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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.



Components



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

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

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

- A doctor reads 50 hospital charts and counts the number of preventable injuries
- 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
- A trained nurse inspects the abdominal incisions of all post-operative patients and uses a standard form to record potential wound infections.
- Two trained doctors each read the same 50 hospital charts and count the number of patients who developed a wound infection after surgery



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



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*



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



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



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



4 Basic Methods of Collecting Data

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

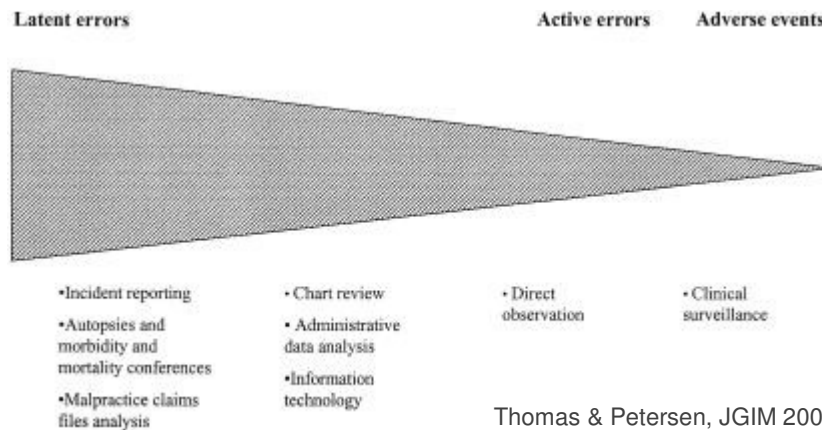


Measurement Methods

- 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



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





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

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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 24h 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 176 activities per patient per day and an estimated number of 1.7 errors per patient per day. For the ICU as a whole, a serious 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 inconvertible disease, but rather as preventable phenomena.



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



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



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



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



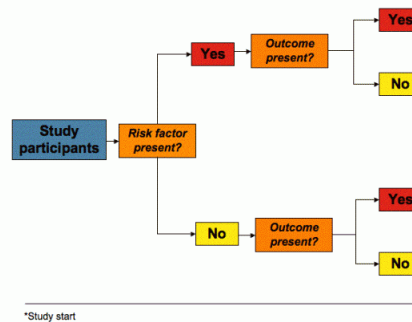
Author Reflections: Lessons and Advice

- 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



Hernandez, et al

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





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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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 completed a pre-operative and post-operative risk survey. Patients who did not undergo surgery at another hospital or who died or were transferred to another hospital within 30 days after surgery were excluded.

RESULTS: Four hundred thirty-eight patients were included. The mean age was 72 years. One hundred thirty-nine patients developed SSI, 31% of whom were classified after discharge. The overall incidence rate (OR) was 26.7%. The OR was 1.19 for clean, 1.59 for clean-contaminated, 11.7% for contaminated, and 22.2% for dirty operations. The OR was 1.04 for NNIS System risk index 0 and 0.93 for index 1. Risk factors for SSI in logistic regression analysis were: dirty or contaminated (OR: 2.5, 95% CI: 1.7-4.0), dirty and longer than 6 days (OR: 6.5, 95% CI: 2.2-19.0), and length of surgery greater than the 75th percentile (OR: 3.1, 95% CI: 1.6-6.4). Patients with SSI had a longer hospital stay than did noninfected patients (16.1 vs. 11.1 days, $P < .001$).

CONCLUSIONS: SSI is a major problem in this hospital, which has a higher OR associated for clean operations than those of developed countries. In developing countries, prevention of SSI should include active surveillance and intervention targeting modifiable risk factors (Infect Control Hosp Epidemiol 2005;30:473-477).

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

Hernandez K, Ramos E, Seas C, Henostroza G, Gotuzzo E. *Infection Control and Hospital Epidemiology* 2005;30:473-477.

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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



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



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



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



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



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



Chart Review

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





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Ross Baker

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



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

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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, nononcologic 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 7.2 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 7.2% 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.

Abstract

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

Objective: To estimate the incidence of adverse events among hospital patients in Canada.

Design: A cross-sectional study of hospital admissions in Canada.

Setting: Five provinces in Canada: British Columbia, Alberta, Ontario, Quebec, and Nova Scotia.

Participants: A random sample of hospital admissions in each province.

Measurements and Main Results: The overall incidence rate of adverse events was 7.2% (95% confidence interval 5.7-9.3). Among patients with adverse events, 36.9% (95% confidence interval 32.0-41.8%) were judged to be preventable. The most common preventable adverse events were falls (11.8%), medication errors (11.5%), and patient identification errors (10.5%).

Conclusion: The incidence of adverse events among hospital patients in Canada is 7.2% (95% confidence interval 5.7-9.3). About 37% of these events are preventable.



- **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



- **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



- **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



- **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



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



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
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- 2(XX)
- 3(XX)
- 4(XX)



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Thank You