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Patient Safety Research Introductory Course

Session 2

Principles of Patient Safety Research: An Overview

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- Professor of Medicine, Harvard Medical School
- Professor of Health Policy and Management, Harvard School of Public Health

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Aim

To focus on the “research” aspect in Patient Safety. Five important domains will be discussed in detail:

1) Measuring harm
2) Understanding causes
3) Identifying solutions
4) Evaluating impact
5) Translating evidence into safer healthcare

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Overview

1) Why Research Is Needed
2) Theory
3) Examples
4) Interactive
5) Conclusions

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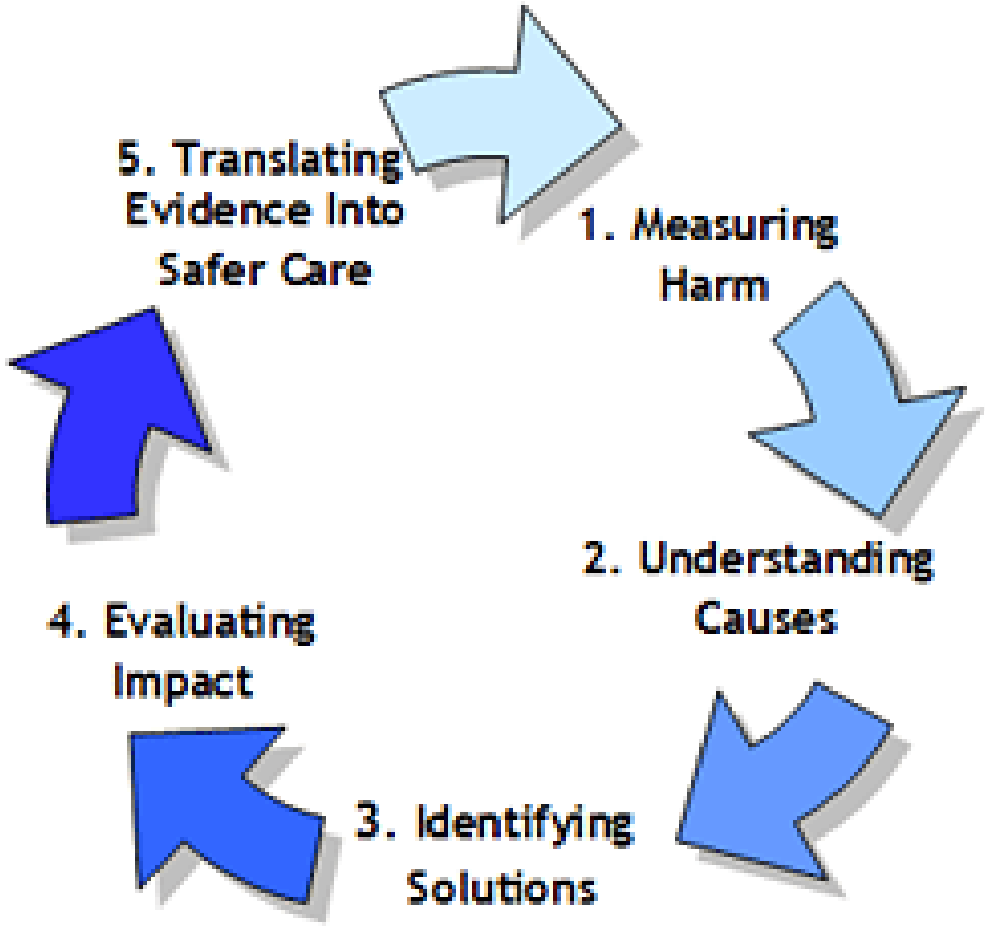
Theory



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Questions for Lecture 2, Principles of Patient Safety Research

(1) Descriptive research is always better than inferential research.
   a. True
   b. False

(2). When is doing qualitative research especially helpful?
   a. When you want to understand the reasons behind a safety issue
   b. When you do not have enough resources to do a large, prospective, quantitative study
   c. both a and b
   d. neither a nor b

(3). When does it make most sense to do an observational research study?
   a. When the human subjects committee requires it
   b. When the magnitude of a problem isn't known
   c. When you want to find out whether or not a solution worked
   d. When you have tested a solution and found that it didn't work well

(4) What is the strongest research design type?
   a. Cross-sectional
   b. Survey
   c. Retrospective
   d. Prospective

Descriptive Research vs. Inferential Research

- Descriptive studies focus on describing phenomena in a specific sample of people, or describing differences between two or more specific samples
  - May find many differences—but what is interpretation?
- Inferential studies study specific samples of people in order to understand how phenomena operate in large groups of individuals
  - Generally more informative in patient safety

Qualitative vs. Quantitative Research

Qualitative	Quantitative
Aim a complete, detailed description	Aim to count features, build statistical models
May know only roughly what looking for	Researcher knows what they are looking for
Best in early phases	Best in later phases
Data in words, pictures, objects	Data in numbers
Rich, time-consuming, less generalizable	More efficient, can test hypotheses, may miss detail

When to Use Qualitative vs. Quantitative

- Qualitative early on, when don't know what are looking for
- Quantitative when want numeric descriptions
- Qualitative can be less expensive—can often get a good sense of safety issues in an organization with this
  - But data are likely to be less persuasive to leadership
- Two approaches are often complementary, especially in evaluation of interventions
  - Quantitative—whether the intervention worked
  - Qualitative—why or why not

Observational Research vs. Interventional

- Observational—typically want to do first, to understand safety problem, specific frequency of problems, potential approaches for addressing them
  - Can get a sense of what "ceiling" is for benefit of intervention
  - Example: doing a study at one hospital to identify adverse events, and to decide what group of adverse events to work on first
- Interventional—to test a solution. Usually have intervention and control groups.
  - Various designs—before-after, on-off, contemporaneous controls
  - Example: studying the surgical checklist in half the surgical services in an organization

Design

- Cross-sectional—single cut at one time through a population
  - Counting the number of adverse events in a hospital on one day
- Retrospective—taking a population, and looking back through a specific period
  - Example: reviewing all deaths for a year
- Prospective—looking forward for a specific period
  - Counting all hospital-acquired infections looking forward with active surveillance over a year

Examples: Measuring Harm—Baker et al

- 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.

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- 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, Adalsteinn Brown, Jafna Cox, Ed Etchells, William A. Ghali, Philip Hébert, Sunvil R. Majumdar, Maeve O'Beirne, Luz Palacios-Derflingher, Robert J. Reid, Sam Sheps, Robyn Tamblyn

See related article page 1678

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CMAJ 2004;170(11)

Patient safety is receiving growing attention in Canada. Numerous legal cases and media stories have highlighted the consequences of unintended adverse events (AEs). In 2002 the Canadian government budgeted $50 million over 5 years for the creation of the 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 at the time of discharge or prolonged hospital stays.[1] Some AEs are the unavoidable consequences of health care, such as an unanticipated allergic reaction to an antibiotic. However, 17%–51% of AEs have been judged in retrospect to have been potentially preventable.[2]

In various countries, hospital chart reviews have revealed that 2.9%–16.6% of patients in acute care hospitals experienced 1 or more AEs.[3–5] 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.[6,7] 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 Harvard Medical Practice Study, which examined the incidence of AEs in New York state hospitals in 1984.[3] The protocol, with modifications, was used in subsequent studies in Australia, the United Kingdom, New Zealand, the United States (in Colorado and Utah) and Denmark.[4,5]

JMAC • 21 MAI 2004; 170 (11)

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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

Background: Study Rationale

- Several US studies indicated 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 was 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."*

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 was significant morbidity and mortality associated with AEs
  - 5.2% resulted in permanent disability
  - 15.9% resulted in death

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)

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

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

Understanding Causes: Andrews

- Objective
  - To enhance understanding of the incidence and scope of adverse events as a basis for preventing them.
- Methods
  - A prospective, observational design analyzing discussion of adverse events during care of all patients admitted to 3 units of a large teaching hospital.
  - Ethnographers attended regularly scheduled meetings of health care providers and recorded and classified all adverse events discussed.
- Results
  - Of the 1047 patients studied, 185 (17.7%) had at least one serious adverse event (linked to the seriousness of the patient's underlying illness).
  - Patients with long stays in hospital had more adverse events; likelihood of an adverse event increased about 6% for each day of hospital stay.
- Conclusion
  - There is a wide range of potential causes of adverse events and particular attention must be paid to errors with interactive or administrative causes.
  - Health-care providers' own discussions of adverse events can be a good source of data for proactive error prevention.

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Introduction: Study Details

- Full Reference
  - Andrews LB, Stocking C, Krizek T, et al. An alternative strategy for studying adverse events in medical care. Lancet. 1997;349:309-313

Link to Abstract (HTML)

Summary

Background Data about the frequency of adverse events related to inappropriate care in hospitals come from studies of medical records as if they represented a true record of adverse events. In a prospective, observational design we analysed discussion of adverse events during the care of all patients admitted to three units of a large, urban teaching hospital affiliated to a university medical school. Discussion took place during routine clinical meetings. We undertook the study to enhance understanding of the incidence and scope of adverse events as a basis for preventing them.

Methods Ethnographers trained in qualitative observational research attended day-shift, weekday, regularly scheduled attending rounds, residents' work rounds, nursing shift changes, case conferences, and other scheduled meetings in three study units as well as various departmental and section meetings. They recorded all adverse events during patient care discussed at these meetings and developed a classification scheme to code the data. Data were collected about health-care providers' own assessments about the appropriateness of the care that patients received to assess the nature and impact of adverse events and how health-care providers and patients responded to the adverse events.

Findings Of the 1047 patients in the study, 185 (17·7%) were said to have had at least one serious adverse event; having an initial event was linked to the seriousness of the patient's underlying illness. Patients with long stays in hospital had more adverse events than those with short

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THE LANCET

An alternative strategy for studying adverse events in medical care

Lori B Andrews, Carol Stocking, Thomas Krizek, Lawrence Gottlieb, Claudette Krizek, Thomas Vargish, Mark Siegler

Summary

Background Data about the frequency of adverse events related to inappropriate care in hospitals come from studies of medical records as if they represented a true record of adverse events. In a prospective, observational design we analysed discussion of adverse events during the care of all patients admitted to three units of a large, urban teaching hospital affiliated to a university medical school. Discussion took place during routine clinical meetings. We undertook the study to enhance understanding of the incidence and scope of adverse events as a basis for preventing them.

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Findings Of the 1047 patients in the study, 185 (17·7%) were said to have had at least one serious adverse event; having an initial event was linked to the seriousness of the patient's underlying illness. Patients with long stays in hospital had more adverse events than those with short stays. The likelihood of experiencing an adverse event increased about 6% for each day of hospital stay. 37·8% of adverse events were caused by an individual, 15·6% had interactive causes, and 9·8% were due to administrative decisions. Although 17·7% of patients experienced serious events that led to longer hospital stays and increased costs to the patients, only 1·2% (13) of the 1047 patients made claims for compensation.

Interpretation This study shows that there is a wide range of potential causes of adverse events that should be considered, and that careful attention must be paid to errors with interactive or administrative causes. Health-care providers' own discussions of adverse events can be a good source of data for proactive error prevention.

Lancet 1997; 349: 309–13

Introduction

Various terms are chosen to designate inappropriate care and adverse outcomes experienced by patients during their hospital care—adverse or untoward events, maloccurrences, complications, medical injuries, therapeutic misadventures, substandard care, unexpected outcomes, preventable deaths, iatrogenic injuries, mishaps, errors, negligence, or malpractice. This range of terms is complemented by an array of definitions chosen to suit the particular goals of the people using them. Within the hospital setting, the assessment of whether a health-care professional's action or inaction is appropriate or not may be undertaken for teaching purposes, for quality assurance purposes, for review of a provider's staff privileges, or to assess the provider's or hospital's potential legal liability. Outside researchers, using various methods, may enter the hospital environment with their own definitions of appropriate care to find out how the management of a particular type of diagnosis or treatment can be improved[1] or to assess the costs of implementing legal changes in the handling of malpractice cases, such as through the adoption of a no-fault system.[2]

In social-policy debates, the many potential definitions

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Background: Study Rationale

- Idea of study was to enhance understanding of the incidence of adverse events as a basis for preventing them
  - Data on frequency of adverse events related to inappropriate care in hospitals often comes from medical records
- However, chart analyses alone may be inadequate to determine the frequency of adverse events
  - Doctors alerted research team to high level of errors in hospitals and described many errors not recorded in patients' records

Methods: Study Design and Objectives

- Design: prospective, observational ethnographic study
  - Ethnographers recorded adverse events incidentally mentioned at regularly scheduled meetings and developed a classification scheme to code the data
- Objectives:
  - To undertake a study of potential adverse events in hospitalized patients and assess the incidence, cause and response to error
  - To develop a deeper understanding of adverse events than what may be available in after-the-fact analysis of medical records and prospective studies examining particular procedures

Methods: Study Population and Setting

- Setting: 3 units at a large, tertiary care, urban teaching hospital in the US
  - During the study there were 1,047 patients in the three units
  - One-third of the patients admitted more then once for a total of 1,716 admissions
- Population: attending surgeons and physicians, fellows, residents, interns, nurses, and other health-care practitioners on ten surgical services

Methods: Data Collection

- Four ethnographers trained in qualitative observational research chronicled discussion of adverse events at regular meetings
  - Each was given a month of additional training to enable them to carry out field work in a medical setting
  - Recorded information about all adverse events in patient care mentioned in discussions at these meetings
  - Did not ask questions or make clinical judgments
- Over a 9-month period ethnographers observed:
  - Attending physician rounds
  - Residents' work rounds
  - Nursing shift changes
  - Case conferences
  - Additional scheduled meetings in three study units
  - Departmental and section meetings

Results: Key Findings

- Patient demographics
  - Patients were evenly distributed by sex and race
  - Source of payment reflected national distribution
- 17.7% (185) patients experienced serious events that led to longer hospital stays and increased costs to the patients
  - 37.8% of adverse events caused by an individual
  - 15.6% had interactive causes
  - 9.8% due to administrative decisions
  - The highest proportion (29.3%) of adverse events occurred during post-operative monitoring and care vs. during surgery itself
- Only 1.2% (13) of patients experiencing adverse events made claims for compensation

Results: Key Findings (2)

- Occurrence of initial adverse event linked to the seriousness of the patient's underlying illness
  - Patients with long hospital stays had more adverse than those with short stays
  - Likelihood of experiencing an adverse event increased about 6% for each day of hospital stay
  - Occurrence of adverse events was broadly unaffected by differences in ethnicity, gender, payer class and age

Author Reflections: Lessons and Advice

- If one thing could be done differently in the study…
  - *"We would fund greater distribution of the results and fund a follow-up study on how to use them to improve care."*
- Advice for researchers
  - *"Researchers should work closely in the development of health care facilities to assure that research on incidence of errors is considered from the beginning."*
- Study is easily adaptable to various settings
  - E.g. such a study could be undertaken by one observer trained in participant observation with a computer and statistics program

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Identifying Solutions: Overview Reggiori

- Methods
  - In a district rural hospital in Uganda, 850 surgical patients evaluated prospectively over a 3-year period to compare the clinical efficacy of:
    - *Conventional postoperative penicillin therapy with single-dose ampicillin prophylaxis for hernia repair and ectopic pregnancy, and with*
    - *Single-dose ampicillin-metronidazole prophylaxis for hysterectomy and caesarean section.*
- Results
  - High rate of postoperative infection after conventional treatment with penicillin for 7 days was significantly reduced with the new regimen: .
  - Length of stay and postoperative mortality rates also significantly reduced.
- Conclusion
  - Single-dose ampicillin prophylaxis with or without metronidazole, although rarely used in developing countries, is more cost effective than standard penicillin treatment.

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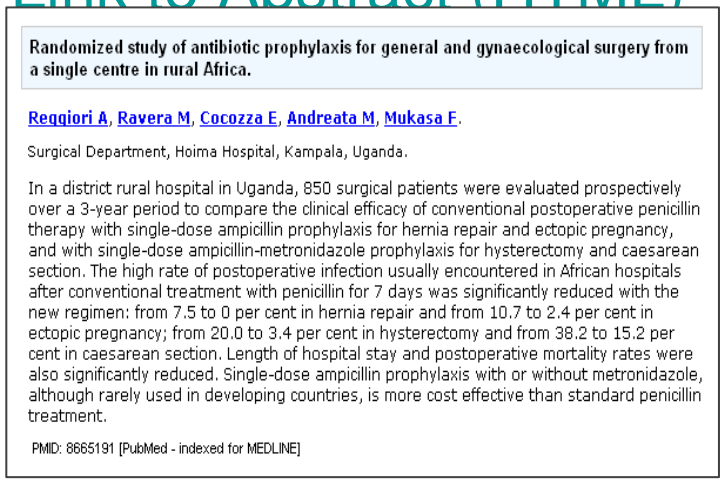
Introduction: Study Details

Reggiori A et al. Randomized study of antibiotic prophylaxis for general and gynaecological surgery from a single centre in rural Africa. British Journal of Surgery, 1996, 83:356–359

Link to Abstract (HTML)



Randomized study of antibiotic prophylaxis for general and gynaecological surgery from a single centre in rural Africa.

Reggiori A, Ravera M, Cocozza E, Andreata M, Mukasa F.

Surgical Department, Hoima Hospital, Kampala, Uganda.

In a district rural hospital in Uganda, 850 surgical patients were evaluated prospectively over a 3-year period to compare the clinical efficacy of conventional postoperative penicillin therapy with single-dose ampicillin prophylaxis for hernia repair and ectopic pregnancy, and with single-dose ampicillin-metronidazole prophylaxis for hysterectomy and caesarean section. The high rate of postoperative infection usually encountered in African hospitals after conventional treatment with penicillin for 7 days was significantly reduced with the new regimen: from 7.5 to 0 per cent in hernia repair and from 10.7 to 2.4 per cent in ectopic pregnancy; from 20.0 to 3.4 per cent in hysterectomy and from 38.2 to 15.2 per cent in caesarean section. Length of hospital stay and postoperative mortality rates were also significantly reduced. Single-dose ampicillin prophylaxis with or without metronidazole, although rarely used in developing countries, is more cost effective than standard penicillin treatment.

PMID: 8665191 [PubMed - indexed for MEDLINE]

Link to Full Text

Can be ordered online at:

http://www.bjs.co.uk

Background: Opening Points

- Postoperative wound and deep infection remains a major concern in developing countries
  - In sub-Saharan Africa, records of postoperative infections are rare and few studies are available
  - Nonetheless, infection rates as high as 40-70% have been observed
- Poor conditions in hospitals may contribute to the high rate of postoperative infection
  - Poor sterility and hygiene of operating theatres and wards
  - Lack of trained personnel
  - Emergency surgical procedures often performed on patient presenting late in the course of the illness

Methods: Study Design and Objectives

- Design: randomized clinical trial
- Objectives:
  - To compare the clinical effectiveness of conventional postoperative penicillin therapy with single-dose ampicillin prophylaxis for hernia repair and ectopic pregnancy
  - To compare the clinical effectiveness of conventional postoperative penicillin therapy with single-dose ampicillin-metronidazole prophylaxis for hysterectomy and caesarean section
  - To measure the impact of different antimicrobial regimes on factors such as duration of postoperative stay and cost of care

Results: Key Findings

- Ampicillin regime significantly reduced the incidence of postoperative infection compared with conventional treatment with penicillin:
  - From 7.5 to 0% after hernia repair
  - From 10.7 to 2.4% after surgery for ectopic pregnancy
  - From 20 to 3.4% after hysterectomy
  - From 38.2 to 15.2 % after caesarean section
- Patients receiving ampicillin also experienced significant reductions in:
  - Length of hospital stay
  - Postoperative mortality rates
  - Post-operative complications for patients with invasive surgeries (hysterectomy and caesarean)

Results: Cost Analysis

- Average cost for an admission day in Hoima Hospital in 1992 was $3 USD, inclusive of personnel cost, drug, supplies and utilities
- Cost savings with new regimes
  - Ampicillin-metronidazole regimens were cheaper than the full penicillin course
  - Duration of postoperative stay was shorter for both groups of patients receiving ampicillin prophylaxis

Conclusion: Main Points

- Postoperative infection rates in developing countries are often underestimated and undocumented
- High postoperative infection rates can be significantly reduced, even in settings with resource constraints
  - Antibiotic prophylaxis with ampicillin is effective in reducing the postoperative morbidity rate in clean general surgery and gynaecology operations
  - Single-dose ampicillin prophylaxis, though rarely used in developing countries, is more cost effective than standard penicillin treatment

Author Reflections: Lessons and Advice

- What barriers or problematic issues did you encounter when setting up the research and how did you overcome them?
  - *"We faced challenges changing the behaviour and habits of paramedical staff.*
  - *We convinced them by showing them that the infection rate was really different between the two regimes and that their work could be made easier."*
- Research is feasible and applicable in other developing countries
  - *"It is applicable everywhere because it is very simple and the result is to again simplify patient care. No technology or sophisticated items*

Author Reflections: Ideas for Future Research

- Message for future researchers from developing countries
  - *"Try always to find new ways to improve patients care. Don' be satisfied with what you know already and learn from others."*
- Recommendation for future research project
  - *"To analyze the importance of the human factor (doctors, nurses, etc) in patients care and to identify the most crucial aspects."*

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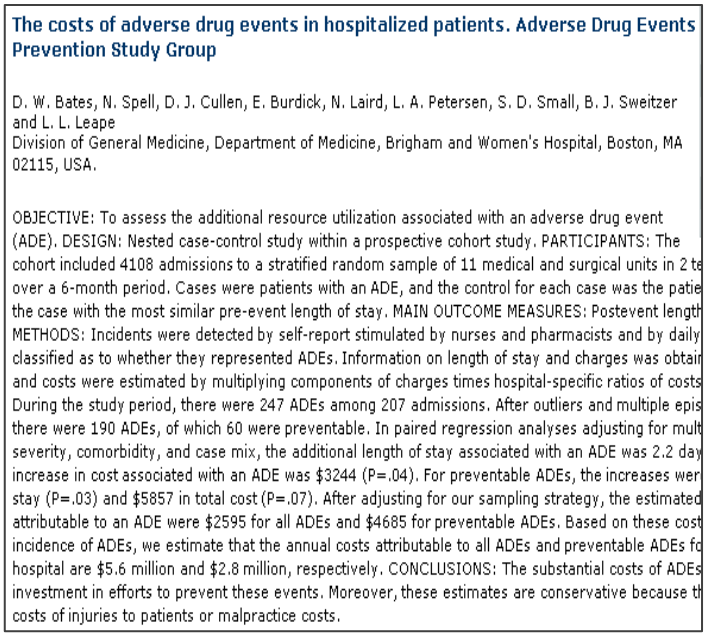
Evaluating Impact: Study Details

- Full Reference

  - Bates DW, Spell N, Cullen DJ, et al. The costs of adverse events in hospitalized patients. JAMA 1997;277:307-11

Link to Abstract (HTML)



The costs of adverse drug events in hospitalized patients. Adverse Drug Events Prevention Study Group

D. W. Bates, N. Spell, D. J. Cullen, E. Burdick, N. Laird, L. A. Petersen, S. D. Small, B. J. Sweitzer and L. L. Leape
Division of General Medicine, Department of Medicine, Brigham and Women's Hospital, Boston, MA 02115, USA.

OBJECTIVE: To assess the additional resource utilization associated with an adverse drug event (ADE). DESIGN: Nested case-control study within a prospective cohort study. PARTICIPANTS: The cohort included 4108 admissions to a stratified random sample of 11 medical and surgical units in 2 te over a 6-month period. Cases were patients with an ADE, and the control for each case was the patie the case with the most similar pre-event length of stay. MAIN OUTCOME MEASURES: Postevent length METHODS: Incidents were detected by self-report stimulated by nurses and pharmacists and by daily classified as to whether they represented ADEs. Information on length of stay and charges was obtain and costs were estimated by multiplying components of charges times hospital-specific ratios of costs During the study period, there were 247 ADEs among 207 admissions. After outliers and multiple epis there were 190 ADEs, of which 60 were preventable. In paired regression analyses adjusting for mult severity, comorbidity, and case mix, the additional length of stay associated with an ADE was 2.2 day increase in cost associated with an ADE was $3244 (P=.04). For preventable ADEs, the increases wer stay (P=.03) and $5857 in total cost (P=.07). After adjusting for our sampling strategy, the estimated attributable to an ADE were $2595 for all ADEs and $4685 for preventable ADEs. Based on these cost incidence of ADEs, we estimate that the annual costs attributable to all ADEs and preventable ADEs fo hospital are $5.6 million and $2.8 million, respectively. CONCLUSIONS: The substantial costs of ADEs investment in efforts to prevent these events. Moreover, these estimates are conservative because th costs of injuries to patients or malpractice costs.

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Not currently available online

Background: Study Rationale

- Due to the ongoing economic crisis in US hospitals, only cost-effective quality improvement efforts are likely to be pursued
  - To reduce the cost of adverse drug events, the cost of these events must first be defined
- Research team wanted to be able to justify investing in interventions to reduce ADE frequency
  - Lots of scepticism, especially on the part of Chief Financial Officers

Methods: Study Design

- Design: cost analysis using a nested control study within a prospective cohort study
  - Incidents detected by self-report by nurses and pharmacists and chart review and classified if reporting an ADE
  - Data on length of stay and charges obtained from billing data and estimated costs targeted for analysis

Methods: Data Collection

- Three methods of data collection:
  - Passive data collection: nurses and pharmacists reported incidents
  - Active data collection: nurse investigators solicited information from personnel regarding ADEs twice daily
  - Chart review: nurse investigators reviewed charts daily
- Types of data collected:
  - Patient data: demographics, primary insurer and impact of adverse drug event during hospitalization
  - Outcome variables: length of stay and total charges

Results: Key Findings

- Length of stay increased by 2.2 days for all ADEs and 4.6 days for preventable ADEs
- Total costs increased by $3244 for all ADEs and $5857 for preventable ADEs

Conclusion: Main Points

- Substantial costs of adverse drug events to hospitals should provide incentives to invest in efforts to prevent these events
  - Estimates found in this study are conservative since they do not include the cost of injuries to patients or malpractice costs
- Hospitals can justify devoting additional resources to develop systems that reduce the number of preventable ADEs
  - Not only improves patient care but also to reduces ADE-related expenses

Author Reflections: Lessons and Advice

- Advice for researchers
  - Consider adding an economic evaluation to primary safety epidemiological studies - expensive part is finding adverse events
  - Serious lack of data on these sorts of costs in different countries and settings - more data is desperately needed
- This kind of work is especially needed for developing countries in which resources tend to be scarce
  - Research feasible any time a group is collecting primary data about adverse events AND has access to cost or resource utilization data
    - *Not an easy combination to identify!*

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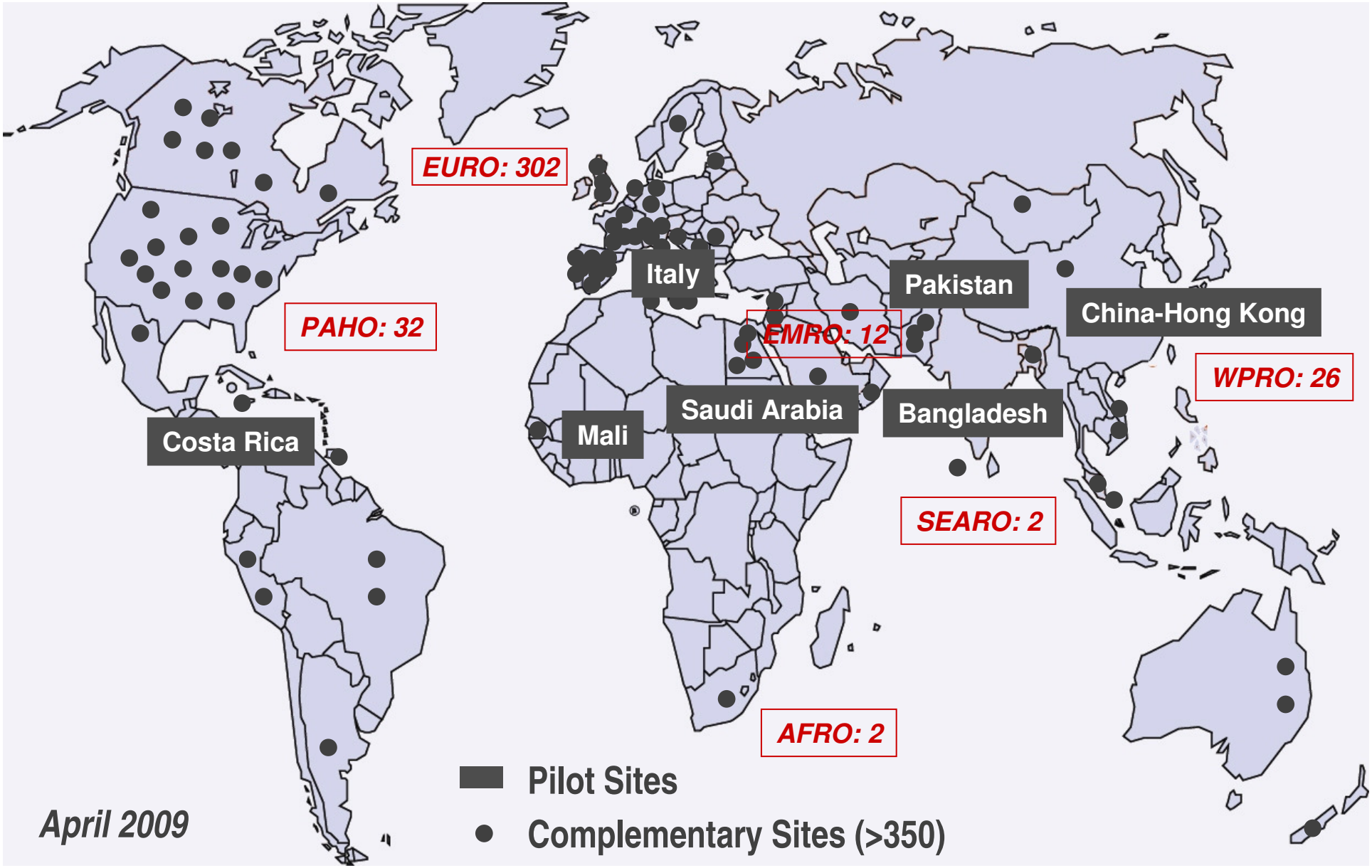
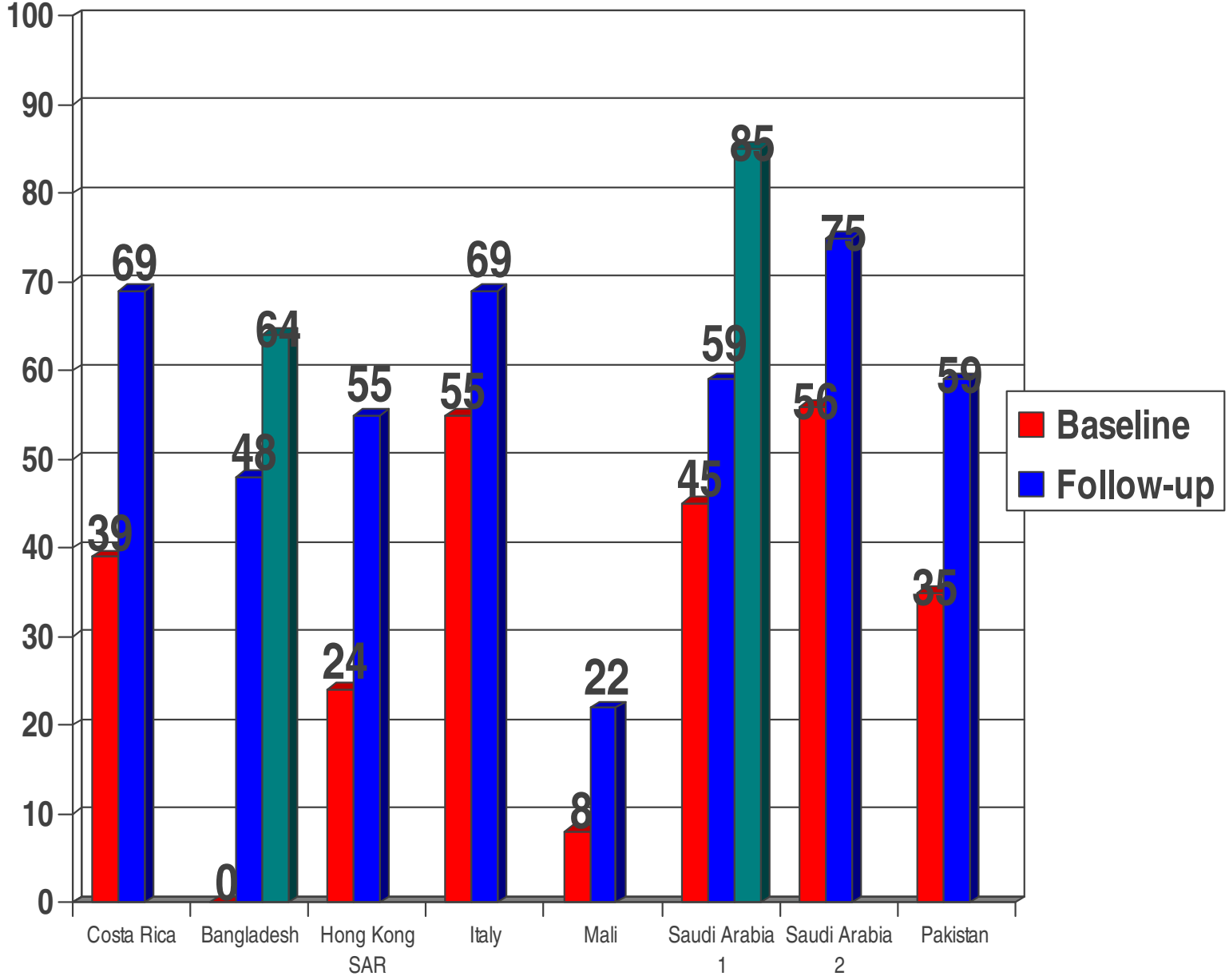
Translating Evidence Into Practice

- Clean Care Is Safer Care
  - Handwashing using alcohol-based handrub

Field Testing of the WHO Guidelines on Hand Hygiene in Health Care (2006-2008)



Hand Hygiene Compliance Improvement in Pilot Sites



Interactive

- Participant reports of research projects currently involved in or considering

References

- Primer: Hulley SB, Browner W, Cummings SR et al. Designing Clinical Research: an epidemiologic approach. 3rd ed. LWW 2006
- Brown C, Hofer T, Johal A, Thomson R, Nicholl J, Franklin BD, Lilford RJ. An epistemology of patient safety research: a framework for study design and interpretation. Parts 1-4. Qual Saf Health Care. 2008.
- Full descriptions of more classic research studies on World Alliance website

  http://www.who.int/patientsafety/research/en/

Conclusions

- Five key domains in patient safety research
  - Selection of study type will depend on domain
  - Also on resources available
  - Qualitative and quantitative studies are both valuable
- Need more evaluations of solutions in particular
  - But often have to define problem in a particular setting and having data can enable move to action

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Answer: Questions for Lecture 2, Principles of Patient Safety Research

(1) Descriptive research is always better than inferential research.

b. False

(2). When is doing qualitative research especially helpful?

c. both a and b

(3). When does it make most sense to do an observational research study?

b. When the magnitude of a problem isn't known

(4) What is the strongest research design type?

d. Prospective

Thank You

Thank You