World Health Organization | Patient Safety

A World Alliance for Safer Health Care

Introduction to Patient Safety Research

Presentation 3 - Measuring harm: Malpractice claims analysis

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3: Overview

- **Objective**
  - To develop a framework for investigating missed and delayed diagnoses, advance understanding of causes, and identify opportunities for prevention.
- **Methods**
  - Retrospective review of 307 closed malpractice claims in which patients alleged a missed or delayed diagnosis in the ambulatory setting.
- **Results**
  - A total of 181 claims (59%) involved diagnostic errors that harmed patients. 59% of these errors associated with serious harm and 30% resulted in death.
  - Most common process breakdowns were failure to: order an appropriate diagnostic test (55%), create a proper follow-up plan (45%), obtain an adequate history or perform adequate physical examination (42%).
  - Leading contributing factors: failures in judgment (79%), vigilance or memory (59%), knowledge (48%) and patient-related factors (46%).
- **Conclusions**
  - 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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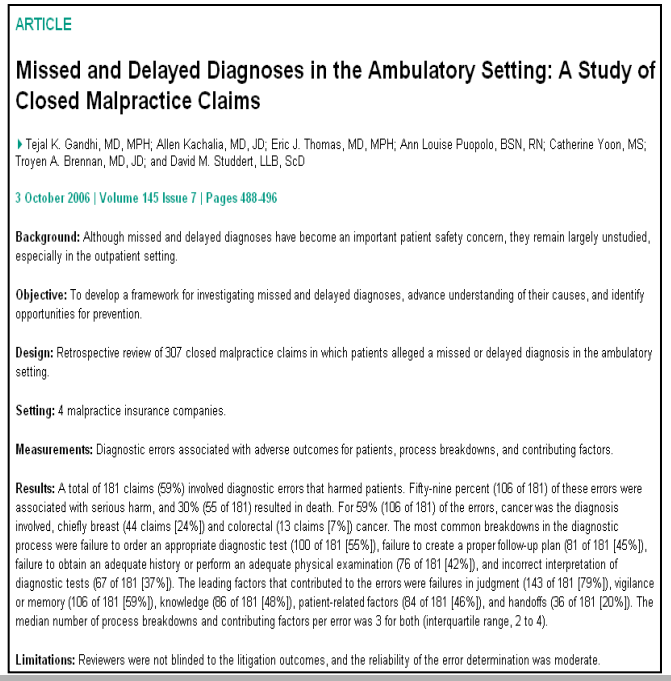
4: Introduction: Study Details

- **Full Reference**
  - 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; Allen Kachalia, MD, JD; Eric J. Thomas, MD, MPH; Ann Louise Puopolo, BSN, RN; Catherine Yoon, MS; Troyen A. Brennan, MD, JD; and David M. Studdert, LLB, ScD

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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.

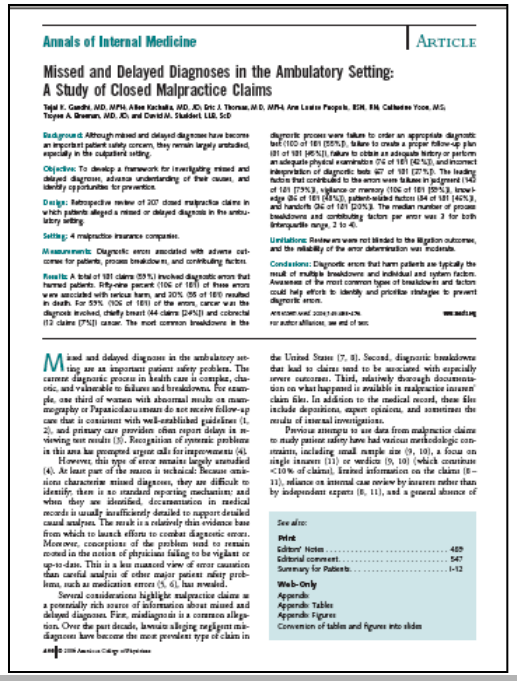
Design: Retrospective review of 307 closed malpractice claims in which patients alleged a missed or delayed diagnosis in the ambulatory setting.

Setting: 4 malpractice insurance companies.

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

Results: A total of 181 claims (59%) involved diagnostic errors that harmed patients. Fifty-nine percent (106 of 181) of these errors were associated with serious harm, and 30% (55 of 181) resulted in death. For 59% (106 of 181) of the errors, cancer was 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 (76 of 181 [42%]), 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 handoffs (36 of 181 [20%]). The median number of process breakdowns and contributing factors per error was 3 for both (interquartile range, 2 to 4).

Limitations: 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

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Missed and delayed diagnoses in the ambulatory setting are an important patient safety problem. The current diagnostic process in health care is complex, chaotic, and vulnerable to failures and breakdowns. For example, one third of women with abnormal results on mammography or Papanicolaou smears do not receive follow-up care that is consistent with well-established guidelines (1, 2), and primary care providers often report delays in reviewing test results (3). Recognition of systematic problems in this area has prompted urgent calls for improvement (4).

However, this type of error remains largely unstudied (4). At least part of the reason is technical: Because omissions characterize missed diagnoses, they are difficult to identify; there is no standard reporting mechanism; and when they are identified, documentation in medical records is usually insufficiently detailed to support detailed causal analysis. The result is a relatively thin evidence base from which to launch efforts to combat diagnostic errors. Moreover, conceptions of the problem tend to remain rooted in notions of physicians failing to be vigilant or up-to-date. This is a less nuanced view of error causation than careful analysis of other major patient safety problems, such as medication errors (5, 6), has revealed.

Several considerations highlight malpractice claims as a potentially rich source of information about missed and delayed diagnoses. First, misdiagnosis is a common allegation. Over the past decade, lawsuits alleging negligent misdiagnoses have become the most prevalent type of claim in the United States (7, 8). Second, diagnostic breakdowns that lead to claims tend to be associated with especially severe outcomes. Third, relatively thorough documentation on what happened is available in malpractice insurers' claim files. In addition to the medical record, these files include depositions, expert opinions, and sometimes the results of internal investigations.

Previous attempts to use data from malpractice claims to study patient safety have had various methodologic constraints, including small sample size (9, 10), a focus on single insurers (11) or verdicts (9, 10) (which constitute <10% of claims), limited information on the claims (8–11), reliance on internal case review by insurers rather than by independent experts (8, 11), and a general absence of

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5: Introduction: Patient Safety Research Team

- **Lead researcher – Professor David Studdert, LLB, ScD, MPH**
  - Federation Fellow, Faculty of Law
  - University of Melbourne in Melbourne, Australia
  - Field of expertise: health services research
- **Other team members:**
  - Dr. Tejal Gandhi, MD, MPH
  - Dr. Allen Kachalia, MD, JD
  - Dr. Eric Thomas, MD, MPH
  - Ann Louise Puopolo, BSN, RN
  - Catherine Yoon, MS
  - Dr. Troyen A. Brennan, MD, JD

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6: Background: Opening Points

- Current diagnostic process in health care is complex, chaotic, and vulnerable to failures and breakdowns
  - Missed diagnoses are difficult to identify
  - There is no standard reporting mechanism
- There is only a small evidence base to inform efforts to combat diagnostic errors
  - Documentation in medical records is usually insufficiently detailed to support detailed causal analyses

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7: Background: Study Rationale

- Missed and delayed diagnoses are an important patient safety concern but remain largely unstudied, especially in the outpatient setting
- Malpractice claims are a rich potential source of information about missed and delayed diagnoses
  - Misdiagnosis is a common allegation
  - Misdiagnoses that lead to malpractice claims tend to be associated with especially severe outcomes
  - Relatively thorough documentation on what happened is available in malpractice insurers' claim files

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8: Background: Study Rationale (2)

- Part of a larger project, called the Malpractice Insurers Medical Error Prevention Study (MIMEPS)
  - Goal of MIMEPS was to test potential for medical malpractice insurance files to shed light on factors contributing to medical errors
  - Funded by the US Agency for Healthcare Research and Quality

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9: Background: Setting Up the Research Team

- **MIMEPS drew together a team of leading patient safety researchers from Harvard and Brigham and Women's Hospital**
  - ***"We were lucky in that established groups of patient safety researchers with expertise relevant to this study were at Harvard and the Brigham and Women's Hospital.***
  - ***These are major centres of patient safety research, and much of the research in patient safety began at these institutions."***

10: Background: Setting Up the Research Team (2)

- Study lead by internal medicine physicians (Drs. Gandhi and Kachalia)
  - Expertise in primary care necessary to understand clinical context for missed and delayed diagnoses in the ambulatory setting
- Obtaining funding
  - Received grant from the Agency for Healthcare Research and Quality (for research on various aspects of patients safety)

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11: 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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12: Methods: Study Population and Setting

- **Setting:**
  - Data obtained from four malpractice insurance companies based in the northeast, southwest and west United States
    - Insurers contributed claim files in proportion to their annual claims volume
  - Collectively these companies insured approximately 21 000 physicians, 46 acute care hospitals and 390 outpatient facilities
- **Population:**
  - Data were extracted from random sample of closed claim files from insurers between 1984 and 2004
  - From these, reviewed 429 diagnostic claims alleging injury due to missed or delayed diagnosis
  - 307 of these took place in the ambulatory setting and were selected for further analysis

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13: Methods: Data Collection

- Physician-investigators trained reviewers in the content of claim files, use of study instruments and confidentiality procedures
  - 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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14: Methods: Data Collection (2)

- Step 1: reviewers assessed severity and possible causes of the adverse outcome
  - 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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15: 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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16: Methods: Data Analysis and Interpretation

- **Study examined the characteristics of the claims, patients, injuries and the frequency of various contributing factors**
  - Characteristics of error subgroups were compared (Pearson chi-square tests)
  - Measured interrater reliability of the injury and error determinations (percentage agreement and kappa scores)

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17: 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
- Most common breakdowns in the diagnostic process were:
  - 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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18: 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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19: 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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20: Conclusion: Study Impact

- **Academic impact**
  - Proposed a framework and methodology for studying missed and delayed diagnoses
- **Policy impact**
  - Several of the insurers studied have taken the findings and are developing interventions to help their insured institutions address high risk areas identified in the study.
- **Practice impact**
  - Advanced knowledge among patient safety researchers about missed and delayed diagnoses

21: Conclusion: Practical Considerations

- **Study duration**
  - Approximately 48 months
- **Cost**
  - MIMEPS was a $4 million US study (direct and indirect costs).
  - Portion devoted to two analyses of missed and delayed diagnosis (this paper was one of a pair) was probably $500,000 US.
- **Additional resources**
  - Computers, statistical programming packages (STATA, SAS)
- **Required competencies**
  - Clinical expertise, patient safety experts, statistical experts
- **Ethical approval**
  - Took approximately 18 months to obtain all ethics approvals at all the sites involved in the study

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22: Author Reflections: Lessons and Advice

- **If one thing in the study 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 may be feasible and applicable 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"*
  - *"Patient safety research is probably more important in the developing world than anywhere else."*

23: Author Reflections: Selecting Design

- **Possible alternative research methods**
  - *"A variety of methods could be used to study missed diagnoses, including chart review or analysis of events gathered in adverse event reporting systems."*
- **Challenge**
  - *"The problem is finding a large enough number of the errors to be able to begin to discern patterns of breakdowns."*
- **Solution**
  - *"Claims offered this advantage. About 40% of US malpractice claims are for alleged errors in diagnosis, so here was an enriched and untapped sample."*

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24: Author Reflections: Overcoming Barriers

- **What barriers or problematic issues did you encounter when setting up your research and how did you overcome these?**
  - *"The largest barrier was convincing five medical malpractice insurers to collaborate with us on the study and share their claims data. This was not easy to do; this type of information is protected very closely.*
  - *In the end, we were able to secure agreement with most (but not all) of the insurers we approached. Agreeing to focus only on closed (i.e. completed) claims was a an important compromise."*
- **Securing ethical approval**
  - *"Another barrier was securing the approximately 20 ethics approvals we needed to do this multi-site study. There was no way around this and the barrier could only be crossed with hard work and patience."*

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25: Author Reflections: Ideas for Future Research

- **Recommendations for future research in developing countries**
  - *"I believe there will be much more commonality than difference in the etiology of medical error between developing and developed worlds, but getting these practical research issues right is an essential precursor to good work.*
  - *My sense is that a major priority is to derive methods that are suitable—namely, fit the data sources, map appropriately to etiological factors, and are realistic for the data collection constraints of the local environment.*
  - *Any research focused on doing that—which would essentially be methods-oriented research—would be very valuable."*

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26: Additional Resources and Tools

- Versions of the SAQ, as well as SAQ Users Manual and additional data can be downloaded at:
  - http://www.utpatientsafety.org