Adverse Event Reporting Systems

Laura Morlock, PhD, MA
Albert W. Wu, MD, MPH
The Johns Hopkins Bloomberg School of Public Health
Section A: Adverse Event Reporting Systems: Definitions and Functions

Laura Morlock, PhD, MA
Outline of Section

- Reporting systems: definition and functions
- Mandatory vs. voluntary systems
- Example: aviation reporting systems
- Lessons from aviation for health care
Institute of Medicine Report (1999)

- Reporting systems are a key strategy for learning from errors and preventing their recurrence
Reporting System Uses

- Reporting systems are:
  - Particularly useful for identifying types of errors that occur too infrequently for individual health care organizations to readily detect based on their own data.
  - For detecting patterns of errors that point to systemic issues affecting all health care organizations.
1. Hold providers accountable for performance—mandatory reporting systems
2. Provide information that leads to improved safety—voluntary reporting systems

Conceptually these purposes are not incompatible, but in reality they can prove difficult to satisfy simultaneously.
Mandatory Systems

- Usually focus on errors associated with serious injuries or death
- Generally are operated by state regulatory programs with authority to investigate specific cases and levy sanctions
- Examples
  - National Practitioner Data Bank
  - New York Patient Occurrence Tracking System (NYPORTS)
Voluntary Systems

- Most reports on errors result in minimal injury or no harm
- The intent is to identify vulnerabilities in systems that could cause future injury
- Reports are submitted anonymously or with confidentiality to an external group for aggregation, analysis, and feedback
- Used in industries where safety is paramount, e.g., nuclear power, petrochemical processing, steel production, military operations, and air transportation
Example: Aviation Reporting Systems

- Risk of dying on a domestic jet flight
  - 1 in 2 million flights (1967–1976)
  - 1 in 8 million by 1990s
Example: Aviation Reporting Systems

- Factors associated with improvement
  - Better technology
  - Teamwork training
  - Error reporting systems
  - Encouragement to report
Example: Aviation Reporting Systems

- Two reporting systems
  1. Serious passenger injury or substantial aircraft damage reported and investigated by the National Transportation Safety Board (mandatory)
  2. The Aviation Safety Reporting System (ASRS): confidential system for reporting “near misses”
The Aviation Safety Reporting System (ASRS)

- Confidential system for reporting “incidents”
  - Cases that violated good practice or established rules but that did not result in an accident = “near misses”
- Widespread participation
  - ~30,000 reports/year
- Incidents analyzed for root causes
- Reports communicated directly to those involved, others who might face similar situations, and entire aviation community
Importance of Near Misses

- Underlying causes may be very similar to those associated with full-blown accidents
- Greater frequency allows for quantitative analysis
- Fewer barriers to reporting by workers (fewer liability concerns)
- Recovery patterns can be captured, studied, and used for safety improvement
Lessons for Health Care?

- Importance of consensus among stakeholders during system design
- Importance of keeping the system’s operations objective and free of control by stakeholders
- Benefits of a voluntary reporting system
  - “In one way or another, all incident reporting becomes voluntary . . .”
- External reporting system, in contrast to an “in-house process” will yield a larger sample size, increasing potential to detect patterns otherwise not discernible
Definition and functions of adverse event reporting systems
Mandatory vs. voluntary systems
Example: aviation reporting systems
Lessons from aviation for health care
Section B

The Value of “Near Misses”
Understanding the “incident causation model”
An example from occupational safety
The “causal continuum hypothesis”
A Review: Why Is Information on Near Misses of Value?

- It is believed that the underlying causes are similar to those associated with harmful events.
- Their greater frequency allows for quantitative analysis.
- Fewer barriers to reporting by workers (fewer liability concerns).
- Recovery patterns can be captured, studied, and used for safety improvement.
Successive layers of defenses, barriers, and safeguards

Incident Causation Model

1. Technical failure
2. Human operator failure
3. Organizational failure

4. Dangerous situation

5. Return to normal
   - yes
   - no

6. Adequate defenses?
   - yes
   - no

7. Developing incident

8. Adequate (human) recovery?
   - yes
   - no

9. Adverse event

Phase 1: Initial failure occurs triggered by human error or a technological or organizational failure which creates …

Phase 2: A dangerous situation of increased risk, but still without actual consequences, which may be accompanied by …

Phase 3: Inadequate defenses due to a failure of established safeguards
Phase 4: In a near miss, the most probable results (harm) are mitigated by either …
   - Chance
   or
   - Recovery
   ► Defined as a second set of informal human actions in which a developing high-risk situation is detected, understood, and corrected in real time
Incident Causation Model

- Technical failure
- Human operator failure
- Organizational failure
- Dangerous situation
- Near miss
  - Adequate defenses?
    - Yes: Return to normal
    - No: Developing incident
  - Chance
    - Yes: Adverse event
    - No: Developing incident

Example from Occupational Safety

- You are working on a platform some twenty feet above the floor, and you accidentally drop a hammer
Scenario 1

- The hammer falls, bounces once, but doesn’t leave the deck of the platform
Scenario 2
- The hammer falls, bounces off the deck of the platform and over the edge
- No one was working below the platform, and the hammer falls harmlessly to the floor
Example from Occupational Safety

Scenario 3
- The hammer falls, bounces off the platform, and strikes a worker below you
- Luckily, she was wearing a hard hat, which protected her from serious injury
Example from Occupational Safety

- Scenario 4
  - The hammer falls, bounces off the platform, and strikes a worker below you
  - He had just taken off his hard-hat to scratch his head
  - He receives a serious injury
Scenario 5

- The hammer falls, bounces off the platform, and strikes a worker below you
- The worker, having taken off his hard-hat, is stunned by the impact and stumbles backwards into a high-voltage electrical panel
- The panel was supposed to have been de-energized for personnel protection; but there was a miscommunication with other workers, so another panel 10 feet away was de-energized instead
- The worker is electrocuted
The Causal Continuum Hypothesis

- The idea, however, that the underlying causes of no-harm events are similar to those associated with patient harm is an assumption that has not been adequately tested in health care.
- The size and scope of the MEDMARX data base provides an excellent opportunity for examining this “causal continuum hypothesis”
Section C

Testing the Causal Continuum Hypothesis in Health Care
Comparing near-miss and harmful medication errors: Testing the causal continuum hypothesis using data from the MEDMARX National Reporting System
Study Objectives

- Compare the causes and contributing factors associated with near-miss and harmful medication errors
- Examine whether near-miss and harmful medication errors are similar in motivating patient safety improvements (actions taken in response to the errors)
Study Sample

- All medication errors reported by participating hospitals to MEDMARX
- Time frame: 1999–2005
- Number of hospitals reporting: 677
  - 577 general community hospitals
  - 54 critical access hospitals
  - 46 academic medical centers
Analytic Methods

- Compared no-harm and harmful medication errors regarding the likelihood of reporting a specific cause, contributing factor, and action taken.
- Utilized simple correlations, logistic regression models, and odds ratios.
- Corrected for “clustering” of reports by hospital.
- Repeated the analysis separately within hospitals for those 100 hospitals with the greatest frequency of reports.
Study Results

- 836,174 medication errors reported
- 16,052 (1.9%) errors resulted in patient harm, including 109 deaths
  - 47% of hospitals reported less than one harmful event per year
- 95% of medication error records reported at least one cause
- 30% reported at least one contributing factor
- 43% reported one or more actions taken
Most Frequent Reported Causes

- Human performance deficit
- Failure to follow procedure/protocol
- Inaccurate/omitted transcription
- Computer entry error
- Documentation error
- Communication problem
- Knowledge deficit
- Error in written order
- Failure of system safeguard
- Inadequate patient monitoring
Most Frequently Reported Contributing Factors

- Distraction
- Workload increase
- Inexperienced staff
- Shift change
- Cross coverage
- Agency/temporary staff
- Emergency situation
Causal Patterns for Medication Errors

- Causal patterns for harmful and no-harm medication errors

Graph: Scatter plot showing the log-odds of reporting a cause given that harm has occurred versus the log-odds of reporting a cause given that harm has not occurred. The correlation coefficient is 0.94.
Contributing factor patterns for harmful and no-harm medication errors
Most frequently reported
- Informed staff who made initial error
- Informed staff involved in error
- Education/training provided
- Communication process enhanced
- Informed patient/caregiver
Reported Actions Taken to Prevent Future Errors

- Least frequently reported
  - Staffing practice/policy modified
  - Computer software modified/obtained
  - Policy/procedure changed
  - Environment modified
  - Policy/procedure instituted
  - Formulary changed
In general, actions more likely in response to harmful events
- Institutional-level actions—such as instituting or changing a policy or procedure
  - 3 to 4 times more likely in response to harmful events in general
  - 21 to 23 times more likely in response to permanent injury or death of a patient
Conclusions and Implications

- Study results support the causal continuum hypothesis
- Patterns of causes and contributing factors are similar for no-harm and harmful errors
- Actions taken in response are more likely for harmful errors, suggesting missed opportunities for learning from near-miss events
Returning to the Incident Causation Model

Incident Causation Model

- Technical failure
  - Human operator failure
  - Organizational failure
- Dangerous situation
  - Adequate defenses?
    - yes: Near miss
    - no: Developing incident
- Adequate (human) recovery?
  - yes: Developing incident
  - no: Adverse event

Section D

Reporting Systems: Lessons and Challenges
What we have learned: Characteristics of successful reporting systems
First-, second-, and third-generation issues and challenges
Characteristics of Successful Reporting Systems

- **Nonpunitive**
  - Reporters are free of fear of retaliation or punishment from others as a result of reporting

- **Confidential**
  - The identities of the patient, reporter, and institution are never revealed to a third party

- **Independent**
  - The program is independent of any authority with power to punish the reporter or organization

Source: Leape.
- **Expert analysis**
  - Reports are evaluated by experts who understand the clinical circumstances and who are trained to recognize underlying systems causes
- **Timely**
  - Reports are analyzed promptly
  - Recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified
Characteristics of Successful Reporting Systems (cont.)

- Systems oriented
  - Recommendations focus on changes in systems, processes, or products, rather than on individual performance

- Responsive
  - The agency that receives reports is capable of disseminating recommendations, and participating organizations agree to implementing recommendations when possible
Reporting Systems: First-Generation Issues

- Mandatory vs. voluntary
- Comprehensive vs. focused
- Adverse events or errors
  - Harm, no harm, or both?
- Include near misses?
Reporting Systems: First-Generation Questions

- What should be reported?
- Who should report?
- What format should be used?
  - Free text vs. check boxes
- What is the most appropriate timeframe for reporting?
- How to reduce barriers to reporting
- How to reduce reporting burden
  - Strategies for the integration of multiple reporting systems
Methodological Issues

- Adverse event reporting systems—such as MEDMARX—result in large, complex databases
- Error reports are voluntarily reported from many facilities
- The frequency and type of reports may be influenced by facility and reporter characteristics
Developing meaningful coding categories and taxonomies
Analytic and statistical challenges, particularly in analyzing very large databases from multiple organizations
Facilitating expert analysis
Ensuring timely feedback
Evaluating the impact on patient safety

- How do we know at the facility level that we are improving?
- How can each facility best learn from the experiences of others?
- How do we know at the system/national level that we are improving and patients are safer?
Example: Assessing Aviation Safety

- The number of airline fatalities worldwide was at approximately the same levels in 1945 and 2004.

- While the number of airline passengers increased per year from …
  - 9 million in 1945 to
  - 1.8 billion in 2004
Pressures exist at both the institutional level (e.g., report cards) and the national level to measure impact on safety through establishing error rates.

Methodological challenges are daunting:
- Standardizing definitions of errors
- Developing measures of risk exposure (rate denominators)
- Standardizing surveillance methods
One Example: Quantifying Risk Exposure

- A hospitalized patient experiences a narcotic overdose
- What is the most appropriate indicator of risk exposure (denominator)?
  - Patients
  - Patient days
  - Prescribed or dispensed medication doses
  - Administered medication doses
  - Prescribed or dispensed or administered narcotic doses
In Conclusion …

- These third-generation issues and challenges are likely to require a long journey of experimentation and discovery.
- How can we best learn from others who have longer experience with safety reporting systems?
  - Aviation safety?
  - Hospital-acquired infection reporting?