Missed and Delayed Diagnoses in the Emergency Department: A Study of Closed Malpractice Claims From 4 Liability Insurers

Allen Kachalia, MD, JD Tejal K. Gandhi, MD, MPH Ann Louise Puopolo, BSN, RN Catherine Yoon, MS Eric J. Thomas, MD, MPH Richard Griffey, MD, MPH Troyen A. Brennan, MD, JD David M. Studdert, LLB, ScD From the Division of General Medicine (Kachalia, Gandhi, Puopolo, Brennan) and Department of Emergency Medicine (Griffey), Brigham and Women's Hospital, Boston, MA; Harvard School of Public Health, Boston, MA (Yoon, Brennan, Studdert); and the University of Texas Health Science Center, Houston, TX (Thomas).

Study objectives: Diagnostic errors in the emergency department (ED) are an important patient safety concern, but little is known about their cause. We identify types and causes of missed or delayed diagnoses in the ED.

Methods: This is a review of 122 closed malpractice claims from 4 liability insurers in which patients had alleged a missed or delayed diagnosis in the ED. Trained physician reviewers examined the litigation files and the associated medical records to determine whether an adverse outcome because of a missed diagnosis had occurred, what breakdowns were involved in the missed diagnosis, and what factors contributed to it. Main outcome measures were missed diagnoses, process breakdowns, and contributing factors.

Results: A total of 79 claims (65%) involved missed ED diagnoses that harmed patients. Forty-eight percent of these missed diagnoses were associated with serious harm, and 39% resulted in death. The leading breakdowns in the diagnostic process were failure to order an appropriate diagnostic test (58% of errors), failure to perform an adequate medical history or physical examination (42%), incorrect interpretation of a diagnostic test (37%), and failure to order an appropriate consultation (33%). The leading contributing factors to the missed diagnoses were cognitive factors (96%), patient-related factors (34%), lack of appropriate supervision (30%), inadequate handoffs (24%), and excessive workload (23%). The median numbers of process breakdowns and contributing factors per missed diagnosis were 2 and 3, respectively.

Conclusion: Missed diagnoses in the ED have a complex cause. They are typically the result of multiple breakdowns in the diagnostic process and several contributing factors. [Ann Emerg Med. 2007;49:196-205.]

0196-0644/\$-see front matter Copyright © 2007 by the American College of Emergency Physicians. doi:10.1016/j.annemergmed.2006.06.035

SEE EDITORIAL, P. 206.

INTRODUCTION

Medical error continues to capture the attention of the medical profession, policymakers, and the public.¹ Inpatient care has been the major focus of attention, but there is increasing recognition of the risks of iatrogenic harm in the outpatient setting, including the emergency department (ED).²⁻⁵ Diagnostic errors are of particular concern and throughout the last decade have

become the most prevalent type of malpractice claim in the United States.^{2,6,7}

The ED is an especially challenging environment in which to consistently make accurate and timely diagnoses. Patients often present with high-acuity illness, elevating the stakes from the outset.⁸ Triage, consultations, admissions, discharge, and other steps in emergency care are operationally complex and must usually be executed under tight time constraints. Emergency physicians seldom have a continuous relationship with the

Editor's Capsule Summary

What is already known on this topic

Mistaken or delayed diagnoses in the emergency department (ED) can produce adverse outcomes. The mechanisms by which they occur are poorly understood.

What question this study addressed

Seventy-nine closed malpractice claims involving mistaken or delayed ED diagnoses were intensively scrutinized to develop descriptions of the settings in which such failures occurred and to explore possible contributing factors.

What this study adds to our knowledge

Most diagnostic failures resulted from multiple contributing factors; they were not "single-point" failures. Diagnostic failures were spread over a variety of clinical conditions; in this collection of cases, there was no single clinical condition or group of conditions that could be targeted for amelioration.

How this might change clinical practice

At present, understanding of the origins of diagnostic failures in ways that might be practically addressed in practice is minimal. The traditional approach has been punishment and training. The multifactorial nature of diagnostic failures suggests that novel approaches are needed to improve performance.

patients they treat, and the continuous nature of an ED necessitates a perpetual cycle of shift changes and handoffs.^{8,9} Supervision needs are high because trainees with widely varying clinical backgrounds and skills participate in care delivery. These intrinsic pressures of emergency care are amplified by crowding¹⁰⁻¹² and increasing utilization by uninsured patients.¹³

Previous studies of missed diagnoses in the ED have focused on specific diagnoses or used epidemiologic methods to identify clinical risk factors.^{8,14-20} However, little is known about the system-of-care factors that lead to diagnostic errors. Medical malpractice claims files present a potentially valuable source of information. They often involve severe injuries; they represent a powerful catchment point for information on errors; and by drawing together documentation from both formal legal inquiries and confidential internal investigations, they present a substantially richer body of information about the antecedents of medical injury than the medical record alone. Several clinical areas,^{2,21-25} most notably anesthesiology,²⁶ have made impressive use of malpractice claims file analysis.

We analyzed a sample of medical malpractice claims involving allegations of misdiagnosis in the ED. The study goal was to determine specifically where breakdowns in the diagnostic process occurred and what contributing factors (systems, cognitive, and patient-related) played a role in their occurrence. Such descriptive information may help to identify priority areas for interventions to enhance safety in the ED.

MATERIALS AND METHODS

Four malpractice insurance companies based in 3 regions in the United States (northeast, southwest, and west) participated in the study. Collectively, the insurers covered approximately 21,000 physicians, 46 acute care hospitals (20 academic and 26 nonacademic), and 390 outpatient facilities. Institutional review boards at the investigators' institutions and at each review site approved the study.

Data were extracted from random samples of closed malpractice claims files at each insurer. The claims file is the repository of information accumulated by the insurer during the life of a claim. It captures a wide variety of data and usually includes the statement of the claim, interrogatories, depositions, and other litigation-related documents; reports of internal investigations; expert opinions from both sides; medical reports and records detailing the plaintiff's pre- and postevent condition; and, while the claim is open, medical records pertaining to the episode of care at issue. We reacquired the relevant medical records from insured institutions for sampled claims.

Following previous studies, we defined a claim as a written demand for compensation for medical injury.^{27,28} Claims involving missed or delayed diagnosis were defined as those alleging an error in diagnosis or testing that resulted in a delay in appropriate treatment or a failure to act or follow up on diagnostic test results. We excluded allegations related to pregnancy or to care rendered solely in the inpatient setting. We focused on the outpatient setting, including the ED, because of the prevalence of this type of claim and the perceived importance of outpatient diagnostic errors in patient safety research and medical malpractice policy.

We established a target number of claims for each site, which represented the insurer's estimate of the total number of claims closed during the previous 5 years that would be eligible for inclusion in the sample. Working with staff at the insurers, we used administrative databases to generate lists of candidate claims and reviewed narrative summaries to confirm that they met the applicable category definition. We began with the most recently closed claims and moved back in time until the target number was reached. We anticipated that the claims of missed diagnosis would implicate care during long periods and multiple sites of care, with a majority of the sites being the primary care physician's office. The principal location of alleged errors was not known before commencement of the claim file reviews.

We reviewed a total of 429 claims of missed or delayed diagnoses, 122 (28%) of which involved allegations of substandard diagnostic care in the ED. This analysis focuses on those ED claims.

Sampled claims files were reviewed at the insurers' offices or insured facilities by physicians. We used board-certified attending physicians, fellows, or third-year residents in internal

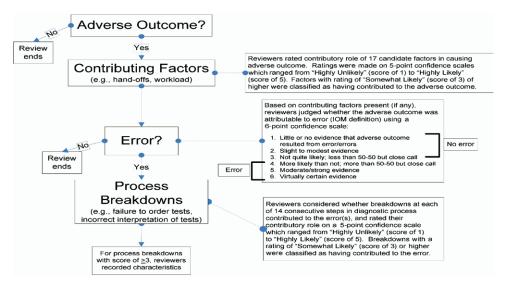


Figure 1. Review sequence and relationship between adverse outcomes, errors, contributing factors, and breakdowns.

medicine to conduct the reviews. Physician investigators (A.K., T.K.G., E.J.T.) trained the reviewers in the content of claims files, use of the study instruments, and confidentiality procedures in 1-day sessions at each site. The reviewers were also assisted by a detailed manual. Reviews took 1.4 hours per file on average. Resource constraints and the labor-intensiveness of reviews dictated use of 1 reviewer per file. However, to test the reliability of the review process, 42 of the 429 diagnostic claims were rereviewed by a second reviewer from the same group who was unaware of the first review.

A sequence of 4 instruments guided the review. Figure 1 overviews the review process and key determinations. For all claims, administrative details of the case (Administrative Screening Data Form) were recorded. Next, reviewers verified that the patient had sustained an adverse outcome (Outcome Assessment Form) and graded its severity on a 9-point severity scale, ranging from emotional injury only to death.²⁹ To simplify presentation of our results, we grouped scores on this scale into 5 categories (emotional, minor, significant, major, and death).

To make the error determination, reviewers were led through questions that considered the potential role of a range of contributing factors (Human Factors Form) in causing the patient's adverse outcome; these factors were selected according to a review of the patient safety literature and covered system-, clinician-, and patient-related factors. Reviewers then judged, in light of all available information and their decisions about contributing factors, whether the adverse outcome was due to diagnostic error. We used the Institute of Medicine's definition of error, namely, "the failure of a planned action to be completed as intended (ie, error of execution) or the use of a wrong plan to achieve an aim (ie, error of planning)."³⁰ The error determination was based on prevailing practice approaches and technology available when the alleged error occurred. Reviewers recorded their judgment on a 6-point confidence scale, ranging from 1, "little or no evidence that adverse outcome resulted from error/errors" to 6, "virtually certain evidence that adverse outcome resulted from error/errors." Claims that scored 4 ("more likely than not that adverse outcome resulted from error/errors; more than 50-50 but a close call") or higher were classified as having an error.

Finally, for claims with errors, reviewers completed a form (Missed and Delayed Error Form) that collected additional clinical information about the missed diagnosis, including the setting and the importance of involved clinicians' contributions (graded on 5-point Likert scale, ranging from "somewhat important" to "highly important"). This form also presented reviewers with a defined sequence of diagnostic steps (eg, medical history/physical examination, test ordering, creation of follow-up plan) and asked them to grade their confidence that a breakdown had occurred at each step (5-point Likert scale, ranging from "highly unlikely" to "highly likely"). If a breakdown was judged to have been at least "somewhat likely" (score of 3 or higher on the scale), reviewers were directed to consider a non–mutually exclusive list of reasons for the breakdown at this point in the diagnostic process.

Reviewers were not blinded to the litigation outcomes, because it was logistically impossible to censor this information in the files. However, they were instructed to ignore this outcome and exercise independent clinical judgment in rendering injury and error determinations. Training sessions stressed that the study definition of error is not synonymous with the legal definition of negligence and that a mix of factors besides merit influences whether claims are paid during litigation.

A secondary review was conducted by a board-certified emergency physician (R.G.), who considered free-text summaries of all claims in which the original reviewer had determined that a missed diagnosis led to an adverse outcome. This special review was conducted because we became concerned that the original reviewers' lack of specialty training in emergency medicine may have led to incorrect determinations as to what qualified as missed diagnoses. This retrospective check on the work of the original reviewers focused on the possibility of false positives; for cases judged not to involve adverse outcomes or error, there was insufficient information about the clinical circumstances to support a secondary review.

Primary Data Analysis

The hand-completed data forms were electronically entered and verified by a professional data entry vendor and sent to the Harvard School of Public Health for analysis. Additional checks and data cleaning were performed by study programmers to ensure the data set's quality. Analyses were conducted with the SAS 8.2 (SAS Institute, Inc., Cary, NC) and Stata/SE 8.0 (Stata Corporation, College Station, TX) statistical software packages.

The primary unit of analysis is the entire sequence of care in a claim judged to involve diagnostic error that led to an adverse outcome. For ease of exposition, we hereafter refer to such sequences as "missed diagnoses." We examined characteristics of the claims, patients, and injuries in our sample and the frequency of the various process breakdowns and contributing factors. κ Scores were used to measure interrater reliability of the injury and error determinations.³¹

RESULTS

One hundred twenty-two of the claims alleged diagnostic error in the ED. The claims alleged injuries sustained between 1979 and 2001. All the claims were closed between 1984 and 2003. In 80% of the claims, the alleged diagnostic error occurred in 1990 or later, and in 46%, it occurred in 1994 or later.

In 3% (4/122) of the claims, no adverse outcome or change in the patient's clinical course was evident. Thirty-two percent (39/122) of the claims contained an adverse outcome but no error. The remaining 65% (79/122) of the claims involved a diagnostic error that was linked to an identifiable adverse outcome. This group of 79 missed diagnoses is the focus of our analyses.

In 40 of the 42 claims that underwent 2 independent reviews, the original reviewers agreed about whether an adverse outcome had occurred (95% agreement). There was 72% agreement among the reviewers about whether an error had occurred (κ =0.42, 95% confidence interval -0.05 to 0.66).

In the secondary review, the emergency physician reviewer agreed with 55 of the 79 original error determinations (70%). For the rest, he was not comfortable verifying the original determination without further information beyond the short narrative available to him. In no case did he determine that a mistake had been made with respect to the original error determination. Table 1. Key characteristics of 79 diagnostic errors in the ED.

Characteristics	No.	%	
Patient characteristics			
Age, y			
Mean	41	N/A	
SD	20	N/A	
Range	1–81	N/A	
Female	35	44	
Health insurance*			
Private	28	58	
Uninsured	7	15	
Medicaid	4	8	
Medicare	4	8	
Other	6	13	
Clinicians involved [†]			
Emergency physician	41	52	
Primary care physician	22	28	
Surgeon	16	20	
Radiologist	13	16	
Nurse	8	10	
Trainees [*]	44	56	
Adverse outcome [§]			
Psychiatric/emotional only	1	1	
Minor physical	9	11	
Significant physical	26	33	
Major physical	12	15	
Death	31	39	
Missed or delayed diagnosis			
Fracture	15	19	
Infection	12	15	
Myocardial infarction	8	10	
Cancer	7	9	
Cerebral vascular disease	6	8	
Embolism	4	5	
Appendicitis	4	5	
Other abdominal disease	4	5	
Peripheral vascular disease	3	4	
Aneurysm	2	3	
Other cardiac disease	2	3	
Other	12	15	

N/A, not applicable.

*Patient's health insurance was missing in 30 claims (38%). Percentages calculated using nonmissing observations as the denominator.

 $^{\dagger}\text{Percentages}$ do not sum 100% because multiple providers were involved in some errors.

*Resident, fellow, or intern.

[§]The levels of injury represent groupings of the scores on the National Association of Insurance Commissioners' 9-point severity scale: psychiatric/emotional only (1), minor (2 and 3), significant (4-6), major (7 and 8), and death (9). ^{II}Other than cancer.

Characteristics of Study Subjects

The mean age of patients was 41 years (median 39 years), with 13% of missed diagnoses occurring in the care of children (Table 1). Of these missed diagnoses, 39% led to death and 48% involved adverse outcomes rated as significant (33%) or major (15%).

The types of missed diagnoses were diffuse. The leading types were fractures (19%), infections (15%), myocardial infarction (10%), and cancer (9%), which together accounted for more than half. Overall, the missed diagnoses tended to

Example 1. A 72-year-old woman with history of coronary angioplasty presents by ambulance for chest pain, nausea and vomiting, diarrhea, shortness of breath, and bilateral arm tingling. An EKG revealed new ST depressions that were not diagnosed; the ED physician did not compare with an old EKG. Cardiac enzyme tests were not ordered. The patient was discharged with a diagnosis of gastroenteritis. A cardiologist reviewed the EKG later and noted the abnormalities but did not immediately notify the ED. After the ED was notified, the patient was asked to return. The patient subsequently died from the myocardial infarction.

Example 2. A 44-year-old man with obesity and history of peptic ulcer disease presented to the ED with anorexia, epigastric pain, and blood-streaked emesis. He was tachycardic and mildly hypotensive. Blood was drawn for laboratory tests, and results were within normal limits. The patient was given ketorolac and then discharged. The patient sustained a cardiac arrest 2 days later. He was found to have had a perforated duodenal ulcer.

Example 3. A 9-year-old girl presented to the ED 4 times in 1 week with fever, sore throat, and back and abdominal pain. During the first visit, a throat culture was taken and later was positive for streptococcus, but it was not specifically reported to anyone. During the next 2 visits, the culture results were not reviewed, and the patient was diagnosed with a viral syndrome. She presented for her fourth ED visit with paralysis and loss of bladder control. After some delay in evaluation during that fourth visit, she was found to have an epidural abscess.

Example 4. A 30-year-old man presented to ED with jaw pain after trauma. He was evaluated by a first-year surgical house officer, who ordered a CT scan for head trauma. No facial radiographs or CTs were ordered. The patient was diagnosed with a jaw fracture 3 weeks later.

Example 5. A 29-year-old woman was treated by an ED house officer and attending physician for injuries after a motor vehicle crash. A chest radiograph of another patient was mistakenly read by the house officer and attending physician. Consequently, a pneumothorax was missed. The patient was discharged with a diagnosis of a rib fracture. A radiologist read the correct radiograph and diagnosed a pneumothorax. The patient was called back to the ED. At that time, she had developed a tension pneumothorax.

Example 6. A 55-year-old man with hypertension presented to the ED with 6-7 days of back and flank pain. He was sent for an intravenous pyelogram (IVP) to evaluate for renal stones. Because of an exceedingly busy ED, his systolic blood pressure of 70 was not diagnosed until after the IVP. He was then taken to the operating room for emergency aortic abdominal aneurysm rupture more than 12 hours after he presented.

Figure 2. Clinical examples of identified diagnostic errors.

Table 2. Diagnostic steps and frequency of breakdowns ateach step.

Step	No.	%*
Patient notes problem and seeks care	3	4
Provider performs medical history and physical examination	33	42
Provider orders appropriate tests	46	58
Ordered tests performed in a timely manner	3	4
Ordered tests performed correctly	1	1
Test results transmitted to and received by the provider	13	16
Test results transmitted to and received by the patient	6	8
Interpretation of test results	29	37
Provider orders consultation (or referral) [†]	26	33
Requested consultation (or referral) occurs [†]	1	1
Creation of proper follow-up plan	21	27
Patient adherence with plan	6	8

*Calculated as a percentage of 79 claims with identified errors.

[†]A failure to order a consultation in the ED includes the failure to order an immediate consultation in the ED, the failure to order an appropriate outpatient subspecialty referral, and the failure of trainees to consult with more senior physicians.

involve acute rather than chronic conditions. The median interval between when diagnosis should have been made (ie, in the absence of error) and when it actually was made was 2.5 days (mean 68 days; SD 528 days). One third (26/79) of delays spanned fewer than 24 hours.

Approximately half of the missed diagnoses (52%) involved emergency physicians. The next most frequent contributors were general internists (28%) and surgeons (20%). Trainee physicians were involved in 56% of the missed diagnoses; in three quarters (32/44) of these events, a trainee had the highest contributory rating of any personnel involved.

Figure 2 provides clinical examples of the missed diagnoses. Table 2 shows, in chronologic order, the framework used by reviewers to locate breakdowns in the diagnostic process; it also shows the frequency of breakdowns at each step. The 4 leading breakdowns were failure to order tests (58%), inadequate medical history and physical examination (42%), incorrect interpretation of tests (37%), and failure to request a consultation (33%).

Table 3 details the 3 most common breakdowns. Among failures to order appropriate diagnostic tests, radiographs were the test most frequently missed (22%), followed by computed tomography (CT) (17%), cardiac enzyme levels (15%), ultrasonography (13%), and hematologic laboratory tests (11%). Plain radiographs led the list of the misinterpreted tests, accounting for more than half of them (52%). Clinicians failed to order tests because they did not recognize that they were required (93%) or lacked knowledge that the test was indicated (52%); they misinterpreted tests primarily because of errors in clinical judgment (62%) and inexperience (24%).

The 3 most common contributing factors were mistakes in judgment (87% of missed diagnoses), lack of technical competence or knowledge (58%), and lapses in vigilance or memory (41%) (Table 4). Ninety-six percent of missed

Table O	Detelle	+			م من برما م برما م	:	م مالد	dia dia antia invasa ana
Table 3.	Details	or the 3	most	common	preakdowns	In	the	diagnostic process.

Process Breakdown	Reason for Breakdown	Percentage Within Category	Tests*	Percentage Within Category
Failure to order appropriate	Provider did not believe tests were required	93	Radiologic study	61
diagnostic/laboratory	Provider lacked appropriate knowledge	52	Plain radiograph	22
tests (n=46)	Failure of communication among providers	7	СТ	17
			Ultrasonography	13
			Blood tests	30
			Cardiac enzymes	15
			Blood cell counts	11
			Blood cultures	7
			Other study	30
Inadequate medical	Incomplete physical examination	48	N/A	N/A
history/physical	Providers lacked appropriate knowledge	42	N/A	N/A
examination (n=33)	Failure to elicit relevant information	27	N/A	N/A
	Patient provided inaccurate history	24	N/A	N/A
Incorrect interpretation of	Error in clinical judgment	62	Radiographic scan	66
diagnostic/laboratory	Inexperience	24	Plain radiograph	52
tests (n=29)	Failure of communication among providers	14	CT	7
	Whose misinterpretation?		Blood test	14
	Emergency physician	48	Blood cell counts	10
	Radiologist	41	Other	17
	Primary care physician	10	ECG	10

Table 4. Factors contributing to diagnostic errors.

Factor	No.	%*
Cognitive factors	76	96
Judgment	69	87
Knowledge	46	58
Vigilance or memory	32	41
Communication factors	28	35
Handoffs	19	24
Establishment of clear lines of responsibility	5	6
Conflict	2	3
Other communication factor	7	9
Systems factors	29	37
Supervision	24	30
Workload	18	23
Interruptions	4	5
Fatigue	3	4
Technology	0	0
Ergonomics	0	0
Patient-related factors	27	34
Patient nonadherence	8	10
Atypical presentation	6	8
Complicated medical history	6	8
Substance abuse	6	8
Poor historian	4	5
Psychiatric issue	3	4
Obesity	2	3
Language barrier	1	1

*Calculates as a percentage of 79 claims with identified errors.

diagnoses involved at least 1 of these "cognitive" factors. The other leading contributing factors were patient-related factors (34%), lack of appropriate supervision (30%), inadequate handoff (24%), and excessive workload (23%).

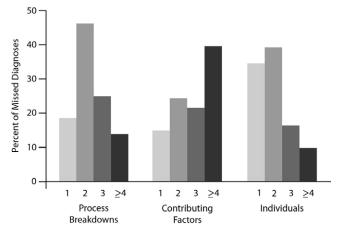


Figure 3. Number of process breakdowns, contributing factors, and individuals associated with missed diagnoses.

Missed diagnoses frequently involved multiple breakdowns, contributing factors, and contributing clinicians (Figure 3). The median number of process breakdowns per missed diagnosis was 2; 81% had at least 2 process breakdowns, 38% had at least 3, and 13% had at least 4, which left only 15 missed diagnoses that involved a breakdown at only 1 point in the care process ("single-point breakdowns"). A majority (8/15) of these single-point breakdowns were failures to order tests.

The median number of contributing factors per missed diagnosis was 3; 85% had at least 2 contributing factors, 61% had at least 3, and 39% had at least 4. Hence, although cognitive factors contributed to virtually all missed diagnoses, they operated alone in only one third of cases; in the remaining two thirds, they were present alongside other contributing factors. With respect to contributing clinicians, two thirds (52/ 79) of the missed diagnoses involved more than 1 clinician, 27% of the errors had at least 3, and 10% had at least 4.

The factors that contributed to missed diagnoses involving trainees differed from those that led to missed diagnoses without trainees in several ways. The trainee events were more likely to involve inadequate supervision (55% versus 0%), patient-related factors (48% versus 17%), and excessive workload (36% versus 6%).

LIMITATIONS

The use of malpractice claims for addressing patient safety has limitations. First, severe injuries are probably overrepresented because they are more likely to trigger litigation. Second, certain breakdowns or contributing factors may not have been discernible in claims file review, even though they played a role; to the extent that this occurred, the prevalence findings for such estimates will be lower bounds, and the multifactorial causality we observed probably understates the true complexity of missed diagnoses. Alternatively, reviewers may have overstated the role of some breakdowns or contributing factors, particularly cognitive factors in circumstances in which the reasons for the adverse outcome were difficult to explain.

Third, certain factors or breakdowns that lead to litigated missed diagnoses cases may differ systematically from the factors or breakdowns that lead to nonlitigated ones, although we know of no reason why they would. To the extent that the profile of missed diagnoses in malpractice claims diverges from that of missed diagnoses more broadly, some of the targets for intervention our findings highlight may have a disproportionately large impact on the type of events that prompt claims.

Our study had several other limitations. EDs in teaching hospitals are overrepresented in our sample, so the missed diagnoses we identified may not be generalizable to every ED. Reviewers were general internists, not emergency physicians. The lack of this specialist perspective may have led to some misidentification of missed diagnoses, process breakdowns, and contributing factors (both false positives and false negatives).

Finally, reviewers' judgments about the appropriateness of care is likely to have been influenced by hindsight bias.³²⁻³⁴ One possible version of this bias is knowledge of the litigation outcome, which may have encouraged findings of errors in paid claims and vice versa.^{35,36} A second version relates to the presence of adverse outcomes, especially severe ones, which may have prompted inferences that care was inappropriate. A third, more general version of hindsight bias may have stemmed from reviewers' recognition that the data source was a malpractice claim file.

DISCUSSION

By reviewing malpractice claims files related to care in the ED, this study identified 79 missed diagnoses that varied widely in type, often involved acute illnesses, and frequently resulted in severe injury. The cause of these events was complex, with the majority involving multiple breakdowns in the diagnostic process, several contributing factors, and more than 1 provider. The most common breakdown points were test ordering and interpretation, performance of the medical history and physical examination, and initiation of consultations. Cognitive factors contributed to almost every missed diagnosis, but they usually acted in concert with other types of factors, particularly supervision, handoffs, workload levels, and patient-related factors.

Most research into diagnosis errors in the ED has been aimed at specific diagnoses, particularly myocardial infarctions, fractures, and infections.^{8,14-20,37-40} Studies have identified problems in diagnostic steps such as history taking, interpretation of ECGs and radiographs, and clinical decisionmaking.^{40,41} Previous research has also identified gaps in clinician knowledge, mistakes in judgment, fatigue, and poor handoffs as factors in missed diagnoses.⁴²⁻⁴⁴ Our findings echo these results.

From a prevention perspective, targeting interventions at selected diagnoses with high potential for being overlooked may produce significant gains. Such an approach is well suited to the use of explicit clinical algorithms designed by appropriate experts. However, serious diagnostic errors—at least those evident in malpractice claims data—cover a broad range of diagnoses; the top 3 diagnoses accounted for less than half of the misses identified in our study sample. Such dispersion suggests that error prevention strategies aimed at specific diagnoses, even the most prevalent ones, will leave a large number of diagnostic problems unaddressed. Furthermore, designing and implementing interventions diagnosis by diagnosis may be logistically impractical; for example, diagnostic algorithms may not prospectively capture all atypical presentations.

As the patient safety movement has gathered momentum during the past decade, experts have increasingly pushed for attention to causes of error at the systems level, noting that this approach has the potential for cross-cutting gains.^{2,8,16,45,46} We sought to adopt this perspective in examining the heterogeneous group of missed and delayed diagnoses found among malpractice claims.

Breakdowns in the diagnostic steps that require active clinician decisionmaking—specifically, conducting patient medical histories and physical examinations, ordering and interpreting tests, ordering consultations, and creating follow-up plans—were common, occurring in all but 2 of the missed diagnoses (97%). Failure to order appropriate tests was the most frequent breakdown. Appropriate test ordering, like other steps that involve active decisionmaking, requires 2 key ingredients: the availability of the right information on which to base the decision and correct application of cognitive skills to this information. We found the latter component to be particularly problematic. The same was generally true with the other active decisionmaking steps.

There have been many attempts to implement clinical decision support systems for diagnosis and treatment determinations.⁴⁷⁻⁵⁰ Although evaluations have demonstrated benefits in the selection of treatments,⁵¹⁻⁵⁵ evidence of the value in the diagnostic area is more mixed.^{48,50,56-59} Workflow impediments and efficiency concerns appear to have obstructed adoption or effectiveness.^{48,56-58} This study's findings emphasize the importance of continuing to press for successful implementation of decision support systems.

Process breakdowns at steps in which clinician decisionmaking played no, or a relatively minor, role—for example, the proper performance of ordered tests, transmission of test results, and follow-through on requested consultations were much less common. Nonetheless, breakdowns in some such "passive" steps are still cause for concern. In 1 in 6 missed diagnoses, for example, test results did not reach the correct clinicians.

The problem of transmission of critical test results in clinical practice is now well recognized.^{60,61} Breakdown in transmission is especially troubling in the ED setting, where tests are generally ordered for immediate review. EDs should therefore pay close attention to their communication policies and procedures for critical test results, including strategies such as direct communication of findings between radiology or laboratories and the ordering providers.

Problems in test result transmission also highlight the stresses on continuity of care—shift changes, multiple providers per patient, and discharge back to the primary care provider—that are, to some degree, essential features of emergency treatment. Not surprisingly, handoff breakdowns were present in almost a quarter of the missed diagnoses we identified. There is a growing awareness of the implications of discontinuities in care; our findings underscore the fact that the diagnostic process in the ED is also affected.⁶² Strategies being promoted nationwide to improve these discontinuity problems through standardized handoff procedures and communications⁶³ should not ignore the ED.

Excessive workload in the ED was identified as a contributing factor in almost a quarter of the cases. This is consistent with reports that EDs today are frequently crowded.^{11,12,63,64} The significant harm associated with excessive workload levels suggests that whereas the traditional image of hurried providers rapidly triaging and treating patients in the ED may provide for an exciting work environment, it also poses a threat to patient safety.

ED staff in academic medical centers face the dual challenge of providing high-quality care and providing excellent training to medical students and house officers from multiple specialties. Supervision of residents has drawn increasing attention today, especially in light of the "80-hour" workweek in teaching hospitals.⁶⁵ The prevalence of supervision problems in the errors we identified suggests that ongoing efforts in this area may pay dividends in patient safety. Close oversight of trainees' diagnostic evaluations in the ED may bring particularly large returns at times of high workload or when complicating patient factors such as atypical presentation and complicated medical histories are involved. Of course, this strategy poses major implementation challenges because times of hectic workload are often exactly the moments when supervision is most difficult.

Awareness of the potential severity of patient injury caused by missed diagnoses in the ED should motivate efforts to avoid these breakdowns. Our findings highlight potential opportunities for achieving this. In terms of prioritization, the lower proportion of missed diagnoses that involved breakdowns in more passive cognitive points in the diagnostic process suggests that, even though interventions targeted at these steps will improve patient safety, better support for active cognitive processes has the potential to avert more harm. Addressing problems with particular contributing factors—such as handoffs, supervision, and workload—may also prove to be high-yield strategies.

Cost and feasibility remain key challenges for mounting interventions. Challenges associated with measures to guard against cognitive errors have proved to be especially formidable.^{66,67} Crossmatching frequent process breakdowns with underlying contributing factors may help. For example, automatically doublechecking clinician interpretations of test results might be useful in reducing breakdowns in this step. Enhanced staffing during periods of heavy workload might improve supervision (attending involvement) of trainee physicians. However, even targeted interventions may face serious implementation problems and may introduce new safety concerns.⁶⁸⁻⁷⁰ The net effects of such interventions should thus be carefully evaluated.

In conclusion, missed diagnoses in the ED can have severe consequences and are a major patient safety concern. They are also complex, involving multiple process breakdowns and contributing factors. Prevalent breakdown points and contributing factors represent targets of opportunity in preventing missed diagnoses. Use of medical malpractice claims data to unravel their cause and identify such targets has limitations but may offer valuable insights.

The authors thank Allison Nagy and Ilina Chaudhari for their invaluable assistance with data collection.

Supervising editor: Robert L. Wears, MD, MS

Authors contributions: TAB and DMS conceived the study and obtained funding. AK, TKG, and DMS designed this analysis. TKG, ALP, EJT, and DMS designed the data collection instruments. AK, TKG, ALP, EJT, and DMS trained physician reviewers. TAB and DMS undertook recruitment of participating sites. ALP, CY, and DMS managed the data collection, including quality control. RG contributed to quality control efforts after the data had been collected. AK, TKG, CY, and DMS analyzed the data. AK, TKG, and DMS drafted the article, and all authors contributed substantially to revision of its intellectual content. AK, TKG, and DMS take responsibility for the paper as a whole. *Funding and support:* This study was supported by grants from the Agency for Healthcare Research and Quality (HS011886-03) and the Harvard Risk Management Foundation. Dr. Studdert was also supported by grant KO2HS11285 from the Agency for Healthcare Research and Quality.

Publication dates: Received for publication November 13, 2005. Revisions received March 15, 2006, and June 7, 2006. Accepted for publication June 26, 2006. Available online December 1, 2006.

Reprints not available from the authors.

Address for correspondence: David M. Studdert, LLB, ScD, Department of Health Policy and Management, Harvard School of Public Health, 677 Huntington Avenue, Boston, MA 02115; 617-432-5209, fax 617-432-4494.

REFERENCES

- 1. Altman DE, Clancy C, Blendon RJ. Improving patient safety: five years after the IOM report. *N Engl J Med.* 2004;351:2041-2043.
- Phillips RL Jr, Bartholomew LA, Dovey SM, et al. Learning from malpractice claims about negligent, adverse events in primary care in the United States. *Qual Saf Health Care*. 2004;13: 121-126.
- 3. Gandhi TK, Weingart SN, Borus J, et al. Adverse drug events in ambulatory care. *N Engl J Med.* 2003;348:1556-1564.
- Thomas EJ, Studdert DM, Burstin HR, et al. Incidence and types of adverse events and negligent care in Utah and Colorado. *Med Care.* 2000;38:261-271.
- 5. Biros MH, Adams JG, Wears RL. Errors in emergency medicine: a call to action. *Acad Emerg Med.* 2000;7:1173-1174.
- Chandra A, Nundy S, Seabury SA. The growth of physician medical malpractice payments: evidence from the national practitioner data bank. *Health Aff (Millwood).* 2005;Suppl Web Exclusives: W5-240-W5-249.
- Selbst SM, Friedman MJ, Singh SB. Epidemiology and etiology of malpractice lawsuits involving children in US emergency departments and urgent care centers. *Pediatr Emerg Care*. 2005; 21:165-169.
- 8. Fordyce J, Blank FSJ, Pekow P, et al. Errors in a busy emergency department. *Ann Emerg Med.* 2003;42:324-333.
- 9. Kuhn G. Circadian rhythm, shift work, and emergency medicine. *Ann Emerg Med.* 2001;37:88-98.
- Asplin R, Magid J, Rhodes R, et al. A conceptual model of emergency department crowding. *Ann Emerg Med.* 2003;42:167-172.
- 11. Derlet R, Richards J, Kravitz R. Frequent overcrowding in U.S. emergency departments. *Ann Emerg Med.* 2001;8:151-155.
- 12. Trzeciak S, Rivers EP. Emergency department overcrowding in the United States: an emerging threat to patient safety and public health. *Emerg Med J.* 2003;20:402-405.
- McLaughlin CG, Mortensen K. Who walks through the door? the effect of the uninsured on hospital use. *Health Aff (Millwood)*. 2003;22:143-155.
- McCarthy BD, Beshansky JR, D'Agostino RB, et al. Missed diagnoses of acute myocardial infarction in the emergency department: results from a multicenter study. *Ann Emerg Med.* 1993;22:579-582.
- Pope JH, Aufderheide TP, Ruthazer R, et al. Missed diagnoses of acute cardiac ischemia in the emergency department. *N Engl J Med.* 2000;342:1163-1170.
- Espinosa JA, Nolan TW. Reducing errors made by emergency physicians in interpreting radiographs: longitudinal study. *BMJ*. 2000;320:737-740.

- 17. Graff L, Russell J, Seashore J, et al. False-negative and falsepositive errors in abdominal pain evaluation: failure to diagnose acute appendicitis and unnecessary surgery. *Acad Emerg Med*. 2000;7:1244-1255.
- Trautlein JJ, Lambert R, Miller J. Malpractice in the emergency room: a critical review of undiagnosed appendicitis cases and legal actions. *Qual Assur Util Rev.* 1987;2:54-56.
- Pimentel L, McPherson SJ. Community-acquired pneumonia in the emergency department: a practical approach to diagnosis and management. *Emerg Med Clin North Am.* 2003;21:395-420.
- 20. Thomas HG, Mason AC, Smith RM, et al. Value of radiograph audit in an accident service department. *Injury.* 1992;23:47-50.
- Elshove-Bolk J, Simons M, Cremers J, et al. A description of emergency department-related malpractice claims in The Netherlands: closed claims study 1993-2001. *Eur J Emerg Med*. 2004;11:247-250.
- 22. Hurwitz B. Learning from primary care malpractice: past, present and future. *Qual Saf Health Care*. 2004;13:90-91.
- Kravitz RL, Rolph JE, McGuigan K. Malpractice claims data as a quality improvement tool, I: epidemiology of error in four specialties. *JAMA*. 1991;266:2087-2092.
- Rolph JE, Kravitz RL, McGuigan K. Malpractice claims data as a quality improvement tool, II: is targeting effective? *JAMA*. 1991; 266:2093-2097.
- American Society of Anesthesiologists (ASA) Closed Claims Project. Available at: http://depts.washington.edu/asaccp/ ASA/index.shtml. Accessed January 31, 2006.
- 26. Cheney FW. The American Society of Anesthesiologists Closed Claims Project: what have we learned, how has it affected practice, and how will it affect practice in the future? *Anesthesiology*. 1999;91:552-556.
- Weiler PC, Hiatt HH, Newhouse JP, et al. A Measure of Malpractice: Medical Injury, Malpractice Litigation, and Patient Compensation. Cambridge, MA: Harvard University Press; 1993.
- Studdert DM, Brennan TA, Thomas EJ. Beyond dead reckoning: measures of medical injury burden, malpractice litigation, and alternative compensation models from Utah and Colorado. *Indiana Law Rev.* 2000;33:1643-1686.
- National Association of Insurance Commissioners. National Association of Insurance Commissioners, Malpractice Claims: Final Compilation. Brookfield, WI: National Association of Insurance Commissioners; 1980.
- Kohn LT, Corrigan JM, Donaldson MS. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 1999.
- Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33:159-174.
- Caplan RA, Posner KL, Cheney FW. Effect of outcome on physician judgments of appropriateness of care. *JAMA*. 1991; 265:1957-1960.
- Fischhoff B. Hindsight is not equal to foresight: the effect of outcome knowledge on judgment under uncertainty. J Exp Psychol. 1975;1:288-299.
- 34. Woods DD, Cook RI. Perspectives on human error: hindsight biases and local rationality. In: Durso FT, Nickerson RS, Schvaneveldt RW, et al, eds. *Handbook of Applied Cognition*. New York, NY: John Wiley & Sons; 1999.
- Guthrie C, Rachlinski JJ, Wistrich AJ. Inside the judicial mind. Cornell Law Rev. 2001;86:777-830.
- 36. LaBine SJ, LaBine G. Determinations of negligence and the hindsight bias. *Law Hum Behav.* 1996;20:501-516.
- Mehta RH, Eagle KA. Missed diagnoses of acute coronary syndromes in the emergency room: continuing challenges. *N Engl J Med*. 2000;342:1207-1210.

- Pelberg AL. Missed myocardial infarction in the emergency room. Qual Assur Util Rev. 1989;4:39-42.
- Mayer JA, Lewis EC, Slymen DJ, et al. Patient reminder letters to promote annual mammograms: a randomized controlled trial. *Prev Med.* 2000;31:315-322.
- 40. Guly HR. Diagnostic errors in an accident and emergency department. *Emerg Med J.* 2001;18:263-269.
- Rusnak RA, Stair TO, Hansen K, et al. Litigation against the emergency physician: common features in cases of missed myocardial infarction. *Ann Emerg Med.* 1989;18:1029-1034.
- 42. Croskerry P. The cognitive imperative: thinking about how we think. *Acad Emerg Med.* 2000;7:1223-1231.
- Wears RL, Perry SJ. Human factors and ergonomics in the emergency department. Ann Emerg Med. 2002;40:206-212.
- 44. White AA, Wright SW, Blanco R, et al. Cause-and-effect analysis of risk management files to assess patient care in the emergency department. *Acad Emerg Med.* 2004;11:1035-1041.
- 45. Goldman L, Kirtane AJ. Triage of patients with acute chest pain and possible cardiac ischemia: the elusive search for diagnostic perfection. *Ann Intern Med.* 2003;139:987-995.
- 46. Graber M, Gordon R, Franklin N. Reducing diagnostic errors in medicine: what's the goal? *Acad Med.* 2002;77:981-992.
- Bates DW, Kuperman GJ, Wang S, et al. Ten commandments for effective clinical decision support: making the practice of evidence-based medicine a reality. *J Am Med Inform Assoc.* 2003;10:523-530.
- Hunt DL, Haynes RB, Hanna SE, et al. Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systematic review. *JAMA*. 1998;280: 1339-1346.
- 49. Friedman CP, Gatti GG, Franz TM, et al. Do physicians know when their diagnoses are correct? implications for decision support and error reduction. *J Gen Intern Med.* 2005;20:334-339.
- Garg AX, Adhikari NKJ, McDonald H, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. *JAMA*. 2005;293:1223-1238.
- Dexter PR, Perkins S, Overhage JM, et al. A computerized reminder system to increase the use of preventive care for hospitalized patients. *N Engl J Med.* 2001;345:965-970.
- McDonald C. Protocol-based computer reminders, the quality of care and the non-perfectibility of man. N Engl J Med. 1976;295: 1351-1355.
- 53. McDonald CJ, Hui SL, Smith DM, et al. Reminders to physicians from an introspective computer medical record: a two-year randomized trial. *Ann Intern Med.* 1984;100:130-138.
- 54. Mosen D, Elliott CG, Egger MJ, et al. The effect of a computerized reminder system on the prevention of postoperative venous thromboembolism. *Chest*. 2004;125:1635-1641.

- Overhage JM, Tierney WM, McDonald CJ. Computer reminders to implement preventive care guidelines for hospitalized patients. *Arch Intern Med.* 1996;156:1551-1556.
- Graber MA, VanScoy D. How well does decision support software perform in the emergency department? *Emerg Med J.* 2003;20: 426-428.
- 57. Borzo J. Software for symptoms. *Wall Street Journal.* May 23, 2005:R10.
- 58. Selker HP, Beshansky JR, Griffith JL, et al. Use of the Acute Cardiac Ischemia Time-Insensitive Predictive Instrument (ACI-TIPI) to assist with triage of patients with chest pain or other symptoms suggestive of acute cardiac ischemia: a multicenter, controlled clinical trial. *Ann Intern Med.* 1998;129:845-855.
- Friedman CP, Elstein AS, Wolf FM, et al. Enhancement of clinicians' diagnostic reasoning by computer-based consultation: a multisite study of 2 systems. *JAMA*. 1999;282:1851-1856.
- 60. Roy CL, Poon EG, Karson AS, et al. Patient safety concerns arising from test results that return after hospital discharge. *Ann Intern Med.* 2005;143:121-128.
- 2005 Joint Commission National Patient Safety Goals. Available at: http://www.jointcommission.org/PatientSafety/NationalPatientSafety Goals/05_npsgs.htm. Accessed August 26, 2006.
- 62. Gandhi TK. Fumbled handoffs: one dropped ball after another. Ann Intern Med. 2005;142:352-358.
- 63. Joint Commission for Accreditation of Healthcare Organizations. 2006 Joint Commission National Patient Safety Goals. Available at: http://www.jointcommission.org/PatientSafety/NationalPatient SafetyGoals/06_npsgs.htm. Accessed August 26, 2006.
- 64. Derlet RW, Richards JR. Overcrowding in the nation's emergency departments: complex causes and disturbing effects. *Ann Emerg Med.* 2000;35:63-68.
- 65. Sox CM, Burstin HR, Orav EJ, et al. The effect of supervision of residents on quality of care in five university-affiliated emergency departments. *Acad Med.* 1998;73:776-782.
- 66. Graber ML, Franklin N, Gordon R. Diagnostic error in internal medicine. *Arch Intern Med.* 2005;165:1493-1499.
- Famularo G, Salvini P, Terranova A, et al. Clinical errors in emergency medicine: experience at the emergency department of an Italian teaching hospital. *Acad Emerg Med.* 2000;7: 1278-1281.
- Ash JS, Berg M, Coiera E. Some unintended consequences of information technology in health care: the nature of patient care information system-related errors. *J Am Med Inform Assoc.* 2004; 11:104-112.
- Koppel R, Metlay JP, Cohen A, et al. Role of computerized physician order entry systems in facilitating medication errors. *JAMA*. 2005;293:1197-1203.
- Wears RL, Berg M. Computer technology and clinical work: still waiting for Godot. JAMA. 2005;293:1261-1263.

Did you know?

You can save your online searches and get the results by e-mail.

Visit www.annemergmed.com today to see what else is new online!