are not considered to be serious by the clinician are not reported	~Like, you know, if it was a one off, one device where there's an issue, we probably wouldn't report that. And again, it would depend on the magnitude.
Feedback on how reported information is used	Hospital quality committee gives feedback to department or industry to initiate action	A hospital-wide mechanism is in place where incident reports more severe than moderate are escalated to the senior level and feedback is provided to hospital department or industry to initiate action on incident	~a hospital wide mechanism for reporting any irregularity in the care of the patient. And so a device malfunction would fall under that. You can then grade your incident report, as a mild, moderate, severe or critical. And a moderate, really anything above moderate escalates that incident report to a senior level. And a critical, and if you file a critical incident report, then that goes directly to our hospital quality committee and every critical incident is reported. So those would be your mechanisms to escalate it and to have it identified as an issue. And through those mechanisms, it would then get referred back to the appropriate division or to the company and action would be initiated as a result of it. So that is probably the most common way of doing it

Theme	Code	Definition	Example
Feedback on how reported information is used	Follow-up occurred with managers of catheterization and laboratory	After a hospital incident report is completed, there is follow-up with the managers of catheterization and laboratory	~There was follow up with the manager of both the catheterization laboratory, the nurse managers, because the nurses were involved, and also the manager of the cardiac centre. ~Our hospital, again the incident has to be reported by either, by someone on the team, whether it be a nurse or a clinician on the team. And then, that gets reported to the nurse manager of that operating room or area, and that essentially then goes to an online system where you get a notification, by email, telling you that an adverse incident has occurred and that you need to now log onto the adverse event reporting system, and review it and then also make potential edits or corrections as you see fit, as someone who was involved in the situation. And then that gets reviewed by the managers of the hospital, who then decide whether it needs to go, you know, further or need further review.
Feedback on how reported information is used	Meetings and education sessions are held in hospital	After a hospital incident report is completed, meetings and education are held to understand the error	~There were meetings regarding the incident and follow up and education, in terms of actually, education back, ..

Theme	Code	Definition	Example
Feedback on how reported information is used	Follow-up occurs with nurse(s) involved and manager of cardiac centre	After an error is reported, there is follow-up with the nurse(s) involved and manager of cardiac care	~There was follow up with the manager of both the catheterization laboratory, the nurse managers, because the nurses were involved, and also the manager of the cardiac centre. ~Our hospital, again the incident has to be reported by either, by someone on the team, whether it be a nurse or a clinician on the team. And then, that gets reported to the nurse manager of that operating room or area, and that essentially then goes to an online system where you get a notification, by email, telling you that an adverse incident has occurred and that you need to now log onto the adverse event reporting system, and review it and then also make potential edits or corrections as you see fit, as someone who was involved in the situation. And then that gets reviewed by the managers of the hospital, who then decide whether it needs to go, you know, further or need further review.

Theme	Code	Definition	Example
Feedback on how reported information is used	Manufacturer improved the device safety based on feedback from the hospital	Manufacturer improved the medical device safety after hospital reported error and provided additional information	~If and when it malfunctions, and put more safeguards into the algorithms, including more sound alarms, more wording or explanation on the screen, because it has a screen that we use, a touch screen that we to program the injection contrast. And, everything goes through this touch screen type of thing and that's how the system alarms you or tells you how to do things properly. And so anyway, that was fed back and they actually made changes as well. ~I: Okay. And did you find, Dr. (name), that when you reported the error or the malfunction to the manufacturer they were receptive in the sense that they acknowledged that it could potentially have been a malfunction versus a human error with the user of the device? P: They were receptive to this fact, because they did make more safeguards available, for this to happen, and also, when we actually looked on their website, they actually, unfortunately, there were actually a lot of reports of this happening in the past, so it wasn't the first thing. It wasn't a first time for this technology to, for this to happen and the incident to happen. So, it's not the first time, like, I said, so, they did not, they did not actually feed back that it was necessarily human error to us...

Theme	Code	Definition	Example
Feedback on how reported information is used	Manufacturer improved and resolved device functionality based on feedback from the hospital	The information provided from the hospital allowed the manufacturer to improve the device functionality	~If and when it malfunctions, and put more safeguards into the algorithms, including more sound alarms, more wording or explanation on the screen, because it has a screen that we use, a touch screen that we to program the injection contrast. And, everything goes through this touch screen type of thing and that's how the system alarms you or tells you how to do things properly. And so anyway, that was fed back and they actually made changes as well. ~I: Okay. And did you find, Dr. (name), that when you reported the error or the malfunction to the manufacturer they were receptive in the sense that they acknowledged that it could potentially have been a malfunction versus a human error with the user of the device? P: They were receptive to this fact, because they did make more safeguards available, for this to happen, and also, when we actually looked on their website, they actually, unfortunately, there were actually a lot of reports of this happening in the past, so it wasn't the first thing. It wasn't a first time for this technology to, for this to happen and the incident to happen. So, it's not the first time, like, I said, so, they did not, they did not actually feed back that it was necessarily human error to us...
Feedback on how reported information is used	Uncertainty about what happens to error report	Staff are not sure how the information in the error report is used by the hospital	~What was interesting about that incident was that the, when people coming in, because I stayed with her, even though she wasn't my patient, I stayed with her to stabilize her. And people kept coming in to see her, like, for example, the dialysis team and the infection control team. And none of these people were aware of that, you know, that complication with that particular apparatus. And I mean, for large degree, the physicians wouldn't be, because they don't do glucoscans. And my physician is a very, very top notch guy. I'd trust him with my life. He just missed it, as I told him, I probably would have when I did it as well. Because you see that warning ten thousand times, and it never applies.

Theme	Code	Definition	Example
Feedback on how reported information is used	Frustration from clinician on lack of feedback	There is some frustration among clinicians on the lack of feedback on device incident or malfunction reported	~So I think there's some frustration among clinicians that nothing ever happens. You report it, and you don't get any feedback. And then, I think there's also a lack of appreciate, failure to appreciate the importance of actually reporting a device malfunction. Because you have only one, but if ten people had this problem across the country, it might be a problem. And so, we need to accept that is important to report.
Future use of medical device	Ensure availability of devices in stock	Additional medical devices should be available in stock, in instances where the device in use is faulty	~One was a situation where we had originally placed the patient under a general anaesthetic, accessed the patient, performed our required imaging procedures and placed the device in the renal artery. And then the device, according to the energy source, kept relaying a fault. And we were unable to continue the procedure, in a patient who is already under a general anaesthetic. So, from an interventional radiology standpoint, when you've planned a particular case, requiring specific components or devices, and you find out that they aren't actually, it's a problem if you have a limited stock of these. And you don't have a back up device immediately available.
Future use of medical device	Replacement of old equipment	Medical device is replaced if the original one cannot be fixed	~they could not fix the problem, so we ended up with a sort of a newer version of their power equipment. And they have to replace the old power equipment because it wasn't safe for us to go ahead and use. So that was, originally, our biomedical people discovering the problem, meeting with the company, seeing what was out there, sort of online, what different hospitals had gone ahead and reported. And sort of demanding a fix to the problem
Future use of medical device	Disinvestment/discontinuation of specific device	Hospital disinvests or ceases to use medical device	~So, we just made a local, most of us who are doing this work, continued to kind of avoid using the particular product.

Theme	Code	Definition	Example
Future use of medical device	Change in surgical procedure as a preventive measure	Clinician modifies surgical procedure to prevent future errors from occurring with medical device	~you can make it in a very dilute form or a more concentrated form. And, I may be counselled and advised by my partners on how I might have changed the dilution of the agent, one way or another, or chosen a different agent.
Future use of medical device	In-servicing from manufacturer	In-servicing from the manufacturer will fix the medical device problem	~simple in-servicing will fix the problem
Future use of medical device	Continue with use of device if no alternative therapy exists	If no alternative therapy is available, the clinical procedure with the medical device in question will be performed	~But we don't usually have an option not to do it. It's just the nature of our field.
Future use of medical device	Temporary disinvestment/discontinuation of medical device	Hospital ceases to use medical device until manufacturer provides a solution that render the medical device safe to use	~ If that has been a problem, then we would pull it and wait until the company could either provide with something that is safe or source out another vendor.
Future use of medical device	Device returned to manufacturer and hospital requested refund	A hospital staff member will return a malfunctioning device to the manufacturer and request a refund	~And what we usually do is send it back to the company. As we, youknow, cause we paid for it, and we ask them to pay us back.
Hospital knowledge and experience	RN inability to troubleshoot problems with medical device	RN does not have the expertise to troubleshoot problems with the medical device	~ Something that happens relatively frequently with dialysis machines is there's some kind of error with the dialysis machine and we are not experts at troubleshooting the machines.

Theme	Code	Definition	Example
Hospital skill and knowledge	RN sometimes is unable to differentiate between an incident and a near miss	Nurse finds it a challenge at times to distinguish between an incident and a near miss	~P: I think sort of clarifying what example an incident is, because there are things that people that aren't clinicians would think was an error that I certainly wouldn't think was an error. I: Okay. So perhaps more education then, in recognizing what an incident is, or, versus a near miss, or a device malfunction would be - P: Absolutely. I think we're all pretty clear on what a device malfunction is. The whole near miss is a huge grey area.
Hospital skill and knowledge	Hospital staff unaware of error reporting system	Hospital staff is unaware of error reporting system due to rare medical device-related incidents	~a barrier is just the fact that they are fairly uncommon and therefore, since it's not a common thing, we don't do it every day. So people may become less aware and be more likely to gloss over.
Hospital staff knowledge and experience	Clinician's ability to recognize error or device malfunction during clinical procedure	Recognition of medical device-related incident or malfunction is related to clinician's knowledge and experience	~Once the surgeon does it right or does everything right, and it fires and there's a true malfunction, the surgeon has to know, in fact, if there is a malfunction. There are certain things that will happen. One is that it may not feel right when it's fired. It may not extract easily when you try to extract it once you've finished the firing; there's something wrong. So the surgeon himself or herself has to be attuned to what that instrument should, how it should work and what it should feel like when it works. Right
Hospital staff knowledge and experience	Clinician recognizes clinical manifestations of patient	The clinician recognizes a potential incident from the patient's clinical manifestations	~or the patient, you know or there's a clinical factor, the patient becomes unstable.

Theme	Code	Definition	Example
Hospital staff knowledge and experience	Nursing staff is unable to or has limited knowledge on how to use the device properly	Nursing staff may be unable to or has limited knowledge on how to use the device properly	~Sometimes the nursing staff are there but they don't know how to use it, so you know, it just adds to frustration for me. It doesn't add to anything, it might just add to maybe a little bit of a delay but that's about it. If I think about the, another equipment is like a hydro-jet or equipment that we use to come through the liver on an open liver operation.
Hospital staff knowledge and experience	Individual(s) who knows how to use or troubleshoot the device are not in the OR	Individuals (e.g. hospital staff, manufacturer representatives, etc.) who know how to use the device properly are not always present in the OR	~And I don't understand the nuances of how to get it working well. And the tech that supports the product isn't in the OR and, cause they're not often in the OR. When they sell it to you, that's, you know, they usually are there at the beginning and then they're not there after you've bought it. And, the nurse, you know, the nurses are usually informed in terms of how to troubleshoot some of the things. But you know, occasionally, you have nurses that aren't in the room that know how to use it, so you know, we kind of stand there and look at each other and say 'You know, this isn't working well and you need to fix it.' and I don't know how to fix it and they don't know how to fix it.
Hospital staff knowledge and experience	Clinician's reliance on nurses in clinical procedure	Success of clinical procedure is related to proper set up of instruments by nurse	~The other thing that dictates everything going fine is the nurse who sets up the instrument for you, and hands it to you. She has to be familiar with the instrument. And so there is in-servicing, the nurses (inaudible 31:07). If there's a new nurse who's learning, there's always a circulating nurse who oversees the assembling of the stapler, to ensure that it's done right. After that, there's a procedure that we go through, whereby the nurse, we hand off the stapler, and the nurse checks the stapling device to ensure that we have, what we call, two intact doughnut rings.

Theme	Code	Definition	Example
Hospital staff knowledge and experience	Rapid, constant turnover limits experience with medical device	High turnover with medical devices makes it a challenge to gain experience with medical device	~ that there is a larger volume of new variants or products coming online: a newer stent, a newer catheter, newer wire; newer central venous catheter, new embolic agent. There's a greater turnover, with a shorter experience of individual products. Well, any one of us will have a broad experience in a category of procedure in which those products may be employed.
Hospital staff knowledge and experience	Referring clinicians may not have capacity to recognize problems	Clinicians who transfer patients to tertiary care hospital may not have the capacity to recognize medical device-related problems	~ I can assure you that in Thunder Bay, the clinicians who are local have no idea how to recognize problems with these devices.
Hospital staff knowledge and experience	Outside imaging/information difficult to interpret	Clinician finds it a challenge to interpret imaging information performed outside the hospital	~And, if, when imaging studies are performed at outside institutions, the interpretation of the imaging can be very murky, as it related to the presence of a device showing up on a CAT scan and determining 'Is it in good position? Has it done what it's supposed to do?' and getting that information back to me. Often, if the information just comes back, in a paper format, it's useless. I can't determine whether the device has a problem or not.

Theme	Code	Definition	Example
Impact on patient care	Patient transfer to institution from external jurisdiction	There is a lack of ownership among hospital staff for patients who are transferred to hospital from an external jurisdiction	~I think it's specific to our institution as a quaternary and tertiary centre, that these are not patients being treated within five kilometres, who live within five kilometres of the hospital. So, capturing the long term follow up, for these devices, and you know, relating to my interventional and surgery side, the surgery side, because we have regular clinics, is much better at following up the results of an intervention, than the interventional radiology side, where the proceduralist in interventional radiology may not necessarily have ownership of that patient and relies on the other clinicians who quote unquote 'own' the patient or are more responsible for them, to recognize problems.
Impact on patient care	Difficult to monitor patients referred from a distance	Follow-care is a challenge for patients who are transferred to hospital from an external jurisdiction	~Other instances would be the fact that many of our patients come from outside our local jurisdiction, and in terms of following up with patients, as a clear example, patients are referred to us from as far away as Thunder Bay. ~And it can be, we have certain regular protocols for monitoring the performance of endovascular stent grafts for aneurysm repair. And it can be exceedingly difficult to capture the patient and bring them back to Toronto, to re-image them, and reassess the device.
Incentive for error reporting	Hospital to receive reimbursement from manufacturers to replace device or part of it	An incentive to submit a report on an incident or a device malfunction to manufacturer, where hospital will receive a reimbursement to replace entire or part of device	~one of our incentives to report is to get reimbursed by the company, because we didn't think that their product was working well. So you actually want to report that so that they can, you know, there is a system with these companies, often, that if you report something missing, they have a look at it. You send, you know, the stapler, say, that misfired. You send it back to them and they have a look at it, and they'll reimburse you if there was something faulty with the product. So reporting is largely to do with that.

Theme	Code	Definition	Example
Incentive for error reporting	Safety issues with device that may cause problems	An incentive to submit a report on an incident or a device malfunction to manufacturer is raise an awareness of the safety issues with the device	~If we thought something was unsafe or something wasn't working well and was causing problems, then I guess for safety reason, that would be another incentive to report it.
Incentive for error reporting	Recognition from manager for reporting error	Recognition for error reporting acts as a positive reinforcement for hospital staff	~The manager went out of her way to try to recognize my contribution and I said that would have a big impact on people, because people like to be recognized for work they do. Especially nurses like positive reinforcement, to know that their actions are being respected or appreciated. So, there's that.
Incentive for error reporting	Clinician wants to understand why device malfunctioned	Clinician reports errors to understand the cause of the medical device malfunction	~It's also the nature of, certainly, the nature of the clinician who wants to understand why the device has malfunctioned, and that's one of the major impetus to also report an incident, so that you get an understanding of how to improve the device and to ensure an incident like this doesn't happen again.
Incentive for error reporting	More complex problems (electrical component) are more likely to be reported to medical engineering	More complex problems (electrical component) are more likely to be reported to the hospital medical engineering department	~an electric generator involved, then we try to do incident forms then. And those are the kind that medical engineering will be involved with, because there's an electrical component. If it's just a stapler, and it's a single use item, then you know, we may or may not involve medical engineering.
Incentive to error reporting	Clinician wants to reduce the risk of medical device-related incident from reoccurring	Clinician reports errors in order to reduce the risk of medical device-related incidents from happening in the future	~if I have a device that breaks, you know, that's the manufacturer's problem. So I mean, I want that not to happen anymore. So there's no negative impact on me if I report that. In fact, it's only going to make my job better.

Theme	Code	Definition	Example
Information sharing	Dissemination of information to colleagues and general public	Information on medical device problem is shared with colleagues and the general public	~Our pathologist Dr. (name 10:11) looked at our pathology specimens and we were the first in the world to actually report with this valve, which subsequently was taken off the market and actually has resulted in numerous lawsuits, so - not involving us directly, but within the company. So, that was one that a single surgeon noticed, then brought it to the attention of several surgeons and then disseminated the information publicly. So that's another way that device malfunctions can be, are brought to our attention.
Information sharing	Information exchange at peer-reviewed meeting	Information on medical device problem is shared at peer-reviewed meetings	~And then the other primary way is there may be something that has been happening outside of our immediate environment that industry brings to our attention, or our colleagues at peer review meetings. Those would be the main ways we find out about things.
Information sharing	Collegial opinion/experience, ie. "word of mouth"	Information on medical device problem is shared among colleagues	~ This particular stent graft is a new one, from a very popular company, that other colleagues of mine had made comments that they were not as happy with the – it usually comes in three pieces we call a body and two legs. And other colleagues of mine had noted some problems with the legs (and/in 11:40) similar issues of graft thrombosis. It wasn't clear to me - I had personally never seen one with this particular device before
Information sharing	Encourage hospital staff to discuss any medical device-related incidents that they experienced, if they report them and why	Discussions among hospital staff should be encourage to talk about any medical device-related incidents that occurred, if they were reported and why	~It probably wouldn't be a bad idea to do an audit every once in a while. (laugh) You know? Just to, you know, just to see if anybody's actually come up with any, you know, has experienced anything and ask them if they've actually, if they've reported it and if they haven't reported it, why did they not report it. And so, it might, you know, stimulate more people to report them. Or, it's, you know, just maybe they don't think it's a very big deal but if they look at the big picture, you know, and the potential of harm.

Theme	Code	Definition	Example
Information sharing	Notify and discuss medical device problem with colleagues and potential users	Clinician will inform colleagues and potential users of problem with medical device	~if there's a problem with a device, I mean I think everyone in our group, you know, whatever group it is, whichever device, usually you let everyone know about the issue. And we discuss it. And you know, clearly, if there was a concern, we would stop using it. That would, so I think if anybody ever has a problem with anything, it's, the knowledge or the issue is addressed with everyone who potentially could be involved in this, using that type of equipment, for sure. I: So that would be related to – oh sorry, I was going to say to information sharing. P: So, so, if there's an issues with a faulty device, it would be communicated to, that this happened, it would be communicated to anybody who would potentially use that device, for sure.
Information sharing	Collegial opinion/experience, ie. "word of mouth"	Clinicians discuss interesting cases and patients to try to identify potential resolutions	~The other thing is we do have other, non M and M rounds, where we discuss interesting cases and problem patients. So that would also be discussed in that way as well.
Information sharing	Consult with colleagues for resolutions on novel clinical procedures	Clinicians consult with colleagues about their experience with the use of new medical devices	~Um, yes, I would say, if I'd had challenges with that device before, then I would look to have another colleague around, who might have used it a couple of extra times. And that's, I definitely see this in interventional radiology, compared with my surgical practice, that there is a larger volume of new variants or products coming online: a newer stent, a newer catheter, newer wire; newer central venous catheter, new embolic agent. There's a greater turnover, with a shorter experience of individual products. Well, any one of us will have a broad experience in a category of procedure in which those products may be employed.

Theme	Code	Definition	Example
Liability	Clinician follows regulator's standard for clinical procedure and patient selection	Clinician takes appropriate steps to protect his/her professional reputation	~ And, at a personal level, the only thing that protects me from a class action lawsuit if something is discovered ten years down the road, is the fact that I carried the procedure out and the patient selection within Health Canada guidelines.
Liability	Risk of hospital's reputation	Hospital's reputation may be at risk with potentially device malfunctions, such as improper sterilization.	~Cause the letter probably didn't explain it well enough, you know, the corporate letter. And then, there were those patients who actually did have complications, right, which is normal in any kind of surgery. And they, of course, they questioned whether the complication was due to the device and, we had to reassure them, 'Absolutely not.' So, that was sort of, this global umbrella thing that affected all of us, even though there was no deliberate malfunction, it was a company that felt that their sterilization process, that something had gone wrong, and they couldn't, they weren't sure, so they had to send out a cover letter.
Liability	Risk of manufacturer's reputation	Manufacturer's reputation is at risk with potentially device malfunctions, such as improper sterilization.	~Cause the letter probably didn't explain it well enough, you know, the corporate letter. And then, there were those patients who actually did have complications, right, which is normal in any kind of surgery. And they, of course, they questioned whether the complication was due to the device and, we had to reassure them, 'Absolutely not.' So, that was sort of, this global umbrella thing that affected all of us, even though there was no deliberate malfunction, it was a company that felt that their sterilization process, that something had gone wrong, and they couldn't, they weren't sure, so they had to send out a cover letter.
Medical device procurement process	Review of contractual obligations	Hospital reviews contract with manufacturer	~If there is a concern about in inordinate high number of malfunctions, then I guess senior management gets involved in terms of addressing it with the company. If the company can't address the issue appropriately, then there's some discussion about, you know, contractual obligations back and forth.

Theme	Code	Definition	Example
Medical device procurement process	Follow-up with manufacturer on device malfunction	Medical device-related incident is reported in hospital and procurement department follow-up with manufacturer to address the problem	~it's almost taken out of the hand of the surgeon, in the sense that there is an official report, a report on the malfunction. It goes through several hands in terms of information. Then it goes through purchasing who then follows up with the company, on the product, and that particular lot number. Now the company will then issue a review letter, back to the hospital, addressing that particular product and that particular malfunction. Now, the hospital itself keeps track of these malfunctions.
Medical device procurement process	Verify safety of devices with available documentation	Procurement department reviews documentation on medical device before purchasing it for the hospital	~before a product can be brought in the hospital, it has to have the proper international documentation that it's safe.
Medical device procurement process	Conduct quality assurance of device prior to purchase decision	Biomedical engineering group performs a quality assurance and tests on medical devices and keep records of devices that have been tested	~We have to get the technique verified by the company, ah, techniques for disassembling, assembling, sterilizing. The hospital checks the equipment, things like Xray machines,C-arms, cautery, tourniquets machines, on a regular basis, rotating basis. So there's a record kept of when those have last been tested. And as I say, our biomedical engineering group, the first example I gave you, with the power equipment, they go ahead and sort of check things, sort of on a random basis, continually, looking for any potential problems, especially products which may be newer products that have been brought into the hospital.

Theme	Code	Definition	Example
Medical device procurement process	Incorporation of clauses in industry contracts	Procurement department can incorporate clauses in manufacturer contracts to improve their response to device malfunctions	~So when you negotiate contracts, with those companies, there's all sorts of clauses you put in those contracts. There's, you know, there's a whole series of different clauses that go into, which have nothing to do with this. You could always add another clause, saying that if your response to instrument malfunction is ineffectual, we have the option of reviewing/changing our contract obligations, you know, something to that effect. Right? So there are ways of doing that. But other than that, there's no way you can influence a company to do anything that is minimally legally required of them, right?
Medical device procurement process	Procurement department should allow frontline staff to test device and understand how it works	Procurement department should allow frontline staff to test medical device in practice to understand how to use it	~before we purchase equipment, the nurses who ultimately are going to be using them, should be the people who are deciding which devices we use." So they brought in the four devices with three bio-technical people, to show them to us and give us a brief inservice on them. And my first case in point was these people don't use them. Like none of these people ever use a glucoscan and they're giving us an inservice on it. To me, it's the same as the rep not being a nurse, explaining to me how to use a glucoscan, to me, it's ridiculous.
Medical device procurement process	Data on errors reported are used to negotiate contract with manufacturer	Hospital used data collected from the error report to negotiate a new contract with the manufacturer	~And they log them so that when another contract comes up, they have some evidence, kind of thing, that we've been having issues.

Theme	Code	Definition	Example
Medical device procurement process	Risk of severed relationship between hospital and manufacturer if hospital discontinues use of product	Hospital staff is concerned about being responsible for a severed relationship between the hospital and manufacturer if he or she reports a medical device-related incident when manufacturer representative is in the OR	~Now this company is a big company and has a major role in our operating room, for sourcing of many different implantable devices as well as sort of tools. So, if anyone was a little bit nervous, cause they're present all the time, so if that's pulled and it goes to another company, then that person might feel, you know, someone who's reporting it might feel responsible that they've sort of, lost business.
Medical device procurement process	Risk of severed relationship between hospital and manufacturer if hospital discontinues use of product	Hospital staff is concerned about being responsible for a severed relationship between the hospital and manufacturer if he or she reports a medical device-related incident when manufacturer representative is in the OR	~Now this company is a big company and has a major role in our operating room, for sourcing of many different implantable devices as well as sort of tools. So, if anyone was a little bit nervous, cause they're present all the time, so if that's pulled and it goes to another company, then that person might feel, you know, someone who's reporting it might feel responsible that they've sort of, lost business.
Organizational culture	Hospital encourages staff to report errors	Hospital culture encourages hospital staff to report errors	~So all I can say is that ah, my hospital, we encourage incident reports to be filed by anyone, could be a nurse; could be a porter, could be a clinician, could be a physiotherapist. So the environment actually encourages the reporting; the environment actually encourages a reporting of any adverse event or potential adverse event.

Theme	Code	Definition	Example
Organizational culture	Clinicians are required to report device incidents and near misses	Hospital culture requires that the staff reports device incidents and near misses	~it's the culture in the hospital, for the most part, that would make clinicians or surgeons or whatever, report a device incident. It's the culture in the hospital. We have a very strict culture to report device incidents or any type of incidents for that matter. ~I think any malfunction that occurs is reported. I can tell you, like, for instance, I was doing a procedure and the fluoroscopic machine all of a sudden powers down, right at the moment that we were deploying a device. And it just shut off. So, you know, nothing happened to the patient, but that was reported as an incident, because that is a potential risk, potentially something could have happened, very badly. And it needs to be understood why the fluoroscopic machine shut down. It needs to be repaired and safeguards put in so that doesn't happen again. So it could be a near miss, as well.
Organizational culture	Institutional reporting to media/public	Hospital reports to general public about the use of new technologies and novel procedures performed at institution	~There are instances where if we're performing a 'first in Canada' event, our institution is very interested to publicize those. And obviously, the institution PR people would not be interested in publishing a 'first in Canada' event that didn't go well. the institution itself, has a quality review, do try and pick up on adverse events and avoid them. But, they're very interested in publicly tooting their own horn, and being seen to be at the forefront of employing new technologies
Organizational culture	Hospital and its staff maintain very high standard of care	Hospital and its staff maintains a very high standard of care for patients and don't want the same incident to happen to another patient	~Because we have like a very high level standard of care. So it just wouldn't be, it wouldn't be acceptable to have that happen again. I mean, it was, the patient didn't have, it wasn't a really bad burn, but it was a burn nonetheless and embarrassing to everybody. But we didn't want that happen to anybody else.

Theme	Code	Definition	Example
Organizational culture	Hospital is less punitive when incident is reported compared with the past	Hospital staff observed a cultural change over time in hospital where incident report is less punitive	~And that's a huge cultural change. Because I can tell you, being here for twenty five years, when we used to make a mistake, we'd wait to see what the outcome was before we told anybody. Actually, 'we' meaning the team. The PSLS has become a non-punitive thing, which, they used to say that before, that when there was an incident. You know what I mean? But the incident used to still be followed by your manager and it felt as though you were getting your hand slapped. So again, it, the culture has changed in that respect, that I think a lot more people report things now then they did the past.
Organizational culture	Expansion of processes from one clinical specialty to another specialty	Processes (e.g., morbidity and mortality rounds) executed in one hospital department have not expanded to another department	~So, what I'm really fascinated about at my institution, is that those processes that are employed on the surgical side are now being adopted on the interventional radiology side, at our hospital. ~And these include regular morbidity and mortality rounds, and both the results of the morbidity and mortality rounds are reported to a hospital quality of care committee, from both departments.

Theme	Code	Definition	Example
Organizational culture	Hospital demands increased monitoring of incidents	Hospital is increasing demanding hospital incident reports on a regular basis	~And the quality of care committee at our hospital has become more insistent and demanding for regular reports from, as an example, from radiology, where traditionally, interventional radiology wasn't in the habit of tracking as closely their complications or results.
Organizational culture	Hospital committee oversees operational issues for ORs	A reporting system process for incidents exists and is overseen by hospital committee	~There's a clear line of reporting documenting and handling of these incidences with respect to, the report goes to corporate peri-op, which is our committee overseeing operational issues for the ORs at both campuses, or all three campuses.
Organizational culture	Change from punitive culture to a more education one for medical device error reporting	To encourage the recognition, reporting and resolution of medical device-related incidents, a shift from a punitive culture to a more educational one must occur	~For within the hospital itself, I think the cultural change is a challenge. I think it's probably getting better but I'm not sure if the hospital is doing it, cause they want everything documented and I think that's good. But I believe that ends of being a culture of punitive, it feels more of a punitive kind of culture as opposed to an educational thing, from what's coming down the pipe. I don't have a great solution to that. And I don't think the problem happens that often, I'll be quite frank. I mean, I don't know if orthopaedics has a problem with their devices. Our devices, if they are problematic, like I said, it's often operating error.
Organizational culture	Hospital staff are encouraged to report near misses	Hospital encourages it staff to report near misses	~Like, I said, we have this near miss, even this near miss, so they want in the (name)Institute, they actually, (I 15:45) encourage people to report anything which even could potentially be a problem.

Theme	Code	Definition	Example
Organizational culture	Hospital has a non-punitive culture towards error reporting	Hospital has a non-punitive culture with its staff towards error reporting	~I: Okay. So the culture in your institution encourages - P: Yeah I: to be transparent and to report, versus, so they see it more as information versus a punitive, you know, it's not a punitive (inaudible 21:14). P: Exactly. Yeah.
Organizational culture	Hospital and its staff maintain very high standard of care	Hospital and its staff maintains a very high standard of care for patients and don't want the same incident to happen to another patient	~Because we have like a very high level standard of care. So it just wouldn't be, it wouldn't be acceptable to have that happen again. I mean, it was, the patient didn't have, it wasn't a really bad burn, but it was a burn nonetheless and embarrassing to everybody. But we didn't want that happen to anybody else.
Organizational culture	Hospital staff are quick to resolve medical device problem	When a problem occurs with a medical device, the hospital staff is quick to resolve it.	~So, I would say, I mean, specifically with devices, I think there's, you know, we're kind of the opposite in the sense that, you know, if there's a problem with the device, we're very quick to jump on it, because it affects how we, how we work and it can impact our outcomes and that.
Organizational culture	Increase collaboration across institutions to track performance of medical devices	There should be increased collaborations across institutions to track medical devices and their application in clinical procedures	~I'm fascinated by the fact that the hospitals will get together in an organized fashion for purchasing, this centre called Plexus which is supposed to realize certain cost savings to institutions. If they need ten devices amongst six hospitals, you know, they'll approach the manufacturer as a group, to purchase and get a discount. But, there's no ah, where money is concerned, that's, they're willing to collaborate. Where tracking the results of these devices and application of these procedures, there's, these types of registries can cost a hundred thousand dollars a year to participate in. So, those savings, in my mind, would be well suited towards establishing registries that are at arms length from the manufacturer.

Theme	Code	Definition	Example
Organizational culture	Expansion of processes from one clinical specialty to another specialty	Processes (e.g., morbidity and mortality rounds) executed in one hospital department have not expanded to another department	~So, what I'm really fascinated about at my institution, is that those processes that are employed on the surgical side are now being adopted on the interventional radiology side, at our hospital. ~And these include regular morbidity and mortality rounds, and both the results of the morbidity and mortality rounds are reported to a hospital quality of care committee, from both departments.
Performance of medical device	Device deployment is complex	Clinician find many devices complex to deployment during a clinical procedure	~ Many of these devices are quite tricky to deploy and there are a series of steps that have to be followed.
Personal attitude of health care professional	Error reporting procedure can be complicated	Hospital staff perceives error reporting procedure to be complicated	~I think that when you're talking about a device, I think a lot of it is the paperwork to file the incident is very easy but the paperwork to follow up a, you know, at the government level if there's an adverse event or whatever, I think can be quite complicated. And luckily, I don't have to do that.

Theme	Code	Definition	Example
Personal attitude of health care professional	Intimidated and/or fear of legal implications	Hospital staff is worried about legal implications with error reporting	~And there's not a strong culture for this, although it's not supposed to be punitive, a lot of people feel that it. I mean, I suppose it's a little less so when it's a piece of equipment, but the reporting system itself is time, is labour intensive, as far as time goes. And a lot of people that aren't familiar with it, just like anything else, because they don't do it that often, find it very intimidating. And they think of the legal implications and whatnot. So the easiest default is just not to do anything.
Personal attitude of health care professional	Error reporting is time-consuming	Hospital staff perceives error reporting to be time-consuming	~Quite often, that person doesn't want to document it because it requires time.
Personal attitude of health care professional	Fear of risk of clinician's reputation, loss of credentials and-or privileges at hospital	Clinician fears risk of his/her reputation as a result of error reporting	~I think if I had been using a device in an off label fashion, and had a malfunction or a patient incident, then if I ever had a similar problem present itself, I would have to think twice about the potential for appearing in front of my morbidity and mortality review, more than once, for the same problem.
Personal attitude of health care professional	Fear of punishment for error reporting	Hospital staff fears risk of punishment as a result of error reporting	~So I do think there are some inherent barriers in reporting potential problems, which are cultural and people would look at it as a punitive, in a punitive manner. And I think it's actually getting worse that way, I'll be quite frank with you. Cause the hospital is asking, is trying to document everything. And then it becomes more of, it seems the push from above is that it's becoming more of a punitive kind of thing as opposed to an educational kind of thing. So, I'm not sure if we're going in the right direction or not.
Personal attitude of health care professional	There are no barriers to reporting	The hospital staff is unaware of any barriers to error reporting	~I don't think I have any barriers on reporting it. I don't know that we're always in agreement with the reports that we get back.

Theme	Code	Definition	Example
Personal attitude of health care professional	Fear of risk of nurse's reputation, loss of credentials and-or privileges at hospital	Nurse fears risk of his/her reputation as a result of error reporting	~There's definitely a professional culture around it
Preventive actions	Develop an alternate plan if problem occurs with device	If a medical device does not perform according to the original plan in the operating room, an alternate plan is executed as a resolution	~most of this stuff is recognized right at the time of surgery. And an alternate plan is carried out. So it's hard for me to think of a specific example right now, but you know, for when it does happen, you might have to go to a bigger implant, maybe a different implant. So you have a plan B, in the operating room, if the problem is really implant or device related and there's no substitute other than another device.
Preventive actions	Track information in incident report and identify ways to reduce risk of future similar medical device-related incidents	Hospital use the information in the incident report to identify ways to reduce the risk of similar medical device-related incidents from reoccurring	~And you know, just that we had a process, because we do fill out an incident report, that's a patient incident report, so that all of, that they're all tracked, and just ways, and we identify ways to avoid that.
Preventive actions	Clinicians plan on how to prevent similar errors from occurring	Clinicians get together and discuss how to prevent similar errors from occurring in the future	~And then we either plan for how to deal with the case in the future, if that's the case, or what we do is we discuss the case and see how the problem might be prevented in the future. Basically, we're learning, hopefully, we're all learning from a single person's mistake or whatever outcome there was, to try to prevent the same thing from happening in the future.

Theme	Code	Definition	Example
Preventive actions	Implementation of safety checklist to mitigate/manage incidents if they arise	Safety checklists are implemented to mitigate or manage medical device-related incidents if they occur	~Locally, we've instituted in interventional radiology, some of the same safety processes that we use in the operating room in vascular surgery. The most clear example is an interventional radiology safety checklist, before a procedure is started. And as part of that safety checklist, we include the actual devices that are required. And for this type of procedure, we now require a second catheter to be available, in the room
Preventive actions	Plan and troubleshoot with colleagues at quality review rounds/case conferences	Multidisciplinary team to plan the use of medical device in clinical procedure, including off-label use	~when we're in that situation, we employ a multidisciplinary review, where we'll sit down with an interventional radiology colleagues, several vascular surgeons, sometimes a cardiac surgeon, sometimes another hepatobiliary surgeon, and we'll discuss the plan ahead of time. We'll be reviewing whether or not it's appropriate to employ a device in this particular off label use.
Preventive actions	Implementation of safety checklist to mitigate/manage incidents if they arise	Safety checklists are implemented to mitigate or manage medical device-related incidents if they occur	~If they're on intact, then our index of suspicion that something is wrong is raised and we do a variety of things to check for that. And then the other thing is that the surgeon themselves, there's a few steps after you've done, everything looks fine; there's a few steps that we do to ensure that we have a secure anastomosis.
Preventive actions	Quality assurance of device by hospital staff	Quality assurance of medical device is performed by hospital staff mitigate or prevent medical device-related incidents	~, it has to pass through the development, like at the engineering stage. Then it would have to pass through the respiratory therapy department, because they must have trialled it before they switched. And then, it would have had to go through, you know, they all have to have policy and procedure manuals on any new equipment we had. Like it had gone through multiple layers of people, and this was never caught. And it easily could have killed somebody.

Theme	Code	Definition	Example
Preventive actions	Review of operation performed among hospital staff	Hospital debrief on operation performed to determine if clinical procedure went as planned and if any problems occurred	~Well, there's different safeguards in place. I mean, there's obviously the real time recognition, if it's not gone in according to plan. There's a brief at the end of every operative case, you know, 'How did everything go? Was everything fine? Were there any problems?' And so that typically then can, gets recorded. That does get recorded on the operative record, if there was a problem with an implant that caused a change in a procedure or a modification. But, usually, the factor that's important to it, is experience in recognition
Preventive actions	Planning on off-label use of device by multidisciplinary health professionals	Multidisciplinary team to plan the use of medical device in clinical procedure, including off-label use	~But that's a clear example of me employing a device in an off label use, for, the only other consequence was a re-do exposure of the patient's old liver transplant, with probably risks that would have exceeded those which I exposed the patient to, using this, in this off label application. Often, when we're in that situation, we employ a multidisciplinary review, where we'll sit down with an interventional radiology colleagues, several vascular surgeons, sometimes a cardiac surgeon, sometimes another hepatobiliary surgeon, and we'll discuss the plan ahead of time. We'll be reviewing whether or not it's appropriate to employ a device in this particular off label use.
Preventive actions	Safety checklists are used as cues to ensure that everything is in order	Hospital staff reviews safety checklists to ensure that everything is in order	~we do have like an electronic recording, like our electronic documentation actually, we have a checklist. So we actually go through all the checklist. So that prompts us to make sure that everything has, is in working order and is going.

Theme	Code	Definition	Example
Preventive actions	Hospital implements course of action	Hospital staff implements a course of action to manage a medical device problem as a risk mitigation strategy	~we're taking proactive measure to make sure that it doesn't have a negative consequence for our patients. Now, when we take those leads out, there has been, first of all, the patients are aware they have a lead that's on advisory. And that was done previously. So when a company puts something on advisory, they provide advice as to how to manage that particular problem. As an institution, you review what, the appropriate clinicians come together and decide whether or not they agree with the management that the company is recommending and then they will implement their course of management.
Preventive actions	Plan and troubleshoot with colleagues at quality review rounds/case conferences	Hospital staff participates in quality review rounds/case conference as a risk mitigation strategy	~the institution itself, has a quality review, do try and pick up on adverse events and avoid them
Preventive actions	Find a balance between use of safety checklist and health care delivery	Although safety checklists will help to reduce of medical device-related incident or malfunction, hospital still must focus on health care delivery for patients	~Obviously, there's a balance, where we're operating in a system where our budgets from government don't even keep up with inflation. So you have to go ahead and provide patient care, so more frequent reporting, more qualified people to go ahead and do the checks is great. But the same can be said about having more nurses on the floor per patient, more nurses in the ICU, more operating time. So, it's, all of those are important. It's not that any one is more important than the other. We have to provide patient care. We have to provide patients with safe patient care. And we can't necessarily be taking large amounts of the budget that we use to deliver patient care and have it done just in the checking of things. We could end up literally bringing our hospital to a standstill. So, it's sort of a balance of everything, all the activities that you do.

Theme	Code	Definition	Example
Preventive actions	Nurse conducts independent check of programming of equipment	Nurse conducts an independent double-check of colleague's programming of equipment	~I think there have been some situations where we've suggested an independent double check on the programming of the equipment.
Preventive actions	Implement safety checklists to mitigate/manage incidents if they rise	Safety checklists are implemented to mitigate or manage medical device-related incidents if they occur	~so I think that are far as trying to identify them, more frequent checks, which means more money which means more salary.
Preventive actions	Clinical review of pre-clinical trial results	Clinician reviews pre-clinical trial results to understand how medical device should performance	~So I think each, any device that we use has information about what would be expected about the performance of the device in the pre-clinical trial. And we would go to that to assess it and see whether this is something that would be expected for that devices.
Preventive actions	Clinical review of manufacturer instructions	Hospital staff reviews manufacturer instructions on how to management a medical device problem as a risk mitigation strategy	~we're taking proactive measure to make sure that it doesn't have a negative consequence for our patients. Now, when we take those leads out, there has been, first of all, the patients are aware they have a lead that's on advisory. And that was done previously. So when a company puts something on advisory, they provide advice as to how to manage that particular problem. As an institution, you review what, the appropriate clinicians come together and decide whether or not they agree with the management that the company is recommending and then they will implement their course of management.

Theme	Code	Definition	Example
Preventive actions	Risk mitigation strategies are developed for physicians	Risk mitigations strategies to reduce the risk of medical device-related incidents are developed for physicians	~And then we'll come up with a strategy for the physicians to be able to deal with. So, on the physician's part, it's the decision whether to use the device every again. And if it's something that's already been in someone, then you have to decide what the risk and benefits are. If the risk for taking it out outweigh the benefits of, or the risks of leaving it in, then you know, you have to make that decision on a device by device instance
Problem solving	Conflict in initial problem of error between hospital and manufacturer	Conflict is present between the hospital and manufacturer on initial access to the malfunctioned medical device for problem solving	~and ultimately that instrument, and this is where the conflicts sometimes occur, is who then, have the first right of inspecting that device and understanding its breakage. Most companies have a policy of inspecting their own broken devices. But many hospitals have their own policies as well of wanting to do this. And so, that's where sometimes, some of the friction occurs, is what is the sequence; what's the path of that broken product review, between the hospital and the company' So in this case, there was both. But there was some friction, because both parties wanted first access to the implant that broke. So there was no clinical thing.
Problem solving	Hospital staff and manufacturer representative were unable to resolve device problem	Hospital staff and manufacturer representative were unable to rectify the medical device malfunction	~I mean, on a couple of occasions, we've had two or three people who are well versed in the stapling, and they can't, you know, rectify the issue. And one time, the sales rep was even in the OR that day, and the sales rep was unable to rectify it.
Problem solving	Challenges with trouble-shooting a problem	Challenges with trouble-shooting a medical device problem is associated with a lack of understanding on how it is used	~It's more of, possibly, you know, someone not understanding how to use the equipment or how to, if we have a problem some of the gas insufflation on a laparoscopic procedure, how to troubleshoot that.

Theme	Code	Definition	Example
Professional culture	Clinician follows regulator's standard for clinical procedure and patient selection	Clinician follows regulator's standard for clinical procedure and patient selection to protect himself from a potential liability	~ And, at a personal level, the only thing that protects me from a class action lawsuit if something is discovered ten years down the road, is the fact that I carried the procedure out and the patient selection within Health Canada guidelines.
Professional culture	Hospital staff not open to discuss each other's complications	Hospital staff is not as open to discuss each other's complications with the use of medical devices	~the culture is one that, I don't think we're open to looking at each other's complications as well as we should
Professional culture	Lack of compliance in independent check of programming of equipment among RNs	There is a potential lack of compliance in independent check of programming of equipment among RNs	~I'm not sure that there's total compliance with that.
Professional culture	Transition among RNs from observer to more active role required	Nurses should play a more active role in patient care, including medical device-related incidents	~I try to encourage my colleagues to take full responsibility for everything that happens to their patient. Which I don't think is taught, culturally, to nurses today. I mean, it certainly wasn't taught to me when I was growing up, you know, or when I was first being educating. You're taught to a certain extent, to be an observer and then to perhaps state what you observe and then let others decide what should transpire, as opposed to directing what should transpire. Do you know what I mean? So there's a huge barrier there, to me, that the nurses should be empowered to take responsibility for what's going on.

Theme	Code	Definition	Example
Professional culture	More empowerment for RNs	Nurses should be more empowered to take responsibility for patient care, including medical device-related incidents	~I try to encourage my colleagues to take full responsibility for everything that happens to their patient. Which I don't think is taught, culturally, to nurses today. I mean, it certainly wasn't taught to me when I was growing up, you know, or when I was first being educating. You're taught to a certain extent, to be an observer and then to perhaps state what you observe and then let others decide what should transpire, as opposed to directing what should transpire. Do you know what I mean? So there's a huge barrier there, to me, that the nurses should be empowered to take responsibility for what's going on.
Professional culture	RNs to play more active role in refusing to use defective equipment	Nurses should be more vocal about refusing to use medical devices with problems	~I say "No, I don't use that piece of equipment anymore, because I don't trust it." And people say "Well, that's what was ordered." And I say, well, I go to the physician and I say "Look, I don't use that piece of equipment and here's why. And I've identified that problem and it needs to be changed." And a lot of people say "Well, you've been here forever so that's why you can do those kind of things." But I say "No, I've been doing that since forever.
Reporting system and process	Clinician completes necessary regulatory paperwork	Clinician completes necessary regulatory paperwork for complex clinical procedure	~if this is an elective situation, I take the time to explain this to the patient. If this is a device, for example, a 'first in Canada' application, I'll explain it to the patient and their family. In addition, I'll also have to complete certain regulatory paperwork, from Health Canada Approval. But I will tell the patient and their family 'This is a device which we've used for other situations or which is useful for other situations. And we've never used it in your circumstance. But it offers certain theoretical advantages.' And I can think of another application for a very difficult patient problem, where I had to use a stent graft designed for the arteries, in a vein

Theme	Code	Definition	Example
Reporting system and process	Hospital wide mechanism for incident reporting	Clinician submits hospital incident report	~if you recognize that you had a device related incident, then the most frequently used option by a clinician is to file an incident report. And that is, that's a hospital wide mechanism for reporting any irregularity in the care of the patient.
Reporting system and process	Manufacturer is notified of error and has their quality assurance department examine the medical device	Defective medical device is sent to manufacturer to be examined by their quality assurance department	~And it's bagged and kept for the vendor. ~That is then, the vendor is then notified. They come and pick it up and then they take it to their quality assurance department.
Reporting system and process	Computerized system increases ease of use and number of reports	A computerized reporting system will increase its ease of use and the number of error reports entered	~we have the PSLS, which is supposed track these incidents. And once you're used it, it is pretty user friendly. It's on every computer, pretty much, in the hospital now. Whereas before, you had to go find a form and fill it out. So I think a lot of them get filled out a lot more than they have in the past.
Reporting system and process	Automatic registration of malfunctioned instrument in hospital	Device malfunctions are registered automatically by the hospital	~We have policies and guidelines on malfunctioning, that automatically registers the instrument that malfunctioned; the actual malfunction; obviously the surgical team involved in that thing, identifying the type of malfunction, and then identifying not only the product but the lot number and the serial number. So that, and that automatically, there's a reporting mechanism in place, in the hospital, irrespective of whether the surgeon wants it or not. (laugh) It automatically registers these malfunctioning devices.

Theme	Code	Definition	Example
Reporting system and process	Contribute to and receive reports from a multi-institutional registry	Hospital contributes to and receives reports from a multi-institutional registry	~ the second part of my answer is that at our particular hospital, we maintain a database of risk adjusted benchmarked quality outcomes, from this type of procedure. We're the only participating facility in all of Canada. It's called the vascular quality initiative. And we are required to submit peri-operative patient and procedural data, to a registry in which more than two hundred centres participate. And then, we get monthly, we get a semi annual outcomes reports, benchmarking our quality and our performance, against other comparable centres. This database is centred around general outcomes, IE length of stay, mortality, complications, limb ischaemia, these sorts of things. It's not really focused on devices. It's centred on outcomes. But it is, kind of a, if we notice we have a quality problem, this is almost a real time feedback.
Reporting system and process	Clinician reports error to manufacturer	Clinician reports medical device-related incident directly to a manufacturer representative	~ I did report the device, this situation and event, to the company. ~So, if the device has not performed as expected during its deployment and has malfunctioned during deployment, that's a clear, I report that to the company representative; often, they're present during the procedure. And they'll get immediate feedback.
Reporting system and process	RN reports error to manufacturer	Nurse reports medical-device related incident directly to manufacturer representative	~I personally don't, but I tell the nurses to. It's kind of a hierarchy where you say, you know, 'Report this.' and so the nurses then file a, you know, they have all of the channels of who sells the product to the hospital and how much of these things are, you know, how much we pay for them and all that. So there is a channel where I say to them 'Report that this wasn't working.' or 'Send this back to the company.' And so that gets done by the nursing admin here at our hospital.

Theme	Code	Definition	Example
Reporting system and process	Debrief on operation performed among hospital staff	Hospital staff performs a debrief after each operation to discuss if it went as planned	~The other reporting requirement is as I described earlier, which is the operating room requirement, with the debrief at the end of the case. So that always gets recorded in writing, based on a verbal discussion about how the case went. Did it go according to plan or not? If it didn't, then the issues that were surrounding that get discussed.
Reporting system and process	Device malfunction or incident documented in operative report	Device malfunctions or incidents are documented in hospital operative report	~in neither of those cases did I report medical device malfunction to, as a medical device malfunction. The oxygenator incident, that was documented in my operative report.
Reporting system and process	Hospital participation in database of risk adjusted benchmarked quality outcomes	Hospital participates in a vascular quality initiative registry	~maintain a database of risk adjusted benchmarked quality outcomes, from this type of procedure. We're the only participating facility in all of Canada. It's called the vascular quality initiative. And we are required to submit peri-operative patient and procedural data, to a registry in which more than two hundred centres participate. And then, we get monthly, we get a semi annual outcomes reports, benchmarking our quality and our performance, against other comparable centres. This database is centred around general outcomes, IE length of stay, mortality, complications, limb ischaemia, these sorts of things. It's not really focused on devices. It's centred on outcomes. But it is, kind of a, if we notice we have a quality problem, this is almost a real time feedback.
Reporting system and process	Patient safety and learning system to report on patients with odd clinical outcomes	Patient adverse outcomes are reported in a patient safety and learning system	~we have what we call a PSLS, a patient safety and learning system. So anytime something goes wrong with anyone or a patient has any odd outcome of anything, you're supposed to make a comment of it. You're supposed to make a report of it.
Reporting system and process	Clinician notifies nurse of medical device-related incident	The clinician notifies the nurse of the medical device-related incident that occurred during the clinical procedure	~the surgeon brought it to my attention, because in charge to the service.

Theme	Code	Definition	Example
Reporting system and process	Internal registry to track outcomes of vascular surgeries	An internal registry exists in one hospital department (surgical) but have not been developed in another department (radiology)	~Now we have a database and registry function on the surgical side, which we have yet develop on the, um, or mature, on the radiology side. And, I see kind of a mirroring of the two, eventually. But this is a trickle down effect of the hospital quality of care committee, wanting more accountability from the individual departments.
Reporting system and process	Clinician reports error to manufacturer	Hospital frontline staff (e.g., nurse) reports incident directly to manufacturer	~Outside of the incident report, then it becomes far more informal documentation. And it then becomes that clinician's responsibility to contact the company directly or, and begin a dialogue about the incident. Or, in the, or the clinic per say, that is managing that type of patient, you contact the clinic, and they begin that dialogue with the company. So, that is probably a less official way that it is done in the hospital. And certain companies have more or less stringent criteria about what they want to hear about and are more receptive to hearing about things.
Reporting system and process	Hospital staff notifies regulators of medical device-related incident	Hospital staff notifies regulator of medical device-related incident	~When it comes to a specific device related problem, I haven't had one yet where I thought it was a fundamental device problem that requires Health Canada being notified. But that's also a process that we would consider. If it was truly a device problem that affected patient safety, then we would notify Health Canada. And I know that has been done in the hospital in the past, and that's what we would do as well, if we felt it was specifically device related.
Reporting system and process	Voluntary reporting for less serious medical device-related incidents	Hospital has a voluntary reporting system for less serious medical device-related incidents	~And there's, again, usually voluntary reporting. But different divisions can work it differently so it's less voluntary
Reporting system and process	Mandatory reporting for more serious medical device-related incidents	Hospital has a mandatory reporting system for more serious medical device-related incidents	~and there's mandatory for certain types of cases. You know, more serious cases are, such as death, are part of a corporate culture to be reported, on a mandatory basis and to try and find explanations. So the hospital does have mechanisms in place for that.

Theme	Code	Definition	Example
Reporting system and process	Hospital staff reports error to manufacturer	Hospital reports medical-device related incident directly to manufacturer representative	~And if, as a group, we believe that the device, that we had a device related incident, then that is definitely fed back to the company representatives.
Reporting system and process	Clinician reports life threatening problem with medical device to regulator	If the medical device-related problem is deemed to life-threatening , then it is reported to the regulator	~I've never been involved in an issue where there was a life threatening situation due to a faulty device. I haven't, I've never seen that. So, but clearly, if that were the case, you know, we would definitely report that, like, Health Canada, for sure.
Reporting system and process	RN reports error to procurement department	Nurse reports medical-device related incident to procurement department	~Well, in terms of the staplers, our hands are sort of tied, because we have contracts with, you know, different vendors, right? So, when we have the staplers or the re-loads that go with them, if they're not functioning properly, all we can really do is lodge a complaint through our buying group.
Reporting system and process	Hospital medical engineering department reports consistent error to regulator	If the medical device problem is consistent, then it is reported to the regulator	~if it's a consistent thing, I know that our medical engineering department has actually notified Health Canada,
Reporting system and process	Hospital medical engineering department reports consistent error to ECRI Institute	If the medical device problem is consistent, then it is reported to ECRI Institute	~there's an acronym, it's called an ECRI
Reporting system and process	Clinician reports incident to nurse manager or individual in charge of cath lab, electrophysiology lab or the OR.	If there is an issue with a medical device, the clinician will report it to the nurse manager or individual who is in charge of the cath lab, electrophysiology lab or the OR	~so we would, I mean, if we have an issue, we would report it to our nurse manager, in the cath lab. Like, for me, or whatever lab, wherever you'd be putting the devices in, there would be a nurse manager and there would also be a director. So there would be someone in charge of the cath lab, or the electrophysiology lab or the OR for example. And so that person plus the nurse manager, the clinical manager would be -

Theme	Code	Definition	Example
Reporting system and process	Hospital has a database for reporting all errors	Hospital has a database for reporting all errors, not just medical-device related incidents	~I know there are databases in place for some procedures, but not report, that report everything, like basically, it's just a global database
Reporting system and process	RN completes product complaint form	Nurse completes a product complaint form when an incident or malfunction has occurred with a medical device	~A product complaint form is completed.
Reporting system and process	Set up a global system where error can be reported easily	A global database where error reporting is straightforward should be set up instead of an institutional database	~I think there should be some kind of a, probably more global rather than just institutional set up where we can actually log the information in a fairly simple manner, where, you know, it wouldn't take any more than five minutes to input information. And because the reality is, I think the incidents of medical related devices, at least that we use, is pretty low, for the most part.
Reporting system and process	RN completes a hospital incident report if medical device doesn't perform as intended	If the medical device does not perform as intended, the nurse will complete a hospital incident report	~ when the machine itself does something wonky like changes its program, that sort of thing, we do file an incident report on it.
Reporting system and process	Hospital online reporting system categorizes severity of adverse events	Hospital online reporting system categorizes the severity of adverse events from mild to critical	~So there's different criteria in terms of the severity of the adverse event, depending on what happened to the patient for instance. For instance, if it was an adverse event that did not affect their outcome versus an adverse event that caused a mortality. And then it get elevated to another level, for instance, if it was an adverse event that for instance, caused a mortality. So there is the online reporting system, for the hospital, that they keep track of. And again, there's a system in place for all adverse events, whether they be mild adverse events related to a device malfunction or a serious, critical incident.

Theme	Code	Definition	Example
Reporting system and process	Clinician reports incident to hospital	Clinical reports the medical device-related incident to the hospital	~it was reported to the hospital.
Reporting system and process	RN notifies manager of medical device-related incident	The nurse notifies the manager of the medical device-related incident that occurred during the clinical procedure	~I bring it to our managers attention
Reporting system and process	Future implementation of provincial vascular surgery database	Hospital will contribute to provincial database for all errors observed in vascular surgery once it is implemented	~well we don't have a separate database for patients aside from the OR report, as of yet. The database is coming within the next months.

Theme	Code	Definition	Example
Reporting system and process	Future implementation of provincial vascular surgery database	Hospital will contribute to and participate in provincial database for all errors observed in vascular surgery once it is implemented	~But we don't have a database where we track device related specific problems that could be perhaps educational and learn from it. We don't have that database yet. I: Okay. Thank you. And you did mention earlier about a database that'll be available in a few months time. So is this an initiative that'll be coming soon at your hospital, to improve the recognition, reporting and resolution of device related incidents or it's not specific to just - P: No. Right. So it's not specific to device related problems. But it's a prospective database that is going to be done for all vascular procedures. And it's provincial based. So every vascular institution in the province will have to belong to this database. And in the database, as well as patient demographics, and the procedure will be follow up and complications. So, indeed, that will be captured there. But it will not be a specific device database.
Reporting system and process	Adoption of registries on performance of medical devices	A central registry for medical device-related incidents or malfunctions and where manufacturers have no control over should be developed	~I think the adoption of widespread benchmarking, risk adjusted registries are extremely important. Many places, if you just bring in a device, a new device to try for a particular procedure, you may like it; you may not. It may perform and meet expectations; it may not. There may be a complication or there may not. Until we, but your actual denominator in number of procedures is going to be relatively small. So unless different hospitals are all collaborating and following up on their experiences with these devices, and reporting them to a central registry that the manufacturers don't have control over, we may not be able to recognize this.

Theme	Code	Definition	Example
Reporting system and process	Automation of reporting incidents and/or malfunctions	An automatic infrastructure or process of reporting incidents and/or malfunctions should be developed, so as many are captured as possible	~certain big university hospitals, they all have processes in place, is to create an infrastructure or a process that automatically kicks in, regardless of what the surgeon says, regardless of what the nurse says. There's an automatic – it can't be swept under the rug
Reporting system and process	Implement a database for device-related problems	Hospital should implement a database for medical device-related problem whether it is related device malfunctions or human error	~is to have some kind of database for device related problems. And to be quite frank, I don't think it happens that often. And I think the times that it does happen, it's often operator error. I think rarely is it an engineering problems of the device itself. So I do often think it's a education of the operator problem.
Reporting system and process	Report device malfunction/incident to regulator to raise awareness nationwide	To increase awareness of medical device-related malfunction/incident nationwide, a mechanism should be inplace to facilitate error reporting to regulator	~I do think there should be some format where we feel comfortable talking to Health Canada, if we believe that it is an engineering problem with the device, that we can have someone to go up the food chain and say 'This needs to be documented for the rest of the country to know that these problems do exist.' So I think that conduit would be relatively important.
Reporting system and process	Have a nationwide database to raise awareness nationwide	A nationwide database should be set up to see what devices function and which ones have complications	~So it would be nice to have kind of a more, maybe Canada based database, or Canada wide database so we can extract information and kind of see what devices work; which ones have more complications and so on.

Theme	Code	Definition	Example
Reporting system and process	Mandate a review or debrief of operative cases performed among hospital staff	Hospital should mandate staff to perform a debrief after each operation to discuss if it went as planned and record any adverse event that occurred	~it's just having a corporate structure that mandates that there is a review. And part of it, with every operative case, there's the mandatory brief. And so there, right from the get go, there's a mandatory review of the case. And if there was an adverse event with the device, it could be recorded then, and flagged. And then those could be reviewed on a monthly basis, depending on their severity and what there is to learn or their recurrence. And so, that's not a big stretch. That's not too hard to do, from what we currently do. It's still somewhat, that second piece is somewhat voluntary in terms of which cases ultimately do get reviewed, and it's at the discretion of the division, but other than death, there's a lot of discretion as to what would get review from a medical device problem.
Response from manufacturers	Hospital has dedicated quality assurance employee	Hospital has dedicated quality assurance employee who ensures that it maintains the quality of patient care	~I think that we have a good process to notify and we have a QA person who's job it is to follow up on all these things.
Response from manufacturers	Manufacturer worked closely with hospital to resolve problem with medical device	The manufacturer and hospital staff worked closely together to fix a medical device problem	~I did actually have that from the water pic company that it was connected to an electrical generator. They were much more forthcoming and worked very closely with us to rectify the problem. I don't see the disposable stapler companies being so forthcoming in trying to work with us. And, I mean, these staplers aren't cheap. So you know, it's very frustrating to not get any sort of resolution from their end of things.

Theme	Code	Definition	Example
Response from manufacturers	Manufacturer/distributor does not respond adequately on reported incidents	Hospital staff feels that manufacturer/distributor does not always provide an adequate resolution to medical device errors reported	~ We fed that information back to the company. And I was a little bit disappointed with the company's response. They indicated to me, and I had to chase them for this information, that they had fed this to their central office and that we shouldn't worry because other, this was some unique circumstance, and that this was probably a problem with the patient, and not the device, because they hadn't heard of this at an inordinately high level.
Response from manufacturers	Manufacturer/distributor do not respond adequately to reported incidents	Hospital staff feels that manufacturer/distributor does not always provide an adequate resolution to medical device errors reported	~None of the review letters ever stated that, even though I know that a product truly malfunctioned. What the letter say is, was an acknowledgement that they reviewed the lot number, the serial number. They reviewed their production processes for that lot number. And that issues, all issues have been reviewed and resolved. That was it. That was the extent of it, right? Or, there was no known production issues. So, that's useless to us, right?
Response from manufacturers	Delayed response from manufacturer to hospital	Manufacturer response on medical device-related incident is too late for hospital	~So I think that does play a role in acceptance of a device malfunction or reporting of it. I think that's a problem. But I also think it's a problem in understanding how to have a report done and a result that's constructive. So I can send a concern off to the company, and I don't get, and I, as an individual, may get feedback in six months about a problem with the device, long past when I actually had the problem
Response from manufacturers	Limited information provided to hospital staff for industry protection	Hospital staff feels that manufacturer/distributor does not always provide limited information on medical device errors to protect its reputation	~There's no way to, I mean, the industry is going to protect industry

Theme	Code	Definition	Example
Response from manufacturers	Manufacturer didn't find any problem with the device	Manufacturer did not find any errors with the medical device	~And then, we get a report back from the vendor, indicating that they have done due diligence in looking at the product and of course, they never find anything wrong with it. They don't come out and say that it's user error, but you know, they insinuate that they've looked and couldn't find anything wrong with it.
Response from manufacturers	Hospital staff are frustrated with same response from manufacturer	Hospital staff feels that they always receive the same response from the manufacturer about the medical device problem	~So, you know, it becomes a bit frustrating when we do everything the way we're taught, and then, we get the same response from the vendors all the time.
Response from manufacturers	Manufacturer send standard letter to hospital	Manufacturer sends hospital letter as a response to the medical device problem	~I would say the letters that they send me are pretty much a form letter. You know, they'll add in the surgeon's name or the date or the, you know, the specific stapler or the re-load, but you know, essentially, the content of the letter is pretty similar with each event.
Response from manufacturers	Hospital would like manufacturer to take more ownership of medical device-related incident	Hospital would like manufacturer to take more ownership of medical device-related incident	~ it would be nice to see that a vendor takes ownership, that, you know, rather than them always saying it's user error. You know, if they were able to say 'Well, gee, you know, we actually discovered there was an issues in the manufacturing.' or 'That day, it was a bad lot.' or something.
Warning or advisory from manufacturers	Warning and/or notification about risk of device malfunction	Manufacturer issued warning about potential risk of device malfunction	~With respect to the defibrillators and the leads, then that again, that one is something we're not reporting to the company that the device malfunctioned. They reported to us that the device is at risk of malfunctioning.

Theme	Code	Definition	Example
Warnings or advisories	Informed hospitals, ORs and surgeons of potential problem with medical device	Manufacturer informed hospitals, ORs and surgeons of potential problem with the medical device (e.g., sterility)	~The company that makes the staplers we use, a particular type of stapler that we use for bariatric surgery, sent out a letter of notice to the hospital and the operating room and us, the surgeons. They didn't disseminate this information for obvious reasons, that there was some concern that they couldn't reliably assure us of the sterility of their instruments from a given date to a given date.
Warnings or advisories	No warning or notification from manufacturer communicated with hospital staff	No warnings or notification from manufacturer were received or communicated with hospital staff on medical device problem	~And there was no warning or report from the manufacturer or, you know the - P: There was no, again, this is part of it. Perhaps at a managerial level, or you know, the CEO gets feedback or talk to appropriate people at that level
Warnings or advisories	Hospital received warning from manufacturer about potential problem with medical device	Hospital received warning from manufacturer about potential medical device problem	~we didn't identify any adverse events on the patient care, which is good. But if there's material that's not being completely sterilized, you would be concerned you could cause an infection in an operation. So the problem was noted before we actually had a clinical adverse event.
Warnings or advisories	No warnings issued on medical device problems	No warnings are issued by the regulators on medical device problems	~ They assured me that they would include this in their international registry of issues. However, I never saw any – this is an FDA approved device – I never saw any FDA or Health Canada warnings come out from this device or device component.
Warnings or advisories	Clinician follows regulatory guidelines for personal protection	Clinician follows regulatory guidelines to protect him or herself from a class action lawsuit	~' And, at a personal level, the only thing that protects me from a class action lawsuit if something is discovered ten years down the road, is the fact that I carried the procedure out and the patient selection within Health Canada guidelines

Theme	Code	Definition	Example
Warnings or advisories	Hospital learned from regulator that other institutions has similar problem with device	Hospital staff report error to regulator and was informed that other institutions experienced similar ones	~So our medical engineering department will lodge, er, log complaints on some of these products. And funny enough, one of the staplers that we were having issues with, that the vendor had said to us 'Oh no, no. They've looked at it. There's nothing wrong with it.' When our med eng people logged it with Health Canada, he was able to discover that there were lots of other centres with the same complaints, which we found very interesting.

I=Interviewee; P=Participant

APPENDIX 3: CHARACTERISTICS OF TELEPHONE INTERVIEWS (n=16)

Hospital	Participant	Sex	Years in Practice	Specialty
A	1	M	23	Cardiac surgeon
	2	M	12	Cardiologist
	3	M	29	General surgeon
	4	M	14.5	Interventional radiologist
	5	M	29	Orthopedic surgeon
	6	M	13	Vascular surgeon
	7	M	27	Registered nurse (critical care/intensive care unit)
	8	F	27	Registered nurse (operating room)
B	9	F	25	Cardiac surgeon
	10	M	4	Cardiologist
	11	F	7	General surgeon
	12	M	2	Interventional radiologist
	13	M	27	Orthopedic surgeon
	14	M	9	Vascular surgeon
	15	F	19	Registered nurse (critical care/intensive care unit)
	16	F	39	Registered nurse (operating room)

F=Female; M=Male

APPENDIX 4: MEDICAL DEVICES INCIDENTS AND THEIR CAUSE

Medical Device	Cause of Incident
Instrumentation to insert implant	Combination of how device is made by manufacturer, complexity of device and training of hospital staff
Devices for stapling	Device malfunction
Devices for stapling	Inadequate training on device
Defibrillator	Device malfunction
Catheter for renal denervation	Device malfunction
Radio frequency ablation catheters	Device malfunction
Devices for the optics	Device malfunction
Endovascular aneurysms repair stent grafts	Difficult to ascertain
Linear endoscopic staplers	Human error
Glucoscan	Human error
Oxygenator	Human error
Tourniquet	Human error
Stent	Human error and medical device lack of safety feature
IVC filter	Device malfunction
Infusion pumps	Device malfunction and programming error
Dialysis and ECLS machines	Programming error and mechanical problems

ECLS=Extra corporeal life support; IVC=Inferior vena cava

APPENDIX 5: INTERVIEW RESULTS-FACTORS THAT INFLUENCE THE RECOGNITION OF MEDICAL DEVICE-RELATED INCIDENTS

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Education and training	Hospital staff is aware of medical error or incident reporting mechanism	~There's definitely a mechanism to deal with it, sure, and there's an awareness of it, I think. There's an awareness of medical error and that, for sure, in our, I think we have a culture of looking for that here.	ACA1		
Hospital staff knowledge and experience	Clinician recognizes clinical manifestations of patient			~or the patient, you know or there's a clinical factor, the patient becomes unstable.	BCA1
Hospital staff knowledge and experience	Clinician's ability to recognize error or device malfunction during clinical procedure	~Once the surgeon does it right or does everything right, and it fires and there's a true malfunction, the surgeon has to know, in fact, if there is a malfunction. There are certain things that will happen. One is that it may not feel right when it's fired. It may not extract easily when you try to extract it once you've finished the firing; there's something wrong. So the surgeon himself or herself has to be attuned to what that instrument should, how it should work and what it should feel like when it works. Right	AGS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Hospital staff knowledge and experience	Clinician's ability to recognize error or device malfunction during clinical procedure	~And frankly, the surgeon is most responsible for that. I mean, the team is there, at the time of the case, and obviously is there to help. But, once the patient leaves the procedure, the operating room, it's on the surgeon to monitor the progress and follow it. So it's surgeon experience and diligence, really.	AOS1		
Hospital staff knowledge and experience	Clinician's ability to recognize error or device malfunction during clinical procedure	~clinicians as well, I mean, we always have like an, sort of an expert in the room or experts sort of close by, that's always sort of monitoring, you know, especially sort of newer staff maybe, that aren't as familiar with some of the devices.	ARN2		
Performance of medical device	Device didn't perform according to manufacturer instructions	~There were certainly a couple times where the device did not work as advertised. So in that particular situation, I think it's related to a learning curve, on new devices. No significant adverse event happened to the patient, although we had to make the incision a little bit bigger and that's essentially the only adverse event. But certainly, it had not performed as we thought it would, which was related mostly to inexperience.	AVS1	~instances where the device may not perform according to expectation. Many of these devices are quite tricky to deploy and there are a series of steps that have to be followed.	BVS1
Performance of medical device	Device does not perform as intended	~if there's a problem with a piece of equipment, we notice it right away, because (laugh) because it's not working and we can't do what we want to do.	ACA1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Performance of medical device	Device does not perform as intended	~Yeah, this is purely a surgeon driven and process driven in the OR. So, the surgeon, a) has to know what's supposed to happen when you fire. He has to set up the instrument appropriately for the appropriate fire.	AGS1	~it's usually the stapler, intra-operatively, and most times, it's involving the liver or vessels leading in and out of the liver, if they're doing a transplant or something like that, where they go to to fire it, it either doesn't fire, or sometimes, it fires and then when the surgeons have a closer look at the staple line, not all the staples have come out of the stapler. So, it's not a clear separation. And these are things that are always picked up right at the time, because most of the time, it's done under direct vision, IE laparoscopy.	BRN1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Performance of medical device	Device malfunctions and is faulty	~There have been battery issue themselves, where the, with time, the batteries are recharged and then the cycling failed and then the, the battery just died prematurely.	ACS1	~it's either that the device malfunctions ~But typically, it's because a device malfunctions and we recognize that the device has malfunctioned. ~ P: So, it's really technology related. I: And when you say malfunctions, it doesn't work as per the manufacturer instructions? P: That's, yeah. I: Or – okay. P: Right. Well, by manufacturer instructions or the device breaks. I mean, it's not about an instruction, it's about a faulty device.	BCA1
Performance of medical device	Increase in frequency of device malfunctions in newer medical devices			~it may be a problem that we are recognizing within our division or within our scope. There was one example of a particular kind of valve that was new on the market, and was very quickly adopted by many centre. But within our division, we noticed a particular complication was occurring more frequently in this valve than in other valve. And that was what was called a peri-valvular leak, where the blood leaks around the valve. And in fact, we were concerned within our	BCS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				division. We analyzed our data, within our division.	
Performance of medical device	Increase in reporting malfunctions	~people who aren't familiar with the devices, or at least don't know the interest in the devices, there was concern, because there was these reporting malfunctions here and there and here and there.	AGS1		
Performance of medical device	Medical device may be faulty but improvement can be delayed over long period of time			~ Like, I don't hear that 'Okay, the stapler was misfired.' Occasionally, I'll get word back to say 'Yes, it was a faulty stapler.' But more often than not, I don't get the feedback about individual cases. But I do see that over time, they will come to me, you know, a year later, and say 'Okay, there used to be this thing wrong with it.' or 'This used to be a limitation and now we've done this to advance it.' So, it's more of a culture, I guess, of trying to perfect their instruments and a culture that we have built in just through the competition of, you know, all of these other companies that are making similar devices, that they want to do, they want to have the best device on the market, and they're trying to tweak it, and to work out some of these problems.	BGS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Performance of medical device	Routine monitoring/imaging of medical device			~ If you perform an intervention, under image guidance, you'll go ahead and do that, and then you have to do a follow up examination, during the same procedure, of what you just did. That's a routine, 'should be' a routine practice	BIR1
Warnings or advisories	Hospital received warning about potential problem with medical device			~we didn't identify any adverse events on the patient care, which is good. But if there's material that's not being completely sterilized, you would be concerned you could cause an infection in an operation. So the problem was noted before we actually had a clinical adverse event.	BOS1
Warnings or advisories	Informed hospitals, ORs and surgeons of potential problem with medical device	~The company that makes the staplers we use, a particular type of stapler that we use for bariatric surgery, sent out a letter of notice to the hospital and the operating room and us, the surgeons. They didn't disseminate this information for obvious reasons, that there was some concern that they couldn't reliably assure us of the sterility of their instruments from a given date to a given date.	AGS1		
Warnings or advisories	No warning or notification communicated with hospital staff	~And there was no warning or report from the manufacturer or, you know the - P: There was no, again, this is part of it. Perhaps at a managerial level, or you know, the CEO gets feedback or talk to	ARN1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		appropriate people at that level			
Warnings or advisories	Hospital learned that other institutions has similar problem with device			~So our medical engineering department will lodge, er, log complaints on some of these products. And funny enough, one of the staplers that we were having issues with, that the vendor had said to us 'Oh no, no. They've looked at it. There's nothing wrong with it.' When our med eng people logged it with Health Canada, he was able to discover that there were lots of other centres with the same complaints, which we found very interesting.	BRN1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Warnings or advisories	Manufacturer/distributor broadly reports incidents/replaces defective devices			~And the company had had a number of similar reports, and they had ascertained that there was a fault in the manufacturer of part of the connector between the cable and the energy source. And they had also looked at their own quality assurance processes and realized that only a small subset of the catheters that they had sold were at risk for this problem. They had actually sent out a letter, warning all of the clinician that this strictly results in non-functional catheter and that we would simply have to replace the catheter and carry on, and that we should be aware of the fact that we need to have a stock of catheters available and that the company would go on, and this is a six thousand dollar device. And they would take responsibility for the costs of any defect catheters. But the manufacturers response was what I would consider much more, there was more communication with clinicians. There was a greater interest to receive the feedback.	BIR1
Warnings or advisories	No warning issued from regulators			~this is an FDA approved device – I never saw any FDA or Health Canada warnings come out from this device or device component.	BVS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Warnings or advisories	No warnings about problems with medical device			~ They assured me that they would include this in their international registry of issues. However, I never saw any – this is an FDA approved device – I never saw any FDA or Health Canada warnings come out from this device or device component.	BVS1
Warnings or advisories	Warning and/or notification about risk of device malfunction			~With respect to the defibrillators and the leads, then that again, that one is something we're not reporting to the company that the device malfunctioned. They reported to us that the device is at risk of malfunctioning.	BCS1

I=Interviewee; P=Participant

APPENDIX 6: INTERVIEW RESULTS-FACTORS THAT INFLUENCE THE REPORTING OF MEDICAL DEVICE-RELATED INCIDENTS

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Clinician communication with patient	Clinician informs patients and/or family of potential problem with medical device	~Our hospital decided, probably a little prematurely, to notify every single patient we operated on in that time period. So, there was phone calls left right and centre, panic.	AGS1		
Clinician communication with patient	Clinician informs patients and/or family of risks involved with novel procedure			~And we're all very concerned that if there's an incident, that it's not related to patient selection. But when we're discussing the procedure and getting consent for the procedure from the patients, we are very careful to relay our previous experience and we're anxious for them to understand, 'You're about to undergo something novel -'	BIR1
Clinician communication with patient	Clinician informs patients and/or family of incident with medical device	~The culture is changing in the sense that, in all those incidents that I've discussed the physicians went directly to the family members, immediately after the incident, like as soon as the patient was stabilized and divulged what happened.	ARN1	~And it was reported to the patient	BCA1
Clinician communication with patient	Clinician informs patients and/or of incident with medical device	~spoke with the patient directly	ARN2	~the incident was disclosed to the family and the patient when the patient was awake. So it was an internal management of the problem.	BCS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Clinician communication with patient	Clinician informs patients and/or family of incident with medical device	~We have a responsibility to tell the patient. ~the patient, after the following day, the patient, discussed with the patient what happened and fortunately, there was no real ill toward events in either one of those. So it was a fairly easy conversation. We just said that the graft did not deploy well. "We put in another graft and it seemed to work just fine." In the other situation, the patient ended up with a bit of a bigger incision, and again, the patient did fine. We did discuss with the patient that the, you know, for instance, the closure device didn't work very well, so that's why the incision had to be made larger	AVS1	~whenever I do things off label, I open myself to the risks of liability later. So, we have a culture of honesty and trying to be as upfront with the patient. And there've been instances where we've offered patients something novel, and they've declined, because of our description. I: Right. Or the risks involved. And so you – er, sorry, please. I'm interrupting - P: Um, or the lack of knowledge around the risks involved	BIR1
Clinician communication with patient	Clinician informs patients and/or family of incident with medical device	~the first thing that prompts it is certainly care of the patient and an obligation to report an adverse event. There's an ethical obligation and medical/legal obligation to report to the patient an adverse event, irrespective of the consequence.	AOS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Clinician communication with patient	Clinician informs patients and/or family of incident with medical device	~Like, I think there's some defibrillator leads, for instance that have failed. And they cause the device just to stop working. Well, that's dangerous. So, what we've done is we've identified the patients, because we know which patients get what device, and then we call them back in, and explain to them, what the issues are. If they've already got the device implanted, you know, most devices, if they're inside someone, it's not that easy to take them out. So you would have to explain to them what the risks are; ...	ACS1		
Clinician communication with patient	Clinician informs patients and/or family of manufacturer advisory	~what the company has done to mitigate the risks; what the company feels the potential problems are, in terms of keeping the device in, and then, the resolution, what the resolution would be, which would be, say, take the (lead out, 25:53) or just put a new lead in.	ACS1	~so the company knows who's got it. So the company notifies them and the hospital notifies them. So when a patient comes in, they know what, it's on advisory. Then we recommend the treatment.	BCS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Clinician communication with patient	Clinician informs patients and/or of risks involved with novel clinical procedure			~if this is an elective situation, I take the time to explain this to the patient. If this is a device, for example, a 'first in Canada' application, I'll explain it to the patient and their family. In addition, I'll also have to complete certain regulatory paperwork, from Health Canada Approval. But I will tell the patient and their family 'This is a device which we've used for other situations or which is useful for other situations. And we've never used it in your circumstance. But it offers certain theoretical advantages.' And I can think of another application for a very difficult patient problem, where I had to use a stent graft designed for the arteries, in a vein	BVS1
Clinician communication with patient	Clinician informs patients and/ or family of risks involved with off-label use of device			~we will present that also in our discussion to the patient and their family, you know, that this plan has been subjected to a multidisciplinary review	BVS1
Clinician communication with patient	Clinician informs patient and/or family of risks involved with clinical procedure			~whenever I do things off label, I open myself to the risks of liability later. So, we have a culture of honesty and trying to be as upfront with the patient. And there've been instances where we've offered patients something novel, and they've declined, because of our description. I: Right. Or the risks involved. And so you – er, sorry, please. I'm interrupting -	BIR1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				P: Um, or the lack of knowledge around the risks involved ~But when we're discussing the procedure and getting consent for the procedure from the patients, we are very careful to relay our previous experience and we're anxious for them to understand, 'You're about to undergo something novel -' I: Right. P: 'that we don't know the ten year consequences for this.	
Feedback on how reported information is used	Follow-up occurs with nurse(s) involved and manager of cardiac centre			~There was follow up with the manager of both the catheterization laboratory, the nurse managers, because the nurses were involved, and also the manager of the cardiac centre. ~Our hospital, again the incident has to be reported by either, by someone on the team, whether it be a nurse or a clinician on the team. And then, that gets reported to the nurse manager of that operating room or area, and that essentially then goes to an online system where you get a notification, by email, telling you that an adverse incident has occurred and that you need to now log onto the adverse event	BCA1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				reporting system, and review it and then also make potential edits or corrections as you see fit, as someone who was involved in the situation. And then that gets reviewed by the managers of the hospital, who then decide whether it needs to go, you know, further or need further review.	
Feedback on how reported information is used	Hospital quality committee gives feedback to department or industry to initiate action			~a hospital wide mechanism for reporting any irregularity in the care of the patient. And so a device malfunction would fall under that. You can then grade your incident report, as a mild, moderate, severe or critical. And a moderate, really anything above moderate escalates that incident report to a senior level. And a critical, and if you file a critical incident report, then that goes directly to our hospital quality committee and every critical incident is reported. So those would be your mechanisms to escalate it and to have it identified as an issue. And through those mechanisms, it would then get referred back to the appropriate division or to the company and action would be initiated as a result of it. So that is probably the most common way of doing it	BCS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Feedback on how reported information is used	Meetings and education sessions were held in hospital			~There were meetings regarding the incident and follow up and education, in terms of actually, education back, ..	BCA1
Incentives for error reporting	Clinician doesn't want to work with equipment that doesn't function	~I think there's motivation for us, in that we don't want to work with equipment that doesn't work	ACA1		
Incentives for error reporting	Clinician wants to understand why device malfunctioned			~It's also the nature of, certainly, the nature of the clinician who wants to understand why the device has malfunctioned, and that's one of the major impetus to also report an incident, so that you get an understanding of how to improve the device and to ensure an incident like this doesn't happen again.	BCA1
Incentives for error reporting	Hospital to receive reimbursement from manufacturers to replace device or part of it			~one of our incentives to report is to get reimbursed by the company, because we didn't think that their product was working well. So you actually want to report that so that they can, you know, there is a system with these companies, often, that if you report something missing, they have a look at it. You send, you know, the stapler, say, that misfired. You send it back to them and they have a look at it, and they'll reimburse you if there was something faulty with the product. So reporting is largely to do with that.	BGS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Incentives for error reporting	Known problem with device may not always be reported			~if it's really just another bad stapler or you know, it's an ongoing thing, I might not do an incident form.	BRN1
Incentives for error reporting	More complex problems (electrical component) more likely to be reported to medical engineering			~an electric generator involved, then we try to do incident forms then. And those are the kind that medical engineering will be involved with, because there's an electrical component. If it's just a stapler, and it's a single use item, then you know, we may or may not involve medical engineering.	BRN1
Incentives for error reporting	Recognition from manager for reporting error	~The manager went out of her way to try to recognize my contribution and I said that would have a big impact on people, because people like to be recognized for work they do. Especially nurses like positive reinforcement, to know that their actions are being respected or appreciated. So, there's that.	ARN1		
Incentives for error reporting	Safety issues with device that may cause problems	~So, in terms of reporting, you know, I think that there is a big education piece that's required to inform people, ...	ACS1	~If we thought something was unsafe or something wasn't working well and was causing problems, then I guess for safety reason, that would be another incentive to report it.	BGS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Incentives to error reporting	Clinician wants to reduce the risk of medical device-related incident from reoccurring	~if I have a device that breaks, you know, that's the manufacturer's problem. So I mean, I want that not to happen anymore. So there's no negative impact on me if I report that. In fact, it's only going to make my job better.	ACA1		
Incentives to error reporting	Hospital to receive reimbursement from manufacturers to replace device or part of it			~They had actually sent out a letter, warning all of the clinician that this strictly results in non-functional catheter and that we would simply have to replace the catheter and carry on, and that we should be aware of the fact that we need to have a stock of catheters available and that the company would go on, and this is a six thousand dollar device. And they would take responsibility for the costs of any defect catheters. But the manufacturers response was what I would consider much more, there was more communication with clinicians. There was a greater interest to receive the feedback.	BIR1
Information sharing	Collegial opinion/experience, ie. "word of mouth"	~Well, actually, there's no, again, there's really no formal process to report these things. But we do, as I said, for the last question, we do discuss the majority of the cases, both informally and formally. So many of us will meet, during the day, and discuss cases, like, during a coffee. And see what the, and we do this	AIR1	~And if there is a problem, it's not unusual for us to get together at very short notice, go ahead and discuss and come to at least a potential resolution until the problem can be solved. So I don't think there's any barriers	BOS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		proactively as well, obviously.			
Information sharing	Collegial opinion/experience, ie. "word of mouth"	~that are related to maybe the team approach, where it's a teaching institution and it just didn't go exactly the way that you'd wanted it to. ~The other thing is we do have other, non M and M rounds, where we discuss interesting cases and problem patients. So that would also be discussed in that way as well.	AVS1	~ This particular stent graft is a new one, from a very popular company, that other colleagues of mine had made comments that they were not as happy with the – it usually comes in three pieces we call a body and two legs. And other colleagues of mine had noted some problems with the legs (and/in 11:40) similar issues of graft thrombosis. It wasn't clear to me - I had personally never seen one with this particular device before	BVS1
Information sharing	Dissemination of information to colleagues and general public			~Our pathologist Dr. (name 10:11) looked at our pathology specimens and we were the first in the world to actually report with this valve, which subsequently was taken off the market and actually has resulted in numerous lawsuits, so - not involving us directly, but within the company. So, that was one that a single surgeon noticed, then brought it to the attention of several surgeons and then disseminated the information publicly. So that's another way that device malfunctions can be, are brought to our attention.	BCS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Information sharing	Encourage hospital staff to discuss any medical device-related incidents that they experienced, if they report them and why	~It probably wouldn't be a bad idea to do an audit every once in a while. (laugh) You know? Just to, you know, just to see if anybody's actually come up with any, you know, has experienced anything and ask them if they've actually, if they've reported it and if they haven't reported it, why did they not report it. And so, it might, you know, stimulate more people to report them. Or, it's, you know, just maybe they don't think it's a very big deal but if they look at the big picture, you know, and the potential of harm.	ARN2		
Information sharing	Information exchange at peer-reviewed meeting			~And then the other primary way is there may be something that has been happening outside of our immediate environment that industry brings to our attention, or our colleagues at peer review meetings. Those would be the main ways we find out about things.	BCS1
Information sharing	Notify and discuss medical device problem with colleagues and potential users	~if there's a problem with a device, I mean I think everyone in our group, you know, whatever group it is, whichever device, usually you let everyone know about the issue. And we discuss it. And you know, clearly, if there was a concern, we would stop using it. That would, so I think if anybody ever has a problem with anything, it's, the knowledge or the issue is addressed with everyone who potentially could be involved in this, using that type of equipment, for sure.	ACA1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		I: So that would be related to – oh sorry, I was going to say to information sharing. P: So, so, if there's an issues with a faulty device, it would be communicated to, that this happened, it would be communicated to anybody who would potentially use that device, for sure.			
Organizational culture	Hospital encourages staff to report errors			~So all I can say is that ah, my hospital, we encourage incident reports to be filed by anyone, could be a nurse; could be a porter, could be a clinician, could be a physiotherapist. So the environment actually encourages the reporting; the environment actually encourages a reporting of any adverse event or potential adverse event.	BOS1
Organizational culture	Change from punitive culture to a more education one for medical device error reporting	~For within the hospital itself, I think the cultural change is a challenge. I think it's probably getting better but I'm not sure if the hospital is doing it, cause they want everything documented and I think that's good. But I believe that ends of being a culture of punitive, it feels more of a punitive kind of culture as opposed to an educational thing, from what's coming down the pipe. I don't have a great solution to that. And I don't think the problem happens that often, I'll be quite frank. I mean, I don't know if orthopaedics has a problem with their	AVS1	~we're trying to move to a system of reporting critical incidents where theres is quote 'no blame'. And I think that is the kind of system that we have to have, is that this is important information for patient care. And that it should not be a blame situation; it's an information situation and the information needs to be disseminated with recommendations.	BCS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		devices. Our devices, if they are problematic, like I said, it's often operating error.			
Organizational culture	Clinicians are required to report device incidents and near misses			~it's the culture in the hospital, for the most part, that would make clinicians or surgeons or whatever, report a device incident. It's the culture in the hospital. We have a very strict culture to report device incidents or any type of incidents for that matter. ~I think any malfunction that occurs is reported. I can tell you, like, for instance, I was doing a procedure and the fluoroscopic machine all of a sudden powers down, right at the moment that we were deploying a device. And it just shut off. So, you know, nothing happened to the patient, but that was reported as an incident, because that is a potential risk, potentially something could have happened, very badly. And it needs to be understood why the fluoroscopic machine shut down. It needs to be repaired and safeguards put in so that doesn't happen again. So it could be a near miss, as well.	BCA1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Organizational culture	Expansion of processes from one clinical specialty to another specialty			~So, what I'm really fascinated about at my institution, is that those processes that are employed on the surgical side are now being adopted on the interventional radiology side, at our hospital. hese include regular morbidity and mortality rounds, and both the results of the morbidity and mortality rounds are reported to a hospital quality of care committee, from both departments.	BVS1 &BIR 1
Organizational culture	Hospital and its staff maintain very high standard of care	~Because we have like a very high level standard of care. So it just wouldn't be, it wouldn't be acceptable to have that happen again. I mean, it was, the patient didn't have, it wasn't a really bad burn, but it was a burn nonetheless and embarrassing to everybody. But we didn't want that happen to anybody else.	ARN2		
Organizational culture	Hospital and its staff maintain very high standard of care	~I think our institutional culture is pretty proactive about quality assurance.	ACS1		
Organizational culture	Hospital committee oversees operational issues for ORs	~There's a clear line of reporting documenting and handling of these incidences with respect to, the report goes to corporate peri-op, which is our committee overseeing operational issues for the ORs at both campuses, or all three campuses.	AGS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Organizational culture	Hospital demands monitoring of incidents			~And the quality of care committee at our hospital has become more insistent and demanding for regular reports from, as an example, from radiology, where traditionally, interventional radiology wasn't in the habit of tracking as closely their complications or results.	bVS1 &BIR 1
Organizational culture	Hospital encourages staff to report errors	~there's an incentive, for where I work, there's a big incentive to make sure that everything works properly. And if it doesn't, then, you know, we need to fix it. So I think that we're pretty proactive.	ACA1	~We encourage reporting of adverse events. And I think there's a lot of support from the entire administration to follow up.	BOS1
Organizational culture	Hospital has a non-punitive culture towards error reporting	~I: Okay. So the culture in your institution encourages - P: Yeah. I: to be transparent and to report, versus, so they see it more as information versus a punitive, you know, it's not a punitive (inaudible 21:14). P: Exactly. Yeah.	ACA1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Organizational culture	Hospital is less punitive when incident is reported compared with the past	~And that's a huge cultural change. Because I can tell you, being here for twenty five years, when we used to make a mistake, we'd wait to see what the outcome was before we told anybody. Actually, 'we' meaning the team. The PSLS has become a non-punitive thing, which, they used to say that before, that when there was an incident. You know what I mean? But the incident used to still be followed by your manager and it felt as though you were getting your hand slapped. So again, it, the culture has changed in that respect, that I think a lot more people report things now then they did the past.	ARN1		
Organizational culture	Hospital staff are closely monitored by institution			~we're used to being scrutinized.	BVS1
Organizational culture	Hospital staff are encouraged to report anything that could lead to a problem	~Like, I said, we have this near miss, even this near miss, so they want in the (name)Institute, they actually, (I 15:45) encourage people to report anything which even could potentially be a problem.	ACA1		
Organizational culture	Hospital staff are encouraged to report near misses	~Like, I said, we have this near miss, even this near miss, so they want in the (name)Institute, they actually, (I 15:45) encourage people to report anything which even could potentially be a problem.	ACA1		

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Organizational culture	Hospital staff are quick to resolve medical device problem	~So, I would say, I mean, specifically with devices, I think there's, you know, we're kind of the opposite in the sense that, you know, if there's a problem with the device, we're very quick to jump on it, because it affects how we, how we work and it can impact our outcomes and that.	ACA1		
Organizational culture	Institutional reporting to media/public			~There are instances where if we're performing a 'first in Canada' event, our institution is very interested to publicize those. And obviously, the institution PR people would not be interested in publishing a 'first in Canada' event that didn't go well. the institution itself, has a quality review, do try and pick up on adverse events and avoid them. But, they're very interested in publicly tooting their own horn, and being seen to be at the forefront of employing new technologies	BVS1
Reporting system and process	Hospital staff reports error to manufacturer	~If it happens to be a device failure, then we would actually contact the device company and find out if there were any recalls or any problems that they've have recognized at other hospitals.	ARN2	~No. I think I described, as much as I know, is kind of, I kind of know who to complain to, like the nurse, who will complain to the, like, I know our point person in the OR is (name), right? So she's the person that we will complain to if we have a problem with an instrument. But I'm not sure of the protocol or I'm not sure of any initiatives that, where they're specifically looking at these issues, no.	BGS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Reporting system and process	Hospital staff reports error to manufacturer	~You have to report to the company	ACS1	~Outside of the incident report, then it becomes far more informal documentation. And it then becomes that clinician's responsibility to contact the company directly or, and begin a dialogue about the incident. Or, in the, or the clinic per say, that is managing that type of patient, you contact the clinic, and they begin that dialogue with the company. So, that is probably a less official way that it is done in the hospital. And certain companies have more or less stringent criteria about what they want to hear about and are more receptive to hearing about things.	BCS1
Reporting system and process	Hospital staff reports error to manufacturer	~If it's a defect that would, that it doesn't affect the patient or is not recurrent, we probably would only talk to the company about it.	ACA1	~that was fed back to the device company who manufactured it; so that they actually improved the device.	BCA1
Reporting system and process	Hospital staff reports error to manufacturer	~So, there's a certain reporting back to the company of what you might consider premature failures of the, you know, a lot of devices will fail. They all have, may have life expectancies. But if it's outside the realm of what you would expect, like if a lead only lasts for a year, and they're supposed to be, you know, fifteen, twenty year leads, then obviously, that would raise concern.	ACS1	~if the device has not performed as expected during its deployment and has malfunctioned during deployment, that's a clear, I report that to the company representative; often, they're present during the procedure. And they'll get immediate feedback. ~And if, as a group, we believe that the device, that we had a device related incident, then that is definitely fed back to the company representatives.	BVS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Reporting system and process	Hospital staff reports error to hospital biomedical engineering department	~There is reporting to biomedical, who then would be out there checking equipment and checking for issues related to the biomedical aspects of whatever you're using.	ACS1		
Reporting system and process	Automatic registration of malfunctioned instrument in hospital	~We have policies and guidelines on malfunctioning, that automatically registers the instrument that malfunctioned; the actual malfunction; obviously the surgical team involved in that thing, identifying the type of malfunction, and then identifying not only the product but the lot number and the serial number. So that, and that automatically, there's a reporting mechanism in place, in the hospital, irrespective of whether the surgeon wants it or not. (laugh) It automatically registers these malfunctioning devices.	AGS1		
Reporting system and process	Clinician completes necessary regulatory paperwork			~if this is an elective situation, I take the time to explain this to the patient. If this is a device, for example, a 'first in Canada' application, I'll explain it to the patient and their family. In addition, I'll also have to complete certain regulatory paperwork, from Health Canada Approval. But I will tell the patient and their family 'This is a device which we've used for other situations or which is useful for other situations. And we've never used it in your circumstance. But it offers certain theoretical advantages.'	BVS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				And I can think of another application for a very difficult patient problem, where I had to use a stent graft designed for the arteries, in a vein	
Reporting system and process	Clinician reports incident to hospital	~Well, yeah, so you could have an incident report within the hospital. You can have a near miss report to the hospital, which are more quality types of things, that they, or if there was a problem that happened.	ACS1	~it was reported to the hospital.	BCA1
Reporting system and process	Clinician reports incident to nurse manager or individual in charge of cath lab, eletrophysiology lab or the OR	~so we would, I mean, if we have an issue, we would report it to our nurse manager, in the cath lab. Like, for me, or whatever lab, wherever you'd be putting the devices in, there would be a nurse manager and there would also be a director. So there would be someone in charge of the cath lab, or the electrophysiology lab or the OR for example. And so that person plus the nurse manager, the clinical manager would be -	ACA1		
Reporting system and process	Clinician reports life threatening problem with medical device to regulator	~I've never been involved in an issue where there was a life threatening situation due to a faulty device. I haven't, I've never seen that. So, but clearly, if that were the case, you know, we would definitely report that, like, Health Canada, for sure. ~If it were, it's never happened, but I mean, I've seen it, it's happened in the industry, you know, in cardiology, in	ACA1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		interventional cardiology; if there's a recurrent theme, like, if something happened twice, I'd probably like, you know, report it to Health Canada. ~And it ended up getting, I don't know if we had, we had some problems with it, but some other people did and it ended up being, it was reported to Health Canada and it was taken off the market.			
Reporting system and process	Clinician reports recurring problem with medical device to regulator	~If it was a defect that seemed to be recurrent and was affecting patient outcome, I think it would definitely be reported to Health Canada.	ACA1		
Reporting system and process	Clinician reports recurring problem with medical device to regulator	~There's reporting to Health Canada, if it's a device under investigation or if it's a, you know, if it's in use, there's different implications to the device. So if you've put in the device under a research study, say, that has a different kind of reporting. You have to report to the company and to the regulatory agencies or you can report directly to the regulatory and they'll deal with it. There are all these incidents that get registered with Health Canada and with FDA that you can look at, to see if there's been other incidents of the same type.	ACS1		
Reporting system and process	Computerized system increases ease of use and number of reports	~we have the PSLS, which is supposed track these incidents. And once you're used it, it is pretty user friendly. It's on every computer, pretty much, in the	ARN1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		hospital now. Whereas before, you had to go find a form and fill it out. So I think a lot of them get filled out a lot more than they have in the past.			
Reporting system and process	Debrief on operation performed among hospital staff	~The other reporting requirement is as I described earlier, which is the operating room requirement, with the debrief at the end of the case. So that always gets recorded in writing, based on a verbal discussion about how the case went. Did it go according to plan or not? If it didn't, then the issues that were surrounding that get discussed.	AOS1		
Reporting system and process	Device malfunction or incident documented in operative report	~I guess it would have been in the OR report that it was documented. So it was documented on, I guess on the official record, as well.	AVS1		
Reporting system and process	Future implementation of provincial vascular surgery database	~well we don't have a separate database for patients aside from the OR report, as of yet. The database is coming within the next months.	AVS1		
Reporting system and process	Hospital has a database for reporting all errors	~I know there are databases in place for some procedures, but not report, that report everything, like basically, it's just a global database	AIR1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Reporting system and process	Hospital has a reporting system to record all near misses	~We have a system of near miss and error reporting, so there's a system for that, for sure. ~I: Okay. And that's not only, is it specific to medical devices or - P: No, it's not. I: procedures in - P: It's for everything. So even, medications or it could even be a near miss, like the person who mopped the floor, didn't indicate, put a caution out and somebody slipped and fell, you know, those kinds of things.	ACA1		
Reporting system and process	Hospital inventory supplier reports error to and returns device to manufacturer			~It, the one that fails, we try and gather the lot number, and a form is filled out, to go with that particular failed item, and we have an inventory supervisor who then contacts the vendor. It's returned to the vendor,	BRN1
Reporting system and process	Hospital medical engineering department reports consistent error to ECRI Institute			~there's an acronym, it's called an ECRI	BRN1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Reporting system and process	Hospital medical engineering department reports consistent error to regulator			~if it's a consistent thing, I know that our medical engineering department has actually notified Health Canada,	BRN1
Reporting system and process	Hospital online reporting system categorizes severity of adverse events			~So there's different criteria in terms of the severity of the adverse event, depending on what happened to the patient for instance. For instance, if it was an adverse event that did not affect their outcome versus an adverse event that caused a mortality. And then it get elevated to another level, for instance, if it was an adverse event that for instance, caused a mortality. So there is the online reporting system, for the hospital, that they keep track of. And again, there's a system in place for all adverse events, whether they be mild adverse events related to a device malfunction or a serious, critical incident.	BCA1
Reporting system and process	Hospital participation in database of risk adjusted benchmarked quality outcomes			~maintain a database of risk adjusted benchmarked quality outcomes, from this type of procedure. We're the only participating facility in all of Canada. It's called the vascular quality initiative. And we are required to submit peri-operative patient and procedural data, to a registry in which more than two hundred centres participate. And then, we get monthly, we get a semi annual	BVS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				outcomes reports, benchmarking our quality and our performance, against other comparable centres. This database is centred around general outcomes, IE length of stay, mortality, complications, limb ischaemia, these sorts of things. It's not really focused on devices. It's centred on outcomes. But it is, kind of a, if we notice we have a quality problem, this is almost a real time feedback.	
Reporting system and process	Hospital sent device parts to manufacturer			~But we did sent that off, and um, to the vendor. The vendor was actually in the hospital the next day and had a look at it. The pieces went out to the supplier	BRN1
Reporting system and process	Hospital staff notifies regulators of incident with medical device	~When it comes to a specific device related problem, I haven't had one yet where I thought it was a fundamental device problem that requires Health Canada being notified. But that's also a process that we would consider. If it was truly a device problem that affected patient safety, then we would notify Health Canada. And I know that has been done in the hospital in the past, and that's what we would do as well, if we felt it was specifically device related.	AVS1		
Reporting system and process	Hospital wide mechanism for incident reporting			~if you recognize that you had a device related incident, then the most frequently used option by a clinician is to file an incident report. And that is, that's a hospital wide mechanism for	BCS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				reporting any irregularity in the care of the patient.	
Reporting system and process	Internal registry to track outcomes of vascular surgeries			~Now we have a database and registry function on the surgical side, which we have yet develop on the, um, or mature, on the radiology side. And, I see kind of a mirroring of the two, eventually. But this is a trickle down effect of the hospital quality of care committee, wanting more accountability from the individual departments.	BVS1 &BIR 1
Reporting system and process	Mandatory reporting for more serious medical device-related incidents	~and there's mandatory for certain types of cases. You know, more serious cases are, such as death, are part of a corporate culture to be reported, on a mandatory basis and to try and find explanations. So the hospital does have mechanisms in place for that.	AOS1		
Reporting system and process	Manufacturer is notified of error and has their quality assurance department examine the medical device			~And it's bagged and kept for the vendor. ~That is then, the vendor is then notified. They come and pick it up and then they take it to their quality assurance department.	BRN1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Reporting system and process	RN completes a hospital incident form			~we actually do an in-house incident form, just to sort of log, you know, that we've had issues with, sometimes, it ends up that it's a particular lot number, that, you know, might be a bad batch or something.	BRN1
Reporting system and process	RN completes a hospital incident report			~ when the machine itself does something wonky like changes its program, that sort of thing, we do file an incident report on it.	BRN2
Reporting system and process	RN completes product complaint form			~A product complaint form is completed.	BRN1
Reporting system and process	RN includes manager of medical engineering in hospital incident form			~And in which case, if it's a case like that, then I often will include the manager of our medical engineering department on that incident form so that they're attuned to it.	BRN1
Reporting system and process	RN reports error to manufacturer	~ If there's been a malfunction, the nurses automatically kick in and do a report and then send it down to, I guess, the OR manager, who then sends it down to purchasing, to track down and report to the company, to discuss the malfunction.	AGS1	~I personally don't, but I tell the nurses to. It's kind of a hierarchy where you say, you know, 'Report this.' and so the nurses then file a, you know, they have all of the channels of who sells the product to the hospital and how much of these things are, you know, how much we pay for them and all that. So there is a channel where I say to them 'Report that this wasn't working.' or 'Send this back to the company.' And so that gets done by the nursing admin here at our hospital.	BGS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Reporting system and process	RN reports error to procurement department			~Well, in terms of the staplers, our hands are sort of tied, because we have contracts with, you know, different vendors, right? So, when we have the staplers or the re-loads that go with them, if they're not functioning properly, all we can really do is lodge a complaint through our buying group.	BRN1
Reporting system and process	Patient safety and learning system to report on patients with odd clinical outcomes	~we have what we call a PSLS, a patient safety and learning system. So anytime something goes wrong with anyone or a patient has any odd outcome of anything, you're supposed to make a comment of it. You're supposed to make a report of it.	ARN1		
Reporting system and process	Voluntary reporting for less serious medical device-related incidents	~And there's, again, usually voluntary reporting. But different divisions can work it differently so it's less voluntary	AOS1		
Reporting system and process	Hospital staff reports error to manufacturer		ACS1	~ I did report the device, this situation and event, to the company. ~So, if the device has not performed as expected during its deployment and has malfunctioned during deployment, that's a clear, I report that to the company representative; often, they're present during the procedure. And they'll get immediate feedback.	BVS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Reporting system and process	Clinician notifies RN of medical device-related incident	~the surgeon brought it to my attention, because in charge to the service. ~first it's brought to my attention and I bring it to our managers attention	ARN2		
Reporting system and process	Contribute to and receive reports from a multi-institutional registry			~ the second part of my answer is that at our particular hospital, we maintain a database of risk adjusted benchmarked quality outcomes, from this type of procedure. We're the only participating facility in all of Canada. It's called the vascular quality initiative. And we are required to submit peri-operative patient and procedural data, to a registry in which more than two hundred centres participate. And then, we get monthly, we get a semi annual outcomes reports, benchmarking our quality and our performance, against other comparable centres. This database is centred around general outcomes, IE length of stay, mortality, complications, limb ischaemia, these sorts of things. It's not really focused on devices. It's centred on outcomes. But it is, kind of a, if we notice we have a quality problem, this is almost a real time feedback.	BVS1
Reporting system and process	Device malfunction or incident documented in operative report			~in neither of those cases did I report medical device malfunction to, as a medical device malfunction. The oxygenator incident, that was documented in my operative report.	BCS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Reporting system and process	Hospital staff completed incident report and updated patient's chart	~And we filled out an incident report and we documented it in the patient's chart	ARN2		
Reporting system and process	Hospital staff reported in hospital incident form	~I reported it, yeah. We have a form here and we let the company know about it. I didn't (report it 7:26) anybody else	ACA1		
Reporting system and process	Hospital staff reported incident to manufacturer	~I reported it, yeah. We have a form here and we let the company know about it. I didn't (report it 7:26) anybody else	ACA1		
Reporting system and process	RN notifies manager of medical device-related incident	~I bring it to our managers attention	ARN2		
Reporting system and process	Clinician follows regulatory guidelines for personal protection			~' And, at a personal level, the only thing that protects me from a class action lawsuit if something is discovered ten years down the road, is the fact that I carried the procedure out and the patient selection within Health Canada guidelines	BIR1
Reporting system and process	Hospital has dedicated quality assurance employee	~I think that we have a good process to notify and we have a QA person who's job it is to follow up on all these things.	ACS1		

I=Interviewee; P=Participant

APPENDIX 7: INTERVIEW RESULTS-FACTORS THAT INFLUENCE THE RESOLUTION OF MEDICAL DEVICE-RELATED INCIDENTS

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Education and training	Clinician participates in interdepartmental formal rounds	~And then we hold, do our formalized rounds both within ourselves, interventional radiology and with vascular surgery and with radiology, the department of medical imaging as well.	AIR1		
Education and training	Have adequate training for staff on use of new device	~Or more commonly, was the learning curve just too steep and was the training not adequate enough, to avoid the problem? And most companies are quite good about training courses. And some of them make the training courses mandatory before you use new devices. But it's, you know, it's still somewhat flexible. I mean, surgeons are on their own accord, so to speak or left to their own, to achieve a comfort level with an implement, whether it's an old one or particularly a new one that they're going to try. And so they've gotta be, they have to adopt a certain comfort measure on their own, before trying it. Now, is that standard and uniform? No, people are different. And so, you may have people who are a little more cavalier and others who are extremely cautious. And so, I'm sure there's a bell curve as to where those individuals fall. But, mitigating the problems are usually, mostly have to do	AOS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		with training and technique of the surgeon.			
Education and training	Hospital interaction with manufacturer on education	~We're in contact with manufacturers quite frequently, for educational purposes. And they often do come in the operating room, because they're, if we're doing a complicated case, and they may want, we may want their help. So, they certainly are intricately involved.	AVS1		
Education and training	Manufacturer provides training for new staff	~where we have new fellows who are learning. We'd show them how to do it; we're work with them. And then they're still having trouble. So we got the company to come in and give them like a day long symposium kind of, on it. So, I think we're pretty proactive about trying to make sure that everybody understands how to use the equipment properly.	ACA1		
Education and training	Nurse educator provides continuous education on equipment programming to hospital staff			~I: Okay. Okay. All right. Thank you. And I just, you mentioned earlier, continuous education efforts. So would that imply a nurse educator having a session or some sort of, um, education rounds, related to, for instance, programming of infusion pumps or would it also involve a manufacturer representative coming to the hospital and providing some in-servicing or an education session? P: There've been both.	BRN2

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Education and training	Provide continuous education to hospital staff on how to operate a medical device			~Well, I think the human errors in reprogramming the infusion pumps, I don't know, continuous education; reminding people they have to be very careful when they do this.	BRN2
Education and training	Report and discuss incidents with colleagues at quality review rounds/case conferences			~If there was no other kind of, good chance, again, I would, usually the same people at the morbidity and mortality review are a head of our case conference, where we would, are also present at our pre-operative case conferences. And I would present the plan again. We'd discuss the previous event, and say 'Look, is there another way? Is there a different device? Any other suggestions?' So, I don't think I'd be worried about any personal consequences.	BVS1
Education and training	Report and discuss incidents with colleagues at quality review rounds/case conferences			~ And it's not really got a, you wouldn't really report that incident to the manufacturer. It's strictly a complication of either the patient selection or the selection of that particular agent, for that indication. And the results of that, or the adverse, the complication, would be reviewed at morbidity and mortality rounds.	BIR1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Education and training	Report and discuss medical device-related incident at morbidity and mortality rounds	~Mortality and morbidity rounds. So those types of cases are presented in an official manner, so we can learn from them. They're not in a punishment, punitive kind of way. It's more what was done; what could have been done, to prevent the problem and what can be done in the future.	AVS1	~whether or not, recognizing a device malfunction that is, that's really an education process. And so, we try and improve, through our rounds and morbidity and mortality, providing information to people so they're better able to recognize a device malfunction. But again, that's very informal.	BCS1
Education and training	Report and discuss medical device-related incidents at morbidity and mortality rounds	~we hold our morbidity and mortality rounds in interventional radiology twice a month. So we discuss most of the cases that people have had either complications or difficulties with	AIR1	~Other instances, if we've had several events, we have continuous quality improvement process, where we're having morbidity and mortality rounds on a monthly basis.	BVS1
Education and training	Report and discuss medical device-related incidents at morbidity and mortality rounds	~we certainly, we have internal morbidity and mortality rounds. Each division will have them internally. And (as a quality 22:33) assurance round, they're protected under the privacy legislation, under the guise of quality assurance. That happens internally.	AOS1		
Education and training	Update hospital staff with in-services on safety tools and on medical device features	~We actually do in-services, weekly in-services as well, just to update people on all of the, sort of some of the tools that we use and anything that's knew or maybe alert someone to, you know, 'If it doesn't turn on, maybe this is what, you know, the tourniquet has a safety feature so that you can't accidentally turn it off during the surgery.' So definitely teaching.	ARN2		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Feedback on how reported information is used	Manufacturer improved and resolved device functionality based on feedback from the hospital			~If and when it malfunctions, and put more safeguards into the algorithms, including more sound alarms, more wording or explanation on the screen, because it has a screen that we use, a touch screen that we to program the injection contrast. And, everything goes through this touch screen type of thing and that's how the system alarms you or tells you how to do things properly. And so anyway, that was fed back and they actually made changes as well. ~I: Okay. And did you find, Dr. (name), that when you reported the error or the malfunction to the manufacturer they were receptive in the sense that they acknowledged that it could potentially have been a malfunction versus a human error with the user of the device? P: They were receptive to this fact, because they did make more safeguards available, for this to happen, and also, when we actually looked on their website, they actually, unfortunately, there were actually a lot of reports of this happening in the past, so it wasn't the first thing. It wasn't a first time for this technology to, for this to happen and the incident to happen. So, it's not the first time, like, I said, so, they did not, they did not actually feedback that	BCA1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				it was necessarily human error to us... ~Typically, what will happen is again, the device or whatever that has malfunctioned will usually be fed back to the manufacturer, and also will sometimes go to, for instance, our in-house biomedical, for assessment and understanding of how the device, why the device malfunctioned. And typically, feedback that we give to them, as clinicians, as to what happened, they will use that information to, hopefully, resolve the situation.	
Future use of medical device	Clinician will make decision based on direct experience	~So, in terms of resolution, if you've had, you know, physician's often will base action on direct experience.	ACS1		
Future use of medical device	Continue with use of device if no alternative therapy exists			~But we don't usually have an option not to do it. It's just the nature of our field.	BCS1
Future use of medical device	Device returned to manufacturer and hospital request refund	~And what we usually do is we send it back to the company. And we, you know, cause we paid for it, and we ask for them to pay us back.	ACA1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Future use of medical device	Disinvestment/discontinuation of medical device	~ If that has been a problem, then we would pull it and wait until the company could either provide with something that is safe or source out another vendor.	ARN2	~We stopped putting in the device. ~Most of the devices that we utilize, the patient needs some form of that device. So, and it tends to be a life threatening issue. So there are, in many cases, not options to not have the device versus having it. What we have options with is what kind, what company make the device or what specific form of the device may go in. So, we have options, we have choices as to what goes in, and some choices prove to be better than others in the long run.	BCS1
Future use of medical device	Disinvestment/discontinuation of specific device	~So, generally, what we do is if it's malfunctioning, I mean, we don't use it.	ACA1	~you can make it in a very dilute form or a more concentrated form. And, I may be counselled and advised by my partners on how I might have changed the dilution of the agent, one way or another, or chosen a different agent.	BIR1
Future use of medical device	Disinvestment/discontinuation of specific device	~And they actually removed the product a couple of days later, from the hospital. ~Well, in the second instance I named you, like, I said, they removed the equipment all together	ARN1	~So if there's a product of concern, we remove that product from the hospital.	BOS1
Future use of medical device	Disinvestment/discontinuation of specific device			~as soon as an incident occurs, intra-operatively, the item is pulled off the field, if it's possible.	BRN1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Future use of medical device	Disinvestment/discontinuation of specific device	~I mean, so generally, um, generally I would say that, you know, most people who do medical procedures are very, we have long memories. And if the equipment doesn't, even if it's just not a major issue, if we have a difficulty with equipment, we tend not to use it.	ACA1	~So, we just made a local, most of us who are doing this work, continued to kind of avoid using the particular product. ~So, I don't think the process was resolved at a central level. And ultimately, it was left to me, to just make a decision in the interest of my future patients, to avoid using that particular product from that company. And I can say that while that device was previously stocked in our consignment in the hospital, the hospital and my colleagues made a decision just not to stock that particular device. ~two of my partners at my hospital, had seen similar events and had just made a decision and a comment 'We won't use these.'	BVS1
Future use of medical device	Disinvestment/discontinuation of specific device	~I think, you know, say, something that comes to mind is say, a valve that you've had some issue with, which is more of a design issue. You probably just would never use the device again. ~So if you've had a problem with something, you're probably less likely to use it in the future, as a simple thing. If you have been notified that there are problems with a specific device, you'll probably be less likely to use it again.	aCS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Future use of medical device	Ensure availability of devices in stock			~One was a situation where we had originally placed the patient under a general anaesthetic, accessed the patient, performed our required imaging procedures and placed the device in the renal artery. And then the device, according to the energy source, kept relaying a fault. And we were unable to continue the procedure, in a patient who is already under a general anaesthetic. So, from an interventional radiology standpoint, when you've planned a particular case, requiring specific components or devices, and you find out that they aren't actually, it's a problem if you have a limited stock of these. And you don't have a back up device immediately available.	BIR1
Future use of medical device	In-servicing from manufacturer	~simple in-servicing will fix the problem	AGS1		
Future use of medical device	Replacement of old equipment			~they could not fix the problem, so we ended up with a sort of a newer version of their power equipment. And they have to replace the old power equipment because it wasn't safe for us to go ahead and use. So that was, originally, our biomedical people discovering the problem, meeting with the company, seeing what was out there, sort of online, what different hospitals had gone ahead and reported. And sort of demanding a fix to the	BOS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				problem	
Future use of medical device	Temporary disinvestment/discontinuation of medical device	~ If that has been a problem, then we would pull it and wait until the company could either provide with something that is safe or source out another vendor.	ARN2		
Information sharing	Consult with colleagues for resolutions on novel clinical procedures			~Um, yes, I would say, if I'd had challenges with that device before, then I would look to have another colleague around, who might have used it a couple of extra times. And that's, I definitely see this in interventional radiology, compared with my surgical practice, that there is a larger volume of new variants or products coming online: a newer stent, a newer catheter, newer wire; newer central venous catheter, new embolic agent. There's a greater turnover, with a shorter experience of individual products. Well, any one of us will have a broad experience in a category of procedure in which those products may be employed.	BIR1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Medical device procurement process	Conduct quality assurance of device before purchase decision			~We have to get the technique verified by the company, ah, techniques for disassembling, assembling, sterilizing. The hospital checks the equipment, things like Xray machines,C-arms, cautery, tourniquets machines, on a regular basis, rotating basis. So there's a record kept of when those have last been tested. And as I say, our biomedical engineering group, the first example I gave you, with the power equipment, they go ahead and sort of check things, sort of on a random basis, continually, looking for any potential problems, especially products which may be newer products that have been brought into the hospital.	BOS1
Medical device procurement process	Data on errors reported are used to negotiate contract with manufacturer			~And they log them so that when another contract comes up, they have some evidence, kind of thing, that we've been having issues.	BRN1
Medical device procurement process	Follow-up with manufacturer on device malfunction	~it's almost taken out of the hand of the surgeon, in the sense that there is an official report, a report on the malfunction. It goes through several hands in terms of information. Then it goes through purchasing who then follows up with the company, on the product, and that particular lot number. Now the company will then issue a review letter, back to the hospital,	AGS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		addressing that particular product and that particular malfunction. Now, the hospital itself keeps track of these malfunctions.			
Medical device procurement process	Frontline staff who will use equipment in practice to test device and understand how it works	~before we purchase equipment, the nurses who ultimately are going to be using them, should be the people who are deciding which devices we use." So they brought in the four devices with three bio-technical people, to show them to us and give us a brief inservice on them. And my first case in point was these people don't use them. Like none of these people ever use a glucoscan and they're giving us an inservice on it. To me, it's the same as the rep not being a nurse, explaining to me how to use a glucoscan, to me, it's ridiculous. ~But these are the people who ultimately are going to be purchasing the equipment, and they don't have a – You know what I mean? The next one is, it shouldn't be a five minute inservice where you show me how it works, and then me go out to use it. It should be you leaving the device there, and allowing me to screw around with it, right?	ARN1		
Medical device procurement process	Incorporation of clauses in industry contracts	~So when you negotiate contracts, with those companies, there's all sorts of clauses you put in those contracts.	AGS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		There's, you know, there's a whole series of different clauses that go into, which have nothing to do with this. You could always add another clause, saying that if your response to instrument malfunction is ineffectual, we have the option of reviewing/changing our contract obligations, you know, something to that effect. Right? So there are ways of doing that. But other than that, there's no way you can influence a company to do anything that is minimally legally required of them, right?			
Medical device procurement process	Procurement department should allow frontline staff to test device and understand how it works	~So, you know, the guys are bent out of shape that I'm screwing around with it without them telling me. And I'm like 'Well, if I can break it by screwing around with it, then we don't need it either.' That actually, I'm trying to put the glucoscan stick upside down, and he's going "That's upside down." And I'm like "I'm aware that it's upside down. But I want to see if it'll fit in upside down." He goes "Well, if you do that, you might break the machine." And I'm like, "This is the reality of the situation. We're going to be doing this in the dark quite often." Right. Or with a flashlight under our arm. And if the chem stick can go in backwards, you can guarantee it's going to, on all the machines. People do it all the time. It's hard to see at night, blah, blah, blah. My point being is that	ARN1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		the idea is to give us an opportunity to give input, but the input is useless because the implementation of the idea is lost right at the grassroots level. It should be somebody like me, a front care worker, a frontline worker, saying, you know them coming to this thing 'Here's a glucoscan.' You know what I mean? 'Keep it for a month.' You know what I mean? 'And tell us whether you like it or not at the end of the month. And then we'll give you another one, or we'll give you three and you can use them all.' And there, being the reality of how the device functions.			
Medical device procurement process	Review of contractual obligations	~If there is a concern about in inordinate high number of malfunctions, then I guess senior management gets involved in terms of addressing it with the company. If the company can't address the issue appropriately, then there's some discussion about, you know, contractual obligations back and forth. ~for our purchasing department to then contract the company specifically to address these issues. Right? And they, the companies are pretty good at addressing these issues.	AGS1	~If we have a contract with that vendor, we don't necessarily, we would consider that, we would have that written into all of our contracts, that if there's a problem like that, we're not, we're no longer bound by the agreement, as far as using a product of theirs or a certain portion of their product and that the product would not be brought back into use in the hospital until the problem was adequately corrected. And we would be looking at other vendors to bring in other products until the problem was fixed.	BOS1
Medical device procurement process	Verify safety of devices with available documentation			~before a product can be brought in the hospital, it has to have the proper international documentation that it's safe.	BOS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Organizational culture	Hospital and its staff maintain very high standard of care	~Because we have like a very high level standard of care. So it just wouldn't be, it wouldn't be acceptable to have that happen again. I mean, it was, the patient didn't have, it wasn't a really bad burn, but it was a burn nonetheless and embarrassing to everybody. But we didn't want that happen to anybody else.	ARN2		
Organizational culture	Hospital staff are quick to resolve medical device problem	~So, I would say, I mean, specifically with devices, I think there's, you know, we're kind of the opposite in the sense that, you know, if there's a problem with the device, we're very quick to jump on it, because it affects how we, how we work and it can impact our outcomes and that.	ACA1		
Organizational culture	Hospital staff are quick to resolve medical device problem	~We have an excellent biomed department that is really in tune with, and will respond right away about incidents that we've had and actually been very proactive (with resolving.30:00). For instance, we had an incident with a temporary ventricular support device that had a couple of problems and that, when they identified them, they took care of it, and did all the reporting and went to the company. And we met with the company but they were the ones who were really very much at the forefront of identifying and resolving what went on.	ACS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Preventive actions	Clinical review of manufacturer instructions			~we're taking proactive measure to make sure that it doesn't have a negative consequence for our patients. Now, when we take those leads out, there has been, first of all, the patients are aware they have a lead that's on advisory. And that was done previously. So when a company puts something on advisory, they provide advice as to how to manage that particular problem. As an institution, you review what, the appropriate clinicians come together and decide whether or not they agree with the management that the company is recommending and then they will implement their course of management.	BCS1
Preventive actions	Clinical review of pre-clinical trial results	~So I think each, any device that we use has information about what would be expected about the performance of the device in the pre-clinical trial. And we would go to that to assess it and see whether this is something that would be expected for that devices.	ACS1		
Preventive actions	Clinicians plan on how to prevent similar errors from occurring	~And then we either plan for how to deal with the case in the future, if that's the case, or what we do is we discuss the case and see how the problem might be prevented in the future. Basically, we're learning, hopefully, we're all learning from a single person's mistake or whatever outcome there was, to try to prevent the same thing from happening in the future.	AIR1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Preventive actions	Develop an alternate plan if problem occurs with device	~most of this stuff is recognized right at the time of surgery. And an alternate plan is carried out. So it's hard for me to think of a specific example right now, but you know, for when it does happen, you might have to go to a bigger implant, maybe a different implant. So you have a plan B, in the operating room, if the problem is really implant or device related and there's no substitute other than another device.	AOS1		
Preventive actions	Find a balance between use of safety checklist and health care delivery			~Obviously, there's a balance, where we're operating in a system where our budgets from government don't even keep up with inflation. So you have to go ahead and provide patient care, so more frequent reporting, more qualified people to go ahead and do the checks is great. But the same can be said about having more nurses on the floor per patient, more nurses in the ICU, more operating time. So, it's, all of those are important. It's not that any one is more important than the other. We have to provide patient care. We have to provide patients with safe patient care. And we can't necessarily be taking large amounts of the budget that we use to deliver patient care and have it done just in the checking of things. We could end up literally bringing our hospital to a standstill. So, it's sort of a balance of everything, all the activities that you do.	BOS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Preventive actions	Hospital implements course of action			~we're taking proactive measure to make sure that it doesn't have a negative consequence for our patients. Now, when we take those leads out, there has been, first of all, the patients are aware they have a lead that's on advisory. And that was done previously. So when a company puts something on advisory, they provide advice as to how to manage that particular problem. As an institution, you review what, the appropriate clinicians come together and decide whether or not they agree with the management that the company is recommending and then they will implement their course of management.	BCS1
Preventive actions	Implement safety checklists to mitigate/manage incidents if they rise			~so I think that are far as trying to identify them, more frequent checks, which means more money which means more salary.	BOS1
Preventive actions	Implemented a safety checklist to mitigate/manage incidents if they rise			~Locally, we've instituted in interventional radiology, some of the same safety processes that we use in the operating room in vascular surgery. The most clear example is an interventional radiology safety checklist, before a procedure is started. And as part of that safety checklist, we include the actual devices that are required. And for this type of procedure, we now require a second catheter to be available, in the room	BIR1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Preventive actions	Increase collaboration across institutions to track performance of medical devices			~I'm fascinated by the fact that the hospitals will get together in an organized fashion for purchasing, this centre called Plexus which is supposed to realize certain cost savings to institutions. If they need ten devices amongst six hospitals, you know, they'll approach the manufacturer as a group, to purchase and get a discount. But, there's no ah, where money is concerned, that's, they're willing to collaborate. Where tracking the results of these devices and application of these procedures, there's, these types of registries can cost a hundred thousand dollars a year to participate in. So, those savings, in my mind, would be well suited towards establishing registries that are at arms length from the manufacturer.	BVS1 &BIR 1
Preventive actions	RN conducts independent check of programming of equipment			~I think there have been some situations where we've suggested an independent double check on the programming of the equipment.	BRN2
Preventive actions	Plan and troubleshoot with colleagues at quality review rounds/case conferences			~when we're in that situation, we employ a multidisciplinary review, where we'll sit down with an interventional radiology colleagues, several vascular surgeons, sometimes a cardiac surgeon, sometimes another hepatobiliary surgeon, and we'll discuss the plan ahead of time. We'll be	BVS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				reviewing whether or not it's appropriate to employ a device in this particular off label use. ~the institution itself, has a quality review, do try and pick up on adverse events and avoid them	
Preventive actions	Planning for continued use of device if no alternative option exists	~Now, if there was only one option, and that was the only thing that was available, then I guess, because you would use the thing again, you'd want assurances that whatever had happened was either explainable, based on a 'Well, this is just a one of. It will probably never happen again' or if it's something that others have reported, then, and you really need to use the device, then you want to again, make sure that whatever the problem is has been resolved.	ACS1		
Preventive actions	Risk mitigation strategies are developed for physicians	~And then we'll come up with a strategy for the physicians to be able to deal with. So, on the physician's part, it's the decision whether to use the device every again. And if it's something that's already been in someone, then you have to decide what the risk and benefits are. If the risk for taking it out outweigh the benefits of, or the risks of leaving it in, then you know, you have to make that decision on a device by device instance	ACS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Preventive actions	Planning on off-label use of device by multidisciplinary health professionals			~But that's a clear example of me employing a device in an off label use, for, the only other consequence was a re-do exposure of the patient's old liver transplant, with probably risks that would have exceeded those which I exposed the patient to, using this, in this off label application. Often, when we're in that situation, we employ a multidisciplinary review, where we'll sit down with an interventional radiology colleagues, several vascular surgeons, sometimes a cardiac surgeon, sometimes another hepatobiliary surgeon, and we'll discuss the plan ahead of time. We'll be reviewing whether or not it's appropriate to employ a device in this particular off label use.	BVS1
Preventive actions	Quality assurance of device performed by hospital staff	~, it has to pass through the development, like at the engineering stage. Then it would have to pass through the respiratory therapy department, because they must have trialled it before they switched. And then, it would have had to go through, you know, they all have to have policy and procedure manuals on any new equipment we had. Like it had gone through multiple layers of people, and this was never caught. And it easily could have killed somebody.	ARN1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Preventive actions	Review of operation performed among hospital staff	~Well, there's different safeguards in place. I mean, there's obviously the real time recognition, if it's not gone in according to plan. There's a brief at the end of every operative case, you know, 'How did everything go? Was everything fine? Were there any problems?' And so that typically then can, gets recorded. That does get recorded on the operative record, if there was a problem with an implant that caused a change in a procedure or a modification. But, usually, the factor that's important to it, is experience in recognition	AOS1		
Preventive actions	Safety checklist to reduce risk of incidents	~If they're on intact, then our index of suspicion that something is wrong is raised and we do a variety of things to check for that. And then the other thing is that the surgeon themselves, there's a few steps after you've done, everything looks fine; there's a few steps that we do to ensure that we have a secure anastomosis.	AGS1		
Preventive actions	Safety checklists are used as cues to ensure that everything is in order	~we do have like an electronic recording, like our electronic documentation actually, we have a checklist. So we actually go through all the checklist. So that prompts us to make sure that everything has, is in working order and is going.	ARN2		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Preventive actions	Track information in incident report and identify ways to reduce risk of future similar medical device-related incidents	~And you know, just that we had a process, because we do fill out an incident report, that's a patient incident report, so that all of, that they're all tracked, and just ways, and we identify ways to avoid that.	ARN2		
Response from manufacturer	Manufacturer worked closely with hospital to resolve problem with medical device			~I did actually have that from the water pic company that it was connected to an electrical generator. They were much more forthcoming and worked very closely with us to rectify the problem. I don't see the disposable stapler companies being so forthcoming in trying to work with us. And, I mean, these staplers aren't cheap. So you know, it's very frustrating to not get any sort of resolution from their end of things.	BRN1

I=Interviewee; P=Participant

APPENDIX 8: INTERVIEW RESULTS-BARRIERS TO THE RECOGNITION, REPORTING AND RESOLUTION OF MEDICAL DEVICE-RELATED INCIDENTS

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Conflicts of interest	Clinicians have more vested interest in medical device versus nurses	~nurses will be easier cause they have no vested, sort of biased interest one way or another, where the surgeons will be harder to convince	AGS1		
Education and training	Clinician is unaware of barriers for device incident recognition, reporting and resolution			~I don't, I haven't, I don't think there are. In our institution, I don't believe there are barriers in terms of reporting or resolving these issues. I think the reporting system is a very, is accurate. It's fairly robust. In terms of resolution of the incident, I think we have a process to resolve the incident, whether it be through hospital means; through working with the companies to understand why the device malfunctioned. I think there are a number of processes in place that we are able to resolve the incidents in an effective manner. ~In our hospital, again, our recognition of adverse events, reporting adverse events, and with technology devices, I think again, is very, is a good process. We have a very good process for that. And, again, resolving them in our institution, I don't know what everyone	BCA1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				else does, but I can tell you, at our institution, I mean, we, again, we work through a process. And until people are comfortable the adverse event is resolved, then it, you know, it doesn't get closed. Again, if the adverse event is a minor adverse event and everyone tends to agree that this is something that's minor and if it was related to a device malfunction, again, we recognize that and we work through it to understand why the device didn't work. Now, that may not be through the hospital; it may be through the manufacturer. So again, I don't think we have a major problem with that at our hospital. Devices do malfunction, (inaudible 23:45). So, but in terms of resolving them, and the process, in terms of reporting, I don't have any problems with that.	
Education and training	Clinician is unaware of hospital database for medical device-related incidents	~There is no database, as far as I know, where we actually report at the hospital, where we do report complications for medical device ~But I'm not aware of any that exist just for complications and device failures.	AIR1		
Education and training	Hospital staff is aware of medical error or incident reporting mechanism	~there's definitely a mechanism to deal with it, sure, and there's an awareness of it, I think. There's an awareness of medical error and that, for sure, in our, I think we have a culture of looking for	ACA1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		that here.			
Education and training	Lack of awareness of implications of not reporting errors	~And there's not a strong culture for this, although it's not supposed to be punitive, a lot of people feel that it. I mean, I suppose it's a little less so when it's a piece of equipment, but the reporting system itself is time, is labour intensive, as far as time goes. And a lot of people that aren't familiar with it, just like anything else, because they don't do it that often, find it very intimidating. And they think of the legal implications and whatnot. So the easiest default is just not to do anything. ~But it surprises me that the person that may be reporting it to me, or that I see, you know, involved in it, doesn't realize that that level of implication. And I say "Well, first, you have to document it."	ARN1		
Education and training	Lack of knowledge of how to report an error	~I don't know sort of the SOP for that, you know, personally, cause that's not my position.	ACA1		
Education and training	Lack of knowledge of how to report an error for device incident or malfunction			~ knowledge of how to complain and time factors, like, not knowing how to make a complaints or lodge a complaint and you know, often what happens is you troubleshoot it enough that you	BGS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				kind of get through the case and then you can't be bothered, you know, you don't have time and you can't be bothered putting a complaint in. You know, you get busy and you move on to the next case.	
Education and training	Lack of knowledge of ownership of error			~But so, I'm not sure so that it's a professional image. To some extent, it is a medical legal issue. If you, like, who, if a device has malfunctioned, was it because of how it was implanted or whether it was a fundamental problem with the device. So I think there is some fear of a medical legal problem, and who has ownership of that.	BCS1
Error reporting compliance	Clinician doesn't report isolated incidents that aren't deemed to be serious	~Like, you know, if it was a one off, one device where there's an issue, we probably wouldn't report that. And again, it would depend on the magnitude.	ACA1		
Error reporting compliance	RN is unlikely to report human errors to hospital			~ There have been incidences where it's been a human error in the programming of the machine. And I don't think that incident reports get completed for that. ~And what I mean by that is if I mis-program or incorrectly program a pump, and a nurse that I'm working with recognizing it, from nurse to nurse, we tend to just fix the program. So I think we don't necessarily identify that type of thing as being a quote 'incident.'	BRN2

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Error reporting compliance	Reporting not always consistent among RNs	~So in those, in both those instances, whether or not a report gets made by the actual nurse who might have come across that is questionable. They may pass it on to somebody. But I see events like this take place on, I don't want to say a regular basis, but I see them take place on a, (sigh) certainly the occurrences I would say, are at least a few times a year, where the implications of what happened were life threatening.	ARN1		
Error reporting compliance	Reporting of medical device-related incident is voluntary, so compliance is low	~The other reporting requirement is as I described earlier, which is the operating room requirement, with the debrief at the end of the case. So that always gets recorded in writing, based on a verbal discussion about how the case went. Did it go according to plan or not? If it didn't, then the issues that were surrounding that get discussed.	AOS1		
Error reporting compliance	RN does not report isolated incident with stapler			~So if the first one fails, then they get a replacement.	BRN1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Feedback on how reported information is used	Frustration from clinician on lack of feedback			~So I think there's some frustration among clinicians that nothing ever happens. You report it, and you don't get any feedback. And then, I think there's also a lack of appreciate, failure to appreciate the importance of actually reporting a device malfunction. Because you have only one, but if ten people had this problem across the country, it might be a problem. And so, we need to accept that is important to report.	BCS1
Feedback on how reported information is used	Uncertainty know what happens to report	~What was interesting about that incident was that the, when people coming in, because I stayed with her, even though she wasn't my patient, I stayed with her to stabilize her. And people kept coming in to see her, like, for example, the dialysis team and the infection control team. And none of these people were aware of that, you know, that complication with that particular apparatus. And I mean, for large degree, the physicians wouldn't be, because they don't do glucoscans. And my physician is a very, very top notch guy. I'd trust him with my life. He just missed it, as I told him, I probably would have when I did it as well. Because you see that warning ten thousand times, and it never applies.	ARN1	~I've never had any follow up.	BRN2

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Hospital knowledge and experience	Awareness of incident occurs in follow-up	~it's most follow up and we as interventional radiologists, in, well, at least in Ottawa, don't really follow our patients. Most of the time, they're followed by other clinicians. So we're only kind of made aware of the incidents when, either in the follow ups, if they have a follow up study for whatever is done or when it gets brought to our attention by the referring service.	AIR1		
Hospital skill and knowledge	RN sometimes is unable to differentiate between an incident and a near miss			~P: I think sort of clarifying what example an incident is, because there are things that people that aren't clinicians would think was an error that I certainly wouldn't think was an error. I: Okay. So perhaps more education then, in recognizing what an incident is, or, versus a near miss, or a device malfunction would be - P: Absolutely. I think we're all pretty clear on what a device malfunction is. The whole near miss is a huge grey area.	BRN2
Hospital skill and knowledge	RNs inability to troubleshoot problems with medical device			~ Something that happens relatively frequently with dialysis machines is there's some kind of error with the dialysis machine and we are not experts at troubleshooting the machines.	BRN2

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Hospital staff knowledge and experience	Clinician's reliance on nurses in clinical procedure	~The other thing that dictates everything going fine is the nurse who sets up the instrument for you, and hands it to you. She has to be familiar with the instrument. And so there is in-servicing, the nurses (inaudible 31:07). If there's a new nurse who's learning, there's always a circulating nurse who oversees the assembling of the stapler, to ensure that it's done right. After that, there's a procedure that we go through, whereby the nurse, we hand off the stapler, and the nurse checks the stapling device to ensure that we have, what we call, two intact doughnut rings.	AGS1		
Hospital staff knowledge and experience	Inability or limited knowledge on how to use the device properly			~Sometimes the nursing staff are there but they don't know how to use it, so you know, it just adds to frustration for me. It doesn't add to anything, it might just add to maybe a little bit of a delay but that's about it. If I think about the, another equipment is like a hydro-jet or equipment that we use to come through the liver on an open liver operation.	BGS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Hospital staff knowledge and experience	Individual(s) who knows how to use or troubleshoot the device are not in the OR			~And I don't understand the nuances of how to get it working well. And the tech that supports the product isn't in the OR and, cause they're not often in the OR. When they sell it to you, that's, you know, they usually are there at the beginning and then they're not there after you've bought it. And, the nurse, you know, the nurses are usually informed in terms of how to troubleshoot some of the things. But you know, occasionally, you have nurses that aren't in the room that know how to use it, so you know, we kind of stand there and look at each other and say 'You know, this isn't working well and you need to fix it.' and I don't know how to fix it and they don't know how to fix it.	BGS1
Hospital staff knowledge and experience	Nursing staff is unable to or has limited knowledge on how to use the device properly			~And I don't understand the nuances of how to get it working well.	BGS1
Hospital staff knowledge and experience	Outside imaging/information difficult to interpret			~And, if, when imaging studies are performed at outside institutions, the interpretation of the imaging can be very murky, as it related to the presence of a device showing up on a CAT scan and determining 'Is it in good position? Has it done what it's supposed to do?' and getting that information back to me. Often, if the information just comes	BVS1 &BIR 1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				back, in a paper format, it's useless. I can't determine whether the device has a problem or not.	
Hospital staff knowledge and experience	Rapid, constant turnover of device limits experience with medical device			~ that there is a larger volume of new variants or products coming online: a newer stent, a newer catheter, newer wire; newer central venous catheter, new embolic agent. There's a greater turnover, with a shorter experience of individual products. Well, any one of us will have a broad experience in a category of procedure in which those products may be employed.	BIR1
Hospital staff knowledge and experience	Referring clinicians may not have capacity to recognize problems			~ I can assure you that in Thunder Bay, the clinicians who are local have no idea how to recognize problems with these devices.	BVS1 &BIR 1
Hospital staff knowledge and experience	Hospital staff unaware of error reporting system	~a barrier is just the fact that they are fairly uncommon and therefore, since it's not a common thing, we don't do it every day. So people may become less aware and be more likely to gloss over.	ACS1		
Impact on Patient Care	Difficult to monitor patients referred from a distance			~Other instances would be the fact that many of our patients come from outside our local jurisdiction, and in terms of following up with patients, as a clear example, patients are referred to us from as far away as Thunder Bay. ~And it can be, we have certain regular protocols for monitoring the performance of endovascular stent grafts for aneurysm repair. And it can	BVS1 &BIR 1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				be exceedingly difficult to capture the patient and bring them back to Toronto, to re-image them, and reassess the device.	
Impact on patient are	Patient transfer to institution from external jurisdiction			~I think it's specific to our institution as a quaternary and tertiary centre, that these are not patients being treated within five kilometres, who live within five kilometres of the hospital. So, capturing the long term follow up, for these devices, and you know, relating to my interventional and surgery side, the surgery side, because we have regular clinics, is much better at following up the results of an intervention, than the interventional radiology side, where the proceduralist in interventional radiology may not necessarily have ownership of that patient and relies on the other clinicians who quote unquote 'own' the patient or are more responsible for them, to recognize problems.	BVS1 &BIR 1
Liability	Clinician follows regulator's standard for clinical procedure and patient selection			~ And, at a personal level, the only thing that protects me from a class action lawsuit if something is discovered ten years down the road, is the fact that I carried the procedure out and the patient selection within Health Canada guidelines.	BIR1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Liability	Risk of hospital's reputation	~Cause the letter probably didn't explain it well enough, you know, the corporate letter. And then, there were those patients who actually did have complications, right, which is normal in any kind of surgery. And they, of course, they questioned whether the complication was due to the device and, we had to reassure them, 'Absolutely not.' So, that was sort of, this global umbrella thing that affected all of us, even though there was no deliberate malfunction, it was a company that felt that their sterilization process, that something had gone wrong, and they couldn't, they weren't sure, so they had to send out a cover letter.	ASG1		
Liability	Risk of manufacturer's reputation	~Cause the letter probably didn't explain it well enough, you know, the corporate letter. And then, there were those patients who actually did have complications, right, which is normal in any kind of surgery. And they, of course, they questioned whether the complication was due to the device and, we had to reassure them, 'Absolutely not.' So, that was sort of, this global umbrella thing that affected all of us, even though there was no deliberate malfunction, it was a company that felt that their sterilization process, that something had gone wrong, and they couldn't, they weren't sure, so they had to	AGS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		send out a cover letter.			
Medical device procurement process	Risk of severed relationship between hospital and manufacturer if hospital discontinues use of product	~Now this company is a big company and has a major role in our operating room, for sourcing of many different implantable devices as well as sort of tools. So, if anyone was a little bit nervous, cause they're present all the time, so if that's pulled and it goes to another company, then that person might feel, you know, someone who's reporting it might feel responsible that they've sort of, lost business.	ARN2		
Performance of medical device	Device deployment is complex			~ Many of these devices are quite tricky to deploy and there are a series of steps that have to be followed.	BVS1
Performance of medical device	Experimental procedure performed on patient			~So this particular incidence, and this device, is a high profile, I'll use the term experimental program. And people are very interested for it to go well. So there may be some, we all had some sphincter tightening when we report incidence around this device and program.	BIR1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Performance of medical device	Increase in frequency of device malfunctions in newer medical devices			~it may be a problem that we are recognizing within our division or within our scope. There was one example of a particular kind of valve that was new on the market, and was very quickly adopted by many centre. But within our division, we noticed a particular complication was occurring more frequently in this valve than in other valve. And that was what was called a peri-valvular leak, where the blood leaks around the valve. And in fact, we were concerned within our division. We analyzed our data, within our division.	BCS1
Performance of medical device	Increase in reporting malfunctions among staff who are unfamiliar with device	~people who aren't familiar with the devices, or at least don't know the interest in the devices, there was concern, because there was these reporting malfunctions here and there and here and there.	AGS1		
Performance of medical device	Learning curve associated with use of new device	~usually when you make a transition from one product to another, there is always this transition curve where the surgeon somehow subjectively, feels that his complication rate has gone up, in terms of malfunctions, leaks, whatever	AGS1	~it's really just new devices that are associated with incidences, more so than old devices. Because new devices are in, you know, by their nature, not, have not been tested. We have limited use with them. And you know, the comfort level with new devices, with any type of devices, is really related to experience. So I don't think it really has to do with the type of devices. It has more to do with the experience with the	BCA1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				device.	
Performance of medical device	Long-term function and impact of device on patient is unknown	~Yeah. I mean, that's probably about the best I could do. I mean, you know, more commonly in orthopaedics, it would be premature failure of an otherwise well inserted device, for, you know, reasons that perhaps the implant has not been properly or not thoroughly vetted in terms of its long term impact and function. I'm talking specifically about newer implants that don't have a track record. And so they go in the way they're supposed to, but they fail much, much sooner than anyone would have anticipated.	AOS1		
Performance of medical device	Medical device features doesn't alert hospital staff of errors			~ By viewing the monitor, yeah; there's no alert in the infusion pumps.	BRN2

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Performance of medical device	Medical device may be faulty but improvement can be delayed over long period of time			~ Like, I don't hear that 'Okay, the stapler was misfired.' Occasionally, I'll get word back to say 'Yes, it was a faulty stapler.' But more often than not, I don't get the feedback about individual cases. But I do see that over time, they will come to me, you know, a year later, and say 'Okay, there used to be this thing wrong with it.' or 'This used to be a limitation and now we've done this to advance it.' So, it's more of a culture, I guess, of trying to perfect their instruments and a culture that we have built in just through the competition of, you know, all of these other companies that are making similar devices, that they want to do, they want to have the best device on the market, and they're trying to tweak it, and to work out some of these problems.	BGS1
Performance of medical device	Off-label use of medical device	~The important thing to prevent it in the future is usually problems occur with patient indication and technique. So, was it the right patient, in terms of the indication for the procedure? And if it wasn't, maybe that influenced the negative adverse event.	AOS1	~ And we may often be in a situation where we've employed a device in a circumstance where the device probably wouldn't have been, shouldn't have been expected to perform adequately for that application.	BIR1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Performance of medical device	Off-label use of medical device			~and suddenly, you've having to troubleshoot that situation. There are other instances where devices are manufactured and marketed for particular applications, but because of the nature of our practices as a quaternary care centre, we'll receive patients with very unusual and difficult, complex problems, where we're often put in situations where we're using a device for a clinical application in which it was never intended. ~because of the nature of our practices as a quaternary care centre, we'll receive patients with very unusual and difficult, complex problems, where we're often put in situations where we're using a device for a clinical application in which it was never intended.	BVS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Performance of medical device	Signals misinterpreted by hospital staff	~I actually had a patient with the same oxygen system, in the unit. And, with our old system, what happened was it had a loud, sort of, large noise when it was giving oxygen, because of the way the system was, and we have, what we call rain out. It's humidity in the larger bore tubing. And what happens is when fluid starts to get in there, it makes a 'pop, pop, pop, pop' noise. The new one, when it had the same problem, and it's just rain out; it's normal. It's like condensation inside the tube. When this happened, it was a much, I remembered it was a much lower pop, because I assumed the device is using less oxygen. So it was like a 'bloop, bloop'. And I heard it and it took me a while to sort of, to figure out what the noise was, because it was different and then I realized 'Oh, it's the regular system.' and I thought 'I'll have to deal with that.' And then suddenly, that noise stopped, the 'bloop, bloop' went, and my patient de-satted, just like the other patients had, quite suddenly. And what I recognized was the new system didn't have enough oxygen blowing through it to get through this little elbow of water sitting in the bottom of the tubing.	ARN1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Personal attitude of health care professional	Fear of risk of clinician's reputation, loss of credentials and-or privileges at hospital	~So that would be probably the biggest natural barrier. And then going on to that would be, (extension) to that would be potential credentialing issues, privileges at the hospital. So, you know, there would be a vested invest in the provider, to perhaps try and conceal it. So that would be a barrier. I'm not saying that that is commonly excised. But if you're trying to tick off a box that would be under the guise of 'barrier', that would be the obvious one	AOS1		
Personal attitude of health care professional	Fear of risk of nurse's reputation, loss of credentials and-or privileges at hospital	~There, just, you want to, well, I guess, you know if you screwed up, there's a certain professional thing, for a professional image. But I can't imagine that your choice of a device, if you've chosen one particular device that is prone to failure, that's going to make you look bad. But I think it's more if you've screwed it up somehow, you might want to not report it, because it's just an embarrassment to you, I suppose. But I think that would be lower down on the list.	ACS1		
Personal attitude of health care professional	Cases are resolved through trouble shooting so there is no need for reporting			~ knowledge of how to complain and time factors, like, not knowing how to make a complaints or lodge a complaint and you know, often what happens is you troubleshoot it enough that you kind of get through the case and then you can't be bothered, you know, you don't have time and you can't be	BGS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				bothered putting a complaint in. You know, you get busy and you move on to the next case.	
Personal attitude of health care professional	Error reporting is time-consuming	~And I think the other major issue is time that it takes to input such processes into the database.	AIR1		
Personal attitude of health care professional	Error reporting is time-consuming	~Quite often, that person doesn't want to document it because it requires time.	ARN1		
Personal attitude of health care professional	Error reporting is time-consuming	~I guess there's the inconvenience of having to report, to ask the questions. You may just want to, if something breaks or fails, then you may just go to get another one, rather than take the, you know, go to the next step to really investigate too carefully, I guess. Expediency is a barrier, just, you want to move on. You want to finish this care of this patient and get to the next case so time is a barrier. Knowing where to access things, again, if it's not a common occurrence, then you may not know where to go, what, ah, who to call	ACS1	~ knowledge of how to complain and time factors, like, not knowing how to make a complaints or lodge a complaint and you know, often what happens is you troubleshoot it enough that you kind of get through the case and then you can't be bothered, you know, you don't have time and you can't be bothered putting a complaint in. You know, you get busy and you move on to the next case.	BGS1
Personal attitude of health care professional	Error reporting procedure can be complicated			~I think that when you're talking about a device, I think a lot of it is the paperwork to file the incident is very easy but the paperwork to follow up a, you know, at the government level if	BOS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				there's an adverse event or whatever, I think can be quite complicated. And luckily, I don't have to do that.	
Personal attitude of health care professional	Fear of legal liability			~But so, I'm not sure so that it's a professional image. To some extent, it is a medical legal issue. If you, like, who, if a device has malfunctioned, was it because of how it was implanted or whether it was a fundamental problem with the device. So I think there is some fear of a medical legal problem, and who has ownership of that.	BCS1
Personal attitude of health care professional	Fear of punishment for error reporting	~there's always fear of retribution	ARN2		
Personal attitude of health care professional	Fear of punishment for error reporting among hospital staff	~So I do think there are some inherent barriers in reporting potential problems, which are cultural and people would look at it as a punitive, in a punitive manner. And I think it's actually getting worse that way, I'll be quite frank with you. Cause the hospital is asking, is trying to document everything. And then it becomes more of, it seems the push from above is that it's becoming more of a punitive kind of thing as opposed to an educational kind of thing. So, I'm not sure if we're going in the right direction or not.	AVS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Personal attitude of health care professional	Fear of risk of clinician's reputation, loss of credentials and-or privileges at hospital	~the biggest barrier would be, I mean, the biggest barrier overall, I think, in medical errors is people don't want to be known as someone who made a medical error.	ACA1	~I think if I had been using a device in an off label fashion, and had a malfunction or a patient incident, then if I ever had a similar problem present itself, I would have to think twice about the potential for appearing in front of my morbidity and mortality review, more than once, for the same problem.	BVS1
Personal attitude of health care professional	Fear of risk of clinician's reputation, loss of credentials and-or privileges at hospital	~The last thing I guess, there's a little bit of, whether it's cultural or more personal, I guess nobody likes to have complications in a procedure or device failures, which is kind of linked. So I think some people find it difficult to, I guess admit to complications.	AIR1	~There's definitely a professional culture around it	BRN2
Personal attitude of health care professional	Hospital staff doesn't perceive medical device-related incidents as an issue			~I don't see it a huge, like the whole issue of incidents, I don't think is a huge issue for me . I kind of see it as more a, you know, these instruments are trying to help us do operations safely and you know, yes, you have problems with them and yes, you kind of are getting used to them and getting to know how they're used and half the time, they're probably issues with me, not using it correctly or me putting too much in a stapler and then having it misfire, or something or expecting too much of the product.	BGS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Personal attitude of health care professional	Intimidated and/or fear of legal implications	~the obvious barrier in our (group 23:28) business would be medical legal, would be the fear of a medical legal incident. And so that would potentially cause a lack of disclosure, particularly if there's no obvious external or tangible evidence that there's been a device malfunction.	AOS1		
Personal attitude of health care professional	Intimidated and/or fear of legal implications	~And there's not a strong culture for this, although it's not supposed to be punitive, a lot of people feel that it. I mean, I suppose it's a little less so when it's a piece of equipment, but the reporting system itself is time, is labour intensive, as far as time goes. And a lot of people that aren't familiar with it, just like anything else, because they don't do it that often, find it very intimidating. And they think of the legal implications and whatnot. So the easiest default is just not to do anything.	ARN1		
Personal attitude of health care professional	RN is unaware of barriers to error reporting			~I don't think I have any barriers on reporting it. I don't know that we're always in agreement with the reports that we get back.	BRN1
Problem solving	Challenges with trouble-shooting a problem			~It's more of, possibly, you know, someone not understanding how to use the equipment or how to, if we have a problem some of the gas insufflation on a laparoscopic procedure, how to troubleshoot that.	BGS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Problem solving	Conflict in initial problem solving of error between hospital and manufacturer	~and ultimately that instrument, and this is where the conflicts sometimes occur, is who then, have the first right of inspecting that device and understanding its breakage. Most companies have a policy of inspecting their own broken devices. But many hospitals have their own policies as well of wanting to do this. And so, that's where sometimes, some of the friction occurs, is what is the sequence; what's the path of that broken product review, between the hospital and the company' So in this case, there was both. But there was some friction, because both parties wanted first access to the implant that broke. So there was no clinical thing.	AOS1		
Problem solving	Hospital staff and manufacturer representative were unable to resolve device problem			~I mean, on a couple of occasions, we've had two or three people who are well versed in the stapling, and they can't, you know, rectify the issue. And one time, the sales rep was even in the OR that day, and the sales rep was unable to rectify it.	BRN1
Professional culture	Lack of compliance in independent check of programming of equipment among RNs			~I'm not sure that there's total compliance with that.	BRN2
Professional culture	Staff not open to discuss each other's complications	~the culture is one that, I don't think we're open to looking at each other's complications as well as we should	AVS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Response from manufacturers	Manufacturer didn't find any problem with the device			~and we do get letters back when we send things out. And they said they had checked it through their quality control and they didn't find that there was anything wrong with it.	BRN1
Response from manufacturers	Delayed response from manufacturer to hospital			~So I think that does play a role in acceptance of a device malfunction or reporting of it. I think that's a problem. But I also think it's a problem in understanding how to have a report done and a result that's constructive. So I can send a concern off to the company, and I don't get, and I, as an individual, may get feedback in six months about a problem with the device, long past when I actually had the problem.	BCS1
Response from manufacturers	Hospital staff are frustrated with same response from manufacturer			~So, you know, it becomes a bit frustrating when we do everything the way we're taught, and then, we get the same response from the vendors all the time.	BRN1
Response from manufacturers	Hospital would like manufacturer to take more ownership of medical device-related incident			~ it would be nice to see that a vendor takes ownership, that, you know, rather than them always saying it's user error. You know, if they were able to say 'Well, gee, you know, we actually discovered there was an issues in the manufacturing.' or 'That day, it was a bad lot.' or something.	BRN1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Response from manufacturers	Limited information provided to hospital staff for industry protection	~There's no way to, I mean, the industry is going to protect industry	AGS1		
Response from manufacturers	Manufacturer distributor/ does not respond adequately to reported incidents	~None of the review letters ever stated that, even though I know that a product truly malfunctioned. What the letter say is, was an acknowledgement that they reviewed the lot number, the serial number. They reviewed their production processes for that lot number. And that issues, all issues have been reviewed and resolved. That was it. That was the extent of it, right? Or, there was no known production issues. So, that's useless to us, right? ~I have a long standing relationship with some of these companies, where I pick up the phone and say "Guys, I don't care what you're saying. There's something wrong with your instrument." Or that particular product. And, I mean, I'll give you an example, there was, for a while, a series of problems with a special stapling device for gastric bypass surgery. It happened out of the blue. Prior to that, there was no problem. After that, there seemed to be, there seemed to be, no I had no real data, okay, but there seemed to be, in my mind, something wrong. And so I spoke to the company. And the Canadian company is just a subsidiary of	AGS1	~ We fed that information back to the company. And I was a little bit disappointed with the company's response. They indicated to me, and I had to chase them for this information, that they had fed this to their central office and that we shouldn't worry because other, this was some unique circumstance, and that this was probably a problem with the patient, and not the device, because they hadn't heard of this at an inordinately high level. ~And I was a little bit disappointed with the company's response. They indicated to me, and I had to chase them for this information, that they had fed this to their central office and that we shouldn't worry because other, this was some unique circumstance, and that this was probably a problem with the patient, and not the device, because they hadn't heard of this at an inordinately high level.	BVS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		the big multinational in the States, right? So they decide whatever they decide, and the Canadian company just echoes whatever's decided, irrespective of whether they know there's an issue or not. Right? So, I had the conversation with the Canadian company on several occasions. And I kept bring it up and bringing it up. And I said "You know what? Guys, I love your product, but you're starting to piss me off. There's, you know, I've used this product long enough to know that something has changed. Either your production has changed; your chain of suppliers or your sourcing of materials has changed. Something has changed, because the tolerances of these instruments are not as good as they used to be, at least, not in my hands." So, I had, so I was saying 'Either I've changed or the instrument has.' But, you know? (laugh) So I was at an international meeting somewhere in the States and they went to the effort of hooking me up with their research and development engineers, two of them, to have a discussion on the issues. And they wanted to sit down and discuss what I thought was wrong with them, right, particularly along the tolerances and that. So basically, I gave them my opinion, and I said "Look, I think what's gone on here, cause I've heard rumours, and you			

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
		can correct me if I'm wrong, is that you've changed your supplier for steel. You've gone to China. The tolerances of their steel material that you use in your instrumentation are much worse than what you had before, which was American based. And now you've got products that have lousier tolerances. They may meet the minimum industry standard, but they're different than what you were producing before. Now you can correct me if I'm wrong here." Nobody said anything. 'Well, we'll look into it. We'll look into it.' Sure enough, six month later, that's exactly what had happened			
Response from manufacturers	Manufacturer sends standard letter to hospital			~I would say the letters that they send me are pretty much a form letter. You know, they'll add in the surgeon's name or the date or the, you know, the specific stapler or the re-load, but you know, essentially, the content of the letter is pretty similar with each event.	BRN1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Response from manufacturers	Manufacturer can provide immediate feedback to hospital about problem with device			~maybe more of that feedback on individual incidents, might be good. Like, getting that kind of immediate feedback, if I have a problem with a hydro-jet and it's not working, rather than just open up a new hydro-jet, you know, having an understanding whether that hydro-jet was actually faulty or not. ~I think more immediate feedback maybe about particular incidences, and it's more education for me, because there's probably a lot of the times, and maybe the majority of times, where it's a lack of knowledge that I have, about using it, rather than the product necessarily being faulty.	BGS1
Response from manufacturers	Manufacturer didn't find any problem with the device			~And then, we get a report back from the vendor, indicating that they have done due diligence in looking at the product and of course, they never find anything wrong with it. They don't come out and say that it's user error, but you know, they insinuate that they've looked and couldn't find anything wrong with it.	BRN1

APPENDIX 9: INTERVIEW RESULTS-INTERVENTIONS OR STRATEGIES TO IMPROVE THE RECOGNITION, REPORTING AND RESOLUTION OF MEDICAL DEVICE-RELATED INCIDENTS

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Education and training	Adequate training on medical device should be provided as patient care responsibilities are shifted from one health care profession to another			~Dialysis nurses are given, I think it's like a six week training program on how to run these machines, when the responsibility for running the machines transitioned to the bedside nurse, we were given eight hours. So there's a definite education component to that. The same thing is happening with ECLS, the extra corporeal life support machines. For year, it was perfusionists who were at the bedside and ran the machines. Perfusionists do an eighteen month course to do that. And again, we were given an eight hour training session and the perfusionists leave now. And so, I think errors are happening because we're getting short tracked on training with some of these devices. I: Okay. Okay. So more training and perhaps continuous training on these types of devices, you feel would help to reduce the risk of human errors when using these specific medical devices? P: Absolutely. And again, these are responsibilities that are being	BRN2

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				transitioned from different healthcare professionals in, onto the bedside nurse.	
Education and training	Clinician is unaware of hospital initiatives to improve recognition, reporting and resolution of incidents			~I: Okay. And in terms of new initiatives to improve reporting or recognition and resolution, are you aware of any? Or? P: I'm not, no.	BRN2

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Education and training	Ensure hospital staff receives adequate training on device	~You know, quality assurance is pretty critical now, for most hospitals. The results of conventionally done procedures and their outcomes are a much bigger part of what gets reported. Technical problems with devices and all that kind of stuff is more of, you know, an internal, technical, glitch type issue that's usually operator dependent and can kind of get sorted out. But, that kind of review has to be formalized and forced a little bit more. But you know, technology advances are pretty substantial. And some surgery is actually getting easier than it is harder, because of the advances in some devices. So, it just needs the right amount of training in them, for the most part.	AOS1	~I think more immediate feedback maybe about particular incidences, and it's more education for me, because there's probably a lot of the times, and maybe the majority of times, where it's a lack of knowledge that I have, about using it, rather than the product necessarily being faulty.	BGS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Education and training	Have adequate training for staff on use of new device	~Or more commonly, was the learning curve just too steep and was the training not adequate enough, to avoid the problem? And most companies are quite good about training courses. And some of them make the training courses mandatory before you use new devices. But it's, you know, it's still somewhat flexible. I mean, surgeons are on their own accord, so to speak or left to their own, to achieve a comfort level with an implement, whether it's an old one or particularly a new one that they're going to try. And so they've gotta be, they have to adopt a certain comfort measure on their own, before trying it. Now, is that standard and uniform? No, people are different. And so, you may have people who are a little more cavalier and others who are extremely cautious. And so, I'm sure there's a bell curve as to where those individuals fall. But, mitigating the problems are usually, mostly have to do with training and technique of the surgeon.	AOS1		
Education and training	Hospital staff is unaware of initiatives to recognition, reporting and recognition of device-related incidents	~No (new initiatives on recognition, reporting, and resolution)	ARN2	~But I'm not sure of the protocol or I'm not sure of any initiatives that, where they're specifically looking at these issues, no.	BGS1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Education and training	Hospital staff is unaware of hospital initiative to improve the recognition, reporting and resolution of device-related incidents			~So, are you aware, (name) of any initiatives that are underway at (hospital name) to improve the recognition, reporting and resolution of device related incidents? P: I don't think there is.	BRN1
Education and training	Increase awareness (of reporting) among health professionals	~I think that's the biggest thing is just having, just people making sure that they're aware that we should be reporting these issues. I think that's the most important thing, education. I think for the, like, I said, I think for the most part, it's something that we, we actually talk about a lot. But there could be gaps, especially in, not necessarily physicians, but other allied health professionals like nursing or physiotherapy or the other, respiratory therapy, something like that. There may be, for, I mean, education's good for all of us.	ACA1		
Education and training	Increase awareness on recognition, reporting and resolution of medical device-related incidents among health professionals			~we need to educate all clinicians and so that's everybody. It's nursing, allied health, physicians. So everybody should be aware it can happen, everyone should, and there has to be…	BCS1
Education and training	Provide continuous education to hospital staff on how to operate a medical device			~Well, I think the human errors in reprogramming the infusion pumps, I don't know, continuous education; reminding people they have to be very careful when they do this.	BRN2

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Education and training	Training on how and what to report error	~and how do we go about reporting the incidents. ~I think it's important too, in terms of how major or minor the incidents are. Obviously, anything that's major and provides a major morbidity should be reported.	AIR1		
Education and training	Training to increase awareness of reporting system to hospital staff	~I think education is important to, for, you know, that the reporting system's in place and to let us know what's available ~, I think the availability of the systems, and education about the systems. So if there was something in place already, it would be certainly nice to have somebody let us know about it	AIR1		
Education and training	Update hospital staff with in-services on safety tools and on medical device features	~We actually do in-services, weekly in-services as well, just to update people on all of the, sort of some of the tools that we use and anything that's knew or maybe alert someone to, you know, 'If it doesn't turn on, maybe this is what, you know, the tourniquet has a safety feature so that you can't accidentally turn it off during the surgery.' So definitely teaching.	ARN2	~ I don't think the manufacturer for the infusion pumps, but we've had the manufacturer come in for other items and give in-services on other items. I've never had the infusion pump manufacturer come in, no.	BRN2

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Organizational culture	Expansion of processes from one clinical specialty to another specialty			~So, what I'm really fascinated about at my institution, is that those processes that are employed on the surgical side are now being adopted on the interventional radiology side, at our hospital. These include regular morbidity and mortality rounds, and both the results of the morbidity and mortality rounds are reported to a hospital quality of care committee, from both departments.	BVS1 &BIR 1
Organizational culture	Increase collaboration across institutions to track performance of medical devices			~I'm fascinated by the fact that the hospitals will get together in an organized fashion for purchasing, this centre called Plexus which is supposed to realize certain cost savings to institutions. If they need ten devices amongst six hospitals, you know, they'll approach the manufacturer as a group, to purchase and get a discount. But, there's no ah, where money is concerned, that's, they're willing to collaborate. Where tracking the results of these devices and application of these procedures, there's, these types of registries can cost a hundred thousand dollars a year to participate in. So, those savings, in my mind, would be well suited towards establishing registries that are at arms length from the manufacturer.	BVS1 &BIR 1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Professional culture	Lack of compliance in independent check of programming of equipment among RNs			~I'm not sure that there's total compliance with that.	BRN2
Professional culture	More empowerment for RNs	~I try to encourage my colleagues to take full responsibility for everything that happens to their patient. Which I don't think is taught, culturally, to nurses today. I mean, it certainly wasn't taught to me when I was growing up, you know, or when I was first being educating. You're taught to a certain extent, to be an observer and then to perhaps state what you observe and then let others decide what should transpire, as opposed to directing what should transpire. Do you know what I mean? So there's a huge barrier there, to me, that the nurses should be empowered to take responsibility for what's going on.	ARN1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Professional culture	RNs to play more active role in refusing to use defective equipment	~I say "No, I don't use that piece of equipment anymore, because I don't trust it." And people say "Well, that's what was ordered." And I say, well, I go to the physician and I say "Look, I don't use that piece of equipment and here's why. And I've identified that problem and it needs to be changed." And a lot of people say "Well, you've been here forever so that's why you can do those kind of things." But I say "No, I've been doing that since forever.	ARN1		
Professional culture	Hospital staff not open to discuss each other's complications	~the culture is one that, I don't think we're open to looking at each other's complications as well as we should	AVS1		
Professional culture	Transition among RNs from observer to more active role required	~I try to encourage my colleagues to take full responsibility for everything that happens to their patient. Which I don't think is taught, culturally, to nurses today. I mean, it certainly wasn't taught to me when I was growing up, you know, or when I was first being educating. You're taught to a certain extent, to be an observer and then to perhaps state what you observe and then let others decide what should transpire, as opposed to directing what should transpire. Do you know what I mean? So there's a huge barrier there, to me, that the nurses should be empowered to take responsibility for what's going on.	ARN1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Reporting system and process	Adoption of registries on performance of medical devices			~I think the adoption of widespread benchmarking, risk adjusted registries are extremely important. Many places, if you just bring in a device, a new device to try for a particular procedure, you may like it; you may not. It may perform and meet expectations; it may not. There may be a complication or there may not. Until we, but your actual denominator in number of procedures is going to be relatively small. So unless different hospitals are all collaborating and following up on their experiences with these devices, and reporting them to a central registry that the manufacturers don't have control over, we may not be able to recognize this. ~I'm fascinated by the fact that the hospitals will get together in an organized fashion for purchasing, this centre called Plexus which is supposed to realize certain cost savings to institutions. If they need ten devices amongst six hospitals, you know, they'll approach the manufacturer as a group, to purchase and get a discount. But, there's no ah, where money is concerned, that's, they're willing to collaborate. Where tracking the results of these devices and application of these procedures, there's, these types of registries can cost a hundred thousand	BVS1 &BIR 1

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
				dollars a year to participate in. So, those savings, in my mind, would be well suited towards establishing registries that are at arms length from the manufacturer.	
Reporting system and process	Automation of reporting incidents and/or malfunctions	~certain big university hospitals, they all have processes in place, is to create an infrastructure or a process that automatically kicks in, regardless of what the surgeon says, regardless of what the nurse says. There's an automatic – it can't be swept under the rug	AGS1		
Reporting system and process	Automation of review of causes and resolution	~but there has to be systems in place that ensure that there's an automatic review and that there's an automatic tracing of that device to the production, to the actual model and to the company that can report on it.	AGS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Reporting system and process	Future implementation of provincial vascular surgery database	~But we don't have a database where we track device related specific problems that could be perhaps educational and learn from it. We don't have that database yet. I: Okay. Thank you. And you did mention earlier about a database that'll be available in a few months time. So is this an initiative that'll be coming soon at your hospital, to improve the recognition, reporting and resolution of device related incidents or it's not specific to just - P: No. Right. So it's not specific to device related problems. But it's a prospective database that is going to be done for all vascular procedures. And it's provincial based. So every vascular institution in the province will have to belong to this database. And in the database, as well as patient demographics, and the procedure will be follow up and complications. So, indeed, that will be captured there. But it will not be a specific device database.	AVS1		
Reporting system and process	Have a Canada-wide database to raise awareness nationwide	~So it would be nice to have kind of a more, maybe Canada based database, or Canada wide database so we can extract information and kind of see what devices work; which ones have more complications and so on.	AIR1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Reporting system and process	Implement a database for device-related problems	~is to have some kind of database for device related problems. And to be quite frank, I don't think it happens that often. And I think the times that it does happen, it's often operator error. I think rarely is it an engineering problems of the device itself. So I do often think it's a education of the operator problem.	AVS1		
Reporting system and process	Mandate a review or debrief of operative cases performed among hospital staff	~it's just having a corporate structure that mandates that there is a review. And part of it, with every operative case, there's the mandatory brief. And so there, right from the get go, there's a mandatory review of the case. And if there was an adverse event with the device, it could be recorded then, and flagged. And then those could be reviewed on a monthly basis, depending on their severity and what there is to learn or their recurrence. And so, that's not a big stretch. That's not too hard to do, from what we currently do. It's still somewhat, that second piece is somewhat voluntary in terms of which cases ultimately do get reviewed, and it's at the discretion of the division, but other than death, there's a lot of discretion as to what would get review from a medical device problem.	AOS1		

		Hospital A		Hospital B	
Theme	**Code**	**Text**	**ID**	**Text**	**ID**
Reporting system and process	Report device malfunction/incident to regulator to raise awareness nationwide	~I do think there should be some format where we feel comfortable talking to Health Canada, if we believe that it is an engineering problem with the device, that we can have someone to go up the food chain and say 'This needs to be documented for the rest of the country to know that these problems do exist.' So I think that conduit would be relatively important.	AVS1		
Reporting system and process	Set up a global system where error can be reported easily	~I think there should be some kind of a, probably more global rather than just institutional set up where we can actually log the information in a fairly simple manner, where, you know, it wouldn't take any more than five minutes to input information. And because the reality is, I think the incidents of medical related devices, at least that we use, is pretty low, for the most part.	AIR1		

I=Interviewee; P=Participant

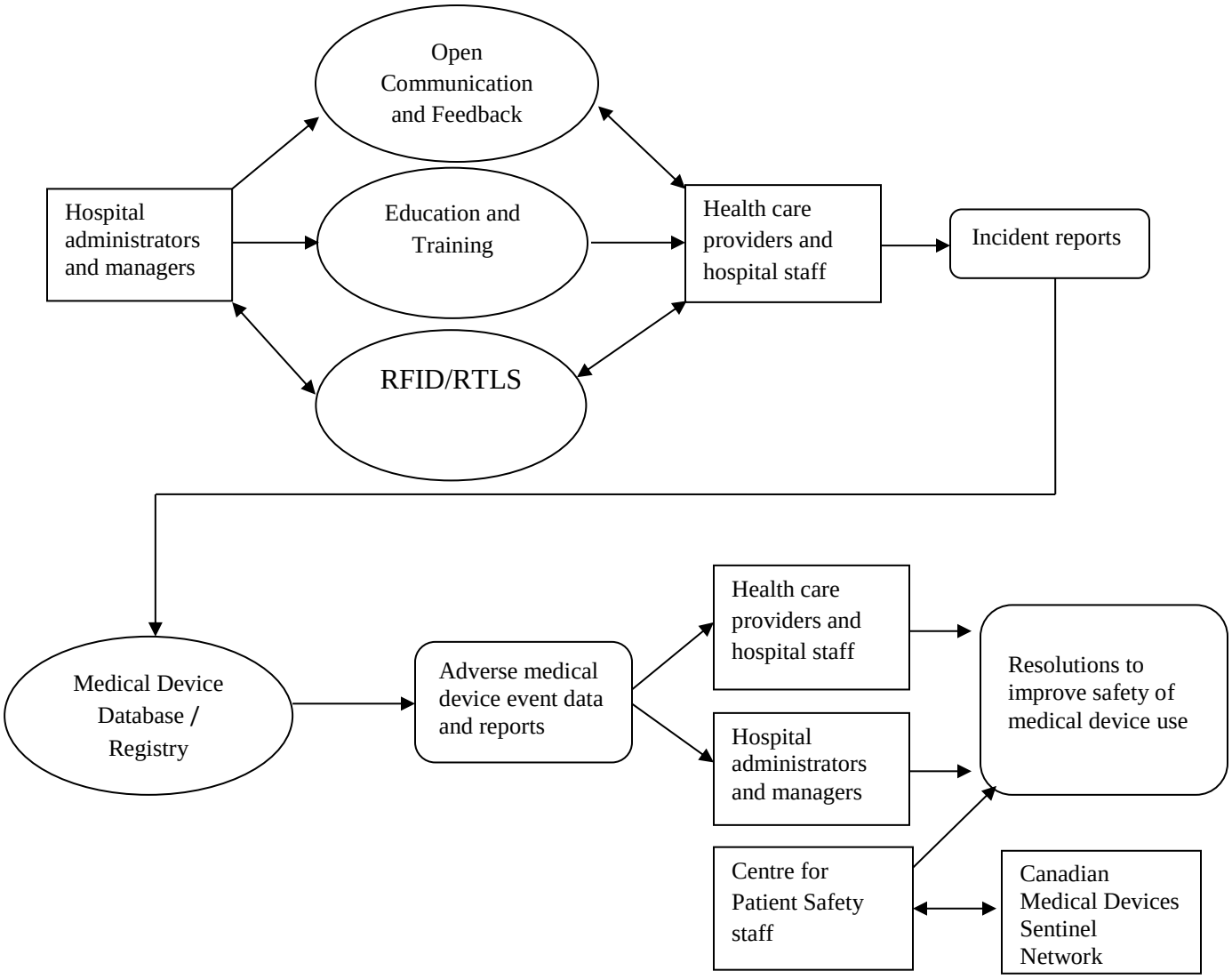
APPENDIX 10: THEMATIC SUMMARY OF INTERVIEW RESPONSES

Medical Device Surveillance Element	Theme
Factors that Influence the Recognition of Medical Device-Related Incidents	• Education and training • Hospital staff knowledge and experience • Performance of medical device • Warnings or advisories
Factors that Influence the Reporting of Medical Device-Related Incidents	• Clinician communication with patient • Feedback on how reported information is used • Incentives for error reporting • Information sharing • Organizational culture • Reporting system and process
Factors that Influence the Resolution of Medical Device-Related Incidents	• Education and training • Future use of medical device • Information sharing • Medical device procurement process • Organizational culture

Medical Device Surveillance Element	Theme
	• Preventive actions
Barriers to the Recognition, Reporting and Resolution of Medical Device-Related Incidents	• Conflicts of interest • Education and training • Error reporting compliance • Feedback on how reported information is used • Hospital staff knowledge and experience • Impact on patient care • Liability • Medical device procurement process • Performance of medical device • Personal attitude of health care professional • Problem solving • Professional culture • Response from manufacturers
Interventions or Strategies to Improve the Recognition, Reporting and Resolution of Medical Device-Related Incidents	• Education and training • Organizational culture

Medical Device Surveillance Element	Theme
	• Professional culture • Reporting system and process

APPENDIX 11: CONCEPTUAL FRAMEWORK FOR MEDICAL DEVICE SURVEILLANCE IN A CANADIAN HOSPITAL CONTEXT



Appendix 12 Cost Items of Proposed Medical Device Surveillance System Framework

Phase	Cost Categories	Individual Cost Items
Developmental	Equipment Human Resources Education and training Overhead	• Equipment purchases (e.g., servers, computer software, and licenses) • Miscellaneous computer equipment (e.g., computers, laptops, personal computer wireless cards) • Hourly costs of hospital staff members involved, including staff in Center for Patient Safety, biomedical engineers, and information technology staff to set up surveillance system • Preparation of user and training manuals and presentations for hospital staff members • Training of two or three reporters among hospital staff to represent hospital at CMDSNet • Public utilities (e.g., telephone service and Internet connectivity)
Operating and maintenance	Equipment Human resources Education and training Overhead	• Maintenance of surveillance system • Depreciation of equipment and eventual replacement costs • Personnel costs related to performance of quality control and data review and receiving feedback from intended users • Data report production • Continued education and training of new and current staff members • Public utilities (e.g., telephone service and Internet connectivity)
Upgrades and enhancements	Equipment Human resources Education and training Overhead	• System upgrades and enhancements based on feedback from intended users (e.g., increase flexibility in data entry, and render user interface more intuitive) • Provide education and training of system upgrades and enhancements to intended users • Public utilities (e.g., telephone service as Internet connectivity)

CMDSNet = Canadian Medical Devices Sentinel Network

Appendix 13 Potential Benefits of Proposed Medical Device Surveillance System

Perspective	Individual potential benefits
Patient	• Reduced risk of adverse event, incident, or malfunction and failure associated with the use of medical devices • Fewer patient complications and decreased length of hospital stay as a result of AMDEs or device malfunctions and failures • Reduced patient morbidity and mortality • Surveillance data will be instrumental in the identification of patterns associated AMDEs or medical devices prone to malfunctions or incidents
Health care professional	• Increased awareness of error reporting system and transparency among hospital staff members • Decreased risk of health professional liability • Surveillance data would be used to identify and define training needs among hospital staff members
Institutional	• Decreased risk of institutional liability • Early signal detection of the AMDEs or device malfunctions would lead to a quicker response by the health care provider and hospital • Participation in and information sharing with members of CMDSNet • Regular communication with Health Canada to improve product labeling, user manual, and product by manufacturers • Reports produced from surveillance data will be disseminated to hospital administrators and managers, as well as health care professionals • Increased transparency among patients, health care professionals, and hospital decision-makers • More accurate forecasting of expenditures and minimized ad hoc expenditures • Cost savings related to standardization, lower maintenance cost, reduced search time for equipment, less delay in patient treatment and equipment downtime, improved patient care and shorter hospital stay
Industry	• Inform future device iterations • Understand market potential of a new device

AMDE = adverse medical device event; CMDSNet = Canadian Medical Devices Sentinel Network

Chapter 4

Continuous Quality Improvement Data Reported by Wireless, Smart Infusion Pumps: A Case Study

4.0 ABSTRACT

Background

In their Quality Improvement Plan, the Ottawa Hospital (TOH) states that it aims to be in the top 10 percent of North American hospitals in quality care delivery and patient safety. Medication errors associated with the use of infusion pumps in hospital patients can cause serious harm or death in patients and increased costs to the health care system. Our study reviewed the continuous quality improvement (CQI) data collected from the newly procured wireless smart infusion pump system implemented at TOH in February 2014.

Methods

Data were downloaded from 1,600 pumps at TOH. We reviewed and evaluated the CQI data collected from the pumps usage between April 27, 2014 and April 25, 2015 to assess Dose Error Reduction Software (DERS) compliance with the master drug library (MDL) and the frequency of soft limit events and drug hard limits attempted.

Results

Although the number of monthly infusion starts is lower in some clinical care areas compared with others, the CQI data indicates that DERS compliance with the new pump system ranged from 72.14% to 100%. We did not identify patterns on the occurrence of soft and hard limit

events during the study period but found the birthing unit and oncology had the largest proportion of soft limit overrides compared with the remaining CCAs. We also designed a CQI data analysis process to audit the performance of the infusion pumps.

Conclusions

The study findings provided some information on patterns of use to inform TOH's goal to enhance the delivery of quality care and patient safety. We presented a CQI data analysis process to monitor the performance of the wireless infusion pump system. The proposed process can help the hospital staff to closely monitor to monitor which drugs are more prone to hard limits attempted and CCAs with DERS compliance below TOH standards.

4.1 BACKGROUND

The US Food and Drug Administration (FDA) defines an external infusion pump as a medical device used to deliver fluids into a patient's body in a controlled manner.[1] Infusion pumps are used for different purposes and are available in a variety of types and models. These devices are used worldwide in healthcare facilities, as well as in the home. The infusion pumps being discussed in this paper are large volumetric pumps used for infusing medications, blood and IV fluids.

Medication errors associated with the use of infusion pumps is a common problem, potentially causing serious harm or death in hospitalized patients, and increased costs to the health care system.[2] According to data collected from 850 US hospitals in 2008, 58% of parenteral medication errors occur during their administration, and 79% of harmful errors happen when medication was administered intravenously.[3] Health Canada received reports on 425 incidents that involved infusion pumps between 1987 and March 2003 that resulted in 20 fatal incidents and 135 injuries. Types of errors reported include flow or dosage problems (n=182), false or no alarm (n=60), and leaks (n=30).[4] Between 2005 and 2008, the FDA received 56,000 reports of adverse events associated with the use of infusion pumps across several brands and models, including 500 deaths.[5] The discrepancy in the volume of incidents reports between Canada and the US may be due in part to the number of infusion pumps in use in each jurisdiction and the awareness of existing incident reporting systems among health care providers.

In 2004, Baker et al. measured the incidence of adverse events in patients in four Canadian acute care hospitals. The estimated incident rate of adverse events along hospital admissions was approximately 7.5% (185,000/2,500,000), and 2.8% (n=70,000) of these may be preventable. The authors found that drug- or fluid-related events were deemed to be responsible for 23.0% of adverse events (85/360) according to the 1,512 patient charts reviewed by physicians.[6] Eleven years after the seminal study, the authors reported limited progress in patient safety improvement in hospitals.[7] Patients, who receive drugs intravenously, likely will experience more severe adverse events as the intravenous drugs are delivered to the body more rapidly than oral medications.[8]

A whitepaper on infusion pumps published in April 2010 by the FDA indicated that infusion pumps have contributed to improvements in patient care, allowing for a greater level of control, accuracy, and precision in drug delivery, and thereby reducing medication errors when compared with earlier manual methods of titrating IV infusions. At the same time, the FDA suggested that like other medical devices, infusion pumps are not without risks.[9] From 2005 through 2009, 87 infusion pump recalls were conducted by firms to address identified risks. Appendix 1 lists the recalls issued from the FDA and the associated rationale. The recalls were classified as Class 1 or 2, which represent the more severe type of recall as use of the product can cause serious injury or death.[10]

In February 2014, the Institute for Safe Medication Practices (ISMP) Canada published a call to action for hospitals to improve the optimal use of smart pumps. ISMP Canada recommended a commitment from hospitals to purchase and use smart infusion pumps with Dose Error Reduction Software (DERS) features, to ensure the consistency and regular updates and audits of

drug administration, to provide resources and training to staff, to solicit feedback from users, and report errors internally and to patient safety organizations.[11] DERS is configurable and allows an organization to build a drug library with appropriate safety limits for each drug.

Drug library parameters are typically developed by a multidisciplinary team that reviews drug data and clinical practice to determine the acceptable dosing limits in each clinical care area (CCA).[12] Prior to implementation, drug concentrations and dosing limits are standardized. Once implemented, drug libraries must be maintained and updated on a regular basis.[8] The recent addition of wireless capability by manufacturers to yield a "smart wireless" infusion pump is intended to address some of the obstacles of keeping drug libraries on infusion pumps updated.

The Canadian Patient Safety Institute published a literature review in 2014 on the economics of patient safety in acute care. Based on eight studies on the economic burden on adverse events and adverse drug events, costs per medication error ranged from CAD$403 to CAD$632.[13] Hertzel and Sousa published a systematic review in 2009 that evaluated the use of smart pumps for the prevention of medical errors.[14] The authors concluded that there was a lack of well-designed studies to draw firm conclusions about the impact of smart pumps on medication errors.

The Ottawa Hospital

The Ottawa Hospital (TOH) is a tertiary care facility located in Ottawa, Canada with approximately 1,149 beds and an average length of stay of 8.5 days. The hospital team consists of 11,813 staff and 1,300 physicians. TOH has three campuses (i.e., the General, Civic and Riverside), each with dedicated clinical areas. High-risk obstetrics and prenatal and mental

health services, minimally invasive surgery and the Prevent Alcohol and Risk-Related Trauma in Youth program are provided across all campuses.[15]

TOH aims to be among the top 10 percent of hospitals in North America in delivering safe, high-quality care, and the Quality Improvement Plan outlines strategies intended to achieve this goal. One of its objectives is to increase the proportion of patients receiving medication reconciliation upon admission. To reduce the risk of medication errors, medication reconciliation incorporates a comprehensive and systematic review of a patient's prescriptions and will inform the physician of the individual's medical history.[16]

In February 2014, the hospital replaced its pump technology, Colleague CXE volumetric infusion pumps (Baxter), with the Spectrum Generation 2 Infusion System (Baxter) across six CCAs throughout the hospital as the current technology was approaching the obsolete phase. The patient safety features of the Spectrum infusion pumps are outlined in Appendix 2. Prior to the go-live date of the new pump system, the nurse educators were responsible to ensure that all nurses were trained, and they became the point of contact following the training sessions. Also, the Biomedical Engineering Department received service training from the manufacturer.

The Spectrum infusion pumps offer the ability to update drug libraries and associated limits wirelessly and provide continuous quality improvement (CQI) data that can be uploaded to a data server wirelessly.[17] The Pharmacy Department at TOH maintains the master drug library (MDL). The MDL is a software tool where the hospital pharmacy stores information on all IV and epidural drugs, as well as associated CCAs and infusion parameters for each drug entry.[18]

Periodically, the Pharmacy Department receives a request from a user to add a drug to the MDL. After reviewing the request and consulting with a content expert for advice, the Pharmacy Department will decide whether to accept the request. The department will send the revised MDL to the Biomedical Engineering Department. The MDL then is uploaded wirelessly to all the infusion pumps across the hospital. The Biomedical Engineering Department then will confirm if they were transmitted to all pumps using the pump software, SIGMA Gateway, and user interface. Since February 2014, the Pharmacy Department issued 14 revisions to the MDL adding new drugs and adjusting the infusion parameters. With the previous Colleague pumps MDL updates were completed manually by a biomedical technician.

Continuous Quality Improvement Data

In practice, the user programs a pump by selecting the CCA, followed by the drug, concentration and dosage parameters. If the dosage parameters are outside the dosage limits as indicated in the MDL, a limit alert will display on the screen of the pump.[19] Smart pumps provide soft and hard limits. Soft limits prompt users to reconsider a predetermined drug dosage but permits them to select the dosage, whereas hard limits prevent users from proceeding with a dosage outside of the hard limits.[8]

The smart pump technology automatically captures data on alerts, the medication administered, the initial dose programmed, the user actions, the CCA, physical location of the pump, and the date and time. These data can then be sent through the wireless connectivity to the Sigma Gateway Server that resides on the hospital's information system.[20] The information in the system reports can help to identify high risk practices, compliance with the drug library limits,

medications with the highest occurrences of errors, the number of averted errors by identifying nears misses, and dosing limits that are not aligned with clinical practice.[20] The identification of incorrect safety limits can help to inform the drug library updates,[21] and can help to assess their utilization and usefulness in averting errors.

Objectives

Not all hospitals have a defined process in place to download and analyze the CQI data as part of their routine.[22] Also, there is insufficient published literature that investigates the types of data to help inform a formal CQI data analysis process following the introduction of a new wireless, smart pump system in a hospital facility. Routine monitoring of CQI data can help to understand the patterns of use in clinical practice. More specifically, analyses of DERS compliance and proportions of overrides of soft limit events and hard limits attempted can help to ensure the effective use of the new system technology and patient care enhancement. This information can inform the Pharmacy and Biomedical Engineering Departments on revisions required to the MDL and nurse education managers on training opportunities to ensure safer devices with enhanced programmes and user interfaces, and the CCAs to optimize the full benefits of smart wireless pumps.[22]

The study objectives were to:

1. Estimate DERS compliance with the implementation of wireless, smart infusion pumps at TOH;
2. Investigate the patterns of use of infusion pumps by measuring the frequency of monthly soft limits exceeded and pullbacks and hard limits attempted by CCA over a one year period; and

3. Design a CQI data analysis process to monitor DERS compliance and identify drugs with a high frequency of hard limits attempted.

4.2 METHODS

Study Design

Our study was descriptive in design, and the CQI data associated with DERS compliance and soft limit and hard limit events were reviewed and analyzed. Because we did not analyze patient level data, we did not require approval from the hospital's ethics board. Instead, we submitted a data request for the TOH to disclose the CQI data and received permission to access the data necessary to conduct our study.

Data Collection

Data were downloaded from 1,600 Spectrum pumps across TOH. We reviewed and evaluated the outcomes in the CQI summary reports using data collected from the pumps between April 27, 2014 and April 25, 2015 to assess DERs compliance and the occurrence of soft limits and hard drug limits events (Appendix 3). Although training was completed prior to the rollout of the new pump system, it is possible that additional training may have occurred post-deployment. On April 24, 2014, a training care area was introduced to segregate training events to ensure the data were not confounded with other events.

Data Analysis

1. Estimate DERS Compliance with the New Wireless, Smart Infusion Pumps

DERS compliance for the MDL was measured by the percentage of infusions in DERS mode on a monthly basis by CCA (Appendix 3). In contrast, infusion starts in BASIC mode bypass the limits programmed in the MDL.

2. **Measure the Frequency of Soft Limits Exceeded and Pull Backs and Hard Limits Attempted**

The frequency of soft limit and hard limit events that occurred per month between April 27, 2014 and April 25, 2015 by CCA was measured. Soft limit events are reported as double confirmation or pullbacks (Appendix 3). Double confirmation is the number of times the user overrides the limits in the MDL, and pullbacks are the number of times the user declines to overrides the drug limits. Hard limit alerts cannot be overridden.

3. **Design a CQI Data Analysis Process to Monitor the Performance of the Wireless, Smart Infusion Pumps**

According to the Accreditation Canada Handbook, the evaluation of the infusion pumps consists of an investigation of incidents associated to the pump use, review of the CQI data, monitoring evaluations of competence, and solicitation of feedback from pumps users and families.[23]

Our design of the CQI data analysis process was based on the Define, Measure, Analyze, Improve, Control (DMAIC) Principles. The DMAIC principles is a Six Sigma continuous improvement methodology designed to define objectives, gather data, conduct the appropriate analysis and investigation, identify corrective or improvement actions, implement improvements

and continue to monitor the process.[24] This process can be adapted to assess DERS compliance and MDL effectiveness with the objective of improving clinical practice and MDL content.

The Director of the Pharmacy Department and Manager of Biomedical Engineering Department were consulted on the earlier versions of the proposed process. On September 15, 2015, the CQI data analysis process was presented to the Safe Medication Practice Committee (SMPC) at TOH for their feedback. The committee members include pharmacists, risk and quality assurance managers, physicians, and nurse educators. In the initial phase, the SMPC members agreed to review the DERS compliance and the frequency of the hard limits attempted on a quarterly basis. A DERS compliance of less than 95% would trigger an investigation to determine the cause and identify and implement corrective actions to increase the compliance for the next cycle. Also, the committee was interested in the top five drugs with highest number of hard limits attempted compared with the total number of hard limits attempted across the hospital over a quarterly basis. They also felt that it was important to review the top five drugs with the highest number of hard limits attempted for each CCA.

4.3 RESULTS

1. DERS Compliance

During the study period, the total number of infusion starts in DERS mode was 572,543, and the total number of infusion starts in the same period was 588,402. The most frequent infusion starts occurred in medicine/surgery, critical care and oncology. Appendix 4 shows that the compliance with the new pump system ranged from 72.14% in anesthesiology (OR) to 100% in the birthing

unit and neonatal care areas. The greatest variation across 12 months was observed in anesthesia (OR) and neonatal care areas. For instance, the proportion of infusion starts ranged from 72.14% to 84.35% in anesthesia (OR) and 76.34% to 100% in the neonatal care area.

2. **Frequency of Soft Limits Exceeded and Pull Backs and Hard Limits Attempted**

Soft Limits (Double Confirmation)

Between April 27th, 2014 and April 25th, 2015, the number of events where the user exceeded the MDL soft limit alerts was 48,573 (87.25%) across all CCAs. We did not identify any trends as the number of monthly double confirmations varied per CCA (Appendix 5).

Soft Limits (Pullbacks)

The number of events where the user pulled back from overriding the MDL soft limits was 7,101 (12.75%) across all CCAs (Appendix 6). Similar to the frequency of double confirmations, we were unable to identify any patterns during the study period associated with the frequency of pullbacks.

The largest proportion of soft limit double confirmations versus pullbacks was reported in the birthing unit (96.34%), and oncology (95.41%) care areas, and the lowest proportion was found in the neonatal care area (42.62%). In medicine/surgery, anesthesia (OR) and critical care, the proportions of overrides were 74.64%, 79.36% and 81.92%.

Hard Limits Attempted

The frequency of hard limits attempted was 14,931 over a one year timeframe. In anesthesia (OR), birthing unit and critical care, the highest number of hard limits attempted was reported in May 2014 compared with the other months (Appendix 7). For the other CCAs, the frequency of events observed was consistent across the study period.

3. CQI Data Analysis Process to Monitor Performance of the Wireless, Smart Infusion Pumps

Table 1 outlines the CQI data analysis process framework adapted from the DMAIC principles[24] to help inform the performance assessment of the new wireless, smart infusion pump system. The elements of the framework consist of defining TOH standards for DERS compliance across all CCAs (i.e., 95% or greater) and identifying the top five drugs with the highest frequency of hard limits attempted, a review and analysis of the CQI data reports, investigating and developing corrective action plans, follow-up with the CCA(s) to ensure the implementation of the action, and regular monitoring of the data.

Table 1: CQI Data Analysis Process Framework Based on Define, Measure, Analyze, Improve, Control Principles[24]

Principles	Description	CQI Data Analysis Process Framework at TOH
Define	Define the problem, improvement activity, opportunity for improvement, the project goals, and customer (internal and external) requirements.	Define the metrics, such as DERS compliance targets and the frequency of hard limits attempted for specific drugs across the hospital and in each CCA.
Measure	Measure process performance through data collection.	Review the data reports on a quarterly basis to assess DERS compliance and frequency of hard limits attempted.
Analyze	Analyze the process to determine root	Identify CCAs with DERS compliance

Principles	Description	CQI Data Analysis Process Framework at TOH
	causes of variation, poor performance (defects).	below 95% and the top five drugs with the highest frequency of hard limits attempted across the hospital and in each CCA.
Improve	Improve process performance by addressing and eliminating the root causes.	**DERS compliance:** Investigate the cause and define, develop and implement corrective actions to increase DERS compliance. **Hard limits attempted:** Investigate the cause of hard limits attempted. If cause is associated with the mechanical functionality of the pump, no further action is required. Otherwise, define, develop and implement corrective actions to reduce frequency of hard limits attempted for specific drugs.
Control	Control the improved process and future process performance.	Follow-up with impacted CCA(s) and monitor CQI data to ensure corrective actions were implemented and continue to monitor the data.

CCA: Clinical care area; CQI: Continuous quality improvement; DERS: Drug Error Reduction System; TOH: The Ottawa Hospital

Appendix 8 outlines the flowchart to monitor the performance of the wireless, smart infusion pumps at TOH. It presents the steps in the CQI data analysis process used to assess DERS compliance by CCA and identify the top five drugs at TOH and in each CCA with the highest frequency of hard limit events on a quarterly basis.

The Biomedical Engineering Departments will produce the CQI reports on a quarterly basis to avoid additional burden on the hospital staff given their current workload. The Pharmacy Department then would review these reports to evaluate the DERS compliance and the frequency

of hard limits attempted overall and by CCA. If DERS compliance is below 95% in any of the CCAs, the Pharmacy Department will commence an investigation on the cause of low compliance with the nurse educator, followed by the development and implementation of corrective actions in the CCA. The top five drugs with the greatest number of hard limits attempted per CCA also will trigger an investigation and appropriate actions. These actions can consist of education sessions for the pump users or an update to the parameters of specific drugs in the MDL that more accurately reflects clinical practice. The Pharmacy Department would send the updated MDL to the Biomedical Engineering group to be uploaded on all pumps in use.

The CQI data analysis framework is based on the fundamentals of the medical device surveillance framework presented in Chapter 3.[25] Both frameworks are designed for a hospital setting and incorporate a database, an open communication feedback mechanism, an education and training component, and corrective actions or resolutions that ultimately will lead to improved patient care. Regular feedback to the pump users and increased communication across hospital departments are paramount to improve transparency and to raise awareness of the pump performance at TOH.

This process also would allow users to reflect on the results and communicate their insights on the daily ease of use to the nurse educators and the Pharmacy Department. A closed loop flowchart with a feedback system can facilitate the continuous monitoring of the CQI data and to implement required changes to improve the performance of the pump, as well as any adjustments to the CQI data analysis process, as required.

Study Plan to Measure the Effectiveness and Acceptability of CQI Data Analysis Process on DERS Compliance and Hard Limits Attempted

Study Objectives

The CQI data analysis process will be implemented at TOH monitor the DERS compliance and number of hard limits attempted across the hospital and by CCA.

Our study objectives are as follows:

1. To measure the effectiveness of the CQI data analysis process on monitoring the DERS compliance and top five drug with the highest frequency of hard limits attempted across TOH and by CCA; and
2. To assess the acceptability of the CQI data process by the hospital staff.

Study Design and Setting

We will conduct a pre- and post-study to measure the effectiveness of the CQI data analysis process to monitor the DERS compliance and the frequency of hard limits attempted for specific drugs at TOH. In addition, we will interview the staff in the Biomedical and Pharmacy Departments and nurse educators to inquire about their perception of and experiences with the CQI data analysis process and solicit information about suggestions for improvement. This study will require approval by the Ottawa Hospital Research Ethics Board.

Selection Criteria

The DERS compliance and the number of hard limits attempted collected by the infusion pump system leading to the implementation of the CQI data analysis process over a three month period (i.e., Period 1) were eligible for inclusion. Data collected for three months following the implementation of the data analysis process (i.e., Period 2) to reflect the proposed review cycle also met the inclusion criteria. CQI data that were unrelated to DERS compliance or the hard limit events or were collected outside the study period were excluded.

Implementation of CQI Data Analysis Process

At least one meeting will be scheduled with the Pharmacy and Biomedical Engineering Departments to review the objectives of the process. As well, the roles and responsibilities of hospital staff involved and flowchart will be reviewed, and meeting participants will be encouraged to ask questions and provide feedback to ensure that they understand the requirements.

Data Collection Procedures

The data collection procedures will follow the flowchart outlined in Appendix 11.

The Biomedical Engineering Department will download the data on DERS compliance and hard limits attempted collected during Period 1 to produce the CQI reports. These reports will present the DERS compliance by CCA and the top five drugs with the highest frequencies of hard limits attempted across the hospital and by CCA.

The Pharmacy Department will review the DERS compliance report to assess if compliance is below 95% in at least one CCA. If compliance is 95% or greater in all CCAs, no further action is required. Otherwise, the Pharmacy Department will contact the nurse educator in CCA(s) with a low compliance to determine the cause of the result and to decide on the corrective actions for implementation. In the hard limits attempted reports, the Pharmacy Department will compare the top five drugs for the whole hospital with the top five drugs for each CCA to determine which drugs are common across the hospital and which ones are specific to a CCA. An investigation of the causes of these hard limits attempted with the nurse educators in the CCAs would ensure that the corrective actions would be implemented. The actions will involve additional education sessions by the nurse educators for the pump users or modifications to the data parameters for specific drugs in the MDL by the Pharmacy Department. The revised MDL would be sent to Biomedical Engineering to be uploaded wirelessly to all infusion pumps in use.

In Period 2, the Biomedical Engineering Department will download the data on DERS compliance and hard limits attempted collected to produce the CQI reports for comparison with the results in reported in Period 1. These reports will be reviewed by the Pharmacy Department and compared with the ones produced in Period 1.

Outcome Measures

DERS compliance will be measured as the percentage of infusion pump runs in DERS mode in proportion to the total infusion pump runs by CCA.

For the hard limits attempted, the top five drugs will be measured as having the highest number of hard limits attempted across the hospital or by CCA compared with the total number of hard limits attempted across the hospital or by CCA.

Statistical Analyses

We will use descriptive statistics to present the monthly DERS compliance for Periods 1 and 2. As well, we will calculate the proportion of hard limits attempted across the hospital and by CCA over the total number of hard limits attempted across the hospital and by CCA for the study period. All proportions in Period 1 and 2 will be compared using Pearson's chi-square (χ^2) test for independence and Fisher's exact test for counts less than 5 with statistical significance at a p-value of less than 0.05.

The detailed CQI data for hard limits attempted includes the drug name, parameters entered, parameters programmed in MDL for the specific CCA, event date and time, and physical location of the pump in the hospital (for example, ward or department). Using these data, we will perform logistic regression analyses to measure the relationship between the CCA, event month, event time, pump location with the proportion of frequency of hard limits attempted per drug versus the total number of hard limits attempted.

Proportions lie between 0 and 1 inclusive and, therefore, will likely have a binomial distribution.[26] The aforementioned explanatory variables are categorical variables, and dummy variables will be created for each categorical level of these variables. One dummy variable will represent the base level for each explanatory variable, and the other dummy variables will be

compared to it. The logistic regression model assumes a relationship between the log odds of the hard limit event and the risks factors (i.e., CCA, month, and pump location). The parameter for each categorical level (for example, birthing unit) represents the log odds ratio of a hard limit event compared with the other categorical levels of the same explanatory variable (for example, CCA), keeping the other variables (for example, event month and pump location) fixed.

Residuals will help to determine if the model is appropriate. Since the observations will likely have different variances for logistic regression, the deviance residual is recommended. The deviance residual is defined as the likelihood ratio chi-squared statistic. Observations with a deviance residual greater than two may suggest a lack of fit. Multicollinearity among the explanatory variables also will be examined using the correlation matrix. This statistical phenomenon occurs when at least two explanatory variables in the model are highly correlated, and it can lead to an overestimation or underestimation of estimates, inaccurate variances, or incorrect inferences about the relationship between the explanatory and dependent variables.[26] P-values less than 0.05 are considered to indicate statistical significance, and a two-sided test will be conducted.

Interviews with Biomedical Engineering and Pharmacy Departments

After the CQI data analysis process has been implemented and undergone one review cycle, semi-structured interviews with the Biomedical Engineering and Pharmacy Departments will be conducted to inquire about their perceptions about the effectiveness of the framework to monitor the performance of the infusion pump system. More specifically, the interviews will solicit their acceptance of the process and their suggestions for improvement (for example, facilitate

communication and follow-up with nurse educators or Biomedical Engineering Department, change length of review cycle, appropriateness of CQI reports, etc.).

The Normalization Process Theory (NPT) toolkit described in Chapter 3 will help to inform the development of the interview guide.[27] As previously mentioned, this theory can provide some insight on the human processes inherent in the implementation and integration of the CQI data analysis process in hospital practice. The interview questions will center on the four constructs of the NPT. They include coherence (i.e., hospital staff's capacity to cooperate and coordinate their actions to implement the CQI data analysis process), cognitive participation (i.e., hospital staff's commitment to operationalize the CQI data analysis process), collective action (i.e., how the hospital staff operationalizes the CQI data analysis process), and reflexive monitoring (i.e., how the hospital staff appraises the ways that the CQI data analysis process impacts them and their surroundings).[27]

The responses will be recorded by hand and analyzed in an inductive manner. Responses will be analyzed by one reviewer and verified by a second reviewer as soon as the transcripts are prepared. The constant comparative technique will be used to identify to identify the coding framework and to determine how to merge or expand the thematic codes. The data analysis will focus on a detailed description of emerging themes to identify the overall impression of, the strengths and challenges with, and strategies to enhance the CQI data analysis process to support its sustainability at TOH.

4.4 DISCUSSION

The CQI summary data presented information about infusion pump usage in the CCAs and drugs prone to constant alerts and overrides. Routine reviews of the CQI reports, therefore, can guide the education sessions and MDL updates to enhance their clinical applicability and DERS compliance.[3]

Previous research reported that users in some instances override the soft limit alerts and, therefore, can compromise the full benefits and features of a smart pump.[19] Potential causes of alert rates that can lead to overrides include: i) overly conservative MDL drug limits; ii) MDL limits inconsistent with current clinical evidence or practice; and iii) variations in nurses' pump-programming methods and workarounds.[3] Regular feedback and interventions and education to reduce the risk of medication errors can identify practice trends within the care team and help to ensure the maximum potential of the safety enhancing features of the smart pump system.

Meticulous planning, such as the inclusion of appropriate stakeholders, evaluation of software capabilities, evaluation of hospital practices, standardization of operating systems and procedures, development of drug libraries, and staff training, are required before the new system goes live.[8] The ISMP identified key steps for the successful deployment of a new smart pump technology. They include: i) ownership of the process; ii) technological readiness; iii) physical environment and readiness; iv) staff education; v) special patient (and clinical) care areas; vi) vendor support; and vii) rollout.[8]

The ECRI Institute recommended regular training and assessment for current and new users of infusion pumps in health care facilities to ensure that their skill and knowledge are adequate. In

addition, they recommended that frontline workers be involved in the evaluation of new medical devices prior to their purchase decisions.[28] Similar to the study findings in Chapters 2 and 3, Frequent education to the users on the smart pump technology can help them to properly use it and increase compliance.[21] The incorporation of drug libraries alone, however, is not enough to resolve all medical errors. The aforementioned infusion pump integration, where pump servers are connected with other information systems, is one way to address many of these errors.

Limitations

The interpretation and application of the findings may be influenced by several limitations. One important challenge with the CQI data analysis process is the lack of information on the patient profile. TOH has not implemented the Positive Patient Identification technology for drug infusions. This means that individual drug dosage limit alerts cannot be linked back to specific patients, so there is no patient context within the CQI data to supplement the analysis.[19] Despite the ability to produce detailed reports that specify the CCA, drug, concentration, dosage, and location of the pump, CQI data alone precludes an accident investigation without information on patient care.[29]

It is recommended that smart pumps be integrated with the medical administration process.[3] The integration of the wireless pump system into TOH electronic medication administration record would allow the programmed dose to be compared to the patient's prescription and help to confirm if an adverse drug event occurred. Pump integration into an electronic medication administration record can link the pump events to the patient's prescription and help to understand what factors prompt the nurse to program a dose that exceeds the drug limit in the

MDL. This systems integration would increase the data available for analyzing specific events by linking them to the patient and provider.

Although DERS compliance ranged from 72.14% to 100% with the new pump system, we were unable to accurately measure the percentage change in compliance as the legacy Colleague pumps did not consistently collect this information. In addition, this model did not have the updated MDL installed on most of the older pumps. Moving forward, data captured in the new pumps will facilitate the close monitoring of compliance and soft and hard limits events by CCA and drug in the future.

Directions for Future Research

Data on the user experience can guide the design, purchase and appropriate use of the medical device.[30] Human factors engineering, such as user interface design, plays an important role in improving safe medical practice and ensuring speedy adoption of the new technology. Additional safety features include enhanced programming options, convenience, and portability.[21] For instance, adjustments to the software can allow the user to enter their rationale for overriding a soft limit alert. Research that incorporates a human factors evaluation would help to better understand any risks in undermining the benefits demonstrated in this study if users choose to opt-out of the drug library.

Interviews with the users or observational analyses to watch the user behaviours can provide valuable insights on why differences in DERS compliance exist in some CCAs. Further

investigation is required to understand the reasons for user behaviours and how best to address them to achieve a culture of safety among the users.[19]

A CQI data analysis process was designed to assess DERS compliance by CCA and identify the top five drugs in each CCA with the greatest number of hard limits attempted. We outlined a study plan to measure the effectiveness of the CQI data analysis process and its acceptability among the hospital staff. Future iterations of the process can incorporate a review of the top five drugs with the highest frequency of soft limit events by CCA.

4.5 CONCLUSIONS

We conducted a review of the CQI summary data retrieved from the new infusion pump system to help inform the design of a formal CQI data analysis process. The CQI data identified overrides attempted and exceeded and measured DERS compliance per CCA over a one year period. During the study period, the compliance ranged from 72.14% in anesthesia (OR) to 100% in neonatal care areas. Moreover, we were unable to detect time trends on the frequency of soft and hard limit events for the study period but observed that the greatest percentage of soft limit overrides occurred in birthing unit and oncology CCAs. As well, the authors designed a CQI data analysis process to monitor the performance of the wireless, smart pumps across all CCAs. A study plan to measure the effectiveness and acceptability of the process by the hospital staff is described.

CQI data can provide some insight on MDL updates necessary to improve and maintain compliance and reduce the frequency of soft and hard limit events reported. As drug libraries are

updated and as these pumps are integrated with the electronic medication administration record, TOH will be able to link the soft or hard limit events to a patient's prescription to investigate if an adverse event occurred and to prevent similar events in the future. Systems integration would enable the clinical staff to have a complete account of the patient's medical history; thus, reducing the risk of medication errors in hospitalized patients.

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APPENDIX 1: FDA RECALLS SINCE 2005 ON VOLUMETRIC INFUSION PUMPS

Year	Recall Class	Model	Reason for Recall (verbatim)
2015	1	Master Drug Library Software version 8.0, Product Code 35723V080, to be used with SIGMA Spectrum Infusion System (Pump)	"Loading/Bolus default dose settings in the Master Drug Library and the values shown on the pump during programming may differ. MDL drug dose time in seconds will round to the nearest integer in minutes on the pump dose setup screen (20 sec may show as 1 min on the pump display). The pump will administer drugs as configured. The discrepancy may cause therapy delay or unintended rate of delivery."[31]
2015	1	Plum A Infusion Pump System	"One lot of alarm assemblies used in Plum A+ and Plum A+3 infusion pumps may fail to sound at all volume levels."[32]
2015	1	Plum A Infusion Pump System	"Plum A+ infusion system pole clamp assemblies were discovered to be cracked. If the knob on the pole clamp assembly is cracked, the infuser cannot be attached to the IV pole since the knob is used to tighten and loosen the grip of the pole clamp to the pole."[33]
2014	2	GemStar infusion pump	"Some patients are obtaining access to the dosage reset codes required to change the settings on GemStar infusion pumps and are subsequently changing the infusion rate set by their doctors. Patients are obtaining access to these codes via website sponsors by downloading the GemStar User/Service Manual featured on the sponsors' websites."[34]
2014	2	CADD-Solis Medication Safety Software, Administrator CD, Version 3.1	"Smiths Medical has identified an issue with a single batch (Lot Number 2752712) of CADD"-Solis Medication Safety Software Administrator 3.1 CDs. CADD"-Solis Medication Safety Software Administrator 3.1 CDs were sent with the CADD"-Solis Medication Safety Software Point of Care 3.1 software loaded on them."[35]
2014	2	SPECTRUM Pump, Model No. 35700BAX	"One Service Technician may not have correctly serviced specific Sigma Spectrum Infusion Pumps according to established procedures during the time period of 5/5/2014 through 6/3/2014."[36]
2014	2	GemStar infusion pump, List numbers 13000 and 13100	"The connection between the beeper subassembly and the pump may fail. The GemStar infusion pump will identify this failure during the "self-test" while powering up which will result in a Beeper Error ("code 10/001/000"). This Beeper Error (code 10/001/000) is a service alarm that places the pump in an inoperable mode and requires service before it

Year	Recall Class	Model	Reason for Recall (verbatim)
			can be returned to service."[37]
2014	2	Hospira MedNet Medication Management Suite	"Hospira MedNet 5.5, 5.8.1, and 5.8.2 contains software defect where the dosing units of "nanog/kg/min" and "milliUnits/min" are not sent to a Plum A+ device (Version 13.40, 13.41, and 13.4.2) via Auto Programming when those dosing units are not properly established in the customized drug library."[38]
2014	2	Plum LifeCare 5000 Series and Plum XL families	"There is the potential for the door roller assembly on the Plum LifeCare 5000 Series and Plum XL families of infusers to break. In the event of a broken door roller pin, the door cannot appropriately lock the cassette in the right position. Depending on the conditions of a broken door roller pin, a number of events can occur."[39]
2014	2	Alaris Pump model 8100 with software version 9.1.18	"CareFusion is recalling the Alaris Pump model 8100 version 9.1.18 because it may have a software issue that results in situation where the pump module will not properly delay an infusion when the "Delay Until" option or "Multidose" feature is used." [40]
2014	2	GemStar Docking Station, used with GemStar infusion pump	"There are two situations that may occur when using the GemStar Docking Station, List Number 13075-XX-XX, in conjunction with the GemStar infusion pump: 1) when the Docking Station is used in conjunction with a GemStar Phase 3 pump (List 13000-XX, 13100-XX, or 13150-XX) the potential exists for the GemStar Phase 3 pump to fail to power up while connected to the Docking Station, and 2) when either a."[41]
2014	1	Alaris Pump Module (Model 8100), Version 9.1.18 Software by CareFusion 303, Inc	"CareFusion is recalling the Alaris Pump model 8100, version 9.1.18, because the pump may have a software failure where the pump module will not properly delay an infusion when the "Delay Until" option or "Multidose" feature is used. This issue does not impact the "Delay For" Option. The software failure also causes the pump to not properly deliver a multidose infusion as expected under certain conditions".[42]
2014	1	Hospira Inc., Abbott Acclaim Infusion Pumps and Hospira Acclaim Encore Infusion Pumps - Broken Door Assemblies May Result in Over-Infusion or	"Hospira received customer reports of broken door assemblies on the Abbott Acclaim infusion pumps and the Hospira Acclaim Encore infusion pumps. When the door is closed properly, it helps ensure that the tubing is seated properly to ensure appropriate flow of therapy to the patient. If the door assembly breaks, it may prevent the door from closing properly and an over-infusion or a delay of therapy may occur. If the door cannot be closed, the pump cannot be used which can result in a delay of therapy. Use of these affected products may cause serious adverse

Year	Recall Class	Model	Reason for Recall (verbatim)
		Delay of Therapy	health consequences, including death".[42]
2014	1	Baxter Healthcare Corporation, Sigma Spectrum Infusion Pumps with Master Drug Library Model No. 35700BAX and 35700ABB - System Error May Interrupt or Delay Therapy	"Baxter has received over 3500 reports of System Error 322 "Link Switch Error (low)" incidents in which the device has malfunctioned, including nine severe adverse events and no deaths. The System Error 322 occurs when the pump improperly detects that the door is open when it is physically closed. A System Error 322 may lead to an interruption or delay in therapy. If the System 322 occurs, the Sigma Spectrum infusion pump stops the infusion, an alarm sounds, and a light flashes (a visual "322" alarm). This requires a clinician to reset the alarm, reprogram the pump, and confirm the infusion is running properly. The use of affected product may cause serious adverse health consequences, including death".[42]
2013	No recalls reported		
2012	1	CareFusion Alaris Pump Module, Model 8100 – Motor Stall	"CareFusion has received reports of customers experiencing motor stalls during infusion with the Alaris Pump Module, model 8100. Most of the motor stalls reported have occurred at high infusion rates (typically over 900 ml/hr). However, the firm cannot rule out the possibility of motor stall occurrence at lower infusion rates. When a motor stall occurs, the Alaris PC unit and the Alaris Pump Module display the visual error code 242.4030 with an audible alarm that is followed by a termination of infusion. Termination of infusion, especially in high risk patients, could result in serious injury or death".[43]
2012	1	CareFusion Alaris Pump Module, Model 8100 – Keyboard Overlay	"There is a potential risk that the pump module door keypad overlay may separate from the keypad assembly. This product may cause serious adverse health consequences, including death".[43]
2012	1	SIGMA Spectrum Infusion Pump Model 35700 - Expanded Recall	"Based on additional analyses since the initial recall, SIGMA expanded their recall to include additional affected units manufactured from January 18, 2005 through November 1, 2010, with the exception as noted above. These units may fail suddenly causing inaccurate flow conditions during use, ranging from back flow to over-infusion, including free flow. The pump does not issue an alarm when this occurs. These conditions could result in serious injury or death".[43]

Year	Recall Class	Model	Reason for Recall (verbatim)
2011	No recalls reported		
2010	1	Baxter Colleague Single and Triple Channel Volumetric Infusion Pumps - Recall, Refund and Replacement	"On May 3, 2010, the FDA ordered Baxter Healthcare Corporation to recall and destroy all Colleague infusion pumps in the US market. FDA determined that this action was necessary, since Baxter failed to adequately correct, within a reasonable timeframe, the deficiencies in the Colleague pumps still in use. This recall is a consolidation of all previous open Colleague recalls".[44]
2010	1	WalkMed, Inc. Triton Pole Mount Infusion Pump	"It is possible the pump door may not be closed when the latch is down and the pump door open alarm may not alert the user to this condition. This may result in a free flow condition which may result in over delivery of therapy and lead to serious injury or death".[44]
2010	1	SIGMA Spectrum Infusion Pump Model 35700	"These units may fail suddenly causing inaccurate flow conditions during use, ranging from back flow to over-infusion, including free flow. The pump does not issue an alarm when this occurs. These conditions could result in serious injury or death".[44]
2009	1	Baxter Colleague Single and Triple Channel Volumetric Infusion Pumps	"The company identified software and battery usage failures that result in a delay in or interruption of infusion that may cause serious injury and/or death".[45]
2008	No recalls reported		
2007	1	Cardinal Health Alaris® Infusion Pump Module (formerly Medley™ Pump Module), Model 8100	"During the manufacturing or servicing of the mechanism assembly, the occluder springs were misassembled (overlapping [nested], missing, bent or broken). If a spring is misassembled, there is a potential for inaccurate flow rate which may lead to a patient's harm due to over-infusion".[46]
2007	1	Baxter Upgraded Colleague CX Single Channel Volumetric Infusion Pumps	"A field service technician did not perform all of the hardware Recall: upgrades required in accordance with Baxter's corrective action procedures related to eight open Colleague recalls. The service technician certified in the service documentation that the upgrades were done on the affected pumps even though the upgrades were not done. These incomplete upgrades were performed from May 22, 2007, through August 7, 2007".[46]

Year	Recall Class	Model	Reason for Recall (verbatim)
2007	1	Baxter Healthcare Corp. COLLEAGUE® and FLO-GARD® Volumetric Infusion Pumps	"The firm identified repair, inspection & test data sheets, which included electrical safety data, for the pumps, that were falsified".[46]
2007	1	Baxter Healthcare Corp. Upgraded COLLEAGUE® Triple Channel Volumetric Infusion Pumps	"A software irregularity causes the newly upgraded COLLEAGUE® Triple Channel Volumetric Infusion Pumps to alarm, display an error code (16:310:867:0002) and stop the infusion in all three channels. This occurs during user programming with all three channels infusing fluids at the same time. In reported cases, the pump stopped infusing which caused it to activate an audible and a visual alarm".[46]
2006	1	Cardinal Health Alaris ® SE Infusion Pumps	"Some Alaris SE infusion pumps have a design defect that can cause over-infusion of medications into a patient's bloodstream. The touch-sensitive keypad used to program the pump sometimes registers a number twice when it has been pressed only once ("key bounce"). Thus the pump would deliver more than the intended amount of medication, leading to over-infusion. Over-infusion can potentially result in serious harm or death to the patient".[47]
2006	1	Baxter Healthcare Corp. COLLEAGUE® and COLLEAGUE® CX Volumetric Infusion Pumps	**"Battery Undercharging:** The pump's battery charge level indicator may overstate the battery power level and shut down when operating on battery power if not charged for a full 12 hours following a "low battery" alarm. **False Air Detection Alarms:** If the pump's tubing is stretched or pulled, the pump's sensors may misinterpret this tension as air in the line, resulting in a false alarm and shutting down the pump. **Gearbox Wear:** Worn parts in the pump's motor can cause the pump to shut down and interrupt therapy. **Under-infusion:** If there is an obstruction during tube-loading, the upper jaw of the pump head can be moved out of alignment, resulting in insufficient fluid delivery. **Non-detection of upstream occlusion:** Improperly spiked bags, use of a source container which has had all air removed, improper venting of the container, and an unopened air vent above the burette chamber may result in the pump not detecting an upstream occlusion. Any of these failures may delay or interrupt therapy, which could result in a life-threatening situation for patients,

Year	Recall Class	Model	Reason for Recall (verbatim)
			depending on the type of therapy being administered".[47]
2005	1	Baxter Healthcare Corporation COLLEAGUE® Volumetric Infusion Pumps	"The pump's batteries have been known to experience battery swelling and/or excessive discharge failures. Both of these failures will result in irreversible damage to the battery. If either one of these failures occurs, the pump would be incapable of operating on battery power for the expected amount of time, thus leading to interruption or prevention of therapy and the possible death and/or serious injury of patients. Additionally, it should be noted that when the batteries become damaged due to excessive discharge, the battery charge level indicator will overstate the amount of battery charge remaining".[48]
2005	1	Baxter Healthcare Corporation COLLEAGUE® Volumetric Infusion Pumps	"The pumps can shut down while supplying critical medication and fluids to patients. Critically ill patients needing continuous delivery of life-sustaining medications at the time of the pump's failure could be seriously harmed". [48]

APPENDIX 2: PATIENT SAFETY FEATURES OF SPECTRUM GENERATION2 INFUSION SYSTEM[17]

Feature	Description (verbatim)
Generation 2 Error Prevention Features	• Single step titration error prevention system • Check flow at start of infusion • Secondary infusion container check
Smart System Support	• Consultative MDL development support and guidance • IT resources assist in implementation of server, wireless pump connectivity, and integration with HIS • Go-live and post installation support • Goal of 100% staff training
Smart Architecture	• Bi-directional wireless communication • Fast and reliable MDL updates • HL7 and XML interfaces
Rapid and Intuitive Workflow	• Rapid priming of standard IV administration sets • Quick drug search within library • "ON" to "Run" in 25 seconds • On-board digital help screens
Standard Set Technology	• Uses Baxter's standard IV administration sets • Ease of priming • Ease of set-up • Drives set standardization and efficient use of inventory • Reduction in total cost of ownership

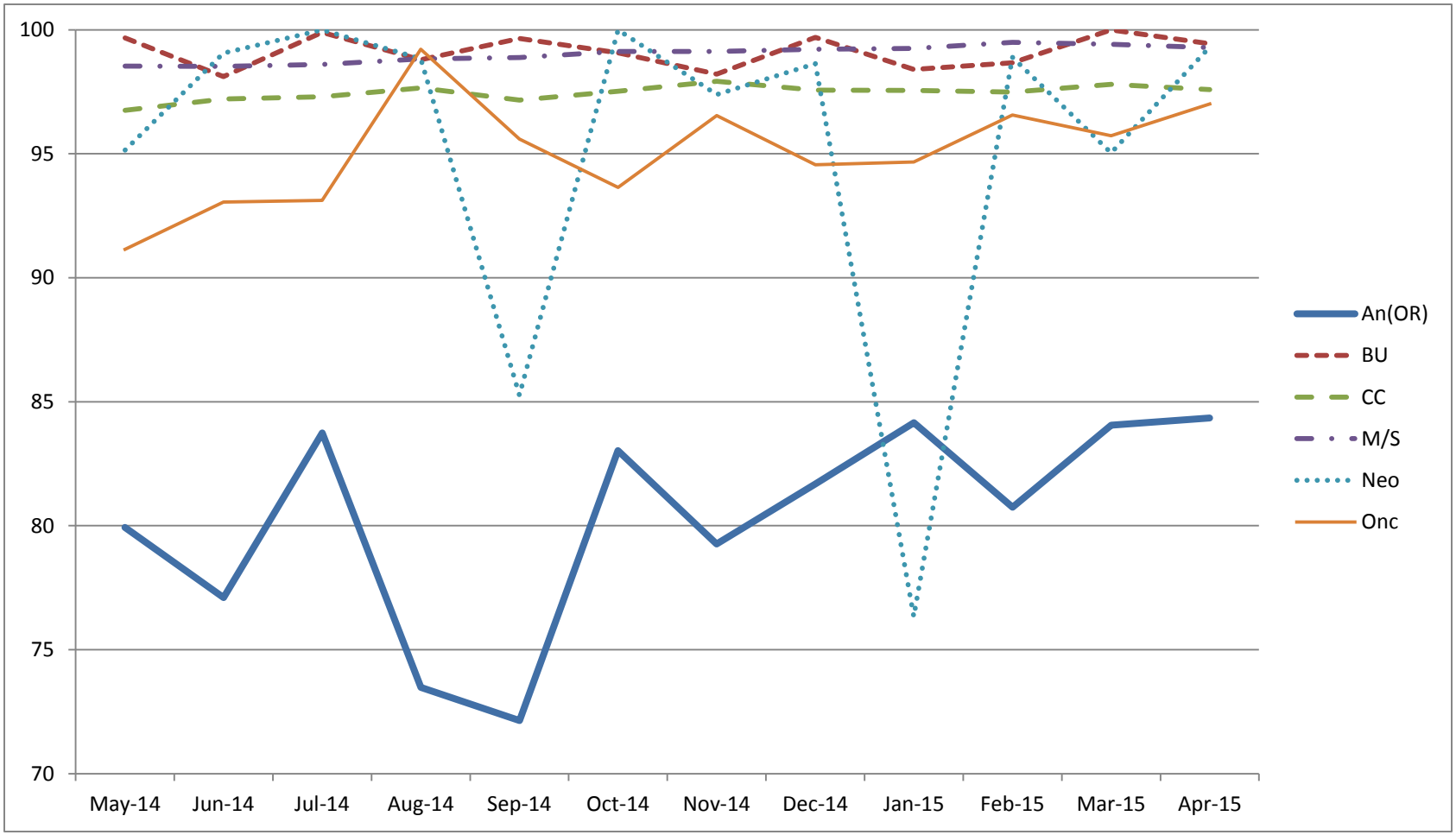
CQI=Continuous quality improvement; HIS= Hospital information system; IV=Intravenous; IT=Information technology; MDL=Master drug library

APPENDIX 3: CONTINUOUS QUALITY IMPROVEMENT REPORTS[49]

Report	Description	Data Measurement Reviewed
DERS Compliance	The report presents the number of drug infusions that have been started in either DERS or BASIC mode. The BASIC mode allows the selection of mL/hr setup and bypasses the DERS mode. It summarizes the number of infusions that have been programmed using either the drug library or basic mode.	• Percentage of infusions in DERS mode per month by CCA.
Soft Limit Exceeded	The report presents the number of incident of 'Dose Rate Soft Limit Exceeded' warnings has occurred in each clinical care area. Double confirmation events represent the frequency the user exceeded the MDL soft limits and the user accepted the parameters. Pullback events represent the frequency the user exceeded the MDL soft limits and the user declined the reprogrammed the parameters.	• Frequency of MDL soft limits exceeded (double confirmation) per month by CCA. • Frequency of MDL soft limits attempted (pull back) per month by CCA.
Device or Hard Limit Attempted	The report presents the number of incidents of 'Device' or 'MDL Hard Limit Attempted' warnings that has occurred by drug and clinical care area. Hard dose limits cannot be exceeded. Rates must be reset within the hard limits to run the pump.	• Frequency of MDL hard limits attempted per month by CCA.

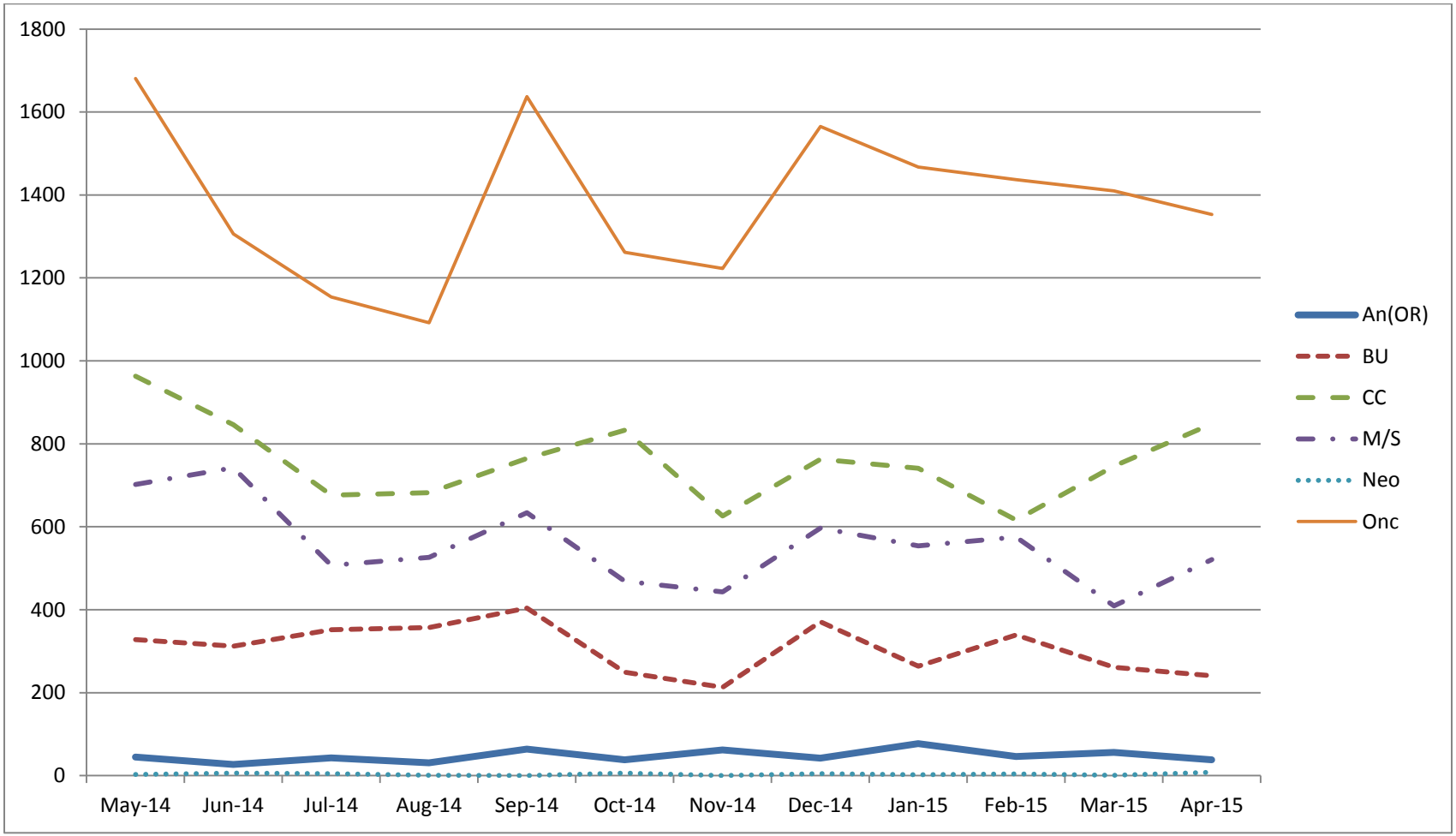
CCA=Clinical care area; DERS=Dose error reduction software; MDL=Master drug library

Appendix 4: DERS Compliance (%) per Month by Clinical Care Area



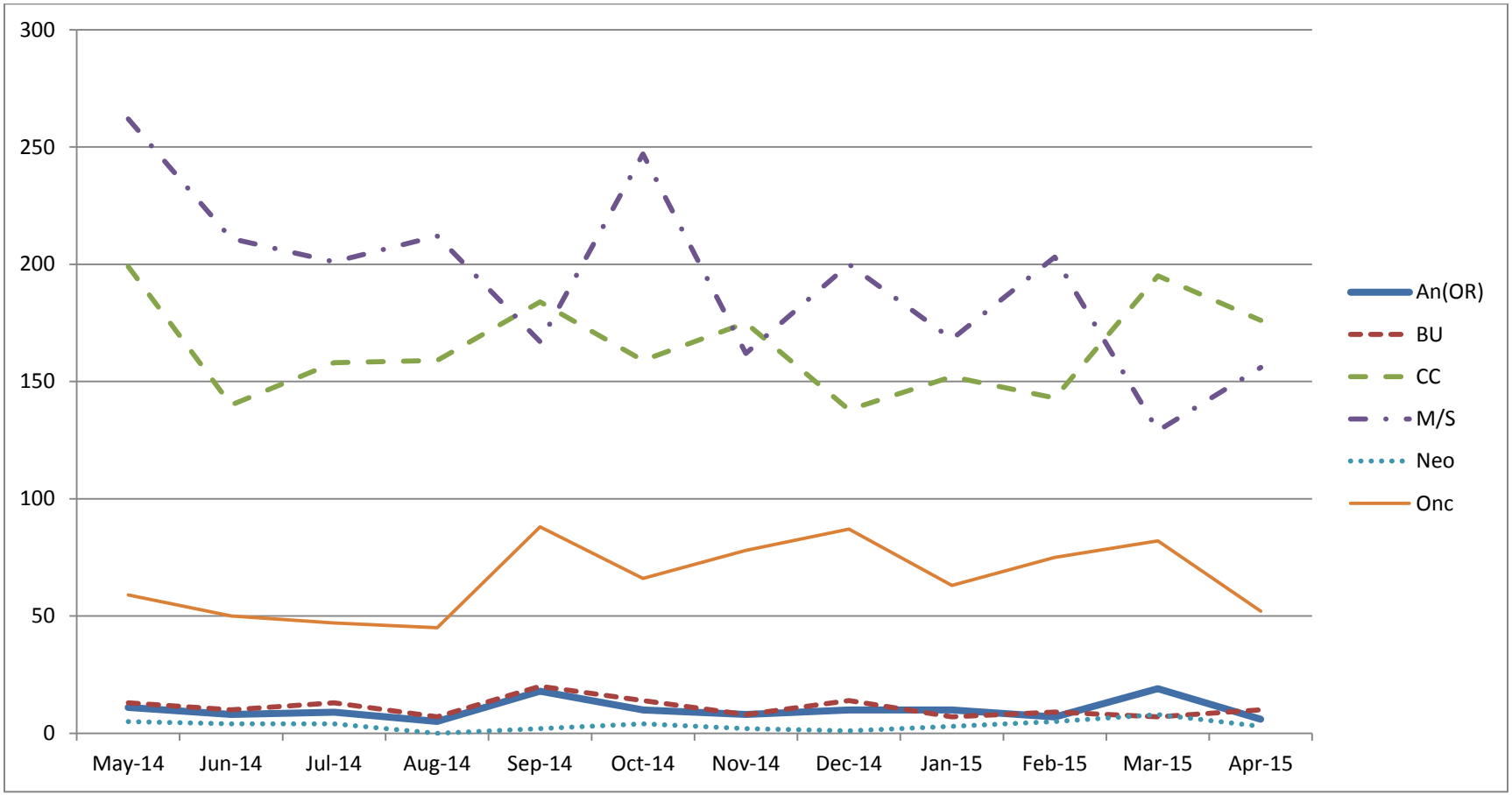
An(OR)=Anesthesia (OR); BU=birthing unit; CC=critical care; M/S=medicine/surgery; Neo=neonatal; Onc=oncology

Appendix 5: Frequency of Soft Limits Exceeded (Double Confirmation) per Month by Clinical Care Area



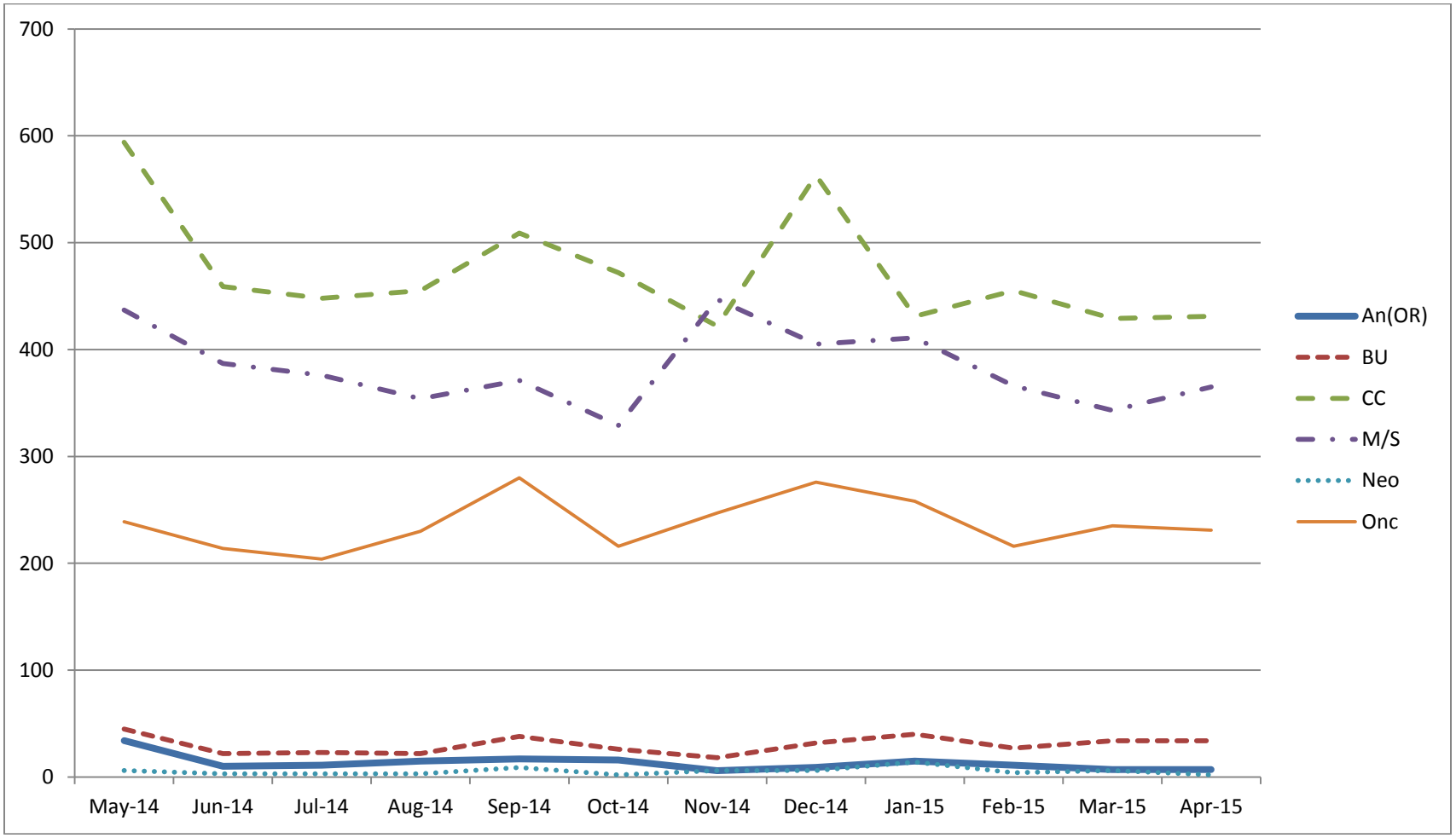
An(OR)=Anesthesia (OR); BU=birthing unit; CC=critical care; M/S=medicine/surgery; Neo=neonatal; Onc=oncology

Appendix 6: Frequency of Soft Limits Exceeded (Pullbacks) per Month by Clinical Care Area



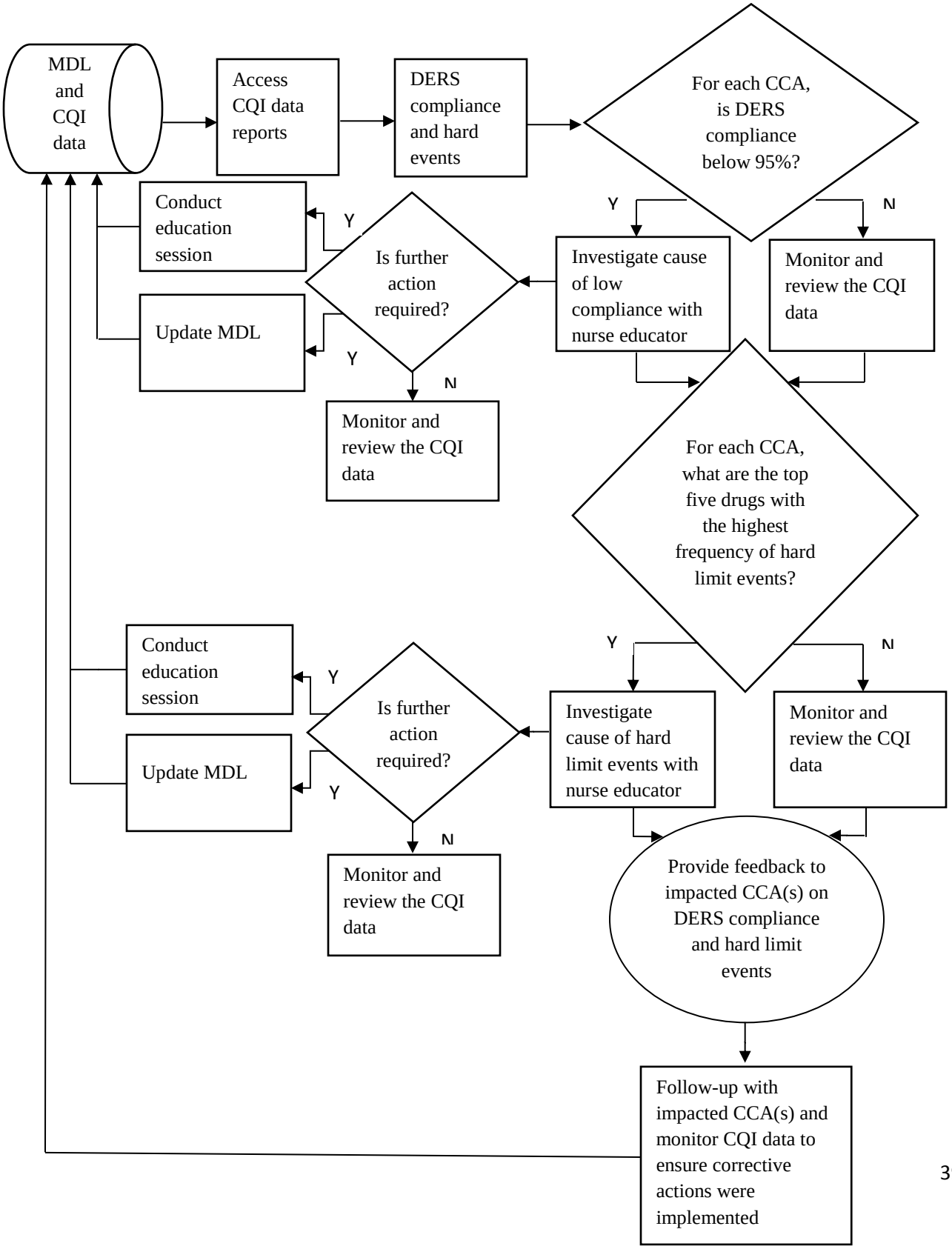
An(OR)=Anesthesia (OR); BU=birthing unit; CC=critical care; M/S=medicine/surgery; Neo=neonatal; Onc=oncology

Appendix 7: Frequency of Hard Limits Attempted per Month by Clinical Care Area



An(OR)=Anesthesia (OR); BU=birthing unit; CC=critical care; M/S=medicine/surgery; Neo=neonatal; Onc=oncology

Appendix 8: CQI Data Analysis Process to Monitor the Performance of Wireless, Smart Pumps at TOH



Chapter 5

5.0 SUMMARY AND IMPLICATIONS

Medical devices are used to diagnose, treat, or prevent a disease or abnormal physical condition without any chemical action in the body and can result in incidents and malfunctions. Medical device-related incidents have gained increased attention through media reports of injuries, recalls, and class-action lawsuits. PMS is an important component to monitoring medical device strategy. It is complementary to the premarket studies as PMS are more likely to detect serious but rarer adverse event due to larger sample sizes and inclusion of specific populations. Medical device surveillance also can detect long-term problems that are not reported in premarket studies due a shorter follow-up, improper use of the device or device-drug interactions not found in a controlled study setting.[1]

This thesis sought to identify and collect information on existing hospital-based surveillance systems and gain a greater understanding on factors that influence incident recognition, reporting, and resolution to enhance current or develop new surveillance systems. The medical device surveillance and smart infusion pump systems would benefit from close monitoring of the data collected to help identify actions that can ameliorate their functionality and usability to maintain their relevance and effectiveness in health services delivery and patient care.

The purpose of the systematic review and telephone interviews were to identify factors that influence the recognition, reporting, and resolution of medical device-related incidents and interventions for surveillance improvement. As the systematic review revealed a dearth of

evidence in this area, detailed information from key informants about the nature of device incidents and reporting systems was required. Physicians and nurses were interviewed to identify devices giving rise to incidents; the nature of those incidents and outcomes; explore factors that influence incident occurrence, recognition reporting and resolution; and the nature of hospital incident reporting systems. The results of both studies revealed that personal attitudes, awareness and perception of incident reporting systems, organizational culture, and feedback to health care professionals impacted the reporting of incidents. Recognition was related to devices not performing to manufacturer instructions, the staff knowledge and experience, and the clinical manifestations of patients. Suggestions to improve medical device safety and surveillance centered on education and training on the appropriate use of the medical devices and any incident reporting systems, and how to report errors.

A case study of a smart wireless infusion pump system based on the CQI data summaries identified patterns of use across TOH in terms of DERS compliance and the frequency of soft and hard limit events. Moreover, a CQI data analysis process to monitor the performance of the new infusion pump system, based on the design principles of the medical device surveillance presented in Chapter 3, is presented. This initiative is an ongoing project with the Biomedical Engineering and Pharmacy Departments at TOH. A study plan to measure the effectiveness and acceptability of the CQI data analysis process by the hospital staff following its implementation is described.

The findings of this thesis can help to improve strategies that enable incident identification and reporting, analysis and interpretation, and sharing of data to guide decision-making about device

purchase, use, training, process improvement, disinvestment, and reassessment. In addition, the CQI data analysis process can help to transform data collected by the infusion pumps into information used by TOH to monitor which drugs are more prone to hard limits attempted and CCAs with DERS compliance less 95%. The CQI reports produced by the Biomedical Engineering Department will trigger the Pharmacy Department to investigate the causes of the events and implement solutions.

The current chapter briefly summarizes the findings, strengths and limitations of the overall thesis, and directions for future research, and highlights the implications of the results for various audiences, such as the hospital decision makers, clinicians, researchers, and manufacturers.

Brief Summary of Results

1. Factors that Influence the Recognition, Reporting, and Resolution of Incidents Related to Medical Devices and Other Healthcare Technologies: A Systematic Review

In our systematic review, we identified 30 studies on factors that influence the recognition, reporting, and resolution of incidents in a hospital setting and interventions or suggestions to improve medical device surveillance. There is a dearth of evidence on this research topic as most of the studies focused on error reporting, and were not specific to medical devices. Central themes that emerged for incident reporting were personal attitudes, awareness and perception of incident reporting systems, organizational culture, and feedback to healthcare professionals. Moreover, awareness and complexity of any existing local surveillance systems or persons responsible for error reporting influenced a health care professional's decision to report an incident. Barriers to reporting were fear of punishment, lack of feedback and trust, and lack of familiarity with local reporting systems and processes. One can conclude that incidents may be

under-reported due to failure to recognize or report them for the aforementioned reasons.

2. How Can We Improve the Recognition, Reporting and Resolution of Medical Device-Related Incidents in Hospitals? A Qualitative Study of Physicians and Registered Nurses

In our telephone interviews, several participants attributed the recognition of incidents to devices not operating as intended and to the hospital staff's knowledge and professional experience on both medical device performance, and clinical manifestations of patients. Persons or parties notified of a device-related incident were the hospital, patient and their families, manufacturers and, in severe cases, the regulator. Less serious errors or near misses, however, sometimes were not reported. In numerous instances, physicians discontinued with the use of a device if it malfunctioned, and the problem remained unresolved.

Common barriers to incident reporting indicated by the interviewees were similar to the ones reported in the published literature. Suggestions to improve medical device safety surveillance centered on education and training to ensure that the staff are able to use the medical device properly and know what and how to report errors. In terms of medical device surveillance, some respondents viewed the implementation of registries and databases as effective approaches to gauge the performance of medical devices in clinical practice. We presented a medical device surveillance framework in a Canadian hospital context designed to monitor device malfunctions and incidents that can lead to patient adverse events.

3. An Investigation of the Continuous Quality Improvement Data Automatically Reported by Wireless Smart Infusion Pumps

This case study reviewed the CQI data summaries over a one year period retrieved by the wireless smart infusion pumps system at TOH. A CQI data analysis process to measure the effectiveness of the wireless, smart infusion system at TOH was proposed. The DERS compliance ranged from 72.14% in anesthesia (OR) to 100% in neonatal, but we were unable to identify any trends in the occurrence of soft and hard limit events. The proportion of soft limit overrides compared with pullbacks was observed in the birthing unit and oncology. A CQI data analysis process framework to monitor the performance of the wireless, smart infusion pump system was presented. The full potential of a wireless smart pump system can be realized if it is integrated with the electronic medication administration record. This systems integration can link the pump events to the patient's prescription and facilitate an accident investigation to prevent similar errors in the future; thus, improving patient safety in a hospital facility.

Summary of Study Strengths

The doctoral thesis is the first to investigate factors that influence the recognition, reporting and resolution of medical device-related incidents. A systematic review identified a dearth of evidence specific to medical devices, and telephone interviews with physicians and nurses in two Canadian tertiary care hospitals were performed to inquire about their experiences with the use of devices. The case study on infusion pumps proposes a CQI data analysis process to monitor the impact of the new wireless smart infusion pumps at TOH on DERS compliance and hard limit events. This is initiative is an ongoing project with the Biomedical Engineering and Pharmacy Departments at TOH.

The first installment of this thesis was a comprehensive systematic review of the published and grey literature on factors that influence recognition, reporting and resolution of incidents in a

hospital context. The results based on 30 relevant studies helped to identify the evidence gaps on medical device surveillance and informed the development of our telephone interview questionnaire with physicians and RNs. Furthermore, our qualitative research study solicited information from physicians and RNs on factors that influence the recognition, reporting, and resolution of device-related incidents and improvement strategies for medical device surveillance in a Canadian hospital facility.

Our semi-structured telephone interviews permitted participants to discuss their experience and concerns related to medical device-related incidents without feeling intimidated by their peers or superiors and retain their anonymity. Both our systematic review and telephone interview responses helped to inform the design of a hospital surveillance system to reduce the risk of medical device-related incidents.

Finally, our case study presented an analysis of the CQI summary data collected from the wireless smart infusion pump system over a one year period. We also proposed a CQI data analysis process to monitor the effectiveness of the wireless, smart infusion pump system at TOH. This process can help to recognize training opportunities and improvements to the MDL that is reflective of clinical practice.

Summary of Study Limitations

For our systematic review, the study selection was restricted to studies published in languages spoken by the authors, including English, French, Italian, and Spanish; however, Morrison et al. found no systematic bias when English-language restrictions were imposed in systematic

reviews.[2] Also, the majority of the literature in our study did not focus on medical devices, but the results related to incidents can be theorized to medical device surveillance systems.

In the telephone interview study, responses may not be relevant to other health care settings given the clinical procedures provided and patient population served in tertiary care hospitals. Study participants were not randomly selected to take part in our interviews. Instead, they were recommended by the research team and their colleagues, so there is a potential for responder bias. It was a challenge to determine if the devices incidents resulted from a device malfunction, user error or insufficient knowledge on their proper use, as well as the severity of device incidents. In addition, the principal investigator relied on the interviewees' audio cues since she was unable to see interviewee's physical gestures or nuances over the telephone.

For our case study on infusion pumps, events identified in the CQI data were not linked to any patient prescription records or electronic medication administration record, so further investigation would be required to understand the precise cause of the event and effective resolutions. Furthermore, the integration of the aforementioned medication administration record can link the soft or hard limit events to the patient's prescription and identify the occurrence of an adverse drug event and prevent these events in the future.

Summary on Directions for Future Research

The doctoral thesis was exploratory in design as previous published literature had not explored the recognition, reporting and recognition of medical device-related incidents nor examined the CQI data collected from a new wireless infusion pump system over a one year period in a tertiary

care hospital. The studies conducted also identified key evidence gaps to help guide directions for future research.

Our systematic review and telephone interviews have increased our understanding of factors that influence the recognition, reporting, and resolution of incidents, including those related to the use of medical devices, in a hospital context. Interventions or suggestions to improve medical device surveillance also were discussed. Future studies can examine the impact of organizational and cultural attributes identified to attain and maintain quality improvement methods and innovations in health care organizations, such as hospitals, based on a 2013 study. Authors of a 2012 Cochrane Systematic Review on the effectiveness of audit and feedback on the practice of healthcare professionals and patients suggest that future studies can compare and contrast different approaches to deliver feedback to health care professionals.

In addition, interviews with hospital administration staff, the biomedical engineering department, manufacturers, and patients can shed some light on the design and development of an effective medical device surveillance system. Future research can compare the medical device malfunctions experienced by the interview respondents to reports of recalls to assess their prevalence and severity in clinical practice. A review of how reported device malfunctions were addressed by the hospital in relation to their official policies and procedures warrants an investigation.

An investigation of surveillance systems in other sectors, such as transport, and machinery and equipment, can provide valuable insights in their mechanisms used to recognize, report, and resolve incidents that can lead to serious errors.

A pre- and post-study to measure the effectiveness of the CQI data analysis process to monitor the DERS compliance and the frequency of hard limits attempted for specific drugs at TOH. In addition, we will interview the staff in the Biomedical and Pharmacy Departments and nurse educators to inquire about their experience with the CQI data analysis process as part of their routine practice and solicit information about suggestions for improvement. The Normalization Process Theory will help to guide the interview script.

Lastly, future research can observe and investigate reasons for user behaviours with medical devices, including smart infusion pumps, and how best to address them to strengthen quality care delivery and patient safety culture in a hospital.

Implications of Study Findings

The results of the thesis have implications for various audiences, such as hospital decision makers, frontline clinicians, researchers, and manufacturers that are described as follows:

Hospital Decision Makers

The results of the systematic review and telephone interviews helped to inform a framework for medical device surveillance system in a Canadian hospital context with the intent to improve the safety of device use in hospitalized patients. Components of the system incorporated an adverse

medical device event database, an open communication and feedback strategy between the hospital administrators and frontline workers, education and training for the hospital staff to strengthen the patient safety culture and to raise awareness of current incident reporting systems, and an integration of medical devices with information systems. Also, participation in the Canadian Medical Devices Sentinel Network (CMDSNet) would permit hospitals to benefit from timely new safety information to make informed decisions concerning the appropriate use of medical devices due to more comprehensive incident data and earlier regulatory interventions. CMDSNet involves a group of dedicated and trained representatives from at least 10 acute or community based healthcare facilities within Canada. Important considerations to ensure the optimization of the surveillance system include a review of the benefits and costs, a detailed implementation plan and a continuous evaluation to incorporate changes that will ensure the system's relevance over time. Lastly, a CQI data analysis process would allow a close monitoring of drug limits with a greater risk of medication errors that to can lead an improvement in hospital performance.

Frontline Clinicians

Frontline clinicians are the backbone in the recognition, reporting, and resolution of medical device-related incidents. Obstacles occur that can prevent them from recognizing and reporting errors that occurred in their patients. If non-existent in their local setting, they should advocate for increased education and training and a non-punitive culture would provide them with the opportunity to tell the complete story without the fear of retribution. Clinicians should continue to consult with their colleagues and review the evidence on matters related to the risk associated with the use of specific medical devices for their patient populations and known resolutions to

mitigate their reoccurrence. Also, they should ensure transparency with patients, colleagues, hospital administrators, and regulators if they intend to use a medical device for an experimental procedure or for off-label use to reduce risk of litigation and to protect their professional reputation. Furthermore, regular reviews of CQI data reports derived from data collected from smart infusion pump systems with wireless capabilities can provide important insights on reducing the risk of severe medication errors for hospitalized patients, such as adjustments to the MDL or education sessions for the hospital staff.

Researchers

In addition to the directions for future studies previously stated, researchers can assess the most effective use of data collected from the proposed medical surveillance and the wireless smart infusion pump system, to help identify and resolve medical device and medication errors that can lead to severe adverse events, as well as an understanding of their use in clinical practice. Awareness of limitations with current reporting systems in Canada and internationally can assist hospitals to improve their processes, policies, and procedures to increase and enhance error reporting among their staff members. Increased incident reporting also would provide regulators with a more complete description of medical device use and related incidents across jurisdictions; thus, allowing them to make informed decisions about their regulation.

Manufacturers

As per the telephone interview results, hospital staff are frustrated by their perceived lack of feedback from the manufacturers to investigate the cause of the device malfunction or incident. Likewise, if a medical device malfunction remains unresolved, clinicians will be inclined to use

an alternative technology or procedure for their patients. When manufacturers receive an error report, it would benefit them to collaborate with the hospital in the investigation of potential causes and resolutions for the error rather than respond with a standard comment that the error was caused by the user. This approach would help to safeguard a mutual trust between the manufacturer and the hospital that could lead to a decreased exposure to medical device problems for patients.

5.1 CONCLUSIONS

Medical devices enable effective diagnosis and treatment using less invasive techniques in many instances and improve health care delivery and patient outcomes. The medical device lifecycle incorporates development, regulatory approval, health technology assessment, and post-market surveillance phases. Despite their benefits, device-related incidents can lead to adverse events and deaths, recalls, and class-action lawsuits.

Research to date consists primarily of observational studies that describe incident rates, but there is insufficient evidence on the type and number of and reasons for device recalls. Post-market surveillance used to collect data on adverse events associated with the use of medical devices can help to address the risks of device-related adverse events that is facilitated by structures surveillance systems. There is a limited understanding on current hospital-based surveillance systems, as well as factors that influence incident recognition, reporting, and resolution. This information would help to enhance existing or develop new surveillance systems.

The results of our systematic review indicated that the four primary barriers to error reporting. They include fear of punishment or censor, uncertainty regarding what should be reported, uncertainty as to how incident reports will be used, and lack of time. Potential strategies to improve incident reporting included accessible electronic error reporting systems, training about what to report and how, and follow-up on the error reported. None of the selected studies described the resolution of incidents by health care professionals.

Responses from the telephone interviews of physicians and RNs revealed that the hospital staff's knowledge and experience, as well as the patient's clinical characteristics, and device performance were important factors in incident recognition. Proposed initiatives to improve medical device surveillance included education and training, organizational and professional cultures, and improved reporting systems and processes. A medical device surveillance framework informed by the results of the systematic review and telephone interviews was outlined.

An assessment of the CQI data collected from a wireless smart infusion pump system and analysis process can help to identify quality improvement opportunities on patient safety improvement at TOH. The findings of this doctoral thesis can contribute to the development of a medical device surveillance system that would help to improve health care delivery and patient safety in a health care institution.

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