



2014

Annual Benchmarking Report

Malpractice Risks in the Diagnostic Process

crico | strategies

A division of the Risk Management Foundation of the Harvard Medical Institutions, Inc.

In the past 12 months, have you or someone in your practice:

- Treated a new patient on the assumption that a prior diagnosis was correct?
- Failed to establish a differential diagnosis based primarily on confidence in the initial diagnosis?
- Based a diagnosis on a misinterpreted test or lab result?
- Referred a patient to a specialist despite a lack of confidence the patient would book the appointment?
- Heard second hand that one of your patients recently died of an undiagnosed condition?



**MARK E.
REYNOLDS**
*President
CRICO*

Over the past 15 years, health care providers have steadily addressed the underlying issues that lead to malpractice claims and suits related to medication mishaps and errors in obstetrical and surgical care. That focus and response has led to fundamental changes in how surgery patients and intrapartum mothers are assessed and monitored, and how clinicians recover from missteps before patients are harmed. In that same timeframe, however, relatively scant attention has been paid to errors during the diagnostic process which, according to the data from the Comparative Benchmarking System (CBS) are more common than obstetrical errors, and more costly than surgical cases. The analysis detailed in our 2014 Report opens our eyes to where and when diagnosis-related errors most commonly occur, and furthers discussion about the changes necessary to prevent them.



Let's Not Miss This Opportunity



HEATHER RIAH *Assistant Vice President, CRICO Strategies*

The bright media lights that shone on the recent case of a mismanaged Ebola diagnosis exposed the everyday challenges faced by clinicians to get the right diagnosis “right away.” Of course, in most cases, the missed diagnosis is not exotic, and the details are not considered newsworthy. Within health care, however, diagnosis-related events cannot be relegated to the back page. Thus, the awareness raised by high-profile events helps to maintain efforts (and resources) directed at the common problems that hinder clinicians during the diagnostic process and result, too often, in patient harm. In support of those efforts, we are pleased to offer this year’s *Annual Benchmarking Report: Malpractice Risks in the Diagnostic Process*.

This Report examines more than 4,700 diagnosis-related malpractice cases that demonstrate the pitfalls that put patients at risk of a missed or significantly delayed diagnosis. Most notably, our analysis pinpoints where in the clinician’s thought process mistakes are most likely to occur. Understanding the vulnerabilities in the cognitive process of reaching a diagnosis is crucial information. Should you focus on ensuring that physicians update each patient’s personal and family history? Are vague or ambiguous test results being inappropriately dismissed? Do multiple providers who synthesize the same evidence fail to reconcile differing conclusions and, thus, leave the patient with no answers... or the wrong answer?

Organizations striving to understand these issues need to dig deeper into what triggers their diagnosis-related claims and discern how other organizations have responded to similar vulnerabilities. To that end, we are grateful for the commitment of the members of our CBS community who have made this Report possible. Through this collective analysis, and active collaboration of our partner organizations and dedicated experts, we have an opportunity—and an obligation—to reduce patient harm. We hope this Report accelerates the development and adoption of a broader set of effective solutions to the cognitive and systemic problems that can impede prompt and accurate diagnoses.

Sincerely,



Heather Riah

“We assume we’re right when we make a diagnosis unless we hear otherwise, then we keep making the same mistake over and over again.”

Robert Trowbridge, MD
Maine Medical Center

**OVER
VIEW**

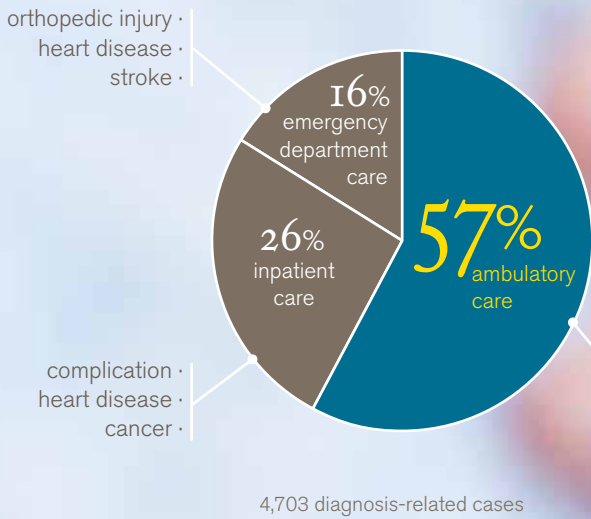
CRICO Strategies' Comparative Benchmarking System contains more than 300,000 open and closed medical malpractice cases representing more than \$25 billion in reserves and losses. These cases represent more than 400 hospitals and 165,000 physicians from both commercial and captive insurers.

In 23,527 cases filed from 2008–2012, claimants alleged failures in:



Failures in the

Diagnostic Process



most diagnostic failures happen in **ambulatory care**

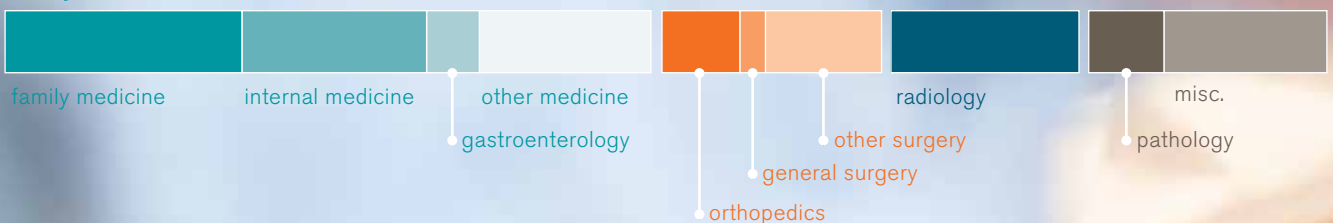
2,685 ambulatory diagnosis cases
 \$ 631 M total incurred losses
(includes reserves on open cases, and payments on closed cases)

- top 3 missed diagnoses**
- cancer
 - heart disease
 - orthopedic injury

AMB DX: WHO IS INVOLVED?

RESPONSIBLE SERVICES:

49% medicine



AMB DX: WHAT GOES WRONG?

73% lapses in clinical judgment

- 25% patient behavior (adherence to plan)
 - 24% communication breakdowns
- Cases generally have multiple factors identified.

LEADING ISSUES IN CLINICAL JUDGMENT:

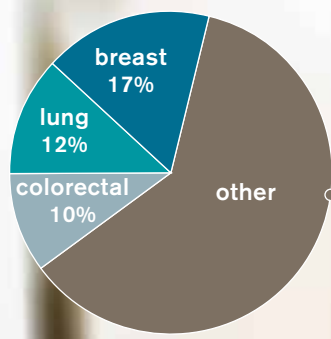
- 31% failure to or delay in ordering a diagnostic test
- 23% misinterpretation of a diagnostic test
- 22% failure to establish a differential diagnosis
- 18% failure to or delay in obtaining a consult or referral
- 8% failure to rule out an abnormal finding

AMB DX: WHAT IS MISSED?

45% cancer

- 6% heart disease
- 6% orthopedic injury

MISSED CANCERS:

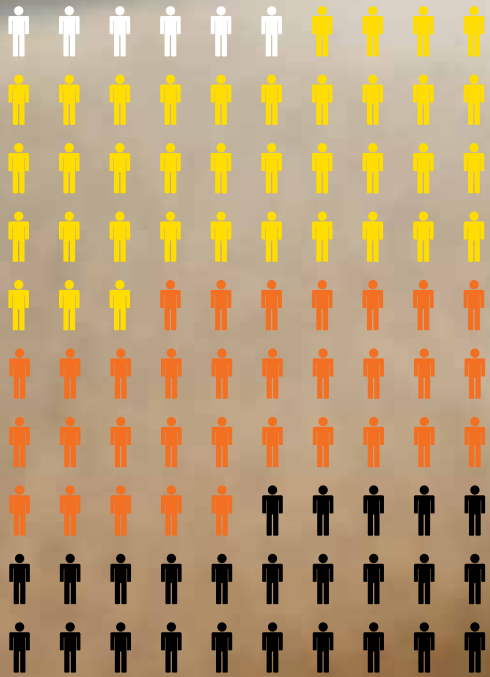


- most common other cancers:
- skin
 - gastrointestinal
 - prostate
 - urinary
 - head and neck
 - uterine and cervical

AMB DX: WHAT IS THE OUTCOME?

SEVERITY:

- 6% low
- 37% medium
- 58% high including death



52 years old
average age of patients who died

CBS cases are reviewed and coded by nurses with comprehensive clinical experience to identify problematic actions, omissions, and system breakdowns. In addition to the relevant medical records, clinical taxonomy specialists have access to documents used to investigate or defend the case, which can include clinical expert opinions, deposition transcripts, and court proceedings.

ANALYZING THE DIAGNOSTIC PROCESS

Together with the patient's injury, the contributing factors identified in the coding process help us outline the events leading to a malpractice claim or suit. To understand what most commonly leads to an allegation of error, CRICO maps the contributing factors to the key cognitive, testing, or communication actions that compose the diagnostic process. While patients and providers don't necessarily proceed along a direct A to B to C to diagnosis course, CRICO's analysis gives those working to reduce diagnostic errors a clinically relevant framework for prioritization and resource allocation.

A single case often has multiple contributing factors. This CBS Report analyzes more than 8,400 factors from 2,685 ambulatory diagnosis-related cases. More than 82 percent of those factors have been mapped to one of the 12 steps in CRICO's diagnostic process of care framework, from the

patient noting a problem through compliance with a follow-up plan.

Although each of the 12 steps deserves individual attention by patient safety improvement leaders, this Report looks at three broad phases in the diagnostic process where the problems—and the potential remedies—are relatively similar: 1) the initial diagnostic assessment, 2) testing and results processing, and 3) communication and coordination of follow up.

This aggregate data analysis clearly identifies specific risk points in each of those stages most commonly cited in malpractice cases; providing a good starting point for efforts to reduce harm to patients and risk to providers. Triangulating this information with other narrowing data (e.g., final diagnosis, injury severity, responsible service) gives analysts and leaders even more actionable evidence with which to stimulate improvement initiatives.

Analyzing the Diagnostic Process

The CBS taxonomy enables data analyses along the process of care that help identify where breakdowns most commonly occur. Each of the 12 steps described below presents focal points for more detailed analysis and opportunities for provider training and systems improvements.



58%
of cases involve
assessment
failures

INITIAL DIAGNOSTIC ASSESSMENT

Covers the patient's presentation with a complaint, through the physician's assessment, differential diagnosis, and test orders. Factors that trigger malpractice allegations are primarily related to voids in the physician's evaluation of the patient's history and cognitive processing related to presentation, differential diagnosis, and test ordering.

1. Problem Noted, Care Sought

Issues: Access, scheduling, or waiting issues impede the patient from raising a relevant health problem, or delays him or her from seeking care for a recognized problem.

2. History and Physical Conducted

Issues: The patient's (personal and family) history is not fully recorded or updated; the physical examination is absent or inadequate.

3. Patient Assessed and Symptoms Evaluated

Issues: The patient's complaints or symptoms are not thoroughly addressed.

4. Differential Diagnosis Established

Issues: A narrow diagnostic focus, failure to establish a differential diagnosis, or reliance on a chronic condition or previous diagnosis.

5. Diagnostic Test(s) Ordered

Issues: The ordering of appropriate tests/imagings/labs is impeded by an incomplete or biased assessment.



29%
of cases involve
testing
failures

TESTING AND RESULTS PROCESSING

From the scheduling, performance, and interpretation of diagnostic tests, through the management of the test results. The factors that trigger malpractice allegations are primarily related to breakdowns in clinical systems for test result management, the cognitive skills related to interpretation, and communication of results to the ordering physicians.

6. Tests Performed

Issues: Ordered test/imaging is not performed, performed incorrectly, or specimen is mislabeled or mishandled.

7. Test Interpreted

Issues: Report of findings are determined to be incomplete or inaccurate; abnormal findings not ruled out.

8. Test Results Transmitted to/Received by Ordering Physician

Issues: Receipt/review of test result by ordering physician is not completed, or is significantly delayed.



46%
of cases involve
follow-up
failures

FOLLOW UP AND COORDINATION

Encompasses decisions made and actions taken after assessment and testing, including consultations and communication. The factors driving malpractice allegations are primarily related to failure to involve specialty consultation and breakdowns in communication among caregivers and between caregivers and the patient.

9. Physician Follows Up with Patient

Issues: Findings are not communicated to the patient, follow-up testing is not arranged, or follow up is not documented.

10. Referrals/Consults

Issues: Appropriate referrals to specialists (or consults) are not made or adequately managed, or identification of the physician responsible for ongoing care is unclear.

11. Patient Information Communicated Among Care Team

Issues: Failure by one or more provider to fully review or share patient information that influences ongoing diagnostic process.

12. Patient and Providers Establish Follow-up Plan

Issues: Patient fails to adhere to the follow-up plan, including appointments and treatment regimen.

More than half of the cases in this study reflect missed opportunities early in the diagnostic process, before and during the formation of a differential diagnosis. This is when physicians determine whether to rely on instinct or which tests, if any, should be ordered. This is also when the risk of a missed or delayed diagnosis is highest.

INITIAL DIAGNOSTIC ASSESSMENT

What physicians have seen most often, and most recently, can bias how they weigh the current evidence. The terminology around the failure to establish a differential diagnosis is well known: anchoring, cognitive framing, premature closure, and most commonly, narrow diagnostic focus. It is also, of course, what works for the vast majority of patient encounters. Physicians see patterns because they are there. They employ diagnostic heuristics because they are efficient. In addition to the confidence of experience, physicians are challenged by the tension between utilization and productivity. A belief that excessive probing and expanding the differential is unlikely to further benefit the patient in the exam room (and will irritate those in the waiting room) has to be balanced against the assuredness that enough information is in hand.

Unfortunately, missing pieces of the diagnostic puzzle can trip even the most accomplished providers. Without an updated family history, a

comprehensive exam, and a thorough review of the medical record, a physician with the right intentions can make a wrong decision. Discounting symptoms or signals that don't support the diagnostic hypothesis (she's too young, it's just hemorrhoids, he's a big eater) puts patients and providers at risk of missing elusive, but not necessarily rare, diagnoses.

Analysis of missed opportunities during the initial assessment indicate that applying some universal practice standards might have illuminated what the clinicians failed to see: updating the family history, listening to the patient's complete story, expanding—then narrowing—the differential diagnosis, asking what non-supportive labs or test results could be revealing. Often, physicians who respond to internal or external pressure to make a diagnosis—despite absent or contrary indicators—later regret not having kept the diagnostic process open until they had more supportive information in hand.

Assessment errors reflect process shortcuts and omissions, rather than unusual circumstances.

TOP ASSESSMENT ERRORS IN AMBULATORY DIAGNOSIS-RELATED CASES (N=2,685)

22%

failure to establish a differential diagnosis

9%

failure to rule out an abnormal finding

8%

failure to note available clinical information

7%

focus on/assumption of chronic/previous diagnosis

6%

overreliance on negative findings (despite continued complaints)

3%

OF CASES HAD AN ATYPICAL PRESENTATION.

CASE EXAMPLE



Lack of appreciation for significant elements of the patient's history and physical led to a missed PE.

A 33-year-old obese patient with remote history of asthma, and on oral contraceptives, presented to her primary care clinician with a three-day complaint of right thigh pain, swelling, and red streaking on her skin. On exam, her right inguinal lymph nodes were enlarged and antibiotics were prescribed. Three days later, she returned with complaint of new onset shortness of breath, chest pain, and rapid heart rate. The patient had diminished breath sounds. Her physician thought she was having an asthma flare and advised her to continue antibiotics and asthma medications. Later the same day, emergency personnel were called to the patient's home after she fell. She was brought to a local Emergency Department where she quickly decompensated and died. Autopsy revealed a large pulmonary thromboembolism. (Case settled: \$450K)

assessment

58% of cases



INITIAL DIAGNOSTIC ASSESSMENT

- 1. Problem Noted, Care Sought**
1% of cases analyzed had errors identified in this step.
- 2. History and Physical Conducted**
7% of cases analyzed had errors identified in this step.
- 3. Patient Assessed and Symptoms Evaluated**
26% of cases analyzed had errors identified in this step.
- 4. Differential Diagnosis Established**
34% of cases analyzed had errors identified in this step.
- 5. Diagnostic Test/Lab Ordered**
31% of cases analyzed had errors identified in this step.

"In our vignette-based study, physicians rarely asked for help when they most needed it to solve difficult cases. In the midst of case scenarios presented on the computer, they were asked if they would like to seek referrals, speak with a colleague, do more diagnostic testing, consult a clinical decision support engine or other reference materials. However, despite the difficulty of these cases, they mostly chose not to. We physicians sometimes have a problem accepting our limitations, acknowledging uncertainty and deciding when to seek help. And poor calibration and over-confidence in our accuracy could lead to diagnostic errors."

Hardeep Singh, MD

Michael E. DeBakey Veterans Affairs Medical Center and Baylor College of Medicine

On average, a third of patients with a health complaint will undergo diagnostic testing. The ordering physicians and patients rely on the proper performance, interpretation, and transmittal of the results to reach diagnostic certainty. More than one in four of the malpractice cases in this study involved breakdowns in one or more of these testing-related steps in the diagnostic process.

TESTING AND RESULTS PROCESSING

Sending patients (or specimens) for testing is fraught with opportunities for something to go wrong. Staff, and the systems they use, have to make certain that the right patient gets the right test and safeguard that specimens are properly handled. Specialists who are, essentially, expected to be infallible in their interpretation and communication skills, need training and protocols that minimize misreads or misdirected results. Primary care providers need to ensure that their interpretations of the results align with the specialists', and that they comprehend the full extent of the report. Together, the providers ordering and performing diagnostic tests have to guarantee that the reasons for testing are clearly expressed and that results are timely, unambiguous, and communicated in a logical format via the proper channels.

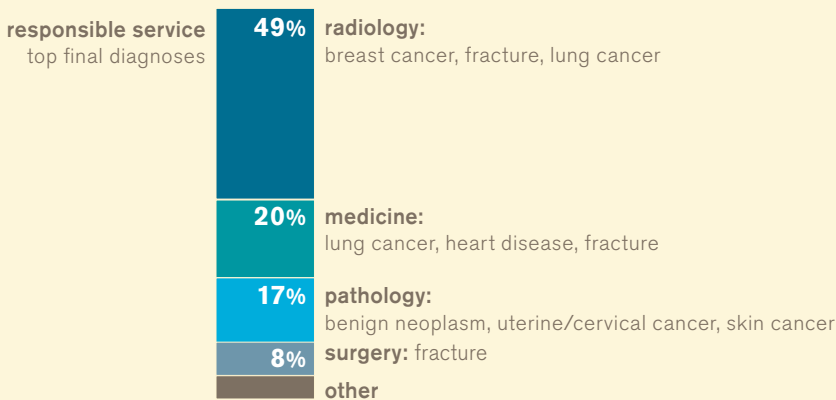
Misinterpretation of diagnostic studies is among the most common factors in failure to diagnose cases from an ambulatory setting. Hindsight provides malpractice plaintiffs with knowledge of

precisely what to look for in test or lab results—or in a consultation report—leaving defendant physicians having to answer “Why didn’t you see this then?” Protocols for reducing the types of errors that most often involve test results in malpractice cases alleging a diagnostic failure need to address both interpretive accuracy and communication of results to the ordering physicians and, when appropriate, to patients directly.

Analysis of cases with breakdowns in the testing process indicate that an unflagging assumption that reported findings are thorough and accurate, or received and understood, is not a best practice. Results inconsistent with ongoing symptoms, other findings, or trusted instincts should be questioned to better understand where to probe further along the diagnostic pathway. Physicians who accept that infallibility is unrealistic, and pursue the range of possibilities when the puzzle pieces don’t fit, are better positioned to reach an accurate and timely diagnosis and avoid allegations of malpractice.

Radiology is the responsible service in nearly half of cases involving misinterpretation.

SERVICES NAMED IN A CASE WITH A MISINTERPRETED TEST (N=608)



CASE EXAMPLE

A misread X-ray of patient with pneumonia led to respiratory failure and death.

A 55-year-old male was diagnosed by his primary care clinician with sinusitis and prescribed an antibiotic. Six days later, he was evaluated in an urgent care clinic for shortness of breath, labored breathing, extreme fatigue, and chest pain with cough. The patient had a temperature, a fast heart rate, and low oxygen saturation. After he was treated with an aerosolized nebulizer, his oxygen saturation improved. Based on her negative interpretation of a chest X-ray, the urgent care clinician diagnosed a viral URI and instructed the patient to see his family doctor the next day. Two days later, the X-ray was read by a radiologist with impression of pneumonia. The clinic called the patient and instructed him to go to his local Emergency Department for evaluation and treatment. Before he could get to the ED, the patient died of respiratory failure associated with pneumonia. (Case settled: \$110K)

testing

29% of cases



TESTING AND RESULTS PROCESSING

6. Tests Performed

3% of cases analyzed had errors identified in this step.

7. Test Interpreted

23% of cases analyzed had errors identified in this step.

8. Test Results Transmitted to/ Received by Ordering Physician

5% of cases analyzed had errors identified in this step.

“Physicians tend to be overly trusting of diagnostic testing results. They generally believe that tests are definitive, and tend to discount the reality that each test has its limitations in sensitivity and specificity. We should incorporate test results in our decisions based on Bayesian analysis, but few physicians actually take this approach, and few tests results actually include the data on test characteristics that would allow these calculations. Compounding the problem, few medical schools include formal training on how to appropriately interpret test results, and where to find the best information on test ordering and result interpretation. Another factor here is the growing distance between the clinicians who are ordering tests and the services providing them: the clinical laboratory and the radiology department. The results are typically just passed back and forth, never really discussed.”

Mark L. Graber, MD

President, Society to Improve Diagnosis in Medicine

Errors at any step in the diagnostic process can misdirect providers in the later stages if they rely on myopic thinking or inaccurate findings. As a preliminary diagnosis is pursued, some evidence may support it, some might not. By the time someone on the patient's care team reaches a "let's start again" point, there is momentum behind the preliminary diagnosis that has to be slowed or redirected.

FOLLOW UP AND COORDINATION

For many patients with an undetermined condition, the diagnostic process is non-linear. Assessment leads to testing that leads to consults that lead to more assessment and testing—sometimes spread out over weeks or months. As one possible diagnosis is ruled out, the process backs up a step or two or three, and proceeds down an alternate path. With each new interaction between the patient and the system, with each new referral or test result, comes opportunities for breakdowns in the communication of critical information and gaps in the coordination of care across an expanding list of providers.

In outpatient settings, care coordination becomes even more challenging than it is in the confines of a hospital. Patients have to communicate to multiple clinicians, clinicians have to communicate with each other, electronic systems may or may not communicate across platforms. Patients are being asked to be more engaged in their care, but that doesn't mean they should have to carry the entire burden. An individual who doesn't feel well, who is anxious to know why, and who has sat in multiple waiting rooms for tests and exams, needs

caregivers and health care systems to maintain vigilance throughout an accurate diagnosis and the initiation of a care plan. Physicians—and the other clinicians who see the patient during his or her diagnostic journey—are less vulnerable to errors when they are clear about which individual provider is coordinating the patient's course. Patients are less vulnerable when the coordinating provider clearly communicates test results, follow-up steps, and (if appropriate) a treatment plan.

Analysis of cases that fall under this stage of the diagnostic process indicate that decisions, documentation, and communication related to consultative support significantly impacts diagnostic success. Well-coordinated care with timely consults and comprehensive communication will most likely raise awareness of unresolved concerns and redirect the cognitive process. On the other hand, even a diagnostic process along the correct path can be impeded or misdirected if the providers responsible for confirming the diagnosis and establishing a care plan fall short or leave issues unresolved and unassigned.

follow up
46% of cases



FOLLOW-UP AND COORDINATION

9. Physician Follows Up with Patient

18% of cases analyzed had errors identified in this step.

10. Referrals/Consults Ordered

19% of cases analyzed had errors identified in this step.

11. Patient Information Communicated Among Care Team

12% of cases analyzed had errors identified in this step.

12. Patient and Providers Establish Follow-up Plan

15% of cases analyzed had errors identified in this step.

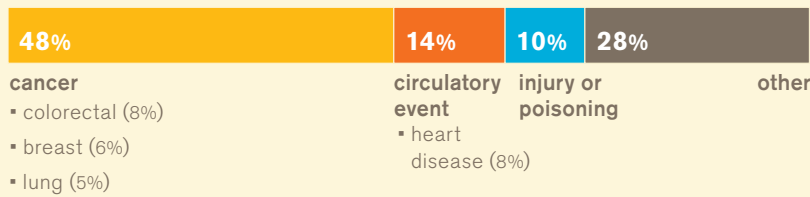
“As a caring physician and humble diagnostician, I’m interested in knowing when I’m wrong and what I can do better. I want to be able to acknowledge uncertainty, so I can say to the patient: ‘It’s not always easy to sort out with certainty every patient with headaches (or chest pain, etc.). It doesn’t look like you have anything serious, but let’s keep the door open, and feel free to call me if you’re not getting better.’

“Practicing this way requires creating a safe space for me and my colleagues to look for, and learn from errors. It means creating an atmosphere where I am not afraid of losing my job if I make a wrong diagnosis, as we all inevitably do. Instead, we need a culture where each person on the team is highly respectful, and feels like ‘we’re all in this together’ and is not afraid to admit or share errors.”

Gordon D. Schiff, MD
Brigham and Women’s Hospital

Referral errors are most commonly a missed cancer.

TOP FINAL DIAGNOSES IN CASES LACKING AN APPROPRIATE REFERRAL OR CONSULT (N=487)



Referral errors are noted twice as often in community-based cases.

22%

COMMUNITY SETTING

PERCENT OF AMBULATORY DIAGNOSIS-RELATED CASES WITH A FAILURE TO ORDER A CONSULT OR REFERRAL.

11%

ACADEMIC SETTING

CASE EXAMPLE



Multiple missteps in the referral process preceded patient’s death from cardiac failure.

An 51-year-old female with a history of attention deficit disorder and hyperlipidemia had been treated by her primary care physician for 14 years. Her high cholesterol was treated with medications and she was otherwise asymptomatic. Due to a family history of cardiac disease, the patient requested a cardiology referral for evaluation. Her PCP ordered the referral and a stress test. The office reports sending the referral information to the patient, however, the patient did not receive it. After the patient called the practice multiple times, a referral was scheduled (three months after initial request). On the day she was to have her cardiology appointment, the patient died. Her death was attributed to significant coronary artery disease, with hyperlipidemia noted. (Case settled: \$150K)

The difference between a timely or a delayed diagnosis rarely hinges on a single act or omission by a single clinician during a single encounter. More typically, missed diagnoses reflect a cascade of aberrant decisions, systems breakdowns, and failures to reset the process when evidence contradicts diagnostic certitude.

WHERE TO LOOK, WHAT TO LOOK FOR

A malpractice allegation of a missed or delayed diagnosis implies that hindsight is a mirror reflecting what was knowable when the patient first presented. Starting from the outcome of his or her particular diagnostic journey, a plaintiff can backtrack through the pitfalls in that process: the questions not asked, the tests not ordered, the consults not sought, the dots not connected. And, in retrospect, the clinicians involved in that patient's care are left to contemplate, "how could this have happened?"

The CBS data we have analyzed tell us that diagnosis-related errors evolve in myriad ways, sometimes linear, but often from cyclical patient encounters and clinical decisions. In real time, a clinician has to wait for the results of ordered tests; to see whether or not symptoms resolve, respond to treatment, or worsen; to read the report from a referral—and rely on the patient to be a collaborative part of the health care team. By itself,

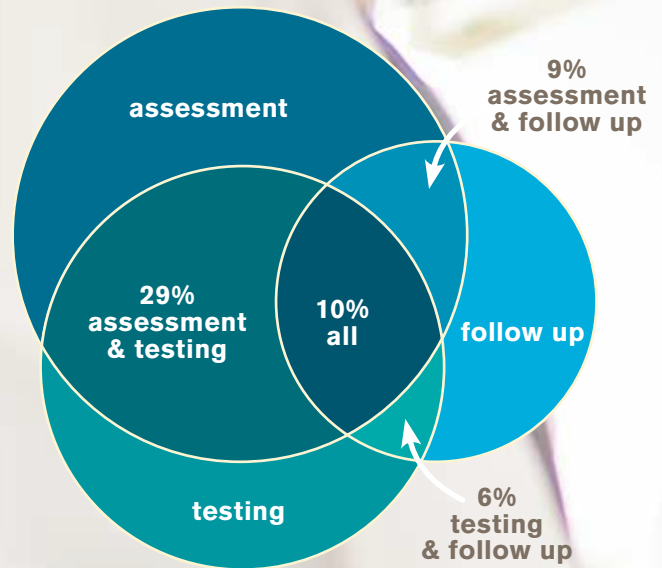
a wrong assumption, a misread image, or a failure to close the loop with a colleague can misdirect the patient's subsequent care. When those errors build upon or overlap one another, the delay in getting back on the right diagnostic path can be consequential...and indefensible.

A failure to detect breast cancer can occur over years; an undetected ankle fracture can be realized in days; a missed MI is often discovered after the patient's demise. On the surface, the factors that lead to such a broad range of adverse events may seem incomparable, but they all find purchase in CRICO's process of care 12-step framework. As we explore the more common case types: delayed cancers, fractures, cardiac events, we are able to pinpoint which step (or steps) prove most vulnerable for those particular conditions. Providers can begin to unveil where they are most exposed to a faulty cognitive pattern or what systems they can adjust to limit communication breakdowns.

Errors in assessment, testing, and follow up frequently overlap in a single case.

Adverse events that trigger a malpractice allegation often reflect multiple mistakes, or missed opportunities to recover from the initial error. Most (82%) of the contributing factors mined from the cases in this Report could be mapped to CRICO's process of care framework: 12 distinct steps assigned to three diagnostic phases (assessment, testing, follow up). This diagram illustrates that errors commonly take place during more than one phase of the patient's route from presentation to diagnosis. Further investigating cases that expose a cross-section of errors enables clinical and patient safety leaders to identify underlying systems issues that recurrently impede providers from completing the diagnostic process successfully.

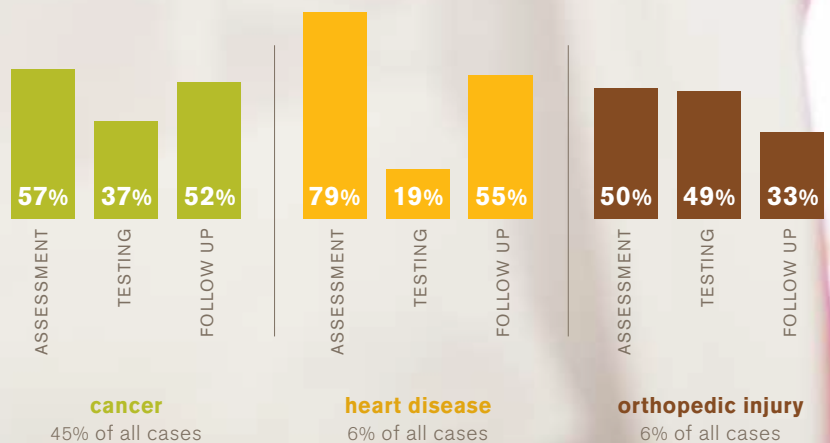
OVERLAP OF ERRORS IN INDIVIDUAL CASES



Certain steps in the diagnostic process are more vulnerable in some case types than others.

For the most commonly missed diagnoses in this CBS study, breakdowns in assessment, testing, and follow up occur at varying degrees. These distributions illustrate the importance of employing a multi-pronged approach to risk reduction. For example, improvements aimed at initial assessment can still leave patients exposed during follow up and care coordination.

DISTRIBUTION OF ERRORS: PATTERNS FOR THE TOP THREE CASE TYPES



Professional liability insurers, attorneys, and—for those malpractice cases that proceed to trial—jurors, must weigh dispassionate biostatistics against the emotional impact of an altered life.

LESSONS FROM CLOSED MALPRACTICE CASES

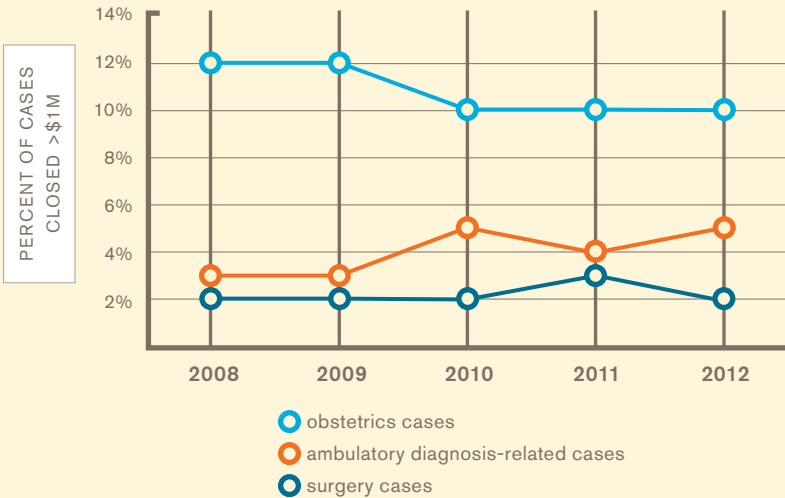
In any malpractice claim or suit, the plaintiff has to establish that the defendant(s) had a professional relationship with the patient, and prove the defendant(s) were negligent in caring for the patient and that negligence led to the patient's injury (or death). For diagnosis-related malpractice cases, the disposition often hinges on whether or not a defendant clinician could have made an earlier diagnosis and if an earlier accurate diagnosis would have altered the patient's prognosis, or his or her quality of life.

Sixty-three percent of the 2,596 diagnosis-related cases closed from 2008–2012 were dropped, denied, or dismissed with no indemnity payment. For the plaintiffs, these discharged cases often represent a gap between inflated expectations for modern medicine and the realities of its limitations. Knowledge of the final diagnosis prompts questions as to why it wasn't identified sooner. Physicians named in diagnosis-related cases are reliant on the standard of care for patients with similar presentations and their

documentation of the diagnostic process they pursued. Plaintiffs who eventually determine that their diagnosis wasn't significantly delayed by their health care providers are unlikely to sustain a malpractice allegation beyond that discovery. Insurers defending clinicians against allegations that are not supported by medical experts—and who have adequate documentation to support the care rendered—seek the most efficient closure that enables those providers to return their full focus to practicing medicine.

Just over one-third of the diagnosis-related cases closed with an indemnity payment, almost exclusively via settlement. Although practices vary by insurer and jurisdiction, in general, settlement of a malpractice allegation is acknowledgement that the patient was harmed and the insured provider's failure to meet the standard of care contributed to that harm. Cases that identify deviations from the standard of care are an especially rich source for clinicians and patient safety leaders to tap into for education and training opportunities.

The percent of ambulatory diagnosis-related cases closing with a payment greater than \$1M appears to be increasing.



The disposition and cost among medical malpractice cases varies by allegation category.

ALLEGATION TYPE	# CASES CLOSED	% CLOSED WITH PAYMENT	% CLOSED WITH A PAYMENT >\$1M	AVERAGE INDEMNITY
AMBULATORY DIAGNOSIS	2,596	35%	4%	\$442K
SURGERY	6,552	29%	2%	\$315K
OBSTETRICS	1,148	42%	11%	\$949K

cases closed 2008–2012

ARE GUIDELINES THE STANDARD OF CARE?

Can a guideline, algorithm, or similar decision support tool be cited in a medical malpractice lawsuit as the standard of care? Generally, the answer is no: the standard of care, as determined in court, is the consensus among experts of the typical practice of an average clinician in the local setting. A guideline or algorithm by itself is not a de facto standard of care.

Decision support tools are not mandatory but rather, advisory—serving as references (similar to medical text books) that clinicians can employ for cognitive support. They do not dictate or establish a standard of care for physicians and nurses who may consider them in their medical practice.

In some cases an organization or a clinical department may adopt all or part of any decision support tool as policy or protocol, which could then be construed as the care standard for clinicians in that organization or department. Under those circumstances, clinicians who make diagnostic or treatment decisions less thorough than, or contrary to, the adopted algorithm or guideline are advised to consistently document the rationale for their decisions.

WHAT WORKS

Reducing the Risk of Diagnosis-related Malpractice Cases

Reducing Cognitive Errors

Many of the cognitive pitfalls in the diagnostic process are found at the key decision points: differentiating a red flag from a red herring; choosing what, if any tests to order; deciding whether or not to refer the patient to a specialist. While the amount of clinical intelligence available to providers is ever expanding, it only amends a physician's diagnostic abilities if it can be accessed at any of those decision points. The following examples illustrate a variety of approaches to helping providers improve their diagnostic accuracy and efficiency.

Guidelines to Reduce Missed Cancers

To reduce the likelihood of missed breast or colorectal cancers, CRICO periodically convenes specialists and primary care physicians (PCPs) to apply what they know as health care providers to what they see in the malpractice data. The primary output is practical decision support tools designed to help PCPs manage both screening protocols and symptomatic patients.

Each tool provides data and cases that illustrate the top risks providers face and recommendations for better test result management, referrals management, documentation, and communication. Key aspects of patient assessment—especially personal and family history—guide PCPs to risk-level recommendations for screening. For patients with specific complaints (e.g., rectal bleeding, breast lump/mass) flow charts outline recommended testing, referrals, and follow up. Each decision support tool is updated biannually.

Electronic Support

Posting key clinical information to an electronic checklist enables physicians to confirm a hunch or see what alternate conditions they might consider. Organizations across the CBS community have built homegrown systems, such as DxPlain (developed at Massachusetts

General Hospital) or adopted commercial tools such as Isabel (in use at University of California, San Francisco, among others), or VisualDx, which features an extensive library of medical images. On the near horizon, IBM's Watson for Healthcare is expected to become a valuable diagnostic resource.

Teamwork

At Vanderbilt University Medical Center, Dr. Michael Laposata has brought pathologists (and others) deeper into the diagnostic process than is commonplace elsewhere. Thus, rather than just exchanging clinical information back and forth without any dialogue, Vanderbilt's diagnostic management teams (DMT) bring the power of expanded expertise and shared understanding to the diagnostic process. Under the DMT structure, physicians, laboratory directors, and technicians produce patient-specific analyses for all cases in multiple areas of laboratory medicine and anatomic pathology.

Addressing Systemic Issues

Each step of the diagnostic process leaves providers reliant on one or more systems to track patients and their clinical information. The gaps between those steps and any weaknesses in those systems expose patients and providers to the risk of information crucial to the diagnostic process being delayed, misdirected, or not seen or acknowledged. Efforts to prevent systemic errors involve both high and low-tech solutions.

Referrals Management Through HIT

The decisions around seeking a referral for an unresolved diagnosis are a common focal point of diagnosis-related malpractice cases. But even an appropriate referral has to be properly managed to ensure that the patient was seen by the specialists, and that his or her findings and



recommendations have been received, read, and shared by the ordering provider. In an effort to minimize the risks of mismanaged referrals, four Harvard-affiliated health care providers are tackling the common problems that challenge their unique HIT systems. Against a common framework, each team is designing, testing, and deploying IT enhancements to their respective referral management systems aimed at closing patient safety gaps from the initial order to follow-up reports. Each organization will gain the enhanced ability to track compliance with internal standards for each step in the process (e.g., appointments scheduled/completed, reports acknowledged by ordering MD), and to produce metrics that help them target substandard performance.

Finding Incidental Findings

To increase the likelihood that an ordering physician will notice findings incidental to the reason a test or image was ordered, Radiologist and other specialists in some organizations have reconfigured their reports, including more prominent display of incidental findings. Such changes are driven by the concern that the ordering clinician reading the lab or radiology report may not look beyond the result that prompted the test order, thus missing secondary findings that require follow up. This protects providers from missing key information and patients from missed diagnoses.

Multi-pronged Approach

In recognition that diagnostic errors cut across weaknesses in human and systems performance, Maine Medical Center (MMC) is raising awareness among

clinicians of the general problem, and developing tools and skills to report and analyze specific events. MMC aims to overcome the stagnation of patient safety improvement often attributed to the underlying complexity.

First, MMC developed a diagnostic error reporting system that involves anonymous submission and very few questions. Then, to further capitalize on increased awareness and reporting of diagnostic errors, MMC increasingly employs its root cause analysis process. By reviewing diagnostic errors for systems causes—rather than strictly cognitive errors by individuals—MMC has been able to identify opportunities for training or systems redesign, e.g., interdisciplinary training in affective bias, and diagnostic pauses or checklists.

Research

Since 2005, the Society to Improve Diagnosis in Medicine (SIDM) has brought together a broad spectrum of perspectives to better understand the nature, causes, and remedies for diagnostic errors. SIDM's goal is to ensure that diagnoses are timely and accurate. With stakeholders representing patients, clinicians and their health care colleagues, health systems, payors and risk managers, educators and researchers, SIDM prompts and supports collaborative efforts to improve the quality of the diagnostic process. Through the annual Diagnostic Error in Medicine conference and other, year-round, activities, SIDM members work to increase awareness of the problem and bring forth potential remedies. One of SIDM's main goals is to help health care providers accurately count diagnostic error and measure diagnostic efficiency.



Data is the most valuable tool we have to understand error.

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For more information about the CBS database and Strategies' services and products, contact: Gretchen Ruoff, MPH, CPHRM, 617.679.1312 or gruoff@rmf.harvard.edu.

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