CANADIAN PAEDIATRIC
ADVERSE EVENTS STUDY

cpsi icsp
Canadian Patient Safety Institute
Institut canadien pour la sécurité des patients

Canadian Patient Safety Institute
Suite 1414 , 10235 - 101 Street
Edmonton, AB, Canada
T5J 3G1
Toll Free: 1-866-421-6933
Phone: 780-409-8090
Fax: 780-409-8098

Institut canadien pour la sécurité des patients
Bureau 410, 1150 chemin Cyrville
Ottawa, (Ontario) K1J 7S9
Téléphone: 613-730-7322
Télécopieur: 613-730-7323

Suggested Citation: ?

This publication is available as a free download from: **www.patientsafetyinstitute.ca**

The Canadian Patient Safety Institute would like to acknowledge funding support from Health Canada. The views expressed here do not necessarily represent the views of Health Canada.

ISBN: 978-1-926541-54-9 (print)

INVESTIGATORS

ANNE G. MATLOW

MSc MD FRCPC. Department of Paediatrics, SickKids, Toronto; Department of Paediatrics, University of Toronto; University of Toronto Centre for Patient Safety

VIRGINIA FLINTOFT

BN, MSc, Department of Health Policy, Management and Evaluation, University of Toronto, Toronto, Ontario;

G. ROSS BAKER

PhD, Department of Health Policy, Management and Evaluation, University of Toronto, Toronto, Ontario; University of Toronto Centre for Patient Safety

DOUGLAS COCHRANE

MD FRCSC, Department of Surgery, University of British Columbia and BC Patient Safety & Quality Council, Vancouver, BC

CATHERINE M. G. CRONIN

MD, MBA, FRCPC, FRCPI, FAAP, Department of Paediatrics and Child Health, University of Manitoba, Winnipeg Manitoba (currently Interior Health Authority, Kelowna, BC)

MAITREYA COFFEY

MD FAAP FRCPC, Department of Paediatrics, SickKids, Toronto; Department of Paediatrics, University of Toronto; University of Toronto Centre for Patient Safety,

EYAL COHEN

MD FAAP FRCPC, Department of Paediatrics, SickKids, Toronto; Department of Paediatrics, University of Toronto; University of Toronto Centre for Patient Safety,

RITA DAMIGNANI

PT, Department of Quality and Risk Management, SickKids, Toronto

ROBERT DUBÉ

MD FRCPC Department of Paediatrics, CHU Ste-Justine, University of Montreal, Montreal, QC

ROGER GALBRAITH

MD FRCPC, Department of Paediatrics, Faculty of Medicine, University of Calgary, Calgary, AB

DAWN HARTFIELD

MD FRCPC, Department of Pediatrics, Faculty of Medicine and Dentistry, University of Alberta, Edmonton, AB

LEIGH ANNE NEWHOOK

MD FRCPC, Discipline of Pediatrics, Memorial University, and Janeway Child Healthcare centre, Eastern Health, St.John's, NL

CHERI NIJSSEN-JORDAN

MD MBA FRCPC, Department of Paediatrics, Faculty of Medicine, University of Calgary, Calgary, AB

TABLE OF CONTENTS

ACKNOWLEDGEMENT

Acknowledgements: The following people were responsible for physician, nurse, health record professional and hospital recruitment; assisting with obtaining local ethics approval and overall coordination of their provincial study component. We extend our sincere gratitude to them for their leadership and particularly their partnership in this research study: Cheryl Crummel and Dr. Leigh Anne Newhook (Newfoundland and Labrador); Darlene Boliver (Nova Scotia); Marie-Suzanne Lavallée, Christiane Beauchamp and Dr. Robert Dubé (Québec); Rita Damignani, Dr. Maitreya Coffey and Dr. Ann Bayliss (Ontario); Dr. C. Gerarda Cronin, (Manitoba); Jennifer Conlin, Dr. Roger Galbraith and Dr. Cheri Nijssen-Jordan (Alberta-Calgary); Rena Pandya and Dr. Dawn Hartfield (Alberta- Edmonton); Judy Komori and Dr. Douglas Cochrane (British Columbia).

We extend our sincere thanks to the following individuals for their dedication to the study and assistance in collecting the data upon which this study is based: Stage 1 reviewers: Cheryl Crummel and Sharon Penney (Newfoundland and Labrador); Stacy Burgess and Julie MacLean (Nova Scotia); Christiane Beauchamp and Lucie Lafond (Québec); Susan Ferri, Wilhelmine Giffening and Janette Reimer (Ontario); Dianne Burnand, Linda Lutz and Susan McAleenan (Alberta-Calgary); Melba Athaide, Linda Manasterski and Linda Willis-Hagan (Alberta-Edmonton); and Sandra Christiansen and Anne-Marie White (British Columbia). Stage 2 reviewers: Drs. Lynette Bowes and Leigh-Anne Newhook (Newfoundland and Labrador); Drs. Dorothy Barnard and Leigh-Anne Newhook* (Nova Scotia); Drs. Marilyn Dusseault and Bernard Girodias (Québec); Drs. Nirit Bernhard and Jane Healey (Ontario); Drs. Dorothy Barnhard, Darcy Beer and Adriana Condello (Manitoba); Drs. Roger Galbraith and Brian Kelly (Alberta-Calgary); Drs. Dawn Hartfield and Leigh Wincott (Alberta-Edmonton); Drs. Barrie MacLean and David Riddell (British Columbia). We gratefully acknowledge the support and assistance provided by the 22 hospital corporations participating in the study and their health record departments for providing access to the hospital charts reviewed for the study. We thank the members of the safety review committee: Dr. Micheline Ste-Marie (Montreal Children's Hospital) and Dr. Ed Etchells (Sunnybrook Health Sciences Centre, Toronto). We also thank Dr. Alex Kiss (Clinical Epidemiology Unit, Sunnybrook Hospital, Toronto, Ontario) for his assistance with statistical modeling.

MAIN MESSAGES

1 IN ORDER TO IMPROVE THE SAFETY OF CHILDREN HOSPITALIZED IN ACUTE CARE, A FULL UNDERSTANDING OF THE INCIDENCE AND TYPES OF HARM CAUSED BY HEALTHCARE IS REQUIRED. NUMEROUS NATIONAL STUDIES HAVE ADDRESSED THIS PROBLEM IN ADULT POPULATIONS, BUT PAEDIATRIC STUDIES HAVE BEEN LACKING.

2 THE CANADIAN PAEDIATRIC ADVERSE EVENTS STUDY (CPAES) IS THE FIRST NATIONAL STUDY OF THE EPIDEMIOLOGY OF AES IN HOSPITALIZED CHILDREN. IN ADDITION TO DETERMINING THE INCIDENCE OF AES IN CHILDREN HOSPITALIZED IN CANADA, THE STUDY WAS DESIGNED TO DETERMINE AND COMPARE THE TYPES AND PREVENTABILITY OF AES IN ACADEMIC PAEDIATRIC CENTRES (APC) AND LARGE COMMUNITY HOSPITALS (CH). THE CPSI-FUNDED STUDY: INCIDENCE AND TYPES OF ADVERSE EVENTS IN CHILDREN HOSPITALIZED IN LARGE COMMUNITY HOSPITALS IS NESTED WITHIN THE LARGER CPAES.

3 THE CPAES INVOLVED 22 HOSPITALS (7 APCS AND 15 CHS) IN 7 PROVINCES. OF 3669 HOSPITALIZED CHILDREN STUDIED, 9.2% EXPERIENCED AES.

4 THE TYPE OF HOSPITAL SETTING IMPACTED THE LIKELIHOOD OF DEVELOPING AN AE. CHILDREN IN ACADEMIC CENTRES HAD SIGNIFICANTLY MORE AES (11.2%) THAN THOSE IN COMMUNITY HOSPITALS (3.3%),(ADJUSTED ODDS RATIO (95% CI) 2.98 (1.65-5.39), P=0.0003).

5 THE INCIDENCE OF PREVENTABLE ADVERSE EVENTS WAS NOT SIGNIFICANTLY DIFFERENT BETWEEN HOSPITAL TYPES BUT NON-PREVENTABLE ADVERSE EVENTS WERE MORE COMMON IN ACADEMIC HOSPITALS (ADJUSTED ODDS RATIO (95% CI) 4.39(2.08-9.27), P=0.0001).

MAIN MESSAGES

6 PATIENT AGE AND REASON FOR HOSPITALIZATION ALSO IMPACTED THE LIKELIHOOD OF HAVING AN AE. NEONATES NEEDING INTENSIVE CARE (ICU) FOR AT LEAST A DAY WERE 10 TIMES AS LIKELY TO HAVE AN AE AS THOSE NOT NEEDING ICU CARE. SURGICAL PATIENTS OVER 28 DAYS AGE WERE TWICE AS LIKELY TO HAVE AN AE AS THEIR MEDICAL COUNTERPARTS.

7 ATTENTION TO SURGICAL SAFETY IS KEY TO REDUCING HARM IN CHILDREN HOSPITALIZED IN ACUTE CARE, PARTICULARLY IN APCS. IN CHS A FOCUS ON EMERGENCY ROOM CARE FOR TODDLERS AND MATERNAL/ OBSTETRICAL CARE IS REQUIRED. DIAGNOSTIC ADVERSE EVENTS, UNDER-RECOGNIZED AS A SAFETY CONCERN IN PAEDIATRICS, ARE COMMON AND USUALLY PREVENTABLE; CHILDREN OVER AGE 1 WERE MOST VULNERABLE.

EXECUTIVE SUMMARY

Over 9% of children admitted to acute care hospitals in Canada experience harm caused by healthcare management, leading to death, disability, prolonged hospital stay, or readmission. These data are new and unique, and represent the results of the recently completed Canadian Paediatric Adverse Events Study (CPAES), the first national study of its kind conducted to examine the problem of paediatric patient safety. As per the results of the 2004 Baker-Norton Canadian Adverse Events Study, the CPAES data tell us that it is not just adults who are vulnerable to healthcare associated harm, but children hospitalized in the acute healthcare system in Canada are vulnerable as well. As children cannot advocate for their own safe care, paediatric practitioners and decision makers alike must be cognizant of the various hazards in paediatric healthcare in order to focus attention and channel resources toward the necessary system improvements.

The primary objective of the landmark CPAES was to characterize the incidence and types of AEs experienced by children hospitalized in acute care. In Canada, 68% of paediatric admissions are to community hospitals (CHs); while there are fewer paediatric intensive care unit admissions, complex procedures (e.g. solid organ transplant, cardiac surgery), and vulnerable patient populations (e.g. transplant, hematology/ oncology, hemodialysis) in CHs, the fact that the majority of children in the country are hospitalized there underscores the need to study patients hospitalized in CHs as well as in academic paediatric centres (APCs) in order to make robust conclusions on the scope of the problem. The CPSI-funded study: Incidence and types of adverse events in children hospitalized in large community hospitals captured AE data on children hospitalized in 15 CHs in 7 provinces, and contributed important data to the larger CPAES, in which an additional 7 APCs were studied. Studying both types of hospitals also enabled a comparison of AEs experienced in APCs and CHs.

Close to four thousand patient records from these 22 hospitals were reviewed to generate the results of the CPAES, and the results attest to the complexities of paediatric care, in particular the complex interactions between hospital setting and patient characteristics, such as age and reason for admission. The overall 9.2% incidence of AEs was not evenly distributed across APCs and CHs: children in APCs were over three times as likely to experience an AE as those in CHs (11.2 vs 3.3%). Furthermore, when patient characteristics were taken into account, neonates who needed intensive care for at least a day were found to be 10 times as likely to have an AE as those not needing intensive care. Children beyond the neonatal age (> 28 days) with a surgical diagnosis were found to be twice as likely to experience an AE as patients with a medical diagnosis. While children under one year of age experienced the majority of AEs due to medical procedures and clinical care, children over age one experienced more due to diagnostic error and medications.

The services most responsible at the time of the AE and the types of AEs experienced differed in APCs and CHs. Surgery and the intensive care units were the most responsible services significantly more commonly in APCs, compared to the emergency department and maternal/ obstetrics services which were more commonly responsible in CHS. Surgical AEs, which were most common AE overall, occurred significantly more commonly in APCs, and along with AEs due to medical procedures and clinical care, accounted for just over 70% of AEs. In contrast, AEs due to clinical management predominated in CHs; along with AEs due to diagnostic error and surgery they accounted for over 75% of CH AEs. AEs occurring in APCs were considered less likely to have been prevented than those occurring in CHs.

The CPAES has shown us that AEs are common in infants and children hospitalized in Canada. Based on the results of the CPAES, the single most effective strategy for improving the overall safety of acute care in pediatrics in Canada would be to focus on improving surgical safety, particularly in APCs. The safety of children in intensive care units in APCs can also be improved. CHs are uniquely positioned to reduce diagnostic AEs and improve outcomes in emergency and maternal/obstetrical care. Let the CPAES be the call to action that has been needed to improve paediatric patient safety, and the catalyst to apportioning the resources and attention required to ensure safe healthcare delivery to all children hospitalized in Canada.

CONTEXT

The landmark Canadian Adverse Events Study, known as the Baker-Norton report, indicated that 7.5% of adults admitted to hospital experience adverse events, and served as a call to action to improve the safety of healthcare delivery to adults in Canada (1). While the vulnerability of children to iatrogenic harm is increasingly being recognized, there has been no similar national study describing the magnitude of the problem in the paediatric population. The American Academy of Pediatrics has advocated the need for increased awareness of pediatric patient safety issues and actions to reduce preventable harm (2), however a better understanding of the scope and burden of pediatric harm is essential in order to design and effect these actions.

Recent epidemiological studies of adverse events (AEs) have enhanced our understanding of pediatric patient safety in acute care hospitals, however their scope has been limited (3-8). Trigger tool methodology is considered a sensitive and efficient way to detect adverse events, however a comprehensive TT for the detection of AEs in pediatrics was lacking. The Canadian Pediatric Trigger Tool (CPTT) was recently validated for this purpose (9). Recognizing the need for a large scale study to assess harm in pediatric patients, we used the CPTT in the multicentre Canadian Paediatric Adverse Event Study (CPAES) to: 1) determine the rate, type, severity, and preventability of AEs occurring in children hospitalized in Canada, and 2) to compare the epidemiology of AEs in children hospitalized in academic pediatric centres (APCs) with those of children in community hospitals (CHs). The CPSI funded study: Incidence and types of adverse events in children hospitalized in large community hospitals, was nested within the larger CPAES.

IMPLICATIONS

Paediatric patient safety at a national level has received little attention around the globe. Consequently, except for decision makers and senior administrators in the paediatric arenas, hazards in paediatric care and the need for directed resources and action have not been at the forefront of the minds of general healthcare policy and decision makers. Demonstration of the burden of harm experienced by children in the acute care setting, and in particular demonstrating that the incidence may be higher than in adults should be a call to action to protect our children, among the most vulnerable members of our society as well as its future.

METHODS

Design

Cross-sectional study by retrospective chart review based on the protocol originally developed for the Harvard Medical Practice Study and adapted by other national studies (1, 10-17).

Study Sample

Seven geographic nodes were established (British Columbia, Northern Alberta, Southern Alberta, Manitoba, Ontario, Quebec, and the Atlantic provinces of Nova Scotia and Newfoundland), each consisting of one APC and two CHs (Box 1). In the Atlantic node, two smaller APCs participated due to the relatively small population size in each province. An APC was defined as a pediatric hospital with a full-time core postgraduate training program in pediatrics and pediatric surgery, and a neonatal intensive care unit (NICU). To participate in the study, APCs contributed to the cost of reviewer training and local chart audit. Of the 10 sites invited to participate two declined and were not replaced.

CHs were eligible for inclusion if they had at least 1000 pediatric admissions in fiscal year 2008 including newborns, an NICU or special care nursery, and no full-time core pediatric or pediatric surgical residency training. For logistical reasons the sample of CHs was limited, where possible, to facilities within 250 kilometres of the node APC. One CH invited to participate could not obtain ethics approval and was replaced with the next CH selected for that geographic node. Participating hospitals gave permission to access their patient charts. Two hundred and forty charts per APC (120 from each Atlantic APC) and 140 per CH yielded a total sample of 3640 hospital admissions targeted for review. This sample has the power to detect real difference in AE rates between types of hospital assuming an incidence of 15% $\alpha= 0.05$ and $\alpha=0.90$. Oversampling was carried out anticipating unavailability of 10% of charts.

Using a standardized algorithm, the site or regional Decision Support Departments or Health/ Medical Records Analysts selected a stratified random sample of hospital admissions (patient charts) for each participating hospital for fiscal year 2008. The reference population sampling frame from which the study sample was selected included all admissions for patients under 19 years old who had a minimum hospital stay of 24 hours, or who died within the first 24 hours of admission. Children with a most responsible diagnosis related to obstetrics or psychiatry were excluded, as were all patients, except newborns, transferred from or to another acute care hospital during the index hospitalization. All patients were assigned a unique study number.

Patients were selected randomly from four predetermined age groups (AGs) [AG1 (neonates):0-28 days; AG2: 29-365 days; AG3: >1-5 years; AG4: >5- 18 years]. For AG1 the chart sample was selected to reflect the proportion of neonates in Canada admitted to NICU for ¬>24 hours (13%). Charts were sampled from Medicine and Surgery for the remaining three AGs and AE results weighted to reflect the national 2:1 ratio for pediatric admissions to Medicine and Surgery in 2008.

Definitions

An AE was defined as an unintended injury or complication resulting in: i) disability at the time of discharge, ii) death, iii) prolonged hospital stay or v) subsequent hospitalization, and caused by health care management (9-17). To be included the AE had to occur within 3 months prior to or during the index admission and be detected during the index hospitalization or within 3 months following discharge. "Health care management" included the decisions and actions of individual hospital staff, as well as the broader systems and care processes, and included acts of commission and omission. To qualify as an AE, the event had >50% likelihood of being caused by health care management as judged by the physician reviewer. Similarly, AEs were considered preventable if they were judged to have had >50% likelihood of being preventable. Assessments of causation, preventability and whether the AEs were related to acts of commission, omission or both, were made by physician reviewers upon structured chart review.

The incidence of AEs was defined as the weighted percentage of patients experiencing an AE. The 35 items in the CPTT used to screen patients' charts for physician review are listed in Table 1.

Data Collection

A 2-stage chart review was conducted. In stage one at each site a nurse or health record technologist (HRT) (medical records technician in Quebec) reviewed all charts using the CPTT for evidence of triggers, and collected information related to medical care and patient complexity. In stage 2, physicians reviewed the triggered charts for the presence of AEs, classified each according to cause, determined their preventability and identified the most responsible provider service. Using professional judgment, they estimated the number of additional hospital days directly attributable to the AE.

Prior to chart review in the field, all reviewers participated in a two-day training session where a standard set of anonymized pediatric hospital charts were reviewed using a customized training manual. Reviewers were assessed for proportion agreement on each of 19 cases. For the nurse/HRT, the proportion agreement for trigger positive charts was 87% (95% CI 83% , 90%) and for the physician reviewers the proportion of agreement for AEs was 66% (95% CI 57%,76%).

Data were entered directly into a secure web-based database at the University of Toronto Department of Health Policy, Management and Evaluation and stored for analysis.

Analysis:

The analysis of Stage1 data included the number and percent of charts positive for each of the 35 triggers (Appendix 2). Stage 2 data were analyzed to determine the incidence and preventability of events including the distribution by location (academic v community), age-group (Table 1), degree of harm (Table 2), responsible service (Table 4) and procedures or events to which events were related (Table 5), Unique patients comprise the denominator unless otherwise stated. To determine the Canadian incidence of adverse events for this population sample, national weighted point estimates and 95th percent confidence intervals (95% CIs) for AEs were calculated using a 2-stage stratified sampling technique (Table 1),; results were weighted for the total number of charts per hospital and then for hospitals per type in each province, based on data from the Canadian Institute for Health Information. The chi-square test for trend was used to compare the incidence of adverse events among hospital types.

A logistic regression model was created and adjusted by pre-admission medical status variables in order to calculate the risk of experiencing an adverse event across age-groups and hospital types. Similar logistic regression models were run to determine the likelihood of adverse event preventability

All analyses were carried out using SAS Version 9.1 (SAS Institute, Cary, NC, USA).

Ethics:

Ethics approval was obtained from the University of British Columbia, University of Alberta, University of Calgary, University of Manitoba, University of Toronto, Dalhousie University, and Memorial University. Local hospital ethics approval was obtained where required.

RESULTS

Of the 3669 hospital admissions reviewed 1692 (46.1%) were from APCs and 1977 (53.9%) from CHs (Fig. 1). In stage 1 reviews 1083 patient charts (29.5%) had at least one CPTT trigger (Table 2), significantly more from APCs than from CHs (38.8% vs 21.6%, respectively, $p < 0.0001$). Overall, 237 (9.2% weighted, 95% CI 5.1-13.3) patients experienced AEs, the incidence in APCs (11.2%) being significantly higher than that in CHs(3.3%). AEs in academic hospitals were less likely to have been prevented.

The preadmission medical status variables: being on high alert medications, technological device dependency and complex chronic condition were independently associated with having an AE. The incidence of preventable AEs was not significantly different between hospital types, but adverse events in academic hospitals were less likely to be preventable. (adjusted odds ratio (95% CI) 4.39(2.08-9.27), p=0.0001) (Table 3). Significantly more events in academic centres resulted in temporary harm requiring prolonged stay (p=0.03) as well as recovery from event-related one-month impairment (p=0.01).

Neonates in neonatal ICUs had significantly higher AE rates than those not in neonatal ICUs. In children > 28 days the weighted proportion of preventable events was significantly higher among surgical than medical patients (p=0.005.) The service identified as most responsible at the time each of the 287 AEs occurred was Surgery (34.1%), Medicine (29.3%) and evenly distributed across Emergency, ICU, Maternal/ Obstetrics and Other for the remaining 36.6% of patients (Table 4). In the APCs AEs were attributed most often to Surgery and ICU (p <0.0001 and p=0.002, respectively) and in the CHs to Emergency and Maternal/Obstetrics (p=0.02 and p <0.0001, respectively) (Table 4). AE rates on medical services were similar in APCs and CHs.

Analysis of the distribution of types of AEs by age group and by hospital type (Table 5) revealed that in both APCs and CHs, neonates experienced the majority of AEs related to "other clinical management". In APCs, AG2 children experienced the majority of surgery-related AEs (38%). Children up to 1 year experienced 77% of AEs related to medical procedures (p=0.02), while those over 1 year experienced 80% of the drug-related AEs (p=0.0005). In CHs the majority of surgery-, diagnostic-, and drug-related AEs identified occurred in children over 5 years old (64%, 47% and 43%, respectively).

DISCUSSION

Based on our study, 12.4 % of children admitted to APCs and 3.6% of children admitted to CHs in Canada in 2008 experienced an AE. Among the 9.2% of hospitalized children who experienced an AE, surgical AEs predominated, particularly in APCs, while diagnostic AEs and those due to 'other clinical management' predominated in CHs. In CHs, AEs occurring in the emergency department were significantly more common in children from 1 to 5 years of age (AG3) than in children of other ages; Medically-related AEs are significantly more common in children in their first year of life (AG1 and AG2). Drug-related AEs were significantly more common in AG3 particularly in APCs. Older children (AG4) experienced the majority of surgical-, diagnostic-, and drug-related AEs identified in CHs.

Similar to previous pediatric studies (2, 3, 18, 19) we found that, after weighting for distribution and adjusting for medical complexity, higher rates of AEs occurred in academic hospitals or health centers. This finding persisted despite adjustment for medical complexity. It is likely that several factors contributed to the differences in AE rates between APCs and CHs. First, the risk adjustment model may not have accounted fully for the true differences in patient acuity. Second, the complexity of care in APC means that patients may receive care from several different providers, which may increase the risk of AEs related to miscommunication and coordination of care. Third, the scope, depth and focus of documentation in patients' charts may differ between APCs and CHs. Finally, APCs are challenged to educate medical novices through to a level of expertise while ensuring safe, quality care. This challenge is heightened by the lack of standards and methods to robustly gage a trainee's readiness to assume a higher degree of responsibility in a safe manner(20).

Certain populations emerged as particularly vulnerable to AEs. Twenty percent of neonates admitted to NICUs for at least 24 hours experienced AEs, which was ten times higher than those without NICU admissions, attesting to the high acuity of illness in NICUs. Surgical patients older than 28 days were almost twice as likely to experience AEs as medical patients of the same age, and their AEs were more likely to be preventable. The predominance of surgically-related AEs in our study differs from previous reports in children (2,4), perhaps because in Canada most surgery in children under 5 years is performed in APCs. An earlier study in one Canadian pediatric center found that 48% of children undergoing surgery experienced complications, which included a number of AEs (21).

Further insights into the types and distribution of AEs in children have emerged from our study. AEs were most commonly related to acts of commission than omission, more so in APCs. Although the overall incidence of AEs was less in CHs, those attributable to Emergency Department visits were more common in CHs than in APCs. Diagnostic AEs were also significantly more common in CHs. Diagnostic errors are a recognized hazard in emergency care, and may be related in part to the lack of familiarity of adult emergency room physicians with pediatrics and the lack of standardized emergency pediatric protocols (1). Our overall rate of ADEs (32/ 3669, 0.87%) was less than the 11.1% reported by Takata et al using an ADE-specific trigger tool, and closer to that reported in other studies of pediatric ADEs (5,22,23). Relative to other types of AEs however, ADEs were less than half as frequent as surgical AEs, and in APCs and CHs respectively AEs due to medical procedures and diagnostic error were more common than ADEs. This underscores the fact that a multipronged approach is required to improve pediatric patient safety, of which safe medication delivery is but one component.

Our study has several limitations. Inherent in TT methodology is the documentation bias of retrospective chart review, and the subjective assessment of preventability (8). The threshold of harm we used to define an AE was similar to that used in previous national AE studies (24) and higher than that used in other pediatric studies (2,3,5,6). Therefore, our results reflect the more serious but underestimate the total harm in hospitalized pediatric patients. Similarly, excluding patients (except neonates) who were transferred from another acute care hospital may have further underestimated the total harm by excluding more complex and challenging cases requiring tertiary care in an APC. Given the absence of a single accepted definition of medical complexity, the criteria we chose were those that could be delineated readily on chart review. Our findings may not be generalizable to all children hospitalized in acute care in Canada since budgetary constraints precluded studying all provinces and territories, and restricted us mainly to larger hospitals close to urban areas. Our sampling strategy precludes understanding of the proportional distribution of AEs by age across Canada however, it does permit direct comparison between age groups. Finally, designation of preventability and omission/commission as well as attribution of number of hospital days prolonged by the AE were based on the physician reviewers' professional judgment and are thus subject to personal bias.

Despite these limitations, it is evident from our study that a significant number of children hospitalized in acute care hospitals in Canada experience iatrogenic harm. While ours is the first national study to focus on AEs in children, we suspect that these findings are not unique to the Canadian setting. Risk factors for patient safety problems in pediatrics are universal and include children's physical characteristics, developmental variability and legal status as a minor, and as a result, many solutions will be unique to this population (25). Children constitute a minority of the population (Statistics Canada 2006 Census: < 15 years = 5,579,835 individuals, > 15 years= 31,074,400) (26), and the overall attention paid to patient safety issues in children has been proportionally scant (27). The child who experiences an AE may be affected physically, functionally, emotionally and psychologically in the short and long term, and may miss school. Pediatric AEs reach beyond the child, affecting the parents (guilt, depression, frustration, missed work, tension in spousal relationships etc), the health care system (cost, occupied beds) and the community.

CONCLUSION AND RECOMMENDATIONS

AEs occur frequently in infants and children hospitalized in Canada and there is an urgent need to make paediatric healthcare safer. More children in APCs experience AEs than those in CHs; these AEs are less likely to be preventable. In order to improve the safety of paediatric health care delivery in Canada, early efforts should focus on surgical and intensive care safety, and resources should be channeled into research investigating into diagnostic AEs and improving outcomes in emergency and maternal/obstetrical care in CHs. The baseline data from the CPAES will allow researchers and hospital safety administrators to use this information to aid surveillance of AEs and ultimately work towards the goal of improving the safety of children hospitalized on Canada.

TABLES

Table 1

35-Trigger Canadian Paediatric Trigger Tool applied to 3669 charts in the stage 1 review and the proportionof charts positive for each trigger and the positive predictive value (ppv) of an adverse event for each trigger

CARE MODULE		Freq (n)	% of Charts	PPV	LCI-UCI*
C 01	Transfusion/ use of blood products	171	4.7%	0.380	0.364 - 0.396
C 02	Any code or arrest (successfully resuscitated)	19	0.5%	0.474	0.457 - 0.490
C 03	Unplanned admission (including readmission) as a result of any health care management within the 3 months prior to OR after discharge from the index hospitalization.	377	10.3%	0.292	0.277 - 0.307
C 04	Infection of any kind	94	2.6%	0.511	0.494 - 0.527
C 05	In hospital stroke	6	0.2%	0.500	0.484 - 0.516
C 06	Transfer to higher level of care	80	2.2%	0.250	0.236 - 0.264
C 07	Catheter infiltration/burn	27	0.7%	0.259	0.245 0.274
C 08	Complication related to Central Venous Catheter (CVC)	26	0.7%	0.500	0.484 - 0.516
C 09	Necrotizing Enterocolitis (NEC)	5	0.1%	0.800	0.781 - 0.818
C 10	Cranial imaging in infants < 3 mos.		0.0%		
C 11	Extreme temperature - <35 degrees Centigrade (35oC) OR > 40 degrees Centigrade (40oC)	116	3.2%	0.172	0.160 - 0.185
C 12	Intubation / reintubation / Accidental extubation	43	1.2%	0.442	0.426 - 0.458
C 13	Emergent C-section delivery (Neonate Only)	55	1.5%	0.218	0.192 - 0.246
C 14	Dissatisfaction with care documented in the medical record and/or evidence of complaint lodged (including documented complaint, conflict between patient/family and staff, discharged against medical advice / Documentation or correspondence indicating litigation, either contemplated or actual	35	1.0%	0.229	0.215 - 0.243
C 15	Unexpected Death	9	0.2%	0.556	0.539 - 0.572
ICU MODULE					
I 1	Readmission to ICU	8	0.2%	0.500	0.484 - 0.516
I 2	In Unit Procedure	6	0.2%	0.500	0.484 - 0.516
I 3	Failed ETT (failed intubation)	10	0.3%	0.300	0.285 - 0.315
LABORATORY MODULE					
L 01	Abrupt drop >25% Hgb or Hct	77	2.1%	0.351	0.335 - 0.366
L 02	Platelet count < 50,000/mm3 (50 X 10 e9L)	29	0.8%	0.448	0.432 - 0.465
L 03	PTT>100 secs or INR>6	10	0.3%	0.600	0.584 - 0.616
L 04	D-dimer (positive by local lab normal)	32	0.9%	0.344	0.328 - 0.359
L 05	Sodium: 120 mmol/L > Na > 150 mmol/L	25	0.7%	0.280	0.266 - 0.295
L 06	Potassium: 3.0 mmol/L > K+ > 6.0 mmol/L	91	2.5%	0.341	0.325 - 0.356
L 07	Rising BUN/Creat > 2 x baseline	13	0.4%	0.462	0.445 - 0.478
L 08	Hypoxia: O2 Sat < 75%	50	1.4%	0.400	0.384 - 0.416
L 09	Positive blood culture	18	0.5%	0.611	0.595 - 0.627
L 10	Gentamicin/Tobramycin: (except CF patients) Trough <2 mg/L or Peak >10mg/L	33	0.9%	0.485	0.469 - 0.501

MEDICATION MODULE					
M 01	Vitamin K (excluding newborns)	32	0.9%	0.344	0.326 - 0.362
M 02	Heparin or Low Molecular Weight Heparin	40	1.1%	0.375	0.359 - 0.391
SURGICAL MODULE					
S 01	Unplanned or Return To surgery	83	2.3%	0.386	0.363 - 0.408
S 02	Intra-operative IV Epinephrine, Norepinephrine, Naloxone, Flumazenil	24	0.7%	0.375	0.353 - 0.398
S 03	Removal / injury or repair of organ	13	0.4%	0.615	0.593 - 0.638
S 04	Wrong site / wrong procedure / wrong patient	1	0.0%	1.000	0.997 - 1.000
OTHER MODULE					
O1	Other / Any other undesirable outcomes not covered above	371	10.1%	0.229	0.216 - 0.243
Total Charts		3669			

* LCI= Lower confidence interval; UCI= upper confidence interval

Table 2

Rates of Triggers, Adverse Events and Preventable Adverse Events overall by type of hospital and by age group by type of hospital

		PATIENTS, NO. (%)				PATIENTS, NO. (%)				
		HOSPITAL TYPE				AGE GROUP				
Variable		Overall	APC	CH		0-28 days	29-365 days	366 days - 5 yrs	>5yrs-18 yrs.	
		n = 3669	n = 1692	n = 1977	p value	n = 927	n = 902	n = 900	n = 940	p value
Patients with >1 Trigger		1083 (29.5)	656 (38.8)	427 (21.6)	<0.0001	146 (34.4)	181 (42.8)	161 (38.4)	168 (39.5)	0.1
Patients with an Adverse Event*		237 (6.5)	172 (10.2)	65 (3.3)	<0.0001	53 (5.7)	62(6.9)	54 (6.0)	68 (7.2)	0.6
Patients with > 1 adverse event**		30(0.8)	26(1.5)	4(0.2)	<0.0001	8(0.9)	9(1.0)	3(0.3)	6(0.6)	0.4
		n=237	n=172	n=65		n = 53	n = 62	n = 54	n = 68	
Patients with a Preventable Adverse Event†		106 (43.1)	66 (37.9)	40 (55.6)	0.010	18(34.0)	14(22.6)	14(25.9)	20(29.4)	0.3
	ACADEMIC PAEDIATRIC CENTRE					COMMUNITY HOSPITAL				
Variable	0-28 days	29-365 days	366 days - 5 yrs	>5yrs-18 yrs.		0-28 days	29-365 days	366 days - 5 yrs	>5yrs-18 yrs.	
	n = 425	n = 423	n = 419	n = 425	p value	n = 502	n = 479	n = 481	n = 515	p value
Patients with >1 Trigger	146 (34.4)	181 (42.8)	161 (38.4)	168 (39.5)	0.09	86 (17.1)	113 (23.6)	101 (21.0)	127 (24.7)	0.02
Patients with an Adverse Event*	42 (9.9)	50 (11.8)	38 (9.1)	42 (9.9)	0.6	11 (2.2)	12 (2.5)	16 (3.3)	26 (5.1)	0.05
Patients with > 1 adverse event**	8(1.9)	9(2.1)	3(0.7)	6(1.4)	0.4	0	10(0.2)	5(0.4)	7(0.2)	0.6
	n = 42	n = 50	n = 38	n = 42		n = 11	n = 12	n = 16	n = 26	
Patients with a Preventable Adverse Event†	18(42.9)	14(28.0)	14(36.8)	20(47.6)	0.2	4 (36.4)	8(66.7)	10 (62.5)	18 (69.2)	0.3

Note: (1) The two hospital types include Academic Pediatric Centre (APC) which has a minimum of 1000 pediatric admissions in fiscal 2008 and a full time residency programme in pediatric Medicine and Surgery and a Community Hospital (CH) which also has a minimum of 1000 pediatric admission in fiscal 2008 but does not offer a fulltime residency progamme in both pediatric medicine and surgery. (2) The four Age Groups (AG) are: AG1 = 0 to 28 days; AG2 = 29 to 365 days (1 year); AG3 = 366 days to 5 years; and AG4 = >5 years to <19 years.

* There is a significant difference in the overall proportion of AEs occurring in an APC versus a CH p<0.0001; a significantly higher proportion of AEs in the 29-365 day age group occur in APCs than in the CHs (p<0.0001)

**The proportion of patients with >1 adverse event was statistically higher in APCs than CHs (p<0.0001) and statistically higher in APCs in all age groups except in the 366 day - 5year age group for which there was no difference when compared to the CH

†The proportion of preventable adverse events was statistically higher in community hospitals than in academic pediatric cemtres in th 29d-365d age group.

Table 3

Logistic Regression* modelled on all adverse events, preventable adverse events and non-preventable adverse events

Variable	Levels	Frequency of AE (n/N)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	p-value
MODELED ON ALL ADVERSE EVENTS					
Hospital Type	Academic	172/1692	3.3 (2.5-4.5)	2.98(1.65-5.39)	0.0003
	Community	65/1977	1	1	
Age Group	0-28 days	53/927	0.78(0.54-1.13)	0.91(0.51-1.60)	0.74
	29-365 days	62/902	0.95(0.66-1.35)	0.93(0.64-1.35)	0.7
	366 days-5 yrs	54/900	0.82(0.57-1.18)	0.81(0.56-1.17)	0.25
	>5yrs-18 yrs.	68/940	1	1	
Prescription medication prior to admission**	One or more	28/234)	2.10(1.38-3.19)	1.01(0.62-1.65)	0.95
	None	209/3435	1	1	
High alert medication prior to admission†	One or more	38/295	2.36(1.63-3.41)	1.47(1.02-2.13)	0.04
	None	199/3374	1	1	
Device dependancy prior to admission††	One or more	20/131	2.76(1.68-4.53)	1.54(1.01-2.35)	0.04
	None	217/3321	1	1	
Complex Chronic Condition on admission‡	One or more	55/500	2.03(1.48-2.79)	1.62(1.13-2.33)	0.009
	None	182/3169	1	1	
MODELED ON PREVENTABLE ADVERSE EVENTS					
Hospital Type	Academic	66/1692	1.97(1.32-2.93)	1.92(0.80-4.61)	0.14
	Community	40/1977	1	1	
Age Group	0-28 days	22/927	0.58(0.34-0.98)	0.60(0.23-1.51)	0.27
	29-365 days	22/902	0.59(0.35-1.01)	0.59(0.29-1.20)	0.15
	366 days-5 yrs	24/900	0.65(0.39-1.09)	0.65(0.34-1.23)	0.18
	>5yrs-18 yrs.	38/940	1	1	
Prescription medication prior to admission**	One or more	11/234	1.73(0.92-3.28)	1.35(0.60-3.04)	0.47
	None	95/3435	1	1	
High alert medication prior to admission†	One or more	10/295	1.20(0.62-2.32)	0.71(0.30-1.65)	0.42
	None	96/3374	1	1	
Device dependancy prior to admission††	One or more	7/131	1.96(0.89-4.31)	1.53(0.46-5.08)	0.49
	None	99/3538	1	1	
Complex Chronic Condition on admission‡	One or more	18/500	1.31(0.78-2.19)	1.12(0.60-2.09)	0.72
	None	88/3169	1	1	
MODELED ON NON-PREVENTABLE ADVERSE EVENTS					
Hospital Type	Academic	106/1692	5.22(3.36-8.11)	4.39(2.08-9.27)	0.0001
	Community	25/1977	1	1	
Age Group	0-28 days	31/927	1.05(0.63-1.75)	1.37(0.78-2.40)	0.28
	29-365 days	40/902	1.41(0.87-2.28)	1.38(0.89-2.14)	0.15
	366 days-5 yrs	30/900	1.05(0.62-1.75)	1.04(0.63-1.73)	0.86
	>5yrs-18 yrs.	30/940	1	1	
Prescription medication prior to admission**	One or more	7.3 (17/234)	2.28(1.35-3.87)	0.85(0.47-1.54)	0.59

	None	3.3 (114/3435)	1	1	
High alert medication prior to admission†	One or more	9.5 (28/295)	3.34(2.15-5.15)	2.17(1.18-3.97)	0.01
	None	3.1 (103/3374)	1	1	
Device dependancy prior to admission††	One or more	9.9 (13/131)	3.19(1.75-5.83)	1.51(0.71-3.25)	0.28
	None	3.3 (118/3538)	1	1	
Complex Chronic Condition on admission‡	One or more	7.4 (37/500)	2.61(1.76-3.87)	1.98(1.41-2.77)	<0.0001
	None	3.0 (94/3169)	1	1	

*The variables in the logistic regression model include hospital, age group, and number and type of medications, technological device dependancy (defined as a device that if it were to fail, or be discontinued, would likely cause the child to suffer a sufficiently adverse health consequence; e.g. a tracheostomy tube), and presence of a complex chronic condition (a medical condition that lasts for 12 months and involves several different organ systems or 1 organ system requiring a high level of specialty care and hospitalization e.g. Cystic fibrosis). These criteria were applied to Newborns if the medication, device or complex condition was presecribed, instituted or diagnosed within 24 hours of birth.

**The child was prescribed medication of any kind prior to the index admission

†The child was prescribed any of the following high alert medications prior to admission: anticoagulants, anti-epileptic, Gastro-Esophageal Reflux, insulin, narcotics and/or Vasoactive-Cardiac medications.

†† Prior to admission was using one or more of: indwelling medication pump/nutritional support (enteral or parenteral) / renal support (urinary catheter or dialysis)/ respiratory support (Apnea Monitor, Home suction, pulse oximetry, tracheostomy, home oximetry)/ stoma care.

‡ ‘Complex Chronic Condition’ diagnosed prior to admission and representing those from “Children with Complex Chronic Conditions, June 2008”.

Table 4

Most responsible service for delivery of care at the time of each of the 279 adverse events, overall by type of hospital, and by age group by type of hospital

	ADVERSE EVENTS, NO. (%)				ADVERSE EVENTS, NO. (%)				
	HOSPITAL TYPE				AGE GROUP*				
Most Responsible Service	Overall n = 279	APC n = 210	CH n = 69	p value	0-28 days n = 63	29-365 days n = 79	366 days - 5 yrs n = 60	>5yrs-18 yrs. n = 77	p value
Surgery	98 (35.1)	88 (41.9)	10 (14.5)	<0.0001	5 (7.9)	31 (39.2)	28 (46.7)	34 (44.1)	
Medicine	83 (29.8)	60 (28.6)	23 (33.3)	0.5	17 (27.0)	21 (26.7)	19 (31.7)	26 (33.8)	0.1
Emergency	23 (8.2)	12 (5.7)	11 (15.9)	0.007	3 (4.8)	6 (7.6)	9 (15.0)	5 (6.5)	0.6
ICU	37 (13.3)	35 (16.7)	2 (2.9)	0.003	21 (33.3)	14 (17.7)	0	2 (2.6)	0.4
Maternal/Obstetrics	15 (5.4)	7 (3.3)	8 (11.6)	0.008	13 (20.6)	1(1.3)	0	1 (1.3)	
Other	23 (8.2)	8 (3.8)	15 (21.7)	<0.0001	4 (6.3)	6 (7.6)	4 (6.7)	9 (11.7)	0.3

	ACADEMIC PAEDIATRIC CENTRE					COMMUNITY HOSPITAL				
Most Responsible Service	0-28 days n = 52	29-365 days n = 66	366 days - 5 yrs n = 42	>5yrs-18 yrs. n = 50	p value	0-28 days n = 11	29-365 days n = 13	366 days - 5 yrs n = 18	>5yrs-18 yrs. n = 27	p value
Surgery	5 (9.6)	31 (47.0)	25 (59.5)	27 (54.0)	<0.0001	0 (0.0)	0 (0.0)	3 (16.7)	7 (25.9)	0.07
Medicine	16 (30.7)	12 (18.2)	14 (33.3)	18 (36.0)	0.1	1 (9.1)	9 (69.2)	5 (27.8)	8 (29.6)	0.01
Emergency	3 (5.8)	5 (7.6)	2 (4.8)	2 (4.0)	0.9	0.0	1 (7.7)	7 (38.9)	3 (11.1)	0.02
ICU	19 (36.5)	14 (21.2)	0 (0.0)	2 (4.0)	<0.0001	2 (18.2)	0 (0.0)	0 (0.0)	0 (0.0)	0.02
Maternal/Obstetrics	6 (11.5)	1(1.5)	0 (0.0)	0 (0.0)	0.003	7(63.6)	0 (0.0)	0 (0.0)	1 (3.7)	<0.0001
Other	3 (5.7)	3 (4.5)	1 (2.4)	1 (2.0)	0.8	1 (9.1)	3 (23.1)	3 (16.7)	8 (29.6)	0.6
Patients with a Preventable Adverse Event†	18(42.9)	14(28.0)	14(36.8)	20(47.6)	0.2	4 (36.4)	8(66.7)	10 (62.5)	18 (69.2)	0.3

*Physician reviewers identified the clinical service responsible for patient care at the time that the adverse event occurred. For patients who experienced more than one adverse event, the most responsible clinical service may have differed for each or some of the adverse events. Therefore, results in this table are reported at the level of the adverse event (n=279) for the 237 patients who experienced one or more adverse events.

Note: (1) The two hospital types include Academic Pediatric Centre (APC) which has a minimum of 1000 pediatric admissions in fiscal 2008 and a full time residency programme in pediatric Medicine and Surgery and a Community Hospital (CH) whichalso has a minimum of 1000 pediatric admission in fiscal 2008 but does not offer a fulltime residency progamme in both pediatric medicine and surgery. (2) The four Age Groups (AG) are: AG1 = 0 to 28 days; AG2 = 29 to 365 days (1 year); AG3 = 366 days to 5 years; and AG4 = >5 years to <19 years.

**The attribution of the MRS at the time of the AE to Surgery and ICU occurred significantly more often in APC than CHs (p<0.0001 and p=0.002, respectively). The attribution of the MRS at the time of the AE to Emergency and Maternal/Obstetrics occurred significantly more often in CHs than APCs (p=0.02 and p<0.0001, respectively). The attribution of the MRS at the time of the AE to ICU and Maternal/Obstetrics occurred significantly more often in AG1 (0-28 days; p<0.0001) and significantly less often in Surgery as compared to children over 28 days (p<0.0001).

Table 5

Distribution of adverse events among 237 patients, grouped by factor to which event was related, overall by type of hospital, and age group by type of hospital

OVERALL COMPARISON OF CLASSIFICATION OF PROCEDURES AND EVENTS TO WHICH AEs WERE RELATED BY HOSPITAL TYPE AND AGE GROUP

	ADVERSE EVENTS, NO. (%)				ADVERSE EVENTS, NO. (%)				
	HOSPITAL TYPE				AGE GROUP*				
Most Responsible Service	Overall n = 237	Academic n = 172	Community n = 65	RR (95% CI)	0-28 days n = 53	29-365 days n = 62	366 days - 5 yrs n = 54	>5yrs-18 yrs. n = 68	p value
Surgical †	78 (32.9)	64(37.2)	14 (21.5)	1.7 (1.0-3.1)	11 (20.8)	24 (38.7)	17 (31.5)	26 (38.2)	0.1
Other Clinical Management‡	47 (19.8)	29 (16.9)	18 (27.7)	0.6 (0.4-1.1)	21 (39.6)	11 (17.7)	9 (16.7)	6 (8.8)	<0.0001
Medical Procedure§	36 (15.2)	30 (17.4)	6 (9.2)	1.9 (0.8-4.9)	14 (26.4)	13 (21.0)	1 (1.9)	8 (11.8)	0.002
Diagnostic Error	34 (14.4)	19 (11.1)	15 (23.1)	0.5 (0.2-0.9)	6 (11.3)	6(9.7)	10 (18.5)	12 (17.6)	0.4
Drug §	32 (13.5)	25 (14.5)	7 (10.7)	1.4 (0.6-3.3)	1 (1.9)	7 (11.3)	13 (24.1)	11 (16.2)	0.007
Anaesthesia	6 (2.5)	5 (2.9)	1 (1.5)	1.9 (0.2-42.7)	1 (1.9)	0	3 (5.6)	2 (2.9)	0.3
AE Not Covered Elsewhere	3 (1.3)	2(1.2)	1 (1.5)	0.8 (0.1-21.0)	0	0	1 (1.9)	2 (2.9)	0.4
Fluid	2(0.8)	1 (0.6)	1 (1.5)	0.4 (0.0-13.8)	0	0	1 (1.9)	1 (1.5)	0.6
Fracture	2(0.8)	2(1.2)	0(0.0)	1.9 (0.1-39.2)	0	0	1 (1.9)	2 (2.9)	0.4
None	3(1.3)	3 (1.7)	0(0.0)	2.7 (0.1-51.0)	1 (1.9)	0	1 (1.9)	1 (1.5)	0.8
Unable to Determine	13 (5.5)	8 (4.7)	5 (7.7)	0.6 (0.2-2.1)	1 (1.9)	7 (11.3)	2 (3.7)	3 (4.4)	0.1

COMPARISON OF CLASSIFICATION OF PROCEDURES AND EVENTS TO WHICH AEs WERE RELATED BY AGE GROUP WITHIN AND BETWEEN THE ACADEMIC PAEDIATRIC CENTRES AND COMMUNITY HOSPITALS

	ACADEMIC PAEDIATRIC CENTRE					COMMUNITY HOSPITAL				
Factor related to event	0-28 days n = 42	29-365 days n = 50	366 days - 5 yrs n = 38	>5yrs-18 yrs. n = 42	p value	0-28 days n = 11	29-365 days n = 12	366 days - 5 yrs n = 16	>5yrs-18 yrs. n = 26	p value
Surgical †	10 (23.8)	24 (48.0)	13 (34.2)	17 (40.5)	0.1	1 (9.1)	0 (0.0)	4 (25.0)	9 (34.6)	0.07
Other Clinical Management‡	15 (35.7)	7 (14.0)	5 (13.2)	2 (4.8)	0.001	6(54.6)	4 (33.3)	4 (25.0)	4 (15.4)	0.1
Medical Procedure§	12 (28.6)	11 (22.0)	1 (2.6)	6 (14.3)	0.02	2 (18.2)	2 (16.7)	0 (0.0)	2 (7.7)	0.3
Diagnostic Error	5(11.9)	3(6.0)	6(15.8)	5(11.9)	0.5	1 (9.1)	3 (25.0)	4 (25.0)	7 (26.9)	0.7
Drug §	0	5 (10.0)	12 (31.6)	8 (19.1)	0.0005	1 (9.1)	2 (16.7)	1 (6.3)	3 (11.5)	0.9
Anaesthesia	1 (2.4)	0	2 (5.3)	2 (4.8)	0.4	0	0	1 (6.3)	0	0.6
AE Not Covered Elsewhere	0	0	0	2 (4.8)	0.2	0	0	1 (6.3)	0	0.6

Fluid	0	0	0	1(2.4)	0.7	0	0	1 (6.3)	0	0.6
Fracture	0	0	0	2 (4.8)	0.2	0	0	0	0	-
None	1(2.4)	0	1(2.6)	1(2.4)	0.7	0	0	0	0	-
Unable to Determine	1(2.4)	5(10.0)	1(2.6)	1(2.4)	0.3	0	2(16.7)	1(6.3)	2(7.7)	0.6

COMPARISON OF CLASSIFICATION OF PROCEDURES AND EVENTS TO WHICH AEs WERE RELATED FOR INFANTS 0-28 DAYS WITH AND WITHOUT A STAY IN NICU, AND FOR INFANTS AND CHILDREN 29 DAYS - 18 YEARS DESIGNATED AS A MEDICAL OR SURGICAL CASE.

	0-28 days††			29 days - 18 years††		
Factor related to event	Non -NICU	NICU	p value	Medicine	Surgery	p value
Surgical †	6(17.7%)	5(26.3%)	0.5	16(18.4%)	51(52.6%)	<0.0001
Other Clinical Management‡	12(35.3%)	9(47.4%)	0.4	16(18.4%)	10(10.3%)	0.1
Medical Procedure§	9(26.5%)	5(26.3%)	0.99	10(11.5%)	12(12.4%)	0.9
Diagnostic Error	5(14.7%)	1(5.3%)	0.4	14(16.1%)	14(14.4%)	0.8
Drug §	0	1(5.3%)	0.4	21(24.1%)	10(10.3%)	0.01
Anaesthesia	1(2.9%)	0	0.99	5(5.8%)	0	0.02
AE Not Covered Elsewhere	0	0	-	1(1.2%)	2(2.1%)	0.99
Fluid	0	0	-	2(2.3%)	0	0.2
Fracture	0	0	-	1(1.2%)	1(1.0%)	0.99
None	1(2.9%)	0	0.99	1(1.2%)	1(1.0%)	0.99
Unable to Determine	0	1(5.3%)	0.4	5(5.1%)	7(7.2%)	0.8

Note: APC = academic pediatric centre, CH = community hospital, CI = confidence interval, RR = relative risk.
Note: (1) The two hospital types include Academic Pediatric Centre (APC) which has a minimum of 1000 pediatric admissions in fiscal 2008 and a full time residency programme in pediatric Medicine and Surgery and a Community Hospital (CH) which also has a minimum of 1000 pediatric admission in fiscal 2008 but does not offer a fulltime residency progamme in both pediatric medicine and surgery. (2) The four Age Groups (AG) are:
AG1 = 0 to 28 days; AG2 = 29 to 365 days (1 year); AG3 = 366 days to 5 years; and AG4 = >5 years to <19 years.
Note: Relative risk is not available for age groups cpomparison, in their place, p values are provided.
*Reviewers selected as many categories as applied when classifying procedures and events. Percentages in this table are based on total number of patients in the section (e.g., APC, CH); as a result, the sum of the percentages is not 100%.

*Children in **1 year - 5year** age group experienced AEs related to medical procedures signifcantly less often (p=0.005) and drug-related AE's significantly more often (p=0.004) than the other age groups.

†In the community hospitals children in **the over age 5 age group** had significantly more surgically related **adverse events** than the other age groups.

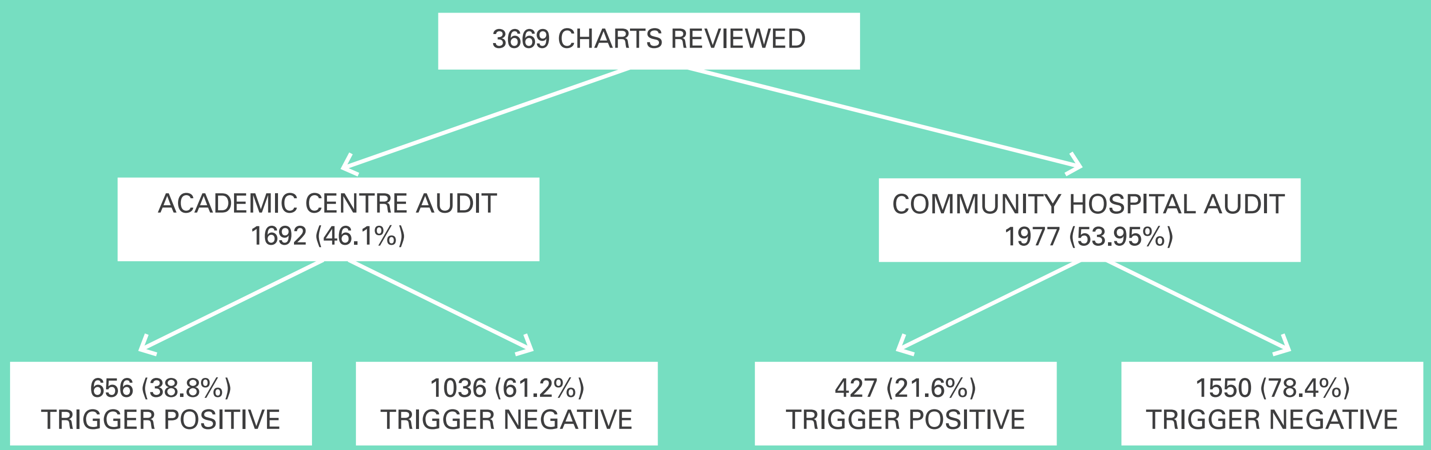
‡'Other clinical management' includes failure of labour to progress or fetal distress resulting in emergency cesarean delivery, inappropriate discharge and inappropriate treatment by primary care giver. In both Academic and Community hospitals adverse events related to 'other clinical management' occurred significantly more often in neonates and significantly less often in children over 5 years

§In the academic centres children >1y to 5y had a signifcantly higher rate of drug related adverse events. Neonates, 0-28d had signifcantly fewer drug-related events whereas, they had signifcantly more medical procedure related adverse events, while children >1y-5 y had signifcantly fewer events.

‡‡ In the infants and children >28 days old those designated as Surgical cases had significantly more AEs classified as related to Surgery (p <0.0001) and those designated as Medical cases had significantly more AEs classified as 'Drug' related AEs (p=0.01) and although small in number the Medical cases had significantly more 'Anaesthesia' related AEs (p=0.02).

Fig 1

REVIEW PROCESS FOR THE CANADIAN PAEDIATRIC ADVERSE EVENT STUDY BY HOSPITAL TYPE



Box 1

Participating centres by geographic node

GEOGRAPHIC NODE	APC	APC-2	CH-1	CH-2
British Columbia (BC)	BC Children's Hospital		Lionsgate Hospital	Victoria General Hospital
Alberta-North	Stollery Children's Hospital		Grande Prairie Care Ctr	Grey Nuns Community Hospital
Alberta-South	Alberta Children's Hospital		Peter Lougheed Health Centre	Chinook Regional Hospital (Lethbridge)
Manitoba*	Children's Hospital of Winnipeg and	l'Hôpital St-Boniface Hospital (NICU only)	Brandon Regional Health Authority	Burntwood Regional Health Authority
Ontario	Hospital for Sick Children		The Credit Valley Hospital	North York General Hospital
Quebec	CHU Sainte-Justine		Hôpital Pierre-Le Gardeur, CSSS du Sud de Lanaudière	Hôpital régional de Saint-Jérôme, CSSS de Saint-Jérôme
Atlantic†	IWK Health Centre and	Eastern Health, Janeway Childrens Health and Rehabilitation Centre	Annapolis Valley District Health Authority	Western Memorial Regional Hospital

* All NICU cases for the Manitoba APC site were selected from St. Boniface Hospital

† Due to the size population size of the Atlantic Node two APCs were invited to participate and half of the APC sample was randomly selected by age group from each. The individual APCs were matched with one regional community hospital.

REFERENCES

1 Baker GR, Norton PG, Flintoft V, Blais R, Brown A, Cox J, Etchells E, Ghali WA, Hebert P, Majumdar SR, O'Beirne M, Palacios-Derflingher L, Reid RJ, Sheps S, Tamblyn R. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. CMAJ. 2004;170(11):1678-86.

2 American Academy of Pediatrics Steering Committee on Quality Improvement and Management and Committee on Hospital Care. Policy Statement- principles of pediatric patient safety: reducing harm due to medical care. Pediatrics 2011;127:1199–1210

3 Miller MR, Elixhauser A, and Zhan C. Patient safety events during pediatric hospitalizations. Pediatrics 2003; 111(6): 1358-1366.

4 Slonim AD, LaFleur BJ, Ahmed W, and. Joseph JG. Hospital-reported medical errors in children. Pediatrics 2003; 111(3): 617 - 621.

5 Woods D, Thomas E, Holl J, Altman S, and Brennan T. Adverse events and preventable adverse events in children. Pediatrics 2005; 115: 155-160.

6 Takata GS, Mason W, Taketomo C, Logsdon T, Sharek PJ. Development, testing, and findings of a pediatric-focused trigger tool to identify medication-related harm in US children's hospitals. Pediatrics. 2008;121(4):e927-35.

7 Sharek PJ, Horbar JD, Mason W, Bisarya H, Thurm CW, Suresh G, Gray JE, Edwards WH, Goldmann D, Classen D. Adverse events in the neonatal intensive care unit: development, testing, and findings of an NICU-focused trigger tool to identify harm in North American NICUs. Pediatrics. 2006 Oct;118(4):1332-40.

8 Larsen GY, Donaldson AE, Parker HB, Grant MJ. Preventable harm occurring to critically ill children. Pediatr Crit Care Med. 2007;8(4):331-6

9 Matlow AG, Cronin CMG, Flintoft V, Nijssen-Jordan C, Fleming M, Brady-Fryer B, Hiltz MA, Orrbine E, Baker GR. Description of the development and validation of the Canadian Paediatric Trigger Tool. BMJ Quality and Safety 2011; 20:416-23

10 Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, Newhouse JP, Weiler PC, Hiatt HH. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. N Engl J Med. 1991; 324(6):370-6.

11 Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, Hebert L, Newhouse JP, Weiler PC, Hiatt H. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. N Engl J Med. 1991;324(6):377-84.

12 Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. The Quality in Australian Health Care Study. Med J Aust. 1995;163(9):458-71.

13 Thomas EJ, Studdert DM, Burstin HR, Orav EJ, Zeena T, Williams EJ, Howard KM, Weiler PC, Brennan TA. Incidence and types of adverse events and negligent care in Utah and Colorado. Med Care. 2000; 38(3):261-71.

14 Davis P, Lay-Yee R, Briant R, Schug S, Scott A, Johnson S, Bingley W. Adverse Events in New Zealand Public Hospitals: Principal Findings from a National Survey. Wellington, NZ. Ministry of Health. December 2001, Occasional Paper No. 3.

15 Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ 2001; 322(7285):517-9.

16 Davis P, Lay-Yee R, Briant R, Ali W, Scott A, Schug S. Adverse events in New Zealand public hospitals I: occurrence and impact. N Z Med J. 2002;115(1167):U271.

17 Davis P, Lay-Yee R, Briant R, Ali W, Scott A, Schug S. Adverse events in New Zealand public hospitals II: preventability and clinical context. N Z Med J 2003 ; 116(1183):U624.

18 Miller MR, Zhan C. Pediatric patient safety in hospitals: a national picture in 2000. Pediatrics 2004;113:1741- 6.

19 Kanter DE, Turenne W, Slonim AD. Hospital-reported medical errors in premature neonates. Pediatr Crit Care Med 2004; 5:119-23.

20 Cooke M., Irby DM, Sullivan W, Ludmerer KM. American Medical Education 100 Years after the Flexner Report. N Engl J Med 2006; 355:1339-1344

21 Proctor ML, Pastore J, Gerstle JT,. Langer JC. Incidence of Medical Error and Adverse Outcomes on a Pediatric General Surgery Service. J Pediatr Surg 2003; 38:1361-1365.

22 Kunac DL, Reith DM, Kennedy J, Austin NC, Williams SM. Inter- and intra-rater reliability for classification of medication related events in pediatric inpatients. Qual Saf Health Care. 2006;15(3):196-201.

23 Kaushal R, Bates DW, Landrigan C Medication errors and adverse drug events in pediatric inpatients. JAMA. 2001;285:2114-2120.

24 de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. Qual Saf Health Care. 2008;17:216-23.

25 Woods DM, Holl JL, Shonkoff JP, Mehra M, Ogata ES, Weiss KB. Child-specific risk factors and patient safety. J Patient Safety 2005;1:17-22.

26 Statistics Canada. 2006 Census. http://www12.statcan.gc.ca/census-recensement/index-eng.cfm Accessed July 25, 2011

27 Committee on Quality of Health Care in America, Institute of Medicine. To Err Is Human: Building a Safer Health System. Kohn LT, Corrigan JM, Donaldson MS, Editors. 1999. National Academy Press, Washington, D.C.

cpsi icsp

Canadian Patient Safety Institute
Institut canadien pour la sécurité des patients

Safe care…accepting no less
Soins sécuritaires…n'acceptons rien de moins

Canadian Patient Safety Institute
www.patientsafetyinstitute.ca

Edmonton Office
Suite 1414, 10235 101 Street, Edmonton, AB T5J 3G1
Phone: 780-409-8090 Fax: 780-409-8098 Toll Free: 1-866-421-6933

Ottawa Office
Suite 410, 1150 Cyrville Road, Ottawa, ON K1J 7S9
Phone: 613-730-7322 Fax: 613-730-7323