Diagnostic Error in Acute Care

ABSTRACT

Errors related to missed or delayed diagnoses are a frequent cause of patient injury and, as such, are an underlying cause of patient safety related events. Autopsy series spanning several decades reveal error rates of 4.1% to 49.8%. Diagnostic errors are encountered in every specialty and are generally lowest, at less than 5%, for perceptual specialties (e.g., radiology, pathology, dermatology) that rely heavily on visual pattern recognition and interpretation. Error rates in other clinical specialties are higher, ranging from 10% to 15%, which is consistent with the added demands of data gathering and synthesis. Additionally, diagnostic errors are frequently the leading or second leading cause of malpractice claims in the United States, accounting for twice as many alleged and settled claims as medication errors. Studies have shown that cognitive errors and system design flawsespecially communication issues—all contribute to diagnostic error. This article reviews the common causes of diagnostic error, the clinical diagnoses most often affected by diagnostic errors, and risk reduction strategies that facilities, diagnosing physicians, and patients themselves can undertake to decrease diagnostic error and increase patient safety. (Pa Patient Saf Advis 2010 Sep;7[3]:76-86.)

> During the last decade, much emphasis has been placed on system solutions to patient safety problems. Hospitals have focused on important issues to mitigate patient harm, including re-engineering systems, improving the culture of safety, reducing communication barriers, and improving patient handoffs. However, diagnostic error, despite being responsible for twice as many adverse events as medication error,¹ has received little attention.

> Diagnostic error is a diagnosis that is missed, incorrect, or delayed, as detected by a subsequent definitive test or finding.² Not all misdiagnosis results in harm and harm may be due to either disease or intervention. Misdiagnosis-related harm is preventable harm that results from the delay or failure to treat a condition actually present when the working diagnosis was either wrong or unknown or from treatment provided for a condition not actually present. Misdiagnoses represent a substantial unmeasured source of preventable mortality, morbidity, and costs.³ However, it is not possible to focus on misdiagnosis-related harm without first understanding the broader issue of diagnostic error.

> The Pennsylvania Patient Safety Authority's taxonomy does not include a category for diagnostic error, and because only those diagnostic errors associated with a Serious Event (i.e., an event resulting in patient harm)

or an Incident (i.e., a near miss or no harm event) are submitted, it is not possible to quantify diagnostic error in Pennsylvania with adverse event reports. Similarly, the Agency for Healthcare Research and Quality (AHRQ) Common Formats-the common definitions and reporting formats that allow healthcare providers to collect and submit standardized information regarding patient safety events-does not include a category specifically for diagnostic error (see http:// www.pso.ahrq.gov/formats/commonfmt.htm). Nonetheless, the Authority reviewed exactly 100 events related to diagnostic error reported between June 2004 and November 2009 in an effort to determine if there were system solutions to diagnostic error, or if diagnostic error was so intimately connected to physicians' cognitive processing that system solutions were not tenable. These events were found by searching on terms such as delayed diagnosis, wrong diagnosis, missed diagnosis, misdiagnosed, failure to diagnose, failure to treat, and medical follow-up.

Statistics

Errors related to missed or delayed diagnoses are a frequent cause of patient harm. In 2003, a systematic review of 53 autopsy studies from 1966 to 2002 was undertaken to determine the rate at which autopsies detect important, clinically missed diagnoses. Diagnostic error rates were 4.1% to 49.8% with a median error rate of 23.5%.* Furthermore, approximately 4% of these cases revealed lethal diagnostic errors for which a correct diagnosis coupled with treatment could have averted death.⁴ Other autopsy studies have shown similar rates of missed diagnoses; one study reported the rate to be between 10% to 12%⁵, while another placed it at 14%.6 Autopsies are considered the gold standard for definitive evidence of diagnostic error, but they are being performed less frequently and provide only retrospective information.

Diagnostic error is encountered in every specialty. A 2008 review of diagnostic error studies showed a diagnostic error rate of less than 5% in the specialties of pathology, dermatology, and radiology, all of which rely heavily on visual interpretation, and from 10% to 15% in most other fields, where data gathering and synthesis play a much stronger role. The rate of diagnostic error in the emergency department (ED) is reported to be between 0.6% and 12%.⁷

^{*} Of the 11 studies with error rates exceeding 30%, 5 involved special populations (e.g., surgical patients, adult inpatients with AIDS, inpatients older than 85 years of age), and 5 were studies of general adult inpatients with overall autopsy rates lower than 31% (ranging from 12% to 100%), indicating, perhaps, that autopsies were performed primarily on cases with a higher level of suspicion for misdiagnosis to begin with. The remaining study was of medical patients with an autopsy rate of 47% and an error rate of 41%.⁴

In the Harvard Medical Practice Study, physician errors resulting in adverse events were more likely to be diagnostic (14%) than drug-related (9%), and of these adverse events, misdiagnoses (75%) were more likely to be considered negligent than others (53%).⁸ Diagnostic errors are also a leading cause of malpractice litigation, accounting for twice as many claims and settled cases as medication errors. In an analysis of 254 high-severity patient injury cases reported from January 2005 through July 2007, CRICO/RMF found that diagnostic error-related cases accounted for the majority of the top five claims categories: diagnostic error (44%), surgical (17%), medical (15%), obstetrics (11%), and medications (5%). The analysis also found that these cases cost the company more than all other categories combined-\$127 million for diagnostic error versus \$123 million for all other categories combined.¹

In 2007, the Agency for Healthcare Research and Quality (AHRQ) identified diagnostic error as an area of special emphasis. AHRQ found that diagnostic error comprised a substantial, costly portion of all medical errors and had resulted in distressing consequences for patients, families, and healthcare professionals. Furthermore, diagnostic error encompassed a broad array of factors including cognitive and systems (e.g., education, training, setting-ofcare, disease-specific, domain-specific) issues.9 Subsequently, AHRQ sponsored research regarding diagnostic error through the Diagnostic Error Evaluation and Research (DEER) project. In 2009, research funded by this grant, in the form of analysis of physician reported errors (n = 583; convenience sample), revealed that 28% of the reported diagnostic errors were rated as major, resulting in patient death, permanent disability, or a near-life-threatening event.¹⁰

Despite these statistics, diagnostic error remains an underemphasized area of patient safety, being both difficult to detect and to dissect. Detection is difficult for several reasons. First, misdiagnosed patients who have not been harmed may never be known, as there are few, if any, systems designed to detect and uncover benign diagnostic error. Second, even those patients who have been harmed through diagnostic error might simply leave a practice, a physician, or a hospital and seek care elsewhere, hindering the ability to aggregate and study diagnostic error data. Finally, individual physicians may never know the true extent of their own diagnostic error rates; feedback loops regarding misdiagnoses are simply inadequate. It has been argued that the lack of these formal feedback loops contributes to physician overconfidence in their own diagnostic abilities.^{7,11,12}

Physician Confidence in Diagnostic Abilities

A prospective, counterbalanced experimental design study found that even experienced physicians were unaware of the correctness of their diagnosis at the time the diagnosis was made. When 72 senior medical students, 72 senior medical residents, and 72 faculty internists were given two- to four-page synopses of 36 diagnostically challenging medical cases, each with a definitive correct diagnosis, students were overconfident in 25% of the cases in which their confidence and correctness were not aligned, residents were overconfident in 41% of the cases, and faculty in 36% of cases. These results show that even experienced physicians may be overconfident about the correctness of their diagnoses at the time that they make them.¹¹

Overconfidence is a sign of miscalibration of one's diagnostic ability. Berner and Graber (2008) argue that even though physicians are well aware of the possibility of diagnostic error, few doctors are willing to admit to diagnostic error in their own practice. Graber reported that only 1% of physicians with whom he had personally spoken over a period of several years admitted to having made a diagnostic error in their own practice.⁷ Despite a global awareness of the problem of diagnostic error, physicians seldom believe that their own error rates are significant, further compounding the difficulty in analyzing diagnostic error.¹² Given the dearth of feedback loops regarding diagnostic error, this is an understandable phenomenon; most physicians, in the absence of concrete information that diagnoses are wrong, conclude that their diagnoses are correct.

An organization's culture may encourage error collection and embrace error analysis—viewing errors as learning opportunities—or it may ignore or hide them. There are variations of culture along the continuum between these points. Open recognition of diagnostic error is one way to help physicians recalibrate their perception of diagnostic error and reduce overconfidence. Until there are mechanisms in place to collect and openly analyze diagnostic errors, calibration of true individual diagnostic error rates will be difficult for physicians to achieve.

Diagnostic Decision Making

Clinical judgment is an essential component of the diagnostic process in medicine. Cognitive psychology literature has identified a dual-process model of reasoning that has been used to analyze diagnostic reasoning processes that occur in medicine.^{13,14} Two systems form the basis of clinical decision making, System 1 (i.e., heuristic, intuitive) and System 2 (i.e., systematic, analytical).¹³

In System 1, the experience of the diagnosing physician determines how well the information (e.g., patient symptoms, history, physical examination findings) is interpreted.¹³ Physicians employ heuristics (i.e., cognitive or mental short cuts) to reach decisions, which are correct in the majority of cases. This type of processing has been referred to as pattern-recognition processing.¹⁴ It happens quickly–almost reflexively. Patients presenting with shortness of breath and pain in the jaw and left shoulder, for example, would easily fit into a recognized pattern for "myocardial infarction." Appropriate tests would be ordered, and the physician would analyze test results and diagnose the patient, who would then receive treatment quickly per known medical guidelines.

System 2 typically occurs when the problem is not recognized, or when the physician chooses to review the case comprehensively for some reason.¹³ It employs hypothesis testing and deductive reasoning, is logically sound, and involves critical thinking. Medical students are taught System 2 decision-making processes early on, creating comprehensive lists of differential diagnoses and analyzing each one for probability and "fit." In the real world, however, there is rarely adequate time to use solely this method. Deliberate consideration and review (i.e., System 2) takes time, and the time pressures that exist in many clinical settings may contribute to errors by causing an abbreviated or shortened clinical assessment.

In reality, physicians use a combination of both models in the practice of medicine. While System 2 is most similar to the scientific approach to medicine, it is rarely used first or alone. Physicians often practice in suboptimal environments. They may be rushed, fatigued, distracted, or faced with severe resource constraints. There may be an emotional reaction to the patient (e.g., positive, negative) or communication issues that may subconsciously influence the cognitive processing of the physician. Therefore, while most physicians undoubtedly would like to practice medicine in an orderly, scientific, well-reasoned fashion similar to System 2's analytical processing, the practice of medicine occurs in situations that have many variables and unknowns. The intuitive model of reasoning used in System 1 is an efficient and effective default method used by all physicians. However, when presented with a challenging case, or one with perplexing characteristics, physicians can make a conscious choice to revert to the analytical approaches of System 2.

Regardless of the system or combination of systems used, diagnosis is a multistep process that requires listening, collecting data regarding symptoms, performing focused examinations, ordering appropriate tests, synthesizing data, and analyzing results, and there are plenty of opportunities for errors among these various steps. Schiff et al.^{10,15} developed and used the DEER taxonomy to classify where errors were occurring in the diagnostic processes (see "DEER Taxonomy Chart Audit Tool," one of several associated tools available from the Authority's Web site at http://www.patientsafetyauthority.org/ EducationalTools/PatientSafetyTools/Pages/home. aspx). In the 2009 study, 583 errors that physicians self-reported were analyzed. Most of the errors (44%) occurred in the laboratory and radiology testing phase (e.g., failure to order, report, process, and follow up on test results); followed by clinician assessment errors (e.g., hypothesis generation, weighing and prioritizing, recognizing urgencies and complications) (32%); history taking (10%); physical examination (10%); and referral or consultation errors and delays (3%).¹⁰ Clinician assessment errors were most closely linked to cognitive errors.

Graber et al. (2005) analyzed 100 cases of diagnostic error in internal medicine using a taxonomy that included no-fault, system-related, and cognitive factors to clarify the basic etiology of diagnostic errors in internal medicine and to develop a working taxonomy for diagnostic error.² Seven of the 100 cases reflected solely no-fault errors, including masked or unusual disease presentation or patient-related factors, such as uncooperative demeanor or deception. Systemsrelated factors contributed to diagnostic error in 65% of the cases, cognitive factors contributed in 74% of the cases, and in 46% of the cases, both systems-related and cognitive factors contributed to diagnostic error. Overall, 228 system-related factors and 320 cognitive factors were identified, with an average of 5.9 factors per case.²

A 2007 analysis of 122 diagnostic errors in the ED involved a random sample of closed malpractice claims from four liability insurers alleging substandard diagnostic care in the ED. Breakdowns were common in the diagnostic steps that required active clinician decision making-specifically, conducting patient medical histories and physical examinations, ordering and interpreting tests, ordering consultations, and creating follow-up plans. Such breakdowns occurred in all but two of the missed diagnoses (97%). Failure to order appropriate tests was the most common breakdown, similar to Schiff's findings.¹⁰ After assimilation of the patient history and physical assessment, physicians must first generate an appropriate diagnostic hypothesis, which then leads to test ordering. An inappropriate or incorrect diagnostic hypothesis will lead to incorrect or absent testing. Cognitive failure occurs when a physician has a correct diagnostic hypothesis but forgets or does not know the correct work-up for that particular diagnosis. In summary, appropriate test ordering, like other steps that involve active decision making, requires these key ingredients: (1) assimilation of physical findings and generation of an appropriate diagnostic hypothesis, (2) the availability of the right information on which to base diagnostic decisions, and (3) correct application of cognitive skills to this information.¹⁶

Commonly Misdiagnosed Conditions

Commonly misdiagnosed conditions include cancer, infection, fractures, myocardial infarction, embolism, neurological conditions, and aneurysms. Table 1 shows the top five misdiagnosed conditions from several studies, three of which were derived from tort claims, which biases the results toward more serious (and—if missed—more costly) diagnoses.

The top five categories of misdiagnoses from Authority reports from January 2005 through August 2009 were metastatic cancer (12%), fractures (4%), pulmonary embolism (4%), acute coronary syndrome (2%), and appendicitis (2%).

Common Causes of Diagnostic Error

Cognitive Processing Errors

Cognitive processing errors, or errors in thinking, are linked to the heuristics frequently used in System 1 (i.e., intuitive) mental processing. Some of the common heuristics employed during the diagnostic process include the following:^{17,18}

 Representative heuristic is using "mental matching" to diagnose conditions with characteristic

STUDY	SETTING	MISDIAGNOSIS	PERCENTAGE (%)
Gandhi TK, Kachalia A, Thomas EJ, et al. Missed and delayed diagnoses in the ambulatory setting: a study of closed mal- practice claims. <i>Ann Intern Med</i> 2006 Oct 3;145(7):488-96. (n = 181)	Ambulatory	Cancer—all types	59%
		Infections	5
		Fracture	4
		Heart attack	4
		Embolism	3
Schiff GD, Hasan O, Kim S, et al. Diagnostic error in medicine: analysis of 583 physician- reported errors. <i>Arch Intern Med</i> 2009 Nov 9;169(20):1881-7. (n = 583)	General internists, medical specialists and emergency physicians at 2 academic medical centers or within 20 smaller teaching or community hospitals	Pulmonary embolism	4.5%
		Drug reaction or overdose	4.5
		Lung cancer	3.9
		Colorectal cancer	3.3
		Acute coronary syndrome	3.1
Kachalia A., Gandhi TK, Puopolo AL, et al. Missed and delayed diagnoses in the emer- gency department: a study of closed mal- practice claims from 4 liability insurers. <i>Ann</i> <i>Emerg Med</i> 2007 Feb;49(2):196-205. (n = 79)	Emergency department	Fracture	19%
		Infection	15
		Myocardial infarction	10
		Cancer	9
		Cerebral vascular disease	8
Hanscom R. CRICO/RMF community targets diagnostic error. CRICO/RMF Insight [online] 2007 Sep [cited 2010 Feb 10]. Available from Internet: http://www.rmf.harvard.edu/ education-interventions/crico-rmf-insight/ archives/092007/art1.htm. (CRICO/RMF diagnosis related claims from 2003 through 2007; n = 314)	80/20 mix of outpatient care and inpatient care	Cancer—all types	38%
		Heart disease	8
		Cerebral vascular disease	5
		Arterial disease	4
		Complications	4

presentations that can predispose diagnosing physicians to a lack of differential diagnoses.

Availability heuristic is the tendency to accept a diagnosis due to ease in recalling a past similar event or case, rather than based upon statistical prevalence or probability.

Biases and limitations related to cognitive processing errors include the following:^{17,18}

- Anchoring is the tendency to stay with an original diagnosis despite evidence to the contrary.
- Premature closure is narrowing the choice of diagnostic possibilities (i.e., hypotheses) too early in the diagnostic process, such that the correct diagnosis is never considered.
- *Satisficing* is the acceptance of less than the ideal or seeking a merely satisfactory solution, which is not necessarily the optimal one.
- Confirmation bias is the tendency to seek out data to confirm one's original idea rather than to seek out or validate disconfirming data.
- Context errors occur when the diagnosing physician is biased by patient history, previous diagnosis, or other factors and the case is formulated in the wrong context.

Table 2 shows a sampling of Authority reports with corresponding potential cognitive errors.

Cognitive errors may have contributed to the events in Table 2, some of which resulted in significant patient harm, but they are unlikely to be the sole contributing factor in these reports. The 2007 review of closed malpractice claims in the ED¹⁶ found that the mean number of process breakdowns and contributing factors per missed diagnosis was two and three, respectively, clearly illustrating that compounding issues contribute to diagnostic errors. The 2005 review of diagnostic errors in internal medicine identified an average of six contributing factors for each diagnostic error.²

Communication Issues

Poor or inadequate communication among clinicians and between clinicians and patients is frequently cited as a contributing factor in diagnostic error.^{7,8,10,16} Several facilities identified the contributing factor of "communication problems between providers" in events reported to the Authority. However, the event narratives did not specify the exact communication problem, which prevents more in-depth analysis. For example, the following report was submitted as a failure to diagnose and treat stroke with a contributing factor of "communication problems between providers" with root-cause analysis (RCA) in progress.

The patient was admitted via the ED with complaints of lower back pain postfall at home seven days prior. The patient's condition deteriorated with mental status changes, requiring urgent transfer to the intensive care unit. RCA in progress.

Another report was submitted as a missed diagnosis of acute coronary syndrome with contributing factors of "communication issues between providers" and

EVENT REPORT	POTENTIAL COGNITIVE PROCESSING ERROR ^{1,2}	POTENTIAL FAILURE(S)
Patient is an infant seen in the ED [emergency department] during high flu season after an epi- sode of vomiting and period of apnea observed by family. Was discharged, but returned later. Family reported that the patient had another episode of apnea. Patient was evaluated and transferred to another facility for clinical impres- sion of apnea and reflux.	Availability heuristic. The tendency to accept a diagnosis based upon recent or vividly recalled cases or events rather than on prevalence or probability.	Authority report stated missed diagnosis of apnea and reflux. Physician poten- tially attributed symptoms to common flu, due to availability. A more thorough physical examination may have led to the discovery of other symptoms indica- tive of apnea and reflux.
Patient seen in the ED on day one and day two for complaints of shortness of breath and chest pain. Diagnosed with an upper respiratory infection and sent home each time. Subsequently later admitted and died. Coroner preliminary report indicated PE [pulmonary embolus] as cause of death.	Anchoring heuristic. The tendency to fixate on first impressions or initial symptoms without considering causes that appear later or those that do not support the initial hypothesis or diagnosis.	Authority report stated missed diagnosis of PE. Physician may have anchored on diagnosis "upper respiratory infection." Once a physician anchors on a diagno- sis, it is very difficult to introduce new differential diagnoses. Physician may not have considered alternate diagnoses on subsequent visits.
Patient seen in ED on day one with complaints of abdominal pain. Patient evaluated, treated, and discharged with diagnosis of UTI [urinary tract infection]. The next day, patient presented to another facility and was diagnosed with a ruptured appendix.	Premature closure. Acceptance of a diagnosis before it has been fully vetted by considering alternative diagnoses or searching for data that contradict the initial diagnosis.	Authority report stated missed diagnosis of appendicitis. Physician omitted tests that would have led to diagnosis of ruptured appendix. Physician may have failed to consider differential diagnoses during history and physical portion of examination.
Patient presented to the ED on day one with complaints of chest pain. Stress test done, results negative, and patient discharged. The next day, patient returned to the ED with chest pain and tachypnea, and the left leg was blue and mottled. Dopplers of lower extremities confirmed extensive DVT [deep-vein thrombosis].	Anchoring heuristic. Premature closure. Representative heuristic. Mental matching to diagnose conditions with characteristic presentations. Predisposes to lack of a differential diagnosis.	Authority report stated missed diagnosis of DVT. Physician may have anchored on diagnosis "acute coronary syndrome" due to complaints of chest pain. Physi- cian may have latched on to representa- tive symptom of chest pain, failing to perform tests to rule out other potential diagnoses (i.e., differential diagnoses).
A young man came to the ED for fainting and syncope, including the inability to speak for a few seconds with lateralizing symptoms and staring. In the ED, lab work was done but no CT [computed tomography] scan was ordered. Patient was discharged home with diagnosis of syncope and dehydration secondary to stress, with instructions to follow up with primary care physician. Subsequently, the primary care physician admitted the patient directly into the hospital, where a CT scan was performed and a brain lesion diagnosed.	Premature closure. Context errors. Occur when the diagnosing physician is biased by patient history, previous diagnosis, or other factors and the case is formulated in the wrong context.	Authority report stated missed diagnosis of brain lesion. Physician may have at- tributed symptoms to "stress" and evalu- ated patient in this context. Physician may have failed to rule out other less likely but more serious diagnoses. Physi- cian may have formulated diagnosis in the context of a young man with admit- ted stress and stopped searching for other plausible diagnoses for symptoms.

2. Groonman I. How doctors think New York (NY). Howship Mifflin Company, 2009

2. Groopman J. How doctors think. New York (NY): Houghton Mifflin Company; 2008.

"lack of information due to dementia." RCA was performed surrounding the physical assessment process.

Patient seen in ED; had been sent from SNF [skilled nursing facility] because he was moaning in discomfort. Patient had a history of dementia and was unable to relate what was wrong. Abdomen was distended; enema had been given by SNF earlier in the day. Oxygen saturation level was 86% on room air. [The patient was] noted to have a urinary tract infection, which was treated. He was discharged but returned immediately. Upon return to the ED, he was bradycardic and then proceeded to full arrest. Blood work was run on the specimens that were in the lab from the initial visit and showed that the troponin level was 20 [elevated; indicative of heart muscle damage; possible myocardial infarction]. Even diagnostic events that do not result in harm can be traumatic for both the patient and the clinician, as the following example illustrates.

The physician entered the patient's room and failed to check the identification band. The physician did ask the patient's name and [then] started talking about a brain aneurysm and [relayed that the patient] would be going for surgery. The patient came to hospital with "leg pain." The physician corrected the error later in the day [before the brain surgery occurred].

In a study involving diagnostic error in ambulatory settings, the diagnostic errors were complex and frequently involved multiple process breakdowns, contributing factors, and clinicians. There was a median of three process breakdowns and three contributing factors per error.¹⁹ In a similar study involving diagnostic error in internal medicine, an average of six different root causes were uncovered for each diagnostic error event, two-thirds of which were considered system-related factors.²

Other System-Related Factors

The fact that cognitive errors rarely are the sole cause of diagnostic error points toward the possibility of system-level interventions to decrease recurrence of diagnostic errors and to mitigate harm from them when they do occur.^{16,20} Common system-related factors that contribute to diagnostic error include those related to specimen identification, test tracking, reporting of abnormal and critical test results, and transitions in care. Diagnostic error reports from the Authority's database illustrate how some of these system-related factors contribute to diagnostic error.

Specimen Labeling

The patient underwent a needle biopsy of the right breast that was diagnosed as ductal carcinoma. Patient then underwent lumpectomy of right breast, and [another] pathologist questioned the results postprocedure after reviewing the tissue. The hospital was notified about the potential wrong diagnosis . . . unable to determine how the specimen was mislabeled.

Communication of Critical Pathology Reports

The patient underwent a transthoracic biopsy of a lung nodule. The pathology result noting cancer was discovered [more than six months later].

Abnormal Test Results

The patient described slipping when coming out of her kitchen; the patient fell on her right side. X-rays were done, and the preliminary report was negative according to the surgeon. The final report revealed a femoral neck fracture, which was available but not seen by the physician [for nearly 15 days].

Poorly Managed Transition in Care

An elderly woman presented to the ED in month one with chest pain and shortness of breath. A chest CT [computed tomography scan] identified multiple emboli and a lung nodule suspicious for carcinoma. The patient underwent a cardiac catheterization and was discharged from the hospital with no documented medical follow up for the lung nodule. The patient returned to the ED in month six with shoulder pain. A CXR [chest radiograph] was performed, and the patient was discharged with instructions to follow up with her physician for a chest CT in regard to the lung nodule. The patient was admitted to the hospital in month seven and has been diagnosed with carcinoma . . .

Focusing attention on system-related factors underlying issues related to specimen labeling, communication of reports, abnormal test results and transitions in care (e.g., work overload, inadequate staffing, unavailable resources) is one way to identify and reduce diagnostic errors in acute care settings.

Healthcare facilities can help the Authority with analysis of diagnostic error events by using the tools

developed in conjunction with this article as a first step in detecting diagnostic error (e.g., the "Deer Taxonomy Chart Audit Tool"), and by submitting event reports with adequate information including the contributing factors and RCA information when performed.

Strategies to Decrease Diagnostic Errors System-Level Strategies

Changing the perception of diagnostic error from "errors in judgment," "errors in thinking," or "physician mistakes" to errors related to cognitive processing, communication, and system design may be the first step toward recognizing and reducing diagnostic error.³ Finding and reporting misdiagnosisrelated patient harm is the second step, although it may be hard to achieve. When the U.S. Department of Health and Human Services Office of the Inspector General investigated methods for identifying adverse events in hospitals (case study; random sample of 278 Medicare beneficiary hospitalizations), it found that hospitals did not provide, and apparently did not have, event reports for 93% of the events (n = 120).²¹ This study analyzed all adverse events, not just those related specifically to diagnostic error (which is more elusive and even more difficult to detect).

Healthcare facilities may consider the following strategies in an effort to increase the detection rate of diagnostic error in their facilities:

- Provide a mechanism to collect diagnostic error reports within the facility (see the "Deer Taxonomy Chart Audit Tool"). Collection and aggregation of diagnostic error data allows for tracking, trending, uncovering patterns, learning across cases, and measuring improvement.^{10,15}
- Continuously improve the culture of safety so that identification and analysis of diagnostic error is acceptable and anticipated.^{15,20} Include diagnostic error as a key part of the quality assurance plan. Identify any diagnostic-related adverse events and incidents that appear repeatedly as possible "normalization of deviance," and intervene as needed.²⁰
- Conduct analysis of events that result in misdiagnosis-related patient harm. Consider a tool similar to the one used in Graber's 2005 analysis of diagnostic error,² which helps practitioners not only identify categories of diagnostic error but also provides underlying causes for the failures.

Event analysis in the medical literature shows that most diagnostic-related errors have multiple causes, and even cognitive aspects of diagnostic error can be mitigated by interventions at the system level.^{16,20} Healthcare facilities may consider the following systemlevel strategies to reduce misdiagnosis-related harm:

- Strategies to combat cognitive errors include the following:
 - Provide information about and encourage the general study of clinical and pathological discrepancies to learn about all types of diagnostic error.^{15,17} Study and test diagnostic

accuracy on standardized cases similar to Johns Hopkins University School of Medicine Clinico-Pathological Conferences (http:// oac.med.jhmi.edu/CPC/) or AHRQ's Web M&M: Morbidity and Mortality Rounds on the Web (http://www.webmm.ahrq.gov/ index.aspx).

- Provide resources for clinical decision support systems that provide accurate estimates of disease probability. DXplain (http://dxplain. org/dxp/dxp.pl) and Isabel (http://www. isabelhealthcare.com/home/default) are two Web-based applications that help physicians make data-driven diagnostic decisions at the point of care. Do not rely solely on physician perception of diagnostic accuracy as a measure of need; research shows that even experienced physicians may be overconfident about the correctness of their diagnoses when they make them.¹¹ Provide point-of-care access to the Internet, electronic medical references, and journals.^{3,7,10,12,16,17,20,22}
- Provide access to computer-assisted feature mapping and/or data visualization tools to enhance the accuracy of diagnostic decision making.^{3,12,20}
- Provide resources and encourage the use of clinical guidelines and clinical algorithms.
 When well-designed, these resources remedy the deficiencies in human judgment by incorporating statistics, epidemiology, and decision theory in a clinically useful format.^{16,22}
- Consider diagnostic checklists to prevent reliance on memory for error-prone processes (e.g., soliciting a complete history, performing a targeted physical examination, ordering appropriate tests). These can be organized around high-risk diagnoses (e.g., cancer, infection, fractures, myocardial infarction) or around care settings (e.g., routine wellness visit checklist that reminds about screening protocols, sick visit checklist that lists "don't miss" diagnoses).^{3,10,15} A general checklist designed to minimize diagnostic error has been previously published²³ and is available as a pocket card at the Authority's Web site (see "A Checklist for Diagnosis").
- Enhance feedback to clinicians regarding diagnoses and errors to increase calibration and reduce overconfidence regarding their own diagnostic error rate. Improving feedback to clinical practitioners may be the most effective debiasing procedure available. This can be accomplished, in part, by means of postmortem autopsies and/or postmortem magnetic resonance imaging, morbidity and mortality conferences, sentinel event analysis, or retrospective audits of admitting versus discharge diagnoses or of diagnoses of patients who return to the ED within 48 hours of discharge.^{7,12,17,20}

- Systems strategies to enhance communication and coordination of care include the following:
 - Migrate toward electronic medical records to ensure that patient information is available to all care providers in real time, in all settings. Develop formal policies regarding the communication of patient information across all care settings.²⁰ Integrate automatic reminders for reporting test results to patients and scheduling follow-up.^{3,7}
 - Ensure an efficient and effective system of communicating abnormal and critical test result procedures directly to the ordering physician and the patient. Monitor the turnaround time of key tests.^{10,12,16,20,22}
 - Ensure that specialty expertise is available when needed, at all times and on all days. Monitor consultation timeliness.^{7,12,20,22}
 - Consider mandatory second opinions on key error-prone diagnoses and second readings of key diagnostic tests.^{12,16,22}
 - Ensure that there is a standardized process for handoff procedures between physicians and across care units.¹⁶
 - Provide close oversight of trainees' diagnostic evaluations especially in cases of high workload or with complex patients or with patients with atypical presentation. Provide a mechanism for supervisory oversight of diagnostic decision-making strategies.¹⁶
 - Ensure strong mechanism for follow-up of discharged patients, especially for high-risk diagnoses or symptoms for which a diagnosis has not yet been assigned (e.g., cancer: rule out cancer; myocardial infarction: chest pain and shortness of breath).¹⁵
- Other system-related factors:
 - Establish pathways for physicians who saw the patient earlier to learn if or when a diagnosis is changed by developing audit protocols to uncover diagnostic error, comparing ED diagnoses to discharge diagnoses, auditing diagnoses of patients who return to the ED within 48 hours after discharge and making note of diagnoses that change from one visit to the next, performing retrospective chart audits to look for changed diagnoses during the course of a hospitalization, comparing consulting/referral diagnoses to referring physician diagnoses by tracking radiology and pathology over-reads and by tracking changes to initial laboratory test results (see the online "Diagnostic Error Measures Worksheet").
 - Develop a mechanism to share the results of these types of audits with all treating physicians in a timely fashion. Soliciting feedback from practitioners regarding diagnostic error

is a critical step in the learning process.^{15,20} In addition to learning when diagnostic error occurs, it is equally important to investigate causes, and this cannot be done without frank conversations with physicians about why these errors occurred.

 Guard against excessive workload and staff fatigue. Minimize disruptions and production pressures so that diagnosing physicians have time to reflect on their diagnostic decisions. Minimize errors related to fatigue by implementing work hour limitations and allowing naps, if needed.^{16,20}

Physician Strategies

Physicians themselves play an important role in the detection and prevention of diagnostic error. Individuals may consider the following strategies to reduce diagnostic error in their practice:

- Improve clinical reasoning and metacognition skills by learning about cognitive errors.^{17,20}
- Use diagnostic time-outs to actively reflect upon the diagnostic process.^{17,20}
- Request second opinions and consultations as needed.^{17,20}
- Request diagnostic feedback from healthcare facilities and colleagues to improve calibration regarding diagnostic error.^{12,17,20}
- For specialists who modify diagnoses of referral patients, notify the referring physician of the modified or changed diagnosis.¹⁷
- Disclose the diagnosis to the patient early. Disclose the probability of having the diagnosis, and what to expect if the diagnosis is correct. If there is no clear diagnosis, disclose this, too.²⁰
- Maintain long-term continuity of care with individual patients to ensure adequate awareness of past mistakes. Survey past patients, and investigate whether diagnostic error occurred.
- Mentor residents and medical students by openly discussing diagnostic thinking patterns, soliciting their diagnostic reasoning, and providing timely and critical feedback regarding their diagnostic processes.^{17,18}

A review of some of the cognitive errors presented earlier shows that even cognitive errors are amenable to both individual and system-level interventions listed above (Table 3).

Using a combination of individual and system-level risk reduction strategies may help decrease both the diagnostic error rate and the rate of misdiagnosisrelated patient harm in healthcare facilities.

Patient Education Strategies

Patients can participate in the effort to reduce diagnostic errors. Facilities can endeavor to educate and empower patients to seek timely follow-up care and medical advice and to become active participants in the diagnostic process. For example, educate patients about diagnostic probabilities and uncertainties to minimize disappointments and surprises and to support and enhance patient initiative in questioning the diagnostic process and outcome. (For more information, see the online "Patient Education Regarding Diagnostic Error").

Conclusion

Despite the fact that the diagnostic process has many steps, is frequently shared between multiple providers and sometimes across multiple settings, and occurs over a period of months or even years, healthcare facilities have at their disposal many strategies that could potentially reduce the diagnostic error rate. Implementing interventions that establish strong and reliable feedback loops between and among physicians regarding diagnostic accuracy is a key step in the error-reduction process. Ensuring that all steps in the diagnostic testing phase occur correctly and that all results are communicated back to ordering physicians and patients is critically important, as are methods to enhance the effectiveness of diagnostic decision making.

In addition to system-level interventions, physicians themselves must actively work toward first recognizing, then analyzing, and finally reducing diagnostic error. Acknowledging the lack of feedback mechanisms in healthcare facilities and seeking out ways to give and receive collegial diagnostic feedback is an important first step. Accepting the possibility of diagnostic error is also important; acceptance of a less than perfect diagnostic record may lead to greater metacognition and recognition of diagnostic error when it does occur. Likewise, mentoring residents by actively discussing diagnostic challenges, diagnostic decisions, and even diagnostic failures will help new physicians develop a more accurate perception of their diagnostic abilities and skills. Universities and teaching hospitals also have a role to play: by illuminating the topic of diagnostic error early in each medical student's education, in both didactic and practical learning settings, there is the potential to reduce physician overconfidence and to correct individual calibration of diagnostic error. Allowing medical students and residents to openly question diagnostic decisions, verbalize their own diagnostic reasoning, and receive specific constructive feedback in a timely fashion are important steps toward enhanced diagnostic accuracy.

Involving patients in the diagnostic process may help reduce diagnostic error. By encouraging and empowering patients to give and receive information with their physicians, to question any step in the diagnostic process, and to report changes in their condition or results of second opinions to their physicians, providers can enable patients to become important partners in the diagnostic process.

The Authority encourages each healthcare facility to begin monitoring diagnostic error rates. Once facilities begin collecting data regarding diagnostic error, the Authority invites use of the sample

Table 3. Sample Authority Event Reports with Associated Individual and System Error **Mitigation Strategies**

EVENT REPORT	POTENTIAL FAILURE(S)	POTENTIAL COGNITIVE PROCESSING ERROR ^{1,2}	INDIVIDUAL STRATEGY	SYSTEM STRATEGY
Patient is an infant seen in the ED [emergency department] during high flu season after an episode of vomiting and period of apnea observed by family. Was discharged, but returned later. Family reported that the patient had an- other episode of apnea. Patient was evaluated and transferred to an- other facility for clinical impression of apnea and reflux.	Authority report stated missed diagnosis of apnea and reflux. Admitted during high flu season; potentially attributed symptoms to common flu, due to availability. A more thorough physical examination may have led to the discovery of other symptoms indicative of reflux.	Availability heuristic. The tendency to accept a diagnosis based upon recent or vividly recalled cases or events rather than on prevalence or probability.	Use checklists for physi- cal examination com- ponents. Use decision support resources, if available. Confer with colleagues, and seek out second opinions.	Provide decision support systems to diagnos- ing physicians. Provide point-of-care clinical resources such as elec- tronic medical records, Internet access, and ac- cess to electronic medi- cal journals and pre- scribing data. Encour- age the use of diagnos- tic checklists to improve systematic examinations and to decrease reliance on memory.
Patient seen in the ED on day one and day two for complaints of shortness of breath and chest pain. Diagnosed with an upper respiratory infection and sent home each time. Subsequently later admitted and died. Coroner preliminary report indicated PE [pulmonary embolus] as cause of death.	Authority report stated missed diagnosis of PE. Anchored on diag- nosis "upper respira- tory infection." Once a physician anchors on a diagnosis, it is very difficult to introduce new differential diag- noses. May not have considered alternate diagnoses on subse- quent visits.	Anchoring heuristic. The tendency to fixate on first impressions or initial symptoms without considering causes that appear later or those that do not support the initial hypothesis or diagnosis	Think beyond the most obvious diagnosis. Perform comprehensive and systematic physical examinations. Use a diagnostic time-out and reflective thinking about the patient and symptoms in a calm environment. Consider worst-case scenarios. Ask, "What do I not want to miss?"	Implement a system to automatically screen patients returning to the ED within 48 hours. Pro- vide decision-support information in the form of clinical algorithms based upon evidence- based medicine. En- sure the availability of specialty consultations 7 days per week, 24 hours per day. Encour- age physicians to seek out second opinions on high-risk populations (e.g., return to the ED within 48 hours).

1. Scott IA. Errors in clinical reasoning: causes and remedial strategies. BMJ 2009 Jun 8;338:b1860.

2. Groopman J. How doctors think. New York (NY): Houghton Mifflin Company; 2008.

"DEER Taxonomy Chart Audit Tool," to trend diagnostic error reports, to identify where in the diagnostic process errors occur, to analyze aggregate results, and to develop and implement both physician- and systemlevel strategies to reduce diagnostic error occurrence.

Notes

- 1. Hanscom R. CRICO/RMF community targets diagnostic error. CRICO/RMF Insight [online] 2007 Sep [cited 2010 Feb 10]. Available from Internet: http://www.rmf. harvard.edu/education-interventions/crico-rmf-insight/ archives/092007/art1.htm.
- 2. Graber ML, Franklin N, Gordon R. Diagnostic error in internal medicine. Arch Intern Med 2005 Jul 11;165(13):1493-9.
- 3. Newman-Toker DE, Provonost PJ. Diagnostic errorsthe next frontier for patient safety. JAMA 2009 Mar 11;301(10):1060-2.
- 4. Shojania KG, Burton EC, McDonald KM, et al. Changes in rates of autopsy-detected diagnostic

errors over time: a systematic review. JAMA 2003 Jun 4;289(21):2849-56.

- 5. Goldman L, Sayson R, Robbins S, et al. The value of autopsy in three medical eras. N Eng J Med 1983 Apr 28;308(17):1000-5.
- 6. Sonderegger-Iseli K, Burger S, Muntwyler J, et al. Diagnostic errors in three medical eras: a necroscopy study. Lancet 2000 Jun 10;355(9220):2027-31.
- 7. Berner ES, Graber ML. Overconfidence as a cause of diagnostic error in medicine. Am J Med 2008 May;121(5 Suppl):S2-S23.
- 8. Leape LL, Brennan TA, Laird N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard medical practice study II. N Eng J Med 1991 Feb 7;324(6):377-84.
- 9. Agency for Healthcare Research and Quality (AHRQ). Special emphasis notice (SEN): AHRQ announces interest in research on diagnostic errors in ambulatory care settings [notice NOT-HS-08-002 online]. 2007

Oct 25 [cited 2010 Mar 17]. Available from Internet: http://grants.nih.gov/grants/guide/notice-files/ NOT-HS-08-002.html.

- Schiff GD, Hasan O, Kim S, et al. Diagnostic error in medicine: analysis of 583 physician-reported errors. Arch Intern Med 2009 Nov 9;169(20):1881-7.
- 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 Apr;20(4):334-9.
- 12. Graber M. Diagnostic errors in medicine: a case of neglect. *Jt Comm J Qual Patient Saf* 2005 Feb;31(2):106-13.
- 13. Croskerry P. A universal model of diagnostic reasoning. *Acad Med* 2009 Aug;84(8):1022-8.
- Schwartz A, Elstein AS. Clinical reasoning in medicine. In: Higgs J, Jones M, Loftus S, et al, eds. *Clinical reasoning in the health professions*. 3rd ed. Boston (MA): Elsevier; 2008:223-34.
- Schiff GD, Kim S, Abrams R, et al. Diagnosing diagnostic error: lessons from a multi-institutional collaborative project. In: Henriksen K, Battles JB, Marks ES, et al., eds. Advances in patient safety: from research to implementation. Rockville (MD): Agency for Healthcare Research and Quality; AHRQ pub No. 05-0021-2. 2005:255-78.

- Kachalia A., Gandhi TK, Puopolo AL, et al. Missed and delayed diagnoses in the emergency department: a study of closed malpractice claims from 4 liability insurers. *Ann Emerg Med* 2007 Feb;49(2):196-205.
- 17. Scott IA. Errors in clinical reasoning: causes and remedial strategies. *BMJ* 2009 Jun 8;338:b1860.
- Groopman J. How doctors think. New York (NY): Houghton Mifflin Company, 2008.
- Gandhi TK, Kachalia A, Thomas EJ, et al. Missed and delayed diagnoses in the ambulatory setting: a study of closed malpractice claims. *Ann Intern Med* 2006;145:488-96.
- Graber ML. Taking steps toward a safer future: measures to promote timely and accurate medical diagnosis. *Am J Med* 2008 May;121(5 Suppl):S43-6.
- U.S. Department of Health and Human Services, Office of the Inspector General. Adverse events in hospitals: methods for identifying events [executive summary online]. 2010 Mar [cited 2010 Mar 8]. Available from Internet: http://oig.hhs.gov/oei/reports/oei/06-08-00221.pdf.
- Elstein AS. Thinking about diagnostic thinking: a 30-year perspective. Adv in Health Sci Educ. 2009;14:7-18.
- 23. Graber ML. Educational strategies to reduce diagnostic error: can you teach this stuff? *Adv Health Sci Educ* 2009;14:63-9.

Self-Assessment Questions

The following questions about this article may be useful for internal education and assessment. You may use the following examples or come up with your own.

A 35-year-old man with no significant past medical history went to the emergency department (ED) complaining of vomiting and periumbilical abdominal pain for four hours. On physical examination, he was afebrile, with a blood pressure of 114/72 and a heart rate of 85. His abdomen was soft, without rebound or guarding. He was diagnosed with gastroenteritis and discharged with antiemetics and instructions to return to the ED for persistent vomiting, pain, or new fever. The patient presented to his primary care physician's office three days later with complaints of persistent abdominal pain; the vomiting had resolved. The primary physician contacted ED personnel to obtain the report. On examination, the patient was afebrile with normal vital signs. He had a diffusely tender abdomen with some localization to the right of the umbilicus. The patient was sent home, with instructions to take over-the-counter medication for the pain. The next day, the patient returned to the ED with persistent pain. He was seen by the same ED attending physician, who asked a colleague to evaluate the case. The second ED attending physician ordered a computed tomography (CT) scan of the abdomen and pelvis. The CT scan revealed a perforated appendix.*

- 1. During the first ED visit, which factor *most likely* contributed to the attending physician's incorrect diagnosis of gastroenteritis?
 - a. Atypical presentation: lack of classic physical signs of appendicitis.
 - b. Lack of awareness: abdominal pain is an uncommon chief complaint in the ED.
 - c. Availability heuristic: accepting a diagnosis (gastroenteritis) due to ease in recalling past similar cases.
 - d. Premature closure: settling on a diagnosis before ruling out other possibilities.
- 2. During the visit with the primary care physician three days later, which event *most likely* contributed to the continued diagnostic error?
 - a. Lack of communication between the primary care physician and the ED personnel regarding the patient's medical history.
 - b. The primary care physician failed to perform a thorough physical assessment of the patient.
 - c. Anchoring bias: the primary care physician relied too heavily on the previous medical report when formulating his own medical conclusions and stayed with the original diagnosis despite evidence to the contrary.
 - d. The patient was not compliant with the ED discharge instructions, further hindering the diagnosis of appendicitis.

^{*} Adapted from: Agency for Healthcare Research and Quality (AHRQ). Missed appendicitis. AHRQ M&M on the Web 2003 Jun [cited 2010 Jul14]. Available from Internet: http://www. webmm.ahrq.gov/case.aspx?caseID=17&searchStr=appendicitis.

- 3. Representative heuristic is the:
 - a. tendency to formulate a diagnosis with information obtained from a second party.
 - b. tendency to accept a diagnosis based upon the ease of recall of past similar cases rather than based upon statistical prevalence or probability.
 - c. use of cognitive shortcuts to formulate a list of diagnostic probabilities representative of the chief complaint.
 - d. use of "mental matching" to diagnose conditions with characteristic presentations.
- 4. The most effective strategy for physicians to evaluate diagnostic decisions and minimize cognitive errors is to:
 - a. always get a second opinion on appendectomy cases.
 - b. take a diagnostic time-out to think broadly about the case; metacognition.
 - c. use diagnostic testing to rule out false-negative presentations.
 - d. ask a patient to relay all pertinent information before beginning the physical examination.

A woman had a pigmented lesion on her leg biopsied by her physician in the hospital and sent to the lab and a pathologist for review. The pathologist correctly determined that the lesion was a melanoma. However, the lab sent the report of another patient (labeled with a different patient name) back to the woman's physician, reporting that the lesion was benign. The physician did not notice the wrong name on the report. The lab realized its mistake eight months later, and notified the physician who told the patient. As a result, the patient's melanoma spread to her groin nodes, and it required more extensive treatment than if the diagnosis been timely.

- 5. Which system-level intervention could the facility implement to best prevent the type of diagnostic error illustrated above?
 - a. Install a diagnostic decision support software system.
 - b. Implement a system of authentication of all abnormal test results, verifying critical patient information.
 - c. Implement a multisystem electronic medical record so that medical information is available across care settings.
 - d. Educate physicians and staff regarding the importance of filing test results in the appropriate medical records.

A woman presented with multiple breast lumps in her left breast. A biopsy of the dominant lump was diagnosed as Stage I breast cancer. She underwent lumpectomy, which removed all lumps but one. She saw several physicians over the next two years, and although the lump was recorded in her medical chart, no physician ever followed up with her about it. Over this period, the breast cancer developed from a treatable Stage I to Stage III, and it metastasized to her brain.

- 6. The above case illustrates principles similar to findings in the literature regarding diagnostic error. Which statement below most accurately describes the etiology of many diagnostic errors?
 - a. Individual, one-time errors in judgment account for the majority of diagnostic errors.
 - b. Patient-related factors account for most instances of diagnostic error-related patient harm.
 - c. Diagnostic errors that reach patients appear to result from the alignment of multiple breakdowns, which in turn stem from a confluence of contributing factors.
 - d. Diagnostic errors can usually be traced to a single, discrete probable cause, which can be resolved through staff education and training.
- 7. Which facility-level strategy is most likely to increase detection of diagnostic error?
 - a. Ensure a culture of safety exists so that the detection and analysis of diagnostic error is acceptable; provide a mechanism to collect diagnostic error data; and conduct analysis of collected events.
 - b. Purchase an error-collection system for frontline reporting; implement mandatory reporting of diagnostic error; and enforce compliance through vigilant auditing of medical records.
 - c. Increase autopsy rates within the facility; track misdiagnosis-related patient harm by provider; and create and publicize comparison reports of harm by provider.
 - d. Purchase diagnostic decision-support software; implement mandatory reporting of diagnostic error; and train physicians in metacognition.

PENNSYLVANIA PATIENT SAFETY ADVISORY

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