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**Patient Safety
Research Introductory
Course**

Session 4

Understanding Causes

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- Professor of Medicine, School of Medicine, Johns Hopkins University





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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.



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Components





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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



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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



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Case

- Post-operative patient
- Patient is penicillin allergic
- Order written for Timentin^R (ticarcillin)
- Antibiotic administered
- Patient has anaphylaxis and cardiac arrest



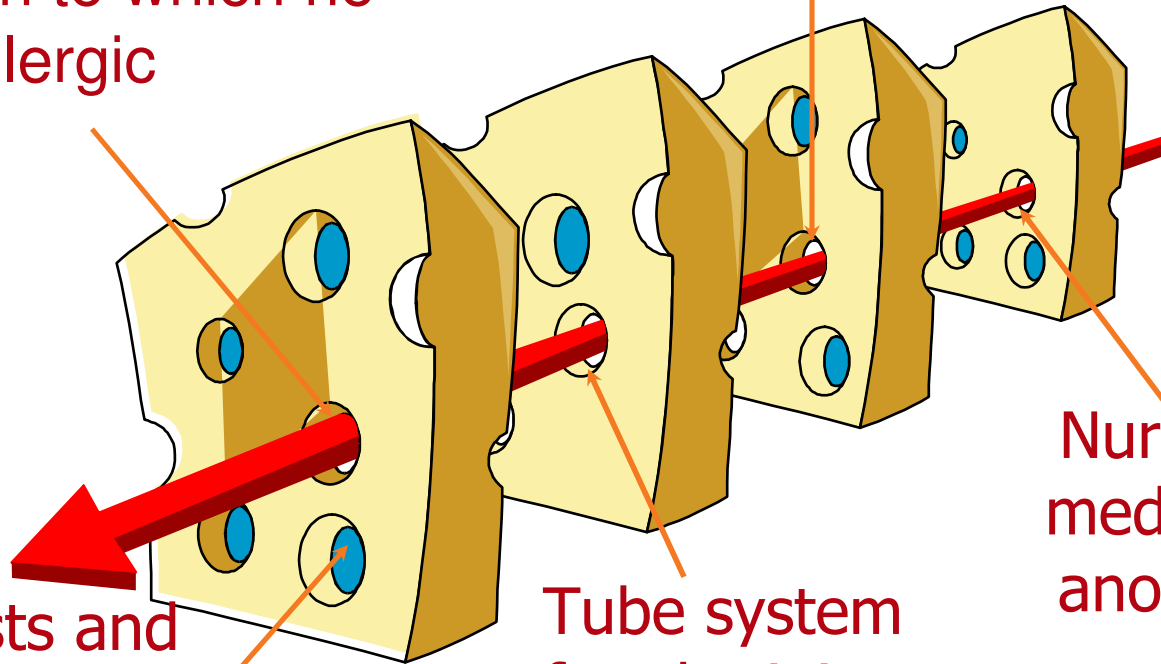
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Fax system for ordering medications is broken

Nurse gives the patient a medication to which he is allergic



Nurse borrows medication from another patient

Tube system for obtaining medications is broken

Patient arrests and dies

ICU nurse staffing



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What Should be Done?

- Be more careful
- Better education
- Make a policy

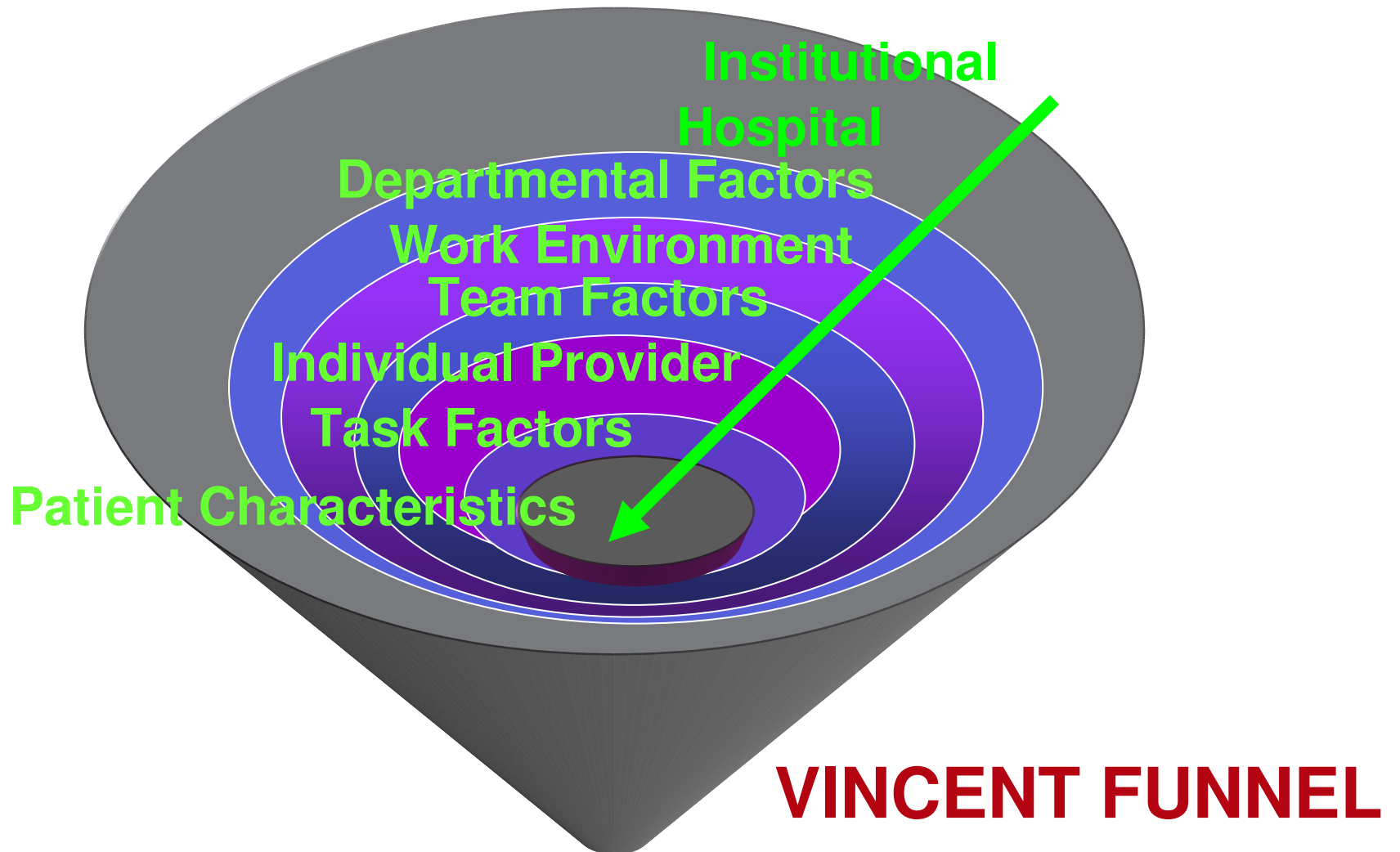
- It's the System!



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Four Basic Methods of Collecting Data

- Observation
- **Self-reports (interviews and questionnaires)**
- Testing
- Physical evidence (document review)



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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**

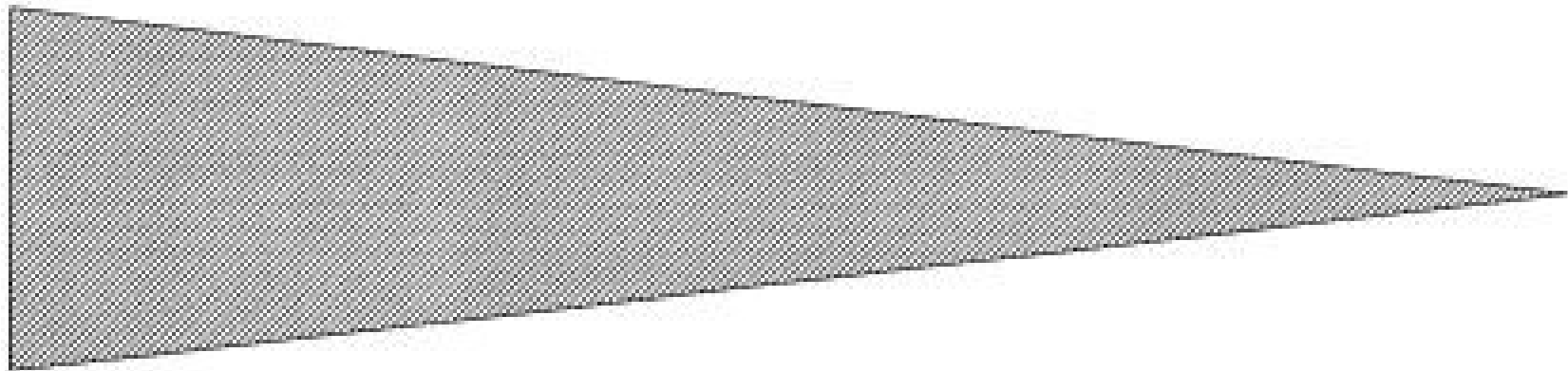


Relative Utility of Methods to Measure Errors

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



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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



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Root Cause Analysis

- What happened
- Why it happened
- Ways to prevent it from happening again
- How you will know you are safer



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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



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Examples

- Anonymous physician survey (Wu)
- Malpractice claims analysis (Studdert)
- Reporting & Learning systems

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



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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





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Types of Questions

- Closed-ended (Standardized items and scales)
- Open-ended
- Semi-structured



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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 (25%), 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.



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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



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Methods: Population and Setting

- Setting: three large academic medical centers
- Population: 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



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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



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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



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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



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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



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Author Reflections:

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



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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 \(PDF\)](#)

ARTICLE

Missed and Delayed Diagnoses in the Ambulatory Setting: A Study of Closed Malpractice Claims

Tejal K. Gandhi, MD, MPH, Alex Kachalia, MD, JD, Eric J. Thomas, MD, MPH, Ann Louise Puopolo, BSN, RN, Catherine Yoon, MS, Trepon A. Utzman, MD, JD, and David M. Studdert, LLJ, ScD

3 October 2006 | Volume 145 Issue 7 | Pages 488-496

Background: Although missed and delayed diagnoses have become an important patient safety concern, they remain largely unstudied, especially in the outpatient setting.

Objective: To develop a framework for investigating missed and delayed diagnoses, advance understanding of their causes, and identify opportunities for prevention.

Design: Retrospective review of 307 closed malpractice claims in which patients alleged a missed or delayed diagnosis in the ambulatory setting.

Setting: 4 malpractice insurance companies.

Measurements: Diagnostic errors associated with adverse outcomes for patients, process breakdowns, and contributing factors.

Results: A total of 107 claims (39%) involved diagnostic errors that harmed patients. Fifty-nine percent (106 of 107) of these errors were associated with serious harm, and 30% (65 of 181) resulted in death. Forty-nine percent (106 of 181) of the errors, cases were the diagnosis involved, chiefly breast (44 claims [24%]) and colorectal (13 claims [7%]) cancer. The most common breakdowns in the diagnostic process were failure to order an appropriate diagnostic test (100 of 181 [55%]), failure to create a proper follow-up plan (81 of 181 [45%]), failure to obtain an adequate history or perform an adequate physical examination (78 of 181 [43%]), and incorrect interpretation of diagnostic tests (67 of 181 [37%]). The leading factors that contributed to the errors were failures in judgment (143 of 181 [79%]), vigilance or memory (106 of 181 [59%]), knowledge (86 of 181 [48%]), patient-related factors (84 of 181 [46%]), and handling (36 of 181 [20%]). The median number of process breakdowns and contributing factors per error was 3 for both (interquartile range, 2 to 4).

Conclusions: Reviewers were not blinded to the litigation outcomes, and the reliability of the error determination was moderate.

Annals of Internal Medicine

ARTICLE

Missed and Delayed Diagnoses in the Ambulatory Setting: A Study of Closed Malpractice Claims

Tejal K. Gandhi, MD, MPH, Alex Kachalia, MD, JD, Eric J. Thomas, MD, MPH, Ann Louise Puopolo, BSN, RN, Catherine Yoon, MS, Trepon A. Utzman, MD, JD, and David M. Studdert, LLJ, ScD

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Conclusions: Reviewers were not blinded to the litigation outcomes, and the reliability of the error determination was moderate.

Contributors: Diagnostic errors that were patients can identify the result of multiple breakdowns and individual and system failures. Awareness of the most common types of mistakes in ambulatory care may help efforts to identify and provide strategies to prevent diagnostic errors.

WHITNEY AND JOHNSON ASSOCIATES, INC., BOSTON, MASSACHUSETTS

See also: [http://www.annals.org](#)

Missed and delayed diagnoses in the ambulatory setting are an important patient safety problem. The current diagnostic process in health care is complex, dynamic, and susceptible to failures and breakdowns. For example, one third of women with abnormal results on mammography or Pap smears do not receive follow-up care that is consistent with established guidelines (1, 2), and primary care providers often report delays in recognizing test results (3). Recognition of systemic problems in health care has prompted specific efforts (4, 5). However, this type of error remains largely unstudied (6). In large part of the errors in ambulatory care, diagnostic errors associated with missed diagnoses, they are difficult to identify, there is no standard reporting mechanism, and when they are identified, discussions to avoid similar events is usually insufficiently detailed to support detailed causal analyses. The work in a relatively new evidence base from which to launch efforts to create diagnostic errors. Moreover, recognition of the problems need to remain focused in the context of physician being, to the highest extent possible, the cause of the error. This is the intended type of error, because the useful analysis of other studies suggest that prevention such as malpractice suits (7, 8) has provided limited effectiveness (9, 10). Several malpractice lawsuits and process errors are a potentially rich source of information about missed and delayed diagnoses from malpractice insurance claims. Over the past decade, lawsuits alleging negligent malpractice have become the most prevalent type of claim in

the United States (11, 12). Second, diagnostic breakdowns that lead to claims tend to be associated with specific source categories. Third, statutory strength demonstrates on what happened in a malpractice lawsuit, claim file. In addition to the medical record, claim file includes diagnostic reports, physician and sometimes the results of external investigations.

Over a 10-year period, we use data from malpractice claims to study patient safety from malpractice malpractice lawsuits, including final sample size (13, 14), a focus on single (15) or multiple (16) claims (which contains a 10% of claims), limited information on the claims (17-21), reliance on internal case review by insurance adjusters than by independent reports (22, 23), and a general absence of

Discussion

Final 439

Content Review 439

Copyright Clearance Center 439

Copyright for Authors 439

Web-only

Appendix

Appendix Tables

Appendix Figures

Correction of Tables and Figures into HTML



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Methods: Study Design and Objectives

- Design: retrospective malpractice claims analysis
 - Retrospective review of closed malpractice claims in which patients alleged a missed or delayed diagnosis in the ambulatory setting
- Objectives:
 - 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



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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



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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



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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



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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)



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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



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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.**



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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%



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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



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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"*



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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*





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<p>Public Quick Clicks</p> <ul style="list-style-type: none"> ▶ GroupWise Web Access ▶ JHEM (Enterprise Messaging) ▶ JHED (Enterprise Directory) ▶ Micromedex ▶ Pathology - Lab Web ▶ JHMI Pager Box ▶ AmiOn 	<p>Internal Links (Within Hopkins Network)</p> <ul style="list-style-type: none"> ▶ Inside Hopkins Medicine ▶ JHH Department of Nursing ▶ WelchWeb/MyWelch/Ask-a-Librarian ▶ JHH Department of Surgery ▶ Johns Hopkins Antibiotic Guide ▶ Johns Hopkins Department Of Medicine ▶ JHU Department of Pediatrics ▶ Internal Medicine Ambulatory Curriculum ▶ JHMI Pathology ▶ Johns Hopkins School Of Medicine Medical Curriculum ▶ JH Medicine Center for Information Systems (JHMCIS) ▶ Report a Medication Event ▶ PSN-Report an Event or Service Concern 	<p>TOP STORY</p> <p>Broadway Research Building Celebration Please mark the afternoon of Tuesday, M 25, as a time for the Johns Hopkins Medi family to celebrate the completion of the Research Building on Broadway. Several events have been planned for faculty, students and staff, as well as other invite guests who have helped to plan, design & construct this wonderful new facility. Mor</p> <p>Garage Spring Cleaning Please note the dates when the following Baltimore parking facilities will be closed</p>
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4/26/04 - The XP Public Workstation migration update

Done Internet



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Medication Event Data Collection Form - Microsoft Internet Explorer

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

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Medication Event Data Collection Form**

Your First Name <input type="text"/>	Your Last Name <input type="text"/>	Pt Location / Unit Inpatient: <input type="text"/> <input type="button" value="v"/> Outpatient: <input type="text"/> <input type="button" value="v"/>
Patient's First Name <input type="text"/>	Patient's Last Name <input type="text"/>	HxNo (DO NOT INCLUDE HYPHENS) <input type="text"/>
Date of Event <input type="text" value="06-07-2004"/> MM-DD-YYYY	Time of Event (Military) <input type="text"/> HHMM	Service: <input type="text"/> <input type="button" value="v"/>
Drug(s) Involved in Event; Maximum of (3) Three; One per line; Use generic name when possible		
Drug 1.) <input type="text"/>		
Drug 2.) <input type="text"/>		
Drug 3.) <input type="text"/>		
SOURCE OF EVENT (Select as many as appropriate)		
PRESCRIBING	DISPENSING	DRUG ADMINISTRATION



Windows taskbar icons: back, forward, stop, refresh, home, search, star, globe, mail, printer, folder, window, close.

SOURCE OF EVENT (Select as many as appropriate)

PRESCRIBING	DISPENSING	DRUG ADMINISTRATION
<input type="checkbox"/> Wrong drug ordered	<input type="checkbox"/> Wrong drug dispensed	Dose Omitted:
<input type="checkbox"/> Wrong frequency ordered	<input type="checkbox"/> Wrong dose dispensed	<input type="checkbox"/> Order not flagged
<input type="checkbox"/> Potential over dose	<input type="checkbox"/> Wrong dosage form dispensed	<input type="checkbox"/> Nurse missed order
<input type="checkbox"/> Potential under dose	<input type="checkbox"/> Wrong concentration dispensed	<input type="checkbox"/> Patient unavailable
<input type="checkbox"/> Wrong route ordered	<input type="checkbox"/> Expired drug dispensed	<input type="checkbox"/> Drug not available
<input type="checkbox"/> Illegible order	<input type="checkbox"/> Labeled in pharmacy incorrectly	<input type="checkbox"/> Wrong drug given
<input type="checkbox"/> Incomplete order	<input type="checkbox"/> Missing Dose	<input type="checkbox"/> Wrong dose/IV rate given
<input type="checkbox"/> Order written on wrong patient	<input type="checkbox"/> Other	<input type="checkbox"/> Wrong route used
<input type="checkbox"/> Drug ordered for pt with documented allergy & no justification	<input type="text"/>	<input type="checkbox"/> Wrong dosage form given
<input type="checkbox"/> No mg/kg calculation	MEDICATION ADMIN. RECORD	<input type="checkbox"/> Wrong time
<input type="checkbox"/> No allergy information on admission order	Manual MAR	<input type="checkbox"/> Wrong patient
<input type="checkbox"/> Duplicate therapy	<input type="checkbox"/> Transcription Discrepancy	<input type="checkbox"/> Duplicate dose given
<input type="checkbox"/> Other	Computer Generated MAR	<input type="checkbox"/> Expired drug given
<input type="text"/>	<input type="checkbox"/> Duplicate drug	<input type="checkbox"/> Mixed/measured/prepared incorrectly on nurse unit
JHH Prescriber I.D. (enter Z0000 if not known)	<input type="checkbox"/> Omitted drug	<input type="checkbox"/> Other
<input type="text"/>	<input type="checkbox"/> MAR D/C'ed without order	<input type="text"/>
	<input type="checkbox"/> Other	Drug Administration Device:
	<input type="text"/>	<input type="checkbox"/> incorrectly adjusted
		<input type="checkbox"/> malfunctioned
		<input type="checkbox"/> Other



Navigation icons: back, forward, home, search, star, globe, refresh, mail, printer, document, folder, window, close.

<input type="checkbox"/>	<input type="checkbox"/> Other <input type="text"/>	<input type="checkbox"/> incorrectly adjusted <input type="checkbox"/> malfunctioned <input type="checkbox"/> Other <input type="text"/>
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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](#)



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Summary

- Can design investigation into reporting and learning systems
- Can also learn from recovery



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Interactive

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



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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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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



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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**



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Thank You