Introduction to Patient Safety Research

Presentation 7 - Understanding Causes: Ethnographic Study

Better Knowledge for Safer Care

2: Table of Contents

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3: Overview

- **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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4: 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)   Link to Full Text (PDF)

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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5: Introduction: Patient Safety Research Team

- **Lead researcher - Lori B. Andrews, JD**
  - **Director and Law Professor, Institute for Science, Law & Technology**
  - **Chicago-Kent College of Law in Chicago, USA**
  - **Field of expertise: law and policy**
- **Other team members:**
  - **Carol Stocking, PhD**
  - **Thomas Krizek, MD**
  - **Lawrence Gottlieb, MD**
  - **Claudette Krizek, JD**
  - **Thomas Vargish**
  - **Mark Siegler, MD**

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6: Background: Opening Points

- **True incidence of adverse events in medical settings not known**
  - **Various studies often report different rates of adverse events depending on their chosen methodology and data source**
  - **Retrospective study of medical records is often the most commonly used study method**
- **Many potential data sources to record and study the incidence of adverse events in hospital settings**
  - **Medical records review one of the most commonly used sources**
  - **However, records often incomplete, sparking an interest in approaching the study of adverse events with different methodology**

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7: 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

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8: Background: Setting Up a Research Team

- ## Selecting collaborators
  - Effectiveness of study relied on the outside observation of health-care providers
  - Ethnographers trained in qualitative observational research chosen to attend regularly scheduled meetings and rounds to collect data on adverse events in medical care
  - Data collected analyzed by members of legal, medicine and surgical departments at a major American research university

- ## Funding
  - Obtained from a medical malpractice study fund at the Robert Wood Johnson Foundation

9: 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**

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10: Methods: Study Population and Setting

- <u>Setting</u>: 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
- <u>Population</u>: attending surgeons and physicians, fellows, residents, interns, nurses, and other health-care practitioners on ten surgical services

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11: 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**

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12: Methods: Data Analysis and Interpretation

- **After data had been collected for two months, an event classification scheme was developed**
  - **368 specific categories of incidents met the study definitions of adverse events and were grouped into nine large areas:**
    - Diagnosis, surgery, anaesthesia, treatment, nutrition problems, drugs, monitoring and daily care, complications and other
  - **Observers double coded sets of data forms regularly at first, then intermittently, to ensure consistency in classifying events and other information**

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13: 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**

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14: 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, payor class and age**

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15: Conclusion: Main Points

- **There are a wide range of potential causes of adverse events that should be considered**
  - **Careful attention must be paid to errors with interactive or administrative causes**
- **Healthcare providers' own discussions of adverse events can be a good source of data for proactive error prevention**

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16: Conclusion: Study Impact

- **Academic impact**
  - Research published in top medical and law journals and in health administration publications
  - Study featured during speeches at legal and medical meetings and taught in law schools across the country
- **Policy impact**
  - Research used by the US National Academy of Sciences in proposing policy
- **Practice impact**
  - Study subject of presentations at numerous national medical meetings and many doctors aware of this study

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17: Conclusion: Practical Considerations

- **Study duration: 27 months**
  - **Study design: 9 months**
  - **Data collection: 9 months**
  - **Analysis: 9 months**
- **Cost**
  - **Over $1 million USD**
- **Required resources**
  - **Team of four ethnographers and three people performing statistical analyses using computers and statistical software.**
  - **Access to hospital information systems, patient charts, incident report forms, potential claim files, claim files, complaint letters from patients, and patient request forms**
- **Ethical approval**
  - **Took 3 months to obtain**

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18: 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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19: Author Reflections: Selecting Design

- **Alternative approaches**
  - **Observers could have been chosen from a field other than ethnography**
  - **Study of medical records could also have been undertaken to record the occurrence of adverse events**
    - However, this method underreports the frequency of errors in hospitals
- **Particular method chosen because of research team's concern about underreporting**
  - **Research team judged the chosen design to give stronger ability to study response errors and other variables**

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20: Author Reflections: Overcoming Barriers

- **Challenge**
  - An initial barrier was the determination of who could say when an adverse event occurred
    - Medical resident, ethnographer, etc?
    - Pros and cons to each type of observer
- **Solution**
  - Barrier was overcome by using ethnographers to record events as adverse events when the health care providers themselves called them adverse events

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21: Author Reflections: Ideas for Future Research

- **Recommendations for future research in developing countries**
  - *"If the country is moving toward computerized medical records, research on how erroneous information can enter a patient's record, be difficult to remove, and compromise patient care."*

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22: Additional References

- "Studying Medical Error *in Situ*: Implications for Malpractice Law and Policy," 54 DePaul Law Review 357 (2005).

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