Methods of assessing the nature and scale of harm

Ph. Michel, MD, PhD
C. Vincent, PhD
“From incident reports, the rate [of medication error] was typically about 2 errors per 1,000 cases. A retrospective chart review yielded a rate of 7/1,000. A computer screening method developed at Salt Lake City [hospitals], uncovered a rate of 38/1,000. Daily chart review produced a rate of 65/1,000. And chart review combined with computer screening revealed roughly 100/1,000 cases”

Relevance of methods depends on:

- WHY
  - Local quality/safety improvement project
  - National survey
- WHAT
  - Main objective: event, cause or consequence (Thomas, J Gen Intern Med 2003)
  - Monitoring progress, providing benchmarks
- WHERE (data rich/poor environments)
- WHO (external / internal assessors)
Need of evidence-based data on relative performance of methods

- All methods used to provide epidemiological estimates
  - Large amount of opinion-based literature

- Need of evidence

- WHO Report
  - To describe the strengths and weaknesses of available methods for assessing nature and scale of harm caused by the health system
  - Extensive literature review
Methods for assessing AE/errors

- Taxonomy based on data sources
- Two main sources
  - Healthcare professionals or patients
    - Passive data collection: waiting for information
    - Active data collection: asking what happened
  - Use of data collected for other purposes
Routinely-collected data

- Medical record review (paper or electronic)
- Administrative databases
- Other specific databases (laboratory, pharmacy)
- Safety/clinical activities (autopsies, M&M conferences)
Professionals / patients

Passively → Surveillance

Claims and complaints
Reporting (Open-ended or focused)

Systematically:
- Quantitative methods
  - Prospective and cross-sectional surveys

Qualitatively:
- Observation by healthcare professional or others (ethnologists)
- Focus group, safety walkrounds
- Single case analysis (FMEA)
- Scenario, simulation

Actively → Observation by healthcare professional or others (ethnologists)
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Non systematically
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Reporting systems

Most widespread data collection
Reporting systems

- Reporting to GMC, UKCC
- Notifiable diseases
- Medicines control agency
- Local safety reporting systems
- National reporting systems
  - NPSA, AIMS
- ... and many more

- Many different purposes
- Monitoring, disciplinary vs reporting for learning
- Mandatory and voluntary
- Safety systems: Information, communication, learning and action
Reporting systems

- System for detecting, reporting, analyzing adverse health-care events and learning from such events
- Primary purpose is to gather qualitative data and learn from experience
- Using forms that allow characterization of the type of event and the circumstances in a format that can be readily entered into a computerized database
Reporting system and epidemiology

- “Reporting systems cannot provide accurate epidemiological data, since
  - The reported incidents are likely to underestimate the numerator,
  - The denominator (all opportunities for incidents) remains unknown” (Cullen 1995)

- But
  - information on patterns and trends
  - useful in the case of rare events
## Reported adverse drug event rates

<table>
<thead>
<tr>
<th>Method of Detection</th>
<th>Rate</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self reporting (voluntary)</td>
<td>0.2</td>
<td>Cullen et al (1995)</td>
</tr>
<tr>
<td>Population record review</td>
<td>0.7</td>
<td>Leape et al (1991)</td>
</tr>
<tr>
<td>Computer screening</td>
<td>3.8</td>
<td>Classen et al (1991)</td>
</tr>
<tr>
<td>Chart review &amp; simulated report</td>
<td>6.5</td>
<td>Bates et al (1995)</td>
</tr>
<tr>
<td>Combination chart &amp; computer</td>
<td>10.0</td>
<td>Jha et al (1997)</td>
</tr>
</tbody>
</table>

From Leape (1997)
Detection of obstetric incidents under optimal conditions  

(Stanhope et al., 1999)

Staff reported 45

Risk Manager 44

Record Review 196
Effectiveness in identifying AE

- Depends on how stimulated is the reporting
  - usually visits of house officers/nurses
- Can be more effective for designated incidents
- All adverse events (O’Neil 93)
  - Daily electronic reminder to physician
  - Nearly same number of AE; only half AE were identical; reported AE more preventable
Adverse Events

Reported Patient Safety Incidents

- Harm
- Near misses
- Errors
- Safety issues
- Equipment problems
- General hassle
What is incident reporting for?

- Assume massive under-reporting
- We do need to increase the information flow - but not because we hope to achieve full reporting
- Ideally a form of communication
- Incident reports act to flag issues and to provide warnings
- Analysis of incidents often neglected but can be very informative
Systematic data collection methods

Non epidemiological designs
Epidemiological designs
Observational studies
Retrospective data collection review of medical records (RMR)

- Retrospective, on a random sample of admissions
- External, independent and specially trained assessors screen inpatient records for various potential indicators of adverse events
  - e.g., death or other undesirable outcome, cardiac or respiratory arrest, transfer from general care to a special unit, return to operating room…
- Implicit professional reviews of the records that met one or more of these criteria carried out by external board-certified physicians to identify adverse events
Prospective data collection

- Studies based on two data sources
  - Medical record only
  - Housestaff + medical record
- Especially useful
  - For the study of errors
  - When there is poor recording of events
AE surveys based on data collected from housestaff in hospitals

- National surveys based on data collected from health professionals
  - as the principal source of information
  - With consultation of medical record
  - France (ENEIS), Spain (IDEA)

- Data collected by external investigators
- Structured data collection forms
- Detection every two days during follow-up
Prospective assessment with housestaff versus RMR

- Comparative study (*Michel BMJ 2004*)
  - Independent AE assessment applied to one sample
- As effective for identifying AE
  - More in medical units, less in surgical ones
  - Little overlap
- Better identification of preventable cases
- Better reliability of AE identification
- Pedagogical and communicative virtues
- Disadvantages: workload and cost
Cross-sectional data collection

- Detection and confirmation the same day
  - Prevalence assessment
- Cross-sectional compared to RMR (Michel BMJ 2004)
  - Less effective but more reliable
  - Large number of false positives
  - Underestimation of the most serious AE
Observational studies

- First used in drug administration error studies (early 1960s) by investigators (drug medication error studies)
- Then using a videotape (errors in theatres)
- Advantages
  - Knowledge of error by subjects is not required
  - Willingness to report is not required
  - Remembering and ability to communicate not required
  - Selective perception of subjects is unrelated
- Limits: observer inference and effect of the observer on the observed
- Used once for studying all adverse events
Focus on the literature from the developing countries

Wider-focus search strategy:
(Adverse drug reaction OR reporting system OR risk management OR Safety management OR Medical audit)
AND (Developing countries OR Africa! OR India OR Brazil)
Methods in developing countries and transitional economies

- All types of methods in the literature from the developing countries
- Large number of studies based on interview, clinical examination and questionnaire comparatively to the studies based on RMR
- Prospective designs mainly used
  - Several cross-sectional studies
Multifaceted prospective designs

- Review followed by clinical examination
  \( (\text{Weismuller, Int J Tuberc Lung Dis 2002}) \)

- Individual assessments of cause of death followed by regular consensus meetings
  \( (\text{El Amin, Health Policy Plan 2002}) \)

- Criterion-based clinical audit with safety issues
  \( (\text{Wagaarachchi, Int J Gynaecol Obstet 2001}) \)
Discussion

Other methods without evidence

- Single case analysis, focus group, safety walkrounds
  - Low-cost and potentially effective in data-poor environments
- Scenario and simulation
Conclusion

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