DEVELOPMENT AND VALIDATION OF A SAFETY AUDIT FOR PEDIATRIC HEALTH CARE FACILITIES: FIRST STEPS TOWARD MAKING THE HOSPITAL A SAFER PLACE FOR CHILDREN

BY

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A Thesis
Submitted to the Faculty of Graduate Studies
in Partial Fulfillment of the Requirements
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DOCTOR OF PHILOSOPHY

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Development and Validation of a Safety Audit for Pediatric Health Care Facilities: First Steps Toward Making the Hospital a Safer Place for Children

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ABSTRACT

Hospitals are hazardous environments for young children. Children's products such as cribs and facility hazards such as electrical outlets, blind cords, and hot tap water can result in injury. While hospitals often provide safety advice regarding these hazards, there are no guidelines or methods to assess whether basic child safety standards are in place in hospitals.

The purpose of this study was to develop and validate a hospital safety audit instrument to identify injury hazards for pediatric patients and visitors, including observed hazards and safety policies. Content validation included an assessment of the evidence for each item, including injuries and hazards, legislation, standards, research, and safety recommendations, and review by an expert panel for content and clarity. Inter-rater reliability testing was conducted at four sites using concurrent observations by volunteer raters and an expert rater. The number and type of hazards identified were compared between raters, rater agreement was evaluated, and sensitivity and specificity analyses were conducted.

Reported pediatric injuries in the hospital setting were similar to serious childhood home injuries, in terms of mechanisms and patterns of injury. No child safety standards for health care facilities were identified; therefore home safety, child care safety, and facility standards formed the basis of the instrument's recommendations. Expert panel review concluded that none of the items met the criteria for deletion, and the instrument was rated as easy to use and comprehensive.

A significant number and range of hazards was identified at all sites. Rater agreement was 75% (kappa 0.50), with the highest agreement for children's products. The most sensitive items were hot water temperature, uncovered electrical outlets, and accessible cords and tubing.

The hospital safety audit instrument reflects current evidence regarding the epidemiology of hospital injuries and hazards and child safety standards. The instrument was applied in a range of pediatric health care settings by multiple raters and demonstrated satisfactory rater agreement and sensitivity. Following further refinement based on these results, future application of the instrument could contribute to a safer hospital environment for children.

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There are numerous individuals, organizations, and institutions that contributed to this study and deserve special acknowledgement.

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I would like to acknowledge the dedication and hard work of the IMPACT staff, who provided administrative support for the duration of the project, and particularly the two research assistants who contributed to development of the original hospital safety instrument, Gemma Briggs and Charlene Cook.

The administrative leadership of Children's Hospital has been supportive and proactive in addressing the issue of hospital safety, and facilitated the development, piloting, and validation of the audit. The Child Health Quality and Risk Management teams provided essential background documents and content expertise, particularly John Reimer, Leslie Galloway, and Gerarda Cronin. Numerous hospital staff were involved in piloting and inter-rater testing, and contributed valuable suggestions in terms of content and format.

The medical and administrative staff of the Medical Arts pediatric clinic participated in inter-rater testing and provided constructive feedback regarding application of the instrument in an outpatient pediatric setting.

I would also like to thank the hospital safety project team at the Children's Hospital of Eastern Ontario (CHEO) and Plan-it-Safe, particularly Shelley Reid, Morag Mackay, and Tracy Selst. The CHEO team is credited with stream-lining and condensing the original checklist and conducting initial pilot work at CHEO.

Experts in product safety and medical devices at Health Canada both in Winnipeg and Ottawa provided essential data and documents, and have been important partners in our longer-term work towards safer hospitals for children in Canada.

Finally, this work would not have been possible without the support of the Winnipeg Foundation, Children's Hospital Foundation, the Winnipeg Regional Health Authority, and Manitoba Health, who have provided core funding, salary support, and project funding.

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ABBREVIATIONS

AAP - American Academy of Pediatrics

ASTM – American Society for Testing and Materials

CAPHC – Canadian Association of Pediatric Healthcare Centres

CCHSA – Canadian Council on Health Services Accreditation

CPS – Canadian Paediatric Society

CPSC – Consumer Product Safety Commission (US)

ECRI – Emergency Care Research Institute

FDA – Food and Drug Administration

HIROC – Healthcare Insurance Reciprocal of Canada

ISO – International Standards Association

JCAHO – Joint Commission on Accreditation of Healthcare Organizations

MAUDE - Manufacturer and User Facility Device Experience (FDA database)

MDR – Medical Device Reporting (FDA database)

DEFINITIONS

adolescent	greater than or equal to 13 years of age and less than 18 years of age
adult	greater than or equal to 18 years of age
child	less than 13 years of age
child safety standard	a reference or guidance document related to the prevention of unintentional injury among children; includes research evidence, published guidelines, recommendations from expert groups or organizations, accreditation standards, product standards, laws, codes, and regulations
harm	physical injury and/or damage to health or property(1)
hazard	potential source of harm(1)
hospital safety	safety of the physical and/or socio-cultural environment of the hospital for patients, staff, and visitors
infant	less than one year of age
injury	transfer of physical energy (mechanical, thermal, chemical, radiation, electrical) to the host in an amount or at a rate that exceeds the body's threshold for tissue damage; injury may also occur as a result of the absence of energy (e.g. oxygen, heat)
patient safety	safety of the physical and/or socio-cultural environment of the hospital for patients; pertains to any health care setting
risk	probable rate of occurrence of a hazard causing harm and the degree of severity of the harm(1)
safety	freedom from unacceptable risk or harm(1)
unintentional injury	injury that does not result from an intentional act by the individual (i.e. self-inflicted, suicide) or another person or group (assault, abuse, homicide)

CHAPTER 1

INTRODUCTION

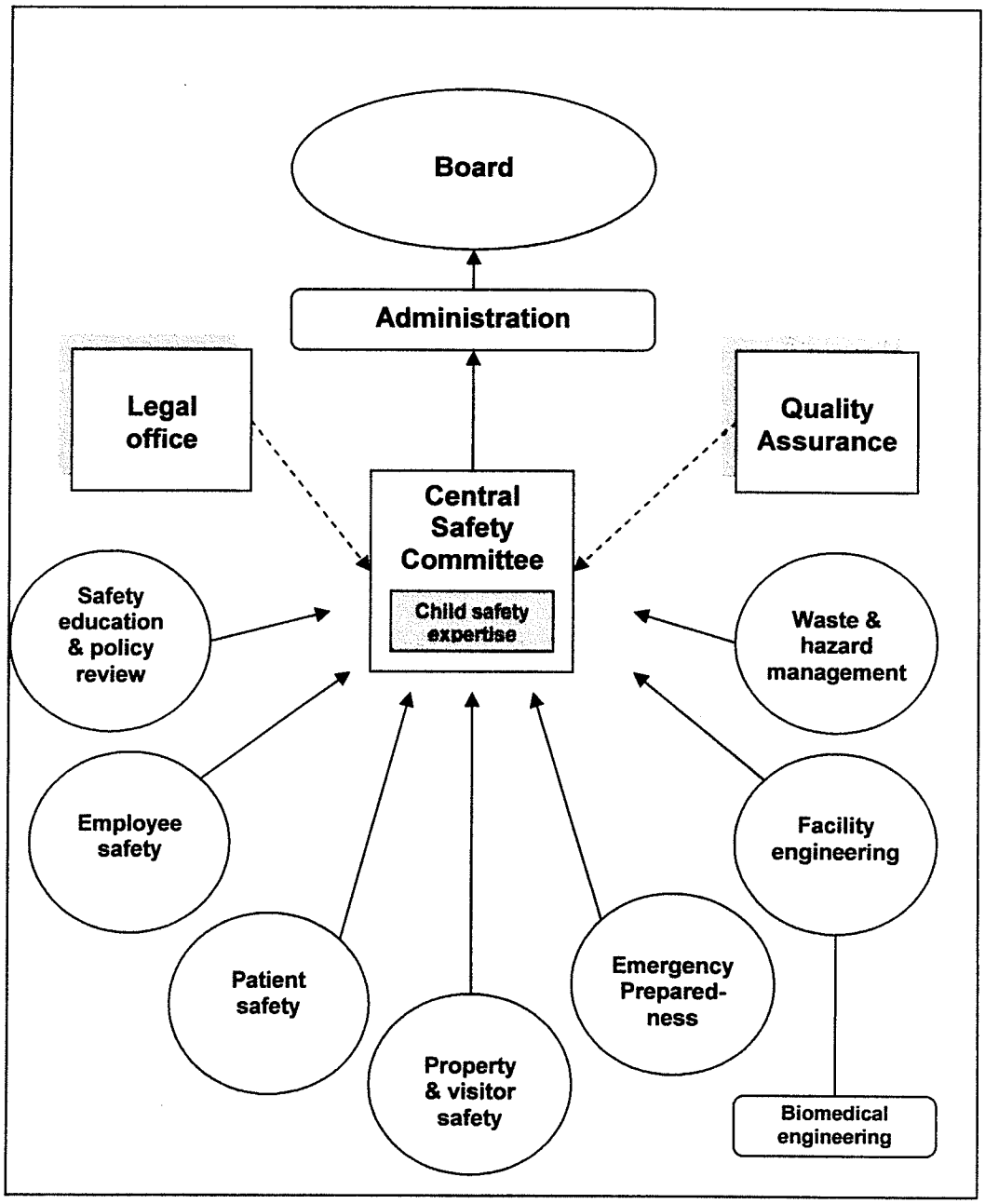
STATEMENT OF THE PROBLEM

Injuries are the leading cause of death and an important cause of morbidity for Canadian children.(2, 3) Patterns of "accidental" injury[1], such as falls, choking, suffocation, and burns, vary significantly by age group, and relate to children's varying exposure to potential hazards in their environment as they mature.(3, 4) Exposure and vulnerability to hazards in the home environment are greatest for infants and toddlers; the majority of fatal and non-fatal home injuries occur in this age group. As children mature and spend more time out of the home, they are more likely to be injured during play and recreational activities at school or in the community, or on the roads. The hospital is a physical environment not unlike the home, where infants and toddlers are exposed to a variety of well-described hazards; children's products, such as cribs and highchairs, toys and play equipment, and facility hazards such as electrical outlets, window covering cords, and hot tap water can result in injury to young pediatric patients.(3, 4) The majority of these injuries could be prevented by applying basic home safety principles to the hospital setting.

[1] Although the term *accident* is more familiar to most readers, the term *unintentional injury* is preferred in the injury prevention literature. Decades of research have shown that injuries are not random, acts of fate, or unpredictable events, contrary to the definition of *accident*. Unintentional injury is differentiated from intentional injury; the latter includes self-inflicted and inflicted injury such as child abuse and homicide.

Child safety standards and recommendations have been developed worldwide to prevent unintentional childhood injury related to children's products, toys, play equipment, furniture, and other hazards.(4-6) The dissemination of child safety information traditionally has been through the health care system, in particular through public health, health care professionals, and children's hospitals, many of which have developed child safety and injury prevention centres.(4, 7, 8) While hospitals are often in the position of providing home safety advice to parents, there are no established guidelines or methods to identify and address injury risks to children in the hospital setting. Although the "patient safety" movement aims to prevent accidental injury to patients, it is focused on preventing injuries related to medical errors. However, the new "culture of safety" encourages organizations and facilities to proactively identify and address risks that are classified as "systems" issues, including risks in the physical environment and related safety policies.(9, 10) Health care facilities have well developed structures and systems in place for the safety and security of the premises, equipment, staff, visitors, and patients. However safety issues related to the pediatric patient and visitor are not typically or routinely addressed. Child safety expertise should be well integrated in these systems (Figure 1.1). This study aims to advance this integration and complement emerging patient safety strategies by designing and validating a hospital safety assessment tool that can be used to identify and prevent potential unintentional injuries among pediatric patients and visitors.

Figure 1.1 Safety management in health care facilities: proposed integration of child safety expertise in existing safety management systems (adapted from ECRI)(11)



STUDY PURPOSE

The purpose of this study was to develop and validate a hospital safety audit instrument which identifies significant injury hazards to children and can be used to determine if a health care facility meets current child safety standards.

STUDY DEFINITIONS

Child safety standards were broadly defined, and included research evidence, published guidelines and recommendations, accreditation and safety standards, and laws and regulations. Relevant child safety standards related to the prevention of unintentional injuries to pediatric patients and visitors, and could pertain to facility design, operation and maintenance, policy, or product and general equipment safety (beds, cribs, furniture, toys and play equipment, strollers/carriages, playpens etc.). Medication safety, medical device safety, medical procedure safety, patient security, and other patient safety issues were not included. Further, occupational health and safety and general environmental safety of the hospital were not included.

RESEARCH QUESTIONS

In order to develop a hospital safety audit instrument, two critical questions must be answered: what are the hazards? and how can they be prevented (avoided or reduced)? Therefore the audit items were selected using two distinct bodies of evidence. The first body of evidence pertains to the actual and potential injury risks for children in the hospital setting, and includes injury epidemiology and the epidemiology of potential hazards. The second body of evidence pertains to the prevention of these injuries and reduction or avoidance of these hazards, and includes a wide variety of child safety standards, including research, published guidelines and recommendations, accreditation

and safety standards, and laws and regulations. An assessment of this evidence was the first step in content validation for the hospital safety instrument. Subsequently, a multi-disciplinary expert panel was assembled to critique the clarity and content of each item. Finally, the instrument was tested at four sites in order to evaluate inter-rater reliability and instrument sensitivity and specificity.

The first three research questions pertain to the development and validation of the audit instrument, and the fourth relates both to its validation and its performance:

1. What are the unintentional injury risks and potential injury hazards relevant to children in the hospital setting?
2. What child safety standards are applicable to the prevention of unintentional injuries and reduction or avoidance of injury hazards in the hospital setting?
3. What is the strength of evidence for inclusion of specific injuries, hazards, and recommendations (child safety standards) in a comprehensive pediatric-focused hospital safety audit instrument?
4. Is this instrument valid and reliable, and does it minimize respondent and administrative burden?

SIGNIFICANCE

There are a number of potential future applications of the instrument and its accompanying handbook. The development and validation process required a synthesis of existing best practices in childhood unintentional injury, product safety, and pediatric health care facility design. As such it may be used as a reference for child safety standards and recommendations. However, first and foremost, the instrument was designed to be used as an assessment tool to assist hospitals in creating a safer physical

environment for pediatric patients and visitors. Other potential applications include pediatric health care facility design, renovation, accreditation, maintenance, policy development, and quality improvement studies or programs.

ORGANIZATION OF THE DISSERTATION

This dissertation is organized as follows. Chapter 2 (History and Development of the Hospital Safety Instrument) provides an overview of the original hospital safety instrument and describes the development process and the pilot testing conducted prior to the study described in this dissertation.

Chapter 3 (Background) provides an overview of the contextual framework and summarizes the relevant literature. First the key contextual issues that pertain to childhood injury in the hospital setting are reviewed, including the patient safety movement, hospital risk management, accreditation standards, and the legal context. Then an overview of injury prevention theory is provided, and a framework for an approach to hospital safety is introduced. This is followed by a review of the literature pertaining to the epidemiology of childhood injury in the hospital setting, child safety standards, and a review of existing hospital safety assessment instruments.

Chapter 4 (Instrument Validation) summarizes the methods and results relating to content validation and instrument refinement. This includes an assessment of the type and strength of evidence for each item using injury and hazard data, legislation, standards, published literature, and expert recommendations, and assessment by an expert panel for content and clarity.

Chapter 5 (Instrument Performance) provides a summary of the methods and results relating to instrument performance, including inter-rater reliability, sensitivity and specificity, and respondent burden. First, the performance assessment methods are described, including testing procedures, sample selection, and data analysis. In the second section of the chapter, the instrument performance results are reported, including a comparison of the number and type of hazards identified by the expert rater and other raters, measures of rater agreement, instrument sensitivity and specificity, and respondent burden.

Chapter 6 (Discussion) presents the study's main findings, assumptions, limitations, and strengths. It then outlines a number of recommendations regarding further refinement and application of the instrument. This is followed by a discussion of policy implications related to the development and dissemination of a hospital safety audit instrument.

This dissertation also includes a series of tables and appendices, which are numbered according to their corresponding chapter. Appendices include the instrument and instrument handbook, participant information and consent forms, the expert panel data collection form, the inter-rater testing procedure, and supplementary tables of selected results.

CHAPTER 2

HISTORY AND DEVELOPMENT OF THE HOSPITAL SAFETY INSTRUMENT

This chapter provides an overview of the original hospital safety instrument and describes its history, development, and pilot testing which was conducted prior to the study described in this dissertation. My role in this pilot work was related to my position as the Medical Director of IMPACT, the injury prevention centre of Children's Hospital, which included offering consultation regarding injury hazards in the hospital, participating as a member of the bed and crib committee, and taking the role of project lead and principal investigator in the developmental work related to the hospital safety instrument.

INSTRUMENT OVERVIEW

The original hospital safety audit was a 135-item instrument designed to identify injury hazards for pediatric patients and visitors in the health care setting, including physical hazards and related safety policies and practices; 52 items pertained to general safety requirements and the remaining items indicated specific criteria for beds, cribs, and other pediatric equipment such as strollers, playpens, highchairs, and car seats. The instrument was designed to be administered by untrained hospital staff from any of a number of disciplines, including nursing, medicine, quality/risk management, injury prevention, and biomedical engineering. The instrument was based on existing home safety checklists, published injury and hazard data, and current safety recommendations. In the original instrument all items were pooled in a comprehensive checklist that was field-tested in two pediatric health care facilities; feedback on content and clarity of the items was

incorporated into a revised instrument. Each item was scored dichotomously (hazard is present or absent) or not applicable.

Instrument Development

The original version of the hospital safety audit was developed in response to a series of potentially significant unintentional injury incidents involving pediatric patients at a local health care facility. Investigation of these incidents revealed a number of potential hazards for children that could be addressed proactively through the application of existing home safety checklists, and eventually led to the development of a comprehensive audit instrument. The instrument development process is summarized here.

Due to the nature of the incidents under investigation, the initial focus of our efforts was crib and bed safety; this led to the development of a multidisciplinary Bed and Crib Committee, which analyzed the incidents and began a process to identify, evaluate, and select new pediatric hospital beds and cribs. This process included a formal investigation of several significant entrapment and injury incidents, a bed/crib standards review, a hospital-wide assessment of beds, stretchers, and cribs, a literature review, and a survey of Children's Hospitals across Canada regarding bed/crib safety issues and practices. British Columbia's Children's Hospital had developed detailed bed/crib product evaluation tools, based on current standards and known injury and hazard patterns; we revised these tools and applied them in the evaluation of hospital beds and cribs available in Canada. Manufacturers meeting minimum design and safety criteria were invited to demonstrate specific bed and crib models at a hospital-wide crib fair, where professionals and parents were asked to evaluate each model with respect to a number of criteria.

Members of the multidisciplinary Bed and Crib Committee performed a detailed formal evaluation of each product; this included assessments by professionals from Biomedical Engineering, Maintenance, Housekeeping, Infection Control, Nursing, Medicine, Pediatrics, Occupational and Environmental Medicine, and Injury Prevention. These efforts eventually led to a recommendation to purchase new cribs and beds with certain design and safety specifications.

The bed and crib safety initiatives stimulated a more comprehensive and proactive approach to hospital safety and provided a forum for discussion of other types of hazards for pediatric patients. These discussions led to the eventual development of a hospital safety checklist by the hospital-based injury prevention program (IMPACT). Banco's work formed the foundation of the first version of our global hospital safety checklist.(12) An environmental scan was conducted to identify existing home safety assessment checklists and guidance documents. Relevant databases were searched for literature and reports concerning the epidemiology of injuries to children in health care facilities and also of incidents/events which implicate potential hazards in the hospital environment. We also reviewed North American hospital safety standards and related recommendations published by organizations such as the Joint Commission on Accreditation of Healthcare Organizations and ECRI. Hazard assessment tools were identified and retrieved. Results of the literature review and environmental scan were incorporated into the development of the hospital safety checklist. The work of BC Children's Hospital and the Bed and Crib Committee contributed to the development of the detailed crib and bed items.

The checklist was initially piloted in 2002 by the Children's Hospital of Eastern Ontario (CHEO, Ottawa) and subsequently at our facility. Major modifications were suggested by the CHEO investigators, and the instrument was further revised into a more condensed and user-friendly format. In August 2003 the newly revised instrument was piloted in a formal unannounced audit of potential hospital hazards conducted by the investigator and a research assistant. All vacant rooms were examined in the Children's Hospital. This audit included the emergency department, clinic areas, patient rooms, washrooms, supply rooms, and play areas. A convenience sample of vacant rooms was used in order to minimize the disruption to normal hospital practices. The results of this audit were reported to hospital administration, along with hazard reduction recommendations. This pilot study provided initial evidence that significant hazards are accessible to children in most areas, and that most can be addressed with minimal resource implications.

The pilot work also demonstrated a need for a companion document to provide users with additional background material, given the intensity of content and the technical nature of many items. Discussions with hospital administration and unit managers regarding the audit results revealed a similar need for documentation of the type and strength of evidence for each item, which could be used when interpreting audit results. Therefore the final instrument developed as part of this study includes: (1) the instrument; and (2) an instrument handbook, which contains operational definitions and instructions, background and rationale, references, and the type and strength of evidence for each audit item.

This dissertation reflects the next steps in the refinement of the instrument, which must precede further application and dissemination to other facilities; these steps include

development of an instrument handbook, and formal assessments of the instrument's validity and its reliability. Following the completion of the work of this dissertation, these data should be considered by a group of facility users and content experts to determine the final content and format of the instrument as well as plans for dissemination and management, such as future review and updates.

CHAPTER 3

BACKGROUND

The purpose of this chapter is to provide a summary of the contextual and background theory which frames an approach to preventing childhood injury in the hospital setting. First, key contextual factors which influence the hospital's response to patient injuries and facility hazards are outlined. This is followed by a description of the injury prevention theory that forms the rationale and conceptual framework for the study methods. The final three sections provide summaries of the published literature regarding hospital injuries and hazards, child safety standards, and hazard surveillance methods used in hospitals and other settings.

CONTEXTUAL FRAMEWORK

A number of contextual factors influence the hospital's response to potential injury hazards and its approach to *hospital safety*, which is defined for the purposes of this study as the prevention of unintentional injuries to patients and visitors.[2] The hospital operates in a complex environment, with continuous challenges for decision-makers, who are faced with limited resources and countless requests for new programs and services. Hospital safety must compete with other compelling priorities of the organization; in doing so, the resources required for hazard surveillance and management must be balanced with opportunity costs and the potential costs of inaction. Both inaction and action have important ethical and legal implications.

[2] In this dissertation, hospital safety includes the safety of the facility, premises, and equipment, and excludes injuries related to the process of care, including medical errors and injuries related to medical equipment and procedures.

Creating a safe environment for patients and striving to "do no harm" reflects fundamental institutional values, but also demonstrates a pragmatic understanding of institutional liability and wise risk management. The international patient safety movement has stimulated many institutions to begin to address patient safety issues in a comprehensive and proactive manner, including establishing internal quality and patient safety programs which work together within existing hospital risk management structures to identify and address a variety of hazards to patients. An understanding of these contextual factors is critical to developing an approach to hospital safety; therefore this section of the chapter will provide an overview of patient safety, hospital risk management, hospital accreditation, and legal issues, and their application to the issue of hospital safety.

PATIENT SAFETY

The most prominent contextual factor of relevance to hospital safety is the emerging patient safety movement. The Institute of Medicine report *To Err is Human* proposed a comprehensive approach for reducing medical errors and improving patient safety in response to their analysis of errors in healthcare – "a leading cause of death and injury."(13) Baker and Norton summarized international patient safety data, experience, and actions, and proposed the formation of an expert panel and a national strategy to address the problem in Canada.(14, 15) The magnitude of the problem in Canada was recently estimated; every year there are 185,000 adverse events among hospitalized patients, with an adverse event rate of 7.5 per 100 hospital admissions.(16) A framework for the Canadian response is summarized in *Building a Safer System,* a 2002 report endorsed by 24 national groups including the Canadian Medical Association, the

Canadian Medical Protective Association, the Canadian Healthcare Association, and the Canadian Council on Health Services Accreditation. (10, 17) Position papers by these organizations affirm their commitment and roles in patient safety.(18, 19) A new National Patient Safety Institute has been established in order to facilitate system changes to create a "culture of safety"; legal and regulatory processes are to be improved, along with measurement and evaluation systems, and public and professional education strategies will be implemented. In the report's model of causation, five categories of adverse events were identified: medications, medical devices, nosocomial infections, medical interventions, and broader system issues. Hospital injuries are incorporated in the latter category, which includes factors in the physical environment and safety-related policies.

The focus thus far in patient safety movements worldwide has been on reducing errors in health care, by incorporating a "culture of safety" and addressing "systems" issues.(10, 13, 15, 19, 20) Unintentional injury is one facet of patient safety that has received little attention; however, fatal hospital falls have been identified as a "sentinel event" by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), and bed rail entrapment of adult patients has been identified as a serious risk management issue.(9, 21-38) The term patient safety was defined in *To Err is Human* as "freedom from accidental injury." Notably, this definition includes medical errors as well as unintentional injuries, and provides part of the contextual framework for addressing this problem at the organizational level. Patient safety in pediatrics is a relatively new area with little published research until recently, and minimal consideration of potential pediatric injury hazards in hospital settings.(39-43)

HOSPITAL RISK MANAGEMENT

Another contextual factor which is closely linked to hospital safety is institutional risk management. Health care risk management has it roots in litigation, due to the malpractice crisis in the United States, but has gradually evolved to a more comprehensive approach, which is closely linked to quality assurance and is more proactive and systems-based.(44-48) There is much overlap between the conceptual theories of patient safety, quality assurance, and hospital risk management.(13, 45-54) Risk management processes operationalize patient safety and quality management concepts to reduce risk to the organization, which includes ensuring safety for patients, staff, and visitors, and optimizing quality of care.(55) These processes represent the organizational strategy to reduce errors and their costs. Hospital risk management includes procedures to reduce exposure from *all* risks - policy, program, operational, financial, human resources, technological, health, and safety - and provides another part of the contextual framework for addressing hospital injuries. Although children face unique risks in hospital settings due to their physical and developmental immaturity, including risks related to medical care as well as the "environment of care", pediatric risk management has received little attention in hospital risk management texts and the research literature.(48, 56)

Risk management guidance documents, tools and checklists have been developed to assist organizations in identifying potential safety hazards in the healthcare environment.(57-61) Few documents make specific reference to children.(56, 62, 63) The Healthcare Insurance Reciprocal of Canada (HIROC) has developed self-appraisal modules based on actual claims data, literature, and research, for use in risk management

activities. These modules are used by organizations on a voluntary basis to identify potential risks in targetted areas. Each module reflects claims experience, inquest findings, legislation, and professional standards and guidelines. Specific unintentional injury content is restricted to falls prevention programs for older adults, the use of bed rails and restraints, and the potential for loose yarn or threads of infant mittens and booties to lead to the loss of a digit as a result of a ligature injury.(64) For the most part, however, hazards to pediatric patients and visitors have not been addressed by existing risk management programs in any comprehensive manner, and no comprehensive assessment methods have been developed.

HOSPITAL ACCREDITATION

Hospital accreditation standards may also influence an institution's response to the issue of hospital safety, as current standards specify minimum safety requirements for facilities. Accreditation is "a model of self-regulation, with an independent agency setting standards and procedures for the quality measurement of the services provided by organizations seeking to be accredited. Accreditation generally encompasses quality assurance and quality improvement processes, and also provides some form of credential (or awarding of accreditation) to indicate the organization has met the necessary requirements of the accrediting agency."(65) Accreditation in health care was developed in the United States by the founders of the JCAHO system, which formed the basis for most accreditation systems worldwide. This system includes a group of standards concerning the Environment of Care; these standards address emergency procedures, security, safety, medical equipment, hazardous materials, and waste management. These standards strongly emphasize but do not replace federal, state and local codes, laws, and

regulations. Although a number of checklists are provided, none address the pediatric patient and visitor.(66-69)

The Canadian Council on Health Services Accreditation (CCHSA) is a non-profit, non-governmental organization which operates the national voluntary accreditation program for health services organizations such as hospitals.(18) The CCHSA accreditation program monitors organizational practices, quality improvement, and risk management activities, all of which may contribute to patient and hospital safety. Compliance with hospital accreditation standards is voluntary in Canada, and there are no legal implications for noncompliance. However, when a facility claims to have accreditation status they assume a legal duty of care, and failure to meet these requirements can be used as evidence of negligence.(70)

The CCHSA has created Environment standards which roughly correspond to JCAHO's Environment of Care standards. They include vague provisions regarding the safety of equipment, supplies, medical devices, and space. "Compromises to safety" are to be reported, and processes for acting on information about hazards, defects, and recalls are to be in place. Laws, regulations, and codes must be met, and the physical space must be "routinely inspected" by "competent internal and external authorities." "Organizations are encouraged to have a proactive, preventative approach including policies and procedures on safety." The CCHSA Environment module notes that the physical environment should have furniture and equipment suitable for clients' ages and developmental levels, but provides no specific guidance in terms of the range or types of hazards of concern for the pediatric patient and visitor.(71)

THE LEGAL CONTEXT

A number of legal principles may influence an institution's approach to hospital safety. These include corporate liability, premises liability, and accountability.

Hospital Liability

Historically, the concept of charitable immunity protected hospitals from liability from the mid-nineteenth century until the mid-twentieth century.(72) Today, hospitals that operate as corporations have legal corporate responsibilities that include liability for the safety of the premises, including the grounds, buildings, and equipment.(54, 70, 73-76) At the organizational level, hospitals have a legal responsibility to uphold a reasonable standard of care. "The standard may be set by conduct prevailing in the community, state, or nation, or it may be a standard that is imposed by a statute, ordinance, regulation, safety order, or hospital rule."(44) If a standard is not maintained and is linked to an injury, the hospital may be liable for damages. This is termed corporate negligence and is a form of tort liability[3]. The hospital is responsible for its corporate decisions and actions, as well as the actions of its employees and persons associated with the hospital, if these acts result in unsafe conditions.

Direct duties of care as established by the courts that are relevant to hospital-related injuries include establishing systems for safe facility operation, including protecting patients from injuries, protecting patients from falls, and patient 'surveillance' for infants and children.(72) In the case of facilities treating pediatric patients, a higher duty of care

[3] A tort is defined as "a civil wrong for which the usual remedy is a judicial action for monetary damages". Negligence is one of many types of possible torts. Tort liability requires a demonstration of four elements: that there was a duty relationship; that there was an act or failure to act that was below the standard of care; the act or failure to act must be the proximate cause of injury or damage; and the act or failure to act must have caused injury or damage to the plaintiff.

is expected. The facility is responsible for protecting all patients from harm. In the case of pediatric patients, there is an increased vulnerability to hazards, and an inability to share the responsibility for personal safety, so the duty of care increases.(48)

Premises Liability

As an occupier/owner of premises, a hospital has duties to persons on its premises – this is termed *premises liability* or *occupiers' liability* and originated in English common law.(74, 77-82) Canadian hospitals have been the subject of numerous legal claims and in some cases have been held responsible for a variety of injuries sustained by visitors and patients, such as falls and malfunctioning equipment.(73) Slips and falls are a well recognized risk and represent the largest proportion of general liability claims for healthcare facilities. Claims related to falls in the healthcare setting include falls out of bed, from tables and stretchers, falls due to unassisted walking, falls due to slippery floors, and falls on hospital parking lots and grounds.(83, 84) Numerous other hazards exist in the health care environment. Staff are responsible for identifying potential risks in day-to-day operations, and hospitals are ultimately held responsible for injuries occurring on the premises.(54)

Corporate liability also dictates that the hospital owes a direct duty of care in maintaining safe premises. "Health institutions have a direct duty to take all reasonable steps to prevent suicide or injury, where such risks present themselves and are reasonably foreseeable."(72) The courts consider that a higher duty of care is owed to patients than to visitors (termed "invitees" by English law) and trespassers, as patients are on the premises related to a contract for hospital services. For patients, the hospital is responsible for any hazards on the premises that could have been discovered by

reasonable skill and care by anyone involved in the construction, repair or maintenance of the facility. In this case hospitals are also liable for the actions of its employees as well as independent contractors. In the case of visitors, the duty is to provide protection from *unusual dangers*, which might include wet wax on the floor, water in an unexpected location, or uneven pavement. Trespassers have the lowest duty of care. In terms of visiting and trespassing children, institutions "must take reasonable precautions to guard against the risk of injury to children if they knew or ought to have known that children might come onto the premises."(77)

Accountability

The principle of accountability has both legal and ethical aspects. The ethical principle of accountability is founded in the individual's right to know about and be protected from hazards. It is also related to the principle of fairness. The Institute of Medicine report *To Err is Human* states: "The public has the right to expect health care organizations to respond to evidence of safety hazards by taking whatever steps are necessary to make it difficult or impossible for a similar event to occur in the future."(13) Sharpe proposes that in the context of patient safety, both individual and institutional accountability should be considered. The responsibility for ensuring that no harm is done is traditionally associated with the clinician, however "a strong case can be made that this role responsibility should also be extended to those who have indirect but significant control over decision-making that affects patient welfare."(85) Sharpe also differentiates retrospective from prospective accountability; the former refers to responsibility for past errors, and is the basis of tort liability, while the latter refers to responsibility for future

events. The systems approach to error reduction is an example of prospective accountability; hazard surveillance would be a specific example.

INJURY PREVENTION FRAMEWORKS AND RELEVANT THEORY

THE HOST-AGENT-ENVIRONMENT MODEL OF CAUSATION

Models of injury causal mechanisms began with John Gordon (1949), who applied traditional epidemiologic methods to describe patterns of injury, demonstrating the nonrandomness of these events. This was a significant development, in the new understanding that injury events could be predicted through studying their circumstances and risk factors, as in other diseases; therefore injuries could be seen as preventable, rather than random "accidents". Gordon noted that the pathogenesis of injury, as in disease, requires the presence of a susceptible host, a predisposing environment, and an inciting agent.(86) The etiology of "accidents" involves study of the interrelationships and causal associations between the host, the agent, and the environment as they combine to produce an injury or event. Prevention strategies are designed to control the interactions between these factors, by reducing the susceptibility of the host, protecting the host from the physical properties of the agent, or modifying the environment (physical, social). These strategies can be multiple and address various points in the causal chain simultaneously. The hazard surveillance approach of this study reflects these principles. Hazard surveillance aims to protect the host from various agents (equipment and facility hazards), addresses both the physical environment and the socio-cultural environment (e.g. safety awareness, procedures, and policies), and uses multiple strategies throughout the causal chain, such as selection of safe equipment, monitoring and elimination of significant hazards, and implementation of safety-related policies.

Energy Transfer and the Definition of Injury

James Gibson (1961) introduced the notion of "energy interchange" to injury causal theory. He proposed that all injury events are attributable to five agents: the five forms of physical energy - kinetic, chemical, electrical, thermal, and radiation.(8, 87-89) Injury is still defined today as the transfer of physical energy to the host in amounts or at rates that exceed human tolerance and result in tissue damage.(8, 89) Haddon later added that the energy is carried by a vector (animate) or vehicle (inanimate) and that injury can occur due to the absence of vital elements (heat, oxygen).(90-93) All of these types of energy are potential hazards to pediatric patients and visitors. The most common type of energy implicated is mechanical energy, seen in falls from furniture, cribs, and play equipment, or down stairs. Chemical energy is responsible for injuries due to topical exposure and ingestion of toxic substances. Short circuits, tampering with electrical outlets or chewing electrical cords results in the transfer of electrical energy. Transfer of thermal energy results in burns, such as from spilled hot beverages, or access to hot tap water or hot radiators. Lack of oxygen is responsible for injury in drowning, choking and suffocation, entrapment, and asphyxia in closed spaces such as unventilated toy boxes.

Haddon's Matrix

In addition to his insights regarding energy transfer, Haddon divided injury events into three phases – pre-event, event, and post-event (corresponding to primary, secondary, and tertiary prevention) - and noted that host, agent, and environmental factors all contribute to the type and nature of energy transfer, the nature and severity of injury, and the degree of host repair and recovery. Haddon proposed a 3 x 4 matrix which combines the injury event temporal sequence (pre-event, event, and post-event factors) with Gordon's host-

agent-environment framework (Table 3.1). Haddon's matrix is the most widely used framework in injury control for the analysis and prevention of specific injuries. It provides a systematic method to identify and classify a broad range of potential risk factors and prevention and control strategies.(8, 94-96) The three rows identify factors of relevance before, during and after the injury event, while the four columns identify factors related to the host, the agent/vehicle, the physical environment and the socio-cultural environment.

Table 3.1 Haddon's matrix applied to bicycle injury

	Host	Agent/Vehicle	Physical Environment	Socio-cultural Environment
Pre-event	Experience Skill Physical size Alcohol use	Bicycle in good repair Functioning brakes Good bicycle fit	Road repair Weather conditions	Funds for bike paths Driver attitudes
Event	Helmet Fall technique	Handlebar design No sharp bicycle parts	Breakaway barriers Safe fall zone with no additional hazards	Helmet legislation
Post-event	Knows first aid		Cell phone Safe recovery zone	911 system ER care

Haddon's matrix can be used retrospectively to analyze contributing factors in the investigation of a specific event; it has been applied in this manner to forensic investigation of injuries. In this context it has been suggested as a useful framework to describe circumstances, determine the cause and manner of death, obtain evidence, and explain investigative results.(97) It has also been used as a framework to analyze medical failures in patient safety.(98) The framework can also be used prospectively to identify potential prevention strategies for a specific injury problem. Haddon's model demands a

multidisciplinary approach, as interventions aimed at changing behaviour (of the host) require behavioural science approaches, interventions to modify the agent or vehicle require engineering approaches, and interventions to improve the outcomes of injury, such as first aid, acute care and rehabilitation, require advances in the medical field.(99)

Haddon's model can be applied to all types of hospital injuries and hazards. For example, in a potential poisoning scenario where a two-year-old patient discovers a corrosive cleaner under the sink in his hospital room, the host is the child, the agent is the chemical energy which is carried by the vector (a bottle of cleaning solution), and the environment includes the physical environment (unlocked cupboard, unsupervised toddler) and the socio-cultural environment (regulations mandating child-resistant closures). A variety of host, agent, and environment factors may modify the likelihood of injury; these factors might be the host's age, development, and his ability to open the container, the amount and toxicity of the product in the container, the presence and effectiveness of a child-resistant closure, and the presence of an adult in the room.

In applying Haddon's matrix to the issue of hospital safety, pre-event factors should take highest priority, as their modification may prevent the injury event or incident from occurring. However event factors should not be neglected, as they also may prevent significant injury. For example, in the above poisoning scenario, an institutional policy of using non-toxic cleaning products in patient care areas is an event strategy but could eliminate toxic ingestions of this nature (the policy does not prevent patient access to the product, but if ingested, there would be no injury). Hazard surveillance is for the most part a primary prevention or pre-event strategy, as it aims to identify and correct or eliminate potential hazards in order to prevent injury incidents from occurring. However

certain "event" and "post-event" factors should also be included in surveillance, such as child-resistant closures (which may prevent ingestion if the container is accessed), and proper labelling of all medications and other potentially toxic products (which aids treatment in the case of ingestion).

With the development of Haddon's framework there was a greater emphasis on multiple and complex causes, including environmental, and later, community and social factors. The shift in focus from individual behaviour to patterns of risk applicable to other individuals and settings led to a more comprehensive "public health" approach to injury, as well as the necessary growth in the number and range of disciplines and sectors involved in injury control that are required to address all of Haddon's phases and factors.(100) This led to a move away from education as the main prevention strategy to an emphasis on modifying products and the environment to reduce the risk of injury. These "passive" approaches evade the difficult task of changing human behaviour. These "engineering" strategies include product and environmental design, construction and manufacturing improvements, and complementary standards and legislation.(101) The current paradigm maintains that all phases and factors identified by Haddon's framework should be considered, with a multipronged approach used which combines the most effective individual countermeasures, with a preference for passive strategies - those that protect the individual automatically, such as engineering and environmental modifications.(8, 95) Hazard surveillance reflects these fundamental principles, as the maintenance of safe facilities and equipment is primarily a passive approach and emphasizes engineering strategies.

CHILDHOOD INJURY IN THE HOSPITAL SETTING

This section of the chapter is critical to the development of the study instrument and relates to the first research question: what are the unintentional injury risks and potential injury hazards relevant to children in the hospital setting? This section provides an overview of the published hospital injury/hazard literature, while a more complete accounting of published and unpublished data sources is found in Chapter 4 and the instrument handbook itself.

OVERVIEW

The ISO's *Guide 50: Safety aspects – Guidelines for child safety* provides guidance to "develop products, structures, installations and services (collectively referred to as *products*) in a way in which the potential for injury to children can be minimized".(6) The guide suggests that a variety of sources be used to identify the potential for injury with a *product* (as defined by the ISO): injury statistics; specialized injury surveillance systems; research studies; investigations of case reports; and complaint data (e.g. consumer/user product-related incident reports, legal claims). The potential application of these sources to the study of pediatric hospital injury is summarized in this section of the chapter.

There are a number of methodologic challenges in summarizing the epidemiology of hospital injuries and hazards, including challenges related to classification and coding, and a variety of limitations of existing data sources. The context for this section of the chapter is the need to create a comprehensive accounting of hospital injuries and potential hazards - including specific mechanism, circumstances, contributing factors, populations

at risk, nature of injury, and outcome - in order to inform the development of a valid audit instrument. First, the limitations of current coding and classification systems and data sources are reviewed. Next, the epidemiologic methods used in patient safety are reviewed, as similar limitations exist in the study of patient safety and hospital safety. This is followed by a summary of the published literature on childhood injury and hazards in the hospital setting. Finally, given the limitations of the existing literature, patterns of injury in the home setting are described, in order to define the nature and severity of injuries that might occur in the hospital setting.

INJURY EPIDEMIOLOGY

Coding and Classification of Injuries

Injuries are classified according to intent: intentional (self-inflicted, assault), unintentional (accidental), and undetermined.(102, 103) Although intentional injuries may occur in the hospital setting, this study considered only unintentional injuries. The International Classification of Diseases (ICD) is the system used by most countries, including the US and Canada, to code mortality and hospitalization data for statistical purposes. For injuries, this system provides a code for the diagnosis, including the type of injury and body part affected (e.g. skull fracture), and a code for the external cause of injury (e.g. fall from playground equipment). Injuries can be coded for intent (e.g. unintentional) as well as mechanism of injury (e.g. fall), and for certain types of injuries, for place of occurrence and activity of the victim.(7, 8, 89, 102, 103) In the *Ninth Revision* (ICD-9) diagnosis codes are known as N-codes and external cause codes as E-codes, while in the *Tenth Revision* (ICD-10), the diagnosis codes begin with S and T, and

external cause codes begin with V, W, X, Y. Substantive changes will be seen with ICD-10, which was implemented in the US for mortality data for the data year 1999.(104)

Injuries occurring in health care facilities could be coded using the ICD system, however this will only occur if the incident is documented in the chart and coded as an injury by the health record analyst. An E-code would be assigned, in theory, as well as the location code which specifies a residential institution as the location of the injury event (E849.7 – includes children's home, dormitory, *hospital*, jail, old people's home, orphanage, prison, reform school). In order to ensure that the hospital was the place of injury rather than another type of residential institution, one could, for example, search for hospitalizations of children under the age of five with a non-injury admitting diagnosis, and then search for the subset with a secondary injury code and this location code. This approach is significantly limited due to lack of capture and coding of injury events occurring in health facilities, lack of temporal information, clinical detail, event circumstances, and intent, therefore primary data sources such as ICD-coded hospitalization discharge abstracts or mortality data cannot be used to study hospital safety.

Injury Variables

Numerous injury-related variables can be used for the purposes of injury surveillance. Useful data elements include items related to the patient (host), items related to the circumstances of injury (agent/environment), and items related to the injury outcome. Core data have been identified for surveillance systems collecting data on all types of injuries. The "minimum data set" includes age, gender, intent, activity when the injury occurred, place of occurrence, nature of injury, mechanism or cause of injury (e.g. traffic injury, drowning), and a unique identifier.(105) For the study of hospital injuries, a

detailed description of the injury event is essential, including the host activity, mechanism of injury, and product/equipment involved. These variables are not captured in administrative data sources, and children injured in the hospital setting are not captured by current injury surveillance systems, as the point of entry is either emergency department registration or trauma-related hospitalization.

Injury Data Sources

Routinely collected ICD-coded injury data that can be used to analyze injury patterns include data derived from death certificates and hospitalization records. These are summarized as vital statistics and hospitalization discharge data, and are typically available at the national, regional, and local level. These data are limited by the lack of event information and contributing factors. In the case of hospital injuries, the major limitation is the inability to identify the hospital as the location of the injury event.

Injury Surveillance Systems

Routinely collected data lack relevant event information as well as detailed information regarding the patient, associated contributing factors, and the injury itself. In response to these limitations, specially designed surveillance systems have been designed to collect in-depth information regarding specific types of injuries (e.g. motor vehicle-related injuries, spinal cord injuries), injury severity (e.g. trauma registries), and for specific populations (e.g. children) and settings (e.g. emergency department). The strength of these systems is that detailed event-related information is collected prospectively in addition to relevant injury-related information such as patient disposition, treatments and procedures, and follow-up care. These surveillance systems are designed and evaluated

using generally accepted epidemiologic principles.(106-108) None of these systems capture injuries occurring in the hospital setting.

PATIENT SAFETY EPIDEMIOLOGY

Given that the methodologic challenges are similar for studying the epidemiology of patient safety and hospital safety, the approaches established by patient safety researchers will be described in this section.

Researchers tend not to use routinely collected ICD-coded data for adverse events in medical care (e.g. E870-E879) for estimating the incidence and patterns of patient injuries, due to significant deficiencies and gaps in coding and reporting.(109-111) Hospital discharge data could be used, in theory, to "count" adverse events, however they are limited in a number of ways: they lack temporal information and clinical content; they lack the ability to measure severity of harm; they do not capture near misses; there is chronic under-reporting of E-codes; and the code may not be specific enough to indicate whether the injury was the result of an error, or whether it was self-inflicted, or unintentional. While some jurisdictions have mandated E-coding for hospitals, some states specifically exclude E870-E879 from reporting requirements.

Methods reported in the literature for collecting patient safety/medical error data include: retrospective review (e.g. morbidity/mortality committees, chart reviews); analysis of malpractice claims data; electronic surveillance, such as using large pharmacy databases (e.g. errors or patterns in medication orders, adverse drug events); and incident reporting. These sources and methods may be regarded as complementary. The incidence and patterns of adverse events in hospitalized patients has been documented by large chart

reviews (15-30,000 charts).(112-115) As this in-depth method is not practical for ongoing surveillance, most institutions use internal incident reporting systems to count and describe patient injuries.

Health care risk management processes require and often mandate reporting of errors and other incidents in order to identify hazards and errors to prevent future occurrences, and also to monitor progress and evaluate success.(46, 55) Incident reporting is the most commonly used method for patient safety research and practice. There are several national patient safety incident reporting systems: JCAHO maintains a voluntary Sentinel Event database (reports from institutions, the public, the media); the Australian Incident Monitoring Study (AIMS) is an anonymous and voluntary system which tracks near misses and adverse events in anesthesia; England (NHS) will implement a national adverse events reporting system in 2004.(116, 117)

Incident reporting systems count three types of events: adverse events, no harm events, and near misses. Such systems may collect data regarding any or all of these types of events. Their goal is to gather qualitative data in order to analyze incidents rather than to "count" incidents, although they are also used to describe prevalence and patterns of errors. Incident reporting is relatively inexpensive, and is valuable in that it includes incidents which could or did lead to an undesirable outcome, rather than counting only events which did lead to injury. Incidents should be reported by the personnel directly involved in the incident, which facilitates a more detailed analysis of the event.

There are a number of limitations of incident reporting systems in terms of their research and epidemiologic application. The main limitations are incomplete ascertainment of

cases, biases and barriers to reporting, and small numbers of significant incidents.(118-121) Incomplete reporting is the most noteworthy of these concerns. Significant errors or hazards that do not result in injury may not be documented (e.g. near miss, no harm events). Also, not all adverse events resulting in injury will be documented. Incident reporting systems are usually voluntary, although they are mandated in some jurisdictions. Underreporting is "endemic"; incident reports likely underestimate the numerator, and the denominator is unknown. There is no standardization of methods of data collection, coding, or analysis; different systems count or include various combinations of adverse events, near miss and no harm events. However a classification system has been developed and validated, which also allows cross-mapping to ICD-10.(122)

Biases and barriers to reporting can be significant.(118, 121, 123) The major reporting bias is termed hindsight bias, which is bias related to the fact that things that were not seen or understood at the time of the accident seem obvious in retrospect.(13) Liability has been cited as a major barrier to reporting, along with guilt, fear of punishment, and fear of professional censure.(15, 124, 125) Medico-legal risk is lower for reporting of no harm and near miss events than for adverse events, and in some jurisdictions reporters are protected from legal discovery.(123)

While voluntary incident reporting systems are an important component of local and regional risk management and patient safety activities, their application in research studies and their role in defining the epidemiology of patient injury are limited. Prospective surveillance and in-depth large chart reviews remain the main sources of data, supplemented by analyses of claims data.

HOSPITAL SAFETY EPIDEMIOLOGY

This section of the literature review includes published reports of injuries to pediatric patients and visitors occurring on hospital premises; it is limited to publications which cite original pediatric data. Publications which describe only adult patients are excluded from this review.

Injury incidents involve over 1% of hospitalized children, with most injuries occurring in children under six years of age.(126-129) The ratio of accident report forms to pediatric inpatients has been reported as 1:182 for infants less than one year of age and 1:83 for children 1-10 years of age, with ratios as high as 1:2 for institutionalized children. (126, 127)Pediatric inpatient falls have been reported as frequently as 1 per 118 admissions.(129) Falls account for 35-40% of injury incidents, however serious injuries, such as fractures, are infrequent outcomes.(12, 127-130) Children with bleeding disorders or bone pathology and are more likely to be injured due to falls.(128, 129) Despite the benign nature of most falls hospitals have been advised to use crib security tops (bubble-tops) for infants who can crawl.(131) One US hospital was found negligent for failing to do so in a case where a child with viral encephalitis crawled out of the crib and suffered a brain injury.(132)

Although most incidents are minor, some children are at risk for life-threatening hazards, mostly involving beds or cribs. Bed-related deaths have occurred due to entrapment between the mattress and the side rails or frame.(23, 26) Entrapment has also been reported for a special care bed, resulting in profound asphyxia.(133) Other bed-related deaths include five cases of children crushed in electric pedestal-style beds by activating the walk-away control.(134-136) Hospital crib-related deaths include two entrapments

between the security top and side rail (137) and one near-miss entrapment between the mattress and the rail.(138) Crib entrapment is typically due to unsafe design (e.g. rail spacing wide than the recommended standard) or poor mattress fit.(131, 138)

The remaining fatalities reported in the literature were due to choking, strangulation, or electrocution. Fatal and near-fatal aspiration has been reported for medication syringe caps (139) and for make-shift pacifiers using bottle nipples.(140) Three children strangulated on intravenous tubing,(141) and one near-miss strangulation was related to an apnea monitor lead.(142) Numerous cases of burns and electrocution due to connecting electrode lead wires and other medical devices into energized line cords or extension cords prompted warnings to hospitals in 1987 and 1993, including a recommendation to consider using childproof outlet caps.(143-146) Although no fatalities have been reported, several warnings have been issued regarding sparking toys causing fires in patients receiving oxygen.(147-149)

Childhood Injury at Home and in the Hospital: A Parallel

Given the limited literature reporting childhood injury and hazards in the hospital setting, the significant limitations of using primary injury data sources and incident reporting systems, and the similarity between risks experienced by young children in the home and hospital environments, the epidemiology of childhood injury is briefly reviewed here, in order to define major patterns of injury and hazardous products that may be relevant in the hospital setting.

Childhood injuries are a very common reason for seeking medical care. Canadian cross-sectional and longitudinal surveys have documented that 10% of children have

experienced at least one injury during the previous year.(150) Similar US studies document that one-fifth to one-quarter of children experience an injury receiving medical attention every year.(151, 152) Patterns of injury vary distinctly by age group, with infants, toddlers, young children, and older children experiencing different external causes of injury.(3, 4) These patterns reflect a number of physical, developmental, social, and environmental factors, which ultimately determine children's exposure to potential injury hazards.(6)

An examination of Canadian injury data (Figure 3.1, Table 3.2) demonstrates that the leading causes of unintentional injury death for infants less than one year of age are choking and suffocation, motor vehicle traffic collisions, and drowning.(2, 3) The leading causes of unintentional injury hospitalization are falls, choking/suffocation, burns, and poisoning.(2, 3) In a large (n = 23,173) population-based study of fatal and hospitalized pediatric injuries among children 0-3 years of age which reported external cause of injury in three-month intervals, injury patterns were similar; in this study the leading causes of death and hospitalization (combined) were falls (29%), poisoning (14%), transportation (12%), foreign body (9%), scalds (5%), and drowning (5%). A population-based study in Ontario demonstrated that falls are responsible for the majority of emergency department visits for injury in this age group, followed by ingestions and burns.(153) These are the most detailed data available for emergency department admissions for injury among Canadian children, and are depicted in Figure 3.1 and Table 3.2. Note that the subsequent figure and table (Figure 3.2, Table 3.3) utilize US emergency department data, due to the lack of detailed emergency department data for Canadian children of this age group.

Infants under the age of one year are at higher risk than any other age group for choking on food and other objects, suffocation on soft objects and plastic bags, and hanging by clothing and cords, particularly in cribs.(3, 154, 155) The increased risk of choking, suffocation, and strangulation relates to physical and cognitive immaturity and mouthing behaviour, as well as exaggerated exposure to related risks in the sleep environment, such as beds and cribs, soft bedding, and unsafe sleep locations.(3, 154-161) These sleep environment factors are of key importance in the hospital, where children spend many hours, often unattended, in cribs and beds.

Figure 3.1 Fatal and nonfatal injuries among children < 1 year of age: leading injury mechanisms (for data see Table 3.2)

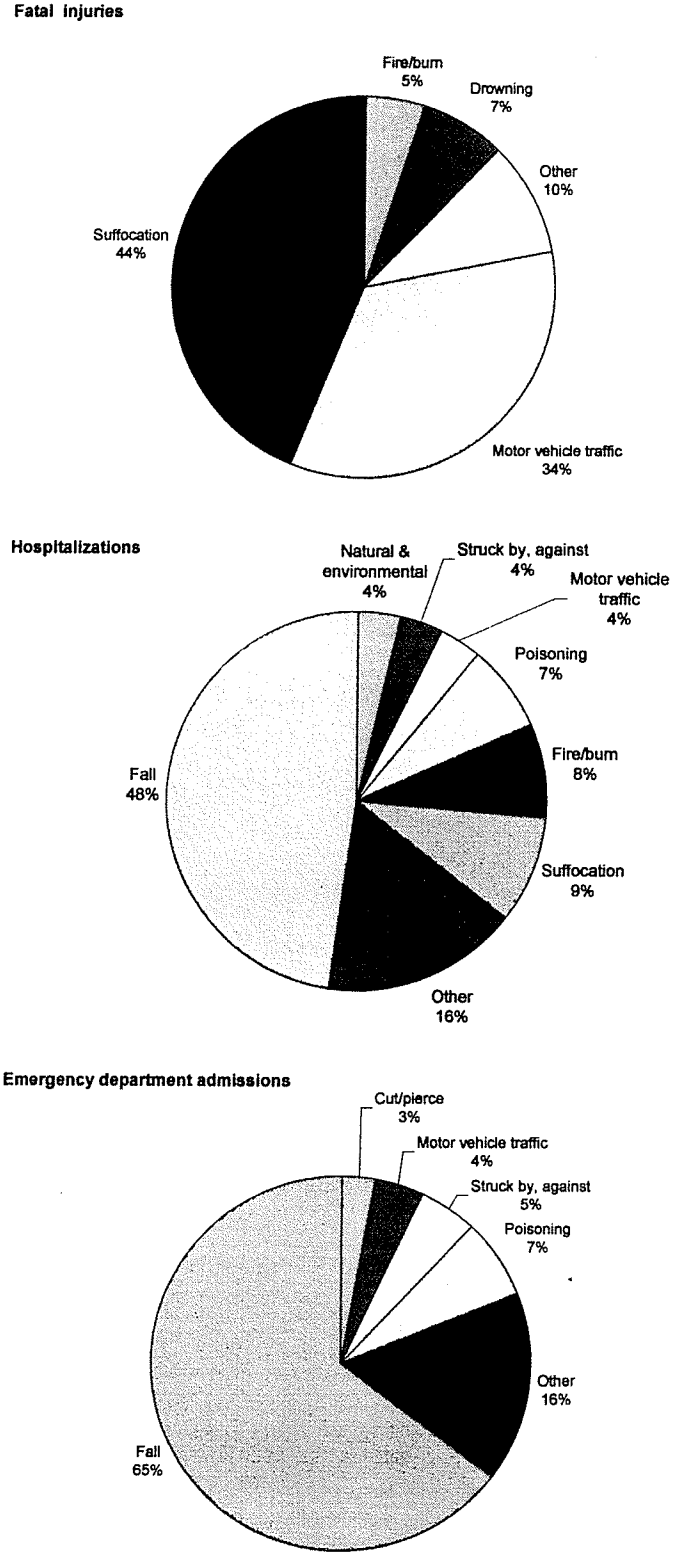


Table 3.2 Fatal and nonfatal injuries among children < 1 year of age: leading injury mechanisms

Circumstance	Fatal Injuries[4]			Hospitalized Injuries[5]			Injuries admitted to the ED[6]		
	Rank	n	%	Rank	n	%	Rank	n	%
Fall				1	810	48%	1	605	61%
Suffocation	1	18	44%	2	155	9%			
Choking on food		*5*	*12%*		*68*	*4%*			
Choking on non-food object		*4*	*10%*		*82*	*5%*			
Suffocation by plastic bag		*1*	*2%*						
Suffocation in bed or cradle		*5*	*12%*		*3*	*0%*			
Hanging in bed or cradle		*2*	*5%*		*1*	*0%*			
Fire/burn		2	5%	3	140	8%			
Fire/flame		*2*	*5%*		*13*	*1%*			
Conflagration-private home		*2*	*5%*		*7*	*0%*			
Ignition of clothing					*1*	*0%*			
Hot object/scald					*127*	*8%*	3	56	6%
Poisoning				4	126	7%	2	65	7%
Medication					*57*	*3%*			
Alcohol					*5*	*0%*			
Motor vehicle exhaust					*1*	*0%*			
Other carbon monoxide					*5*	*0%*			
Motor vehicle traffic	2	14	34%	5	63	4%	5	39	4%
Natural/environmental					60	4%			
Struck by, against					60	4%	4	47	5%
Drowning	3	3	7%		10	1%			
Drowning in bathtub		*2*	*5%*		*5*	*0%*			
Cut/pierce					10	1%	6	26	3%
Transport, other					7	0%			
Overexertion					5	0%			
Machinery					1	0%			
Other specified, classifiable		2	5%		112	7%			
Other specified, NEC					15	1%		152	15%
Unspecified		2	5%		119	7%			
Total		41	100%		1693	100%		990	100%

[4] Canada, 1997, both sexes, age < 1 year. (2)
[5] Canada, 1996-7 fiscal year, both sexes, age < 1 year. (2)
[6] ED = emergency department. Kingston CHIRPP site (includes Frontenac, Lennox, Addington counties), 1994-2000, both sexes, age < 12 months. "Ingested substance" was classified as poisoning, "falling object" was classified as struck by/against, and "sharp object" was classified as cut/pierce for the purposes of this table, in order to compare to the national data categories (E-codes).(153)

Drowning, falls, poisoning, and burns account for the remaining significant injuries in this age group. Drowning is the third leading cause of injury death for infants, and typically occurs in bathtubs. Bathtub drowning occurs almost exclusively in children between 6 and 11 months of age, and can be entirely prevented by restricting access to bathrooms and supervising bathing children at all times.(155) Falls are an important cause of injury hospitalization and emergency department utilization; in this age group, falls from furniture, down stairs, falls in car seats, and falls in infant walkers are commonly reported.(153-155) Falls from furniture peak at 6-8 months and 15-17 months, and falls down stairs peak at 6-8 months and 9-11 months.(153-155) Poisoning rates rapidly increase by 9 months of age, as infants gain gross motor skills, increased mobility, and improved fine motor dexterity.(154, 155) The majority of significant poisoning incidents in this age group implicate medications, an obvious risk in the hospital setting. Burns are an important cause of morbidity for this age group, and typically result from hot liquids, including beverages and hot tap water.(3, 153-155)

Due to their increased mobility, cognitive and physical immaturity, and desire to explore the environment, toddlers are at risk from serious falls, drowning, poisoning, and fires and burns. Similarly, in the hospital environment toddlers' mobility implicates a different set of risks as compared to infants, including exposure to medications, small parts (choking hazards), cleaning agents, and fall hazards (stairs, balconies, windows, play equipment).

The leading causes of unintentional injury death for toddlers are motor vehicle collisions, drowning, fires, and suffocation (Figure 3.2, Table 3.3).(2, 3) The leading causes of unintentional injury hospitalization are falls, poisoning, and fires/burns.(2, 3) Falls are also the leading cause of emergency department visits for injuries in this age group, followed by "struck by/against" and natural/environmental causes (e.g. bites, stings).(162)

Drowning is the second leading cause of unintentional injury death for children 1-4 years of age, following motor vehicle collisions.(2, 3) Drowning rates peak in the second year of life, with bathtub drowning an important cause until 18 months of age.(155) Choking and suffocation are the third leading cause of unintentional injury death for this age group.(2, 3) The incidence of foreign body ingestion/aspiration peaks at 9-11 months of age, and declines thereafter. While the majority of choking and suffocation deaths occur in the first year of life, the majority of hospitalizations occur in the first three years, with an elevated risk of hospitalization persisting until six years of age.(156, 157) Falls are the leading cause of nonfatal injury for toddlers. Falls peak in the second year of life, including falls from furniture and buildings, whereas falls from play equipment begin to increase after 36 months of age.(154, 155) Poisoning also peaks in the second year of life, and rates remain elevated until 5 years of age.(154, 155) Scalds peak in the second year of life, and the risk of scalds remains elevated until after three years of age.(154, 155)

Figure 3.2 Fatal and nonfatal injuries among children 1-4 years of age: leading injury mechanisms (for data see Table 3.3)

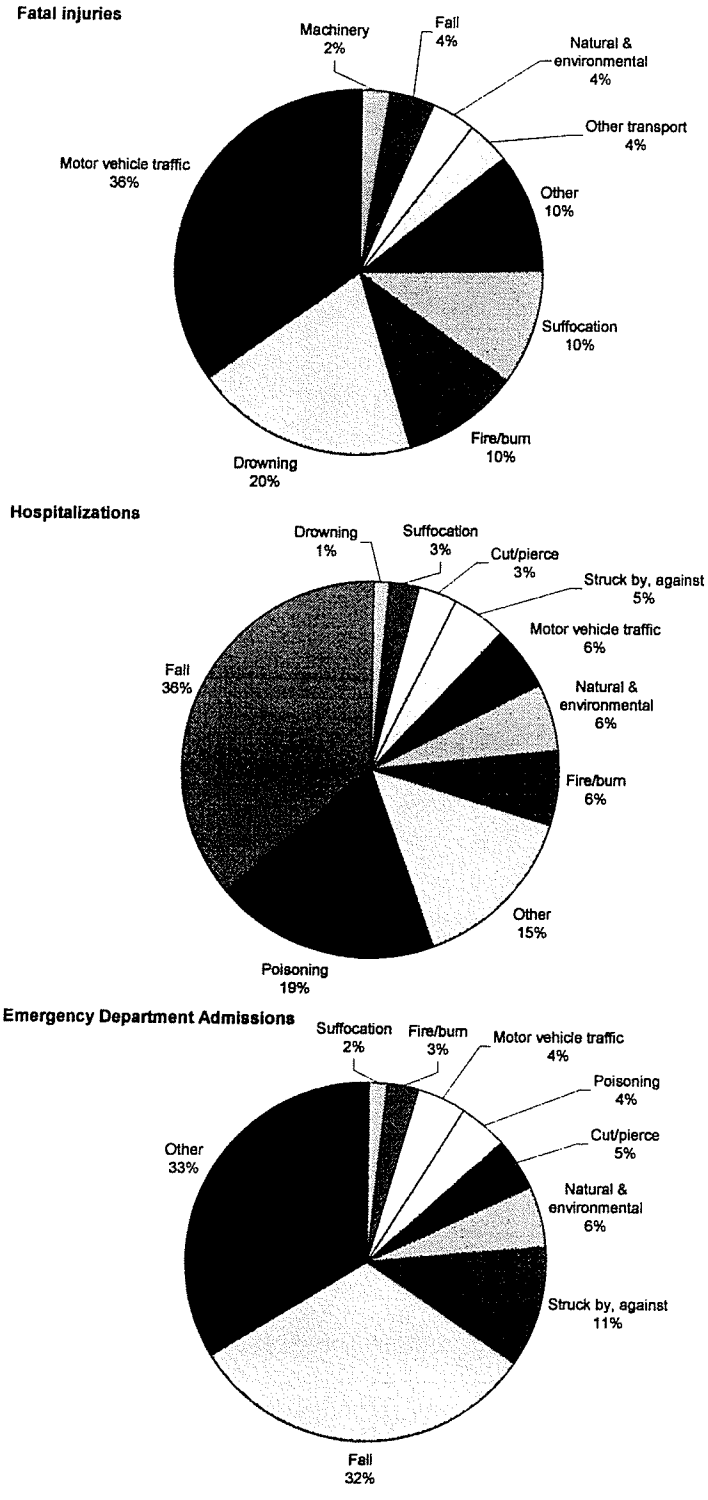


Table 3.3 Fatal and nonfatal injuries among children 1-4 years of age: leading injury mechanisms

Circumstance	Fatal Injuries[7]			Hospitalized Injuries[8]			Injuries admitted to the ED[9]		
	Rank	n	%	Rank	n	%	Rank	n	%
Fall	4	5	4%	1	3011	36%	1	1109	32%
Suffocation	3	13	10%	8	218	3%	8	54	2%
Choking on food		*4*	*3%*		*111*	*1%*			
Choking on non-food object		*3*	*2%*		*94*	*1%*			
Suffocation by plastic bag									
Suffocation in bed or cradle		*1*	*1%*		*1*				
Hanging in bed or cradle		*4*	*3%*		*11*				
Fire/burn	3	13	10%	3	527	6%	7	103	3%
Fire/flame		*13*	*10%*		*86*	*1%*			
Conflagration-private home		*12*	*10%*		*33*	-			
Ignition of clothing		*1*	*1%*		*8*	-			
Hot object/scald					*441*	*5%*			
Poisoning		2	2%	2	1565	19%	5	154	4%
Medication		*1*	*1%*		*1083*	*13%*			
Alcohol					*57*	-			
Motor vehicle exhaust					*2*	-			
Other carbon monoxide					*9*	-			
Motor vehicle traffic	1	44	35%	5	459	6%	6	149	4%
Natural/environmental	4	5	4%	4	480	6%	3	193	6%
Struck by, against				6	409	5%	2	376	11%
Drowning	2	25	20%	9	112	1%			
Drowning in bathtub		*3*	*2%*		*19*	-			
Cut/pierce				7	257	3%	4	166	5%
Transport, other	4	5	4%	10	102	1%			
Overexertion							9	49	1%
Machinery	5	3	2%		57	1%			
Other specified and classifiable		2	2%		765	9%		356	10%
Other specified, NEC		1	1%		52	1%		26	1%
Unspecified		3	2%		243	3%		745	21%
Total		124	100%		8329	100%		3499	100%

[7] Canada, 1997, both sexes, age 1-4 years. (2)
[8] Canada, 1996-7 fiscal year, both sexes, age 1-4 years. (2)
[9] United States, 1992-1995, both sexes, age < 5 years. (162)

Older children become more adept at avoiding some of these risks typically associated with the home, and they begin to encounter new risks on the road and in the community. Pedestrian and play equipment injuries peak in the young school-aged child (5-9 years of age). Later, motor vehicle occupant injuries take the lead.(3, 4) However these injuries are not universally relevant in the hospital environment, and will not be further considered. While hospitalized children may be transported to other facilities for treatment or investigations, they are typically transported by stretcher service or ambulance. Safety recommendations for these types of transport are beyond the scope of the hospital safety instrument described here.

Numerous parallels can be drawn between home and hospital injuries and hazards and their prevention (Table 3.4). The serious injuries seen in infants and toddlers in the home, such as choking, suffocation, drowning, falls, burns, and poisoning, all may occur in the hospital, as the host, agent, and environment characteristics are similar. The children at greatest risk for serious injury in the hospital are similar to those most at risk for these types of injuries in the home - infants and toddlers less than 5 years of age.(2-4) Hospitalized children may be more likely to have motor, cognitive, and other impairments that could increase their risk of injury and impair their ability to "escape" hazards once encountered (such as soft bedding, hot water). However, hospitalized children may also be less mobile, given their illness or reason for hospitalization, affording some protection from hazards. The furniture, products, and equipment implicated in these injuries are similar for both settings; in fact most hospitals purchase standard commercially available children's products, such as playpens, high chairs, carriages, and toys. Therefore safety standards and recommendations relating to these

products are relevant to hospitals. Although hospital beds and cribs differ significantly from residential beds and cribs, guidelines for injury prevention, such as rail spacing, apply to both settings. Similarly, facility features, such as windows that open, window covering cords, stairs, and electrical outlets, are hazards common to the home and the hospital, and prevention guidelines are applicable to both settings.

Table 3.4 Hazards and risk factors for injury in the home and hospital settings compared

Home and Hospital	Hospital
Host Factors	
Age, physical size, developmental factors contributing to risk of injury	Illness or injury, acute/chronic health problems: more limited activity and mobility
	Host vulnerabilities more likely: bone fragility, bleeding disorders, gait/balance disturbance, airway protection, etc.
Agent Factors	
Children's toys, play equipment and play structures, playpens, high chairs, swings, infant seats, car seats (manufacturers, models identical for home and hospital)	Hospital equipment (monitors, intravenous tubing, oxygen tubing, oxygen, etc.)
Cribs (hospital and residential cribs must meet the same basic federal standards)	Cribs may have security tops, mattress position may be altered, creating gaps
Crib hazards (soft bedding, mattress fit, etc.)	Infants more likely to be placed in non-supine positions in the crib (side-lying, prone)
Some youth beds have guard rails	Hospital beds have rails (entrapment risk)
	Electric hospital beds
Fall heights similar (e.g. from furniture, beds, cribs)	Fall surfaces more likely to be non-resilient (commercial-style carpet, linoleum, over concrete sub-floors)
	Access to stairs more likely prevented (fire doors, security)
Uncovered electrical outlets	Greater number of outlets accessible, however more likely to be tamper-proof
Hot tap water (sinks, bath tubs)	Patients are more likely to be supervised in bathroom/bathtub than children at home
Window and blind cords	Windows generally non-operable, falls through windows/screens unlikely
Standing water (buckets, pails, toilets)	Commercial-style fire detection and response (staff training, sprinkler systems, fire doors, fire-resistant materials, automatic sensors/communication)
	Medications more toxic, however storage more likely secure. Cleaning agents more likely toxic.
	Fewer house plants.
Environment Factors	
Children unsupervised for periods of time at sleep and play	Lower supervision ratio (nurse:patient)
	Multiple caregivers (e.g. lowering crib rails)
	Private hospital rooms, modern ward configuration: visual supervision often not possible, auditory supervision difficult
	Strict *No smoking* policies

CHILD SAFETY STANDARDS

This section of the chapter is fundamental to the development of the study instrument, and relates to the second research question: what child safety standards are applicable to the prevention of unintentional injuries and the reduction or avoidance of hazards in the hospital setting? The audit instrument was designed to reflect current child safety standards, which were broadly defined for the purposes of this study, and include laws and regulations; accreditation, facility, and product safety standards; research evidence; and published guidelines and recommendations. An overview of relevant child safety standards in the published literature is presented in this section, while a more complete accounting of published and unpublished data is found in Chapter 4 and the instrument handbook itself.

LEGISLATION

Many laws and regulations have been implemented to protect children from injury. Relevant injury-related legislation in the Canadian context has been summarized in *Canadian Child Health Law: Health Rights and Risks of Children.*(163) The most important types of childhood injury that may occur in the hospital environment include falls, poisoning, drowning, burns, and choking and suffocation. The *Food and Drugs Act* (e.g. drug labelling and child-resistant packaging), the *Hazardous Products Act* (e.g. cribs, playpens, toys), the *National Building Code* (e.g. balcony and stair guarding), and the *National Plumbing Code* (e.g. hot water temperature) are the main legislative and regulatory strategies of importance to these injury issues.(164-166) Hospital cribs and beds are considered medical devices, and as such are regulated under the *Food and Drugs Act.*(167) Provincial legislation that relates to hospital safety includes hospital acts,

public health acts, and occupational health and safety acts, however these are beyond the scope of this study as they do not pertain to pediatric injury risks.(70)

STANDARDS

Numerous types of standards may have relevance to the prevention of pediatric hospital injuries. These may include accreditation standards, facility guidelines and standards, and product standards.

Accreditation standards issued by JCAHO and CCHSA both refer to the safety of the physical environment, as noted in a previous section of this chapter (p.15), but these standards make no reference to specific pediatric-related hazards.

Facility standards have been published for US hospitals, however these are designed for general hospitals.(168) Florida drafted an inpatient pediatric standard for hospitals, which includes a few safety items, however this draft was never implemented due to lack of jurisdiction.(169) Facility design guidelines which emphasize safety for children have been published; these typically address general buildings or child-care facilities rather than health care facilities.(170-174) However, several of these sources offer extensive checklists oriented to child-safe facility design.(170, 171, 174) *Caring for our Children: National Health and Safety Performance Standards* provides an excellent summary of US facility, equipment, and product safety standards and recommendations relevant to child care.(174) Many of these have direct relevance to pediatric health care facilities. A published text summarizing the literature on design guidelines for child health care facilities contains surprisingly little reference to safety issues, although a few recommendations are provided.(175) Pediatric safety guidelines for health care facilities

have also been published by the American Academy of Pediatrics (62) and the American Institute of Architects, but surprisingly few recommendations are provided.(168)

Product and equipment standards of relevance here include the Canadian Standards Association playspaces and equipment standard,(176) and a variety of ASTM and Consumer Product Safety Commission standards which apply to children's products (e.g. strollers, baby gates, play yards, baby walkers, bunk beds, high chairs).(4, 174) Although the latter are US standards, where there is no Canadian equivalent these are useful guidance documents. As noted previously, the ISO's *Guide 50* is a useful document for setting the framework and approach for this issue and is intended to provide guidance for standards development for children's products.(6)

RESEARCH

There is a growing number of summaries of research evidence that relate to pediatric unintentional injury and provide prevention recommendations. The *Canadian Guide to Clinical Preventive Health Care* and the *Clinician's Handbook of Preventive Services* both provide summaries of recommendations based on research evidence.(177, 178) Several recent systematic reviews on pediatric injuries also provide summaries of research evidence that provide prevention recommendations.(179-184) The research literature was further explored for relevant child safety standards during the content validation process and evidence review; these procedures and results are presented in Chapter 4.

Guidelines and Recommendations

Numerous injury prevention guidelines and recommendations have been published relating to each defined injury and hazard. These are not summarized here as they were the subject of the literature review and environmental scan and are summarized in Chapter 4.

HOSPITAL HAZARD SURVEILLANCE

Hospital Safety Assessment Instruments

Three published studies have documented the development and/or application of a hospital safety assessment instrument, also termed environmental audit. Two of these studies examined methods to study general safety hazards relevant to pediatric patients.(12, 185) Banco reported an unannounced "inspection survey" of hazards on three pediatric inpatient services in general hospitals, including patient rooms, hallways, and waiting areas.(12) The survey was based on two existing home safety checklists, and included assessment of bathrooms, radiators, electrical devices, windows, equipment and furniture, cribs, toys, poisons, sharps, and other hazards relevant to children. The checklist categories are presented, however specific content is not provided for individual items. Reliability and validity testing are not reported for this instrument. Stower describes a different hazard inspection process in a pediatric inpatient facility.(185) An inspection form was developed which is completed monthly by health and safety coordinators assigned to specific areas of the hospital. Hazards and potential hazards are identified and recorded for each zone inspected, including patient, public, and administrative areas. For each hazard, a risk score is calculated, a risk assessment is made, and all risks are prioritized at the departmental level. Specific checklists are not

used in this process; the inspectors are expected to identify hazards using their knowledge and experience, and close observation skills. The audit form used for this process is presented, along with a description of the risk analysis method. The third reported hospital safety audit was used in a study of an intervention to reduce institutional falls in the elderly. This audit was conducted by an occupational therapist at baseline, in order to identify fall hazards and implement specific recommendations. The actual instrument is not provided.(186)

Other checklists and audit instruments for the assessment of hospital safety are limited to tools developed for accreditation (67-69, 71) and risk management (64) self-assessment purposes. These tools do not comprehensively identify hazards relevant to children as outlined in the ISO's *Guide 50: Safety aspects – Guidelines for child safety*.(6) These accreditation and risk management tools do not appear to have been formally evaluated. A number of reviews of hospital safety as well as several hospital safety management guidance documents provide narrative content for checklists; some provide instruments or actual checklists, however none of these checklists include specific pediatric risks. Most of these checklists focus on occupational and environmental hazards, fire safety, and code requirements.(11, 57-59, 61, 187-189)

Home Safety Assessment Instruments

Home safety assessment instruments have been used in injury and falls prevention research targeting children and seniors. As the potential hazards in the home setting are similar to those in the hospital setting, home safety assessment instruments were considered for potential application in the hospital setting. Instruments reported in the published literature are summarized here.

A number of checklists and instruments have been used in studies to evaluate the effectiveness of pediatric home safety interventions, including educational and community-based strategies. A household hazard scale developed by Dershewitz assessed 11 potential home hazards. A safety index was calculated using degree of exposure as determined by the home inspector and degree of potential injury severity. Inter-observer agreement was 83%.(190) Gallagher describes a structured home safety assessment conducted by public health inspectors which assessed 29 items related to State Sanitary Code requirements relevant to children, and 37 other potential safety hazards.(191) Kelly describes the use of a standardized home safety assessment form by community health workers; in this study household hazard scores were based on assessment of nine observable household hazards.(192) Although the actual instruments are not published, at least some inspection items are provided for these studies.(190-192) There is no documentation of reliability or validity testing for the latter two instruments.(191, 192)

Numerous checklists and instruments have been developed for application in falls prevention research. The Consumer Product Safety Commission's comprehensive home safety checklist (193) has been evaluated in several settings.(194, 195) An instrument derived from this checklist is reported as having high reliability for 13 slip and trip hazards.(194) A home safety assessment using a 37-item fall hazard instrument was conducted in a study to determine the prevalence of environmental hazards in the homes of people 70 years and older. Significant inter-rater agreement was documented for all hazard items.(196) The Home Environment Survey was found to have good overall reliability (kappa = 0.65-0.92) but the assessment of grab-bars and hazardous furniture was unreliable.(197) Clemson et al. developed and validated the Westmead Home Safety

Assessment instrument, the most widely adopted tool in Australia. The use of an abbreviated version of the Westmead instrument is reported in a case-control study of home hazards and hip fractures; instrument reliability statistics are reported as excellent for six hazards, good to fair for 15 and poor for seven.(198)

Several scales developed to measure fall risk include an assessment of environmental hazards. HOME FAST was developed as a screening instrument to measure the risk of falls among older community-dwelling adults. Mackenzie has described the content validation process for this tool and concluded that it captures relevant home safety items and measures the two main dimensions of the home safety construct, namely environment and function.(199) Reliability testing of the HOME FAST instrument documented kappa scores similar to other home environment checklists.(200) Johnson developed the Home-Screen 14-item scale for community nurses to measure fall risk for seniors in the home, including environmental hazards and unsafe behaviour, and reported adequate construct validity and acceptable internal consistency for this instrument.(201)

Other Relevant Instruments

Donaldson reported the development and validation of a tool to audit the safety policies and practices of community sports clubs.(202) This 81-item questionnaire assesses several aspects of sports-related safety, in terms of whether clubs have written checklists to conduct safety inspections and policies with respect to the safety of equipment and facilities, safe play, injury prevention, and first aid. Although safety audits and facility safety are mentioned, actual audit items are not specifically referenced.

CONCLUSIONS

There are risk management, legal, and ethical grounds for proactively identifying and managing hazards to children in the hospital setting. This "hazard surveillance" approach to preventing hospital injuries is founded in injury control science, and targets host, agent, and environment factors in a multi-pronged strategy, primarily using passive engineering strategies. Although the published literature regarding hospital injuries and hazards is very limited and does not provide a complete account of target hazards, a number of life-threatening incidents have been reported and inform the development of a hazard surveillance instrument. An examination of childhood injury data provides a more complete description of potential injuries and hazards to children, and therefore complements the hospital injury literature. Similarly, although specific hospital safety guidelines are limited, general child safety standards can be applied to the hospital setting.

There are no existing instruments which are designed to identify hazards relevant for pediatric patients in the hospital environment that have been shown to be valid and reliable. The single instrument developed and validated for assessment of hazards to children in the home environment lacks the comprehensive content required for application in the hospital setting. The numerous instruments developed and validated for use in falls prevention research provide falls-related content but do not measure other potential hazards. Checklists that have been developed for use by hospitals lack pediatric content and also have not been subject to reliability and validity testing. In summary, there is a need for a reliable and valid instrument to assess the safety of the hospital for pediatric patients and visitors.

CHAPTER 4

INSTRUMENT VALIDATION

This chapter summarizes the methods and results relating to instrument validation. First, the procedures involved in content validation are described, including reviews of the evidence for inclusion of specific injuries and hazards, and reviews of the evidence for the corresponding child safety standards which address these hazards. Then the expert panel review procedures are summarized. Finally, the instrument validation results are reported, including a summary of the evidence supporting each instrument item and the results of the expert panel.

METHODS

INSTRUMENT VALIDITY

This phase of the study was designed to assess the content validity of the hospital safety audit instrument. A valid test is one that measures what it aims to measure.(203) There are a number of aspects of validity that are often considered. The principle types of validity include face, content, criterion, and construct validity. (203, 204) Face validity is an informal assessment of whether items appear to measure what they are designed to measure, whereas content validity is a formal evaluation of whether the items are relevant, accurate and complete, typically based on the subjective opinion of a panel of experts. Criterion validity compares the results obtained using the instrument with another instrument or predictor; in concurrent validity it is tested against a gold standard concurrently, and in predictive validity it is tested to evaluate how well it predicts future outcomes. Construct validity is a measure of how well an instrument predicts outcomes

that are consistent with the theoretical construct on which the instrument is based. Face validity was not considered here, as detailed content validity analyses were performed. Criterion validity is discussed in the next chapter (sensitivity and sensitivity analyses which use the expert rating as a gold standard) and was assessed as part of instrument performance. Predictive validity would relate to the prediction of future outcomes (injuries or incidents) and would only be relevant if the hazards were identified and then not addressed, which is unethical, or if sites with divergent results were compared in terms of incidents or injuries, however this was not the focus of this study. Construct validity was also not relevant for this application. Therefore a thorough content validity analysis was performed, using two methods. First, reviews of the evidence for inclusion of specific injuries and hazards and corresponding child safety standards were conducted; this was followed by an expert panel review of the instrument.

Hospital Injuries and Hazards

The aim of this phase of the study was to document a comprehensive profile of relevant injuries and hazards, which included all types of unintentional injuries and injury hazards that might occur among pediatric patients and visitors in a typical hospital setting. This profile was used to systematically verify the relevance of each instrument item and to assess the instrument for gaps in content.

Search Strategies

While published reports of hospital injuries and hazards were an essential component of the overall search strategy, incident, complaint, and claims data were identified as important complementary data sources. These data sources provide detailed product and event data, and document rare but significant events. Most are collections of reports from

multiple sources; some of these (e.g. ECRI) represent many sources of incident/complaint data (from consumers, institutions, manufacturers, research and technical literature, and claims data) and represent data and literature from many disciplines, including engineering and medicine. The characteristics and search strategies for each data source are described here.

1. Published research literature

A summary of the published literature search strategy is found in Appendix 4.1.

2. Regulatory agencies

Health Canada: PSIS (Product Safety Information System) is a database which includes voluntary reports of injuries and events implicating products regulated under the Hazardous Products Act (mid-1980s-present; over 8000 records).(205) It is not accessible to the public; therefore a formal request for relevant data was submitted. These data are anonymous and identifying variables are not collected. This information system is subject to Health Canada's strict privacy and confidentiality regulations.

FDA (206, 207): A number of FDA databases are available online and are searchable by keyword, subject, date, product type, and manufacturer. These databases pertain to medical devices such as beds and cribs. Consumer products are not captured. The following databases were searched using relevant keywords, FDA subject headings, and product types:

- MAUDE (Manufacturer and User Facility Device Experience) - reports of adverse events involving medical devices (voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996).

- MDR (Medical Device Reporting) – predates MAUDE. Reports include mandatory manufacturer reports on devices which may have malfunctioned or caused a death or serious injury (1984 – 1996; over 600,000 reports).

- Center for Devices and Radiological Health (CDRH) – Safety Alerts, Public Health Advisories, Notices. These are listed in chronological order on the FDA website, most with links to the actual documents.

- FDA Enforcement Reports - recalls, legal action related to FDA-regulated products.

Department of Health (UK): Medical Devices Agency Safety Notices, Hazard Notices (http://www.medical-devices.gov.uk/). These notices are available online. A systematic manual review of notices was performed.

3. Litigation/claims data

The National Association of Insurance Commissioners (NAIC) reports on closed malpractice claims, including injuries sustained on the hospital premises.(208, 209) These reports were requested through the university document delivery service.

Quicklaw™ is 2500 searchable databases of international statutory materials, court and tribunal decisions, topical collections, and legal news. This database was searched

electronically by keyword and phrase with the assistance of a professional law librarian at the University of Manitoba Law Library.

The Canadian Health Facilities Law Guide (70) cites cases by topic area (e.g. hospital liability). It was searched manually for relevant case law and standards.

Canadian hospital law reference textbooks were also examined for relevant case law, injuries, hazards, and referenced standards.(72, 74, 77)

4. Other databases

ECRI: Health Devices Alerts Database is a searchable database of 860,000 records (1977-present) of medical device hazards, problems, and recalls (www.ecri.org).(206) The abstract database was searched by product category and keyword.

JCAHO: The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) maintains a Sentinel Events database and produces a variety of related reports and documents related to Sentinel Events, which include some unintentional injuries such as serious (fatal or permanently disabling) falls (www.jcaho.org).(206) These reports were searched manually.

Content Analysis

The injury and hazard data retrieved through the search strategies described above were categorized and summarized in tabular form by external cause of injury, specific mechanism, and product type, where these data were available. Categories were determined by the evidence retrieved in the searches but were structured to reflect existing classification systems for injury (ICD) and hazards (ISO). For each category, the

instrument items relating to the category were referenced (Table 4.1). This ensured that all injuries and hazards identified in the literature are reflected in the instrument. Following this process, reverse mapping was performed, in which the instrument items were listed and the evidence was referenced (Table 4.2). This ensured that each item was founded on evidence of a potential for injury or hazard. This information was reported in the instrument handbook.

Table 4.1 Evidence Mapping I: Are all relevant injuries and hazards reflected in the instrument?(example)

Injury and Hazard Categories	*Instrument Items*
Falls	1, 3, 12, 13, 17-20
Same level	1
Other level	3, 12, 13, 17-20
From crib – no bubble top	17
From crib – side rails left down	18
Etc.	

Table 4.2 Evidence Mapping II: Are all instrument items based on evidence of injury or hazard?(example)

Instrument Item	*Injury and Hazard Evidence (citation numbers)*
1.1	32-35
1.2	11, 14, 29
1.3	4
1.4	78
Etc.	

CHILD SAFETY STANDARDS

The aim of this phase of the study was to identify and document child safety standards relevant to the prevention of the hazards and injuries identified in the first phase. These standards included legislation, standards, research, and recommendations, as classified and defined below.

Classification of Standards

A variety of child safety standards are referenced in the instrument. Each instrument item reflects one or more standards which together comprise the current best evidence in terms of addressing or avoiding the specific hazard identified by the item. The type of child safety standard is referenced for each item, in order to inform the user of the nature of the evidence considered. This is meant to assist in the decision-making process once hazards are identified.

For the purposes of this study, child safety standards were classified as: legislation, standard, research, and recommendations. These types are defined as follows, along with the citation guideline for the instrument handbook:

Legislation included any relevant Canadian federal legislation. In the instrument handbook the relevant act and/or regulation was cited and referenced.

Standard included hospital accreditation standards (e.g. JCAHO, CCHSA), risk management standards (e.g. issued by ECRI or HIROC), facility standards and guidelines, and product standards issued by recognized national or international standards organizations (e.g. CSA, ASTM, ISO). In the instrument handbook the issuing body was cited and the standard was referenced.

Research included data regarding injuries and hazards in the published and electronic literature (texts, monographs, journals), and included any type of research evidence including surveillance data, referenced topic reviews, as well as peer-reviewed individual studies and systematic reviews. This category was termed 'References' rather than 'Research' in the instrument handbook.

Recommendations included summaries or statements of expert opinion and included consumer advisories issued by government or other authoritative bodies such as the FDA, CPSC, CPS, or AAP. In the instrument handbook the source (issuing body) was noted and references were provided.

Identification of Standards

Legislation: A review of federal legislation relating to product safety and medical device safety was conducted. Relevant legislation was identified using a number of published sources.(70, 163, 166, 167, 210) Expert consultants at Health Canada were contacted regarding the current status of the 1997 draft hospital bed standard (211) and the 1989 hospital crib regulations,(212) as well as to confirm the current status of relevant regulations.

Standards: JCAHO and CCHSA accreditation manuals and publications were reviewed for accreditation standards. Risk management standards issued by HIROC and ECRI were reviewed. Facility standards were identified through the use of expert informants, as well as a search of the architecture literature and library and an online search. Product standards were identified through current catalogues and indexes maintained by various standards organizations, including the Canadian Standards Association (CSA), Standards Council of Canada (SCC), the International Organization for Standardization (ISO), and the American Society for the Testing of Materials (ASTM).

Research: Standards referenced in the research literature were also identified through the searches of published literature and other data sources.

Recommendations: Expert body recommendations were identified in the literature search and search of other data sources described above. Five key agencies and organizations were identified, and their websites and literature were searched for relevant standards (Health Canada, FDA, CPS, AAP, CPSC).

Ranking Standards for Strength of Evidence

Many hierarchies of research evidence have been developed for ranking strength of evidence. There is not consensus regarding these hierarchies, and in fact there are many differences between them; however, there is consensus in principle that systematic reviews and meta-analyses are superior to individual studies in evaluating a body of evidence, and there is generally consensus in study design ranking. A recent extensive review titled *Systems to Rate the Strength of Scientific Evidence* was prepared for the Agency for Healthcare Research and Quality.(213) This review examined systematic approaches to assessing the strength of scientific evidence in the field of medicine; 19 systems were identified that evaluate study quality and 7 systems were identified for grading the strength of a body of evidence.

For the purposes of this study, one of the latter systems was chosen – the method developed and used by the Canadian Task Force on the Periodic Health Examination.(214) This system was chosen because it is relatively simple, allows non-research evidence to be rated, allowing inclusion of legislation, standards, and other evidence, and Canadian hospitals and health care professionals are familiar with this system. Finally, the other six systems do not have any characteristics that justify their selection over this system. For each instrument item the strength of evidence was rated using this system; ratings were documented in the instrument handbook.

Expert Review

A panel of experts was recruited for the final aspect of content validity assessment. An expert was defined as a professional with specialized expertise of relevance to the issue of pediatric hospital safety, and included pediatricians, nurses, injury prevention professionals, product safety specialists, and biomedical engineers. A maximum of two experts were recruited from each discipline. A participant information and consent form was provided to each rater, and consent was obtained (Appendix 4.2).

Each expert was asked to rate each instrument item in terms of its clarity and relevance, and whether the item should be deleted from the instrument, using a five-point Likert-type scale, on the ranking form provided (Appendix 4.2). The panel was also asked to rate the instrument's comprehensiveness, and to identify any missing items (injuries or hazards). Finally, respondent burden was estimated by the panel (results are presented in Chapter 5). Responses were summarized by calculating the mean score for each item; significant items lacking consensus or needing further discussion were defined as those with a mean score less than 3 for clarity and relevance, and a mean score greater than 3 for consideration of item deletion. These were addressed where necessary through subsequent communication with the panel. Qualitative comments submitted regarding wording and content were analyzed and the instrument was revised accordingly.

Additional information regarding content validity was obtained from the raters involved in inter-rater reliability testing. Following completion of the testing each rater completed a survey to explore reasons for blank and "not applicable" responses, to identify issues in instrument structure and clarity, and to identify missing items (injuries or hazards). These responses were summarized and common issues identified and quantified where possible.

Final Presentation

The level of language (grade level) was estimated for the instrument and the instrument handbook using standard readability statistics available in Microsoft® Word 2002. Clarity and language were also assessed by the expert panel and raters.

Ethical Considerations

Ethical approval was granted by the University of Manitoba Health Research Ethics Board. The injury and hazard data used for this study were in the public domain and/or did not include any identifying information. The expert rating forms were not anonymous, as there was a potential need to contact the experts subsequently to clarify and resolve conflicting recommendations. Written consent was obtained from the expert panel to participate in the study; each was provided with a copy of the participant information and consent form. The expert panel was asked if they would prefer to be identified by name or agency/organization or both, or to remain anonymous, for the final report and for the instrument handbook.

RESULTS

Hospital Injuries and Hazards

Published Research Literature

In the sample of pediatric hospital injury publications retrieved, there was one prospective cohort (215, 216), one case control study (217), one cross-sectional study (113), 12 case series (12, 23, 26, 126-130, 218-221), and 21 case reports.(134-146, 148, 149, 222-226) Study settings included tertiary care hospitals (215, 216), general hospitals (113, 217-220), psychiatric hospitals (217), and hospitals with pediatric wards.(12, 127, 128, 130) Most studies included patients of all ages (26, 113, 126, 215-219, 227) while

four studied pediatric patients exclusively.(12, 128-130) Four additional reports were identified that reported potential hospital hazards for pediatric patients.(12, 131, 228, 229) Although the overall quality of the injury and hazard studies was poor, most contributed descriptive data that were of sufficient detail to be useful for content validation. Each mechanism of injury identified in the literature was tabulated and cross-referenced with instrument items. These results are summarized in Table 4.3, along with the injuries and hazards identified in searches of other, unpublished data sources.

Other Data Sources

Regulatory Agencies

Health Canada: The Product Safety Information System database search resulted in four cases of injuries to children in hospitals. The incident dates ranged from 1987 to 1990. The ages of the children involved were not reported. The products implicated included a playpen (chewed covering from rail, stopped from swallowing material by nurse), a rattle (broke, contained small parts), a soft toy (hole, contained small parts and a nail), and a glass soft drink bottle (shattered). These incidents did not result in injury. A search of the Medical Device Database was then performed, which resulted in 12 cases of patient injuries implicating hospital beds and bed rails. The incident dates ranged from 1982 to 2001. Although the ages of the patients were not reported, at least some of the patients were adults in geriatric or general hospital wards. Most of these incidents occurred prior to the establishment of entrapment prevention guidelines for hospital bed design, and in fact appear to have contributed to standards development in this area. Three definite pediatric incidents were reported, including one case of fatal bed rail entrapment of a 13

year old child with cerebral palsy and two nonfatal but life-threatening cases of entrapment of toddlers between the side rail and the mattress.

FDA: Multiple searches of the MAUDE database resulted in 13 incidents involving pediatric cribs (1997-2003). Several incidents resulted from defective parts or product misuse. Several incidents resulted in a fall from the crib, primarily due to failure of the side rail to latch securely. In one of these cases a neurosurgical wound opened, leaking cerebrospinal fluid, requiring minor surgical intervention. Two cases of entrapment were reported. In the first incident, a child was found hanging in a gap created when the foot of the mattress was raised. In the second incident, an infant was found hanging with his/her neck lodged between the side rail and mattress. Neither case appears to have been fatal. The MAUDE database also contained two reports of children falling from stretchers due to failure of the side rails (1997).

Searches of the MDR database resulted in 22 incidents involving pediatric cribs and beds (1985-1994). In seven cases, children fell out of cribs when the side rail disengaged and lowered. Two of these incidents resulted in fractures (skull, arm), one resulted in a seizure, and another resulted in severe and permanent injury. In three cases a bassinet tipped over and the infant fell out. One child suffered a fatal strangulation injury due to the use of netting over the crib to prevent climbing out. Two fatal bed rail entrapment incidents were reported, both involving older children with disabling conditions (9 and 13 years of age). One fatal crib entrapment of a 14 month-old child implicated a faulty security top and resulted in a product recall. In another case of crib entrapment, in which the side rail spacing was 3.5 inches, a child became lodged between the side rails and was "sawed free". Two cases of potential choking/suffocation implicated crib pad stuffing and

ball bearings which were found in the crib. Two cases of lacerations were reported which were due to sharp edges within the crib.

The CDRH online postings of Safety Alerts, Public Health Advisories and Notices were manually searched, resulting in seven relevant alerts, regarding hospital bed fires, entrapment in hospital bed side rails and restraint devices, electrical hazards associated with monitoring devices, fires and burns related to the use of electric heating pads, potential injuries related to apnea monitor leads, and entrapment in pediatric cribs with security tops.

Multiple searches of the FDA Enforcement Reports resulted in a single relevant safety alert regarding a crib security top entrapment hazard in pediatric cribs with security tops (fatal entrapment incident noted above).

Department of Health (UK): Searches of the Medical Devices Agency's Safety Notices and Safety Action Bulletins resulted in two relevant reports. One fatal incident involved an eight year old child who was operating an electric lift and recliner chair and became entrapped as the chair descended.(230) A similar fatal incident "overseas" is also identified in the report. The second fatal report involved a child who was playing with an electric bed and became entrapped when it was being lowered.(231) Two additional reports concern the risk of fatal entrapment in bed side rails but do not refer to pediatric patients.

Litigation/Claims data

The National Association of Insurance Commissioners (NAIC) reports on closed malpractice claims were requested through the university document delivery service but

the reports could not be located at a member institution. The Quicklaw™ database search resulted in no pediatric cases and only one relevant adult case. In *Creighton v. Delisle Union Memorial Hospital* (1961)[10] a hospital visitor fell on a waxed wet floor, suffered a fracture-dislocation, and was awarded damages. A manual search of the Canadian Health Facilities Law Guide also did not result in any pediatric cases. Relevant case law was cited in several Canadian hospital law reference textbooks, however the majority of cases involved adult patients and visitors. For example, in *Dagenais v. Children's Hospital of Eastern Ontario* (1980)[11] the hospital was held liable when a parent fell as the result of a gap in the asphalt at the edge of a ramp. The only accidental injuries involving children that were retrieved are three cases of serious burns to young children due to steam inhalation equipment (1931,1943,1950) and one case of a Manitoba child who lost ten teeth when he fell from a coat rack after climbing on a radiator in a waiting area.(74, 232)

Other Databases

ECRI: Five major sources of ECRI reports were accessed. The ECRI journal *Health Devices* is indexed by MEDLINE, so these reports were found in the published literature searches described above. The ECRI periodical reference for health care facilities titled *Healthcare Hazard Management Monitor* was searched manually and resulted in 11 relevant documents. The ECRI periodical reference for health care facilities titled *Healthcare Risk Control* was searched manually and resulted in 11 additional relevant documents.

[10] *Creighton v. Delisle Union Memorial Hospital* (1961)34 D.L.R (2d) 606.
[11] *Dagenais v. Children's Hospital of Eastern Ontario* (1980) 1 ACWS (2d) 432 (Ont HC).

The greatest yield of injury and hazard reports resulted from searches of the ECRI Health Devices Alerts databases. The Abstracts search revealed 34 abstracts (1977-2001), and the search of the Action Items revealed 12 abstracts (1985-2003). These abstracts reflect a large number of sources, including published literature, media reports, case law, member hospital reports, and regulatory agency reports from the US, Canada, and the United Kingdom. Some of these abstracts are therefore duplicate reports of incidents described in the searches above, however in some cases the ECRI abstract provided the only reference required to retrieve the original document.

JCAHO: A search of the Sentinel Events database and reports resulted in no relevant data. Although fatal falls and falls resulting in permanent impairment of function are currently defined as sentinel events, no pediatric data are available.

Content Analysis

The purpose of searching published and unpublished data sources for hospital injuries and hazard data was to create a detailed list of reported injuries and hazards in order to ensure that these were represented in one or more instrument items. The injury and hazard data retrieved through the search strategies described above were categorized and summarized in tabular form by external cause of injury, specific mechanism, and product type, where these data were available. For each category, the instrument items relating to the category were referenced. The summary of the results of this procedure is presented in Table 4.3. Following this process, reverse mapping was performed, in which the instrument items were listed and the evidence was referenced (results in the instrument handbook, found in Appendix 4.3).

Table 4.3 Evidence Mapping I: Are all relevant injuries and hazards reflected in the instrument?

Mechanism of Injury	Specific products, equipment and mechanisms	References	Corresponding Checklist Items
Fall	*From bed*	(12, 127-130, 233)	13.3
	From crib – through gap created by elevated mattress support	(138)	11.6, 14.9
	From crib – no bubble top, crawled out	(132)	14.2, 14.4
	From crib – rails improperly secured or not raised	(12, 128)	14.12, 14.13
	From crib - unspecified	(127-130)	14.10
	From stretcher or wheelchair	(12, 129)	21.1, 21.2, 21.4, 21.5
	From other furniture e.g. chair, couch, wagon, rocking horse	(128, 129, 233)	
	From infant seat (no restraint)	(12)	20.1-20.6
	From high chair (no restraint, disrepair, poor balance)	(12)	15.1-15.6
	From roof (suicidal) – climbed out of open window	(234)	12.1, 12.4
	From window (height, lack of screens or guards)	(12)	12.1, 12.4, 14.5, 16.2
	Same level – slips and falls	(12, 129)	1.1, 1.2
	Same level – floor wet	(12)	8.2
	While in an infant walker	(12)	18.14
	While in an infant swing (disrepair, inadequate restraint)	(12)	
	Related to unsafe play	(12)	
	Unspecified	(12, 128, 129, 217, 220, 233)	5.1-5.5, 7.1, 8.1-8.3, 16.3, 17.1, 17.2

Suffocation			
Choking on non-food object	*Syringe cap*	(139, 222, 235, 236)	14.14, 15.4, 16.8, 16.11
	Pacifier, makeshift pacifier	(12, 140, 237, 238)	11.10
	Balloons	(12)	18.3
	Toys (small parts)	(12, 239)	14.14, 15.4, 16.8, 18.1, 18.2, 18.4, 18.6, 18.8
Suffocation in bed or cradle	*Bed entrapment – mattress gap*	(133)	11.6, 13.4, 13.6, 13.8, 14.3
	Bed entrapment – bed rail	(26, 223, 239)	11.6, 13.5, 13.7, 13.8, 14.3, 21.3
	Crib entrapment – mattress gap	(128, 138, 229)	11.6, 14.9
	Crib entrapment – between security top and side rail	(137, 226)	11.6
	Playpen (chewing rail covering, broken, mesh side down)	(12, 239, 240)	11.6, 16.5, 16.7, 16.8, 16.9, 16.12
Other choking/suffocation	*Window/blind cord*	(12)	4.2, 12.2, 12.3, 14.5, 15.4, 16.2
	Orthopedic (arm) sling	(224)	
	Infant apnea monitoring lead	(142)	4.1, 4.2, 14.5, 15.4, 16.2
	Intravenous tubing	(141)	4.2, 14.5, 15.4, 16.2
	Intravenous extension tubing side clamp	(228)	6.1, 14.14, 15.4, 16.8
	Identification bracelet (chewed)	(241)	14.14
	Electrical pull cords	(12)	4.1, 4.2, 14.5, 15.4, 16.2
	Toy boxes (no support for open lid)	(12)	18.12
Poisoning	*Intentional overdose*	(128, 234)	10.1-10.3
	Cleaning agents accessible to children (under sinks, on counters)	(12)	2.1-2.3, 5.1, 5.2, 6.1
	Medication rooms unlocked and accessible to toddlers	(12)	5.1, 5.2, 10.1-10.3

Drowning	*Access to bathroom*	(12)0)	1.4, 1.5, 11.4
	Unsupervised wash buckets	(12)0)	2.1, 2.2, 11.4
Fire/Burn			
Fire/flame	*Sparking toy*	(147-149)7)	18.13
Hot object/liquid	*Radiator*	(12, 127)5)	11.3, 15.4, 16.8
	Hot tap water	(12)0)	1.3, 1.5
	Hot drinks	(128)6)	11.2, 11.7, 15.4, 16.8
	Electrical burn (unprotected socket)	(12)0)	7.2, 15.4, 16.8
	Electrical burn (extension cords)	(12)0)	4.1, 7.1
	Other	(234)1)	11.7
Cut/pierce	*Tables (sharp, pointed)*	(12)0)	
	Syringes/sharps left on patient tables	(12)0)	11.1, 15.4, 16.8
Struck by	*Unspecified*	(128)6)	
Other mechanisms	*Electric beds (crush injuries)*	(242-246)3)	13.1, 13.2
	Electrical injuries (burns, electrocution) related to monitoring equipment connected to power sources	(143-146, 225)2)	
	Digit strangulation (loose threads in infant mittens and booties)	(64)2)	3.1
	Toys (unspecified)	(128)6)	18.1-18.14

The instrument was then revised to reflect injury and hazard data, with revision of existing items and addition of new items as necessary to ensure that reported injuries and hazards were reflected in one or more instrument items. Note that Table 4.3 identifies several injuries and hazards with no corresponding item number. Falling from 'other furniture' and 'unsafe play' do not have specific prevention interventions or policies, which are required to create an instrument item. Sharp corners, such as on tables and other furniture, are so abundant in a health care institution that it is impractical to expect compliance with corner guards or other protective devices. However, these could be considered for high risk areas such as play rooms, and sharp corners can be addressed proactively through selection of furniture and architectural design. Infant swings are rarely used at our institution and were therefore not identified as an equipment type for inclusion, however this could be considered for a future version of the instrument, should other facilities identify that use of infant swings is more widespread. Orthopedic slings and monitoring devices are medical devices, which were specifically excluded from the audit.

CHILD SAFETY STANDARDS

Identification of Standards

A summary of the child safety standards identified for each instrument item is found in the instrument handbook (Appendix 4.3). There were no comprehensive sources of pediatric hospital safety standards identified. Therefore a broader search strategy was necessary, and included general child safety standards (including home and child care standards) and general hospital facility standards.

Legislation: The Hazardous Products Act was the most commonly cited legislation in the instrument handbook, and was particularly relevant for toys and children's products such as playpens and strollers. The Medical Devices Regulations (Food and Drugs Act) pertain to hospital beds and cribs, however there are no specific standards for these products. For hospital cribs, a 1989 Hospital Crib standard is the only reference document available.(212) This document now only serves as a guidance document, as the new Medical Devices Regulations have incorporated a general safety requirement, and the Hospital Crib standard is no longer referenced in the regulations. The Crib Regulations (Hazardous Products Act) do not apply to hospital cribs. Therefore there is actually no Canadian standard for hospital cribs. A draft hospital bed guideline (1997) was produced for industry guidance (211), however this document is no longer being developed, and the CSA standard for electric beds is the only relevant standard at this time.(247) There is no standard for non-electric hospital beds, and there is no standard for hospital beds for children.

Standards: The types of standards identified included accreditation, risk management, facility, and product standards.

Accreditation standards issued by JCAHO and CCHSA refer to hospital safety, however these standards make no reference to specific pediatric hazards. The JCAHO standards provide extensive "life safety" checklists and recommendations which primarily reflect fire and other safety codes. Fire safety items were not included in the instrument, as provincial and territorial regulations exist for fire and life safety in public buildings with which all facilities must comply, and these are not specific pediatric hazards.

The HIROC risk management self-appraisal modules make reference to digit entrapment by loose threads in infant mittens and booties.(64) A corresponding recommendation was therefore added to the instrument. Numerous ECRI risk management standards were identified, including one recent pediatric risk management document (56) which notes a small number of hospital hazards relevant to pediatric patients. These standards were very useful for content validation.

Several facility standards were identified for general hospitals (168, 248, 249) and a single draft facility standard was identified for pediatric inpatients.(169) Facility design guidelines which emphasize safety for children were identified, but these address public or residential buildings and child care (daycare) facilities rather than health care facilities.(170-174) However, several of these sources offered extensive checklists oriented to child-safe facility design.(170, 171, 174) *Caring for our Children: National Health and Safety Performance Standards* provided an excellent summary of US facility, equipment, and product safety standards and recommendations relevant to child care.(174) Many of these have direct relevance to pediatric health care facilities and were used extensively for content validation. The Canadian Pediatric Society's reference guide for child care facilities titled *Well Beings* also provided a large number of injury prevention recommendations and facility checklists that were very useful for content validation.(250)

A large number of relevant product standards were identified, primarily for children's products such as toys, strollers, and playpens, but also for health care facility plumbing, electrical systems, and electric beds. The greatest yield for relevant standards were ASTM (251-262) and CSA.(176, 210, 247, 263-265)

Research: A large number of relevant published and electronic sources were identified, including texts, reports and research literature from numerous disciplines. Several systematic reviews of childhood injury topics were also useful for content validation. Recommendations: Many relevant summaries or statements of expert opinion and consumer advisories issued by government or other authoritative bodies were identified. Commonly cited sources in the handbook included the CPSC (n = 21), Health Canada (n = 14), AAP (n = 7), and CPS (n = 2). The AAP and CPS child care handbooks were cited for numerous items.(174, 250)

Ranking Standards for Strength of Evidence

A summary of the levels of evidence for each item is found in the instrument handbook (Appendix 4.3). The majority of the instrument items were supported by Level III evidence (opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees). There were a few items supported by Level II-2 evidence (Items 1.1, 1.2, 8.1) and Level II-3 evidence (Items 1.3, 12.1). Despite the lack of higher levels of evidence for the other items, the types of Level III evidence cited provide a strong argument for these items, and these should not be under-estimated. These types of evidence include federal legislation and regulations (e.g. Hazardous Products Act), national or international standards (e.g. CSA, ASTM), and recommendations of well respected and authoritative bodies (e.g. Health Canada, CPS, AAP, CPSC).

Expert Review

The revised instrument and handbook were sent to eight experts, with responses received from four. The participating experts were physicians (1), nurses (2), and an injury

prevention specialist (1). They represented potential facility users (3), and contributed expertise in child safety (2), pediatrics (3) and child health quality improvement (1). Two of the reviewers had prior experience with piloting the original instrument, and two had no prior knowledge or exposure.

The expert reviewers were asked to rank each instrument item in terms of its clarity, relevance, and whether the item should be deleted, using a five-point scale. The mean scores for each item are presented in Table 4.4. None of the items met the criteria for lack of consensus or item deletion (scores less than 3.0 for clarity and relevance; scores greater than 3.0 for item deletion). The reviewers ranked the instrument as easy to use (3 scores of 5 on a 5-point scale and one blank response) and comprehensive (4 scores of 5 on a 5-point scale). Suggestions were provided for missing items (specify intravenous and oxygen tubing as strangulation hazards; potential for additional policy questions for certain items). Reviewers commented that certain instrument items were clear only with consulting the instrument handbook, and that the instrument therefore should not be used without the handbook. Diagrams were suggested for a few items where measurements are required. The play equipment and car seat items, although scored as relevant and clear, were described by one reviewer as potentially beyond the scope of the audit. It was also suggested that clarification is required as to whether facilities should audit every room or a sample of rooms.

Table 4.4 Expert panel scores for clarity, relevance, and item deletion[12]

ITEM	Clarity	Relevance	Deletion	ITEM	Clarity	Relevance	Deletion	ITEM	Clarity	Relevance	Deletion
1.1	4.75	4.75	1.00	12.1	4.75	4.75	1.00	17.1	4.50	4.75	1.25
1.2	4.50	4.75	1.00	12.2	4.50	4.75	1.00	17.2	4.50	4.75	1.00
1.3	4.75	5.00	1.00	12.3	4.50	4.75	1.00	18.1	4.75	4.75	1.00
1.4	4.75	4.75	1.00	12.4	4.75	4.25	1.00	18.2	4.50	4.50	1.25
1.5	4.00	4.50	1.25	13.1	4.25	4.75	1.00	18.3	4.75	4.75	1.00
1.6	4.75	4.75	1.00	13.2	4.25	4.75	1.00	18.4	4.75	4.75	1.00
2.1	4.75	4.75	1.00	13.3	4.50	4.75	1.00	18.5	4.75	4.75	1.25
2.2	4.75	4.75	1.00	13.4	4.75	4.75	1.00	18.6	4.75	4.75	1.25
2.3	4.75	4.75	1.00	13.5	4.50	4.75	1.00	18.7	4.75	4.75	1.00
3.1	3.75	3.75	0.75	13.6	4.50	4.75	1.00	18.8	4.25	4.75	1.00
3.2	4.75	4.75	1.00	13.7	4.50	4.75	1.00	18.9	4.50	4.75	1.00
3.3	4.75	4.75	1.00	13.8	4.50	4.75	1.00	18.10	4.50	4.75	1.00
3.4	4.50	4.75	1.00	14.1	4.75	4.75	1.00	18.11	4.50	4.75	1.00
4.1	4.00	4.75	1.00	14.2	4.25	4.75	1.00	18.12	4.75	4.75	1.00
4.2	4.00	4.75	1.00	14.3	4.75	4.75	1.00	18.13	4.50	4.75	1.00
5.1	3.75	4.75	1.00	14.4	4.75	4.25	1.50	18.14	4.75	4.75	1.00
5.2	4.25	4.75	1.00	14.5	4.75	4.75	1.00	19.1	4.75	4.75	1.00
5.3	4.75	4.75	1.00	14.6	4.75	4.25	1.50	19.2	4.75	4.75	1.00
5.4	4.75	4.75	1.00	14.7	4.50	4.75	1.00	19.3	4.75	4.75	1.00
5.5	4.00	4.50	1.25	14.8	4.75	4.75	1.00	19.4	4.75	4.75	1.00
6.1	4.50	4.25	1.25	14.9	4.75	4.75	1.00	19.5	4.75	4.75	1.00
7.1	4.75	4.75	1.00	14.10	3.75	3.75	0.75	19.6	4.75	4.75	1.00
7.2	4.75	4.75	1.00	14.11	4.25	4.75	1.00	19.7	4.75	4.75	1.00
8.1	4.75	4.75	1.00	14.12	4.25	4.75	1.00	20.1	4.75	4.75	1.00
8.2	4.50	4.75	1.25	14.13	4.75	4.75	1.00	20.2	4.75	4.75	1.00
8.3	4.75	4.25	1.50	14.14	4.25	4.75	1.00	20.3	4.75	4.75	0.75
9.1	4.75	4.75	1.00	15.1	4.75	4.75	1.00	20.4	4.75	4.75	1.00
9.2	4.75	4.75	1.00	15.2	4.75	4.75	1.00	20.5	4.75	4.75	1.00
10.1	4.75	4.75	1.00	15.3	4.75	4.75	1.00	20.6	4.75	4.75	1.00
10.2	4.75	4.75	1.00	15.4	4.75	4.75	1.00	21.1	4.75	4.75	1.00
10.3	4.75	4.75	2.00	15.5	4.75	4.75	1.00	21.2	4.75	4.75	1.00
11.1	3.75	4.75	1.75	15.6	4.75	4.75	1.00	21.3	4.50	4.75	1.00
11.2	4.25	4.75	1.75	16.1	4.00	4.75	1.00	21.4	4.50	4.75	1.00
11.3	4.75	4.75	1.00	16.2	4.75	4.75	1.25	21.5	4.75	4.00	1.75
11.4	4.50	4.75	1.00	16.3	4.75	4.75	1.00	22.1	4.75	4.75	1.00
11.5	4.75	4.75	1.00	16.4	4.75	4.75	1.00	22.2	4.75	4.75	1.25
11.6	4.50	4.75	1.00	16.5	4.75	4.75	1.00	22.3	4.75	4.75	1.00
11.7	4.75	4.75	1.00	16.6	4.75	4.75	1.00	22.4	4.75	4.75	1.00
11.8	4.75	4.75	1.00	16.7	4.75	4.75	1.00	22.5	4.75	4.75	1.00
11.9	4.25	4.50	1.00	16.8	4.75	4.75	1.00	22.6	4.75	4.75	1.00
11.10	4.75	4.75	1.00	16.9	4.75	4.75	1.00				
11.11	4.75	4.75	1.00	16.10	4.75	4.75	1.00				
11.12	4.75	4.75	1.00	16.11	4.50	4.75	1.00				
				16.12	4.50	4.75	1.00				
				16.13	4.75	4.75	1.00				
				16.14	4.75	4.75	1.00				

[12] Mean scores are presented. Each item was scored using a five-point scale, from strongly disagree (1) to strongly agree (5).

Final Presentation

The expert reviewers assessed the instrument for clarity and language and provided suggestions for improving clarity and wording changes for a number of items. Although the instrument handbook was not formally assessed by the reviewers, a number of suggestions were submitted. Changes suggested by reviewers were incorporated prior to inter-rater reliability testing. The revised (final) instrument is found in Appendix 4.4.

Readability statistics computed by Word® included the Flesch Reading Ease score and Flesch-Kincaid grade level. The output of the Flesch Reading Ease formula is a number from 0 to 100, with a higher score indicating easier reading. The Flesch-Kincaid Grade Level formula converts the Reading Ease score to a US grade-school level. Word recommends that for most standard documents, one should aim for a Flesch Reading Ease score of 60-70 and a grade level of 7.0-8.0. The instrument's reading ease score was 50.1, with a grade level of 10.3. The instrument handbook's reading ease score was 48.6, with a grade level of 10.8. Given that these are technical documents designed to be used by health professionals with post-secondary education, these readability levels are likely appropriate for the audience and context. However, future revisions could aim to improve readability and lower grade level.

CHAPTER 5

INSTRUMENT PERFORMANCE

This chapter summarizes the methods and results relating to instrument performance, including inter-rater reliability, sensitivity and specificity, and respondent burden. In the first section of the chapter the methods for these performance analyses are described. In the second section of the chapter the instrument performance measures are reported, including a comparison of the number and type of hazards identified by the expert rater and other raters, measures of rater agreement, instrument sensitivity and specificity, and respondent burden.

METHODS

SITES

A sample of pediatric health care sites was audited using the instrument in order to conduct inter-rater reliability testing. A convenience sample of inpatient and outpatient facilities was selected. These sites included one private pediatric office, a hospital-based pediatric clinic, a pediatric emergency department, and a pediatric inpatient ward. Each site was divided into five discrete test areas, consisting of pre-defined public areas (waiting rooms, hallways, bathrooms), and four patient rooms. Each test area was audited by up to four raters, concurrently with the expert rater, resulting in a maximum of 80 paired comparisons (4 clinical sites x 5 test areas at each site x 4 pairs of raters). With the exception of the private pediatric clinic, the test areas were reviewed in advance to ensure that relevant children's products, toys, and equipment would be present. Preparations were made to "stage" test areas as needed, however only to ensure that necessary

equipment was present (e.g. such as moving high chairs, playpens, and infant seats from storage areas into the test areas; selecting rooms with cribs, beds, and stretchers), not to introduce hazards or hazardous equipment.

SUBJECTS

Raters were recruited from the private pediatric office (physicians), a hospital-based injury prevention centre (injury prevention research assistant), and the hospital (pediatricians, nurses, and other hospital staff). For the private pediatric office the raters were physicians and an injury prevention research assistant. For the hospital sites various disciplines were represented. The principal investigator was designated the expert rater in order to ensure the maximum familiarity with potential hospital hazards and with the instrument and instrument handbook.

SAMPLE SIZE

An agreement of 80% between raters has been documented in similar studies.(200) Assuming this level of agreement, a minimum sample size of 39 test areas (paired observations) was estimated, based on two observers and a dichotomous rating.(266) A sample of 80 was chosen to allow for sub-group comparisons to be performed.

PROCEDURE

Each site was rated concurrently by the expert rater and up to four other raters representing a variety of disciplines. The test sites, dates and times were selected to minimize patient and staff disruption. At the test site raters were oriented to the study, the participant information and consent forms were distributed (Appendix 5.1) and consent was obtained.

Raters were provided with: (1) a clipboard and pen, with five copies of the instrument (one copy for each room/area to be tested) labeled with site/area/rater identification numbers; (2) one copy of the instrument handbook; (3) one 16ft/5m tape measure; (4) one small parts test cylinder; (5) one digital thermometer (Hanna Instruments model 9000 professional digital thermometer, range -20-100°C, resolution 0.1°C, accuracy +/- 0.5°C).

The instrument was modified for the purposes of testing, with the deletion of the column marked "room number/location" and the addition of a column to indicate the number of hazards identified in the test area for each item, and a column to list the specific hazards identified for each item. Raters were instructed how to complete the form, including indicating a response for every item, and recording the number and type of each hazard detected.

Raters were not provided training or assistance in completing the audit, in order to reproduce realistic application conditions. They were instructed to indicate "not applicable" for any facility policy or safety behaviours indicated in the instrument. Raters were blinded to each other and to the expert rater by keeping examination/patient room doors closed and not discussing testing or results. At each site, the raters and the expert rater each selected the first of five test areas at random, with one rater per test area. Raters were instructed to hang a coloured tag on the door knob when they had completed that room to indicate that the room was available for another rater. The checklist was then completed for each of the other four test areas in random sequence, using the next available room. All raters conducted the testing concurrently and blinded to each other.

Following completion of the testing each rater completed a brief survey (Appendix 5.1) to explore reasons for blank and "not applicable" responses, and to identify missing items (injuries or hazards). They were also asked to indicate their injury prevention experience/training/employment (number of years) and to rate their injury prevention/safety/child-proofing expertise on a 5-point scale.

A hazard report for each of the sites tested was submitted to the respective administrative directors for their information. Hazards requiring immediate or urgent correction were communicated verbally to the clinic or hospital administration on the day of testing, with written documentation in follow-up.

Data Analysis

Data were coded and entered in Microsoft® Excel 2002 and exported to NCSS 2004 and SPSS 12.0 for analysis. Data analyses included descriptive analyses of raters and hazards and measures of inter-rater agreement and instrument sensitivity and specificity.

Rater Agreement

The reliability of an instrument refers to statistical testing of its reproducibility, and can include measurement of internal consistency, test-retest reproducibility and inter-rater reproducibility (agreement).(203, 204) Only the latter was measured in this study.

Internal consistency estimates reliability based on correlations between groups of instrument items which combined measure a defined characteristic; high correlations reflect homogeneity of the scale. This instrument is not a scale per se, rather an inventory. There are no groups of items which are meant to measure the same hazard; each item represents a single hazard which should be identified.

Test-retest reproducibility was not ethically feasible here, as any hazards noted during testing were recorded and hospital administration notified; some of these hazards were corrected immediately. A very short timeframe for retesting was considered prone to error due to a practice effect, which is a memory or familiarity with the previous responses by the rater.(203) Finally, the hospital physical environment is constantly changing, with new hazards arising and old hazards being addressed at any point in time, which also limits the validity of test-retest reproducibility.

Inter-rater agreement was defined as the degree to which two independent raters agree on the identification of hospital hazards using the hospital safety audit instrument. Two methods were used to measure rater agreement: raw agreement indices and the kappa statistic.

Raw agreement indices

For two raters using an instrument with dichotomous responses, the ratings may be summarized as follows:

	Rater 2		total
Rater 1	-	+	
-	a	b	a + b
+	c	d	c + d
total	a + c	b + d	N

Raw agreement indices are descriptive measures of agreement that can be easily calculated:

observed proportion of overall agreement: $(a + d) / (a + b + c + d)$
proportion of specific agreement for positive ratings: $2d / (2d + b + c)$
proportion of specific agreement for negative ratings: $2a / (2a + b + c)$

The limitation of using the overall agreement measure alone is that there is no way to distinguish between agreement on positive versus negative ratings. When the condition being measured is extremely common or rare, overall agreement may be very high by chance alone. (267)Therefore the proportions of specific agreement for positive and negative ratings are useful additional measures. These estimate the conditional probability that one of the raters will make a positive (or negative) rating if the other rater does. Both of these measures should be high to conclude that agreement is satisfactory.(268)

Kappa

In 1960 Cohen proposed the kappa statistic as a method to assess rater agreement that takes into account agreement by chance. Cohen's kappa is used for categorical dichotomous data and two independent raters and is computed using the following formula (268-271):

$$(P_o - P_e) / (1 - P_e)$$

where P_o is the proportion of observed agreements and P_e is the proportion of agreements expected by chance alone.

"Kappa is an extension of simple percent agreement and may be defined as the proportion of the total amount of agreement not explained by chance for which the observers accounted".(268) Kappa statistics are appropriate for testing the null hypothesis that there is no more agreement than might occur by chance. Kappa is strongly influenced by the prevalence of the condition being measured, which limits its generalizability to populations or settings other than the one from which it was calculated.(272) A

significant limitation of kappa is that kappa values may be low even though there are high levels of agreement and the individual ratings are accurate. This occurs with low prevalence of the condition being measured.(269, 270, 273)

Kappa values range between -1.0 and 1.0, with values greater than zero indicating that agreement is better than by chance, and values close to 1.0 being near perfect agreement. Kappa values will be lower if the sample is homogeneous (lacks variability) or the sample is heterogeneous but the raters are unable to accurately classify items into hazardous/non-hazardous due to differences being small or infrequent. Interpretation of kappa values is somewhat controversial, however there is general consensus that values above .80 are excellent, values between .60 and .80 are good, values between .40 and .60 are fair to moderate, and those less than .40 are poor. (267, 268)

Instrument Sensitivity and Specificity

The inter-rater agreement analyses described above document the agreement of independent raters regarding instrument item responses (Yes/No), however item response agreement may not relate to the agreement of raters regarding the detection of hazards. This instrument was designed with dichotomous responses (Yes/No); for certain items a positive response (Yes) indicates that a hazard is present (e.g. Are cleaning carts or supplies left unattended?) while for others, a positive response indicates that a hazard is not present (e.g. Does the bathtub/shower have a slip-resistant floor?). Therefore, sensitivity and specificity measures were used to evaluate the agreement of raters regarding the detection of hazards. This can be considered a type of criterion validity testing, using the expert rater as the gold standard. For these analyses the hospital safety instrument is considered as a binary diagnostic test, with the "positive" result indicating

that a hazard is present. Sensitivity, specificity, positive and negative predictive values are defined below. (274)

Sensitivity - proportion of test sites with the hazard which have a positive test result.

SENSITIVITY = a / (a + c)

Specificity - proportion of test sites without the hazard which have a negative test result.

SPECIFICITY = d / (b + d)

Positive predictive value – proportion of test sites with positive test result which actually have the hazard.

POSITIVE PREDICTIVE VALUE = a / (a + b)

Negative predictive value – proportion of test sites with negative test result which do not have the hazard.

NEGATIVE PREDICTIVE VALUE = d / (c + d)

		Hazard		
		Present	**Absent**	
Test Result	**Positive**	**a**	**b**	**a + b**
	Negative	**c**	**d**	**c + d**
		a + c	**b + d**	**a + b + c + d**

Data management (coding, entry, editing)

For the rater survey, data were abstracted from the survey forms, coded, and entered in a series of Excel spreadsheets. Discipline and department were entered as free text and then categorized. The number of years of injury prevention experience was coded as: 0, 1, 2, 3, 4, 5, >5, or 88 (blank). Self-rated expertise was coded as 0, 1, 2, 3, 4, 5, or 88 (blank). Missing items identified by the raters were entered as free text and then categorized. Respondents were asked to record item numbers (1.1 - 22.6) for four categories of reasons for items left blank (did not understand, did not know the answer, not enough

time, item did not apply). For these categories, item numbers recorded on the survey form were entered. Other reasons cited by respondents for blank responses were entered as free text. Respondents were asked to record item numbers (1.1 - 22.6) for four categories of reasons for 'not applicable' responses (equipment/hazard not present in the room, not relevant, did not understand, did not know the answer). For these categories, item numbers recorded on the survey form were entered. Other reasons for indicating a not applicable response that were cited by respondents were entered as free text.

For the inter-rater reliability testing, audit form responses were coded and entered in a series of Excel spreadsheets. For each rater observation, the following variables were entered: site number (1-4), room number (1-20), rater number (1-17), item number (1.1 - 22.6), expert response (response circled on the audit form; No = 0, Yes = 1, not applicable = 99, blank = 88), other rater's response (response circled on the audit form; No = 0, Yes = 1, not applicable = 99, blank = 88), hazard present (0 = no; 1 = yes), number of hazards present (n), hazard description (free text). The variable "hazard present" was added to account for the fact that the instrument is designed so that the "incorrect" response (indicating that a hazard is present) may be either 'Yes' or 'No', depending on the item wording; the shaded areas on the form indicate when a hazard is present. For each item, if raters circled the Y/N in a shaded area, the 'hazard present' variable was coded as Yes (1). For each item, if the rater did not indicate the number of hazards present, the 'number of hazards' response was coded as 0 if the Y/N was circled in the unshaded box and as 1 if the Y/N was circled in the shaded box, and if a list of hazards was provided, the corresponding number of hazards was entered.

Following data entry, each variable was checked for valid responses and edited as required. Frequency tables were generated for the 129 item numbers and analyzed to ensure that the data were complete and accurate. Total numbers of observations were calculated and compared to the expected number of observations, including observations grouped by item number, site number, room number, and rater.

Rater description

The characteristics of the raters were reported in a descriptive fashion, including professional background, department, injury prevention/safety experience and self-rated injury prevention expertise.

Hazard analyses

The number and pattern of hazards identified by the raters were reported by site and overall for each item number and item group (counts, sub-totals, free text descriptions). The leading hazards (items and groups) were identified by ranking total hazard counts by item and group for all sites. The proportion of hazards attributable to the leading causes was calculated.

The number of hazards was then described for each site by room and rater, with the mean and median number of hazards reported for each room (all raters) and each rater (all rooms). One-way analysis of variance was used to test for significant differences between the mean numbers of hazards detected by the raters, for each site. This was desired to further explore the patterns of hazard detection demonstrated by the expert and other raters, in order to document whether hazard detection varied significantly or systematically by rater, given the same set of test areas. These analyses were performed

initially to assess the minimum number of hazards present, using the 'hazard present' variable, and then were repeated for the total number of hazards present, using the 'number of hazards' variable. Similarly, one-way analysis of variance was used to test for significant differences between the mean numbers of hazards detected in each room. This was performed separately for each site. This information contributed to a greater understanding of the pattern of distribution of hazards by room and site, as well as to interpretation of subsequent analyses of individual item and item group performance.

Blank and not applicable responses

The items rated as not applicable (coded as 99) and items left blank (coded as 88) were summarized and analyzed. The number of blank responses was tabulated for each rater. For raters with the greatest number of blank responses, the audit items left blank were analyzed in order to identify patterns of response, and to hypothesize reasons for leaving certain items blank. Then the number of blank responses was tabulated for each item number. Items left blank were analyzed to identify potential reasons for non-response, such as items pertaining to hospital policy/practice, or items where the equipment/hazard was not present in the room. Finally, in order to identify the corresponding expert response for all blank responses, counts were performed for each observed combination of expert and other rater response (0,88; 1,88; 99,88).

Items with not applicable responses (coded as 99) were analyzed in a similar fashion. The number of not applicable responses was tabulated for each item number. Each implicated item was analyzed in order to identify potential reasons for selecting this response, such as items pertaining to hospital policy/practice, or items where the equipment/hazard was not present in the room. In order to identify corresponding expert and other rater

responses for all not applicable responses, counts were performed for each observed combination of responses (0,99; 1,99; 99,99; 99,0; 99,1; 99,88).

Inter-rater agreement analyses

Measures of rater agreement included raw agreement indices and the kappa statistic. For these calculations, blank and not applicable responses were not included; these were summarized descriptively as noted above. Although there were multiple raters, the expert rater was paired with each of the independent raters at each site; these were considered as pairs of raters for statistical analyses (expert/other).

For the raw agreement analyses, 2X2 tables were created, as follows:

	Rater 2		total
Rater 1	-	+	
-	a	b	a + b
+	c	d	c + d
total	a + c	b + d	N

Raw agreement indices that were reported included(270):

observed proportion of overall agreement: $(a + d) / (a + b + c + d)$
proportion of specific agreement for positive ratings: $2d / (2d + b + c)$
proportion of specific agreement for negative ratings: $2a / (2a + b + c)$

These were calculated overall, for sub-sets of instrument items, for each instrument item, and for each rater and discipline.

Inter-rater agreement was then assessed using the kappa statistic. Agreement was reported for each item, for sub-groups of items, and for the instrument overall. This was

repeated for each rater and by discipline, to assess the influence of raters and rater discipline on inter-rater agreement.

Sensitivity and specificity analyses

The sensitivity and specificity of the instrument were reported using the 'hazard present' variable, which is equivalent to a "positive" diagnostic test result. For these analyses the expert rater was considered the gold standard. The NCSS binary diagnostic test module was used for sensitivity and specificity calculations. Sensitivity, specificity, and confidence intervals were reported for the instrument overall and for sub-sets of instrument items.

Respondent burden

Respondent burden is defined as the time, energy, and other demands placed on those to whom the instrument is administered. Administrative burden is defined as the demands placed on those who administer the instrument.(204) In this application the respondent is the site where the instrument is being administered – the hospital and its staff and patients. Burden on the hospital includes the time required to administer the instrument, which may have implications for unit managers who coordinate the audit or who accompany auditors to assist in completion; burden also includes any minor disruptions or distractions to daily operations and any special information requests that are required by the audit, such as evidence of safety policies. The acceptability of the instrument to the hospital may be estimated by the degree of missing data and refusal rates (e.g. rooms or areas not accessed).

The burden on the respondent was estimated by the expert panel and by the raters. In terms of administrative burden, estimates of time and equipment required were reported. The time required to administer the instrument was recorded and reported (mean, median, range). Resources required for administration of the instrument were reported, including staff time, supplies, and equipment.

Ethical Considerations

Data

The inter-rater reliability data collection forms were coded to ensure anonymity of the individual raters, their disciplines, and their departments.

Participants

Written consent was obtained from the raters to participate in the study; each was provided with a copy of the participant information and consent form. All hospital site raters were hospital employees and as such are familiar with PHIA and confidentiality policies, and have signed the respective pledges.

Hazards discovered during testing

The hospital and clinic sites were provided with a written report summarizing the hazards found during testing of the instrument; this report was directed to the head administrator (private clinic medical director; Pediatrics and Child Health Department Head).

Ethical and institutional approval

Ethical approval was granted by the University of Manitoba Health Research Ethics Board. The physician operators of the Medical Arts pediatric clinic approved the inter-rater testing procedure at their site. The Child Health Program Team and Nursing Director of Children's Hospital supported, facilitated, and approved the development and

testing of the instrument during various phases of the project, at Children's Hospital inpatient and outpatient sites.

RESULTS

SAMPLE

Five test areas (four patient/examination rooms and one pre-defined public area) at each of four sites were audited in April 2004. A total of 15 pairs of raters participated, resulting in 9675 paired observations. One site had three pairs of raters, while the remaining three sites had four pairs of raters each.

RATER CHARACTERISTICS

Raters included physicians (3), nurses (7), ward clerks (2), and an injury prevention research assistant (1). All were from the Department of Pediatrics and Child Health. At one site with a greater number of volunteers than required, two 'raters' were a team of two individuals who completed a single audit form together, however only one of the teams completed a rater survey and could be identified as a team for the analyses. One rater participated at all four sites, allowing a comparison of results at the four sites sequentially. Two raters had previous exposure to the checklist, allowing a comparison of results between raters exposed and not exposed to the checklist; one rater had participated as an expert reviewer, and one rater had contributed toward the original version of the checklist but was not familiar with the instrument handbook.

Thirteen raters completed a rater survey. Self-reported injury prevention experience and training was variable, with three raters reporting no prior experience, one rater reporting three years of experience, two raters reporting five years of experience, and three raters reporting greater than five years of experience. Self-rated injury prevention expertise was reported on a five-point scale, and ranged from 0 to 5 (mean 3.15, median 3.5, SD 1.7).

HAZARDS IDENTIFIED

A significant number and range of hazards was identified. A total of 223 items were scored as having a hazard present by the expert rater, with a total of 451 hazards recorded by the expert rater (Appendix 5.2). A total of 1008 items were scored as having a hazard present by all raters combined, with a total of at least 1719 hazards. The other raters did not consistently record the number of hazards for each instrument item, and in some cases rated items hazardous that the expert rater did not classify as a hazard, therefore the ratings of the expert rater will be used here to describe hazard patterns.

The following summary of hazards considers both the number of items scored as having a hazard present (items scored in the shaded box on the form which indicates that a hazard is present) and the total number of hazards identified. The total number of hazards reflects the number of single items (e.g. electrical outlet) or groups of items (e.g. a pile of hospital gowns) which qualified as a hazard for a given item. Each group of hazards which constituted a single hazard type and could be corrected with a single action was classified as a single hazard; for example, a pile of hospital gowns with ties at the neck use a drawstring type of closure, which is a hazard, however this would be counted as a single hazard. However single items were counted as distinct hazards, as each would require a separate corrective action (e.g. three uncovered electrical outlets in a room were counted as three hazards).

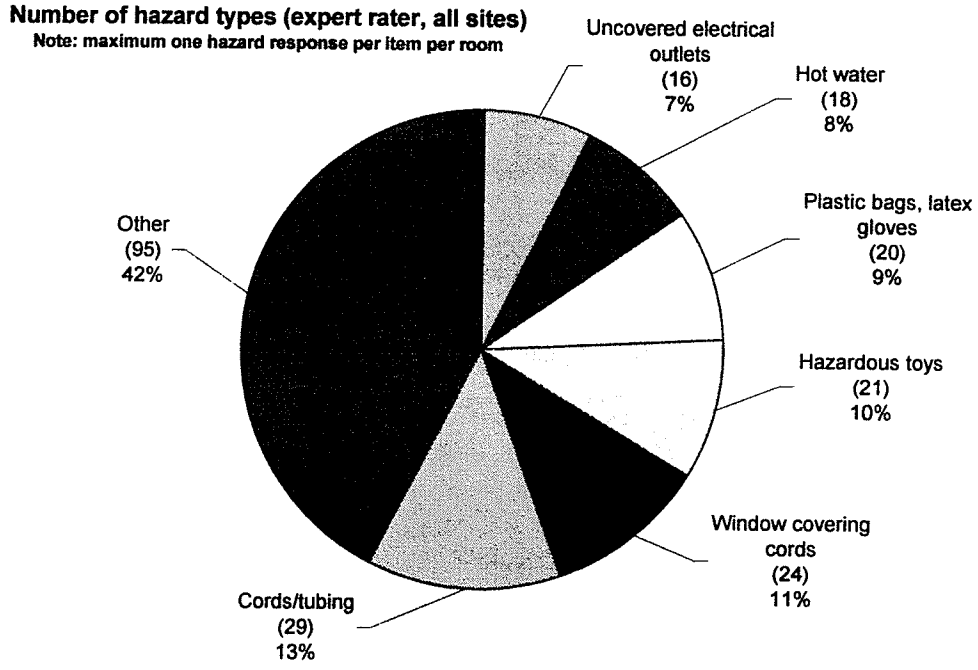
Site 2 had the least number of hazards and Site 1 the greatest number, which appeared to correspond to the amount of furniture and equipment in the test areas. The patient examination rooms at Site 2 were quite bare, with only essential equipment present, whereas the patient rooms at Site 1 had more furniture and equipment that were required

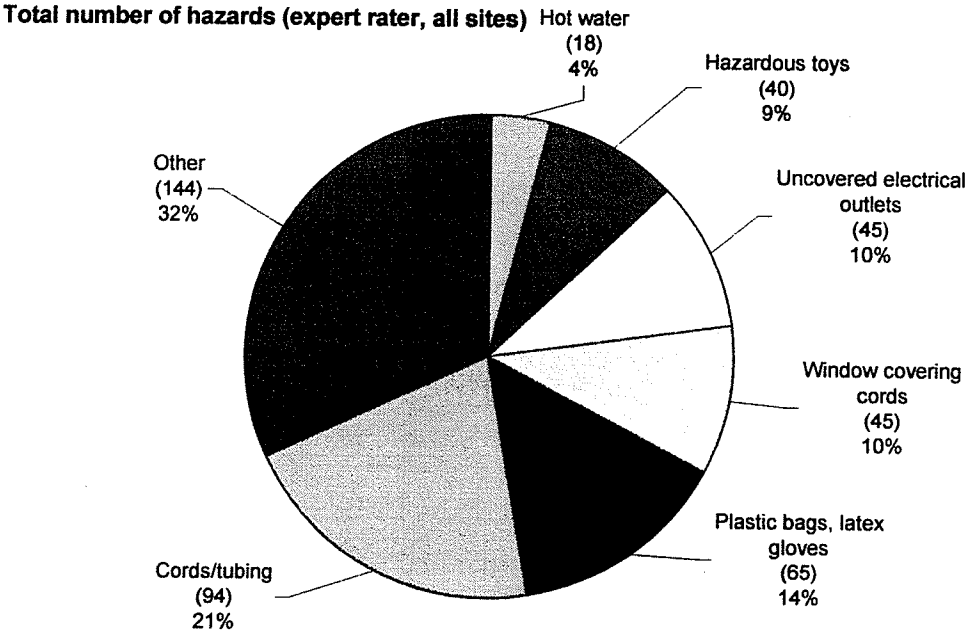
for the test situation (e.g. cribs, beds, playpens, high chairs, stretchers). The distribution of hazards varied between sites, as would be expected, given the observed differences in furniture and equipment by site. For example, Site 1 was the only site with cribs, beds, strollers, high chairs, car seats, and playpens. Stretchers were only found at Sites 1 and 3. Bathing facilities were only present at Site 1, although sinks with hot water were found in all examination rooms.

Six hazard types accounted for 58% of the total hazards identified (Figure 5.1). These were: cords/tubing (13%), window covering cords (11%), hazardous toys (10%), plastic bags and latex gloves (9%), hot tap water (8%), and uncovered electrical outlets (7%). The most significant concern was the documentation of hot water temperatures of 58-60° Celsius at Sites 1, 2, and 3 in public bathrooms and patient rooms, including bathtubs and sinks. This was communicated immediately to hospital administration and has since been reduced to a safe temperature. Numerous types of cords and tubing were accessible in virtually every room, and in many cases were accessible to a potential occupant of the crib, bed, or examination table. These included call bells, oxygen and suction tubing, telephone and electrical cords, and light cords. Some looped window covering cords were lengthy and not secured, and in many cases accessible to young children by placement of furniture and low, wide window ledges. Inner blind cords were present in several sets of blinds. Cleaning solutions were also accessible, including isopropyl alcohol. Toys with small parts, cords/strings, sharp edges and pinch points were found and removed following the audit. Plastic bags, plastic wrap, and latex gloves were accessible in most rooms, often in low drawers and adjacent to examination tables, cribs, and beds. Of note

is that these are all very significant types of hazards, and all can be addressed with minimal effort and resources.

Figure 5.1 Types of hazards identified, all sites combined





The numbers of hazards were identified by site, room, and rater and are presented in Table 5.1. The mean number of hazards varied significantly between raters at Sites 1, 2, and 4, with the expert rater (Rater 1) having the highest mean for Sites 1 and 2 but not for the other sites. The expert rater detected a higher number of technical equipment-related items at Sites 1 and 2, such as entrapment gaps in furniture. Rater 16 documented a greater number of hazards at Site 4. The majority of these "excess" hazards (in relation to the expert and other raters' assessments) at Site 4 had been rated as not applicable or not hazardous by the expert rater (e.g. hand soap).

The mean number of hazards varied significantly between rooms only at Site 3, where there was an unusually high number of items found in storage cupboards in one patient room (Room 13). The finding that the mean number of hazards did not otherwise differ significantly by room suggests that the distribution and detection of hazards was relatively consistent across test areas within each site.

Table 5.1 Number of hazards identified by site, room, and rater

Site	Room	Rater 1	Rater 2	Rater 3	Rater 4	Rater 5	*Mean (rooms)*[*]
1	1	12	9	9	11	7	*9.6*
	2	10	9	8	12	5	*8.8*
	3	15	13	12	15	11	*13.2*
	4	15	10	13	11	7	*11.2*
	5	18	3	16	12	10	*11.8*
	Mean (raters)[**]	*14.0*	*8.8*	*11.6*	*12.2*	*8.0*	
Site	Room	Rater 1	Rater 7	Rater 8	Rater 9		*Mean (rooms)*[*]
2	6	12	5	9	10	*	*9.0*
	7	11	5	11	5	*	*8.0*
	8	9	7	7	5	*	*7.0*
	9	12	10	7	5	*	*8.5*
	10	8	10	6	2	*	*6.5*
	Mean (raters)[**]	*10.4*	*7.4*	*8.0*	*5.4*		
Site	Room	Rater 1	Rater 10	Rater 11	Rater 12	Rater 13	*Mean (rooms)*[**]
3	11	7	8	15	10	9	*9.8*
	12	8	9	15	12	12	*11.2*
	13	16	21	19	16	14	*17.2*
	14	12	17	16	13	13	*14.2*
	15	11	14	13	8	15	*12.2*
	Mean (raters)[*]	*10.8*	*13.8*	*15.6*	*11.8*	*12.6*	
Site	Room	Rater 1	Rater 14	Rater 15	Rater 16	Rater 17	*Mean (rooms)*[*]
4	16	7	6	8	16	5	*8.4*
	17	9	7	8	14	7	*9.0*
	18	12	12	6	15	10	*11.0*
	19	9	16	12	18	10	*13.0*
	20	10	7	10	10	12	*9.8*
	Mean (raters)[**]	*9.4*	*9.6*	*8.8*	*14.6*	*8.8*	

[*] Not significant, $p > 0.05$ (one-way ANOVA) [**] Significant, $p < 0.05$ (one-way ANOVA)

BLANK AND NOT APPLICABLE RESPONSES

Raters were instructed to indicate a response for each item, using the not applicable column to indicate items which pertained to policies and practices that could not be observed in the test situation and for items where the equipment or item was not present in the room.

A total of 75 items (0.8%) were left blank (coded as 88). Blank responses varied by rater, with a mean of 5.0 blank responses per rater (SD 1.3, range 0-16, median 3.0, Table 5.2). For 46 of these, the item was scored not applicable (coded as 99) by the expert rater (61%), suggesting a difference in coding rather than a lack of understanding of the item (Table 5.3). For the two raters with the largest number of blank responses, nine of their blank responses were for items that should have been marked not applicable. For 29 items, the expert rater scored the item as Yes or No (1 or 0); these discrepancies with the other raters are more significant.

Table 5.2 Number of blank responses by rater

Number of blank responses	Rater
0	1, 11
1	4, 10, 15, 16
3	8, 9
4	3
6	17
8	13
9	2, 12
13	5
16	7

Table 5.3 Expert ratings for items left blank by other raters

Expert rater	Other rater	Count
0	88	14
1	88	15
99	88	46

Rating codes: 0 = No, 1 = Yes, 99 = not applicable, 88 = blank response

An analysis of the items left blank revealed that certain items were more likely left blank than others (Table 5.4). Some of these were policies and practices (items 3.4, 5.3, 8.3). Other items were not applicable given the absence of particular equipment in the room. For example, Section 10 pertains to medication, which was present in very few rooms, and Section 1 pertains to bathrooms, which were only present at Site 1 (except for hot water, item 1.3). Item 12.3, however, (checking for an inner blind cord loop) was perhaps left blank due to technical difficulty and a lack of understanding by raters, as noted by raters following testing.

Table 5.4 Number of blank responses by item number

Number of blank responses	Item number
1	2.3, **3.4**, 4.1, 4.2, 7.1, 7.2, 11.1, 11.7, 11.8, 11.12, 12.2, 12.4, 14.14, 18.4, 18.6, 21.2
2	1.1, 1.5, 1.6, **5.3**, 8.1, **8.3**, 11.5, 18.1, 18.7
3	1.2, 2.1, 5.1, 12.3
4	1.4
7	10.1, 10.3
8	10.2

Items in bold face are policy items which should have been coded 99 – not applicable.

A total of 7685 items (79.4%) were scored as not applicable by either the expert rater or at least one of the other raters. The majority of items were rated not applicable by all raters (indicated by 95 not applicable responses, Table 5.5). This was primarily due to the sub-groups of equipment such as beds, cribs, playpens, strollers, and toys that were not found in many of the rooms. For 7393 (96.2%) of items scored not applicable, the item was scored not applicable by the expert rater (Table 5.6), suggesting that for the most part, the use of the not applicable response by the other raters was as intended.

Table 5.5 Number of 'not applicable' responses by item number

Number of 'not applicable' responses	Item number
2	4.2
5	6.1
8	7.2
10	1.3, 5.1, 11.1, 11.4
13	2.2
17	7.1
22	**2.1**, 12.4
23	11.9, 12.2
27	12.1
43	12.3
55	2.3
58	18.2, 18.6
61	1.6
63	11.7
68	3.2, 10.2
71	18.1
74	10.3
76	1.2, 3.3, 18.7
78	**11.5**
80	5.5
84	**9.1**
87	**3.1**, 14.1, **16.14**
89	**15.6**
91	**15.3**, 19.2, 19.3, 19.4
93	**11.10**
95	**11.11, 13.2, 13.3, 14.12, 14.3, 16.13, 17.1, 17.2, 18.13, 18.14, 19.5, 19.7, 20.2, 20.3, 20.4, 20.6, 21.4, 21.5, 22.5, 22.6**

Items in bold face are policy items and items where equipment was not present, and would be appropriately coded 99 – 'not applicable'.

Table 5.6 Distribution of 'not applicable' ratings by rater type

Expert rater	Other rater	Count
0	99	169
1	99	123
99	0	192
99	1	147
99	88	46
99	99	7008

Rating codes: 0 = No, 1 = Yes, 99 = not applicable, 88 = blank response

An analysis of the items rated not applicable revealed that certain items were more likely rated not applicable than others (Table 5.5). The majority of these items were policies and practices or were not applicable given the absence of particular equipment in the room. For example, there were no mittens/booties/blankets and sleepers (item 3.1), no infant carriers (item group 20), no stairs/landings (items 5.5, 11.5), no carpets (item 8.1), and no play structures (item group 17). For 292 of the items scored not applicable by other raters (3.8%), the expert rater scored the item as Yes or No (1 or 0); these discrepancies are more significant. A summary of these items is found in Table 5.7. Items implicated more than the total number of raters (15) were item 5.3 (can staff open locked doors within 60 seconds – keyless entry, safety lock), which could have been interpreted as a policy/practice item; item 8.2 (are floors clean and dry, spills cleaned immediately, and signs posted for spills and when floors are washed or polished), which also could be interpreted as policy/practice; and item 11.9 (are toxic plants accessible to children), which might have been interpreted as not applicable when plants were not in the test area.

Table 5.7 Distribution of 'not applicable' ratings for items scored Yes/No by expert rater

Number of not applicable responses	Item number
1	12.3, 14.12, 18.5, 19.1, 19.2, 19.3, 19.4, 21.1, 21.2, 21.3
2	1.4, 1.5, 11.6, 11.7, 11.8, 14.1, 16.14, 18.12, 18.6, 4.2
3	18.7, 18.9, 3.1, 5.1, 8.1
4	10.2, 11.4, 12.4, 15.6, 18.1, 18.10, 18.4, 5.4, 5.5, 8.3
5	1.3, 12.2, 2.2, 6.1, 7.2
7	11.12, 2.3
8	11.3
9	2.1, 4.1
10	11.1, 12.1
11	10.3
12	3.2, 7.1
13	3.3
17	5.3
21	8.2
23	11.9

INTER-RATER AGREEMENT

Overall rater agreement was 75.1%, with the highest agreement at Site 1 and the lowest agreement at Site 3 (Table 5.8). Agreement for negative ratings was consistently somewhat higher than agreement for positive ratings at all sites, however it should be noted that negative and positive ratings reflect the response to the item question rather than the presence or absence of a hazard (only 45.7% of positive responses also indicate the presence of a hazard). The kappa statistic was 0.50 overall, with a range of 0.37 – 0.57 by site and 0.37 – 0.69 by item group. Inter-rater agreement was highest for the equipment group of items (beds, cribs, playpens) and lowest for the toy group of items.

Table 5.8 Inter-rater agreement overall, and by site and item group*

	Overall agreement	Specific agreement for positive ratings	Specific agreement for negative ratings	Kappa	Kappa SE	Kappa t	Kappa p
All sites	75.1%	72.7%	77.1%	0.50	0.02	22.29	< 0.001
Site 1	78.6%	75.8%	80.8%	0.57	0.03	16.46	< 0.001
Site 2	74.2%	70.4%	77.1%	0.48	0.06	7.60	< 0.001
Site 3	68.4%	67.5%	69.3%	0.37	0.04	8.31	< 0.001
Site 4	77.0%	75.2%	78.6%	0.54	0.05	10.81	< 0.001
General group (A)	73.3%	70.9%	75.4%	0.46	0.03	17.55	< 0.001
Equipment group (B)	85.4%	80.7%	88.2%	0.69	0.06	12.03	< 0.001
Play/toys group (C)	67.9%	69.5%	66.2%	0.37	0.08	4.81	< 0.001
Transport group (D)	81.4%	83.2%	79.1%	0.62	0.10	6.31	< 0.001

** Item group is defined as the four sub-groups of instrument items which correspond to the checklist numbering system (A,B,C,D)*

Inter-rater agreement varied significantly between raters, with overall agreement between 59.6% and 81.2%, and kappa values ranging from 0.19 to 0.62 (Table 5.9). The rater participating at all four sites did not demonstrate a trend of increasing agreement over time. This rater also had prior exposure to the checklist. The rater who had participated as an expert rater (8) had a kappa of 0.51, which was not significantly different from the other raters, when compared using the mean kappa value (0.49, SE 0.03, median 0.52). The team of raters demonstrated one of the lowest kappa values, and MD raters demonstrated slightly better agreement than RN raters.

Table 5.9 Inter-rater agreement by rater*

	Overall agreement	Specific agreement for positive ratings	Specific agreement for negative ratings	Kappa	Kappa SE	Kappa t	p
Rater 2[1]	77.7%	75.4%	79.6%	0.56	0.07	8.07	< 0.001
Rater 3	81.2%	78.9%	83.0%	0.62	0.07	9.03	< 0.001
Rater 4	75.2%	71.9%	77.9%	0.51	0.07	7.29	< 0.001
Rater 5	80.1%	76.9%	82.5%	0.60	0.07	8.54	< 0.001
Rater 7[2]	70.8%	65.9%	74.5%	0.40	0.10	3.96	< 0.001
Rater 8[ER]	76.9%	69.6%	81.4%	0.51	0.10	4.96	< 0.001
Rater 9	75.4%	76.9%	73.7%	0.52	0.12	4.22	< 0.001
Rater 10	76.3%	75.4%	77.1%	0.53	0.09	6.11	< 0.001
Rater 11	61.0%	61.3%	60.7%	0.22	0.09	2.63	0.01
Rater 12[T]	59.6%	57.4%	61.7%	0.19	0.09	2.07	0.04
Rater 13[3]	76.2%	75.0%	77.3%	0.52	0.09	5.91	< 0.001
Rater 14	79.2%	76.1%	81.7%	0.58	0.10	6.10	< 0.001
Rater 15	75.5%	71.6%	78.5%	0.51	0.10	5.15	< 0.001
Rater 16	75.2%	74.3%	76.1%	0.50	0.10	5.26	< 0.001
Rater 17[4]	78.2%	78.7%	77.6%	0.56	0.11	5.25	< 0.001
RN raters	74.1%	71.3%	76.4%	0.48	0.03	15.82	< 0.001
MD raters	76.7%	74.1%	78.8%	0.53	0.06	9.44	< 0.001

** One rater participated at all sites (Raters 2, 7, 13, 17), with the temporal sequence indicated by the superscript number; this rater also had prior exposure to the checklist; one rater also participated as an expert rater (Rater 8); one rater was a team of two individuals (Rater 12).*

Inter-rater agreement varied considerably between items (Appendix 5.3). The percentage overall agreement was 100% for 33 items, 75% or greater for 59 items, 50-74% for 22 items, and less than 50% for 6 items. The remaining items were scored not applicable or blank. For the items for which cell sizes were sufficient to calculate kappa values, six items scored 0.60 or greater, four items scored 0.40-0.59, and 19 scored less than 0.40.

Sensitivity and Specificity

The instrument's sensitivity and specificity in terms of identifying hazards is summarized in Table 5.10. Sensitivity and specificity varied by site, with Sites 3 and 4 having the highest sensitivity and Site 1 having the highest specificity but lowest sensitivity. At least part of this variation can be attributed to the variation in equipment present at the various sites. The equipment and transport groups, which were highly specific but least sensitive, were almost exclusively found at Site 1. The most sensitive items were hot water temperature and uncovered electrical outlets, and accessible cords and tubing.

Table 5.10 Sensitivity and specificity of the instrument overall, by site, and by item group

	Sensitivity (95% CI)	Specificity (95% CI)
Overall	63.2% (59.7-66.6)	81.4% (79.0-83.5)
Site 1	50.2% (44.2-56.2)	90.9% (88.2-93.0)
Site 2	64.1% (55.1-72.2)	82.4% (75.0-88.0)
Site 3	71.7% (65.1-77.4)	64.9% (59.3-70.1)
Site 4	72.1% (65.0-78.3)	79.5% (73.7-84.2)
Core checklist	61.3% (56.2-66.2)	80.1% (76.2-84.1)
Hot water	*96.6% (88.5-99.1)*	*66.7% (20.8-93.8)*
Cords	*82.1% (67.3-91.0)*	*46.2% (28.8-64.5)*
Electrical outlets	*82.5% (70.6-90.2)*	*100% (67.6-100.0)*
Window cords	*69.2% (55.7-80.1)*	*50.0% (9.5-90.6)*
Equipment group	22.7% (12.8-37.0)	95.5% (92.1-97.5)
Beds	*7.1% (2.0-22.7)*	*96.2% (87.0-98.9)*
Cribs	*37.5% (13.7-69.4)*	*97.4% (91.0-99.3)*
High chairs	*75.0% (30.0-95.4)*	*100% (89.3-100.0)*
Playpens	*50.0% (15.0-85.0)*	*91.5% (83.4-95.8)*
Toys	52.0% (41.0-62.8)	*80.5% (70.3-87.8)*
Transport group		
Car seats	*66.7% (30.1-90.3)*	*100% (67.6-100.0)*
Stretchers	*20.0% (3.6-62.4)*	*88.9% (71.9-96.2)*
Strollers	*64.3% (45.8-79.3)*	*100% (87.9-100.0)*

Note: CI = confidence interval

RESPONDENT BURDEN

The time to complete the audit varied by site, with each room requiring between 10 and 30 minutes for assessment, depending on the amount of furniture and equipment present (total audit time 60-150 minutes per site; mean 101, SE 21). The timing of the audit was

such that no interruptions in patient care were experienced; all rooms were vacant at the time of testing. The supplies for a single rater were approximately $65, including the thermometer, tape measure, small parts tester, clipboard, binder, pen, and photocopying.

In terms of respondent and administrative burden, the expert reviewers commented favorably on the potential future application of the instrument in facility construction, operation, and maintenance. One reviewer commented that the greatest barrier to implementing the instrument might be the anticipated time and resources to address issues that are identified. This reviewer also commented that the instrument would be acceptable particularly if it was linked to patient safety and accreditation, and endorsed by the Canadian Pediatric Society and the Canadian Association of Pediatric Healthcare Centres. Another reviewer also noted the important link to patient safety and commented that the tool provides hospitals an opportunity to begin to address patient safety from a more systemic perspective.

CHAPTER 6

DISCUSSION

This chapter presents a discussion of the main study findings, assumptions, limitations, and strengths. It then outlines a number of recommendations regarding further research, development, and application of the instrument. This is followed by a discussion of policy implications.

FINDINGS

A thorough accounting of reported hospital injuries and hazards was only possible through a broad search of multiple published and unpublished sources. Searches of ECRI sources and regulatory agency databases resulted in the greatest yield of detailed case reports, and the published hospital safety literature contributed additional aggregate and descriptive data. The resulting list of reported injuries was not dissimilar from serious home injuries seen in infants and toddlers, in terms of type and severity of injury, as well as products and other hazards implicated. A surprisingly high number of fatal injuries were identified, implicating primarily beds and cribs, but also various products which led to choking, strangulation, and electrical injuries. These injuries were not summarized in any form in the published literature, limiting the ability of hospitals to easily recognize and respond to the issue of hospital safety. The original instrument was found to reflect the majority of the reported injuries and hazards, although several new items were added and many existing items were revised as a result of the injury and hazard data retrieved.

No comprehensive sources of child safety standards for pediatric health care facilities were identified; therefore home safety standards, child care safety standards, and general

hospital facility standards formed the basis of the instrument's recommendations. This lack of specific guidance for health facilities also limits the ability of hospitals to recognize and respond to hospital safety issues. Due to the lack of research evidence in the area of hospital safety, relevant child safety legislation, standards, and expert recommendations were identified to support each instrument item (Level III evidence). The Hazardous Products Act and Medical Devices Regulations (Food and Drugs Act) were the only federal legislation of relevance, and informed numerous instrument items. Existing accreditation standards supported the notion of facility safety however provided no specific guidance for pediatric patients and visitors. Risk management standards published by ECRI were quite informative for numerous items. Facility design guidelines for public, residential, and child care facilities were used extensively for content validation, and provided additional background material for many items. Numerous product standards informed the development of equipment checklists for children's products, particularly ASTM and CSA standards. Many relevant statements of expert opinion and consumer advisories were identified, and represented the major authorities in child safety in North America. These diverse sources provided background and rationale for each item and contributed to content validation. The resulting instrument handbook is the only existing summary of available evidence regarding best practices in child injury prevention applicable to the hospital setting.

Although the expert panel was small in number, the participating experts provided the desired range and balance of expertise for content validation. They represented facility users, including both physicians and nurses, and contributed expertise in injury prevention, inpatient pediatrics, and child health quality improvement. None of the

instrument items met the criteria for lack of consensus or item deletion, and the instrument was rated as easy to use and comprehensive. Suggestions were provided for missing items and clarification of existing items, and illustrations were recommended for future editions. The final instrument's readability scores and estimated grade levels were consistent with a technical document, and suggest that future revisions could aim to improve readability and lower grade level.

A significant number and range of hazards were identified at all sites without any 'staging' of products and equipment. The seven hazard types which accounted for 60% of the total hazards identified are clinically significant and most are easily corrected. Accessible cords and tubing such as light cords, call bells, and oxygen tubing were abundant at the bedside, often within reach of the crib or bed. Some of these cords can be shortened or removed, and others could be stored elsewhere. Placement of the crib away from the wall would reduce accessibility to these and other hazards, such as electrical outlets on bedside panels. Looped and lengthy blind cords were found on interior and exterior windows, and often were accessible by placement of furniture. Some horizontal blinds were found to have the hazardous looped inner cords that have resulted in strangulation deaths in toddlers. The outer 'pull' cords can be shortened and permanently affixed to the wall, and the inner cord hazard can be easily corrected by a device available from any window covering retail outlet or contractor. Numerous cleaning agents were accessible in many rooms, although most of these would produce only mild clinical effects if ingested; however isopropyl alcohol and alcohol-based fixatives were also accessible and are significantly more toxic. Placement of these agents out of reach or storage in a locked supply area would be simple and effective solutions. The temperature

of the tap water was at a hazardous level at three of the four sites (58-60°C). While Legionella growth is a concern for health facilities, the CSA standard for health facilities specifies a maximum hot water temperature of 48°C, which can be achieved by the use of mixing valves in the system to moderate temperature at public and patient sinks and bathrooms while allowing a hotter system-wide temperature to reduce Legionella growth.(263) Hazardous toys with small parts that pose a choking hazard were found in many of the test areas. Routine toy surveillance, which can be performed while cleaning toys and play areas, could eliminate these hazards. Uncovered electrical outlets were found in most of the test areas, and in most cases do not require safety covers. However, unused and accessible outlets in play areas and toddler's rooms should be covered, out of reach, tamperproof, or child-resistant. In some cases this can be achieved simply by placement of furniture. Plastic bags and latex gloves, which are attractive to toddlers and are a suffocation hazard, were found in virtually all rooms and should be stored out of reach. Death due to choking on examination gloves given to children in clinicians' offices has been reported.(275)

Overall rater agreement was 75% (kappa 0.50), with the highest agreement for the equipment (beds, cribs, high chairs, playpens) and transport groups (car seats, stretchers, strollers) and the lowest agreement for toys. The higher agreement found for equipment-related items is likely due to the specific and restricted nature of the inspection required for checking a single piece of equipment, which results in greater clarity and precision than when inspecting a room or space for a range of hazardous items (e.g. cords) or when inspecting a large number of items for a range of hazards (e.g. toys). Rater agreement varied somewhat by rater, although most raters were consistent with the overall measures

of agreement. Prior exposure to the checklist and repeated use did not appear to significantly influence rater agreement, although the study was not designed to detect these differences.

The instrument's sensitivity and specificity in terms of identifying hazards was quite variable, with the most sensitive items being hot water temperature, uncovered electrical outlets, and accessible cords and tubing. These items are quite straightforward and require no special expertise or interpretation, which may explain the higher than average levels of agreement regarding presence/absence of the hazard. The equipment and transport groups were highly specific but the least sensitive. Beds, stretchers, and cribs were the least sensitive item sub-groups, compared to other types of equipment, although small sample sizes and low numbers of actual hazards limited these analyses. At least some of these items may require either illustrations or further explanation in the checklist or instrument handbook. For example, item 13.4 (mattress gap at head or foot of bed) was positive (hazard present) for three beds inspected, however only two raters detected and recorded a gap (2 pairs of raters agreed; 12 pairs disagreed). This measurement would not be familiar to most raters, and could be clarified by an illustration.

ASSUMPTIONS, LIMITATIONS, AND STRENGTHS

Prior to considering the implications of the above findings the study's assumptions, limitations, and strengths warrant discussion.

CONTENT VALIDATION

The main assumption in the first step of content validation was that all relevant hospital injuries and hazards were identified. The injury and hazard searches were limited to

English language sources and North American regulatory agencies; these limitations were deemed appropriate given that health care facilities, equipment, and even children's products differ considerably between many countries, yet are similar (or identical) within North America. Regulatory agency databases were very useful but were limited to cribs, beds, stretchers and other medical equipment, with the exception of the Health Canada Product Safety Information System, which captures injuries due to children's products. Injury and hazard data were generally difficult to identify, likely related to under-reporting out of fear of legal action, and the published literature was of poor quality. Fortunately, the ECRI databases contributed a large number of otherwise unreported cases through their use of active surveillance of the media, legal claims, published literature (with a broader journal selection than PubMed®), and complaints data sources. However numerous ECRI searches were required to retrieve the final set of reported cases.

The main assumption in the identification of relevant child safety standards was that standards not specifically designed for health care facilities are applicable in the hospital setting, including product safety, home safety, and child care (daycare) standards. This assumption arose by necessity due to the limitations of the hospital safety literature. There was very little specific literature identified, and no specific guidance documents, thus there was a need to draw parallels to home and day care safety. Nevertheless, the injuries and hazards identified in the first phase of content validation verified that the mechanisms of injury and products and equipment implicated are similar in both settings, and the subsequent hospital audits confirmed that common household hazards are also present in the hospital. This limitation of the study was also one of its strengths, in terms

of the ability to draw on related areas (home, day care) which have an established literature and existing standards, with confidence that these are also relevant in health care facilities.

Other assumptions in the identification of relevant standards relate to the application of standards from other jurisdictions, the application of federal product safety legislation to users of products, and the application of voluntary standards to users of products. All North American child safety standards were considered relevant, and were referenced as best practice for hospitals. Recommendations issued by the American Academy of Pediatrics and the Consumer Product Safety Commission are for the most part completely relevant in the Canadian context, given the overlap in manufacturing and marketing of children's products between the US and Canada. For items where Canadian standards or legislation exist, these were cited in the instrument handbook. When specific Canadian guidance documents were lacking, sources from other jurisdictions were referenced. Federal product safety legislation pertains to the advertising, sale, and importation of products, and does not technically pertain to users of products such as hospitals. However, the principles of product safety incorporated in the Hazardous Products Act and related industry guidance documents were cited as best practice for hospitals. The basis for this decision was the argument that if a product is unsafe according to the Act, and could therefore not be advertised, sold, or imported, then a hospital should not knowingly use that product. In terms of the application of voluntary standards to users of products, the same principles apply. While voluntary standards such as ASTM consumer product standards also do not technically apply to users, the argument for their inclusion in the handbook was that hospitals should only use products that would be considered

safe according to the standard, and in compliance with user guidelines that are cited within the standard.

The major assumption in the expert review process was that the experts who participated were representative of the potential experts who could critique and best contribute to improving the instrument. Although the expert panel was small in number, the participating experts provided the desired range and balance of expertise for content validation, and contributed detailed and useful comments. The large number of instrument items and the length of the instrument handbook may have resulted in reviewer fatigue in completing a thorough assessment in the written survey format. The lack of review by hospital engineering, risk management, and product safety experts is a potential limitation of the review process and could be addressed in the next stage of instrument refinement.

Instrument Performance

The major assumptions in the inter-rater reliability testing methods were that the sites and rooms inspected were representative of facilities for which the tool was designed, and that the raters were representative of potential users. The instrument was designed for inpatient and outpatient facilities which treat pediatric patients. It was tested in a tertiary care pediatric hospital and a pediatric office practice, and included inpatient rooms, outpatient and emergency department examination rooms, and public areas accessible to and used by children. The rooms tested were selected to ensure that beds, cribs, stretchers, and other children's equipment were present. The raters included physicians, nurses, and unit assistants. Although their self-reported injury experience and expertise

was higher than expected, these raters likely have the same knowledge base and experience as their peers at other pediatric facilities.

The constraints required for controlled inter-rater testing imposed several limitations. First, there were time constraints in the test situation that would have been more flexible in realistic application conditions. Although many items were not applicable in a given room, all 129 items required review and response in each room (this was also dictated by the study design in order to allow paired comparisons). Many rooms had a great deal of furniture, equipment, and supplies to inspect, and a large number of hazards were identified. Raters were constrained to a fairly strict time limit in order to complete the audit in a reasonable length of time, and perhaps could have demonstrated higher agreement given more time in each room. Another limitation was that the raters did not have prior exposure to either the instrument or the handbook in order to simulate realistic conditions and to ensure that all raters had equivalent baseline exposure to the instrument. The lack of opportunity to preview the documents meant that raters were not familiar with the content. This may have adversely affected inter-rater agreement and instrument sensitivity measures. A potential limitation was the use of individuals rather than teams of raters, which was required to limit the number of volunteer staff who were relieved of their duties for the testing period. It is possible that a team approach using staff familiar with the space and equipment being inspected combined with staff from other disciplines and areas could improve rater agreement and instrument sensitivity and specificity. The results of the single team of raters do not support the notion that teams might perform better, however this study was not designed to study the difference between team and individual rater performance.

Despite these limitations, the inter-rater testing was also notable for a number of strengths. Sites and rooms were carefully selected in order to ensure a representative sample of expected equipment, furniture, and hazards; the desired rooms and sites were available and vacant at the time of testing, and the desired equipment was present. A representative sample of volunteer raters was assembled, including most of the desired disciplines, and raters demonstrated great interest and effort in completing the audits. The desired sample size was achieved, and the number and range of hazards identified was adequate for rater agreement analyses.

RECOMMENDATIONS FOR RESEARCH AND FURTHER DEVELOPMENT

There are a number of recommendations for instrument refinement which arise from this study that could address identified weaknesses. In order to produce an instrument which can be disseminated to Canadian health care facilities, the next step should be to bring together representatives of potential user facilities and content experts to review these results and the instrument and handbook in their current format in order to provide recommendations for the final revisions. This group should include one representative from each of the following: pediatricians, pediatric nursing staff, inpatient and outpatient pediatric health care facilities, hospital risk management, quality assurance, health facility legal counsel (lawyer), biomedical engineering, health care facility engineering, housekeeping, purchasing, hospital accreditation (e.g. CCHSA), the public (e.g. parent), injury prevention, product safety, and key stakeholder organizations (CPS, CAPHC, CCHSA). A face to face meeting of these representatives could be informative in terms of recommending final revisions, format, dissemination, and maintenance (ensuring future review and updates). The expert group should first use the instrument in a typical

facility, either before the meeting, at their own facility, and/or during the meeting, at a representative facility, in order to develop a familiarity with the instrument items and the handbook. At the meeting, each instrument item should be reviewed systematically, considering the content validity, rater agreement, and sensitivity/specificity data. This expert review group should then be consulted regarding the following issues.

- The total number of items could be reduced by deletion and/or consolidation of certain items, which could enhance user acceptability.

- The car seat and play equipment groups of items were identified as potentially beyond the scope of the audit, and could be deleted.

- The inclusion of infant swings and an item regarding sharp corners should be considered.

- Weak items, such as those with the lowest agreement and sensitivity/specificity measures, as well as items with high numbers of blank or not applicable responses should be carefully reviewed for relevance and clarity, and should either be revised or deleted. In order to explore reasons for rater disagreement, weak items could be reviewed one on one with raters or potential users; the addition of diagrams or photographs and/or rewording certain items might improve rater agreement for these items.

- Items which are policies could be grouped or identified as policy items to streamline the inspection process.

- Additional policy items could also be considered, as suggested by the expert panel; by grouping or marking policy items as such it would be possible to add policy items without impacting the inspection workload.

- Alternative formats could be explored to enhance user acceptability, such as CD, palm-pilot or online versions. These could be designed to be used to select relevant items or item groups in advance, to track results and action plans, to illustrate inspection procedures and toxic plants, and to link to standards, recommendations, and other references.

- The potential impact on accreditation standards and the potential for integration of elements of the instrument into existing standards should be explored. While this could be discussed at a meeting of this expert group, consultation and liaison with the CCHSA would be an essential parallel process.

- Legal issues, such as institutional liability related to use or nonuse of the instrument, should be clarified. As with accreditation issues, consultation with experts in the area of health facility law would be another parallel process.

- Plans for dissemination require discussion, including issues such as copyright, ownership, funding for printing or producing materials (e.g. CD-ROM) and disseminating materials to facilities, user support, and promotional expenses.

- A process for ensuring future scientific review on a periodic basis should be established, including a mechanism for disseminating updates and revisions.

Once refined, there are a number of potential future research applications for the instrument that could be linked to dissemination and application in other settings. There is a single published report of the types of hazards found in pediatric inpatient facilities. The instrument could be used to measure and compare hazards in various types of health care facilities, in order to describe the epidemiology of pediatric hospital hazards in a larger and more representative sample. This might include general hospitals which treat children in the emergency department, community hospitals which admit infants and young children, long-term pediatric special care facilities or medical group homes. Similarly, the instrument could be used as an intervention, with evaluation of the impact of hazard surveillance on hazard prevalence, staff knowledge, and safety-related policies. Informal feedback from the pilot sites and the raters indicates that the audit process has stimulated policy development and hazard reduction initiatives and has improved staff awareness and knowledge of hospital hazards relevant to children.

The modular format of the checklist was designed to facilitate a range of potential modes of application of the instrument in hospitals and other health care facilities. While inpatient pediatric facilities might use all sections, outpatient facilities might use the general safety checklist (A) and any other section that is relevant, such as toy and play area safety (C). General hospitals with emergency departments or inpatient units treating children might use the general checklist as well as the crib and bed checklists (B). Specific quality improvement projects could use a single item or group of items, such as monitoring compliance with crib safety recommendations or surveillance of toy-related hazards.

POLICY IMPLICATIONS

The dissemination of a new hazard surveillance instrument for health care facilities has a number of policy implications for decision-makers at the facility level. Hospital injuries and hazards must compete against other compelling priorities of the organization, and the resources required for hazard surveillance and management must be balanced with opportunity costs and the potential costs of inaction. Both inaction and action have important ethical and legal implications. There are risk management, legal, and ethical grounds for proactively identifying and managing hazards to children in the hospital setting. Specific priorities and strategies will depend upon the specific type of hazard detected and the risk it presents. Life-threatening hazards clearly should be addressed, as should hazards that a "reasonable" pediatric facility would address as the standard of care. Other "low-hanging fruit" – hazards which are easily minimized with minimal resource implications – could also be addressed. As individual institutions deliberate their specific course of action, the relevant evidence and contextual factors should be reviewed. These should include (1) evidence of the risks and hazards, as documented by injury and hazard data and facility surveillance; and (2) an examination of local contextual factors of importance, such as legal and risk management counsel, operational considerations, resources, ethical issues, and institutional values such as promotion of a safety culture and risk tolerance. Other means of reducing costs would be to integrate child safety proactively in purchasing (review of planned purchases), donations, facility renovation/construction, and maintenance. As in patient safety, all levels of the facility and all departments could take responsibility to consider child safety in routine operation and policies.

There are also a number of policy issues which arose regarding gaps in national injury/hazard surveillance, legislation, and standards. A significant gap in useful incident data has been noted in the broader area of patient safety, both for near-miss and injury events. A similar gap exists for unintentional injury events in health care facilities. Future patient safety surveillance systems should be designed to capture significant unintentional injuries, such as fatal or near-miss events, in addition to other types of patient safety incidents. This should include modules for classifying unintentional injuries occurring in the hospital or other health care settings which reflect ICD injury coding, as well as modules to facilitate capture of significant variables associated with the host (e.g. height, weight, other anthropometric data of relevance for entrapment), the agent (e.g. bed manufacturer, model, type of bed rail, measurement of the entrapment gap, mattress characteristics, etc.) and the environment (e.g. type of facility, level and type of supervision, etc.). Some of these elements could be abstracted from the instrument and handbook.

The Health Canada product safety and medical device databases could also be used to monitor significant events, and hospitals should be made aware of the importance of reporting injury events involving medical devices, including beds, cribs, and stretchers, as well as significant incidents involving consumer products. ECRI is another important source of data for hospitals, and accepts voluntary reports from member institutions. Publication of case reports in the pediatric research literature is another method of ensuring that knowledge regarding significant hazards is accessible to other institutions.

Given that beds and cribs appear to present the highest risk for fatal injury, the lack of specific standards for pediatric hospital beds, stretchers, and cribs is concerning. The

current Medical Devices Regulations impose a general safety requirement rather than specifying design or performance criteria, and the Crib Regulations of the Hazardous Products Act do not apply to hospital cribs. Other significant hazards which are unregulated in Canada include window covering cords (inner and pull cords), latex balloons, high chairs, and infant seats/carriers. There are also a number of products which are regulated in Canada but where existing regulations could be improved to include elements specified in existing standards. For example, entrapment in drop-sided mesh playpens and entrapment in stroller restraint systems are addressed in their respective ASTM standards but not in the relevant Canadian regulations. These and other ASTM standards also include specific consumer warnings which are not required in Canada. Strengthening existing child safety legislation in Canada could benefit children both in their hospital and home environments, and should be seriously considered.

The lack of national accreditation or facility standards which address hazards for pediatric patients also warrants discussion. While risks related to furniture, equipment and space are included in current accreditation self-assessment modules, the unique risks for pediatric patients and visitors are not noted or described. With the new focus on patient safety, attention to hazards in the physical environment may increase, and might encourage the development of these standards. An instrument such as the one studied here may provide guidance for the future development of facility design, construction, and operation standards that could improve hospital safety for children. As noted by the expert panel, uptake and use of the instrument would be more likely if linked to patient safety and accreditation activities, and if endorsed by key child health leaders and stakeholders. Following refinement, future application of the instrument could provide a

broad range of health care facilities the opportunity to begin to address patient safety from a more systemic perspective and could contribute to safer hospital environments for children.

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Appendix 4.1

Published Research Literature Search Strategy

PUBLISHED RESEARCH LITERATURE SEARCH STRATEGY

Inclusion Criteria

The literature search strategy was designed to identify a large number of potentially useful publications, therefore a broad set of selection criteria was used for retrieval. All publications on the subject of unintentional injuries in patients and visitors in health care settings were retrieved for review. Although the priority was to identify pediatric injuries and hazards, a search strategy with age-based limits was too restrictive, so publications relating to any age were included for review. This search aimed to retrieve any original data identifying an injury, an injury event (near-miss, no-harm), or a potential injury hazard (product, equipment, device, or facility/environment hazards such as flooring, window coverings, etc.). No restrictions were placed on study design or size.

Exclusion Criteria

This aspect of the literature review included only published English-language literature. Medical errors, iatrogenic injuries, patient abduction, patient security, intentional injuries and suicide were excluded, as well as occupational injuries.

Databases

Multiple sequential searches of the English-language medical literature were completed between February 2000 and January 2004. One of these searches was completed by a professional health sciences librarian, and one by a professional law librarian. PubMed® was the primary search engine; this database includes over 13.5 million citations in the health field, and includes OLDMEDLINE (1953 – 1965) and MEDLINE. Supplementary searches were completed using CINAHL and EMBASE.

Keywords

A comprehensive list of keywords (Table 4.1) was generated using a small preliminary set of relevant publications, in order to develop a preliminary search strategy; these were used both for the search of published literature, described in this section (Search Strategy I), and the search of other data sources (Search Strategy II), described in the next section. Keywords and phrases were entered as search terms in PubMed, in order to find a preliminary set of relevant publications. These publications were then explored electronically for their MeSH coding and their abstracts reviewed in order to identify additional keywords.

Table 4.1 Literature search and environmental scan keywords and phrases

Host	Injury/Hazard	Setting	Mechanism	Equipment	Other
Infant Child Pediatric Paediatric Patient Inpatient	Injury Accident Hazard	Hospital Ward Health care facility	Fall Burn Suffocation Choking Strangulation Entrapment Electrical injury Poisoning Drowning	Bed Bed rail Crib Toy Intravenous Pacifier Stroller Carriage Playpen High chair Infant carrier Car seat	Safety Risk Management Liability Premises liability

Related Articles link

As no consistent MeSH coding combinations or keywords could be identified, the "Related Articles" link was used as a method to identify a further set of relevant articles, which were analyzed in a similar fashion, until there was no additional yield. The Related Articles link results in a pre-calculated set of PubMed citations that are closely related to the article, based on a word-weighted algorithm using words from the title, abstract, and

MeSH terms. Related Article citations are displayed in rank order from most to least relevant.

Search strategies

All keywords identified in this process were entered in the MeSH Database to identify potential MeSH terms. Free text search terms as well as structured MeSH-based searches were completed, using the following terms in various combinations:

Search terms: terms relating to injury or hazards (accident, injury, safety, hazard); terms relating to specific types of injuries (fall, burn, entrapment, electrical, etc.); terms relating to specific equipment (crib, bed, toy, etc.); terms relating to the hospital setting (hospital, premises), terms relating to legal implications of hospital injuries (liability, premises liability); and terms relating to the pediatric patient (pediatric, child).

MeSH terms: terms related to injuries and hazards (Wounds and Injuries, Accidents, Safety); terms related to the hospital setting (Hospitals, Health Facility Environment, Facility Design and Construction, Nurseries – Hospital, Hospitals - Pediatric); terms relating to equipment (Equipment Safety, Equipment Failure, Infant Equipment, Consumer Product Safety, Beds); terms relating to legal implications of hospital injuries (Liability – legal); and terms related to injury prevention measures (Safety Management, Risk Management).

For the MeSH searches, first the term was exploded, with no subheadings selected. For searches resulting in less than 100 citations, titles and abstracts were browsed for relevance. For results greater than 100 citations and which lacked relevance, additional

MeSH terms, MeSH subheadings and additional keywords were added using AND or NEAR to enhance specificity.

Authors with several relevant publications were searched by name to identify related published work.

Electronic Collections

The *Cochrane Library* was searched using the search terms identified above. The following online sources were browsed for relevant published research literature: the British Medical Journal's online *Collected Resources* "Patient Safety" publications; the National Patient Safety Foundation's bibliographic database; the Agency for Healthcare Research and Quality's *Research Activities* newsletters; the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) website; and the Virginians Improving Patient Care and Safety (VIPC&S) *Patient Safety News Tracker*, which is an up-to-date comprehensive monthly posting of research literature and other news relating to patient safety.

Manual Searches

An additional subset of articles was identified by citations identified by hand searching publications retrieved through the above selection strategies and hand searching documents retrieved through a concurrent search of other data sources (Search Strategy II). Once publications were reviewed for specific injury types and hazard patterns, additional searches were conducted to retrieve similar reports, and additional keywords were added to the list.

Appendix 4.2

Expert panel participant package

(Research Participant Information and Consent Form, Content Validity Reporting Form)

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff.

Title of Study: Is the Hospital a Safe Place for Children? Development and Validation of a Safety Audit for Pediatric Health Care Facilities

Principal Investigator: Dr. Lynne Warda, NA335 – 700 McDermot Avenue, Winnipeg, MB, R3E 0T2, 204-787-1873. Dr. Warda is a doctoral student in the Department of Community Health Sciences, Faculty of Medicine, at the University of Manitoba. This research study is the topic of Dr. Warda's doctoral thesis. Dr. Warda's supervisor is Dr. Michael Moffatt, Professor, Department of Community Health Sciences and Executive Director, Research and Quality, Winnipeg Regional Health Authority, Suite 1800 - 155 Carlton Street, Winnipeg MB, R3C 4Y1, 204-926-7835.

Purpose of Study

The purpose of this study is to develop and validate a hospital safety audit instrument which can be used to determine if a pediatric health care facility meets current child safety standards.

Study procedures

The hospital safety audit instrument is a 135-item "checklist" which aims to identify potential injury hazards for children in pediatric health care settings, including pediatric patients and visitors. You are being asked to participate in an expert panel as part of the content validity testing of this instrument. You will be asked to rate each of 135 instrument items in terms of its clarity, relevance, and redundancy, using a five-point scale. You will be asked to rate the instrument's overall comprehensiveness, and to list any missing items (injuries or hazards). You will also be asked to estimate the respondent burden associated with using this instrument, in terms of time and resources that would be required for its use in a typical hospital setting. Your comments may be submitted electronically, or by FAX, mail, or courier. You may be contacted by the investigator after your submission to discuss certain instrument items for which there is expert panel disagreement. This contact may be electronic, by telephone, or by group teleconference.

Benefits

There may or may not be direct benefit to you from participating in this study. We hope that the information you review in the instrument and its handbook regarding pediatric hospital injuries and hazards may be useful to you in your work. Your participation as an expert reviewer and/or the participation of your organization/agency may be acknowledged in the study report and in the final instrument handbook, at your request.

Payment for participation

You will receive no payment related to taking part in this study.

Confidentiality

Your name and other identifying information will only be used for tracking purposes during the study. The University of Manitoba Health Research Ethics Board may review research-related records for quality assurance purposes.

Voluntary Participation/Withdrawal From the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time.

Questions

You are free to ask any questions that you may have about your rights as a research participant. If any questions come up during or after your participation, contact the Project Coordinator: Ms. Gemma Briggs at 204-789-3528.

For questions about your rights as a research participant, you may contact The University of Manitoba Health Research Ethics Board at (204) 789-3389.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Dr. Lynne Warda or the study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this research study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will not be collected. I authorize the inspection of my research records by The University of Manitoba Health Research Ethics Board.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

Participant signature_____Date _____

Participant printed name: _____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

Printed Name: _____ Date _____

Signature: _____Role in the study: _____

EXPERT PANEL – CONTENT VALIDITY REPORTING FORM (sample)

Part 1 – Item rating

Instrument Item			Comments
1.1	This item is clear and unambiguous	Strongly disagree 1 2 3 4 5 Strongly agree	
	This item is relevant	Strongly disagree 1 2 3 4 5 Strongly agree	
	This item should be deleted	Strongly disagree 1 2 3 4 5 Strongly agree	
1.2	This item is clear and unambiguous	Strongly disagree 1 2 3 4 5 Strongly agree	
	This item is relevant	Strongly disagree 1 2 3 4 5 Strongly agree	
	This item should be deleted	Strongly disagree 1 2 3 4 5 Strongly agree	
Etc. to 22.6			

Part 2 – Overall instrument rating

Instrument Overall			
A	The instrument is easy to use	Strongly disagree 1 2 3 4 5 Strongly agree	
B	The instrument is comprehensive	Strongly disagree 1 2 3 4 5 Strongly agree	
C	There are missing items	Strongly disagree 1 2 3 4 5 Strongly agree	Specify:
D	In your opinion, would the instrument be acceptable to a hospital, in terms of the potential respondent burden it presents (this does not include the burden related to administering the audit but rather having an audit performed)? Consider the time and resources required to accommodate an audit and the potential disruptions posed to the ward.		
E	In your opinion, would the instrument be acceptable to a hospital, in terms of the potential administrative burden it presents (this does not include the burden related to having an audit performed)? Consider the time and resources required to perform an audit.		
F	Please provide any additional comments with respect to content and format changes you would recommend.		

Appendix 4.3

Handbook to Accompany the Pediatric Health Care Facility Audit (Instrument Handbook)

Handbook to Accompany

The Pediatric Health Care Facility Safety Audit

DRAFT

Not for distribution

April 2004

IMPACT, the injury prevention centre of Children's Hospital
Children's Hospital, Winnipeg, Manitoba, Canada

How to Use the Audit Form

This audit is designed to be used in any health care facility that cares for pediatric patients, including inpatient and outpatient facilities, as well as facilities that accommodate child visitors. The audit is divided into four parts. The first checklist (A) is used for patient rooms and public areas. The second checklist (B) is used for children's equipment which is found in patient rooms, public areas, and storage areas (beds, cribs, high chairs, playpens). The third checklist (C) is for play areas and toys and the fourth (D) is for devices used for transporting infants and children (car seats, infant carriers, stretchers, strollers/carriages). While inpatient pediatric hospitals will use all of the sections, outpatient facilities may use the general safety checklist (A) and any other section that is relevant, such as toy and play area safety. General hospitals can use the general safety checklist to evaluate the safety of the facility for pediatric visitors. General hospitals with emergency departments treating children should use both the general safety checklist, for public areas, and the crib and bed checklists.

The audit is designed to be administered by any health care professional or hospital staff, including nursing and medical staff at hospitals and other health care facilities, injury prevention and safety specialists, occupational therapists, facility engineers, maintenance, and housekeeping staff. A multi-disciplinary team is recommended, and at least one member of the team should be familiar with the area being inspected.

As you inspect each patient room or patient care area, circle the response (Y = Yes, N = No) or place a checkmark (X) in the "not applicable" column. The shaded areas identify when a hazard is present. Record the room number or location where hazards are present and note the specific hazard. You may refer to this handbook for further instructions, rationale, and supporting evidence for each audit item.

Equipment

In addition to the checklist and handbook, the following equipment will be required:

- **Tape measure**
- An accurate (+/- 0.5°C) digital **thermometer** with an immersible probe
- **Small parts test cylinder** ($3.99, available from Discovery Toys at 416-620-9191 or online at www.discoverytoysinc.com). An object which fits completely in the testing cylinder is a choking hazard for a child less than 3 years of age (36 months). The cardboard cylinder from a roll of toilet paper (1.25 inches in diameter) trimmed to 2.25 inches in length is a rough approximate, but the testing cylinder is preferred.

How to Use the Audit Handbook

This handbook provides instructions for completing each audit item and provides the background and rationale for each item, including the type of hazard and recommended strategies to prevent or reduce the hazard. The types of evidence supporting the recommendation are provided, as well as the strength of evidence. These are defined below. A glossary of abbreviations follows.

Type of Evidence

Legislation includes any relevant Canadian federal legislation. The relevant act is cited and referenced. Note that provincial/territorial and municipal/local regulations are not cited.

Standard includes hospital accreditation standards (e.g. JCAHO, CCHSA), risk management standards (e.g. issued by ECRI or HIROC), facility guidelines and standards, and product standards issued by recognized national or international standards organizations (e.g. CSA, ASTM, ISO). In the instrument handbook the issuing body is cited and the standard is referenced.

References includes data regarding injuries and hazards in the published and electronic literature (texts, monographs, journals), and includes any type of research evidence including surveillance data, referenced topic reviews, as well as peer-reviewed individual studies and systematic reviews.

Recommendations are published and electronic summaries or statements of expert opinion and may include consumer advisories and public educational materials issued by government or other authoritative professional bodies such as the FDA, CPSC, CPS, or AAP. The source (issuing body) is noted and references are provided.

Strength of Evidence

A variety of methods can be used to rank the strength of evidence which supports a given recommendation. The method used in this handbook is the method used by the Canadian Task Force on the Periodic Health Examination.(1) This system was chosen because it is relatively simple, allows non-research evidence to be rated, allowing inclusion of legislation, standards, and other evidence, and Canadian hospitals and health care professionals are familiar with this system.

I	Evidence obtained from at least one properly randomized controlled trial
II - 1	Evidence obtained from well-designed controlled trials without randomization
II - 2	Evidence obtained from well-designed cohort or case-control analytic studies
II - 3	Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments could also be included in this category.
III	Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Important Notes

- This checklist is not meant to substitute for compliance with established regulations (e.g. Fire codes, Building codes, Occupational Health and Safety standards, provincial and local regulations).
- Medical devices are excluded from this audit.

Glossary of Abbreviations

AAP - American Academy of Pediatrics

ASTM – American Society for Testing and Materials

CCHSA – Canadian Council on Health Services Accreditation

CPS – Canadian Paediatric Society

CPSC – Consumer Product Safety Commission (US)

ECRI – Emergency Care References Institute

FDA – Food and Drug Administration

HIROC – Healthcare Insurance Reciprocal of Canada

ISO – International Standards Association

JCAHO – Joint Commission on Accreditation of Healthcare Organizations

ALL AREAS ACCESSIBLE TO PEDIATRIC PATIENTS AND VISITORS SHOULD BE CHECKED.

A. SAFETY CHECKLIST FOR PATIENT ROOMS AND PUBLIC AREAS

SECTION 1.0: Bathroom

1.1 Does the bathtub/shower have a slip-resistant floor?		
Instruction/Definition:	Inspect the floor of the bath or shower for evidence of a slip-resistant surface (gritty, rough surface which resists slipping when wet). Compare to the sink surface, which is not typically slip resistant.	
Rationale:	Slips and falls in the bath and shower are well recognized risks in health care facilities. Slip-resistant surfaces may help reduce the risk of falls in the bathtub and shower. The current standard for Canadian health care facilities specifies that floors of bathtubs and showers must have a slip-resistant surface.(2)	
Hazard:	Falls	
Type of Evidence:	Legislation:	References: (3-17)
	Standards: ASTM (18), CSA (2), ECRI (19-21), Facility guidelines (6, 11-13, 22-25)	Recommendations: CPS (25), CPSC (26),
Strength of Evidence:	II - 2	

1.2 Are grab bars installed in the bathtub/shower?		
Instruction/Definition:	Inspect the bathtub/shower area for grab bars or handrails that would be accessible to a patient in the bathtub/shower.	
Rationale:	Slips and falls in the bath and shower are well recognized risks in health care facilities. Grab rails or bars can aid in balance and stability in the bath/shower and may reduce the risk of falls.	
Hazard:	Falls	
Type of Evidence:	Legislation:	References: (3, 4, 6-13, 16, 27, 28)
	Standards: ASTM (29), ECRI (20, 30), Facility guidelines (6, 11-13, 24, 31-33)	Recommendations: CPSC (26)
Strength of Evidence:	II - 2	

1.3 Is the maximum hot water temperature less than 49°C (120°F)?	
Instruction/Definition:	Turn on the hot water, allow it to run for at least 2 minutes, and measure the hot water temperature using an accurate (+/- 0.5°C) digital thermometer with an immersible probe.

Rationale:	Pediatric patients are at high risk for tap water scalds. Adult skin sustains a second degree burn in 1 second at 70 degrees, 5 seconds at 60 degrees, and 10 minutes at 49 degrees.(2) Children's skin is thinner and burns faster and at lower temperatures than adults. The current standard for Canadian health care facilities specifies a recommended hot water temperature for patient and public use outlets of 43°C for routine operation, with a 48°C maximum. The standard specifies that maximum temperatures are to be measured and recorded every 6 months for patient baths and showers. Note: The standard also specifies that all patient bathing and shower facilities must have pressure-compensating or thermostatically actuated valves for scald protection (you cannot easily inspect this; check with your facility engineering department).	
Hazard:	Tap water scalds	
Type of Evidence:	Legislation: Standards: ASTM (41, 42), CSA (2), National Plumbing Code (43), Facility guidelines (11, 23, 25, 38)	References: (34-40) Recommendations: AAP (44), CPS (25, 34, 45), CPSC (26)
Strength of Evidence:	II - 3	
1.4 Can the bathroom door be easily and quickly unlocked from both sides?		
Instruction/Definition:	Test the bathroom door locks by closing the door and unlocking from the inside and then from the outside. The lock should be easily disengaged from both sides. In many health care facilities locks on patient doors and bathrooms can be opened using any key or without a key.	
Rationale:	To prevent children from being locked inside the bathroom. Toddlers may be exposed to a variety of hazards in the bathroom, including standing water, hot tap water, slips and falls, and a variety of hazardous products.	
Hazard:	Falls, tap water scalds, drowning, poisoning	
Type of Evidence:	Legislation: Standards: Facility guidelines (12, 24, 25)	References: (34, 46) Recommendations: CPS (25)
Strength of Evidence:	III	
1.5 Are bathroom doors kept closed to prevent toddler access?		
Instruction/Definition:	Inspect all bathroom doors. A door is considered closed if it is fully closed and cannot be opened by exerting pressure on the door without turning the handle. Swinging doors are considered closed if fully closed and not propped open or obstructed.	

Rationale:	To prevent access to bathrooms by young children. Toddlers may be exposed to a variety of hazards in the bathroom, including standing water, hot tap water, slips and falls, and a variety of hazardous products.	
Hazard:	Falls, tap water scalds, drowning, poisoning	
Type of Evidence:	Legislation:	References: (34, 46)
	Standards: Facility guidelines (24, 25)	Recommendations: AAP (44, 47), CPS (25, 45)
Strength of Evidence:	III	

1.6 Is there a functional call bell within patient/caregiver reach?		
Instruction/Definition:	Test the call bell to determine whether it is functioning as designed (e.g. auditory and visual alarm in the hall or nursing station). Determine whether a patient or a caregiver assisting a child would be able to reach the call bell from the toilet, floor, and bathing areas.	
Rationale:	Call bells in the bathroom should be functioning and accessible from the toilet, floor, and bathing areas.	
Hazard:	Falls, tap water scalds, drowning, poisoning	
Type of Evidence:	Legislation:	References: (48-50)
	Standards: ECRI (19, 30), Facility guidelines (11, 32, 50)	Recommendations:
Strength of Evidence:	III	

SECTION 2.0: Cleaning Supplies and Equipment

2.1 Are cleaning carts or supplies left unattended?		
Instruction/Definition:	Inspect the area to determine whether cleaning supplies are unattended and accessible to children.	
Rationale:	Unattended cleaning and maintenance carts may provide access to standing water (filled buckets) or hazardous cleaning agents (corrosive, poisonous), small parts (choking hazards), plastic bags, fall hazards (ladders), as well as electrical equipment and cords.	
Hazard:	Poisoning, drowning, choking/suffocation, burns, falls	
Type of Evidence:	Legislation:	References: (28, 34, 35, 38, 39, 46, 51-57)
	Standards: ECRI (19, 58), Facility guidelines (11, 24, 39, 56, 57, 59, 60)	Recommendations: AAP (25, 44), CPS (25, 45), CPSC (61, 62)
Strength of Evidence:	III	

2.2 Are any hazardous substances or equipment accessible to children (e.g. on cleaning or maintenance carts, under sinks, on counters, in cupboards)?		
Instruction/Definition:	Inspect the area to determine whether any hazardous substances are accessible to children. Check under sinks, in cupboards and drawers, on counters, and on cleaning and maintenance carts.	
Rationale:	Hazardous cleaning and maintenance supplies may include standing water (filled buckets), cleaning agents (corrosive, poisonous), small parts (choking hazards), plastic bags, sharp tools, electrical or battery-operated equipment, and electrical cords.	
Hazard:	Poisoning, drowning, choking/suffocation, burns, electrical injury, lacerations	
Type of Evidence:	Legislation:	References: (28, 34, 35, 38, 39, 46, 51-57)
	Standards: ECRI (19, 58), Facility guidelines (11, 24, 39, 56, 57, 59, 60)	Recommendations: AAP (25, 44), CPS (25, 45), CPSC (61, 62)
Strength of Evidence:	III	
2.3 Are cleaning products clearly marked and stored in their original containers, with all hazardous products in child-resistant containers?		
Instruction/Definition:	Inspect all cleaning products to ensure that they are clearly labeled and in their original containers. Toxic products should be in containers with child-resistant closures, with the lid secured. Check child-resistant closures to ensure that the protective mechanism is engaged.	
Rationale:	To prevent exposure to poisonous and other hazardous substances. Note: MSDS sheets should be easily accessible in the case of accidental exposure to cleaning products involving patients, visitors, or staff.	
Hazard:	Poisoning, burn	
Type of Evidence:	Legislation:	References: (28, 34, 35, 38, 39, 46, 51-57)
	Standards: CSA (63), ECRI (19, 58), Facility guidelines (11, 24, 39, 56, 57, 59, 60)	Recommendations: AAP (25, 44), CPS (25, 45), CPSC (61, 62)
Strength of Evidence:	III	

SECTION 3.0: Hospital Clothing

3.1 Do mittens, booties, blankets and sleepers have loose threads or tight elastic that could cause digit or extremity ligature/strangulation?		
Instruction/Definition:	Inspect clothing supplied by the hospital to families (e.g. hospital garments for infants, donated or new clothing loaned or otherwise provided to families), for loose threads and tight elastic at the wrist and ankle (e.g. infant mittens and booties).	
Rationale:	To prevent digit and extremity strangulation by ligatures formed by loose threads and tight elastic. Digit amputation has resulted from these types of ligatures. Many hospitals have donated clothing depots for families; all donated clothing should be checked for these hazards.	
Hazard:	Digit and extremity entrapment/strangulation	
Type of Evidence:	Legislation:	References: (64-68)
	Standards: HIROC (69)	Recommendations:
Strength of Evidence:	III	
3.2 Does any clothing that is provided to patients by the hospital have drawstrings at the neck or waist?		
Instruction/Definition:	Inspect clothing supplied by the hospital to families (e.g. hospital garments for children, donated or new clothing loaned or otherwise provided to families), for drawstrings at the neck, such as in hooded garments and upper outerwear, and waist, such as in upper outerwear.	
Rationale:	To prevent fatal strangulation resulting from drawstrings and toggles which become trapped on catch points in cribs, play equipment, and school bus doors. Many hospitals have donated clothing depots for families; all donated clothing should be checked for these hazards.	
Hazard:	Strangulation	
Type of Evidence:	Legislation:	References: (34, 70-73)
	Standards: ASTM (74), CPSC (75), Facility guidelines (24, 73)	Recommendations: CPS (25), CPSC (61, 73, 75), Health Canada (70)
Strength of Evidence:	III	
3.3 Are there any choking hazards on infant clothing (e.g. loose buttons, snaps)?		
Instruction/Definition:	Verify that that buttons, snaps, and other fasteners are tightly attached to infant garments and blankets. Toys and other small objects should not be attached to infant garments.	

Rationale:	Loose buttons and snaps on infant garments and blankets are a choking hazard.	
Hazard:	Choking	
Type of Evidence:	Legislation:	References: (76, 77)
	Standards:	Recommendations:
Strength of Evidence:	III	

3.4 Is all donated, loaned, and hospital clothing thoroughly checked for these hazards?		
Instruction/Definition:	Check hospital policies and procedures to ensure that all new and donated clothing is inspected prior to loan and that hospital garments are periodically checked for choking and strangulation hazards.	
Rationale:	See 3.1-3.3	
Hazard:	Choking, strangulation	
Type of Evidence:	Legislation: See 3.1-3.3	References: See 3.1-3.3
	Standards: See 3.1-3.3	Recommendations: See 3.1-3.3
Strength of Evidence:	III	

SECTION 4.0: Cords

4.1 Are telephone, television, extension and other electrical cords either less than 18 cm (7 inches) in length, or securely fixed to the floor, wall, or other object?		
Instruction/Definition:	Inspect the area for any appliance or electrical cords accessible to a child; measure the free length of cords or parts of cords that are not secured to the wall/floor/furniture.	
Rationale:	Infants and toddlers can become entangled in cords that are long enough to encircle the neck (longer than 7 inches) or looped cords which fit over the head (longer than 14 inches). Fatal and near-fatal strangulation has occurred in infants and toddlers due to IV tubing, monitor leads, lamp/appliance/telephone cords, extension cords, light-switch cords, window and drapery cords, string, rope, and decorative ribbon on wall hangings. Children can be injured by falling objects due to pulling on loose appliance cords (e.g. TV, kettle). Young children may be severely burned by chewing on electrical cords. Loose cords on the floor are a tripping hazard for staff, patients, and caregivers.	
Hazard:	Strangulation, struck by falling equipment, burn, electrical injury	
Type of Evidence:	Legislation:	References: (34, 76, 78-83)
	Standards: Facility guidelines (24, 60)	Recommendations: AAP (44), CPS (25), Health Canada (IV tubing, monitor leads) (84) (general) (85)

Strength of Evidence:	III	

4.2 Are there any other cords, call bells, or tubing greater than 18 cm (7 inches) or any looped cords greater than 35 cm (14 inches) that are within reach of children?		
Instruction/Definition:	Inspect the area for any type of cord or tubing accessible to a child; measure the free length of cords or parts of cords that are not secured to the wall/floor/furniture.	
Rationale:	See 4.1	
Hazard:	Strangulation	
Type of Evidence:	Legislation:	References: (34, 76, 78-83)
	Standards: Facility guidelines (24, 60)	Recommendations: AAP (44), CPS (25), Health Canada (IV tubing, monitor leads) (84) (general) (85)
Strength of Evidence:	III	

SECTION 5.0: Doors

5.1 Do all doors close and latch properly?		
Instruction/Definition:	Verify that all doors close and latch securely. Self-closing or automatic doors should close and latch securely without manual assistance.	
Rationale:	To prevent access to areas where hazards may be present (e.g. stairs, bathrooms, medication rooms) and to prevent elopement of pediatric patients.	
Hazard:	Fall, poisoning, burn	
Type of Evidence:	Legislation:	References: (28, 35, 86)
	Standards: ECRI (19), Facility guidelines (87)	Recommendations: CPS (25)
Strength of Evidence:	III	

5.2 Are any doors blocked or propped open?		
Instruction/Definition:	Inspect all doors for any objects that obstruct the path of the door, such as furniture or other equipment.	
Rationale:	Doors should be free from obstruction. Staff should be able to quickly close doors in the case of a fire alarm or fire. Doors propped or blocked open may allow children to access hazardous areas or equipment or to wander from the unit.	
Hazard:	Fire, poisoning, burn, fall	

Type of Evidence:	Legislation:	References: (28, 35, 86)
	Standards: ECRI (19), Facility guidelines (87)	Recommendations: CPS (25)
Strength of Evidence:	III	
5.3 Are staff able to open locked doors within 60 seconds for any room or area accessible to children (e.g. accessible master key, keyless entry)?		
Instruction/Definition:	For any room or area accessible to children, inspect each door that locks for evidence of keyless entry or safety locks (locks that open with any key or without a key). Ask staff who work in the area to unlock the door(s), timing their ability to successfully open the door.	
Rationale:	To prevent children from being locked inside the bathroom or other locked areas. Children may be exposed to a variety of hazards in the bathroom or other locked area, including standing water, hot tap water, medications, and a variety of hazardous products and equipment. In many health care facilities locks on patient doors and bathrooms can be opened using any key or flat metal object (e.g. spoon handle). New staff may not be aware of this safety feature.	
Hazard:	Fall, poisoning, burn, drowning	
Type of Evidence:	Legislation:	References: (34, 46)
	Standards: Facility guidelines (12, 24, 25)	Recommendations: CPS (25)
Strength of Evidence:	III	
5.4 Are all stairs inaccessible to young children?		
Instruction/Definition:	Inspect the area for infant and toddler access to stairs and stairwells. Stairs that are not protected by a door should have an approved safety gate installed. Doors leading to stairs and stairwells should be kept closed.	
Rationale:	Infant and toddler access to stairs and stairwells should be restricted to prevent falls.	
Hazard:	Falls	
Type of Evidence:	Legislation:	References: (28, 35, 86)
	Standards: Facility guidelines (25)	Recommendations: CPS (25)
Strength of Evidence:	III	

5.5 Are all doors leading to stairwells kept closed, and are they designed to be difficult for a toddler to open, but easily opened in case of fire?		
Instruction/Definition:	Inspect doors leading to stairwells to ensure that they are closed, and not blocked or propped open. Doors should be designed to be child-resistant but easily opened by an adult in case of fire, such as with an elevated door knob, safety release mechanism, and/or audible alarm.	
Rationale:	Infant and toddler access to stairs and stairwells should be restricted to prevent falls. Fire safety regulations dictate that doors leading to stairwells must be kept closed and must not be locked, propped open, or otherwise obstructed.	
Hazard:	Falls, fire	
Type of Evidence:	Legislation:	References: (28, 35, 86)
	Standards: ECRI (19), Facility guidelines (25, 87)	Recommendations: CPS (25)
Strength of Evidence:	III	

SECTION 6.0: Storage

6.1 Are there any sharps, medicines or other hazards in drawers or cupboards accessible to children?		
Instruction/Definition:	Check the contents of all drawers and cupboards that are accessible to children for hazardous items (e.g. sharps, poisons, medications, plastic bags, small objects that fit completely in the small parts test cylinder).	
Rationale:	To prevent access to a variety of hazards to children (poisoning, choking/suffocation, laceration).	
Hazard:	Poisoning, choking/suffocation, lacerations	
Type of Evidence:	Legislation:	References: (11, 28, 35, 39, 52, 53, 56)
	Standards: Facility guidelines (11, 25, 39, 56, 60)	Recommendations: CPS (25)
Strength of Evidence:	III	

SECTION 7.0: Electrical

7.1 Are extension and electrical cords placed out of traffic areas to prevent tripping?	
Instruction/Definition:	Inspect traffic areas (halls, doorways, patient rooms) for extension and electrical cords that might present a tripping hazard.

Rationale:	Electrical cords are a well recognized fall hazard in health care facilities. Note that extension cords are not permitted in patient care areas, according to the current national electrical safety standard for health care facilities.(88) Power bars are discouraged, and should be replaced with permanent wiring when possible. Extension cords and power bars, when used, should be tagged and inspected regularly. Electrical cords of all types present a risk of electrical injury to young children; children have been severely burned from chewing on electrical cords and burned or electrocuted from tampering with exposed unused receptacles on extension cords and power cords.	
Hazard:	Falls, burns, electrical injuries	
Type of Evidence:	Legislation:	References: (3-5, 7, 10, 14, 16, 17, 27, 35, 46, 48, 50, 56, 89-91)
	Standards: CSA (88), ECRI (30, 58, 92, 93), Facility guidelines (11, 23-25, 39, 50, 56, 87, 94-96)	Recommendations: CPS (25)
Strength of Evidence:	III	
7.2 Are unused electrical outlets (includes power bars and extension cords) in patient rooms and play areas covered, out of reach, tamperproof, or child-resistant (e.g. GFCI: ground-fault-circuit-interrupter)?		
Instruction/Definition:	Verify that all unused electrical outlets, including receptacles on power bars and extension cords, that are accessible to children, such as in patient rooms and play areas, are either covered, out of reach, tamperproof, or child-resistant. Note that plastic outlet plugs can be removed by some children and may be a choking hazard.	
Rationale:	To prevent burns and electrocution due to children inserting objects into exposed electrical outlets.	
Hazard:	Burns, electrical injuries	
Type of Evidence:	Legislation:	References: (35, 39, 46, 52-56, 91-93, 96-99)
	Standards: ECRI (30, 58, 92, 93), Facility guidelines (11, 23-25, 39, 50, 56, 87, 94-96)	Recommendations: AAP (100), CPS (25, 45), CPSC (61)
Strength of Evidence:	III	

SECTION 8.0: Floors

8.1 Are all carpets securely anchored?		
Instruction/Definition:	Verify that mats and carpets are secured to the floor (immovable) and are not loose or lifting at the corners or edges.	
Rationale:	Loose mats, carpet runners and area rugs have been identified as fall hazards and should be avoided whenever possible. While mats are recommended at entrance areas for absorbing moisture in wet weather, any mat or loose carpet must be securely anchored to prevent tripping. All carpet pieces and area rugs should be properly bound, and folds or irregularities in the carpet surface should be avoided. Any change in flooring (e.g. from tile to carpet) can be hazardous and should be carefully inspected. The transition points where carpets and hard surfaces meet should have a difference in elevation of no more than 1/8 inch, and mats or transition points should be beveled or smoothed to minimize differences in elevation.(21, 101)	
Hazard:	Fall	
Type of Evidence:	Legislation:	References: (3-9, 14-17, 27, 48, 50, 89, 90, 102-104)
	Standards: ECRI (21, 30, 101), Facility guidelines (6, 24, 50, 95, 104)	Recommendations: CPS (25)
Strength of Evidence:	II - 2	

8.2 Are floors clean and dry, spills cleaned immediately, and signs posted for spills and when floors are washed or polished?		
Instruction/Definition:	Inspect all floor surfaces for any moisture and debris. Check to ensure that caution signs have been placed on the floor near the hazard when there is a spill and when floors are being washed or polished (ask area staff about the usual practice, and observe if possible).	
Rationale:	Slippery floors are one of the most common hazards leading to staff, patient, and visitor falls. Wet floors and spills should be signed immediately. When washing floors, dry areas should be provided as a traffic route around wet areas. Slip-resistant flooring should be used when possible for all public areas (lobby, hallways, patient rooms), and waxing should be minimized. Absorbent mats should be paced at entrance doors in wet weather and in winter, but must be carefully secured (see 8.1).	
Hazard:	Falls	
Type of Evidence:	Legislation:	References: (3, 6-8, 13, 27, 28, 33, 39, 46, 48-50, 57, 90, 103-107)

	Standards: ECRI (19-21, 30, 58, 101), Facility guidelines (6, 12, 13, 22, 24, 32, 39, 50, 57, 60, 87, 95, 104-107)	Recommendations: AAP (100), CPS (25)
Strength of Evidence:	III	

8.3 Is slip-resistant footwear worn by patients?		
Instruction/Definition:	Check slippers provided by the hospital for slip-resistant soles (e.g. surgical booties used as slippers). Ask area staff if parents are advised to provide proper footwear for their children, such as avoiding wearing only socks or smooth-soled slippers, and wearing slippers or shoes with slip-resistant or rubber soles (e.g. ward orientation pamphlet, patient safety pamphlet).	
Rationale:	Proper footwear may reduce the risk of falls. On inpatient units children should wear slippers with rubber or slip-resistant soles rather than socks or bare feet. Proper footwear also reduces the risk of puncture wounds and other foot injuries such as burns.	
Hazard:	Falls	
Type of Evidence:	Legislation:	References: Proper footwear (9, 16, 27, 49, 103)
	Standards: Facility guidelines (22)	Recommendations:
Strength of Evidence:	III	

SECTION 9.0: Food

9.1 Are children less than four years of age given or have access to nuts or seeds, gum, candy, popcorn, fish with bones or other foods that are a choking hazard?	
Instruction/Definition:	Check the ward kitchen, snack and pantry areas for foods that are a choking hazard. Check the standardized toddler menus for items that are a choking hazard. Ensure that hospital policies and procedures are in place to restrict toddler access to foods that are a choking hazard.
Rationale:	Foreign body ingestion/aspiration is the fourth leading cause of injury hospitalization and death for children less than four years of age.(108) Foods are involved in a significant proportion of cases of choking and near-choking.(34, 76, 77, 81, 109-112) Most foods implicated in fatal choking are small, round or cylindrical shapes that conform to the contours of the airway (e.g. hot dogs, whole grapes, carrots, peanuts, seeds, and hard candy). Children less than four years of age should not be given certain foods that present a choking hazard, including nuts or seeds, gum, candy, popcorn, and fish with bones. Other hazardous foods require special preparation, such as finely chopping, grating, mashing, or slicing lengthwise (wieners, grapes).

Hazard: Choking		
Type of Evidence:	Legislation:	References: (34, 76, 81, 109, 112)
	Standards: Facility guidelines (24, 25)	Recommendations: AAP (44, 113), CPS (25, 45)
Strength of Evidence:	III	

9.2 For children less than four years of age, are the following foods specially prepared to prevent choking? Grapes and wieners – slice lengthwise or chop; raw carrots, apples–grate, chop.	
Instruction/Definition:	Check the ward kitchen, snack and pantry areas for foods that are a choking hazard. Check the standardized toddler menus for items that are a choking hazard. Ensure that hospital policies and procedures are in place to specially prepare high-risk foods to prevent choking.
Rationale: See 9.1	

Hazard: Choking		
Type of Evidence:	Legislation:	References: See 9.1
	Standards: See 9.1	Recommendations: See 9.1
Strength of Evidence:	III	

SECTION 10.0: Medication Supply Room

10.1 Are medication rooms inaccessible to children and suicidal patients at all times?	
Instruction/Definition:	Check all medication rooms to ensure that the door is closed and locked. The door should not be propped or left open. Ensure that there is a policy regarding closing and locking medication supply room doors at all times.
Rationale: Medication rooms should be inaccessible to children at all times.	

Hazard: Poisoning		
Type of Evidence:	Legislation:	References: (34, 35, 37-39, 46, 50-52, 54-56, 114)
	Standards: ECRI (19, 58), Facility guidelines (11, 12, 24, 39, 50, 56, 59, 60)	Recommendations: AAP (114), CPS (25), CPSC (26, 61, 62, 115)
Strength of Evidence:	III	

10.2 Are all medications stored in their original containers and clearly labeled with the drug name and amount?		
Instruction/Definition:	Check for unlabelled or improperly labeled medications. Verify that hospital policy mandates proper labelling for all medications that are removed from their original containers (drug name and amount, including concentration and volume).	
Rationale:	The type and amount of medication ingested is essential information in the case of accidental ingestion. Proper labelling also may help reduce the risk of medication errors.	
Hazard:	Poisoning	
Type of Evidence:	Legislation:	References: See 10.1
	Standards: See 10.1	Recommendations: See 10.1
Strength of Evidence:	III	

10.3 When not in the medication room are medications kept in a locked cabinet or container?		
Instruction/Definition:	Verify that there are no medications accessible to children and suicidal patients.	
Rationale:	To prevent access to medications. Some hospitals use a medication cart or basket for distributing medications. These carts and containers should be locking to prevent access by pediatric patients or visitors, in case the cart or container is left unattended in a hallway, patient room, or nursing station.	
Hazard:	Poisoning	
Type of Evidence:	Legislation:	References: See 10.1
	Standards: See 10.1	Recommendations: See 10.1
Strength of Evidence:	III	

SECTION 11.0: Miscellaneous

11.1 Are all sharp objects kept out of reach of children?		
Instruction/Definition:	Examine the area for sharps that are not accessible to children.	
Rationale:	Sharp objects should be inaccessible to young children and suicidal patients. Sharps should not be stored in patient rooms, examination or treatment rooms, or other storage areas that are easily accessible. Sharps containers should be kept out of reach.	
Hazard:	Lacerations	
Type of Evidence:	Legislation:	References: (35, 39, 46, 52-54)

	Facility guidelines (25, 39)	Recommendations: CPS (25), CPSC (61)
Strength of Evidence:	III	

11.2 Is there a policy regarding hot beverages on children's wards or in play areas (e.g. cup covers, areas where coffee/tea are restricted)?		
Instruction/Definition:	Verify whether there is a policy regarding hot liquids (e.g. coffee, tea) in the hospital, including on children's wards and in play areas. Policies may include prohibiting hot liquids in certain areas or mandating cup/container covers.	
Rationale:	To prevent injuries from hot liquids. Spilled coffee, tea, and other hot liquids are a well recognized hazard to infants and toddlers. Many pediatric wards prohibit carrying or bringing hot liquids onto the ward, or mandate cup covers to prevent accidental scalds.	
Hazard:	Burns/Scalds	
Type of Evidence:	Legislation:	References: (34, 116)
	Standards: Facility guidelines (25)	Recommendations: AAP (44), CPS (25, 45)
Strength of Evidence:	III	

11.3 Are there any baseboard heaters, radiators, exposed pipes, or hot appliances that are a burn hazard and are accessible to children (surface temperature hotter than 43°C/110°F)?		
Instruction/Definition:	Determine whether any hot surfaces are accessible to children. A surface temperature greater than 110 degrees F is hazardous to a child. Check for baseboard heaters, radiators and pipes under and behind chairs and under tables where a child might crawl or climb.	
Rationale:	To prevent burns. Children can receive contact burns from touching hot surfaces within their reach. Children and adults have been burned in hospitals due to contact with hot surfaces in patient rooms and in waiting areas.	
Hazard:	Burns	
Type of Evidence:	Legislation:	References: (46, 57, 117)
	Standards: Facility guidelines (24, 25)	Recommendations: AAP (44)
Strength of Evidence:	III	

11.4 Is there any standing water which presents a drowning risk to children (e.g. buckets, pails, bathtubs, with 5 cm / 2 inches of water)?		
Instruction/Definition:	Inspect the area for sources of standing water that are accessible to children. Standing water with a depth of two inches (5 cm) in a container or location in which a child could submerse their mouth and nose is hazardous. This includes buckets, wash pails, bathtubs, toilets, etc.	
Rationale:	To prevent drowning. Infants and toddlers have drowned in bathtubs, buckets, toilets, and wash pails partially filled with water. Children can drown in less than a few inches of water.	
Hazard:	Drowning	
Type of Evidence:	Legislation:	References: (34, 38, 46, 118)
	Standards: Facility guidelines (24, 25, 60)	Recommendations: AAP (44, 47, 119), CPS (25, 45), CPSC (61, 115)
Strength of Evidence:	III	
11.5 Are spaces between railings on stairs and landings less than 10 cm (4 inches) wide?		
Instruction/Definition:	Measure the gap between railings.	
Rationale:	To prevent falls and entrapment. Guardrail spacing is designed (1) to prevent falls and (2) to prevent a child's body from slipping through feet-first and trapping the head and neck (entrapment), which can be fatal. The National Building Code specifies that guard rails on balconies and other elevated surfaces must not have any opening that permits passage of a sphere whose diameter is 100 mm (4 inches) and must be constructed to resist climbing (e.g. horizontal rails are not permitted). Other standards use a 3.5 inch diameter sphere (24) or a torso probe with a base of 3.5 x 6.2 inches to assess entrapment hazards of guardrails used in various settings (day care, bunk beds, play equipment).(120, 121)	
Hazard:	Falls, entrapment	
Type of Evidence:	Legislation:	References: (24, 34, 35)
	Standards: National Building Code (122), CSA Playspaces guideline (120), US bunk bed standard (121), Facility guidelines (24, 33)	Recommendations:
Strength of Evidence:	III	

11.6 Does any furniture, structure, or equipment pose an entrapment hazard, such as spaces a child can crawl into or fall through that are greater than 8 cm (3.5 inches) and less than 23 cm (9 inches)?		
Instruction/Definition:	Measure spaces or gaps where a child can crawl into or fall through. Spaces should be small enough to prevent the torso from entering (3.5 inches X 6.2 inches) or large enough to allow the head to pass through (9 x 9 inches).	
Rationale: See 11.5		
Hazard: Entrapment		
Type of Evidence:	Legislation:	References: See 11.5
	Standards: See 11.5	Recommendations: See 11.5
Strength of Evidence: III		
11.7 Is the kitchen area accessible to young children?		
Instruction/Definition:	The kitchen area should be secured with a closed, locked door or a closed door with a handle that is beyond the reach of young children (approximately 48 inches).	
Rationale:	Preschool children should not have access to kitchen or cooking areas, and older children should be supervised by an adult. Typical inpatient kitchens are equipped with appliances (kettles, toasters, and toaster-ovens), cords, and sharp utensils that are hazardous to young children. Due to multiple adult users these facilities can not be made child-safe.	
Hazard: Fires, burns, scalds, lacerations		
Type of Evidence:	Legislation:	References: (34)
	Standards: Facility guidelines (60, 94)	Recommendations: AAP (44), CPS (25)
Strength of Evidence: III		
11.8 Is the mounting hardware of suspended or elevated television, VCR and video equipment tight and secure?		
Instruction/Definition:	Verify that mounting hardware is present and tightly secured to prevent falling.	
Rationale:	To prevent injury from falling equipment. Televisions and other equipment on rolling carts or other elevated surfaces should be permanently secured. Rolling carts should have a stable base to prevent tipping.	
Hazard: Struck-by falling object		
Type of Evidence:	Legislation:	References:

	Standards: ECRI (123)	Recommendations: CPS (25)
Strength of Evidence:	III	
11.9 Are any toxic plants accessible to children?		
Instruction/Definition:	Check plants that are accessible to children for toxicity (see Appendix A for a list of toxic plants).	
Rationale:	To prevent poisoning. Plants, flowers, and landscaping materials accessible to children should be nontoxic.	
Hazard:	Poisoning	
Type of Evidence:	Legislation:	References: (34, 35, 124)
	Standards: ECRI (58), Facility guidelines (24, 25, 124)	Recommendations: CPS (25), CPSC (61)
Strength of Evidence:	III	
11.10 Are makeshift pacifiers prohibited (i.e. using nipples or modified nipples as pacifiers)?		
Instruction/Definition:	Determine whether staff use nipples or modified nipples as pacifiers.	
Rationale:	Pacifiers must meet the standards specified in the Hazardous Products Act. Makeshift pacifiers, which in the past were commonly used in hospital nurseries, do not meet these standards and pose a choking hazard.	
Hazard:	Choking, strangulation	
Type of Evidence:	Legislation: Hazardous Products Act – Pacifiers Regulations (125)	References: (126)
	Standards:	Recommendations: AAP (127)
Strength of Evidence:	III	
11.11 Are pacifier cords longer than 18 cm (7 inches) prohibited as well as pacifier and other cords tied around the neck?		
Instruction/Definition:	Measure pacifier cords observed in the area. Determine whether there is a policy regarding pacifier cords tied around the neck.	
Rationale:	Cords longer than 18 cm (7 inches) can encircle an infant's neck and result in strangulation. Looped cords greater than 35 cm (14 inches) circumference can fit over a child's head and also pose a strangulation risk. Cords of any type should not be tied around children's necks.	

Hazard: Strangulation		
Type of Evidence:	Legislation:	References: (34)
	Standards: Facility guidelines (24)	Recommendations: CPSC (61, 128), Health Canada (129)
Strength of Evidence: III		
11.12 Are plastic bags or plastic film accessible to children?		
Instruction/Definition:	Inspect the area for plastic bags or plastic film that is accessible to children.	
Rationale: Children have been fatally injured playing with plastic bags and plastic film.		
Hazard: Suffocation		
Type of Evidence:	Legislation: Hazardous Products Act (125)	References: (34, 35, 81, 130)
	Standards: Facility guidelines (24)	Recommendations: AAP (44), CPS (25), CPSC (61, 115)
Strength of Evidence: III		

SECTION 12.0: Windows and Draperies

12.1 Can any window which is less than 1 m from the floor or otherwise accessible to a child be opened to more than 10 cm?		
Instruction/Definition:	Open the window to its widest position. Measure the widest opening (space, gap) created.	
Rationale: To prevent falls from windows and entrapment in window openings. To prevent falls from windows the safest measure is to use windows that do not open, or restrict window opening to 10 cm or less. The National Building Code specifies that for windows above the second storey that open and are less than 1 m from the floor, a barrier or railing of at least 1070 mm from the floor must be in place. Other measures that have been recommended for preventing falls from windows include using window guards, and ensuring that all windows close and latch securely.		
Hazard: Falls, entrapment		
Type of Evidence:	Legislation:	References: (34, 35, 37, 38, 46, 55, 131-133)
	Standards: National Building Code (122), Facility guidelines (12, 24, 25, 33, 59, 87)	Recommendations: AAP (44, 100), CPS (25)

Strength of Evidence:	II - 3	
12.2 Are all looped window covering cords less than 18 cm (7 inches) in length or permanently secured to a tie-down device?		
Instruction/Definition:	Raise the window covering to create the longest possible free length of the pull cord. Measure the free length of cord. Inspect tie-down devices to ensure that they are securely and permanently installed; the cording should be fixed in place, fully extended, and tight enough to eliminate any risk of entanglement (looping around the neck).	
Rationale:	To prevent strangulation in window blind and drapery cords. Cordless window treatments are the safest option for children's rooms and play areas. Cords that are longer than 7 inches are a strangulation hazard. Eliminate loops and trim cords to no longer than 7 inches (18 cm) where possible. Permanently secure continuous looped cords to the wall or floor, ensuring that the cord is fully extended and tight enough to eliminate any risk of entanglement (lax cord may be placed over the head or around the neck). Breakaway cord devices may be found on newer models (after 2001), and are identified in the manufacturer's instructions (check with the contractor who installed the window coverings).	
Hazard:	Strangulation	
Type of Evidence:	Legislation:	References: (34, 73, 81, 130, 134-136)
	Standards: ECRI (58), Facility guidelines (24, 73)	Recommendations: CPSC (73, 134-136), Health Canada (129, 137, 138)
Strength of Evidence:	III	
12.3 For horizontal blinds, are you able to grasp the inner cord and pull it out, forming a loop?		
Instruction/Definition:	Lower the blinds. Identify the outer pull cord and the inner cords between the blinds. Grasp one of the inner cords and pull it toward you (you may need to pull upward or downwards to create the loop). Newer style inner cords cannot be pulled into a loop. Older style inner cords can be pulled into a large loop. Repeat for the other side.	
Rationale:	To prevent strangulation in window covering cords. Horizontal blinds manufactured before 2001 that have not been retro-fitted pose a risk of strangulation because the inner cords between the blinds (not the outer pull cord) can be pulled, forming a loop. Children have been fatally injured by playing with the inner loop and placing it over their head. Fatal incidents typically involve infants and toddlers in cribs and playpens adjacent to window blinds.	
Hazard:	Strangulation	
Type of Evidence:	Legislation:	References: See 12.2

	Standards: See 12.2	Recommendations: See 12.2
Strength of Evidence:	III	
12.4 Are cribs, beds, or furniture located near windows that open, or window covering cords?		
Instruction/Definition:	Inspect the area for cribs, beds, chairs, stools, ledges, and furniture that provide children easy access to windows that open and window covering cords.	
Rationale:	To prevent falls from windows and strangulation in window covering cords. Children may climb on top of chairs, tables, ledges, and other furniture, so cords and windows well above the floor may present a hazard. See 12.1, 12.2, and 12.3.	
Hazard:	Falls, strangulation	
Type of Evidence:	Legislation:	References: See 12.1-12.3
	Standards: See 12.1-12.3	Recommendations: See 12.1-12.3
Strength of Evidence:	III	

B. SAFETY CHECKLISTS FOR CHILDREN'S EQUIPMENT

SECTION 13.0: Beds

13.1 Electric beds are not used for patients less than 6 years of age. **13.2 Electric beds for patients older than 6 years of age do not have walk-away controls or have tamper-proof controls or are four-poster style beds.**		
Instruction/Definition:	Determine whether electric beds are used and whether they have walk-away or tamper-proof controls (consult facility engineering or maintenance for assistance). Determine whether there are policies regarding using electric beds for children.	
Rationale:	To prevent injuries due to entrapment or crushing in moving parts of an electric bed. The current national electrical safety standard for health care facilities states that "the use of hydraulic or manual beds in pediatric wards should be considered in order to prevent possible patient injuries".(88) ECRI recommends that electric beds not be used for pediatric or psychiatric patients due to five fatal cases of entrapment of children (3, 5, 5, 6, and 11 years of age) in electric beds with walk-away controls - a one-touch switch which automatically lowered the bed to its lowest position.(139) Note that pediatric visitors may be injured in general hospitals by playing with or around electric beds, and that walk-away controls are hazardous to children.	
Hazard:	Entrapment	
Type of Evidence:	Legislation:	References: (140-144)
	Standards: CSA (88, 145), ECRI (139-143), UL (146)	Recommendations: Health Canada (do not use walk-away controls) (147), AAP (cover bed controls) (100)
Strength of Evidence:	III	
13.3 Is the bed in its lowest position and the bed rails raised when the bed is occupied?		
Instruction/Definition:	Determine whether hospital policy specifies that bed rails should be raised and the bed in its lowest position when the bed is occupied, such as for sleep, or in a patient confined to bed. Verify hospital practice by direct observation or asking area staff.	
Rationale:	To prevent falls from bed. For children confined to bed or who are sleeping, the bed should be in its lowest position and the bed rails should be raised and locked in place. However, children who are observed to climb over the rails repeatedly may be safer with the bed in its lowest position and the rails lowered on one side. Children less than two years of age should sleep in a crib with a security top; some older toddlers may also be safer in a crib with a security top.	
Hazard:	Falls	
Type of Evidence:	Legislation:	References: (50, 148)

	Standards: Facility guidelines (22, 50, 60)	Recommendations: Health Canada (149)
Strength of Evidence:	III	
13.4 When the mattress is pushed to the head or foot of the bed is a gap created at the head or foot of the bed that exceeds 100 mm? **13.5 Is the distance between the end of the side rails and the headboard or footboard greater than 60 mm?** **13.6 When the mattress is pushed to one side of the bed, is the horizontal gap measured from the mattress edge to the inside edge of the side rail greater than 100 mm?** **13.7 Is the vertical spacing between two adjacent horizontal bars of the side rails greater than 100 mm?** **13.8 Is the vertical spacing between the lowest bar above the mattress and the mattress itself greater than 60 mm?**		
Instruction/Definition:	Lower the bed to its lowest position. Measure the specified gaps and spaces using a tape measure. A more detailed assessment for entrapment may be conducted using standardized torso and head probes, as specified in play equipment and bunk bed standards.(120, 121)	
Rationale:	Patients of all ages are at risk for entrapment in the hospital bed, particularly older adults, small or young children who are placed in standard adult beds, and older children with impaired mobility or level of consciousness. Entrapment may occur in any gap or space in the bed that admits the pelvis, torso or neck but entraps the head, neck, or torso. These spaces or gaps may be found between or under side rails, between the mattress and side rails, between split side rails, between the mattress deck and side rails, and between the mattress and headboard or footboard. Gaps can be created by using a mattress other than that specified by the manufacturer, by mattress wear, compression, or position, and by bed design.(150) Smaller children may slip under the lowest rail and become entrapped between the mattress and rail because the head is too large to pass through the space. If the body is suspended (feet off the floor) or the neck or chest is compressed, this is a potentially fatal situation. Cases of entrapment of children in hospital bed rails are rare, however numerous deaths due to entrapment in bunk bed guard rails have been reported, and have resulted in guard rail spacing guidelines for children. For bunk beds, openings within 9 inches above the sleeping surface should either be small enough to prevent passage of a 3.5 by 6.2 inch block or large enough to permit passage of a 9 inch diameter sphere (the size of a child's head). Similar guidelines exist for prevention of entrapment in playground equipment. A rough rule of thumb is that spaces should be either smaller than 3.5 inches (9 cm) or larger than 9 inches (23 cm). The safest spacing for children less than two years of age however, is that specified for cribs, which is 6 cm maximum.	
Hazard:	Entrapment	
Type of Evidence:	Legislation:	References: (34, 35, 81, 121, 146, 149-157)

	Standards: CSA (145), ECRI (150), FDA (153), Health Canada (149, 158), JCAHO (159), Facility guidelines (160)	Recommendations: Health Canada (149)
Strength of Evidence:	III	

SECTION 14.0: Cribs

14.1 All cribs were manufactured after September 1986, as indicated by the date of manufacture on the label.		
Instruction/Definition:	Check crib labels to ensure that they were manufactured after September 1986.	
Rationale:	Cribs manufactured before September 1986 do not meet current safety standards and should not be used.	
Hazard:	Entrapment, falls	
Type of Evidence:	Legislation: Hazardous Products Act Cribs and Cradles Regulations (125)	References: (34, 73, 130, 157, 161-168)
	Standards: ECRI (58), Facility guidelines (24, 73)	Recommendations: CPS (25), CPSC (61, 73, 169), Health Canada (129, 170)
Strength of Evidence:	III	

14.2 All cribs are equipped with overhead restraints (i.e. security tops, bubble tops, canopies).		
Instruction/Definition:	Ensure that all cribs are equipped with overhead restraints such as security tops, bubble tops, or canopies. Cribs which are used exclusively for young infants who cannot crawl or pull to stand do not require overhead restraints, such as cribs in a newborn nursery.	
Rationale:	To prevent falls from cribs. ECRI recommends that an overhead restraint be used for children who can crawl. Overhead restraints should also be used for children who can pull to stand. Given that the age and developmental stage of the occupant of a given crib is unpredictable it is recommended that all cribs be equipped with overhead restraints. Cribs which are used exclusively for young infants who cannot crawl or pull to stand do not require overhead restraints, such as cribs in a newborn nursery. See also 14.3	
Hazard:	Falls	
Type of Evidence:	Legislation:	References: (171) See also 14.3
	Standards: ECRI (58), Facility guidelines (87)	Recommendations: AAP (100)

Strength of Evidence: III		
14.3 Infants and children younger than two years of age and less than 35 inches tall sleep in a crib.		
Instruction/Definition:	Check the hospital policy regarding selection of crib vs. bed for toddlers. Verify hospital practice by direct observation or asking area staff.	
Rationale:	Children younger than two years of age are at risk for entrapment in adult beds, including hospital beds, and should sleep in a crib or a bed designed for children. Older toddlers who are able to climb out of the crib can be injured from falling, particularly the first time they climb out, although studies of falls from beds and cribs in hospitals have shown that typical injuries are minor. Standing height and ability to climb out of the crib unaided have been used as guidelines for consumers to help determine when a child should be transitioned from a crib to a bed. Canadian cribs for use in the home must have a warning that children over 90 cm tall (36 inches) or who can climb out unaided should not use the crib. The hospital crib standard does not state a maximum height. Other crib standards and guidelines typically state that children over 35 inches tall should not use a standard crib, however children taller than 35 inches may sleep in a hospital crib with a secured overhead restraint.	
Hazard:	Entrapment in adult beds, falls	
Type of Evidence:	Legislation: Hazardous Products Act, Cribs and Cradles Regulations (172), Hospital Cribs (173)	References: (34, 130, 157, 161-168, 174-177)
	Standards:	Recommendations: CPS (25), CPSC (169)
Strength of Evidence: III		
14.4 Overhead restraints (security tops, bubble tops, canopies) are used for children who can pull to stand or are greater than 88cm (35 inches) tall or are able to climb out of a crib or playpen.		
Instruction/Definition:	Check the hospital policy regarding the use of overhead restraints on cribs. Verify hospital practice by direct observation or asking area staff.	
Rationale:	To prevent falls from cribs. ECRI recommends that an overhead restraint be used for children who can crawl. Overhead restraints should also be used for children who can pull to stand. Given that the age and developmental stage of the occupant of a given crib is unpredictable it is recommended that all cribs be equipped with overhead restraints. Cribs which are used exclusively for young infants who cannot crawl or pull to stand do not require overhead restraints, such as cribs in a newborn nursery. See also 14.3	
Hazard:	Falls	

Type of Evidence:	Legislation: Hazardous Products Act, Cribs and Cradles Regulations (172)	References: (171) See also 14.3
	Standards: ECRI (178)	Recommendations:
Strength of Evidence:	III	

14.5 Is the crib located adjacent to curtain or drapery cords or other cords greater than 18 cm (7 inches), windows that open, or other hazards accessible to a child in the crib?

Instruction/Definition:	Examine the crib area for hazards accessible to the occupant of the crib, such as windows that open, window covering cords, decorative cords on wall hangings, and other hazards.	
Rationale:	To prevent access to strangulation and fall hazards. Cribs should be located away from hazards such as windows that open, window covering cords, and other cords. See also 12.1-12.4.	
Hazard:	Strangulation, Falls	
Type of Evidence:	Legislation: Hazardous Products Act, Cribs and Cradles Regulations (172)	References: (35, 76, 81, 83, 130, 179) See also 12.1-12.4
	Standards: Facility guidelines (11, 24, 25). See also 12.1-12.4	Recommendations: AAP (44, 180), CPS (25), CPSC (61, 128, 134-136), Health Canada (84, 85, 129, 138). See also 12.1-12.4
Strength of Evidence:	III	

14.6 Are any suspended crib gyms or hanging toys present?

Instruction/Definition:	Examine the crib for suspended crib gyms or crib toys and hanging toys attached to the crib with strings or cords.	
Rationale:	Suspended crib gyms and hanging toys attached to the crib are not practical for use in acute care hospital cribs. When used for long-term patients safety guidelines must be carefully followed. The ASTM Toy Safety standard and Health Canada recommend that manufacturers use warning labelling that states that suspended crib gyms should be removed when children are able to push up on hands and knees or by 5 months of age. If used, hanging toys should have strings or cords less than 18 cm (7 inches) in length (for elastic cords, this is the maximum stretched length).	
Hazard:	Strangulation, Falls	
Type of Evidence:	Legislation: Hazardous Products Act, Cribs and Cradles Regulations (172)	References: (35, 76, 81, 83, 130, 179)

	Standards: ASTM(181), Facility guidelines (11, 24)	Recommendations: AAP (44, 180), CPS (25), CPSC (61, 128, 134-136), Health Canada (84, 85, 129, 138)
Strength of Evidence:	III	

14.7 Are the crib slats (vertical bars) more than 6 cm (2 3/8 in.) apart?		
Instruction/Definition:	Measure the space between the slats with a tape measure.	
Rationale:	To prevent injuries due to entrapment. Current safety standards mandate a maximum gap of 60 mm between the slats. Some hospital cribs have slats that can be temporarily disengaged (raised) to allow caregivers to pass equipment into the crib. The opening created may be an entrapment hazard, so these slats must always be carefully secured in position before leaving the bedside.	
Hazard:	Entrapment	
Type of Evidence:	Legislation: Hazardous Products Act, Cribs and Cradles Regulations (182), Hospital Cribs (173)	References: (35, 130, 179)
	Standards: ECRI (141, 178), Facility guidelines (24, 25)	Recommendations: AAP (180), CPS (25), CPSC (61, 128)
Strength of Evidence:	III	

14.8 Are any slats missing, loose, or cracked?		
Instruction/Definition:	Examine the slats for damage. All of the slats should be firmly secured in place, particularly slats on hospital cribs which raise or move.	
Rationale:	To prevent entrapment and falls. Some hospital cribs have slats that can be temporarily disengaged (raised) to allow caregivers to pass equipment into the crib. The opening created may be an entrapment hazard, so these slats must always be carefully secured in position before leaving the bedside.	
Hazard:	Entrapment, falls	
Type of Evidence:	Legislation: Hazardous Products Act, Cribs and Cradles Regulations (182), Hospital Cribs (173)	References: (34, 35, 130, 165)
	Standards: ECRI (178)	Recommendations: CPSC (61, 128)
Strength of Evidence:	III	

14.9 Does the mattress fit snugly, with less than 3 cm (1.2 in) width between the edge of the mattress and crib side on any side?		
Instruction/Definition:	Push the mattress as far as possible to one side and measure the resulting gap. Push the mattress as far as possible toward the head or foot of the crib and measure the resulting gap. No gap should exceed 3 cm.	
Rationale:	To prevent entrapment. Infants have been fatally injured by becoming trapped or wedged in gaps created between the mattress and crib rail. Only firm, tight-fitting mattresses should be used. A maximum gap of 3 cm is specified by Canadian crib safety regulations.	
Hazard:	Entrapment, suffocation	
Type of Evidence:	Legislation: Hazardous Products Act, Cribs and Cradles Regulations (182), Hospital Cribs (173)	References: (35, 81, 83, 116, 130, 178, 179)
	Standards: Facility guidelines (24, 25)	Recommendations: AAP (180), CPS (25), CPSC (61, 128), Health Canada (129)
Strength of Evidence:	III	
14.10 Is the mattress firm and not more than 15 cm (6 in.) thick?		
Instruction/Definition:	Measure the height (depth) of the crib mattress. The surface of the mattress should be firm (not easily depressed or deformed, and not depressed or deformed by the weight of the child when lying down).	
Rationale:	To prevent falls and suffocation. Canadian crib safety regulations specify a maximum mattress height of 15 cm. Mattresses that are thicker will decrease the available distance between the mattress and the top of the side rail which can facilitate climbing out of the crib. Soft mattresses are hazardous for young infants and have been implicated in numerous sudden unexplained infant deaths during sleep.	
Hazard:	Falls, suffocation	
Type of Evidence:	Legislation: Hazardous Products Act, Cribs and Cradles Regulations (182), Hospital Cribs (173)	References: (35, 81, 83, 116, 130, 178, 179)
	Standards: Facility guidelines (24, 25)	Recommendations: AAP (180), CPS (25), CPSC (61, 128), Health Canada (129)
Strength of Evidence:	III	
14.11 Are catch-points for strangulation present such as exposed hardware or corner posts that extend more than 3 mm above the top end panel at the head or foot of the crib?		

Instruction/Definition:	Examine the tops of the side rails and end panels for protrusions and measure any if found. Examine the interior sides of the crib for hardware or other protrusions that could hook a looped cord or piece of clothing.	
Rationale:	To prevent strangulation. Corner posts or other protrusions that extend beyond the top of the headboard, footboard, or side rails and exposed hardware can lead to a child's clothing becoming caught, resulting in strangulation. Necklaces, pacifier cords around the neck, and other cords in the crib, particularly looped cords, have also been reported as becoming caught on catch-points in the crib. Canadian crib safety regulations specify that protrusions beyond 3 mm above the head or foot of the crib are prohibited. Other standards specify a maximum of 1.5 mm.	
Hazard:	Strangulation	
Type of Evidence:	Legislation: Hazardous Products Act, Cribs and Cradles Regulations (182), Hospital Cribs (173)	References: (34, 81, 83, 183)
	Standards: ASTM (1.5 mm) (184), Facility guidelines (24)	Recommendations: AAP (180), CPS (25), CPSC (61, 115, 128)
Strength of Evidence:	III	
14.12 Are all crib sides locked in their highest position when occupied?		
Instruction/Definition:	Check that all crib sides are in their highest position when the crib is occupied. Verify by direct observation if possible (preferable) or ask area staff and unit managers.	
Rationale:	To prevent falls.	
Hazard:	Falls	
Type of Evidence:	Legislation: Hazardous Products Act, Cribs and Cradles Regulations (182), Hospital Cribs (173)	References:
	Standards: ECRI (178), Facility guidelines (22, 24, 60)	Recommendations: AAP (180), CPS (25), CPSC (61), Health Canada (129)
Strength of Evidence:	III	
14.13 Can a child in the crib release the locked side rails or reach any adjustment mechanisms?		
Instruction/Definition:	Inspect the adjustment mechanisms and determine whether they are accessible to a child in the crib, and if so, whether a child could	

release any safety latches or activate crib controls.		
Rationale:	To prevent the child from tampering with the crib side rails and adjustment mechanisms. Locking mechanisms for hospital crib side rails must require two separate and simultaneous actions so that a child would not be able to lower the side rail.	
Hazard:	Entrapment, falls, pinching	
Type of Evidence:	Legislation: Hospital Cribs (173)	References: (185)
	Standards: ECRI (178, 185), Facility guidelines (24, 25, 60)	Recommendations: CPS (25), CPSC (128)
Strength of Evidence:	III	

14.14 Are there choking/suffocation hazards in the crib such as soft bedding, pillows, toys or other loose items in the crib such as syringe caps?		
Instruction/Definition:	Inspect the crib for soft bedding such as quilts, comforters, sheepskins, pillows, bumper pads, and other decorative items. Check for soft toys and large toys that could be a climbing aid. Check for small items that could be a choking hazard, using the small parts test cylinder.	
Rationale:	To prevent choking, suffocation, and falls. Soft bedding such as quilts, comforters, sheepskins, pillows, bumper pads, and other decorative items has been associated with suffocation deaths and sudden unexplained infant death during sleep, and is not recommended. Soft toys may also be a suffocation hazard. Small items that may be inadvertently left in the crib, such as syringe caps, butterfly needle caps, oral syringe caps, and intravenous supply packaging also may be choking or suffocation hazards. Note: ECRI recommends that only IV extension sets with nonremovable slide clamps or without slide clamps should be used due to the risk of slide clamp aspiration. (186)	
Hazard:	Suffocation, choking, falls	
Type of Evidence:	Legislation:	References: (34, 73, 76, 81, 83, 130, 165, 168, 178, 179, 186-189)
	Standards: ECRI (141), Facility guidelines (24, 25, 73)	Recommendations: AAP (180, 190), CPS (25, 191), CPSC (73, 128), Health Canada (170, 191)
Strength of Evidence:	III	

SECTION 15.0: High Chairs

15.1 Is there a functioning restraint system with both waist and crotch restraints?
15.2 Can the waist strap be buckled without using the crotch restraint?
15.3 Is there a policy that the restraint system must always used?

Instruction/Definition:	Examine the restraint system. Identify the waist strap and the crotch strap or pillar (which may be part of the tray or the seat). Fasten the restraint system as recommended by the manufacturer to ensure that it is functioning properly. Determine whether it is possible to buckle only the waist strap without using the crotch strap. Verify compliance with restraint system use by direct observation or by asking area staff or unit managers.	
Rationale:	Most high chair falls and virtually all fatal injuries could be prevented by the proper use of a sturdy three-point restraint system (waist and crotch restraints). The crotch restraint is required to prevent the child from slipping (submarining) down through the waist strap and falling or becoming trapped with the restraint system or tray compressing the trunk or neck. Restraint designs that allow the waist strap to be fastened without using the crotch restraint may encourage nonuse of the crotch restraint, which is an essential part of the restraint system.	
Hazard:	Falls, entrapment, strangulation	
Type of Evidence:	Legislation:	References: (46, 76, 81, 192, 193)
	Standards: ASTM (194), Facility guidelines (24, 25)	Recommendations: CPS (25), CPSC (61, 128)
Strength of Evidence:	III	
15.4 Are there any hazards accessible to the occupant of the chair, including rough or sharp edges, splinters, small parts, strings/cords, hot surfaces, and hazardous products?		
Instruction/Definition:	Inspect the chair for rough or sharp edges and splinters. Check for small parts that are accessible to the occupant, using the small parts test cylinder. Check for strings or cords adjacent to or attached to the chair that have a stretched length greater than 18 cm (7 inches). Assess the location (or usual location) of the chair to see whether any other hazards are within arms reach, such as electrical or appliance cords, window covering cords, hot surfaces or liquids, medications, and cleaning agents.	
Rationale:	To prevent injuries to the occupant of the chair due to touching or reaching unsafe surfaces or objects.	
Hazard:	Lacerations, choking, strangulation, burns, poisoning	
Type of Evidence:	Legislation:	References:
	Standards: ASTM (194), Facility guidelines (24, 25)	Recommendations: CPS (25)
Strength of Evidence:	III	
15.5 Are there any loose or missing parts?		

Instruction/Definition:	Inspect the chair for loose hardware and missing parts, such as protective acorn nuts (such as over exposed hardware), or protective plastic caps (such as over exposed hardware or ends of tubing). Check the chair for stability.	
Rationale:	To prevent injuries to children in the high chair due to exposed hardware, collapse, or tipping.	
Hazard:	Falls, lacerations, choking	
Type of Evidence:	Legislation:	References:
	Standards: ASTM (194), Facility guidelines (24, 25)	Recommendations: CPS (25)
Strength of Evidence:	III	

15.6 Are the instructions easily accessible to staff?		
Instruction/Definition:	Ask to review a copy of the instruction manual. Verify that a copy is available on the unit where the product is being used and easily accessible to all staff using the product.	
Rationale:	Instruction manuals should be easily accessible to staff for all children's products such as playpens, high chairs, strollers, and infant seats/carriers. These manuals contain weight and height limits and safety warnings that all users should be familiar with.	
Hazard:	Lacerations, choking, strangulation, burns, poisoning	
Type of Evidence:	Legislation:	References:
	Standards: ASTM (194), Facility guidelines (24, 25)	Recommendations: CPS (25)
Strength of Evidence:	III	

SECTION 16.0: Playpens

16.1 Is there a label on the product which states the manufacturer, model name/number, date of manufacture, and a statement that the product complies with the Playpen Regulations (Canada)?		
Instruction/Definition:	Inspect the product determine whether there is a permanently affixed label which states the manufacturer, model name/number, date of manufacture, and a statement that the product complies with the Playpen Regulations (Canada).	
Rationale:	Playpens in use must comply with current safety standards.	
Hazard:	Various	

Type of Evidence:	Legislation: Hazardous Products Act Playpen Regulations (125)	References:
	Standards: Facility guidelines (must comply with ASTM)(24)	Recommendations:
Strength of Evidence:	III	

16.2 Is the playpen located adjacent to curtain or drapery cords or other cords greater than 18 cm (7 inches), windows that open, or other hazards accessible to a child in the playpen?

Instruction/Definition:	Examine the playpen area for hazards accessible to the occupant of the playpen, such as windows that open, window covering cords, decorative cords on wall hangings, and other hazards.
Rationale:	To prevent access to strangulation and fall hazards. Playpens should be located away from hazards such as windows that open, window covering cords, and other cords. See also 12.1-12.4.
Hazard:	Strangulation, falls

Type of Evidence:	Legislation:	References: (35, 76, 81, 83, 130, 179, 195) See also 12.1-12.4
	Standards: Facility guidelines (11, 24, 25). See also 12.1-12.4	Recommendations: AAP (44, 180), CPS (25), CPSC (61, 128, 134-136, 195), Health Canada (84, 85, 129, 138). See also 12.1-12.4
Strength of Evidence:	III	

16.3 Is the pad/mattress provided by the manufacturer used, with no additional mattress or padding?

Instruction/Definition:	Inspect the pad/mattress to assess whether it was provided by the manufacturer. Check for additional mattresses or padding which might be placed on top of the original base (pad or mattress).
Rationale:	Only the pad/mattress designed for the playpen should be used. No additional mattress or padding should be used, as these may create an entrapment risk due to gaps between surfaces, or a suffocation risk, related to soft bedding. Additional padding also raises the floor of the playpen and facilitates climbing out.
Hazard:	Entrapment, suffocation, fall

Type of Evidence:	Legislation:	References: (195)
	Standards: ASTM (196), Facility guidelines (24)	Recommendations: CPSC (61, 195)
Strength of Evidence:	III	

16.4 Are any suspended crib gyms or hanging toys present?		
Instruction/Definition:	Examine the playpen for suspended crib gyms or toys and hanging toys attached to the playpen with strings or cords.	
Rationale: See 14.6		
Hazard: Strangulation		
Type of Evidence:	Legislation:	References: See 14.6
	Standards: See 14.6	Recommendations: See 14.6
Strength of Evidence: III		
16.5 Is the side ever left in the down position on a drop-side mesh playpen or mesh crib?		
Instruction/Definition:	For mesh-sided cribs and playpens, determine if any models have a drop-side. Verify hospital practice regarding leaving the drop-side down by direct observation or asking staff or unit managers.	
Rationale:	To prevent entrapment. Children have been fatally entrapped in the drop-side of mesh cribs which were left in the drop (down) position.	
Hazard: Entrapment		
Type of Evidence:	Legislation:	References: (46, 195)
	Standards: ASTM (196), ECRI (197), Facility guidelines (24)	Recommendations: CPS (25), CPSC (61, 115, 128, 195)
Strength of Evidence: III		
16.6 Does the mesh have a small weave (less than 5 mm / 0.2 inch openings)? **16.7 Is the mesh torn, or does it have holes or loose threads?**		
Instruction/Definition:	Measure the gaps (openings) in the mesh. Inspect the mesh for tears and holes.	
Rationale:	To prevent strangulation. Large mesh on older playpens has resulted in strangulation due to buttons on infant clothing becoming caught in an opening in the mesh. Tears and holes may create a gap greater than 5 mm and also pose a risk of strangulation. Larger holes may result in entrapment.	
Hazard: Strangulation		
Type of Evidence:	Legislation: Hazardous Products Act Playpen Regulations (125)	References: (195) (198)
	Standards: ASTM (196)	Recommendations: CPS (25), CPSC (61, 128, 195)
Strength of Evidence: III		

16.8 Are there any hazards accessible to the occupant of the playpen, including rough or sharp edges, splinters, small parts, strings/cords, hot surfaces, and hazardous products?		
Instruction/Definition:	Inspect the playpen for rough or sharp edges and splinters. Check for small parts that are accessible to the occupant, using the small parts test cylinder. Check for strings or cords adjacent to or attached to the playpen that have a stretched length greater than 18 cm (7 inches). Assess the location (or usual location) of the playpen to see whether any other hazards are within arms reach, such as electrical or appliance cords, window covering cords, hot surfaces or liquids, medications, and cleaning agents.	
Rationale:	To prevent injuries to the occupant of the playpen due to touching or reaching unsafe surfaces or objects.	
Hazard:	Lacerations, choking, strangulation, burns, poisoning	
Type of Evidence:	Legislation:	References:
	Standards: ASTM (194), Facility guidelines (24, 25)	Recommendations: CPS (25)
Strength of Evidence:	III	
16.9 Do the frame/rail covers have any tears or holes?		
Instruction/Definition:	Inspect the rail covers for tears, holes, and other defects.	
Rationale:	The mesh must be securely attached to the top rail; tears or holes in the rail cover may lead to a failure or fold in the mesh side, which can lead to suffocation or entrapment. Defects in the rail cover can lead to exposed hardware, sharp edges or pinching hazards. Children who chew on the top rail can aspirate small pieces of vinyl or plastic.	
Hazard:	Choking, suffocation, laceration, pinching	
Type of Evidence:	Legislation: Hazardous Products Act Playpen Regulations (125)	References:
	Standards:	Recommendations: CPS (25), CPSC (61, 128, 195)
Strength of Evidence:	III	
16.10 Are any vertical bars or slats more than 6 cm apart?		
Instruction/Definition:	Measure the space between the slats with a tape measure.	

Rationale:	To prevent injuries due to entrapment. Current crib safety standards mandate a maximum gap of 60 mm between the slats; playpens with vertical bars or slats present the same risk, and similar guidelines should be followed with respect to slat spacing.	
Hazard:	Entrapment	
Type of Evidence:	Legislation: Hazardous Products Act, Cribs and Cradles Regulations (182), Hospital Cribs (173)	References: (35, 130, 179)
	Standards: ASTM (196), ECRI (141, 178), Facility guidelines (24, 25)	Recommendations: AAP (180), CPS (25), CPSC (61, 128) CPSC (61, 128)
Strength of Evidence:	III	

16.11 Are soft bedding, pillows, toys or other loose items in the playpen such as syringe caps that could present a choking/suffocation hazard?

Instruction/Definition:	Inspect the playpen for soft bedding such as quilts, comforters, sheepskins, pillows, and other decorative items. Check for soft toys and large toys that could be a climbing aid. Check for small items that could be a choking hazard, using the small parts test cylinder.
Rationale:	To prevent choking, suffocation, and falls. Soft bedding such as quilts, comforters, sheepskins, pillows, and other decorative items has been associated with suffocation deaths and sudden unexplained infant death during sleep, and is not recommended. Soft bedding and wedging between mattresses, foam, and cushions have been implicated in infant suffocation deaths in playpens. Soft toys may also be a suffocation hazard. Small items that may be inadvertently left in the playpen, such as syringe caps, butterfly needle caps, oral syringe caps, and intravenous supply packaging also may be choking or suffocation hazards. Plastic bags and plastic sheeting have also resulted in suffocation in playpens. Note: ECRI recommends that only IV extension sets with nonremovable slide clamps or without slide clamps should be used due to the risk of slide clamp aspiration. (186)
Hazard:	Suffocation, choking, falls

Type of Evidence:	Legislation:	References: (34, 73, 76, 81, 83, 130, 165, 168, 178, 179, 186-189, 195)
	Standards: ASTM (196), ECRI (141), Facility guidelines (24, 25, 73)	Recommendations: AAP (180, 190), CPS (25, 191), CPSC (73, 128, 195), Health Canada (170, 191)
Strength of Evidence:	III	

16.12 Are the rail locking devices effective to prevent accidental folding?		
Instruction/Definition:	Lock the rails in place. The rails should not collapse or fold without activating the unlocking mechanism. Check the manufacturer's instructions to ensure that the rails are functioning properly.	
Rationale:	Side rails that are defective or not fully locked in place may collapse, and have resulted in deaths due to neck entrapment.	
Hazard:	Entrapment, Strangulation	
Type of Evidence:	Legislation: HPA Playpen Regulations (125)	References: (195)
	Standards: ASTM (196)	Recommendations: CPS (25), CPSC (61, 195)
Strength of Evidence:	III	
16.13 Are the weight and height limits of the playpen visible or known by staff, and adhered to?		
Instruction/Definition:	Check the playpen label and product instructions for weight/height limits. Verify compliance with weight/height limits by direct observation or by asking area staff or unit managers.	
Rationale:	Manufacturers' recommended weight and height limits should be known to staff and adhered to. The ASTM standard specifies that playpens must have permanent warning labels that include a statement that the playpen must only be used for children who are unable to climb out and who are less than 35 inches tall and weigh less than 30 pounds. Children too large for the playpen can tip it over, climb out, or damage the supporting frame or floor.	
Hazard:	Various	
Type of Evidence:	Legislation:	References:
	Standards: ASTM (196), Facility guidelines (24)	Recommendations: CPS (25)
Strength of Evidence:	III	
16.14 Are the instructions easily accessible to staff?		
Instruction/Definition:	Ask to review a copy of the instruction manual. Verify that a copy is available on the unit where the product is being used and easily accessible to all staff using the product.	
Rationale:	Instruction manuals should be easily accessible to staff for all children's products such as playpens, high chairs, strollers, and infant seats/carriers. These manuals contain weight and height limits and safety warnings that all users should be familiar with.	

Hazard:	Lacerations, choking, strangulation, burns, poisoning	
Type of Evidence:	Legislation:	References:
	Standards: ASTM (194), Facility guidelines (24, 25)	Recommendations: CPS (25)
Strength of Evidence:	III	

C. PLAY AREA AND TOY SAFETY

Check windows, doors, floors, and other aspects of play areas using the Safety Checklist for Patient Rooms and Public Areas (A).

SECTION 17.0 Play Areas

17.1 Do all outdoor play areas comply with the Canadian Standards Association Playspaces and Equipment standard?		
Instruction/Definition:	Inspecting outdoor play areas is beyond the scope of this audit. A certified playground inspector should inspect outdoor play areas to ensure compliance with the current CSA standard.	
Rationale:	To prevent falls and other playground-related injuries.	
Hazard:	Falls	
Type of Evidence:	Legislation:	References: (34, 199)
	Standards: CSA Z614 Children's Playspaces and Equipment(120), Facility guidelines (24, 73, 94)	Recommendations: CPS (25), CPSC (73)
Strength of Evidence:	III	
17.2 If there is an indoor play structure, is the area under and around it covered with adequate surfacing materials?		
Instruction/Definition:	See 17.1. The surfacing materials (type, depth, installation) should be consistent with the CSA standard.	
Rationale:	To prevent injuries due to falls from indoor play equipment. Indoor play equipment is often placed on inadequate surfacing, including carpeted and uncarpeted floors. Falls from a height onto noncompliant surfaces posses a risk of injury, particularly for children with bleeding disorders, low platelet counts, and bone fragility. Current playground surfacing standards and guidelines should apply to all play equipment regardless of whether the structure is installed indoors or outdoors.	
Hazard:	Falls	
Type of Evidence:	Legislation:	References: (200)
	Standards: CSA (120), Facility guidelines (24)	Recommendations: AAP (44), CPSC (61, 201)
Strength of Evidence:	III	

SECTION 18.0 Toy Safety

18.1 Are the batteries in toys accessible to children?		
Instruction/Definition:	Inspect toys with battery compartments. Batteries should be inaccessible to children, with compartments requiring a coin or other tool to open.	
Rationale:	To prevent ingestion and choking of batteries. Most batteries in toys are also small parts, and are a choking hazard.	
Hazard:	Choking, foreign body ingestion	
Type of Evidence:	Legislation: Hazardous Products Act Toys Regulations (125)	References: (46, 76, 81)
	Standards: ASTM (181), Facility guidelines (24)	Recommendations: Health Canada (85), CPSC (202, 203)
Strength of Evidence:	III	

18.2 Can small pieces of toys be broken off (e.g. wheels, eyes, noses)?		
Instruction/Definition:	Inspect toys for small parts or pieces that could be easily detached or broken, such as wheels, eyes, and noses. Check small parts with the small parts test cylinder.	
Rationale:	To prevent choking.	
Hazard:	Choking	
Type of Evidence:	Legislation: Hazardous Products Act Toys Regulations (125)	References: (46, 76, 81)
	Standards: ASTM (181), ECRI (58), Facility guidelines (24, 25)	Recommendations: CPS (25), CPSC (202, 203), Health Canada (85)
Strength of Evidence:	III	

18.3 Are latex balloons prohibited?	
Instruction/Definition:	Inspect the area for latex balloons. Determine whether there is a hospital policy prohibiting latex balloons.
Rationale:	Latex balloons pose a risk of fatal choking to children of all ages, and should not be used in any health care setting. Gift shops and flower/basket retailers operating within the facility should be instructed not to use latex balloons for deliveries within the hospital.
Hazard:	Choking

Type of Evidence:	Legislation:	References: (34, 46, 76, 77, 81, 109, 204)
	Standards: ECRI (58), Facility guidelines (24, 25)	Recommendations: CPS (25), CPSC (115), Health Canada (85)
Strength of Evidence:	III	

18.4 Do toddlers less than 36 months of age have access to toys with small parts such as beads, puzzle pieces, and blocks less than 1.25 inches in diameter, or balls less than 1.75 inches in diameter?

Instruction/Definition:	Assess small parts and small toys with the small parts test cylinder. Measure the diameter of balls using a tape measure.
Rationale:	To prevent choking. Keep toys for toddlers and toys for older children in separate storage and play areas.
Hazard:	Choking

Type of Evidence:	Legislation: Hazardous Products Act Toys Regulations (125)	References: (34, 46, 76, 81, 109, 205, 206)
	Standards: ASTM (181), ECRI (58), Facility guidelines (24, 25)	Recommendations: CPS (25, 45), CPSC(61, 115, 202, 203), Health Canada (85)
Strength of Evidence:	III	

18.5 Do any toys have sharp edges, points, splinters, or pinch points?

Instruction/Definition:	Inspect toys for sharp edges, points, splinters, and pinch points that might cause lacerations, puncture wounds, eye injuries, or pinching/crushing.
Rationale:	Broken toys and toys for older children may injure younger children, particularly infants and toddlers. Broken or damaged toys should be repaired or discarded. Toys for older children should be separated from those for children under three years of age.
Hazard:	Lacerations, eye injuries, pinching

Type of Evidence:	Legislation: Hazardous Products Act Toys Regulations (125)	References: (46)
	Standards: ASTM (181), Facility guidelines (2, 24, 60)	Recommendations: CPS (25), CPSC (202), Health Canada (85)
Strength of Evidence:	III	

18.6 Are any toys constructed with thin or brittle plastic that might break into small pieces or leave jagged edges?		
Instruction/Definition:	Inspect toys for evidence of thin or brittle plastic that might be broken during play and result in small parts of sharp edges.	
Rationale:	To prevent choking and lacerations. Discard unsafe or broken toys.	
Hazard:	Lacerations, choking	
Type of Evidence:	Legislation: Hazardous Products Act Toys Regulations (125)	References: (46, 76, 81)
	Standards: ASTM (181), ECRI (58), Facility guidelines (24, 25)	Recommendations: CPS (25)
Strength of Evidence:	III	

18.7 Are all art materials (crayons/paint sets) non-toxic?		
Instruction/Definition:	Verify that art materials are non-toxic. Materials that are safe for children have a label indicating that they are non-toxic.	
Rationale:	To prevent poisoning.	
Hazard:	Poisoning	
Type of Evidence:	Legislation: Hazardous Products Act Toys Regulations (125)	References: (34)
	Standards: ASTM (181), Facility guidelines (2, 24, 25)	Recommendations: CPS (25), CPSC (202)
Strength of Evidence:	III	

18.8 Is there a process in place to check toys at least monthly for breakage and potential hazards?		
Instruction/Definition:	Determine how often staff inspect toys for hazards or damage.	
Rationale:	To ensure that toys are inspected regularly. Toys should be monitored regularly for evidence of wear and damage, at least monthly. Unsafe or broken toys should be repaired or discarded immediately.	
Hazard:	Various.	
Type of Evidence:	Legislation:	References:
	Standards: Facility guidelines (24, 25, 94)	Recommendations: CPS (25)
Strength of Evidence:	III	
18.9 Are there any toys accessible to toddlers with cords or strings longer than 18 cm (7 inches)? **18.10 Do any toys have looped fabric or cords that could get caught around a child's neck, with a perimeter greater than 35 cm (14 inches)?**		
Instruction/Definition:	Inspect toys for free and looped cords, and measure with a tape measure.	
Rationale:	To prevent strangulation. Note: Pull toys may have cords longer than 7 inches, however they should not be looped, and they should not have beads or toggles on them that could create a loop.	
Hazard:	Strangulation	
Type of Evidence:	Legislation:	References: (76, 81)
	Standards: ASTM (181), Facility guidelines (25, 60)	Recommendations: CPS (25), CPSC (203), Health Canada (85)
Strength of Evidence:	III	
18.11 Are toys that propel objects prohibited?		
Instruction/Definition:	Check for toys that propel or shoot objects. Determine whether there is a policy prohibiting projectile toys.	
Rationale:	Shooting and projectile toys such as rockets, dart guns, and sling shots should be prohibited.	
Hazard:	Eye injuries	
Type of Evidence:	Legislation: Hazardous Products Act Toys Regulations (125)	References:

	Standards: Facility guidelines (24, 25)	Recommendations: CPS (25)
Strength of Evidence:	III	
18.12 Do toy boxes have good ventilation and lightweight lids with safety hinges and no latch, or no lids?		
Instruction/Definition:	Inspect all toy storage boxes and toy chests. For those with lids, ensure that the lid is lightweight, and that there are ventilation holes (applies to containers with internal dimensions of at least 6 inches and a total volume of 1.1 cubic feet). Lids should have safety hinges which prevent sudden closing, and lids should not have latches that might trap a child inside.	
Rationale:	Children have been fatally injured by climbing into and becoming trapped in toy boxes and other storage chests with inadequate ventilation. Heavy lids pose a risk of fatal neck entrapment, head injury, and crushing/pinching. Toy boxes with no lids are the safest option.	
Hazard:	Asphyxia, entrapment, struck by falling object, crushing/pinching	
Type of Evidence:	Legislation: Hazardous Products Act Toys Regulations (125)	References: (34, 46)
	Standards: ASTM (181, 207), Facility guidelines (24, 25)	Recommendations: CPS (25), CPSC (61, 128, 203), Health Canada (85)
Strength of Evidence:	III	
18.13 Are sparking toys prohibited?		
Instruction/Definition:	Determine whether there is a hospital policy prohibiting sparking toys. Check signage near oxygen outlets for warning statements regarding the use of sparking toys near oxygen.	
Rationale:	Sparking toys have caused fires in pediatric oxygen tents and should not be used in the hospital.	
Hazard:	Fire/burn	
Type of Evidence:	Legislation:	References: (13, 93, 208)
	Standards: ECRI (209), Facility guidelines (13, 24)	Recommendations:
Strength of Evidence:	III	

18.14 Are infant walkers prohibited (i.e. wheeled baby walkers)?		
Instruction/Definition:	Inspect the area for baby walkers. Determine whether there is a hospital policy prohibiting baby walkers.	
Rationale:	Baby walkers provide premature mobility to infants that facilitates their access to a variety of hazards including stairs, hot substances, window covering cords, poisonous plants, cleaning agents, and medications. They should not be used in any health care facility.	
Hazard:	Falls, burns, poisoning	
Type of Evidence:	Legislation:	References:
	Standards: Facility guidelines (24, 25)	Recommendations: AAP (44), CPS (25, 45), Health Canada
Strength of Evidence:	III	

D. DEVICES FOR TRANSPORTING INFANTS AND CHILDREN

SECTION 19.0: Car Seats

19.1 Are the instructions for the car seat present (both official languages)?

19.2 Are all labels on the car seat present and legible? (Canadian Motor Vehicle Safety Standard national safety mark, date of manufacture, model #, etc.)

19.3 Are all pieces of the car seat present (e.g. cover, harness, locking clip, LATCH hardware, base, tether strap and hardware)?

19.4 Is the shell cracked or damaged?

19.5 Has the car seat been in a collision or recalled?

19.6 Is the car seat more than ten years old?

Instruction/Definition:	Note: loan programs are beyond the scope of this audit. Have a certified car seat technician check hospital-use car seats on a regular basis. For every car seat check at least the following: Instructions should be present in both official languages for all car seats approved for use in Canada. The labels should be present and legible, and should include the date of manufacture, model number, and national safety mark (maple leaf inside a circle), as well as seat belt routing paths and weight limits. Infant seats should have an airbag warning. Using the manual, check to ensure that all parts are present (examples listed above). Check the shell for cracking or damage. Check to ensure that the car seat has not been in a collision or recalled. Using the date of manufacture and the manual, determine if the car seat is either older than 10 years or past the recommended expiry date.
Rationale:	Car seat loan programs are beyond the scope of this audit. Some hospitals may have car seats for inter-facility transfers or other hospital uses. It is recommended that a certified car seat technician inspect all seats used by the hospital, at regular intervals.
Hazard:	Various
Type of Evidence:	Legislation: Motor Vehicle Safety Act, CMVSS References: Standards: Recommendations: Transport Canada (182)
Strength of Evidence:	III

19.7 Are infants left unattended in car seats (e.g. are car seats ever used for sleeping)?

Instruction/Definition:	Determine whether there is a hospital policy regarding the use of car seats in the hospital. Verify hospital practice by asking area staff and unit managers regarding using car seats as infant seats or for sleeping.

Rationale:	A car seat is not a safe substitute for a crib. If the car seat tips over the infant can suffocate on soft surfaces or bedding and the harness system or the child's position may obstruct the airway. Car seat manufacturers and Transport Canada strongly advise against leaving infants unattended in car seats.	
Hazard:	Suffocation, entrapment	
Type of Evidence:	Legislation:	References: (210-212)
	Standards:	Recommendations: Transport Canada (210)
Strength of Evidence:	III	

SECTION 20.0: Infant Carriers

20.1 Is there a functioning restraint system with both waist and crotch restraints? **20.2 Can the waist strap be buckled without using the crotch restraint?** **20.3 Is the restraint system always used?**		
Instruction/Definition:	Examine the restraint system. Identify the waist strap and the crotch strap. Fasten the restraint system as recommended by the manufacturer to ensure that it is functioning properly. Determine whether it is possible to buckle only the waist strap without using the crotch strap. Verify compliance with restraint system use by direct observation or by asking area staff or unit managers.	
Rationale:	Many falls from infant seats could be prevented by the proper use of a sturdy three-point restraint system (waist and crotch restraints). The crotch restraint is required to prevent the child from slipping (submarining) down through the waist strap and falling or becoming trapped with the restraint system compressing the neck.	
Hazard:	Falls, entrapment, strangulation	
Type of Evidence:	Legislation:	References: (51, 212)
	Standards: ASTM (213)	Recommendations: CPS (25), CPSC (61, 115, 128)
Strength of Evidence:	III	
20.4 Is the infant seat/carrier ever placed on an elevated or soft surface such as a bed or crib?		
Instruction/Definition:	Inspect the area for placement of infant seats and carriers. An elevated surface is any surface above the floor level. Common soft surfaces include chairs, stretchers, sofas, cribs, and beds. Verify usual practice with respect to placement on soft and elevated surfaces by direct observation or by asking unit managers.	
Rationale:	If the infant seat/carrier tips over the infant can suffocate on soft surfaces or bedding and the harness system or the child's position may obstruct the airway. Infants are able to move the seat toward the edge of an elevated surface with normal activity, and falls from elevated surfaces are commonly reported. The ASTM standard specifies that warning labels must state that the child should not be left	

	unattended, and that the seat should not be placed on soft surfaces or near the edge of elevated surfaces.	
Hazard:	Falls, strangulation	
Type of Evidence:	Legislation:	References: (210-212)
	Standards: ASTM (213)	Recommendations: CPSC (61)
Strength of Evidence:	III	
20.5 Are the instructions easily accessible to staff?		
Instruction/Definition:	Ask to review a copy of the instruction manual. Verify that a copy is available on the unit where the product is being used and easily accessible to all staff using the product.	
Rationale:	Instruction manuals should be easily accessible to staff for all children's products such as playpens, high chairs, strollers, and infant seats/carriers. These manuals contain weight and height limits and safety warnings that all users should be familiar with.	
Hazard:	Lacerations, choking, strangulation, burns, poisoning	
Type of Evidence:	Legislation:	References:
	Standards: ASTM (213), Facility guidelines (24, 25)	Recommendations:
Strength of Evidence:	III	
20.6 Are the weight and height limits of the seat visible or known by staff, and adhered to?		
Instruction/Definition:	Check the label and product instructions for weight/height limits. Verify compliance with weight/height limits by direct observation or by asking area staff or unit managers.	
Rationale:	Manufacturers' recommended weight and height limits should be known to staff and adhered to. Children too large for the seat could tip it over or move it across a surface and potentially fall or access other hazards. The handle may not support the weight of a heavier child, resulting in carrier handle failure.	
Hazard:	Various	
Type of Evidence:	Legislation:	References:
	Standards: ASTM (213), Facility guidelines (24, 25)	Recommendations:
Strength of Evidence:	III	

SECTION 21.0: Stretchers

21.1 Are the brakes functional?		
Instruction/Definition:	Activate the stretcher's brakes or wheel locking system. Brakes are considered functional if you cannot move the stretcher once the locking system is activated.	
Rationale: To prevent falls.		
Hazard: Falls		
Type of Evidence:	Legislation:	References: (13)
	Standards: Facility guidelines (13)	Recommendations:
Strength of Evidence: III		

21.2 Do both side rails lock in the raised position?		
Instruction/Definition:	Test both side rails to ensure that they fully raise and lock securely in position.	
Rationale: To prevent falls from the stretcher.		
Hazard: Falls		
Type of Evidence:	Legislation:	References: (13)
	Standards: Facility guidelines (13)	Recommendations:
Strength of Evidence: III		

21.3 Do the stretcher rails create spaces that a child could crawl into or fall through that are greater than 8 cm (3.5 inches) and less than 23 cm (9 inches)?	
Instruction/Definition:	Measure spaces or gaps where a child can crawl into or fall through. Spaces should be small enough to prevent the torso from entering (3.5 inches X 6.2 inches) or large enough to allow the head to pass through (9 x 9 inches).
Rationale:	To prevent falls and entrapment. Guardrail spacing is designed (1) to prevent falls and (2) to prevent a child's body from slipping through feet-first and trapping the head and neck (entrapment), which can be fatal. The National Building Code specifies that guard rails on balconies and other elevated surfaces must not have any opening that permits passage of a sphere whose diameter is 100 mm (4 inches) and must be constructed to resist climbing (e.g. horizontal rails are not permitted). Other standards use a 3.5 inch diameter sphere (24) or a torso probe with a base of 3.5 x 6.2 inches to assess entrapment hazards of guardrails used in various settings (day care, bunk beds, play equipment).(120, 121)
Hazard:	Entrapment

Type of Evidence:	Legislation:	References: See 11.5
	Standards: See 11.5	Recommendations: See 11.5
Strength of Evidence:	III	

21.4 Are both side rails raised when the stretcher is occupied? **21.5 Are infants or toddlers ever left unattended on a stretcher?**	
Instruction/Definition:	Determine whether hospital policy specifies that stretcher rails should be raised when the stretcher is occupied, and whether children may be left unattended on stretchers. Verify hospital practice by direct observation or asking area staff.
Rationale:	To prevent falls from stretchers. Infants, toddlers, and young children should not be left unattended on stretchers, with the exception of pediatric stretchers with overhead restraints (i.e. cribs). The side rails should be raised when the patient is on the stretcher, unless the stretcher is in its lowest position with one rail raised, and the child is awake and alert, ambulatory, and able to reach the floor without assistance.
Hazard:	Falls

Type of Evidence:	Legislation:	References: (106)
	Standards:	Recommendations:
Strength of Evidence:	III	

SECTION 22.0: Strollers/Carriages

22.1 Are the brakes functional?		
Instruction/Definition:	Test the brakes to ensure that they securely lock the wheels and prevent movement of the stroller/carriage.	
Rationale:	To prevent falls, particularly down stairs, and collisions (rolling into traffic or striking other fixed objects).	
Hazard:	Falls, collisions	
Type of Evidence:	Legislation: Hazardous Products Act Carriages and Strollers Regulations (125)	References: (214-216)
	Standards: ASTM (217), Facility guidelines (24, 25)	Recommendations: CPS (25), CPSC (61, 128)
Strength of Evidence:	III	

22.2 Are there any hazards accessible to the occupant of the stroller/carriage, including rough or sharp edges, splinters, small parts, soft bedding, or strings/cords longer than 18 cm (7 inches)?		
Instruction/Definition:	Inspect the stroller for rough or sharp edges and splinters. Check for small parts (e.g. loose hardware) that are accessible to the occupant, using the small parts test cylinder. Check for strings or cords adjacent to or attached to the chair that have a stretched length greater than 18 cm (7 inches) and looped cords with a circumference greater than 35 cm (14 inches).	
Rationale:	To prevent injuries to the occupant of the stroller/carriage due to touching or reaching hazardous surfaces or objects.	
Hazard:	Lacerations, choking, strangulation	
Type of Evidence:	Legislation: Hazardous Products Act Carriages and Strollers Regulations (125)	References: (214-216)
	Standards: ASTM (217), Facility guidelines (24, 25)	Recommendations: CPS (25)
Strength of Evidence:	III	
22.3 Does the stroller/carriage have a sturdy and functioning restraint system with both crotch and waist straps? **22.4 Can the waist strap be fastened without using the crotch strap?** **22.5 Is the restraint system always used?**		
Instruction/Definition:	Examine the restraint system. Identify the waist strap and the crotch strap. Fasten the restraint system as recommended by the manufacturer to ensure that it is functioning properly. Determine whether it is possible to buckle only the waist strap without using the crotch strap. Verify compliance with restraint system use by direct observation or by asking area staff or unit managers.	
Rationale:	Most stroller/carriage falls and virtually all fatal injuries could be prevented by the proper use of a sturdy three-point restraint system (waist and crotch restraints). The crotch restraint is required to prevent the child from slipping (submarining) down through the waist strap and falling or becoming trapped with the restraint system compressing the trunk or neck.	
Hazard:	Falls, entrapment, strangulation	
Type of Evidence:	Legislation: Hazardous Products Act Carriages and Strollers Regulations (125)	References: (214-216)
	Standards: ASTM (217), Facility guidelines (24, 25)	Recommendations: CPS (25), CPSC (61, 128)

Strength of Evidence: III		
22.6 Are children ever left unattended in a stroller or carriage?		
Instruction/Definition:	Determine whether there is a hospital policy regarding supervision of children in strollers and carriages. Verify hospital practice by direct observation or by asking area staff and unit managers.	
Rationale:	Stroller/carriage safety standards mandate that prominent labelling states that children should not be left unattended in the stroller. Children left unattended in strollers have been fatally injured by slipping into one of the leg openings and becoming entrapped, and by tipping over and suffocating or becoming entangled in the harness system. Most deaths have occurred among young children (less than 9 months of age) who were sleeping unattended in strollers/carriages.	
Hazard:	Entrapment, suffocation	
Type of Evidence:	Legislation: Hazardous Products Act Carriages and Strollers Regulations (125)	References: (215, 217)
	Standards: ASTM (217), Facility guidelines (24, 25)	Recommendations: CPS (25), CPSC(61, 115, 128)
Strength of Evidence: III		

APPENDIX

Poisonous House (Indoor) Plants

- **Asparagus Fern** (*asparagus plumosus) (sprengeri*)
- **Avocado** (*persea americana*)
- **Blue Gum** (*eucalyptus globulus*)
- **Buddist Pine** (*poddocarpus Macrophyllus*)
- **Cacti:**
    - **Bunny Ears** (*opuntia microdasy's alkispina*)
    - **Column** (*cereus peruvianus*)
    - **Rats Tail** (*aporocactus flagelliformis*)
    - **Sunset** (*lokwia famatimensis*)
- **Caladium** (Angel's Wings)
- **Century Plant**
- **Crown Of Thorns** (*euphorbia milii splendens*)
- **Cyclamen**
- **Dieffenbachia**
- **Holly**
- **Ivy**:
    - **Cape** (*tenecio macroglossus*)
    - **English** (*hedera helix*)
    - **German** (*senecio mikanioides*)
    - **Glacier** (*hedera helix glacier*)
    - **Gloire de Marengo** (hedera canariensis)
    - **Needlepoint** (*hedera helix sagittlae folica*)
- **Jerusalem Cherry** (*solanum pseudocapsicum*)
- **Mistletoe** (*phoradendron flavescens)*
- **Philodendron**:
    - **Arrowhead** (*syngonium podophyllum*)
    - **Black Gold** (*ph. melanochryson*)
    - **Devil's Ivy** (Pothos) (*scindapsus aureus*)
- **Elephant's Ear** (*philodendron hastatum*)
- **Fiddle Leaf** (*ph. pandurae forme*)
- **Green Gold** (*syngonium podophyllum)*
- **Marble Queen** (*scindapsus aureus*)
- **Ornamental Pepper** (*capsicum annuum*)
- **Silver Vine** (*scindapsus pictus*)
- **Split Leaf** (*monstera colorata*)
- **Sweetheart Vine** (*philodendron scandens*)
- **Red** (*hemigraphis colorata*)
- **Umbrella Plant** (*cyperus*)

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Appendix 4.4

Pediatric Health Care Facility Audit

(Instrument)

How to Use this Form

The audit is divided into four sets of checklists: (A) is for patient rooms and public areas; (B) is for children's equipment found in patient rooms, public areas, and storage areas (beds, cribs, high chairs, playpens); (C) is for play areas and toys; and (D) is for devices used for transporting infants and children (car seats, infant carriers, stretchers, strollers/carriages).

Check all rooms and areas accessible to pediatric patients and visitors. As you inspect each patient room or patient care area, circle the response (Y = Yes, N = No) or place a checkmark (X) in the "not applicable" column. The shaded areas identify when a hazard is present. Record the room number or location where hazards are present and note the specific hazard. You may refer to the handbook for further instructions, rationale, and supporting evidence for each audit item.

Note: This checklist is not meant to substitute for compliance with established regulations (e.g. Fire codes, Building codes, Occupational Health and Safety standards, product safety standards). Medical devices are excluded from the audit.

A. SAFETY CHECKLIST FOR PATIENT ROOMS AND PUBLIC AREAS

1.0 Bathroom	1.1 Does the bathtub/shower have a slip-resistant floor?	Y	N
	1.2 Are grab bars installed in the bathtub/shower?	Y	N
	1.3 Is the maximum hot water temperature less than 49°C (120°F)?	Y	N
	1.4 Can the bathroom door be easily and quickly unlocked from both sides?	Y	N
	1.5 Are bathroom doors kept closed to prevent toddler access?	Y	N
	1.6 Is there a functional call bell within patient/caregiver reach?	Y	N
2.0 Cleaning	2.1 Are cleaning carts or supplies left unattended?	Y	N
	2.2 Are any hazardous substances or equipment accessible to children (e.g. on cleaning or maintenance carts, under sinks, on counters, in cupboards)?	Y	N
	2.3 Are cleaning products clearly marked and stored in their original containers, with all hazardous products in child-resistant containers?	Y	N
3.0 Hospital Clothing	3.1 Do mittens, booties, blankets and sleepers have loose threads or tight elastic that could cause digit or extremity ligature/strangulation?	Y	N
	3.2 Does any clothing that is provided to patients by the hospital have drawstrings at the neck or waist?	Y	N
	3.3 Are there any choking hazards on infant clothing (e.g. loose buttons, snaps)?	Y	N
	3.4 Is all donated, loaned, and hospital clothing thoroughly checked for choking/strangulation hazards?	Y	N

4.0 Cords	4.1 Are telephone, television, extension and other electrical cords either less than 18 cm (7 inches) in length, or securely fixed to the floor, wall, or other object?	**Y**	**N**
	4.2 Are there any other cords, call bells, or tubing greater than 18 cm (7 inches) or any looped cords greater than 35 cm (14 inches) that are within reach of children?	**Y**	**N**
5.0 Doors	5.1 Do all doors close and latch properly?	**Y**	**N**
	5.2 Are any doors blocked or propped open?	**Y**	**N**
	5.3 Are staff able to open locked doors within 60 seconds for any room or area accessible to children (e.g. accessible master key, keyless entry)?	**Y**	**N**
	5.4 Are all stairs inaccessible to young children?	**Y**	**N**
	5.5 Are all doors leading to stairwells kept closed, and are they designed to be difficult for a toddler to open, but easily opened in case of fire?	**Y**	**N**
6.0 Storage	6.1 Are there any sharps, medicines or other hazards in drawers or cupboards accessible to children?	**Y**	**N**
7.0 Electrical	7.1 Are extension and electrical cords placed out of traffic areas and secured to prevent tripping?	**Y**	**N**
	7.2 Are unused electrical outlets (includes power bars and extension cords) in patient rooms and play areas covered, out of reach, tamperproof, or child-resistant (e.g. GFCI: ground-fault-circuit-interrupter)?	**Y**	**N**
8.0 Floors	8.1 Are all carpets securely anchored?	**Y**	**N**
	8.2 Are floors clean and dry, spills cleaned immediately, and signs posted for spills and when floors are washed or polished?	**Y**	**N**
	8.3 Is slip-resistant footwear worn by patients?	**Y**	**N**
9.0 Food	9.1 Are children less than four years of age given or have access to nuts or seeds, gum, candy, or other foods that are a choking hazard?	**Y**	**N**
	9.2 For children less than four years of age, are the following foods specially prepared to prevent choking? Grapes and wieners – slice lengthwise or chop; raw carrots, apples–grate, chop.	**Y**	**N**
10.0 Medication Room	10.1 Are medication rooms inaccessible to children and suicidal patients at all times?	**Y**	**N**
	10.2 Are all medications stored in their original containers and clearly labeled with the drug name and dose?	**Y**	**N**
	10.3 When not in the medication room are medications kept in a locked cabinet or container?	**Y**	**N**

11.0 Miscellaneous	11.1 Are all sharp objects kept out of reach of children?	Y	N
	11.2 Is there a policy regarding hot beverage safety on children's wards or in play areas (e.g. cup covers, areas where coffee/tea are restricted)?	Y	N
	11.3 Are there any baseboard heaters, radiators, exposed pipes, or hot appliances that are a burn hazard and are accessible to children (surface temperature hotter than 43°C/110°F)?	Y	N
	11.4 Is there any standing water which presents a drowning risk to children (e.g. buckets, pails, bathtubs, with 5 cm / 2 inches of water)?	Y	N
	11.5 Are spaces between railings on stairs and landings less than 10 cm wide?	Y	N
	11.6 Does any furniture, structure, or equipment pose an entrapment hazard, such as spaces a child can crawl into or fall through that are greater than 8 cm (3.5 inches) and less than 23 cm (9 inches)?	Y	N
	11.7 Is the kitchen area accessible to young children?	Y	N
	11.8 Is the mounting hardware of suspended or elevated television, VCR and video equipment tight and secure?	Y	N
	11.9 Are any toxic plants accessible to children?	Y	N
	11.10 Are makeshift pacifiers prohibited (i.e. using nipples or modified nipples as pacifiers)?	Y	N
	11.11 Are pacifier cords longer than 18 cm (7 inches) prohibited as well as pacifier and other cords tied around the neck?	Y	N
	11.12 Are plastic bags or plastic film accessible to children?	Y	N
12.0 Windows & Draperies	12.1 Can any window which is less than 1 m from the floor or otherwise accessible to a child be opened to more than 10 cm?	Y	N
	12.2 Are all looped window covering cords less than 18 cm (7 inches) in length or permanently secured to a tie-down device?	Y	N
	12.3 For horizontal blinds, are you able to grasp the inner cord and pull it out, forming a loop?	Y	N
	12.4. Are cribs, beds, or furniture located near windows that open, or window covering cords?	Y	N

B. SAFETY CHECKLISTS FOR CHILDREN'S EQUIPMENT

13.0 Beds	13.1 Electric beds are not used for patients less than 6 years of age.	Y	N
	13.2 Electric beds for patients older than 6 years of age do not have walk-away controls or have tamper-proof controls or are four-poster style beds.	Y	N
	13.3 Is the bed in its lowest position and the bed rails raised when the bed is occupied?	Y	N
	13.4 When the mattress is pushed to the head or foot of the bed is a gap created at the head or foot of the bed that exceeds 100 mm?	Y	N

	13.5 Is the distance between the end of the side rails and the headboard or footboard greater than 60 mm?	Y	N
	13.6 When the mattress is pushed to one side of the bed, is the horizontal gap measured from the mattress edge to the inside edge of the side rail greater than 100 mm?	Y	N
	13.7 Is the vertical spacing between two adjacent horizontal bars of the side rails greater than 100 mm?	Y	N
	13.8 Is the vertical spacing between the lowest bar above the mattress and the mattress itself greater than 60 mm?	Y	N
14.0 Cribs	14.1 All cribs were manufactured after September 1986, as indicated by the date of manufacture on the label.	Y	N
	14.2 All cribs are equipped with overhead restraints (i.e. security tops, bubble tops, canopies).	Y	N
	14.3 Infants and children younger than two years of age and less than 35 inches tall sleep in a crib.	Y	N
	14.4 Overhead restraints (security tops, bubble tops, canopies) are used for children who can pull to stand or are greater than 88cm (35 inches) tall or are able to climb out of a crib or playpen.	Y	N
	14.5 Is the crib located adjacent to curtain or drapery cords or other cords greater than 18 cm (7 inches), windows that open, or other hazards accessible to a child in the crib?	Y	N
	14.6 Are any suspended crib gyms or hanging toys present?	Y	N
	14.7 Are the crib slats (vertical bars) more than 6 cm (2 3/8 in.) apart?	Y	N
	14.8 Are any slats missing, loose, or cracked?	Y	N
	14.9 Does the mattress fit snugly, with less than 3 cm (1.2 in) width between the edge of the mattress and crib side on any side?	Y	N
	14.10 Is the mattress firm and not more than 15 cm (6 in.) thick?	Y	N
	14.11 Are catch-points for strangulation present such as exposed hardware or corner posts that extend more than 3 mm above the top end panel at the head or foot of the crib?	Y	N
	14.12 Are all crib sides locked in their highest position when the crib is occupied?	Y	N
	14.13 Can a child in the crib release the locked side rails or reach any adjustment mechanisms?	Y	N
	14.14 Are there choking/suffocation hazards in the crib such as soft bedding, pillows, toys or other loose items in the crib such as syringe caps?	Y	N
15.0 High Chairs	15.1 Is there a functioning restraint system with both waist and crotch restraints?	Y	N
	15.2 Can the waist strap be buckled without using the crotch restraint?	Y	N

	15.3 Is there a policy that the restraint system must always used?	Y	N
	15.4 Are there any hazards accessible to the occupant of the chair, including rough or sharp edges, splinters, small parts, strings/cords, hot surfaces, and hazardous products?	Y	N
	15.5 Are there any loose or missing parts?	Y	N
	15.6 Are the instructions easily accessible to staff?	Y	N
16.0 Playpens	16.1 Is there a label on the product which states the manufacturer, model name/number, date of manufacture, and a statement that the product complies with the Playpen Regulations (Canada)?	Y	N
	16.2 Is the playpen located adjacent to curtain or drapery cords or other cords greater than 18 cm (7 inches), windows that open, or other hazards accessible to a child in the playpen?	Y	N
	16.3 Is the pad/mattress provided by the manufacturer used, with no additional mattress or padding?	Y	N
	16.4 Are any suspended crib gyms or hanging toys present?	Y	N
	16.5 Is the side ever left in the down position on a drop-side mesh playpen or mesh crib?	Y	N
	16.6 Does the mesh have a small weave (less than 5 mm / 0.2 inch openings)?	Y	N
	16.7 Is the mesh torn, or does it have holes or loose threads?	Y	N
	16.8 Are there any hazards accessible to the occupant of the playpen, including rough or sharp edges, splinters, small parts, strings/cords, hot surfaces, and hazardous products?	Y	N
	16.9 Do the frame/rail covers have any tears or holes?	Y	N
	16.10 Are any vertical bars or slats more than 6 cm apart?	Y	N
	16.11 Are soft bedding, pillows, toys or other loose items in the playpen such as syringe caps that could present a choking/suffocation hazard?	Y	N
	16.12 Are the rail locking devices effective to prevent accidental folding?	Y	N
	16.13 Are the weight and height limits of the playpen visible or known by staff, and adhered to?	Y	N
	16.14 Are the instructions easily accessible to staff?	Y	N

C. PLAY AREA AND TOY SAFETY

Check windows, doors, floors, etc. of play areas using the room/public areas checklist			
17.0 Play Areas	17.1 Do all outdoor play areas comply with the Canadian Standards Association Playspaces and Equipment standard?	Y	N
	17.2 If there is an indoor play structure, is the area under and around it covered with adequate surfacing materials?	Y	N
18.0 Toy Safety	18.1 Are the batteries in toys accessible to children?	Y	N
	18.2 Can small pieces of toys be broken off (e.g. wheels, eyes, noses, etc.)?	Y	N
	18.3 Are latex balloons prohibited in the hospital?	Y	N
	18.4 Do toddlers less than 36 months of age have access to toys with small parts such as beads, puzzle pieces, and blocks less than 1.25 inches in diameter, or balls less than 1.75 inches in diameter?	Y	N
	18.5 Do any toys have sharp edges, points, splinters, or pinch points?	Y	N
	18.6 Are any toys constructed with thin or brittle plastic that might break into small pieces or leave jagged edges?	Y	N
	18.7 Are all art materials (crayons/paint sets) non-toxic?	Y	N
	18.8 Is there a process in place to check toys at least monthly for breakage and potential hazards?	Y	N
	18.9 Are there any toys accessible to toddlers with cords or strings longer than 18 cm (7 inches)?	Y	N
	18.10 Do any toys have looped fabric or cords that could get caught around a child's neck, with a perimeter greater than 35 cm (14 inches)?	Y	N
	18.11 Are toys that propel objects prohibited?	Y	N
	18.12 Do toy boxes have good ventilation and lightweight lids with safety hinges and no latch, or no lids?	Y	N
	18.13 Are sparking toys prohibited?	Y	N
	18.14 Are infant walkers prohibited (i.e. wheeled baby walkers)?	Y	N

D. DEVICES FOR TRANSPORTING INFANTS AND CHILDREN

19.0 Car Seats	19.1 Are the instructions for the car seat present (both official languages)?	**Y**	**N**
	19.2 Are all labels on the car seat present and legible? (Canadian Motor Vehicle Safety Standard national safety mark, date of manufacture, model #, etc.)	**Y**	**N**
	19.3 Are all pieces of the car seat present (e.g. cover, harness, locking clip, LATCH hardware, base, tether strap and hardware)?	**Y**	**N**
	19.4 Is the shell cracked or damaged?	**Y**	**N**
	19.5 Has the car seat been in a collision or recalled?	**Y**	**N**
	19.6 Is the car seat more than five years old?	**Y**	**N**
	19.7 Are infants left unattended in car seats (e.g. are car seats ever used for sleeping)?	**Y**	**N**
20.0 Infant Carriers	20.1 Is there a functioning restraint system with both waist and crotch restraints?	**Y**	**N**
	20.2 Can the waist strap be buckled without using the crotch restraint?	**Y**	**N**
	20.3 Is the restraint system always used?	**Y**	**N**
	20.4 Is the infant seat/carrier ever placed on an elevated or soft surface such as a bed or crib?	**Y**	**N**
	20.5 Are the instructions easily accessible to staff?	**Y**	**N**
	20.6 Are the weight and height limits of the seat visible or known by staff, and adhered to?	**Y**	**N**
21.0 Stretchers	21.1 Are the brakes functional?	**Y**	**N**
	21.2 Do both side rails lock in the raised position?	**Y**	**N**
	21.3 Do the stretcher rails create spaces that a child could crawl into or fall through that are greater than 8 cm (3.5 inches) and less than 23 cm (9 inches)?	**Y**	**N**
	21.4 Are both side rails raised when the stretcher is occupied?	**Y**	**N**
	21.5 Are infants or toddlers ever left unattended on a stretcher?	**Y**	**N**

22.0 Strollers/Carriages	22.1 Are the brakes functional?	**Y**	**N**
	22.2 Are there any hazards accessible to the occupant of the stroller/carriage, including rough or sharp edges, splinters, small parts, soft bedding, or strings/cords longer than 18 cm (7 inches)?	**Y**	**N**
	22.3 Does the stroller/carriage have a sturdy and functioning restraint system with both crotch and waist straps?	**Y**	**N**
	22.4 Can the waist strap be fastened without using the crotch strap?	**Y**	**N**
	22.5 Is the restraint system always used?	**Y**	**N**
	22.6 Are children ever left unattended in a stroller or carriage?	**Y**	**N**

Appendix 5.1

Rater participant package

(Research Participant Information and Consent Form, Audit Form, Rater Instructions, Rater Survey)

RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

You are being asked to participate in a research study. Please take your time to review this consent form and discuss any questions you may have with the study staff.

Title of Study: Is the Hospital a Safe Place for Children? Development and Validation of a Safety Audit for Pediatric Health Care Facilities

Principal Investigator: Dr. Lynne Warda, NA335 – 700 McDermot Avenue, Winnipeg, MB, R3E 0T2, 204-787-1873. Dr. Warda is a doctoral student in the Department of Community Health Sciences, Faculty of Medicine, at the University of Manitoba. This research study is the topic of Dr. Warda's doctoral thesis. Dr. Warda's supervisor is Dr. Michael Moffatt, Professor, Department of Community Health Sciences and Executive Director, Research and Quality, Winnipeg Regional Health Authority, Suite 1800 - 155 Carlton Street, Winnipeg MB R3C 4Y1, 204-926-7835.

Purpose of Study

The purpose of this study is to develop and validate a hospital safety audit instrument which can be used to determine if a pediatric health care facility meets current child safety standards.

Study procedures

The hospital safety audit instrument is a 135-item "checklist" which aims to identify potential injury hazards for children in pediatric health care settings, including pediatric patients and visitors. You are being asked to participate in the inter-rater agreement testing of this instrument; this type of study evaluates how different raters' results are similar or different, using the same instrument (checklist). A sample of inpatient and outpatient pediatric health care facilities will be audited using the instrument in a "test" situation, in order to determine how often raters agree on the presence and absence of hazards using the instrument, and whether their final assessments are similar. You are being asked to be a rater at one test site. The test sites include one private pediatric office, a hospital-based pediatric clinic, a children's emergency department, and a pediatric inpatient ward. All sites are in Winnipeg. Each site will be divided into five discrete test areas, consisting of defined public areas (waiting rooms, hallways, bathrooms), and four patient rooms. Each test area will be audited by five raters, using the hospital safety audit instrument. These assessments will be "blind" to each other, in that the raters will not observe or discuss the other raters' findings. Following completion of the testing each rater will be briefly interviewed to explore reasons for blank and "not applicable" responses, to obtain comments regarding instrument structure and clarity, and to identify items that may be missing from the instrument (injuries or hazards). Your participation in the study will require approximately two hours.

Benefits

There may or may not be direct benefit to you from participating in this study. We hope that the information you review in the instrument and its handbook regarding pediatric hospital injuries and hazards may be useful to you in your work.

Payment for participation

You will receive no payment related to taking part in this study.

Confidentiality

Your name and other identifying information will only be used for tracking purposes during the study. The University of Manitoba Health Research Ethics Board may review research-related records for quality assurance purposes.

Voluntary Participation/Withdrawal From the Study

Your decision to take part in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time.

Questions

You are free to ask any questions that you may have about your rights as a research participant. If any questions come up during or after your participation, contact the Project Coordinator: Ms. Gemma Briggs at 204-789-3528.

For questions about your rights as a research participant, you may contact The University of Manitoba Health Research Ethics Board at (204) 789-3389.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Statement of Consent

I have read this consent form. I have had the opportunity to discuss this research study with Dr. Lynne Warda or the study staff. I have had my questions answered by them in language I understand. The risks and benefits have been explained to me. I understand that I will be given a copy of this consent form after signing it. I understand that my participation in this research study is voluntary and that I may choose to withdraw at any time. I freely agree to participate in this research study.

I understand that information regarding my personal identity will not be collected. I authorize the inspection of my research records by The University of Manitoba Health Research Ethics Board.

By signing this consent form, I have not waived any of the legal rights that I have as a participant in a research study.

Participant signature_____Date _____

Participant printed name: _____

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given their consent

Printed Name: _____Date _____

Signature: _____Role in the study: _____

Rater Instructions

- You have been provided with the hospital safety checklist and its accompanying handbook, which explains each item and provides additional background information. Please consult the handbook to clarify checklist items and instructions.
- Today you will be rating 5 areas: 4 patient rooms (exam rooms or hospital rooms) and one public area (halls/waiting areas/bathrooms).
- The rooms are labeled as Exam Rooms 1-4 with a sign on the door. The checklists are labeled with corresponding numbers.
- Your public areas are: _____
- You have been provided with the following equipment: clipboard, checklist for each room/area, pen, thermometer, tape measure, small parts tester, doorknob tag
- This testing is being done by several raters at the same time, who are blinded to each other's scores. Therefore, while examining each room, please keep the door closed. Do not discuss your findings with the other raters.
- While examining each room, hang the doorknob tag inside the door (on your side of the door). When you have completed examining your room, hang the doorknob tag on the outside of the door. This will let us know you are ready to switch rooms.
- Look carefully at everything in the room, from floor to ceiling. Anything in the room is considered relevant to the checklist.
- Provide a response for every item (Yes, no, not applicable). For each item, note the number of each type of hazard (in the # column) and briefly describe the nature of the hazard in the next (description) column. For example, you may find several sharp objects or several hazardous cords – count them and briefly describe them.
- For policy and staff safety behaviour/practice questions that arise in the checklist, please mark the item 'not applicable'.

Audit Form for Raters (sample)

How to Use this Form

The audit is divided into four sets of checklists: (A) is for patient rooms and public areas; (B) is for children's equipment found in patient rooms, public areas, and storage areas (beds, cribs, high chairs, playpens); (C) is for play areas and toys; and (D) is for devices used for transporting infants and children (car seats, infant carriers, stretchers, strollers/carriages).

Check all rooms and areas accessible to pediatric patients and visitors. As you inspect each patient room or patient care area, circle the response (Y = Yes, N = No) or place a checkmark (X) in the "not applicable" column. The shaded areas identify when a hazard is present. Record the room number or location where hazards are present and note the specific hazard. You may refer to the handbook for further instructions, rationale, and supporting evidence for each audit item.

Note: This checklist is not meant to substitute for compliance with established regulations (e.g. Fire codes, Building codes, Occupational Health and Safety standards, product safety standards). Medical devices are excluded from the audit.

A. SAFETY CHECKLIST FOR PATIENT ROOMS AND PUBLIC AREAS

				#	Description	N/A
1.0 Bathroom	1.1 Does the bathtub/shower have a slip-resistant floor?	Y	N			
	1.2 Are grab bars installed in the bathtub/shower?	Y	N			
	1.3 Is the maximum hot water temperature less than 49°C (120°F)?	Y	N			
	1.4 Can the bathroom door be easily and quickly unlocked from both sides?	Y	N			
	1.5 Are bathroom doors kept closed to prevent toddler access?	Y	N			
	1.6 Is there a functional call bell within patient/caregiver reach?	Y	N			
2.0 Cleaning	2.1 Are cleaning carts or supplies left unattended?	Y	N			
	2.2 Are any hazardous substances or equipment accessible to children (e.g. on cleaning or maintenance carts, under sinks, on counters, in cupboards)?	Y	N			
	2.3 Are cleaning products clearly marked and stored in their original containers, with all hazardous products in child-resistant containers?	Y	N			

Rater Survey

1. Your professional background/discipline:	
2. Your department:	
3. Number of years of injury prevention training/experience/employment: 0 1 2 3 4 5 >5	
4. Rank your injury prevention/safety/child-proofing expertise: (none) 1 2 3 4 5 (expert)	
5. Please list missing items in the checklist (add more on reverse of this page if necessary)	
-	
-	
-	
-	
6. If you left any items blank, what were the reason(s) for not responding?	
Did not understand the item	Item numbers:
Did not know the answer	Item numbers:
Not enough time to complete the item	Item numbers:
Item did not apply	Item numbers:
Other _____	Item numbers:
Other _____	Item numbers:
7. If you responded not applicable to any items, what were the reasons?	
The equipment or hazard was not present in the room	Item numbers:
The item did not seem relevant	Item numbers:
I did not understand the item	Item numbers:
Did not know the answer	Item numbers:
Other _____	Item numbers:
Other _____	Item numbers:

Appendix 5.2

Number and Types of Hazards Identified

Table A. Number and types of hazards identified (all sites, expert rater)

Table B. Total number of hazards identified (all sites, expert rater)

Table C. Number and types of hazards identified (all sites, all raters)

Table A. Number and types of hazards identified (all sites, expert rater)

Note: this table includes a maximum of one hazard response per item per room. The subsequent table indicates the total number of hazards, with the potential of multiple hazards per item per room.

Item Group	Item	Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
1.0 Bathroom	1.1	0	0	0	0	**0**	non-slip tub surface
	1.2	0	0	0	0	**0**	
	1.3	5	5	4	4	**18**	hot water > 49°C
	1.4	0	0	0	0	**0**	
	1.5	0	0	1	0	**1**	bathroom doors left open
	1.6	1	0	2	0	**3**	no call bell in bathroom
		6	**5**	**7**	**4**	**22**	
2.0 Cleaning	2.1	1	1	0	0	**2**	soaps, detergents, disinfectants
	2.2	1	1	0	0	**2**	soaps, disinfectants
	2.3	0	0	0	0	**0**	
		2	**2**	**0**	**0**	**4**	
3.0 Clothing	3.1	0	0	0	0	**0**	
	3.2	1	4	3	0	**8**	hospital gowns with ties
	3.3	0	0	0	0	**0**	
	3.4	0	0	0	0	**0**	
		1	**4**	**0**	**0**	**5**	
4.0 Cords	4.1	2	5	3	3	**13**	TV, telephone, electrical cords
	4.2	5	4	3	4	**16**	bedside cords: call bells, oxygen, equipment
		7	**9**	**6**	**7**	**29**	
5.0 Doors	5.1	0	0	0	0	**0**	
	5.2	1	0	0	0	**1**	doors propped open
	5.3	0	4	0	0	**4**	no safety lock (door requires specific key)
	5.4	0	0	0	0	**0**	
	5.5	0	0	0	0	**0**	
		0	**5**	**0**	**0**	**5**	
6.0 Storage	6.1	1	2	2	4	**9**	small parts, sharps, latex gloves, medications, alcohol-based fixative, isopropyl alcohol

	Item	Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
6.0 Storage (cont'd)		**1**	**2**	**2**	**4**	**9**	
7.0 Electrical	7.1	1	1	1		**3**	unsecured electrical cords
	7.2	5	5	4	2	**16**	uncovered electrical outlets
		6	**6**	**5**	**2**	**19**	
8.0 Floors	8.1	0	0	0	0	**0**	
	8.2	0	0	0	0	**0**	
	8.3	0	0	0	0	**0**	
		0	**0**	**0**	**0**	**0**	
9.0 Food	9.1	0	0	0	0	**0**	
	9.2	0	0	0	0	**0**	
		0	**0**	**0**	**0**	**0**	
10.0 Medication	10.1	0	0	0	0	**0**	
	10.2	0	0	0	0	**0**	
	10.3	0	0	0	4	**4**	medications in drawers (samples)
		0	**0**	**0**	**4**	**4**	
11.0 Miscellaneous	11.1	1	3	1	1	**6**	glass slides, broken toys, pencils, sharps
	11.2	0	0	0	0	**0**	
	11.3	0	0	0	0	**0**	
	11.4	3	0	2	0	**5**	standing water (toilets)
	11.5	0	0	0	0	**0**	
	11.6	4	0	5	1	**10**	furniture with entrapment gaps (cots, chairs)
	11.7	0	0	0	0	**0**	
	11.8	1	0	1	1	**3**	unsecured elevated TV/video equipment
	11.9	0	0	0	0	**0**	
	11.10	0	0	0	0	**0**	
	11.11	0	0	0	0	**0**	
	11.12	5	5	5	5	**20**	plastic bags, latex gloves (bedside, drawers)
		14	**8**	**13**	**8**	**43**	
12.0 Windows and draperies	12.1	0	0	0	0	**0**	
	12.2	5	3	2	5	**15**	drapery cords too long
	12.3	0	3	1	5	**9**	horizontal blind inner loop hazard
	12.4	5	3	1	3	**12**	furniture adjacent to drapery cords

	Item	Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
12.0 Windows and draperies (cont'd)		**10**	**9**	**4**	**13**	**36**	
13.0 Beds	13.1	0	0	0	0	**0**	
	13.2	0	0	0	0	**0**	
	13.3	0	0	0	0	**0**	
	13.4	3	0	0	0	**3**	gap at head/foot of bed
	13.5	4	0	0	0	**4**	gap between rails and head/foot of bed
	13.6	0	0	0	0	**0**	
	13.7	0	0	0	0	**0**	
	13.8	0	0	0	0	**0**	
		7	**0**	**0**	**0**	**7**	
14.0 Cribs	14.1	0	0	0	0	**0**	
	14.2	0	0	0	0	**0**	
	14.3	0	0	0	0	**0**	
	14.4	0	0	0	0	**0**	
	14.5	1	0	0	0	**1**	crib placed adjacent to bedside cords
	14.6	0	0	0	0	**0**	
	14.7	0	0	0	0	**0**	
	14.8	0	0	0	0	**0**	
	14.9	0	0	0	0	**0**	
	14.10	0	0	0	0	**0**	
	14.11	1	0	0	0	**1**	
	14.12	0	0	0	0	**0**	
	14.13	0	0	0	0	**0**	
	14.14	0	0	0	0	**0**	
		2	**0**	**0**	**0**	**2**	
15.0 High chairs	15.1	0	0	0	0	**0**	
	15.2	1	0	0	0	**1**	waist strap can be fastened without the crotch strap
	15.3	0	0	0	0	**0**	
	15.4	0	0	0	0	**0**	
	15.5	0	0	0	0	**0**	
	15.6	0	0	0	0	**0**	
		1	**0**	**0**	**0**	**1**	
16.0 Playpens	16.1	0	0	0	0	**0**	
	16.2	0	0	0	0	**0**	
	16.3	0	0	0	0	**0**	
	16.4	0	0	0	0	**0**	
	16.5	0	0	0	0	**0**	

	Item	Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
16.0 Playpens (cont'd)	16.6	0	0	0	0	**0**	
	16.7	0	0	0	0	**0**	
	16.8	0	0	0	0	**0**	
	16.9	0	0	0	0	**0**	
	16.10	0	0	0	0	**0**	
	16.11	1	0	0	0	**1**	soft bedding in playpen
	16.12	0	0	0	0	**0**	
	16.13	0	0	0	0	**0**	
	16.14	0	0	0	0	**0**	
		1	**0**	**0**	**0**	**1**	
17.0 Play areas	17.1	0	0	0	0	**0**	
	17.2	0	0	0	0	**0**	
		0	**0**	**0**	**0**	**0**	
18.0 Toys	18.1	0	0	0	0	**0**	
	18.2	0	0	4	1	**5**	toys with small parts
	18.3	0	0	0	0	**0**	
	18.4	0	1	3	1	**5**	toys with small parts
	18.5	0	1	2	1	**4**	sharp edges, pinch points (broken toys)
	18.6	0	1	3	1	**5**	plastic toys with thin/brittle plastic
	18.7	0	0	0	0	**0**	
	18.8	0	0	0	0	**0**	
	18.9	0	0	1	1	**2**	toys with cords/strings
	18.10	0	0	0	0	**0**	
	18.11	0	0	0	0	**0**	
	18.12	0	0	0	0	**0**	
	18.13	0	0	0	0	**0**	
	18.14	0	0	0	0	**0**	
		4	**3**	**9**	**5**	**21**	
19.0 Car seats	19.1	1	0	0	0	**1**	no instructions
	19.2	0	0	0	0	**0**	
	19.3	1	0	0	0	**1**	missing parts
	19.4	0	0	0	0	**0**	
	19.5	0	0	0	0	**0**	
	19.6	0	0	0	0	**0**	
	19.7	0	0	0	0	**0**	
		2	**0**	**0**	**0**	**2**	
20.0 Infant Carriers	20.1	0	0	0	0	**0**	
	20.2	0	0	0	0	**0**	
	20.3	0	0	0	0	**0**	
	20.4	0	0	0	0	**0**	

	Item	Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
	20.5	0	0	0	0	**0**	
	20.6	0	0	0	0	**0**	
		0	**0**	**0**	**0**	**0**	
21.0 Stretchers	21.1	1	0	0	0	**1**	brakes nonfunctional
	21.2	1	0	0	0	**1**	side rails do not lock
	21.3	0	0	0	0	**0**	
	21.4	0	0	0	0	**0**	
	21.5	0	0	0	0	**0**	
		2	**0**	**0**	**0**	**2**	
22.0 Strollers and carriages	22.1	1	0	0	0	**1**	nonfunctional brakes
	22.2	2	0	0	0	**2**	sharp edges, long straps accessible to occupant
	22.3	2	0	0	0	**2**	no restraint system (carriages)
	22.4	2	0	0	0	**2**	waist strap can be fastened without the crotch strap
	22.5	0	0	0	0	**0**	
	22.6	0	0	0	0	**0**	
		7	**0**	**0**	**0**	**7**	
TOTAL		**70**	**52**	**54**	**47**	**223**	

Table B. Total number of hazards identified (all sites, expert rater)

Note: This table indicates the total number of hazards, with the potential of multiple hazards per item per room. The previous table includes a maximum of one hazard response per item per room.

Item Group	Item	Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
1.0 Bathroom	1.1	0	0	0	0	0	non-slip tub surface
	1.2	0	0	0	0	0	
	1.3	5	5	4	4	18	hot water > 49°C
	1.4	0	0	0	0	0	
	1.5	0	0	1	0	1	bathroom doors left open
	1.6	1	0	2	0	3	no call bell in bathroom
		6	**5**	**7**	**4**	**22**	
2.0 Cleaning	2.1	1	1	0	0	2	soaps, detergents, disinfectants
	2.2	1	1	0	0	2	soaps, disinfectants
	2.3	0	0	0	0	0	
		2	**2**	**0**	**0**	4	
3.0 Clothing	3.1	0	0	0	0	0	
	3.2	1	4	0	0	5	hospital gowns with ties
	3.3	0	0	0	0	0	
	3.4	0	0	0	0	0	
		1	**4**	**0**	**0**	**5**	
4.0 Cords	4.1	17	11	8	6	42	TV, telephone, electrical cords
	4.2	30	8	9	5	52	bedside cords: call bells, oxygen, equipment
		47	**19**	**17**	**11**	**94**	
5.0 Doors	5.1	0	0	0	0	0	
	5.2	0	4	0	0	4	doors propped open
	5.3	0	4	0	0	4	no safety lock (door requires specific key)
	5.4	0	0	0	0	0	
	5.5	0	0	0	0	0	
		0	**8**	**0**	**0**	**8**	
6.0 Storage	6.1	2	2	6	8	18	small parts, sharps, latex gloves, medications, alcohol-based fixative, isopropyl alcohol

	Item	Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
6.0 Storage (cont'd)		**2**	**2**	**6**	**8**	**18**	
7.0 Electrical	7.1	2	2	1		5	unsecured electrical cords
	7.2	17	10	16	2	45	uncovered electrical outlets
		19	**12**	**17**	**2**	**50**	
8.0 Floors	8.1	0	0	0	0	0	
	8.2	0	0	0	0	0	
	8.3	0	0	0	0	0	
		0	**0**	**0**	**0**	0	
9.0 Food	9.1	0	0	0	0	0	
	9.2	0	0	0	0	0	
		0	**0**	**0**	**0**	0	
10.0 Medication	10.1	0	0	0	0	0	
	10.2	0	0	0	0	0	
	10.3	0	0	0	4	4	medications in drawers (samples)
		0	**0**	**0**	**4**	**4**	
11.0 Miscellaneous	11.1	4	3	1	1	9	glass slides, broken toys, pencils, sharps
	11.2	0	0	0	0	0	
	11.3	0	0	0	0	0	
	11.4	4	0	1	0	5	standing water (toilets)
	11.5	0	0	0	0	0	
	11.6	11	0	8	1	20	furniture with entrapment gaps (cots, chairs)
	11.7	0	0	0	0	0	
	11.8	1	0	2	1	4	unsecured elevated TV/video equipment
	11.9	0	0	0	0	0	
	11.10	0	0	0	0	0	
	11.11	0	0	0	0	0	
	11.12	20	16	20	9	65	plastic bags, latex gloves (bedside, drawers)
		40	**19**	**32**	**12**	**103**	
12.0 Windows and draperies	12.1	0	0	0	0	0	
	12.2	16	5	4	8	33	drapery cords too long
	12.3	0	3	1	8	12	horizontal blind inner loop hazard
	12.4	13	13	1	5	32	furniture adjacent to drapery cords

	Item	Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
12.0 Windows and draperies (cont'd)		**29**	**21**	**6**	**21**	**77**	
13.0 Beds	13.1	0	0	0	0	0	
	13.2	0	0	0	0	0	
	13.3	0	0	0	0	0	
	13.4	3	0	0	0	3	gap at head/foot of bed
	13.5	4	0	0	0	4	gap between rails and head/foot of bed
	13.6	0	0	0	0	0	
	13.7	0	0	0	0	0	
	13.8	0	0	0	0	0	
		7	**0**	**0**	**0**	**7**	
14.0 Cribs	14.1	0	0	0	0	0	
	14.2	0	0	0	0	0	
	14.3	0	0	0	0	0	
	14.4	0	0	0	0	0	
	14.5	1	0	0	0	1	crib placed adjacent to bedside cords
	14.6	0	0	0	0	0	
	14.7	0	0	0	0	0	
	14.8	0	0	0	0	0	
	14.9	0	0	0	0	0	
	14.10	0	0	0	0	0	
	14.11	1	0	0	0	1	
	14.12	0	0	0	0	0	
	14.13	0	0	0	0	0	
	14.14	0	0	0	0	0	
		2	**0**	**0**	**0**	**2**	
15.0 High chairs	15.1	0	0	0	0	0	
	15.2	1	0	0	0	1	waist strap can be fastened without the crotch strap
	15.3	0	0	0	0	0	
	15.4	0	0	0	0	0	
	15.5	0	0	0	0	0	
	15.6	0	0	0	0	0	
		1	**0**	**0**	**0**	**1**	
16.0 Playpens	16.1	0	0	0	0	0	
	16.2	0	0	0	0	0	
	16.3	0	0	0	0	0	
	16.4	0	0	0	0	0	
	16.5	0	0	0	0	0	

	Item	Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
16.0 Playpens (cont'd)	16.6	0	0	0	0	0	
	16.7	0	0	0	0	0	
	16.8	0	0	0	0	0	
	16.9	0	0	0	0	0	
	16.10	0	0	0	0	0	
	16.11	1	0	0	0	1	soft bedding in playpen
	16.12	0	0	0	0	0	
	16.13	0	0	0	0	0	
	16.14	0	0	0	0	0	
		1	**0**	**0**	**0**	**1**	
17.0 Play areas	17.1	0	0	0	0	0	
	17.2	0	0	0	0	0	
		0	**0**	**0**	**0**	**0**	
18.0 Toys	18.1	0	0	0	0	0	
	18.2	5	0	0	3	8	toys with small parts
	18.3	0	0	0	0	0	
	18.4	0	2	13	5	20	toys with small parts
	18.5	0	1	2	1	4	sharp edges, pinch points (broken toys)
	18.6	0	2	3	1	6	plastic toys with thin/brittle plastic
	18.7	0	0	0	0	0	
	18.8	0	0	0	0	0	
	18.9	0	0	1	1	2	toys with cords/strings
	18.10	0	0	0	0	0	
	18.11	0	0	0	0	0	
	18.12	0	0	0	0	0	
	18.13	0	0	0	0	0	
	18.14	0	0	0	0	0	
		5	**5**	**19**	**11**	**40**	
19.0 Car seats	19.1	1	0	0	0	1	no instructions
	19.2	0	0	0	0	0	
	19.3	2	0	0	0	2	missing parts
	19.4	0	0	0	0	0	
	19.5	0	0	0	0	0	
	19.6	0	0	0	0	0	
	19.7	0	0	0	0	0	
		3	**0**	**0**	**0**	**3**	
20.0 Infant Carriers	20.1	0	0	0	0	0	
	20.2	0	0	0	0	0	
	20.3	0	0	0	0	0	
	20.4	0	0	0	0	0	

	Item	Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
	20.5	0	0	0	0	0	
	20.6	0	0	0	0	0	
		0	**0**	**0**	**0**	**0**	
21.0 Stretchers	21.1	1	0	0	0	1	brakes nonfunctional
	21.2	1	0	0	0	1	side rails do not lock
	21.3	0	0	0	0	0	
	21.4	0	0	0	0	0	
	21.5	0	0	0	0	0	
		2	**0**	**0**	**0**	**2**	
22.0 Strollers and carriages	22.1	1	0	0	0	1	nonfunctional brakes
	22.2	5	0	0	0	5	sharp edges, long straps accessible to occupant
	22.3	2	0	0	0	2	no restraint system (carriages)
	22.4	2	0	0	0	2	waist strap can be fastened without the crotch strap
	22.5	0	0	0	0	0	
	22.6	0	0	0	0	0	
		10	**0**	**0**	**0**	**10**	
TOTAL		**177**	**97**	**104**	**73**	**451**	

Table C. Number and types of hazards identified (all sites, all raters)

Note: this table includes a maximum of one hazard response per item per room.

Item Group	*Number of raters*	Site 1 *5*	Site 2 *4*	Site 3 *5*	Site 4 *5*	All sites *19*	Typical hazards cited
1.0 Bathroom	1.1	9	0	0	0	9	non-slip tub surface
	1.2	0	0	0	0	0	
	1.3	21	18	19	19	77	hot water > 49°C
	1.4	3	0	0	0	3	no safety lock on bathroom door
	1.5	2	1	4	0	7	bathroom doors left open
	1.6	5	3	10	0	18	no call bell in bathroom
		40	**22**	**33**	**19**	**114**	
2.0 Cleaning	2.1	10	1	12	5	28	soaps, detergents, disinfectants
	2.2	9	6	10	8	33	soaps, disinfectants
	2.3	8	1	8	4	21	no child-resistant closures
		27	**8**	**30**	**17**	**82**	
3.0 Clothing	3.1	0	0	2	1	3	
	3.2	1	12	6	0	19	hospital gowns with ties
	3.3	0	0	2	**1**	3	
	3.4	0	0	0	1	1	
		1	**12**	**10**	**3**	**26**	
4.0 Cords	4.1	11	12	22	14	59	TV, telephone, electrical cords
	4.2	25	13	17	17	72	bedside cords: call bells, oxygen, equipment
		36	**25**	**39**	**31**	**131**	
5.0 Doors	5.1	3	0	3	3	9	broken cupboard doors, non-latching room doors
	5.2	2	0	4	0	6	doors propped open
	5.3	3	4	2	0	9	no safety lock (door requires specific key)
	5.4	0	0	5	0	5	stairs accessible
	5.5	0	0	1	0	1	
		8	**4**	**15**	**3**	**30**	
6.0 Storage	6.1	3	6	10	19	38	small parts, sharps, latex gloves, medications, alcohol-based fixative, isopropyl alcohol
		3	**6**	**10**	**19**	**38**	
7.0 Electrical	7.1	6	8	15	5	34	unsecured electrical cords
	7.2	22	15	16	10	64	uncovered electrical outlets
		28	**23**	**32**	**15**	**98**	

		Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
8.0 Floors	8.1	0	0	0	0	0	
	8.2	0	0	0	3	3	
	8.3	0	0	0	0	0	
		0	**0**	**0**	**3**	**3**	
9.0 Food	9.1	0	0	0	1	1	
	9.2	0	0	0	0	0	
		0	**0**	**0**	**1**	**1**	
10.0 Medication	10.1	1	0	1	13	15	
	10.2	0	1	0	0	1	
	10.3	1	1	0	11	13	medications in drawers (samples)
		2	**2**	**1**	**24**	**29**	
11.0 Miscellaneous	11.1	1	6	9	12	28	glass slides, broken toys, pencils, sharps
	11.2	0	0	0	0	0	
	11.3	0	0	13	8	21	exposed radiators (temperature unknown)
	11.4	3	0	3	0	6	standing water (toilets)
	11.5	6	0	3	2	11	
	11.6	7	7	25	12	51	furniture with entrapment gaps (cots, chairs)
	11.7	0	0	1	5	6	
	11.8	4	0	3	1	8	unsecured elevated TV/video equipment
	11.9	0	0	1	0	1	
	11.10	0	0	0	0	0	
	11.11	0	0	0	0	0	
	11.12	21	8	23	13	65	plastic bags, latex gloves (bedside, drawers)
		42	**21**	**81**	**53**	**197**	
12.0 Windows and draperies	12.1	0	0	1	0	1	
	12.2	12	12	7	22	53	drapery cords too long
	12.3	3	6	3	16	28	horizontal blind inner loop hazard
	12.4	5	10	4	11	30	furniture adjacent to drapery cords
		20	**28**	**15**	**49**	**112**	
13.0 Beds	13.1	0	0	0	0	0	
	13.2	0	0	0	0	0	
	13.3	0	0	0	0	0	
	13.4	6	0	0	0	6	gap at head/foot of bed
	13.5	4	0	0	0	4	gap between rails and head/foot of bed
	13.6	1	0	0	0	1	
	13.7	0	0	0	0	0	
	13.8	0	0	0	0	0	
		11	**0**	**0**	**0**	**11**	
14.0 Cribs	14.1	0	0	0	0	0	

		Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
	14.2	0	0	0	0	0	
	14.3	0	0	0	0	0	
	14.4	0	0	0	0	0	
	14.5	4	0	0	0	4	crib placed adjacent to bedside cords
	14.6	0	0	0	0	0	
	14.7	0	0	0	0	0	
	14.8	0	0	0	0	0	
	14.9	1	0	0	0	1	
	14.10	0	0	0	0	0	
	14.11	1	0	0	0	1	
	14.12	0	0	0	0	0	
	14.13	0	0	0	0	0	
	14.14	1	0	0	0	1	
		7	**0**	**0**	**0**	**7**	
15.0 High chairs	15.1	0	0	0	0	0	
	15.2	4	0	0	0	4	waist strap can be fastened without the crotch strap
	15.3	0	0	0	0	0	
	15.4	0	0	0	0	0	
	15.5	0	0	0	0	0	
	15.6	0	0	0	0	0	
		4	**0**	**0**	**0**	**4**	
16.0 Playpens	16.1	0	0	0	0	0	
	16.2	0	0	0	0	0	
	16.3	3	0	0	0	3	additional padding in playpen
	16.4	0	0	0	0	0	
	16.5	0	0	0	0	0	
	16.6	2	0	0	0	2	
	16.7	0	0	0	0	0	
	16.8	0	0	0	0	0	
	16.9	0	0	0	0	0	
	16.10	0	0	0	0	0	
	16.11	5	0	0	0	5	soft bedding in playpen
	16.12	0	0	0	0	0	
	16.13	0	0	0	0	0	
	16.14	0	0	0	0	0	
		10	**0**	**0**	**0**	**10**	
17.0 Play areas	17.1	0	0	0		0	
	17.2	0	0	0		0	
		0	**0**	**0**	**0**	**0**	
18.0 Toys	18.1	0	0	0	0	0	
	18.2	0	1	12	5	17	toys with small parts
	18.3	0	0	0	0	0	
	18.4	0	2	12	4	18	toys with small parts
	18.5	0	1	13	3	17	sharp edges, pinch points (broken toys)

		Site 1	Site 2	Site 3	Site 4	All sites	Typical hazards cited
	18.6	0	1	8	3	11	plastic toys with thin/brittle plastic
	18.7	0	0	2	0	2	
	18.8	0	0	0	0	0	
	18.9	0	0	4	2	6	toys with cords/strings
	18.10	0	0	3	1	4	toys with cords/strings
	18.11	0	0	0	1	1	
	18.12	0	0	1	0	1	
	18.13	0	0	0	0	0	
	18.14	0	0	0	0	0	
		0	**5**	**53**	**19**	**77**	
19.0 Car seats	19.1	3	0	0	0	3	no instructions
	19.2	0	0	0	0	0	
	19.3	3	0	0	0	3	missing parts
	19.4	0	0	0	0	0	
	19.5	0	0	0	0	0	
	19.6	0	0	0	0	0	
	19.7	0	0	0	0	0	
		6	**0**	**0**	**0**	**6**	
20.0 Infant Carriers	20.1	0	0	0	0	0	
	20.2	0	0	0	0	0	
	20.3	0	0	0	0	0	
	20.4	0	0	0	0	0	
	20.5	0	0	0	0	0	
	20.6	0	0	0	0	0	
		0	**0**	**0**	**0**	**0**	
21.0 Stretchers	21.1	1	0	1	0	2	brakes nonfunctional
	21.2	2	0	0	0	2	side rails do not lock
	21.3	0	0	2	0	2	entrapment gaps in stretcher rails
	21.4	0	0	0	0	0	
	21.5	0	0	0	0	0	
		3	**0**	**3**	**0**	**6**	
22.0 Strollers and carriages	22.1	2	0	0	0	2	nonfunctional brakes
	22.2	3	0	0	0	3	sharp edges, long straps accessible to occupant
	22.3	10	0	0	0	10	no restraint system (carriages)
	22.4	10	0	0	0	10	waist strap can be fastened without the crotch strap
	22.5	0	0	0	0	0	
	22.6	0	0	0	0	0	
		25	**0**	**0**	**0**	**25**	
TOTAL		**273**	**156**	**323**	**256**	**1008**	

Appendix 5.3

Inter-rater Agreement by Item Number

Appendix 5.3 Inter-rater agreement by item number

	Overall agreement	Specific agreement for positive ratings	Specific agreement for negative ratings	Kappa	Kappa SE	Kappa t	p
1.1	*	*	*	*	*	*	*
1.2	100.0%	100.0%	*	*	*	*	*
1.3	90.5%	40.0%	94.8%	0.36	0.11	3.14	0.002
1.4	84.2%	91.4%	0.0%	*	*	*	
1.5	92.3%	94.7%	85.7%	0.81	0.27	2.96	0.003
1.6	100.0%	100.0%	100.0%	1.00	0.22	4.47	< 0.001
2.1	48.9%	14.3%	63.6%	-0.07	0.10	-0.71	0.48
2.2	55.6%	25.0%	68.4%	0.06	0.10	0.62	0.54
2.3	36.8%	53.8%	0.0%	*	*	*	*
3.1	*	*	*	*	*	*	*
3.2	68.8%	81.5%	0.0%	*	*	*	*
3.3	81.8%	0.0%	90.0%	*	*	*	*
3.4	*	*	*	*	*	*	*
4.1	69.2%	58.3%	75.6%	0.34	0.12	2.78	0.01
4.2	84.7%	90.4%	62.1%	0.53	0.12	4.50	< 0.001
5.1	82.3%	90.3%	0.0%	*	*	*	*
5.2	88.1%	22.2%	93.6%	0.16	0.13	1.23	0.22
5.3	71.4%	83.3%	0.0%	*	*	*	*
5.4	50.0%	66.7%	0.0%	*	*	*	*
5.5	75.0%	85.7%	0.0%	*	*	*	*
6.1	80.0%	78.1%	81.6%	0.60	0.12	5.04	*
7.1	54.9%	64.6%	37.8%	0.15	0.10	1.52	0.13
7.2	84.6%	61.5%	90.4%	0.54	0.11	4.88	< 0.001
8.1	*	*	*	*	*	*	*
8.2	94.4%	97.1%	0.0%	*	*	*	*
9.1	*	*	*	*	*	*	*

9.2	*	*	*	*	*	*	*
10.1	*	*	*	*	*	*	*
10.2	100.0%	100.0%	*	*	*	*	*
10.3	100.0%	*	100.0%	*	*	*	*
11.1	68.8%	75.0%	58.3%	0.33	0.13	2.67	0.008
11.2	*	*	*	*	*	*	*
11.3	65.6%	0.0%	79.2%	*	*	*	*
11.4	75.8%	11.8%	86.0%	0.09	0.05	1.71	0.087
11.5	*	*	*	*	*	*	*
11.6	50.0%	55.7%	42.6%	-0.02	0.12	-0.14	0.890
11.7	83.3%	0.0%	90.9%	*	*	*	*
11.8	75.8%	84.0%	50.0%	0.37	0.15	2.40	0.016
11.9	98.1%	0.0%	99.0%	*	*	*	*
11.10	*	*	*	*	*	*	*
11.11	*	*	*	*	*	*	*
11.12	67.2%	80.4%	0.0%	*	*	*	*
12.1	96.2%	0.0%	98.1%	*	*	*	*
12.2	70.4%	11.1%	82.2%	0.05	0.08	0.64	0.52
12.3	48.4%	65.2%	0.0%	*	*	*	*
12.4	*	*	*	*	*	*	*
13.1	*	*	*	*	*	*	*
13.2	*	*	*	*	*	*	*
13.3	*	*	*	*	*	*	*
13.4	50.0%	55.6%	42.9%	0.11	0.19	0.60	0.55
13.5	0.0%	0.0%	0.0%	*	*	*	*
13.6	93.8%	0.0%	96.8%	*	*	*	*
13.7	100.0%	*	100.0%	*	*	*	*
13.8	100.0%	*	100.0%	*	*	*	*
14.1	100.0%	100.0%	*	*	*	*	*

14.2	100.0%	100.0%	*	*	*	*	*
14.3	*	*	*	*	*	*	*
14.4	*	*	*	*	*	*	*
14.5	75.0%	75.0%	75.0%	0.50	0.35	1.41	0.157
14.6	100.0%	*	100.0%	*	*	*	*
14.7	100.0%	*	100.0%	*	*	*	*
14.8	100.0%	*	100.0%	*	*	*	*
14.9	87.5%	*	0.0%	*	*	*	*
14.10	100.0%	100.0%	*	*	*	*	*
14.11	50.0%	0.0%	66.7%	*	*	*	*
14.12	*	*	*	*	*	*	*
14.13	100.0%	*	100.0%	*	*	*	*
14.14	85.7%	0.0%	92.3%	*	*	*	*
15.1	100.0%	100.0%	*	*	*	*	*
15.2	100.0%	100.0%	*	*	*	*	*
15.3	*	*	*	*	*	*	*
15.4	100.0%	*	100.0%	*	*	*	*
15.5	100.0%	*	100.0%	*	*	*	*
15.6	100.0%	100.0%	*	*	*	*	*
16.1	100.0%	100.0%	*	*	*	*	
16.2	100.0%	*	100.0%	*	*	*	*
16.3	62.5%	76.9%	0.0%	*	*	*	*
16.4	100.0%	*	100.0%	*	*	*	*
16.5	*	*	*	*	*	*	*
16.6	75.0%	85.7%	0.0%	*	*	*	*
16.7	100.0%	*	100.0%	*	*	*	*
16.8	100.0%	*	100.0%	*	*	*	*
16.9	100.0%	*	100.0%	*	*	*	*
16.10	*	*	*	*	*	*	*

16.11	50.0%	50.0%	50.0%	*	*	*	*
16.12	100.0%	100.0%	*	*	*	*	*
16.13	*	*	*	*	*	*	*
16.14	100.0%	100.0%	*	*	*	*	*
17.1	*	*	*	*	*	*	*
17.2	*	*	*	*	*	*	*
18.1	100.0%	*	100.0%	*	*	*	*
18.2	76.0%	83.3%	57.1%	0.42	0.18	2.29	0.022
18.3	*	*	*	*	*	*	*
18.4	86.4%	90.9%	72.7%	0.64	0.21	3.01	< 0.001
18.5	46.2%	50.0%	41.7%	-0.08	0.19	-0.39	0.69
18.6	45.8%	48.0%	43.5%	0.10	0.13	0.78	0.44
18.7	70.0%	82.4%	0.0%	*	*	*	*
18.8	*	*	*	*	*	*	*
18.9	70.0%	25.0%	81.3%	0.06	0.22	0.28	0.78
18.10	66.7%	28.6%	78.3%	0.07	0.25	0.29	0.77
18.11	*	*	*	*	*	*	*
18.12	100.0%	100.0%	*	*	*	*	*
18.13	*	*	*	*	*	*	*
18.14	*	*	*	*	*	*	*
19.1	66.7%	0.0%	80.0%	*	*	*	*
19.2	100.0%	100.0%	*	*	*	*	*
19.3	66.7%	0.0%	80.0%	*	*	*	*
19.4	100.0%	*	100.0%	*	*	*	*
19.5	*	*	*	*	*	*	*
19.6	100.0%	*	100.0%	*	*	*	*
19.7	*	*	*	*	*	*	*
20.1	*	*	*	*	*	*	*
20.2	*	*	*	*	*	*	*

20.3	*	*	*	*	*	*	*
20.4	*	*	*	*	*	*	*
20.5	*	*	*	*	*	*	*
20.6	*	*	*	*	*	*	*
21.1	63.6%	77.8%	0.0%	-0.16	0.25	-0.64	0.52
21.2	88.9%	94.1%	0.0%	0.62	0.29	2.11	0.035
21.3	81.8%	0.0%	90.0%	*	*	*	*
21.4	*	*	*	*	*	*	*
21.5	*	*	*	*	*	*	*
22.1	81.3%	88.9%	40.0%	0.33	0.19	1.79	0.07
22.2	56.3%	22.2%	69.6%	0.13	0.12	1.03	0.30
22.3	100.0%	100.0%	100.0%	1.00	0.25	4.00	< 0.001
22.4	100.0%	100.0%	*	*	*	*	*
22.5	*	*	*	*	*	*	*
22.6	*	*	*	*	*	*	*

* cell sizes less than 5