



**World Health
Organization**

Patient Safety

A World Alliance for Safer Health Care

Introduction to Patient Safety Research

Presentation 1 - Measuring harm: Retrospective chart review



2: Table of Contents

- **Introduction**
 - [Overview](#)
 - [Study Details](#)
 - [Patient Safety Research Team](#)
- **Background**
 - [Opening Points](#)
 - [Study Rationale](#)
 - [Setting Up a Research Team](#)
- **Methods**
 - [Study Design and Objectives](#)
 - [Study Setting and Population](#)
 - [Data Collection](#)
 - [Chart Review Process](#)
 - [Data Analysis and Interpretation](#)
- **Results**
 - [Key Findings](#)
- **Conclusion**
 - [Main Points](#)
 - [Study Impact](#)
 - [Practical Considerations](#)
- **Author Reflections**
 - [Lessons and Advice](#)
 - [Overcoming Barriers](#)
 - [Ideas for Future Research](#)
- **References**
 - [Additional References](#)
 - [Additional Resources and Tools](#)

3: Overview

■ Objective

- To estimate the incidence of adverse events (AEs) among patients in Canadian acute care hospitals.

■ Methods

- Randomly selected 1 teaching, 1 large community and 2 small community hospitals in each of 5 provinces and reviewed a random sample of charts for adult patients in each hospital for the fiscal year 2000.
- Trained reviewers screened all eligible charts, and physicians reviewed the positively screened charts to identify AEs and determine preventability.

■ Results

- AE rate calculated to be 7.5 per 100 hospital admissions.
- Among patients with AEs, preventable events occurred in 36.9% and death in 20.8%. Estimated that 1521 additional hospital days associated with AEs.

■ Conclusion:

- Overall incidence rate of AEs of 7.5% suggests that, of the almost 2.5 million annual hospital admissions in Canada, about 185 000 are associated with an AE and close to 70 000 of these are potentially preventable.

4: Introduction: Study Details

■ Full Reference

Baker GR, Norton PG, Flintoft V, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ*, 2004, 170:1678-1686

[Link to Abstract \(HTML\)](#)

[Link to Full Text \(PDF\)](#)

Abstract

Background: Research into adverse events (AEs) has highlighted the need to improve patient safety. AEs are unintended injuries or complications resulting in death, disability or prolonged hospital stay that arise from health care management. We estimated the incidence of AEs among patients in Canadian acute care hospitals.

Methods: We randomly selected 1 teaching, 1 large community and 2 small community hospitals in each of 5 provinces (British Columbia, Alberta, Ontario, Quebec and Nova Scotia) and reviewed a random sample of charts for nonpsychiatric, nonobstetric adult patients in each hospital for the fiscal year 2000. Trained reviewers screened all eligible charts, and physicians reviewed the positively screened charts to identify AEs and determine their preventability.

Results: At least 1 screening criterion was identified in 1527 (40.8%) of 3745 charts. The physician reviewers identified AEs in 255 of the charts. After adjustment for the sampling strategy, the AE rate was 7.5 per 100 hospital admissions (95% confidence interval [CI] 5.7–9.3). Among the patients with AEs, events judged to be preventable occurred in 36.9% (95% CI 32.0%–41.8%) and death in 20.8% (95% CI 7.8%–33.8%). Physician reviewers estimated that 1521 additional hospital days were associated with AEs. Although men and women experienced equal rates of AEs, patients who had AEs were significantly older than those who did not (mean age [and standard deviation] 64.9 [16.7] v. 62.0 [18.4] years; $p = 0.016$).

Interpretation: The overall incidence rate of AEs of 7.5% in our study suggests that, of the almost 2.5 million annual hospital admissions in Canada similar to the type studied, about 185 000 are associated with an AE and close to 70 000 of these are potentially preventable.

Research
Recherche

The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada

G. Ross Baker, Peter G. Norton, Virginia Flintoft, Régis Blais, Abdelstain Brown, Jaina Cox, Ed Elchells, William A. Ghali, Philip Hubert, Sumit R. Majumdar, Maeva O'Rourke, Luc Pelican-Dorffinger, Robert J. Reid, Sam Shaps, Robyn Tamblyn

5 See related article page 1688

Abstract

Background: Research into adverse events (AEs) has highlighted the need to improve patient safety. AEs are unintended injuries or complications resulting in death, disability or prolonged hospital stay that arise from health care management. We estimated the incidence of AEs among patients in Canadian acute care hospitals.

Methods: We randomly selected 1 teaching, 1 large community and 2 small community hospitals in each of 5 provinces (British Columbia, Alberta, Ontario, Quebec and Nova Scotia) and reviewed a random sample of charts for nonpsychiatric, nonobstetric adult patients in each hospital for the fiscal year 2000. Trained reviewers screened all eligible charts, and physicians reviewed the positively screened charts to identify AEs and determine their preventability.

Results: At least 1 screening criterion was identified in 1527 (40.8%) of 3745 charts. The physician reviewers identified AEs in 255 of the charts. After adjustment for the sampling strategy, the AE rate was 7.5 per 100 hospital admissions (95% confidence interval [CI] 5.7–9.3). Among the patients with AEs, events judged to be preventable occurred in 36.9% (95% CI 32.0%–41.8%) and death in 20.8% (95% CI 7.8%–33.8%). Physician reviewers estimated that 1521 additional hospital days were associated with AEs. Although men and women experienced equal rates of AEs, patients who had AEs were significantly older than those who did not (mean age [and standard deviation] 64.9 [16.7] v. 62.0 [18.4] years; $p = 0.016$).

Interpretation: The overall incidence rate of AEs of 7.5% in our study suggests that, of the almost 2.5 million annual hospital admissions in Canada similar to the type studied, about 185 000 are associated with an AE and close to 70 000 of these are potentially preventable.

Keywords: Canadian Patient Safety Institute, and many health care organizations have initiated efforts to improve patient safety.

One important indicator of patient safety is the rate of AEs among hospital patients. AEs are unintended injuries or complications that are caused by health care management, rather than by the patient's underlying disease, and that lead to death, disability or the need for discharge or prolonged hospital stays.¹ Some AEs are the unavoidable consequence of health care, such as an anaphylactic reaction to an antibiotic. However, 35%–51% of AEs have been judged in retrospect to have been potentially preventable.^{2,3}

In various countries, hospital chart reviews have revealed that 25%–50.0% of patients in acute care hospitals experienced 1 or more AEs.^{4–9} The results of these studies have offered important data on a critical aspect of hospital performance and provided impetus for the development of patient safety initiatives.

There are few Canadian data on AEs in hospital patients.^{10–12} We report on the first Canadian study to provide a national estimate of the incidence of AEs across a range of hospitals using methods comparable to those used in recent studies from other countries. Our study was designed to describe the frequency and type of AEs in patients admitted to Canadian acute care hospitals and to compare the rate of these AEs across types of hospitals, and between medical and surgical care. Additional detailed analyses on the specific nature of the AEs as well as comparisons to other methods for detecting AEs will be reported elsewhere.

Methods

The methods used in this study are based on a protocol developed by the National Medical Practice Study, which examined the incidence of AEs in New York state hospitals in 1994.¹³ The protocol was modified, as needed, to diverge from it to describe the current situation in Canada, New Zealand, the United States (in Colorado and Utah) and Taiwan.^{14–16}

Study Sites

The study was conducted in five hospitals in Canada: a teaching hospital in Ontario, a large community hospital in Alberta, and two small community hospitals in British Columbia, Ontario, and Quebec.



5: Introduction: Patient Safety Research Team

■ Lead researcher - Dr. G. Ross Baker, PhD

- Professor, Health Policy, Management and Evaluation
- University of Toronto in Toronto, Canada
- Field of expertise: patient safety, quality improvement, organizational strategies to improve quality of care



■ Other team members:

- | | |
|---------------------------|---------------------------------|
| ■ Dr. Peter G. Norton | ■ Dr. Philip Hébert |
| ■ Virginia Flintoft, MSc | ■ Dr. Sumit R. Majumdar |
| ■ Dr. Régis Blais | ■ Dr. Maeve O'Beirne |
| ■ Adalsteinn Brown, DPhil | ■ Luz Palacios-Derflingher, MSc |
| ■ Dr. Jafna Cox | ■ Dr. Robert J. Reid |
| ■ Dr. Ed Etchells | ■ Dr. Sam Sheps |
| ■ Dr. William A. Ghali | ■ Dr. Robyn Tamblyn |

6: Background: Opening Points

- **Definition of adverse events (AEs):**
 - AEs are unintended injuries or complications resulting in death, disability or prolonged hospital stay that arise from health care management
- **Rate of adverse events among hospital patients is an important indicator of patient safety**
 - In various countries, hospital chart reviews have revealed that 2.9-16.6% of patients in acute care hospitals experienced 1 or more AEs
- **37-51% of AEs judged to be potentially preventable**
 - However, some are the unavoidable consequences of health care

7: Background: Study Rationale

- Several US studies indicate that substantial harm can result from care, but these results had not been generalized to Canada
 - US Institute of Medicine report “To Err is Human” had very little impact on Canadian healthcare policy makers and system leaders
- There is little Canadian data on AEs in hospital patients
 - *“The failure of US data and studies to prompt greater attention to patient safety in Canada made us realize that local data was needed.”*



8: Background: Setting Up a Research Team

- Developed a competition to select collaborators with the relevant competencies
- In Canada, each province manages its own healthcare system (within a common national framework) - required data from different provinces
 - Recruited local researchers in five provinces (Ontario, Quebec, Nova Scotia, Alberta and British Columbia) to manage local data collection and contribute to the analysis of the results
- Funding
 - Provided by the Canadian Institutes of Health Research and the Canadian Institute for Health Information

9: Methods: Study Design and Objectives

- Design: retrospective chart review
 - Randomly selected community hospitals in five Canadian provinces
 - Reviewed charts for nonpsychiatric, nonobstetric adult patients in each selected hospital for the 2000 fiscal year
- Objectives:
 - To provide a national estimate of the incidence of AEs across a range of hospitals
 - To describe the frequency and type of AEs of patients admitted to Canadian acute care hospitals
 - To compare the rate of AEs across types of hospitals and between medical and surgical care



10: Methods: Study Population and Setting

- **Setting:** four hospitals randomly selected from a list of eligible hospitals in each of the five provinces
 - One teaching hospital
 - One large community hospital (100 or more beds)
 - Two small community hospitals (fewer than 100 beds)
- **Hospital eligibility criteria:**
 - Within 250km of the provincial research centre
 - At least 1500 inpatient admissions in 2002
 - Emergency department open 24 hours
 - Specialty hospitals excluded



11: Methods: Study Population and Setting (2)

- Population: selected a random sample of hospital admissions (patient charts) for the 2000 fiscal year
 - Goal to review 230 charts in each teaching and large community hospital and 142 charts in each small community hospital, for a total sample of 3,720 hospital admissions
 - Of 4,164 hospital admissions sampled from the participating hospitals, 3,745 patient charts (89.9%) eligible for a full screening by stage one reviewers



12: Methods: Data Collection

- Study methods and data collection tools based on established approaches from prior studies, particularly in the US, Australia and Britain (see additional references)
 - Developed a computerized data collection form to ensure complete data entry
 - Provincial physician and nurse leaders underwent training and used a standard set of hospital charts and a training manual

13: Methods: Chart Review Process

- **Stage 1:**
 - Nurses or health records professionals assessed selected hospital chart for presence of one or more of 18 screening criteria sensitive to the occurrence of an AE
- **Stage 2:**
 - Physicians reviewed charts that were positive for at least one screening criterion
 - Reviewers identified and classified the presence of any unintended injuries or complications associated with death, disability, prolonged hospital stay or subsequent hospital admissions
 - Reviewers determined extent to which health care management was responsible for injury and judged preventability of each AE using a six-point scale



14: Methods: Data Analysis and Interpretation

■ Statistical analysis

- Interrater reliability assessed on a random sample of 10% of charts at both stages
- National weighted point estimates and confidence intervals for AEs calculated using a two-stage stratified sampling technique
- Chi-square test to compare AE rates among hospital types
- Backward stepwise logic regression to calculate the risk of an AE across hospital peer groups



15: Results: Key Findings

- Physician reviewers identified AEs in a total of 255 charts
- Weighted AE rate was 7.5 per 100 medical or surgical hospital admissions
- Weighted preventable AE rate was similar across all three hospital types
- More than a third of AEs judged to be highly preventable (36.9%)
 - 9% of deaths associated with an AE judged to be highly preventable
- Most patients who experienced an AE recovered without permanent disability
 - 64.4% resulted in no disability, or minimal to moderate impairment
- However, there is significant morbidity and mortality associated with AEs
 - 5.2% resulted in permanent disability
 - 15.9% resulted in death



16: Results: Key Findings (2)

- Patients who experienced AEs experience longer hospital stays than those without AEs
 - Overall, AEs led to an additional 1,521 hospital days
- Rate of AE varied among different types of services:
 - 51.4% occurred in patients receiving surgical care
 - 45% occurred in patients receiving medical care
 - Most commonly associated with drug or fluid related events
 - 3.6% occurred with other services (dentistry, podiatry, etc.)
- Patient characteristics
 - Men and women experienced equal rates of AEs
 - Patients who had AEs were significantly older (mean 64.9 years) than those who did not (mean 62.0 years)



17: Conclusion: Main Points

- Study suggests that of the nearly 2.5 million annual hospital admissions in Canada similar to the type studied:
 - About 185,000 are associated with an AE
 - Close to 70,000 of these AEs are potentially preventable
- Efforts to improve the safety of medications and surgical services is likely to play an important role in improving patient safety

18: Conclusion: Study Impact

- **Academic impact**
 - Published in the leading Canadian medical journal (Canadian Medical Association Journal) and has been cited more than 400 times
 - Frequently referenced in presentations on patient safety
- **Policy impact**
 - Publication of the study helped launch the Canadian Patient Safety Institute in 2004
 - Patient safety has become an important strategic goal for governments and healthcare organizations
- **Practice impact**
 - Research team provided guidance to several other teams that have undertaken similar studies in Spain, the Netherlands, Japan, Brazil and Germany



19: Conclusion: Practical Considerations

- **Study duration**
 - Four years from conception to write-up (two years from the time funding was obtained)
- **Cost**
 - Study cost \$800,000 CAD (approximately \$615,000 USD)
- **Additional resources**
 - Recruited local researchers to help manage local data collection
- **Required competencies**
 - Clinical expertise, research management skills, statistical analytical skills and patient safety knowledge
- **Ethical approval**
 - Took 3-4 months to obtain
 - Required approval both locally (individual hospitals/regions) and at the university level



20: Author Reflections: Lessons and Advice

- **If one thing in the study could be done differently...**
 - Spend more time training data collectors, and train everyone at once (~ three days of training)
 - Implement web-based data collection
- **Advice for young researchers**
 - *"Find important questions first!"*
- **Feasibility and applicability in developing countries**
 - Dependent upon the quality of documentation in patient files and the availability of experienced researchers and project managers
 - Feasible if good quality medical records are available

21: Author Reflections: Overcoming Barriers

- **Steps taken to ensure study success:**
 - Trained provincial data collectors together to help ensure that each provincial team applied the methods in a consistent fashion
 - Automated the data collection template to improve reliability and facilitate remote transfer of data to a secure computer server
 - Created a series of “test” charts to help ensure reliability after the training and before data collection began
 - Monitored data collection closely, reviewing the results from each team or even working with local reviewers to improve data collection procedures

22: Conclusion: Ideas for Future Research

- This type of study could be repeated in different settings
 - Study tools have already been adapted for paediatric patients and patients in home care
- Research team worked to simplify the methods, but they still are quite time and cost intensive
 - Further efforts to make these efforts useful for concurrent review would be helpful
- More research required into the evaluation of specific patient interventions
 - E.g. improvements in medication management



23: Additional References

■ Additional References

- G. Ross Baker, Peter Norton and Virginia Flintoft. Knowledge translation and patient safety: The Canadian Adverse Events Study. *Health Policy* 1(3): 37-40.
- A. Matlow, V. Flintoft, E. Orrbine, B. Brady-Fryer, C. Cronin, C. Nijssen-Jordan, M. Fleming, M. Hiltz, M. Lahey, M. Zimmerman and G. R. Baker. 2006. The development of the Canadian Pediatric Trigger Tool for Identifying Potential Adverse Events. *Healthcare Quarterly* 8(special issue): 90-93.\
- Baker, G. R. (2004). "Harvard Medical Practice Study." *Qual Saf Health Care* 13(2): 151-152. [Commentary on Brennan, et al. paper]
- Michel, P., Quenon, J. L., de Sarasqueta, A. M., & Scemama, O. (2004). Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. *BMJ*, 328(7433), 199-190.



24: Additional Resources and Tools

- **Study methods based on:**
 - Harvard Medical Practice Study - Leape et al
 - Australian Health Care Study - Wilson et al
 - Utah and Colorado - Thomas et al
 - New Zealand - Davis et al
 - United Kingdom - Vincent et al
 - Danish Adverse Event Study - Schioler et al
- **Additional Resources and Tools**
 - See web appendices to the 2004 study that can be located on the CMAJ website
 - Copies of the data collection tools are available from the authors