World Health Organization

Patient Safety
A World Alliance for Safer Health Care

Patient Safety
Research Introductory
Course
Session 4

Understanding Causes

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Introduction

- Measuring what goes wrong in healthcare involves counting how many patients are harmed or killed each year, and from which types of adverse events

- Once priority areas have been identified, the next step is to understand the underlying causes of adverse events that lead to patient harm. In this session, we will explain several methods with practical examples.

Components

5. Translating Evidence Into Safer Care

1. Measuring Harm

2. Understanding Causes

3. Identifying Solutions

4. Evaluating Impact

1. Provider surveys can be useful for understanding causes of adverse event because:

    a. You can use both standardized and open ended questions

    b. They can capture the wisdom of front-line health care workers

    c. They can be used in developing and transitional country settings

    d. All of the above

2. Which of the following is NOT a "self-report" method of data collection?

    a. Survey completed on-line

    b. Review of hospital charts

    c. One-on-one interviews.

    d. Focus groups

3. Which statement about reviewing malpractice claims analysis is FALSE?

a. Malpractice claims analysis can be good at finding latent errors

b. Malpractice claims data are very representative of problems in medical care

c. Malpractice claims are not standardized in format

d. Malpractice claims provide data from multiple perspectives.

4. Which of these methods can be useful for studying causes of adverse events?

a. Provider surveys

b. Incident reporting

c. Cohort studies

d. All of the above

5. Incident reporting systems are

a. Good for finding latent errors

b. The best method for understanding the causes of adverse events

c. Also referred to as Reporting & Learning systems

d. A and C

Case

- Post-operative patient

- Patient is penicillin allergic

- Order written for Timentin^R (ticarcillin)

- Antibiotic administered
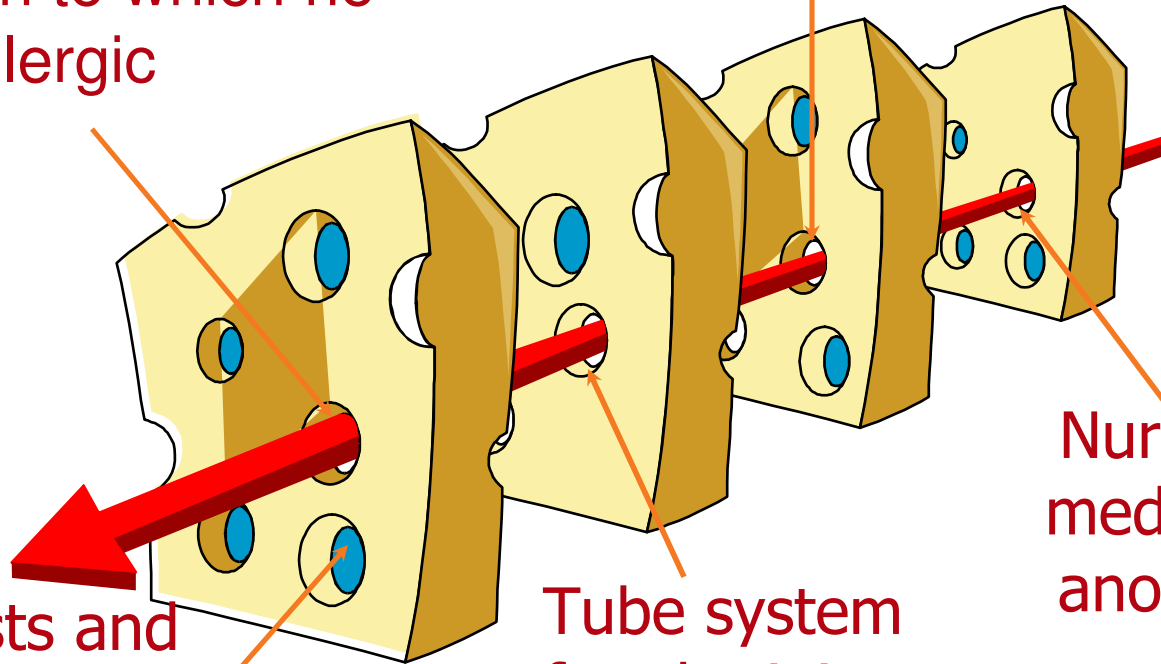
- Patient has anaphylaxis and cardiac arrest

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Nurse gives the patient a medication to which he is allergic

Fax system for ordering medications is broken

Nurse borrows medication from another patient

Tube system for obtaining medications is broken

Patient arrests and dies

ICU nurse staffing

What Should be Done?

- Be more careful

- Better education

- Make a policy

- It's the System!
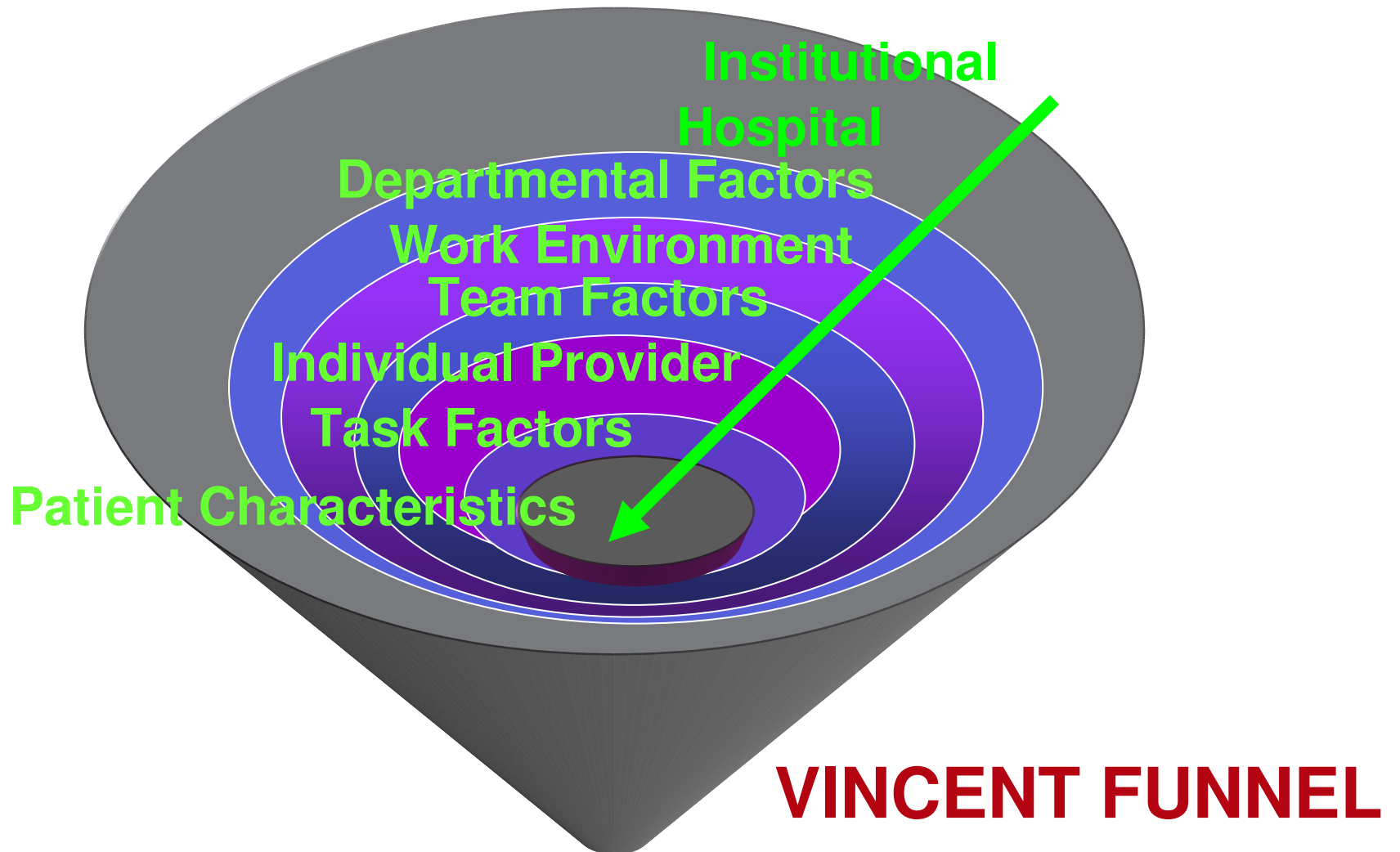
Four Basic Methods of Collecting Data

- Observation

- Self-reports (interviews and questionnaires)

- Testing

- Physical evidence (document review)

Measurement Methods

- Prospective
  - Direct observation of patient care
  - Cohort study
  - Clinical surveillance
- Retrospective
  - Record review (Chart, Electronic medical record)
  - Administrative claims analysis
  - Malpractice claims analysis
  - Morbidity & mortality conferences / autopsy
  - Incident reporting systems

Relative Utility of Methods to Measure Errors

Latent errors

Active errors

Adverse events
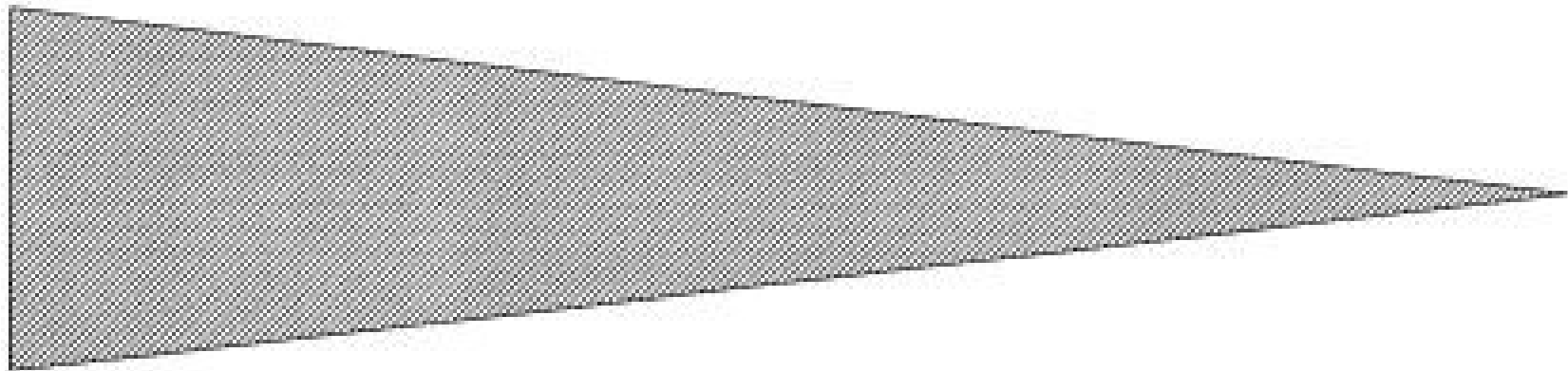
- Incident reporting

- Autopsies and morbidity and mortality conferences

- Malpractice claims files analysis

- Chart review

- Administrative data analysis

- Information technology

- Direct observation

- Clinical surveillance

Thomas & Petersen, JGIM 2003

Clinical Methods

- Morbidity & Mortality Conference [insert foto]

- Root Cause Analysis

- Good for SINGLE CASES at detecting latent errors

- Include information from

  - Multiple providers

  - Different times

  - Different locations

Root Cause Analysis

- What happened

- Why it happened

- Ways to prevent it from happening again

- How you will know you are safer

Potential Research Methods

- Interested in MULTIPLE measurements/descriptions that can be analyzed statistically

- Survey of healthcare staff (interview, survey)

- Analysis of existing data to identify contributing factors

- Prospective data collection using reporting systems or cohort studies

Examples

- Anonymous physician survey (Wu)

- Malpractice claims analysis (Studdert)

- Reporting & Learning systems

- Cohort study (Cullen)

- Association between nurse-patient ratio and surgical mortality (Aiken)

Provider Survey

- Good for latent errors

- Data otherwise unavailable

- Wisdom of crowds

- Can be comprehensive

- Hindsight bias (bad outcome = bad care)

- Need good response rate

Types of Questions

- Closed-ended (Standardized items and scales)

- Open-ended

- Semi-structured

Wu AW, Folkman S, McPhee SJ, Lo B. Do house officers learn from their mistakes? JAMA, 1991, 265:2089-2094

Link to Abstract (HTML)

Do house officers learn from their mistakes?

Wu AW, Folkman S, McPhee SJ, Lo B.

Department of Veterans Affairs, University of California, San Francisco.

Mistakes are inevitable in medicine. To learn how medical mistakes relate to subsequent changes in practice, we surveyed 254 internal medicine house officers. One hundred fourteen house officers (45%) completed an anonymous questionnaire describing their most significant mistake and their response to it. Mistakes included errors in diagnosis (33%), prescribing (29%), evaluation (21%), and communication (5%) and procedural complications (11%). Patients had serious adverse outcomes in 90% of the cases, including death in 31% of cases. Only 54% of house officers discussed the mistake with their attending physicians, and only 24% told the patients or families. House officers who accepted responsibility for the mistake and discussed it were more likely to report constructive changes in practice. Residents were less likely to make constructive changes if they attributed the mistake to job overload. They were more likely to report defensive changes if they felt the institution was judgmental. Decreasing the work load and closer supervision may help prevent mistakes. To promote learning, faculty should encourage house officers to accept responsibility and to discuss their mistakes.

Methods:

- Design: cross-sectional survey

  - Confidential, anonymous survey of physicians using free text and fixed response questions

  - Procedures: Survey mailed out and mailed back - If no reply, two reminder postcards sent

  - Design chosen to provide in-depth responses and ability to test hypotheses

- Other self-report methods which could have been used:

  - Semi-structured interviews

  - Small group discussions

  - Focus groups

  - One-to-one interviews

Methods: Population and Setting

- <u>Setting</u>: three large academic medical centers

- <u>Population</u>: house officers in residency training programs in internal medicine

  - Of all house officers contacted, 114 responded, representing a response rate of about 45%

  - All respondents reported a mistake

Methods: Data Collection

- Study developed a survey to be mailed out to house officers and mailed back once completed. Survey included:
  - Free text description: "most significant mistake and response to it"
  - Fixed response questions using adjective rating response scales
  - Validated scales from "Ways of Coping" instrument

- Survey package was distributed to universe of house officers in three residency training programs
  - Package included a pen and a self-addressed postage paid return envelope
  - Response postcards included a section to indicate that either the survey had been returned or that the recipient wished not to be bothered by any further contacts

Results: Key Findings

- Serious adverse outcome in 90% of cases, death in 31%

- A number of responses to mistakes by house officers identified:

  - Remorse

  - Fear and/or anger

  - Guilt

  - Isolation

  - Feelings of inadequacy

- 54% of respondents had discussed the mistake with a supervising physician

- Only 24% had told the patients or families

Results: Changes in Practice

- Constructive changes were more likely in house officers who accepted responsibility and discussed it

- Constructive changes were less likely if they attributed the mistake to job overload

- Defensive changes were more likely if house officer felt the institution was judgmental

Conclusion: Main Points

- Physicians in training frequently experience mistakes that harm patients
  - Mistakes included all aspects of clinical work

- Supervising physicians and patients are often not told about mistakes

- Overwork and judgmental attitudes by hospitals discourage learning
  - Educators should encourage house officers to accept responsibility and to discuss their mistakes

Author Reflections:

- This type of study could be replicated in developing or transitional countries to uncover local setting-sensitive and culturally relevant findings

Malpractice Claims Analysis

- Good for latent errors

- Multiple perspectives (patients, providers, lawyers)

- Hindsight bias

- Reporting bias

- Non-standardized source of data

- **Gandhi TK, Kachalia A, Thomas EJ, et al. Missed and delayed diagnoses in the ambulatory setting: a study of closed malpractice claims. Ann Intern Med. 2006;145:488-496**

Link to Abstract (HTML)

Link to Full Text (PDF)

Methods: Study Design and Objectives

- <u>Design</u>: retrospective malpractice claims analysis

  - Retrospective review of closed malpractice claims in which patients alleged a missed or delayed diagnosis in the ambulatory setting

- <u>Objectives</u>:

  - To develop a framework for investigating missed and delayed diagnoses in the ambulatory setting

  - To advance understanding of their causes

  - To identify opportunities for prevention

Methods: Study Population and Setting

- ## Setting:

  - Data obtained from four malpractice insurance companies based in the northeast, southwest and west United States

  - Together companies insured ~21 000 MDs, 46 hospitals, 390 outpatient

- ## Population:

  - Data extracted from random sample of closed claim files from insurers (1984 and 2004)

  - 429 diagnostic claims alleging injury due to missed or delayed diagnosis

  - 307 in ambulatory setting selected for further analysis

Methods: Data Collection

- Physician-investigators trained reviewers in the content of claim files, use of study instruments, confidentiality
  - Reviewers used detailed manuals
  - Scoring data forms were developed to extract the data

- For all claims, insurance staff recorded administrative details of the case and clinical reviewers recorded details of the adverse outcome the patient experienced

Methods: Data Collection (2)

- Step 1: reviewers assessed severity, possible causes of AE

  - Scored adverse outcomes on a 9-point severity scale ranging from emotional injury only (1) to death (9)

  - Considered the role of a series of contributing factors (cognitive, system or patient related causes)

- Step 2: reviewers judged whether the adverse outcome was due to diagnostic error

  - Used a 6-point confidence scale ranging from "little or no evidence" (1) to "virtually certain evidence" (6)

  - Claims that scored 4 ("more than 50-50 but a close call") or higher were classified as having an error

Methods: Data Collection (3)

- Step 3: for the subset of claims judged to involve errors, reviewers considered a defined sequence of diagnostic steps

  - E.g. history and physical examination, test ordering, creation of a follow up plan

  - Reviews graded their confidence that a process breakdown had occurred on a five-point Likert scale ranging from highly unlikely (1) to highly likely (5)

Results: Key Findings

- 59% of all ambulatory claims (181 of 307) judged to involve diagnostic errors that led to adverse outcomes.

  - 59% (106 of 181) of these errors were associated with serious harm

  - 30% (55 of 181) resulted in death

  - For 59% (106 of 181) of the errors, cancer was the diagnosis

Key Findings, cont…

- **Most common breakdowns in the diagnostic process :**
  - Failure to order an appropriate diagnostic test - 55%
  - Failure to create a proper follow-up plan - 45%
  - Failure to obtain an adequate history or perform an adequate physical examination - 42%
  - Incorrect interpretation of diagnostic tests - 37%

- **Median number of process breakdowns and contributing factors per error was 3.**

Results: Factors Contributing to Errors

- Most common contributing factors:
  - Failures in judgment - 79%
  - Vigilance or memory - 59%
  - Lack of knowledge - 48%
  - Patient-related factors - 46%
  - Handoffs - 20%

Conclusion: Main Points

- Diagnostic errors that harm patients and lead to malpractice claims are typically the result of multiple breakdowns involving individual and system factors

- Awareness of the most common types of breakdowns and factors could help efforts to identify and prioritize strategies to prevent diagnostic errors

Author Reflections: Lessons / Advice

- ## If one thing could be done differently…

  - *"Our instruments were too long and we collected a good deal of information that was never used. We could have been more targeted in what we extracted from claim files, and consequently more efficient in the reviews."*

- ## Research feasible in developing countries?

  - *"It would depend on (1) whether these countries had large amounts of medico-legal information on medical errors collected in a single place, like a malpractice liability insurer or a health care complaints office; and (2) what the quality and detail of those data were"*

Reporting & Learning System

- Can detect latent errors

- Provide multiple perspectives over time

- Can be a standard procedure

- Reporting bias

- Hindsight bias

All accidents must be reported.

... explain exactly what happened

Medication Event Data Collection Form - Microsoft Internet Explorer

File   Edit   View   Favorites   Tools   Help

Back   Search   Favorites   Media

Address https://www.clinweb.jhmi.edu/webforms/medevent/medevent.cfm?swide=760&sheight=456   Go   Links

The Johns Hopkins Hospital
Confidential
For Peer Review Only
Medication Event Data Collection Form

Your First Name	Your Last Name	Pt Location / Unit
		Inpatient:
		Outpatient:

Patient's First Name	Patient's Last Name	HxNo (DO NOT INCLUDE HYPHENS)

Date of Event	Time of Event (Military)	Service:
06-07-2004 MM-DD-YYYY	HHMM	

Drug(s) Involved in Event; Maximum of (3) Three; One per line; Use generic name when possible

Drug 1.)

Drug 2.)

Drug 3.)

SOURCE OF EVENT (Select as many as appropriate)

PRESCRIBING   DISPENSING   DRUG ADMINISTRATION

SOURCE OF EVENT (Select as many as appropriate)

PRESCRIBING
- [ ] Wrong drug ordered
- [ ] Wrong frequency ordered
- [ ] Potential over dose
- [ ] Potential under dose
- [ ] Wrong route ordered
- [ ] Illegible order
- [ ] Incomplete order
- [ ] Order written on wrong patient
- [ ] Drug ordered for pt with documented allergy & no justification
- [ ] No mg/kg calculation
- [ ] No allergy information on admission order
- [ ] Duplicate therapy
- [ ] Other

JHH Prescriber I.D. (enter Z0000 if not known)

DISPENSING
- [ ] Wrong drug dispensed
- [ ] Wrong dose dispensed
- [ ] Wrong dosage form dispensed
- [ ] Wrong concentration dispensed
- [ ] Expired drug dispensed
- [ ] Labeled in pharmacy incorrectly
- [ ] Missing Dose
- [ ] Other

MEDICATION ADMIN. RECORD
Manual MAR
- [ ] Transcription Discrepancy

Computer Generated MAR
- [ ] Duplicate drug
- [ ] Omitted drug
- [ ] MAR D/C'ed without order
- [ ] Other

DRUG ADMINISTRATION
Dose Omitted:
- [ ] Order not flagged
- [ ] Nurse missed order
- [ ] Patient unavailable
- [ ] Drug not available
- [ ] Wrong drug given
- [ ] Wrong dose/IV rate given
- [ ] Wrong route used
- [ ] Wrong dosage form given
- [ ] Wrong time
- [ ] Wrong patient
- [ ] Duplicate dose given
- [ ] Expired drug given
- [ ] Mixed/measured/prepared incorrectly on nurse unit
- [ ] Other

Drug Administration Device:
- [ ] incorrectly adjusted
- [ ] malfunctioned
- [ ] Other

☐ Other

☐ incorrectly adjusted

☐ malfunctioned

☐ Other

CLINICAL OUTCOME: (CHOOSE HIGHEST APPROPRIATE LEVEL)

0. ○ Event **did not** reach patient.

1. ○ Event reached patient; No treatment or increased monitoring necessary.

2. ○ Event reached patient; Increased monitoring required.

3. ○ Event reached patient; Unplanned treatment or increase in hospital stay (probable or actual) required.

4. ○ Event reached patient; Life-threatening event or serious morbidity or death occurred; Event may have contributed; **Contact the JHH Legal Hotline x5-7949**

NEAR MISS: A potential or actual medication error that did not harm the patient (level 0, 1, or 2) but would **likely** cause **significant** harm if it occurs again.

☐ ←Click here if event is a Near Miss.

Comments (include MD notification for administration errors)

Submit Event   **Clear Event**

Back to Web Forms Repository

Summary

- Can design investigation into reporting and learning systems

- Can also learn from recovery

Interactive

- Investigating the contributing factors in a case example, provided either by instructor or a participant

Summary

- Different methods to measure understand errors and adverse events have different strengths and weaknesses
  - Provider interview/survey
  - Malpractice claims analysis
  - Reporting & Learning systems
  - Direct observation
  - Cohort studies
- Mixed methods approaches can improve understanding

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Thank You