



# How Do We Detect Error in Complex Systems?

## Methods Used to Measure Error and Adverse Events in Hospitalized Children

Dawn S. Hartfield BScMed, MPH, MD, FRCPC  
University of Alberta  
May, 2009

# Methods to Detect Error and Adverse Events

- M&M/Autopsy conferences
- Traditional chart review
- Incident reports
- Direct observation
- Review of malpractice claims
- Review of ICD-9 codes
- Trigger tools



# M&M Conferences and Autopsy



# Advantages:

- Format familiar to health care providers/accreditation bodies

# Disadvantages:

- Hindsight bias
- Reporting bias
- Focus on diagnostic errors
- Infrequent (especially in pediatrics)
- Nonrandom
- Expensive/time-consuming
- Depends on quality of medical record

# Specifically:

- M&M processes
  - no proven benefit in improving care demonstrated
- Autopsy
  - may identify potentially fatal misdiagnoses in 20-40% of cases
- Combined
  - Too few cases discussed to detect incidence and prevalence of error/AE with this method

# Traditional Chart Review



# Advantages:

- Utilizes information available
- Random sample

# Disadvantages

- Time-consuming/expensive
- Quality of medical record is critical
- Reviewer dependent
  - Judgments about AE unreliable
  - Hindsight bias
  - Reporting bias

# Review of Malpractice Claims



# Advantages

- Large pool of data
  - US are 110,000 claims received annually
- Provides multiple perspectives

# Disadvantages:

- Hindsight bias
- Selection bias
- Reporting bias
- Non-standardized data source
- Cannot be used to estimate prevalence of error or AE



# Incident Reports

# Types of Reporting Systems

- **Mandatory**
  - AE must be reported by law, policy/regulation
- **Anonymous**
  - no identifiable details of patient/care providers included
  - Liberate less detailed report, as no follow-up possible
- **Confidential**
  - identifiable details included, then removed after investigation is complete
  - Allows for more complete information than anonymous systems

# Electronic reports are superior to paper

- Simplify process
- Decrease number of forms to complete
- Improve quality and quantity of data collected
- Improved response time
- Improve evaluation and follow-up
- Enhance quality, patient safety and work environment
- Allows for development of a database, and sharing of data with other organizations

**Table 1. Incentives and Barriers to Implementing Reporting Systems**

	Individual	Organizational	Societal
<b>Legal</b>			
Barrier	Fear of reprisals, lack of trust	Fear of litigation, costs, sanctions undermine trust, bad publicity	Legal impediments to peer review, confidentiality, and multi-institutional database
Incentive	Provide confidentiality and immunity	Provide confidentiality and immunity	Ensure accountability, enforce reporting statutes
<b>Cultural (values, attitudes, beliefs)</b>			
Barrier	Dependent on profession, code of silence, fear of colleagues in trouble, skepticism, extra work	Dependent on organization, pathological, bureaucratic, generative cultures, don't want to know	Wide public trend towards disclosure, lack of trust owing to highly publicized medical errors, concerns that professions are too privileged, lack of education about systems effects
Incentive	Professional values, philanthropic, integrity, educational, cathartic	Become a leader in safety and quality, good for business	Enhanced community relations, build trust, improve health care, transparency
<b>Regulatory</b>			
Barrier	Exposure to malpractice, premiums will go up, investigation and potential censure, license suspension and subsequent loss of income	It doesn't apply to us, we do our own internal analysis process, they can't understand our problems anyway	Need more effective regulations, resource intense
Incentive	Prophylactic, follow the rules	Fear of censure	Enhances regulatory trust, more public accountability
<b>Financial</b>			
Barrier	Loss of reputation, loss of job, extra work	Wasted resources, potential loss of revenue, patient care contracts, not cost effective	Cost more tax dollars to enforce, more bureaucracy
Incentive	Safety saves money	Publicity relations, improve reputation of quality and safety	Improves confidence in health care system

(Barach and Small 2000)

White JL. Adverse Event Reporting and Learning Systems: A Review of the Relevant Literature. 2007. Accessed at <<http://www.patientsafetyinstitute.ca/English/toolsResources/caerls/CAERLSConsultation/Documents/CAERLS%20Consultation%20Paper%20AppendixA.pdf>>May20, 2009

**Table 6. Physician versus Nurse Preferences for Reporting Systems**

Issue	Physician Preferences	Nurse Preferences
Rules and Regulations	Voluntary system	Mandatory system to ensure participation
Reportable Events	Both adverse event and near-miss reporting	Adverse event reporting only to reduce workload
Reporting Medium	Flexible (paper, phone, electronic) but strong preference for electronic	Flexible (paper, phone, electronic) but less preference for electronic
Duplicate Reporting (e.g. organizational and regional)	Did not view negatively	Viewed negatively because of workload

(adapted from Escoto et al. 2006)

White JL. Adverse Event Reporting and Learning Systems: A Review of the Relevant Literature. 2007. Accessed at <<http://www.patientsafetyinstitute.ca/English/toolsResources/caerls/CAERLSConsultation/Documents/CAERLS%20Consultation%20Paper%20AppendixA.pdf>>May20, 2009

**Table 7. Conditions Influencing Incident Reporting by Physicians and Nurses**

"I would be more likely to report an error if..."	Residents	Nurses	Significant Difference?
...if it were my own error	54%	91%	yes
...if a resident committed the error	4%	43%	yes
...if a nurse committed the error	38%	42%	no
...if I don't like the person who committed the error	25%	1%	yes
...if the patient was young and healthy	33%	19%	no
...if the patient had an intact mental status	29%	14%	no
...if the error had serious consequences	67%	72%	no

(Wild and Bradley 2005)

White JL. Adverse Event Reporting and Learning Systems: A Review of the Relevant Literature. 2007.  
Accessed at <<http://www.patientsafetyinstitute.ca/English/toolsResources/caerls/CAERLSConsultation/Documents/CAERLS%20Consultation%20Paper%20AppendixA.pdf>>May20, 2009

# Reporting and Learning Systems

- National databases have been developed in the US, Britain, and Japan that compile national data from mandatory and voluntary systems
- Canada is developing a database with the combined efforts of CPSI and PHAC - Canadian Adverse Event Reporting and Learning System (CAERLS)

# Reporting and Learning Systems



Purpose is to identify problems with delivery of care and health system  
NOT reprisal of individuals involved

# Ideal Reporting and Learning Systems



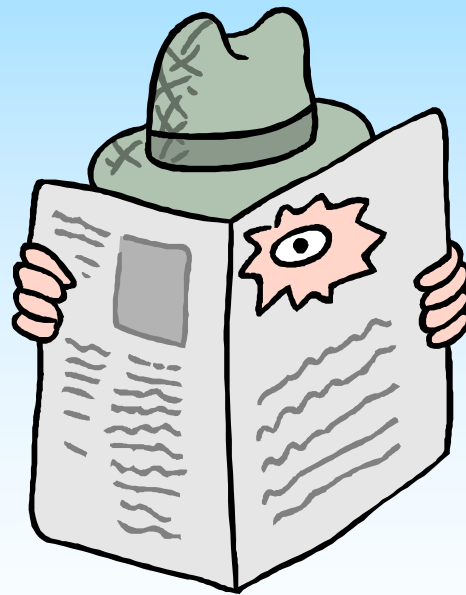
- Use independent organizations for analysis of data with expertise in medicine and safety
- Provide timely feedback to providers
- Suggest systems-oriented solutions
- Organization is responsive to suggested changes
- Confidential
- Non-punitive

# Pitfalls of Reporting and Learning Systems



- Only as good as data provided
- Consistent nomenclature/taxonomy when combining systems
- Compatible software across organizations
- No clear protection from legal system
- Timeliness of reporting and feedback

# Direct Observation of Patient Care



# Advantages:

- Accurate and precise data
- Detail otherwise unavailable
- Identifies more adverse events/active errors than other methods

# Disadvantages:

- Confidentiality concerns
- Time-intensive training of observers to ensure reliability
- Expensive
- Hindsight bias
- Focuses on “sharp-end” or providers, not on system
- Potential Hawthorne effect

# Review of ICD-9 Codes



# Advantages:

- Inexpensive
- Uses data readily available

# Disadvantages

- Data may be incomplete/inaccurate
- Data and clinical context are separate

# Trigger Tools



# Trigger tools:

- Focus on detecting, quantifying and tracking adverse outcomes (not error) over time
- Methodology is related to actual clinical injury
- Can be used in all clinical environments to detect multiple types of AE (trigger list varies per environment)
- Inexpensive - can be introduced without significant technology (but helps!)
- Consistent and accurate way to measure AE

# What is a “trigger”?

- A word/event found as part of a health record (written or electronic) that can be associated with an adverse event
- This triggers a focused chart review to confirm if an adverse event has occurred or not

**TABLE 1** Final Trigger List Used in the Inpatient Pediatrics ADE Trigger Tool Study

Designation	Description
T <sub>1</sub>	Diphenhydramine use
T <sub>2</sub>	Vitamin K use
T <sub>3</sub>	Flumazenil use
T <sub>4</sub>	Antiemetic use <sup>a</sup>
T <sub>5</sub>	Naloxone use
T <sub>7</sub>	Sodium polystyrene use
T <sub>10</sub>	PTT • 100 s
T <sub>16</sub>	Rising serum creatinine <sup>b</sup>
T <sub>21</sub>	Oversedation/lethargy/fall/hypotension
T <sub>22</sub>	Rash
T <sub>23</sub>	Abrupt medication stop
T <sub>25</sub>	Serum glucose • 150 mg/dL
T <sub>26</sub>	Hyperkalemia <sup>c</sup>
T <sub>27</sub>	Called codes
T <sub>28</sub>	Laxative or stool softener use

# What is the process?

- Review team
  - Two primary record reviewers (RN, pharmacy, RT) to screen for triggers
  - Physician - authenticates if AE occurred, then rates severity, answers other queries of the reviewers
- Sampling patient records
  - 10 randomly selected records every 2 weeks of discharged patients (in/exclusion criteria exist)

# What is the process?

- Review process
  - Two primary reviewers independently review each record to look for triggers
  - Apply appropriate trigger “modules” depending on the patient
    - All patients: Cares and Medication
    - Additional as appropriate: Surgical, Intensive Care, Perinatal, Emergency Department
  - “20 minutes per chart” rule (small or large chart) to ensure shorter and longer charts are included in review.
    - Not meant to detect every AE
  - Triggers are recorded
    - If AE without triggers are noted, these are also noted

# What is the process?

- Review process
  - Reviewer examines portion of chart related to trigger to determine if an AE/harm has occurred
  - If an AE has occurred, than a severity/harm score is assigned
  - All data is recorded on standardized worksheets/computer programs
  - Two reviewers meet to discuss independent reviews and document findings on standardized summary sheet
  - Physician reviews consensus of two reviewers using the summary sheet and worksheets if required
    - Physician is final arbitrator
    - Number of AE and harm categories are determined

# What is the process?

- Data Collection
  - Data is collected in two-week blocks and standardized
    - AE per 1,000 patient days
    - AE per 1,000 admissions
    - percent of admission with AE
  - Data is often also presented by type of AE and by severity/harm category

# How good is this method?

- Superior to those previously described in identifying rates of AE/harm
  - Adult literature suggests AE rates measured are 50 times higher than other methods
  - Limited pediatric data available, but demonstrates success
- *Does not measure error* (as error may or may not result in harm); measures true AE/harm

# Pediatric Trigger Tools Do Exist!



- Canadian Association of Pediatric Health Centres (CAPHC) has developed one and is piloting June, 2009:

CAPHC Canadian Paediatric Trigger Tool

# SUMMARY

## Methods to Detect Error and Adverse Events

- M&M/Autopsy conferences
- Traditional chart review
- Incident reports
- Direct observation
- Review of malpractice claims
- Review of ICD-9 codes
- Trigger tools



# Summary:

- Are pros/cons to each method
- Large databases are being developed that detect error and AE using incidence reports
- Trigger Tool methodology is superior in identifying AE/harm and is being used with increasing frequency
- Complimentary information can be generated by using a combination of approaches

