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# Insights

## INTO RISK MANAGEMENT

### @ RISK: DIAGNOSTIC ERROR: EXAMINING FAILURES, REDUCING RISKS

This article is an enduring activity approved for AMA PRA 1 Credit(s)<sup>™</sup> and category 1 credit in Risk Management Study. (See link on p. 6)

In May of this year, **Drs. Martin Makary** and **Michael Daniel** [reported in The BMJ](#) that medical errors are the third leading cause of death in the U.S. after heart disease and cancer, causing at least 250,000 deaths annually. The authors, who are both professors at Johns Hopkins University School of Medicine, defined medical errors as (1) lapses in judgment, skill or coordination of care, (2) mistaken diagnoses, (3) system failures that lead to patient deaths or the failure to rescue dying patients, and (4) preventable complications of care. "People don't just die from heart attacks and bacteria, they die from system-wide failings and poorly coordinated care," says **Makary**. "It's medical care gone awry."

In 2010, a highly regarded, leading patient safety expert, **Robert M. Wachter, MD**, reported that diagnostic errors occurring in hospitals represented cognitive mistakes on the part of its medical staff, with the resultant conclusion that individual hospitals couldn't be held accountable. In his report, he questions that even if hospitals were held accountable for an individual's cognitive error, what could be done to improve the situation without the availability of a convincing solution?

The magnitude of the current death toll – roughly 10 percent of U.S. deaths annually – is striking coming in an era dominated by efforts to reform the health system to ensure safe, high quality, high-value medical care. Patient safety efforts have failed to gain much traction, **Makary** says, because there have been no systematic efforts to study medical errors or to put effective safeguards in place.

According to a recent report from the Institute of Medicine (IOM), *Improving Diagnosis in Health Care*, diagnostic errors are underappreciated and will require a collaborative approach between the entire healthcare team, the patient and his or her family, to show any significant reduction. In addition, the IOM called upon the healthcare community at large to address diagnosis errors by treating them as systemic problems, rather than simply as human errors made by individuals.



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### *The Many Definitions of Diagnostic Error*

A diagnosis that is wrong, missed, or egregiously delayed, based on retrospective review using a gold standard (Label failure) (1)

Any mistake or failure in the diagnostic process leading to a misdiagnosis, a missed diagnosis, or a delayed diagnosis (Process failure) (2)

A missed opportunity to make a correct or timely diagnosis, based on all the available evidence (Process failure) (3)

**The failure to: a) establish an accurate and timely explanation of the patient's health problem(s) or b) communicate that explanation to the patient (4)**



(1) Mark L. Graber, MD, President, Society to Improve Diagnosis in Medicine (SIDM); (2) SIDM members Gordy Schiff, MD, and (3) Hardeep Singh, MD; (4) IOM

# WHY HAVE DIAGNOSTIC ERRORS GONE UNNOTICED?

According to **Robert M. Wachter, MD** in the [September 2010 issue of Health Affairs](#), as the quality and safety movements continue to accelerate, the need to elevate diagnostic errors to their rightful place among safety hazards grows ever more pressing. In an example of how far we need to go, a hospital today could meet the standards of a high-quality organization and be rewarded through public reporting and pay-for-performance initiatives for giving all of its patients diagnosed with heart failure, pneumonia, and heart attack the correct, evidence-based, and prompt care—even if every one of the diagnoses was wrong. Clearly, this anomalous treatment of diagnostic errors must be changed.

*“Diagnostic errors often do not elicit the visceral dread that accompanies events such as wrong-site surgery.”*

Why has consideration of diagnostic error been absent from patient safety initiatives? Key reasons include challenges to measurement, amenability to system wide solutions, and lack of media attention.

To date, patient safety and quality movements have focused mostly on processes, or activities known to be associated with better outcomes. For certain safety targets, process measurement works well. But diagnostic outcomes are harder to measure than processes or structures, and the science of case-mix adjustment is insufficiently advanced to compare apples to apples in many cases. Diagnostic errors frequently have complex causal pathways and might not be revealed for months or even years generally through a sophisticated chart review; even then, expert reviewers often disagree. While initially thought to reflect cognitive miscues, such as failing to adequately consider alternative diagnoses, patient safety experts are finding that system failures are more responsible for diagnosis errors than simply mistakes by individuals.

Diagnostic errors often do not elicit the visceral dread that accompanies events such as wrong-site surgery. High-profile cases have tended to involve terrible medication errors such as the one that led to Betsy Lehman's notable death by chemo overdose, or surgical errors such as the amputation of the wrong body part. One famous medical error, the death of [Libby Zion at New York Hospital in 1984](#), was attributable at least in part to a diagnostic error. But that became known as a death caused by overworked residents and poor supervision, rather than as one caused by a diagnostic error.

Source: Wachter, Robert M.; *Why Diagnostic Errors Don't Get Any Respect—and What Can Be Done About Them*; *Health Affairs*; September 2010; vol. 29 no. 9; 1605-1610

# RISK MANAGEMENT CORNER

*What can be done to reduce diagnostic error and harm? Learn from others:*

## “Take-Home” Messages Described by Physicians Following a Diagnostic Error

### Recommendation:

### Example:

Look beyond the initial diagnosis. Although we always attempt to find one diagnosis that explains all the findings, we should never assume that only one condition explains everything.

- Missed pulmonary embolus in a woman presenting with asthma exacerbation: “Do not assume the obvious.”

Be alert to atypical presentations of diseases that do not follow the normal pattern. Remember that disease X can masquerade as disease Y. Anyone with symptom(s) X should have disease(s) Y ruled out or at least considered.

- Missed myocardial infarction in a man presenting with heartburn after running out of omeprazole: “Always consider atypical presentations with anyone with any kind of chest pain even though patient is convinced otherwise.”

Do not rule out serious disease solely on the basis of age or a negative test result or a negative element of the history or physical exam. Be aware of blunted symptoms in the elderly.

- Missed severe hyponatremia, sodium 115 mEq/L, in a woman presenting with anxiety: “Include electrolyte imbalance in the differential diagnosis of anxiety.”

Reconsider diagnosis if patient follows unexpected course. Reassess and repeat the evaluation if the patient does not respond as expected or the course is not as expected or not everything fits.

- Missed pancreatic cancer in an elderly man with weakness: “When something doesn’t make sense, keep searching... persistent weakness despite treating UTI.”

Arrange more reliable, better follow-up in specific circumstances; provide return parameters; take a more active role in arranging and initiating follow-up, such as a phone call, not just leaving it up to the patient.

- Missed endometrial cancer in a woman with abnormal uterine bleeding: “Call patients on the phone and don’t leave a follow up plan to the next visit. Act right away!”

Broaden the differential in general. Consider “don’t-miss” diagnoses. Rule out the worst-case scenario.

- Missed coronary disease in a man presenting with respiratory distress: “If there is a possibility of a disease with a high morbidity, I should at least do an initial screening.”
- Missed ischemic bowel in a woman with diarrhea and fever: “I learned to be more diligent and methodical in broadening my differential.”

Source: *J Am Board Fam Med* January-February 2012 vol. 25 no. 1 87-97; *Diagnostic Errors in Primary Care: Lessons Learned*; John W. Ely, MD, Lauris C. Kaldjian, MD, PhD and Donna M. D'Alessandro, MD

For more examples and resources, go to: <http://www.improvediagnosis.org/page/Education>

# WHAT PHYSICIANS, PA'S, AND NP'S CAN DO TO REDUCE DIAGNOSTIC ERROR

Until the science of error prevention catches up with the need that exists, your best defense is to adopt common-sense steps that address the most common and important factors known to contribute to diagnostic error and harm. The list that follows presents initial suggestions, acknowledging that diagnosis involves the patient, physician, and other members of the health care team and practice environment.

- ✓ Obtain your own, complete medical history.
- ✓ Perform a focused and purposeful physical examination.
- ✓ Be reflective. Take a diagnostic 'time out.'
  - Was I comprehensive?
  - Did I settle on a diagnosis prematurely?
  - Have I made a diagnosis despite evidence to the contrary?
  - Was my judgment affected by any other bias?
  - Do I need to make the diagnosis now, or can I wait?
  - What is the worst-case scenario?
  - What are the “do not miss” diagnoses that could be relevant?
- ✓ Listen to your patients and their caregivers and make the patient your partner in diagnosis. Ensure he or she knows how to get back to you if symptoms change or persist.
- ✓ Embark on a plan, but acknowledge uncertainty and ensure a pathway for follow-up.
- ✓ Trust your intuition, but keep going — Generate some initial hypotheses and differentiate these with appropriate additional questions, physical examination, or diagnostic tests.
- ✓ Take advantage of second opinions.
- ✓ Use diagnosis-specific decision support resources: DXplain, Isabel, VisualDx, or simple checklists.
- ✓ Ensure all ordered diagnostic tests and consults are completed. Most importantly, communicate and document every result to every patient.
- ✓ Empower your patients. Educate them as to the tests ordered, and when/how results will be relayed. Direct them to call if they haven't received results within a certain timeframe.
- ✓ Speak directly with the staff providing you with diagnostic test results (radiologists, pathologists, and clinical pathologists). If you aren't sure of the most appropriate diagnostic strategy, ask or use online test-ordering advice.
- ✓ Empower your colleagues to let you know if they become aware that a diagnosis you made has changed. Learn from your own diagnostic errors, and others discussed at M&M conferences. Read the online AHRQ Web M&Ms.
- ✓ Learn the causes of diagnostic error and how to avoid pitfalls.



## Sources:

1. Graber ML. Educational strategies to reduce diagnostic error: can you teach this stuff? *Adv Health Sci Educ* 2009;14:63-9.
2. 2010 Pennsylvania Patient Safety Authority
3. Society to Improve Diagnosis in Medicine (SIDM)

# DIAGNOSTIC ERROR: *WHAT'S NEEDED?*

According to **Mark Graber**, MD, founder and president of [The Society to Improve Diagnosis in Medicine \(SIDM\)](#), “Diagnosis is one of the most difficult and complex tasks in healthcare. There are more than 10,000 potential diagnoses, thousands of lab tests, and the problem that symptoms of each diagnosis vary from person to person...Moreover, our healthcare systems are highly complex, which contributes to problems coordinating care and completing the diagnostic process successfully.”

Better identification, analysis, and implementation of approaches to improve diagnosis and reduce diagnostic error are needed throughout all settings of care,” stated **John R. Ball**, MD, JD, of Asheville, NC, chair of the Committee on

*Attributed to: Healthcare Risk Management; November 2015; Vol. 37, No. 11; p. 121-132; Treat Diagnosis Errors as Systemic, Not Individual Human Mistakes*

Diagnostic Error in Health Care for the IOM.

Further, **Paul Epner**, executive vice president of SIDM and chair of the Coalition to Improve Diagnosis, opines that diagnostic errors have no single root cause.

The [IOM's 2015 Improving Diagnosis in Health Care report](#)...“addresses a significant gap in our knowledge, and SIDM intends to drive review and action on the recommendations across the entire healthcare system. It is the responsibility of everyone involved in the diagnostic process to consider the steps they can take to improve outcomes,” **Epner** says. “This begins with healthcare providers and their organizations, which need to establish a culture of safety where these errors can be identified, studied, and addressed.”

## 2016 @ Risk: Live Lecture Series ~ Risk CME Credit Available

### “Transitions of Care”

Coordination Across the Full Continuum

Wednesday, September 15th, 2016

12 noon—1 pm

Rhode Island Hospital

George Auditorium



### “Digital Health: Not Your Parent’s EMR”

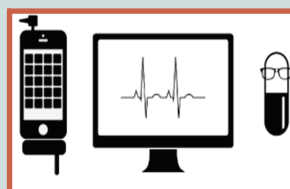
What You Need to Know About mHealth

Tuesday, September 27th, 2016

5 pm—6 pm

Rhode Island Hospital

George Auditorium



## PIAA Response to The BMJ May 2016 article on Medical Error

### ~ *The Other Perspective* ~

Immediately following the release of Makary and Daniels’ article in May of this year, the PIAA, the nation’s leading association representing medical professional liability insurance companies, risk retention groups, captives, trusts, and other entities, [issued a response](#), indicating the article should be put into its proper context. The PIAA felt the authors were overly broad in their characterization of “medical errors,” which would lead to confusion about the exact definitions of preventable harm and medical negligence.

The PIAA asserted that the article assumed a broad definition of medical error that could also be used in the instance of successful medical encounters, and that it omitted to mention that “errors are not per se indicative of negligence.” Making the point that the term, “preventable” was not defined in the article, the PIAA asserted that in hindsight, almost any harm could be deemed preventable.

*“It may never be possible to eliminate harm altogether—there will always be new technologies and treatments with new risks, and protecting patients from one harm may increase their risk of another, which may lead to trade-offs.”* In quoting the National Patient Safety Foundation, the PIAA indicated that an attitude of placing individual responsibility for fault will inevitably impede progress. They, along with others, believe that the primary focus when an adverse outcome or near-error occur should be on how to change the system to make this outcome less likely to happen again.

*Diagnostic errors, when they occur, derive from the complexity of the diagnostic process itself — from minor flaws in our health care systems, and from the inherent limitations of clinical reasoning.*



*The take-home message is not to do more tests to rule out every possible diagnosis: rather, put every **reasonable** diagnosis on the “radar.” Most of those will immediately come back off the radar screen based on further consideration of the patient’s presentation, additional history taking, and additional physical examination procedures, but not, in most cases, based solely on further testing.*

*J Am Board Fam Med January-February 2012 vol. 25 no. 1 87-97; Diagnostic Errors in Primary Care: Lessons Learned; John W. Ely, MD, Lauris C. Kaldjian, MD, PhD and Donna M. D’Alessandro, MD*

## *The Toll of Diagnostic Error*

A decade ago the Institute of Medicine (IOM) report on medical errors, *To Err Is Human*, launched the modern patient safety movement. The report’s findings led to a steady stream of initiatives designed to improve patient safety.

The movement achieved some real gains, focusing on adverse events amenable to system wide solutions such as infections associated with health care and medication errors. Consideration of diagnostic errors was largely absent from these initiatives, which is particularly noteworthy given the frequency of these errors and the fact that delay in diagnosis was noted to be one of the most common cause of claims. In fact, diagnostic errors were noted to be the #1 cause of claims in ambulatory care and #2 in hospitals, (after improper performance of a procedure). In addition, diagnostic errors were found to be the most costly type of malpractice claim, carrying the potential for significant liability because the delay often had the consequence of inflicting great harm on the patient.

In most cases, a diagnostic error can be traced to a failure in assessing the patient, according to the results of CRICO Strategies 2014 annual benchmarking report, [\*Malpractice Risks in the Diagnostic Process\*](#). The report is the product of analyzing more than 4,700 cases related to allegations of missed or significantly delayed diagnosis, filed from 2008 to 2012. While the majority (58%)

of these cases highlighted assessment failures, the analysis explored the entire diagnostic process to help identify where breakdowns most commonly occur.

Another 29% of the cases were traced to faults in testing and results processing. Forty-six percent were related to follow-up and coordination of care.

Of the 7,500 claims in a database maintained by the Physician Insurer’s Association of America (PIAA) filed between 2007 and 2013, a quarter involved a diagnostic delay or error.<sup>3</sup> The problem occurred most frequently with non-surgical physician practices because those practices are frequently where diagnoses are made. For family practice physicians, almost 40% of their claims involved misdiagnosis, and 20% involved missing breast cancer.

The Doctors Company, a malpractice insurer based in Napa, CA, conducted [\*a study of 332 emergency medicine claims\*](#) that closed from 2007-2013 and found that the top patient allegation, which accounted for 57% of claims, was diagnosis-related, including failure to diagnose, delay in diagnosis, and wrong diagnosis. Similarly, physician experts who looked into the data determined that the top factor contributing to patient injury (52% of claims) was patient assessment issues, such as failure to establish a differential diagnosis and failure to order diagnostic tests.

To earn **CME credit** for reading information on **Diagnostic Error** in this issue, go to:

<https://www.surveymonkey.com/r/NMYHZZ5>

## HOW/WHY DO DIAGNOSTIC ERRORS OCCUR?

Diagnostic error is multi-factorial and can present as a perfect storm of multiple factors lining up: *6 factors on average were found per case of diagnostic error* in an internal medicine study. Lack of physician knowledge is least often the problem.

It is more often due to cognitive error, systems errors including communication errors, and most common of all, the combination of cognitive and systems errors. (Graber 2005).

Cognitive errors take place in the physician's head—they concern the thinking process. An example is latching on prematurely to a diagnosis and abandoning the search for evidence to the contrary.

Systems errors occur between the inter-related pieces in healthcare systems. Examples include physicians or other practitioners dropping the ball in the referral-consultation process or in the hand-off process. Another is lost or unreported test results.

In combination, it is often the systems error that is the catalyst for adverse events and claims because 1) by definition a systems error tends to replicate and amplify, and 2) the patient perceives it as the error that didn't have to happen, and 3) if the systems factor is peeled away, the perfect storm may not transpire.

***D*** iagnostic error (DE) is more closely associated with some specialties than others, but it is a significant factor for claims in all specialties.

- ◆ **Diagnostic Error is the #1 cause of medical misadventure claims for all primary care specialties (internal medicine, family and general practice, pediatrics), radiology and emergency medicine, and most of the medical subspecialties.**
- ◆ **DE is the #2 cause of medical misadventure claims for surgical specialties (OB-GYN, general surgery, orthopedics and most of the surgical sub-specialties), but it is most often a close second place.**
- ◆ **Overall, the top diagnosis in claims related to diagnostic error is breast cancer (PIAA Data Sharing Report 1985-2009), with radiology as the primary contributing specialty.**
- ◆ **Acute myocardial infarction is the top subject of diagnostic error in claims for the specialties of adult primary care, emergency medicine and cardiology (PIAA Data Sharing Report 1985-2009).**
- ◆ **Stroke is associated with diagnostic error 9% of the time (Newman-Toker et al 2008).**
- ◆ **For family and general practice, the top diagnoses involved in diagnostic error in descending order were myocardial infarction, breast cancer, appendicitis, colorectal cancer and lung cancer.**
- ◆ **In a study of physician self-reported diagnostic errors, the diagnoses most often involved were pulmonary embolism, drug reaction or overdose, lung cancer, colorectal cancer, acute coronary syndrome, breast cancer and stroke (Schiff et al 2009).**
- ◆ **Certain diagnoses (i.e.: pulmonary embolism and aortic dissection) may not be found until autopsy, however, the rate of autopsies performed in the US has declined steeply, so these and others like it are under-detected at an unknown rate.**

### Sources :

1. *AHC Healthcare Risk Management MAY 2015 Vol. 37, No. 5; p. 49-60; Costly Diagnosis Delays Can Be Avoided With Good Practices*
2. *Society to Improve Diagnosis in Medicine (SIDM)*
3. *Physician Insurers Association of America (PIAA) is the insurance industry trade association that represents a full range of entities doing business in the medical professional liability (MPL) arena.*

### From the Institute of Medicine (IOM), *Improving Diagnosis in Health Care*

#### **1. Facilitate more effective teamwork in the diagnostic process among healthcare professionals, patients, and their families.**

The diagnostic process hinges on successful collaboration among healthcare (HC) professionals, patients, and their families, all of who are critical partners in the diagnostic process. All HC professionals need to be well-prepared and supported to engage in diagnostic teamwork.

#### **2. Enhance healthcare professional education and training in the diagnostic process.**

Getting the right diagnosis depends on all HC professionals involved in the diagnostic process receiving appropriate education and training. Improved emphasis on diagnostic competencies and feedback on diagnostic performance is needed.

#### **3. Ensure that health information technologies (IT) support patients and HC professionals in the diagnostic process.**

Although health IT has the potential to improve diagnosis and reduce diagnostic errors, many experts are concerned that it is not effectively facilitating the diagnostic process and might even be contributing to errors. Collaboration among health IT vendors, users, and the Office of the National Coordinator for Health Information Technology is needed to better align health IT with the diagnostic process.

#### **4. Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice.**

Few HC organizations have processes in place to identify diagnostic errors and near misses in clinical practice; however, collecting this information, learning from these experiences, and implementing changes are critical for achieving progress. HC professional societies also can be engaged to identify high-priority areas to improve diagnosis.

#### **5. Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance.**

The work system and culture of many HC organizations could better support the diagnostic process. For example, organizations should promote a non-punitive culture that values feedback on diagnostic performance, ensures effective communication in diagnostic testing, and designs a work system that supports team members involved in the diagnostic process, including integrating error recovery mechanisms.

#### **6. Develop a reporting environment and medical liability system that facilitates improved diagnosis through learning from diagnostic errors and near misses.**

There is a need for safe environments, without the threat of legal discovery or disciplinary action, in which diagnostic errors, near misses, and adverse events can be analyzed and learned from to improve diagnosis and prevent diagnostic errors. Voluntary reporting efforts should be encouraged and evaluated for their effectiveness. Reforms to the liability system are needed to make HC safer by encouraging transparency and disclosure of medical errors, including diagnostic errors.

#### **7. Design a payment and care delivery environment that supports the diagnostic process.**

Payment likely influences the diagnostic process and the occurrence of diagnostic errors. For example, fee-for service payment lacks incentives to coordinate care, and distortions between procedure-oriented and cognitive-oriented care might be diverting attention from important tasks in the diagnostic process. A fundamental research need is an improved understanding of the impact of payment and care delivery models on diagnosis.

#### **8. Provide dedicated funding for research on the diagnostic process and diagnostic errors.**

Federal resources devoted to diagnostic research are overshadowed by those devoted to treatment. Dedicated, coordinated funding for research on diagnosis and diagnostic error is warranted. Public/private collaboration and coordination can help extend financial resources to address research areas of mutual interest.

*Insights* is published by Lifespan's Department of Risk Management Loss Prevention division. Submissions and ideas are welcome and may be submitted to the department or faxed to **401-444-8963**.

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