



**World Health
Organization**

Patient Safety

A World Alliance for Safer Health Care

Case Series: Introduction to Patient Safety Research

Presentation 5 - Measuring Harm: Prospective Cohort Study



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3: Introduction: Study Details

■ Full Reference

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 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

13.0% for clean, 15.0% 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 contaminated 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;36:473-477).

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

Esteban Hernandez, MD, Elizabeth Seas, MD, Carlos Seas, MD, Gerardo Henostroza, MD, Ezequiel Gotuzzo, MD

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

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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 (*Am J Epidemiol* 2005;162:473-477).

Non-infectious 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 considered among 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, their cause significant morbidity. Approximately 550,000 episodes of SSI occur in the United States every year, accounting for 1.7 million excess 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 is the oldest and largest cooperative surveillance system for SSI and hospital-acquired infections. It has been shown in NNIS System hospitals that SSI rates are decreasing, emphasizing the importance of implementing such programs.^{4,5} In Peru and many other developing countries, few 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 misperception that nosocomial infections are uncommon. Consequently, reports about the incidence of SSI risk factors for acquiring 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 on such a study would permit comparison of the incidence of SSI within this other hospital to the region and abroad and would help when designing interventions to reduce the length of hospital stay and associated costs.

METHODS

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

4: Introduction: Research Team

- **Head researcher - Dr. Carlos Seas, MD, MSc**
 - Associate Professor, Department of Medicine
 - Universidad Peruana Cayetano Heredia in Lima, Peru
 - Field of expertise: infectious diseases, tuberculosis, enteric infections
- **Other team members:**
 - Katherine Hernandez, MD
 - Rocio Ramos, MD
 - German Henostroza, MD
 - Eduardo Gotuzzo, MD



5: Background: Opening Points

- Nosocomial infections are a major public health problem worldwide
- Surgical-site infections (SSIs) are ranked among the most common nosocomial infections, along with pneumonia, urinary tract infections, and bloodstream infections
- Approximately 500,000 episodes of SSI occur in the United States every year
 - Accounts for more than 3.7 million excess hospital days
 - Leads to more than 1.6 billion dollars of extra hospital charges

6: Background: Opening Points (2)

- **Centers for Disease Control and Prevention (CDC) National Nosocomial Infections Surveillance (NNIS) System is the oldest and largest organization collecting data regarding hospital-acquired infections**
 - Significant reductions in hospital-acquired infections have been observed in NNIS System hospitals since it began operating, emphasizing the importance of implementing such programs

Background: Study Rationale

- Few hospitals in Peru and other developing countries have surveillance programs for nosocomial infections
- This is likely due to:
 - Lack of national policies and protocols regarding the issue
 - Scarce human and fiscal resources
 - Misconception that nosocomial infections are uncommon
- There is little data on the incidence of and risk factors for acquiring SSI in these countries
 - Such data could permit regional and international hospital comparisons and help design intervention studies for hospitals in developing countries with scant resources

8: Background: Study Rationale (2)

- The idea for the study came after observing a high rate of surgical site infections in the hospital
 - No data on this issue were available from the hospital
 - There was a need to determine the incidence and associated factors for these infections
 - Rate of infection clearly higher than initially thought
- Study hospital had created an infection control committee by the time study started, but no active surveillance for infections was being performed on a regular basis

9: Background: Setting up a Research Team

- A group of young and vibrant recently graduated physicians with the necessary competencies were recruited for the study
 - Not difficult to find collaborators with the relevant competencies
 - Statistical advice was requested from the university
- **Obtaining funding**
 - Study required a low budget
 - Applied for and received the necessary funds to conduct the study from the university

10: Study Design: Objectives

- **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

11: 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

12: Methods: Study Setting and Population

■ Setting:

- Study conducted at the Hospital Nacional Cayetano Heredia, a 400-bed, tertiary-care hospital affiliated with the Universidad Peruana Cayetano Heredia
- Hospital has 86-bed surgery ward and a 4-bed surgical intensive care unit performing about 200 surgical interventions a month

■ 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

13: Methods: Data Collection

- **Two physicians were trained to interview and observe patients during their hospitalization, searching daily for SSI and potential risk factors**
 - Clinical charts were systematically reviewed and, if necessary, the medical staff in charge of a patient were interviewed
 - Data regarding SSI were obtained from all patients daily during their hospitalization and until 30 days after surgical intervention
 - Surgical interventions were categorized according to the injured organ
 - No attempt was made to isolate microbes from the surgical wounds

14: Methods: Data Collection (2)

- **A form was devised 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

16: Methods: NNIS System Risk Index

- **NNIS System risk index (ranging from 0 to 3) was calculated based on three risk factors, each worth one point:**
 - Contaminated or dirty surgical wound
 - ASA score greater than 2
 - Duration of surgery greater than the 75th percentile for a specific group of surgical procedures

17: Methods: Data Analysis and Interpretation

- **Data were analyzed using SPSS v.10.0.7 software**
 - A P value of less than .05 was considered significant, and all tests were two-tailed
 - Relative risks and 95% confidence intervals were calculated using Epi-Info software
- **Analysis**
 - A logistic regression analysis was performed to identify independent predictors for the development of SSI
 - Variables that attained a P value of less than .1 on univariate analysis were included in stepwise fashion in the multivariate analysis

18: 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**

19: Results: Key Findings (2)

- **When cases were grouped by wound classification, there were:**
 - 7.7% clean
 - 14.7% clean-contaminated
 - 39.5% contaminated
 - 38% dirty
- **Incidence of SSI significantly higher for dirty wounds:**
 - 13.9% for clean
 - 15.9% for clean-contaminated
 - 13.5% for contaminated
 - 47.2% for dirty
 - Incidence was 3.6% for NNIS System risk index 0 (lowest risk) and 60% for index 3 (highest risk)

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, which merits further exploration**

21: Conclusion: Discussion

- **In developing countries, prevention of SSI should include active surveillance and interventions targeting modifiable risk factors**
 - **Specific risk factors such as length of surgery and prolonged use of drains may be targeted for intervention through:**
 - Standards for duration of surgical procedures and adherence to written protocols
 - Surgical staff training and direct supervision of trainees
 - Type of drain used and duration of drainage

22: Conclusion: Study Impact

- **Academic impact**
 - Findings were published in one of the most prestigious journals in the field of nosocomial infections
- **Practice impact**
 - Findings were presented in national meetings to increase awareness of the problem
- **Policy impact**
 - Regular surveillance for SSIs was implemented at the hospital
- **Patient impact**
 - One year after implementing the surveillance and prevention program, there was a decrease in the incidence of SSIs in the hospital

23: Conclusion: Practical Considerations

- **Study duration**
 - One year from conception to write-up
- **Cost**
 - \$1000 USD
- **Additional resources: minimal**
 - Two computers, statistical program, statistical advice at the university
- **Required competencies**
 - Clinical expertise, statistical knowledge
- **Ethical approval**
 - Took two months to obtain

24: Author Reflections: Overcoming Barriers

- **Main obstacle was obtaining permission from the surgical unit in the hospital to conduct the study**
 - Perception amongst surgeons that the research was intended to show that their work was not following international standards
 - Difficult to convince hospital authorities to grant approval for the study (though approval was eventually obtained)

25: Author Reflections: Lessons and Advice

- Researchers should promote multidisciplinary research teams
 - *"If the study could be repeated, it would have been desirable to incorporate surgeons into the study team."*
- *"Clinical findings at the bedside may promote research to answer specific questions about clinical encounters."*

26: Author Reflections: Selecting Study Design

- Since the primary objective was to calculate the incidence of surgical site infections, a cohort study was the most appropriate design to meet this objective
- Other possible study designs:
 - Cross-sectional study could provide incidence of SSI at the hospital at one point in time and are cheaper than other types of studies
 - Case-control study useful for identifying risk factors for these infections

27: Conclusion: Ideas for Future Research

- **May be useful to establish an international network in developing countries to study SSIs and their determinants**
 - **Multi-centric studies to get information on a more regional scale**
 - **Evaluation of knowledge and attitudes towards surgical site infections**
 - **Role of MRSA in surgical site infections**