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**Patient Safety
Research Introductory
Course**

Session 3

Measuring Harm

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Objectives and Overview

- To understand how to measure the magnitude and type of different adverse events that lead to patient harm
- Measuring what goes wrong in healthcare includes counting how many patients are harmed or killed each year, and from which types of adverse events. This session will introduce methods of measuring harm.



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Components





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1. Which of the following measurements includes some “error”?

- a. The proportion of patients undergoing abdominal surgery in a hospital who develop a wound infection
- b. The number of medication errors in an intensive care unit every day
- c. The weight of an individual patient
- d. All of the above

2. Which of the following is NOT a good way to measure errors in the hospital?

- a. A doctor reads 50 hospital charts and counts the number of preventable injuries
- b. A medical student sits at the bedside and uses a standard form to record each time a staff member touches the patient with unwashed hands
- c. A trained nurse inspects the abdominal incisions of all post-operative patients and uses a standard form to record potential wound infections.
- d. Two trained doctors each read the same 50 hospital charts and count the number of patients who developed a wound infection after surgery



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3. On average, how common are medical errors for patients in intensive care units?

- a. One or two errors a week
- b. One or two errors a day
- c. Ten errors an hour
- d. No errors if it is a good unit

4. Which of these is a problem with using chart review to detect adverse events?

- a. Records are often incomplete
- b. Only doctors can review medical charts
- c. Reviewers may disagree about whether or not there was an adverse event
- d. A and C

5. What is an advantage of using direct observation to detect errors?

- a. Observers can see things that would not be noticed otherwise
- b. Observers are always accurate in detecting errors
- c. Direct observation is best for detecting latent errors
- d. A and C



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Measurement is Important

- Evaluate current system
 - Identify high risk areas in health care
 - Learn what is working and what is broken
- Help set priorities – where should we start?
- Reduce harm and improve outcomes

“...we tend to emphasize what is measured”

- John Kenneth Galbraith



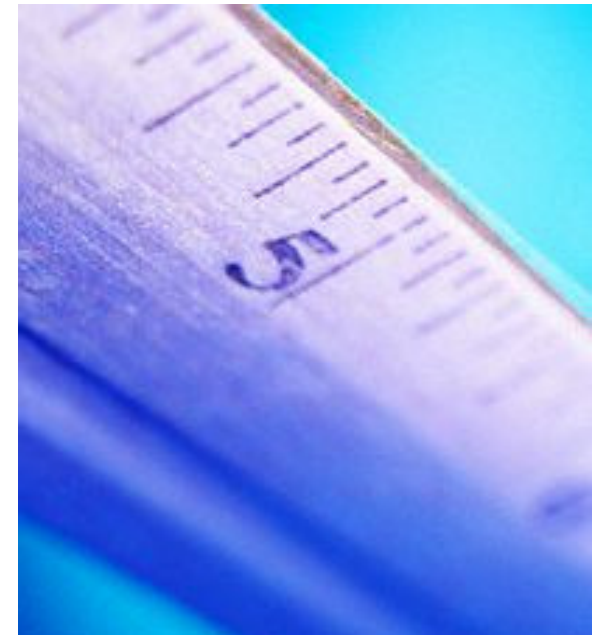
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Definition: Measurement

- The process of applying a standard scale to what you are interested in
- *Every* measurement includes some error
 - Some of that error is random “noise”
 - Some is systematic “bias”
- Task is to minimize noise and understand bias





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No “Standard” Scale for “Safety”

- Become familiar with some measurement “tools”
- Try them out in local context
- Share experience regarding effectiveness, feasibility
- No one is the “expert” in measuring safety in developing and transitional countries



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What Are We Trying to Measure?

- Errors: the failure of a planned action to be completed as intended or use of a wrong plan to achieve an aim
 - Latent errors: defects in the system eg, poor design, understaffing
 - Active errors: errors made by frontline health staff eg, dose errors
- Adverse Events: harm caused by health care
- Safety targets: medication errors, HAI, surgical complications, device complications, identification errors, death



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4 Basic Methods of Collecting Data

- Observation
- Self-reports (interviews and questionnaires)
- Testing
- Physical evidence (document review)



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Measurement Methods

- Prospective
 - **Direct observation** of patient care
 - **Cohort study**
 - Clinical surveillance
- Retrospective
 - **Record review** (Chart, Electronic medical record)
 - Administrative claims analysis
 - Malpractice claims analysis
 - Morbidity & mortality conferences/autopsy
 - Incident reporting systems

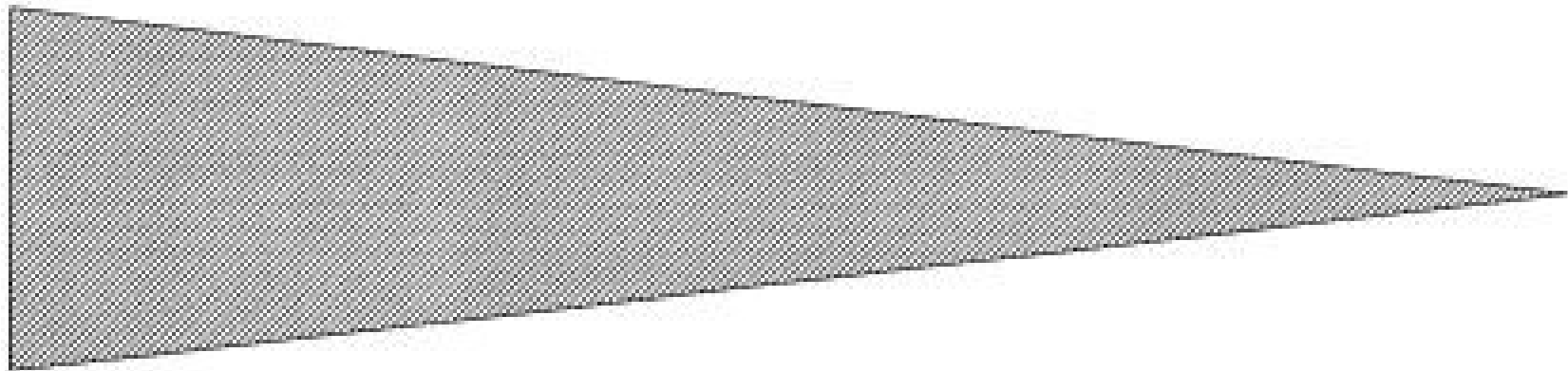


Relative Utility of Methods to Measure Errors

Latent errors

Active errors

Adverse events



- Incident reporting
- Autopsies and morbidity and mortality conferences
- Malpractice claims files analysis

- Chart review
- Administrative data analysis
- Information technology

- Direct observation

- Clinical surveillance

Thomas & Petersen, JGIM 2003



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Direct Observation

- Good for active errors
- Data otherwise unavailable
- Potentially accurate, precise
- Training/expensive
- Information overload
- Hawthorne effect?
- Hindsight bias?
- Not good for latent errors





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Yoel Donchin et al

- Prospective observational study in intensive care unit using direct observation by medical staff and collection of error reports





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Donchin Y, Gopher D, Olin M, et al. A look into the nature and causes of human errors in the intensive care unit. Qual. Saf. Health Care 2003, 12; 143-147

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

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

Objectives: The purpose of this study was to investigate the nature and causes of human errors in the intensive care unit (ICU), adopting approaches proposed by human factors engineering. The basic assumption was that errors occur and follow a pattern that can be uncovered.

Design: Concurrent incident study.

Setting: Medical-surgical ICU of a university hospital.

Measurements and main results: Two types of data were collected: errors reported by physicians and nurses immediately after an error discovery; and activity profiles based on 24-h records taken by observers with human engineering experience on a sample of patients. During the 4 months of data collection, a total of 554 human errors were reported by the medical staff. Errors were rated for severity and classified according to the body system and type of medical activity involved. There was an average of 178 activities per patient per day and an estimated number of 1.7 errors per patient per day. For the ICU as a whole, a severe or potentially detrimental error occurred on average twice a day. Physicians and nurses were about equal contributors to the number of errors, although nurses had many more activities per day.

Conclusions: A significant number of dangerous human errors occur in the ICU. Many of these errors could be attributed to problems of communication between the physicians and nurses. Applying human factor engineering concepts to the study of the weak points of a specific ICU may help to reduce the number of errors. Errors should not be considered as an incurable disease, but rather as preventable phenomena.





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Methods: Study Design

- Design: direct observation mixed methods study
 - Error reports made by physicians and nurses immediately after an error discovery
 - Activity profiles created based on records taken by observers
 - Errors were rated for severity and classified according to the body system and type of medical activity involved
- Population: staff of the medical-surgical ICU of the Hadassah-Hebrew University Medical Center, Jerusalem
- Setting: six-bed ICU unit with additional "overflow" beds



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Methods: Data Collection

- Errors reported by physicians and nurses at time of discovery
 - Discovered errors rated independently by three senior medical personnel on a 5-point scale
- Developed error report form for the use of nurses and physicians to collect data on:
 - Time of discovery
 - Sectional identities of the person who committed the error and person who discovered it
 - Brief description of the error
 - Presumed cause



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Methods: Data Collection (2)

- **Investigators recorded activity profiles based on 24 hour continuous bedside observations**
 - On 46 randomly selected patients representative of population in the unit
 - Provided baseline profile of daily activity in ICU and rate of errors
 - Investigators not medically trained but trained by senior ICU nurse
- **Analyses**
 - Frequency distributions, average activity, error rates, and percentages computed and cross-tabulated using statistical software



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Results: Key Findings

- During 4 months of data collection, a total of 554 human errors reported by the medical staff
 - Technician observers recorded a total of 8,178 activities during their 24 hour surveillances of 49 patients
- Average of 178 activities per patient per day and an estimated number of 1.7 errors per patient per day (0.95% of activities)
 - For the ICU as a whole, a severe or potentially detrimental error occurred on average twice a day
 - Physicians and nurses were about equal contributors to the number of errors, although nurses had many more activities per day



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Author Reflections: Lessons and Advice

- If you could do one thing differently in this study what would it be?

- *"Look at the unit after implementation of the recommendations."*

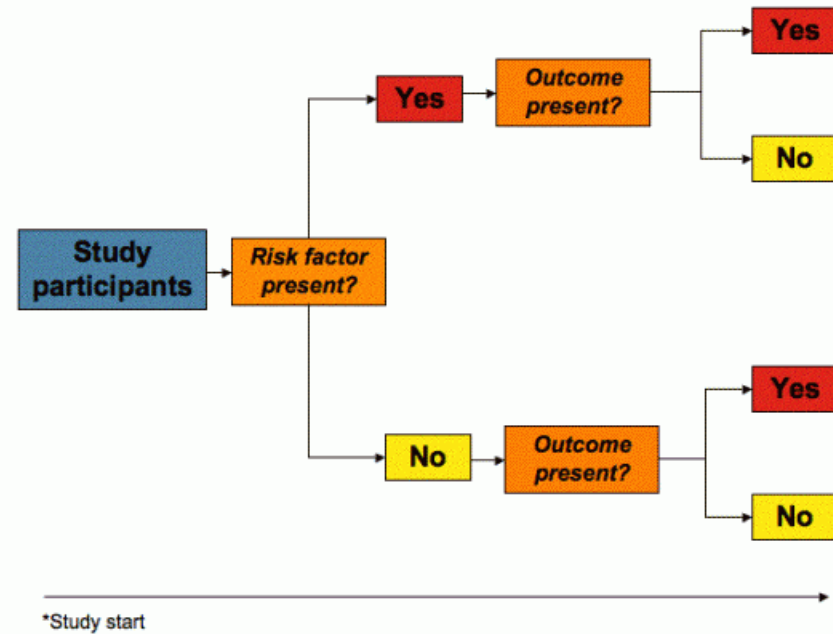
- Would this research be feasible and applicable in developing countries?

- *"I cannot answer this. It is a matter of the ICU not of the country . But the methods are as good for developing countries."*



Cohort / Clinical Surveillance

- Potentially accurate and precise for adverse events
- Good to test effectiveness of intervention to decrease specific adverse event
- Can become part of care
- Expensive
- Not good for detecting latent errors





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Hernandez, et al

- Cohort study to estimate incidence and risk factors for surgical site infection after abdominal surgery in Peru





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Hernandez K, Ramos E, Seas C, Henostroza G, Gotuzzo E. Incidence of and risk factors for surgical-site infections in a Peruvian hospital. *Infection Control and Hospital Epidemiology*, 2005: 473-477

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

ABSTRACT

OBJECTIVE: To determine the incidence of and risk factors for surgical-site infections (SSIs) after abdominal surgery.

DESIGN: A cohort study was conducted from January to June 1998. CDC criteria for SSI and the NNIS System risk index were used.

SETTING: A tertiary-care hospital in Peru.

PATIENTS: Adult patients undergoing abdominal surgery who consented were enrolled and observed until 30 days after surgery. Patients who had undergone surgery at another hospital or who died or were transferred to another hospital within 24 hours after surgery were excluded.

RESULTS: Four hundred sixty-eight patients were enrolled. Their mean age was 37.2 years. One hundred twenty-five patients developed SSIs, 18% of which were identified after discharge. The overall incidence rate (IR) was 26.7%. The IR was

13.9% for clean, 15.9% for clean-contaminated, 13.5% for contaminated, and 47.2% for dirty interventions. The IR was 3.6% for NNIS System risk index 0 and 60% for index 3. Risk factors for SSI on logistic regression analysis were dirty or infected wound (RR, 3.8; CI_{95%}, 1.7-8.4), drain use longer than 9 days (RR, 6.0; CI_{95%}, 2.5-12.5), and length of surgery greater than the 75th percentile (RR, 2.1; CI_{95%}, 1.0-4.4). Patients with SSI had a longer hospital stay than did non-infected patients (14.0 vs 6.1 days; *P* < .001).

CONCLUSIONS: SSI is a major problem in this hospital, which has a higher IR (especially for clean interventions) than those of developed countries. In developing countries, prevention of SSI should include active surveillance and interventions targeting modifiable risk factors (*Infect Control Hosp Epidemiol* 2005;26:473-477).

INCIDENCE OF AND RISK FACTORS FOR SURGICAL-SITE INFECTIONS IN A PERUVIAN HOSPITAL

Katherine Hernandez, MD, Elizabeth Seas, MD, Carlos Seas, MD, Gerardo Henostroza, MD, Eduardo Gotuzzo, MD

ABSTRACT

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Non-routinized infections are a major public health problem worldwide. According to the Institute of Medicine, thousands of deaths are linked to nosocomial infections annually in the United States.¹ Surgical-site infections (SSIs) are the most common nosocomial infections, along with pneumonia, urinary tract infections, and blood stream infections.² Although SSIs are not associated with a high case-fatality rate, they cause significant morbidity. Approximately 250,000 episodes of SSI occur in the United States every year, accounting for 1.7 million extra hospital days and more than 1.6 billion dollars of extra hospital charges.³

The Centers for Disease Control and Prevention (CDC) National Nosocomial Infection Surveillance (NNIS) System in the United States and Europe represent successful data reporting hospital-based infection surveillance programs. Infection prevention interventions have been shown to reduce NNIS System hospital rates in large teaching hospitals, emphasizing the importance of implementing such programs^{4,5} in these and many other developing countries, low hospitals

have established surveillance programs for nosocomial infections. This is likely due to the lack of national policies and protocols regarding the issue, scarce human and financial resources, and the misconception that nosocomial infections are uncommon. Consequently, reports about the incidence of nosocomial infections for teaching SSIs are scarce in these countries.

This study sought to evaluate the incidence of SSI at a national referral hospital in Lima, Peru, and to identify risk factors associated with the development of SSI, using the NNIS System risk index. It was thought that data from teaching hospitals would provide a representative picture of SSI within the entire hospital in the region and abroad and would help when developing prevention and control strategies in developing countries with scarce resources.

METHODS
The study was conducted at the Hospital Nacional Coronado Heredia, a 400-bed, tertiary-care hospital with and with the Universidad Peruana Coronado Heredia. The

Dr. Hernandez and Dr. Seas are Instituto Nacional de Salud (INS) researchers, Universidad Peruana Coronado Heredia, Lima, Peru. Drs. Henostroza and Gotuzzo are from the Department of Microbiology, National Hospital, Hospital Coronado Heredia, Universidad Peruana Coronado Heredia. Dr. Seas is from the Department of Microbiology, National Hospital, Hospital Coronado Heredia, Universidad Peruana Coronado Heredia. Dr. Gotuzzo is from the Department of Microbiology, National Hospital, Hospital Coronado Heredia, Universidad Peruana Coronado Heredia. Address correspondence to Dr. Hernandez at the Department of Microbiology, National Hospital, Hospital Coronado Heredia, Av. Piquillay 100, Lima 15001, Peru (katherine.hernandez@ins.gub.pe).



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Methods: Study Design

- Design: cohort study

- Conducted from January to June 1998, using CDC criteria for SSI and the NNIS System risk index

- **Study objectives:**

- To evaluate the incidence of and risk factors for surgical-site infections (SSIs) after abdominal surgery at a national referral hospital in Lima, Peru
- To identify risk factors associated with the development of SSI, using the NNIS System risk index



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Methods: Study Setting / Population

- Setting:

- Hospital Nacional Cayetano Heredia, a 400-bed, tertiary-care hospital affiliated with the Universidad Peruana Cayetano Heredia
- Hospital has 86-bed surgery ward and 4-bed surgical ICU performing 200 surgical interventions/mo

- Population: patients older than 14 years requiring abdominal surgery who consented to participate

- Evaluated 468 consecutive abdominal interventions
- 83.3% of surgical procedures classified as emergency procedures
 - *Appendectomy most common procedure*
- 59.8% of patients were male
- Mean age was 37.2 years



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Methods: Data Collection

- Two physicians trained to interview & observe patients hospitalization, searching daily for SSI and potential risk factors
 - Clinical charts were systematically reviewed; if necessary, the medical staff were interviewed
 - Data regarding SSI obtained from all patients daily during hospitalization and until 30 days post-op
- **A form to collect data on:**
 - Age and gender
 - Presence of underlying diseases
 - Type of surgery (elective vs. emergency)
 - Preoperative stay (in hours)
 - Total length of hospitalization (in days)
 - American Society of Anesthesiologists (ASA) preoperative assessment score
 - Use and duration of antibiotic prophylaxis
 - Length of surgery
 - Number of surgical interventions per patients
 - Use and duration of drainage



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15: Methods: SSI Classification

- Followed the CDC definitions for SSI and other nosocomial infections to detect all postoperative nosocomial infections
- National Research Council operative-site classification was also used to classify surgical wounds as:
 - Clean
 - Clean-contaminated
 - Contaminated
 - Dirty



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Results: Key Findings

- Overall incidence of SSIs was 26.7%
 - 86.4% occurred with emergency procedures
 - 13.6% occurred with elective procedures
 - 18% of SSIs identified after discharge
- Identified risk factors for SSI were:
 - Dirty or infected wound
 - Drain use longer than 9 days
 - Length of surgery greater than the 75th percentile
- Patients with SSI had a longer hospital stay than non-infected patients



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20: Conclusion: Main Points

- **Overall incidence of SSI in this study (26.7%)** remarkably higher than rates reported in developed countries such as the UK (3.1%) and the Netherlands (4.3%)
- **Study revealed a particularly high incidence of SSI in clean wounds (13.9%),** which merits further exploration



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Chart Review

- Uses readily available data
- Common
- Judgments of adverse events not reliable
- Expensive
- Records incomplete, missing
- Hindsight bias





Ross Baker

- Retrospective hospital chart review to identify adverse events and preventable adverse events in Canada





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, Brian Bain, Adrienne Brown, John Cox, Ed Dubois, William A. Ghali, Philip Fisher, Sarah S. Alexander, Moore O'Brien, Ian Paterson-Duffinger, Robert J. Reid, Sam Sheps, Ranya Tanchik

See www.cma.ca for page 1687

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Keywords: adverse events, patient safety, hospital admissions

Introduction

The importance of patient safety to the care of AEs among hospital patients. AEs are unintended injuries or complications that are due to health care management, rather than to the patient's underlying illness, and that lead to death, disability or a loss of language or prolonged hospital stays.¹ These AEs are not necessarily preventable, but many are, such as an unnecessary antibiotic injection to an allergic patient.² The 1% of AEs that have been judged to be preventable in fact, may actually be 10%–40% of patients in acute care hospitals experienced 1 or more AEs.³ The results of this study have allowed us to estimate the incidence of AEs in a national population and provided impetus for the development of patient safety initiatives.

There are few Canadian data on AEs in hospital patients.^{4–7} The purpose of the Canadian study is to provide a national picture of the incidence of AEs across a range of hospital settings comparable to those used by current studies that, where available, are 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 objectives include to identify the specific nature of the AEs, as well as comparisons to other studies that are being conducted in the reported literature.

Methods

The methodology of this study is based on procedures used by the Institute of Medicine study which was the first to highlight the importance of patient safety in the United States. The 1999 Canadian government budgeted \$20 million over 1 year for the creation of the



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- 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



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- **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



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- **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
- **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



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- **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



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- Physician reviewers identified AEs in a total of 255 charts
- Weighted AE rate was 7.5 per 100 hospital admissions
- 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
- However, there is significant morbidity and mortality associated with AEs
 - 5.2% resulted in permanent disability
 - 15.9% resulted in death



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- **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)
- **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



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Interactive

- Participants give examples of how patients are commonly harmed in their hospitals
- Participants suggest potential feasible methods to measure adverse events in their settings



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Summary

- Different methods to measure errors and adverse events have different strengths and weaknesses
 - Direct observation
 - Chart review
 - Clinical surveillance
 - Administrative data analysis
- Comprehensive efforts to measure might include combinations of measurement methods



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Introduction to Patient Safety Research

“Cases” of Patient Safety Research





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- Answer
- 1(XX)
- 2(XX)
- 3(XX)
- 4(XX)



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Thank You