World Health Organization | Patient Safety

A World Alliance for Safer Health Care

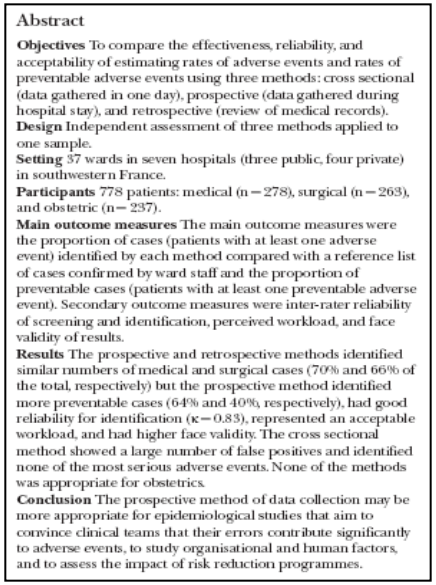
Introduction to Patient Safety Research

Presentation 4 - Measuring Harm: Method Comparison

2: Introduction: Study Details

- **Full reference**
  - **Michel P, Quenon JL, de Sarasqueta AM, Scemama O. Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals. BMJ, 2004, 328;199**

Link to Abstract (HTML)



Abstract

Objectives To compare the effectiveness, reliability, and acceptability of estimating rates of adverse events and rates of preventable adverse events using three methods: cross sectional (data gathered in one day), prospective (data gathered during hospital stay), and retrospective (review of medical records).
Design Independent assessment of three methods applied to one sample.
Setting 37 wards in seven hospitals (three public, four private) in southwestern France.
Participants 778 patients: medical (n=278), surgical (n=263), and obstetric (n=237).
Main outcome measures The main outcome measures were the proportion of cases (patients with at least one adverse event) identified by each method compared with a reference list of cases confirmed by ward staff and the proportion of preventable cases (patients with at least one preventable adverse event). Secondary outcome measures were inter-rater reliability of screening and identification, perceived workload, and face validity of results.
Results The prospective and retrospective methods identified similar numbers of medical and surgical cases (70% and 66% of the total, respectively) but the prospective method identified more preventable cases (64% and 40%, respectively), had good reliability for identification (κ=0.83), represented an acceptable workload, and had higher face validity. The cross sectional method showed a large number of false positives and identified none of the most serious adverse events. None of the methods was appropriate for obstetrics.
Conclusion The prospective method of data collection may be more appropriate for epidemiological studies that aim to convince clinical teams that their errors contribute significantly to adverse events, to study organisational and human factors, and to assess the impact of risk reduction programmes.

Link to Full Text (PDF)

Papers

Comparison of three methods for estimating rates of adverse events and rates of preventable adverse events in acute care hospitals

Abstract

Introduction

Methods

3: Introduction: Patient Safety Research Team

- **Head researcher – Dr. Philippe Michel, PhD**
  - Director, Comité de Coordination de l'Evaluation Clinique et de la Qualité en Aquitaine (CCECQA) or (Regional Centre for Quality and Safety) in Bordeaux, France
  - Field of expertise: patient safety
- **Other team members**
  - Jean Luc Quenon
  - Anne Marie de Sarasqueta
  - Olivier Scemama

4: Background: Opening Points

- There are many different methods of estimating the rates of adverse events in hospital settings. Three of these methods are:
  - Cross-sectional studies
  - Prospective studies
  - Retrospective studies
- Retrospective review of medical records is considered the gold standard for estimating extent of medical injuries in hospitals
  - However, there are limitations with the retrospective method, so alternative methods are needed
    - E.g. Not optimal for assessing impact of risk reduction programs or studying organizational and human factors

5: Background: Study Rationale

- **Accurately estimating the rate of adverse events and near misses is important for meeting objectives such as:**
  - **Assessing the baseline level of the problem**
  - **Evaluating the impact of risk reduction strategies**
  - **Studying the potential of organizational and human factors for reducing patient harm**

6: Background: Setting Up a Research Team

- CCECQA represents a national team of leading experts in patient safety research
  - Represents many areas of expertise, such as drug adverse events, nosocomial infection, surgery related adverse events, etc.
- Study commissioned by the Ministry of Health in France
  - CCECQA chosen to conduct the study because they possessed the necessary technical expertise (methodology, biostatistics, etc.)
  - Ministry of Health provided all necessary funding

7: Methods: Study Design

- Design: independent assessment of three methods for estimating rates of adverse events applied to one sample
  - *"Preferred by the French scientific and political communities because the method involved the field workers and because we were able to better analyse the errors and contributing factors."*

8: Methods: Study Objectives

- **Objectives**
  - **To compare the effectiveness, reliability, and acceptability of three different methods for estimating the rates of adverse events and preventable adverse events:**
    - Cross sectional (data gathered in one day)
    - Prospective (data gathered during hospital stay)
    - Retrospective (review of medical records)

9: Methods: Study Population and Setting

- Population: sample of inpatients in medical, surgical, and obstetric wards in acute care hospitals in Aquitaine, France
  - 37 wards (15 medical, 14 surgical, 8 obstetric) selected in 3 public and 4 private hospitals
  - Study included 778 patients: 278 in medicine, 263 in surgery and 237 in obstetrics
- Sample obtained by two stage cluster stratified process
  - For each hospital in each stratum, wards were selected proportional to the number of hospital beds (proportional allocation)
  - Three fully qualified doctors in each ward identified cases (one for each method)

10: Methods: Data Collection

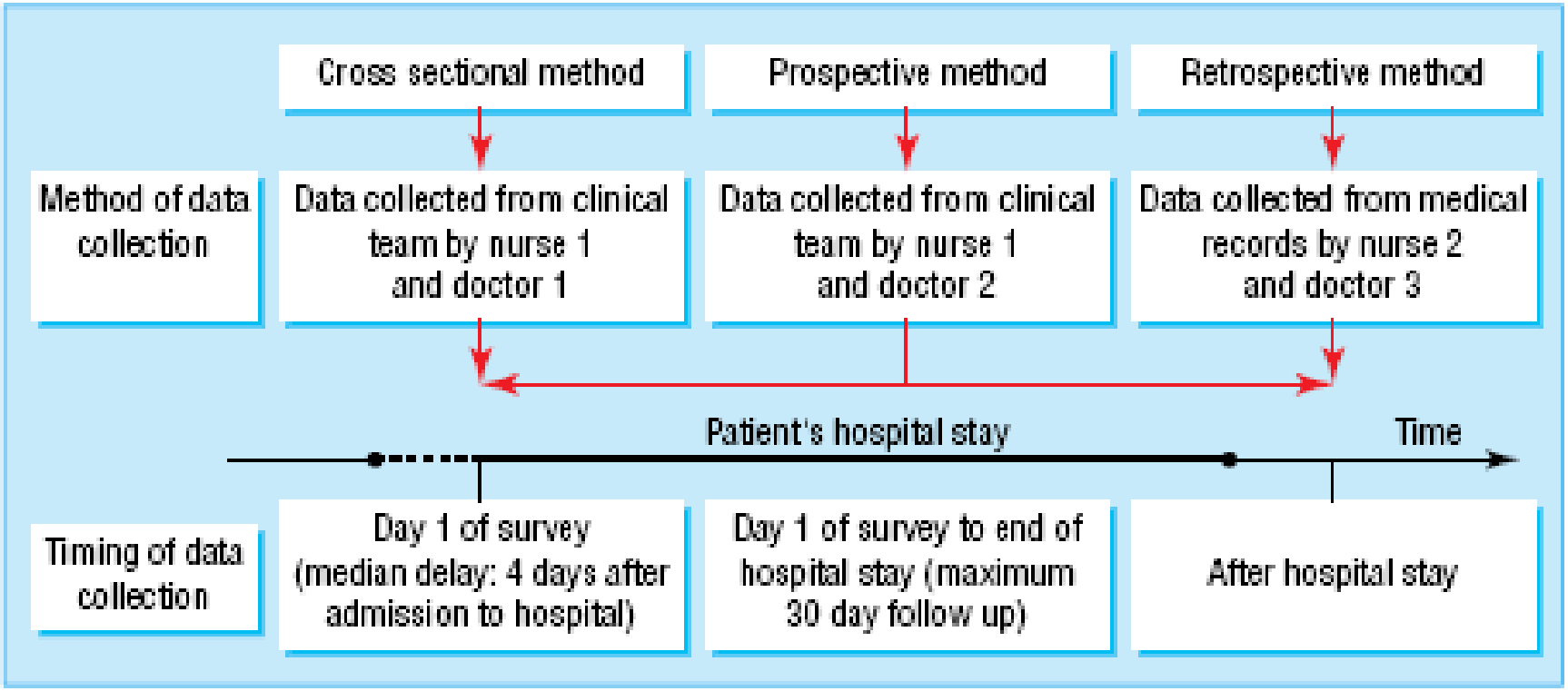
- Complementary questionnaires adapted from an English survey
  - One for detection of adverse events by nurses and midwives
  - One for confirmation of adverse events by doctors
- Independent investigators consecutively applied the three methods to the sample
  - Each questionnaire was used three times, once for each method

11: Methods: Data Collection (2)

- **Cross-sectional**
  - At recruitment, investigators interviewed the head nurse and consulted medical records to detect adverse events
  - If patients screened positive, investigators interviewed the doctor who managed the patient for confirmation of the adverse event
- **Prospective**
  - Detection investigators visited the ward on day 1 of the survey, twice in the 1st week and then weekly up to 4 weeks
  - Cases detected then confirmed by investigators on a weekly basis up to day 30 or discharge
- **Retrospective**
  - Review of medical records began on day 30 of the study using detection and confirmation questionnaires

12: Methods: Data Collection (3)

Fig 1: Method and timing of data collection



13: Methods: Data Analysis and Interpretation

- **Effectiveness of methods determined by the proportion of cases identified in relation to a reference list based on adverse events identified by any one of the three methods**
  - **Proportion of preventable cases detected by each method calculated in relation to this reference list**
  - **Compared effectiveness of the prospective and retrospective methods for identifying cases and preventable cases (Chi-square)**

14: Results: Key Findings

- Prospective and retrospective methods identified similar numbers of medical and surgical AEs (70% and 66%, respectively)
  - Not all cases overlapped, thus both methods are needed to identify a higher proportion of cases
  - Prospective method identified more preventable cases (64% versus 40%), had good reliability, had an acceptable workload, and had higher face validity
- Cross sectional method had a large number of false positives, identified cases that were also found with the other methods and identified none of the most serious adverse events
- None of the methods was appropriate for obstetrics

15: Results: Reference List

- 254 adverse events were identified by at least one of the three different methods
  - 13 adverse events were excluded as false positives, i.e. not truly adverse events (12 by cross sectional and 1 by retrospective)
- Final reference list included 241 adverse events in 174 patients
  - Medicine: 180 adverse events in 80 patients
  - Surgery: 114 adverse events in 80 patients
  - Obstetrics: 17 adverse events in 14 patients
- Nearly one third of patients experienced more than one AE
  - 70% experienced one event
  - 22% experience two events
  - 8% experienced three events

16: Results: Identification Rates

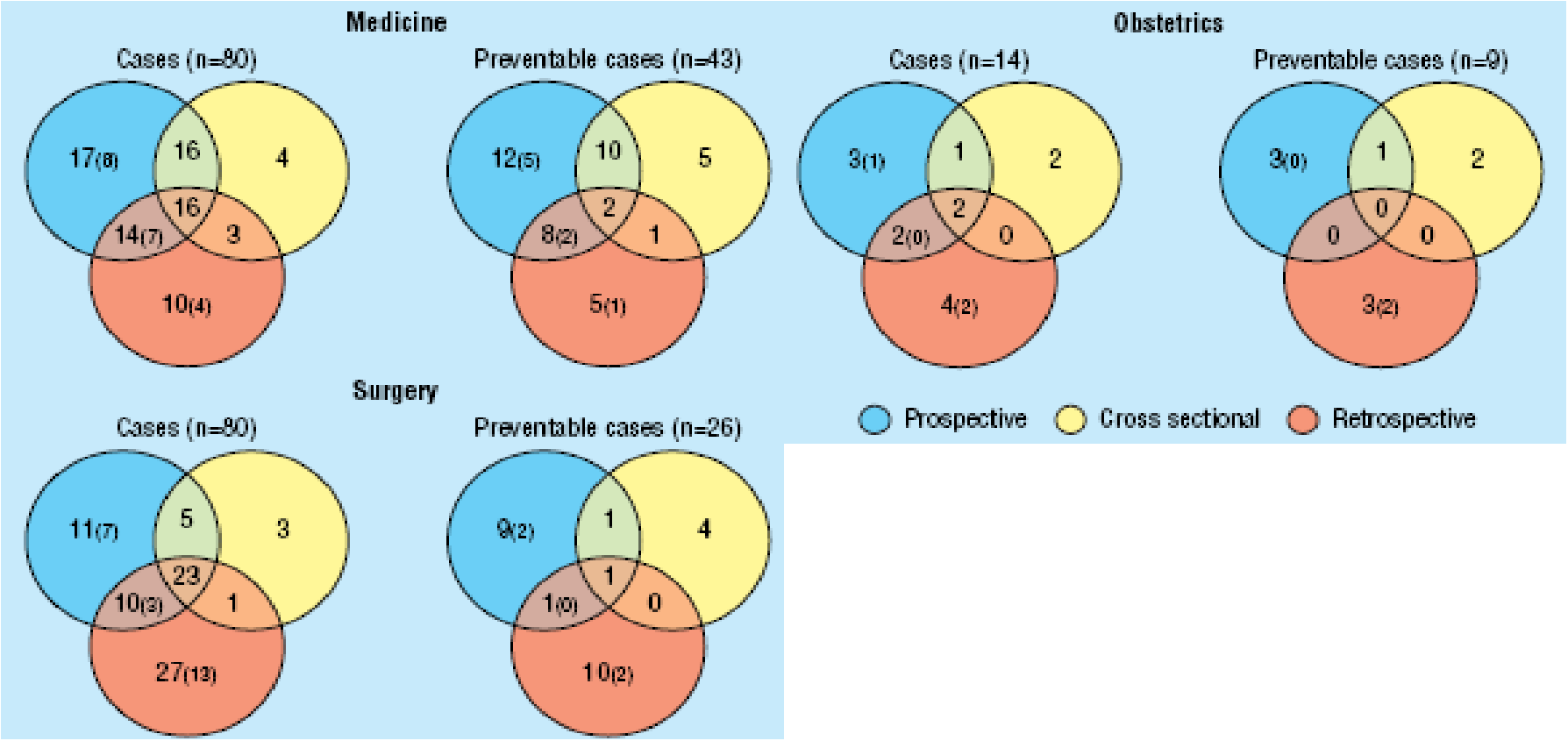


Fig 2 Venn diagrams showing number of cases identified by three methods of data collection. Cases in brackets not identified by cross sectional method as they were identified after first day of data collection

17: Conclusion: Main Points

- **The prospective method is preferable for:**
  - Assessing impact of risk reduction programmes
  - Convincing clinical teams that their errors may contribute significantly to adverse events
  - Improving the assessment of consequences
  - Studying organisational and human mishaps

18: Conclusion: Discussion

Prospective method (data collected during hospital stay)

- **Advantages**
  - Best effectiveness for identifying preventable events
- Good reliability of judgment of iatrogenic nature of events
  - Staff sufficiently involved to understand notion of iatrogenic risk and search for causes
  - Preferred because of their pedagogical and communicative virtues
  - Good appreciation of chain of events and their consequences
  - Possible role as "red flag" for care providers during data collection
- **Disadvantages**
  - Most expensive
  - Heaviest workload, although perceived as acceptable:
    - Several visits for investigators
    - Staff must be available

19: Conclusion: Discussion (2)

Cross sectional method (data gathered on given day)

- Advantages
  - Least expensive
  - Methodological approach fully understood by professionals and appreciated because it is rapid and easily renewed
  - May be sufficient to justify implementation of a risk reduction policy and to define priorities
  - Good reliability of judgment of iatrogenic nature of events; possible role as "red flag" for care providers during data collection
- Disadvantages
  - Consequences of lack of follow up during patient's hospital stay:
    - Lowest effectiveness
    - Lack of validity due to measurement errors (false positives / negatives)
    - Prevalence biased by underestimation of frequency
  - Believed by unit staff to involve an excessive workload for obtaining imprecise estimations

20: Conclusion: Discussion (3)

Retrospective (review of medical records)

- **Advantages**
  - Good effectiveness, even superior in surgery for estimating adverse event incidence
  - Almost no workload for staff
  - Data collection easily planned
  - Method sometimes favoured by surgical teams and centres
- **Disadvantages**
  - Difficulty to judge iatrogenic and preventable nature on basis of sometimes piecemeal data. Therefore:
    - Measurement errors due to quality of medical records and to lesser reliability of judgment of iatrogenic nature
    - Underestimation of preventable events
  - Lower face validity of results, especially for preventability judgment (no involvement of staff)

21: Author Reflections: Practical Considerations

- Study duration (from conception to write-up)
  - Two years, including the pilot
- Cost
  - $200,000 USD
- Required competencies
  - Clinical expertise, statistical knowledge, patient safety experts
- Ethical approval
  - Took four months to obtain

22: Author Reflections: Study Impact

- **Academic impact**
  - Influenced researcher in their methods of measuring patient safety, both in France and in other countries
- **Practice impact**
  - In 2004, results used to set up a national survey to define patient safety indicators
  - Policies on patient safety frequently refer to the findings of this study

23: Author Reflections: Lessons and Advice

- If you could do one thing differently in this study, what would it be?
  - *"Better national and local information before starting the survey"*
- Would this research be feasible and applicable in developing countries?
  - *"Yes, currently being tested (see Itziar Larizgoitia)"*
- What message do you have for future researchers from developing countries?
  - *"Be trained before starting a similar survey"*
- What barriers or problematic issues did you encounter when setting up your research and how did you overcome these?
  - *A bit long to answer...! the most difficult was related to different patient safety experts having diverging ideas of how to measure and in particular how to assess preventability*