



Commonwealth of Massachusetts
Board of Registration in Medicine
Quality and Patient Safety Division

Advisory
Diagnostic Process in Inpatient and Emergency Department Settings

March 2016

Background

The Quality and Patient Safety Division (QPSD) has received a number of Safety and Quality Review (SQR) reports of patient events associated with delayed or missed diagnosis. This Advisory is issued to support health care facilities in the review and development of their approaches to the diagnostic process in the inpatient and emergency department (ED) settings and the overall reduction of diagnostic errors. While some references are provided, this Advisory does not include a comprehensive review of the literature; nor is it intended to provide specific recommendations for evidence-based practice.

Publication of this Advisory does not constitute an endorsement by the Board of any studies or practices described in the Advisory and none should be inferred.

Overview

Clinical diagnostic errors can occur in a variety of ways: a missed diagnosis, treating a patient for the wrong diagnosis, or the failure to recognize and address conflicting patient data. Diagnostic errors are common, frequently preventable and often underreported. There are an estimated 40-80,000 deaths nationally per year from diagnostic error.¹ In a recent survey commissioned by the Betsy Lehman Center, 23% of surveyed adults in Massachusetts reported experiencing a diagnostic error in the last 5 years, with 75% of these errors occurring during treatment at a hospital.² Specialty error rates range from 2-3% in radiology and pathology to 10-20% for internal medicine.^{3,4} Diagnostic errors can be the result of the confluence of insufficient data, communication lapses, variable disease presentations, a variety of provider biases and heuristics (mental shortcuts) and other sources of cognitive error. This advisory will focus on diagnostic processes in the inpatient and emergency department settings.

¹ Graber, ML, et al. The Next Organizational Challenge: Finding and addressing diagnostic error. *Jt Comm J Qual Pt Safety* 2014; 40(3):102-10.

² Betsy Lehman Center for Patient Safety and Medical Error Reduction. 2014. *The Public's Views on Medical Error in Massachusetts*. Cambridge, MA: Harvard School of Public Health.

³ Berner, ES, et al. Overconfidence as a Cause of Diagnostic Error in Medicine. *Am J Med* 2008; 121(5A):S2-S23.

⁴ Graber, M, et al. The Incidence of Diagnostic Error in Medicine. *BMJ Qual Saf* 2013; 22:ii21-ii27.

The Institute of Medicine states that improving the diagnostic process is “a moral, professional and public health imperative.”⁵ A holistic collaborative approach recognizes the complexities and interdependencies of imperfect humans working in their imperfect work environments.⁶ Diagnostic errors should be reframed as missed diagnostic opportunities rather than targets for blame of individual providers.⁷ Hospitals can work to develop a culture where errors are identified and lessons learned are shared in a blame free environment across providers, disciplines and departments. Staff education efforts can be aimed at improving provider self-awareness of how they reach diagnoses, including inherent biases and cognitive shortcuts that may lead to error. As always, enhanced staff communication between disciplines and among colleagues, and the empowerment of staff can help provide needed checks on the diagnostic process and convey concerns about diagnoses, treatment or patient status.

Cases and Lessons Learned

These four representative cases involving delayed diagnosis reported to QPSD share common elements and lessons learned.

Case One The patient presented to the ED with GI symptoms (nausea/vomiting/diarrhea) and tachycardia. The similarity of the patient’s GI symptoms to those of many other patients presenting with a viral illness and the finding of a UTI resulted in the patient being admitted to the inpatient medical unit. The patient was later found to have an ischemic bowel requiring surgical resection.

Case Two The patient presented to the ED with diaphoresis, lightheadedness and nausea, symptoms described by the patient as similar to a prior coronary event. A cardiac workup was negative for acute ischemia, but some conflicting findings on the nuclear stress test and echocardiogram were not appreciated and the patient was discharged to home. The patient was later diagnosed with a pulmonary embolus.

Case Three A diabetic patient presented to the ED with shoulder pain and difficulty breathing one week following a shoulder injury. A previous work-up of the elevated blood sugars steered the team toward a diagnosis of diabetic ketoacidosis and the patient was started on an insulin drip. Worsening pain and vital signs triggered further lab studies and evaluation of the shoulder injury, with an eventual diagnosis of a bacterial infection. Upon retrospective review, the elevated blood sugars were attributed to the infection.

Case Four A pediatric patient with a history of reactive airway disease presented to the ED with shortness of breath, and a reported choking incident on food a few days prior to presentation. Chest x-ray showed possible pneumonia and the patient was started on antibiotics. Failure of symptoms to respond resulted in additional work-up and removal of a fragment of food in the right main stem bronchus. Upon internal review it was noted that there was a lack of

⁵ National Academies of Sciences, Engineering, and Medicine. 2015. Improving Diagnosis in Health Care. Washington, DC: the National Academies Press.

⁶ Henriksen, K, et al. The Pursuit of Better Diagnostic Performance: A human factors perspective. *BMJ Qual Saf* 2013; 22:ii2.

⁷ Singh, H. Editorial: Helping Health Care Organizations with Defining Diagnostic Errors as Missed Opportunities in Diagnosis. *Jt Comm J Qual Pt Safety* 2014; 40(3):99-101.

appreciation for family concerns about the connection of the choking incident to the patient's symptoms.

Lessons Learned included:

- Adequate time and attention needs to be given to obtaining a detailed history and description of symptoms from the patient and family members, with careful regard for their concerns.
- Premature closure of the differential diagnosis can result in persistent treatment of an incorrect diagnosis.
- Data inconsistent with the working diagnosis should prompt reassessment of the patient.
- Worsening patient status should lead to consultation with the team, colleagues and/or specialists.
- The nursing staff should advocate for the patient and be comfortable using the "chain of command" process when there is concern for the patient's worsening condition.

General elements and confounders in diagnostic process

One case of diagnostic error may be shaped by an average of 5.9 clinical factors⁸, such as data availability, provider time and resources, and clinical team communication. Malpractice data for ED cases have also shown that key pieces of information were often not available to the physician.⁹ Some of the most common components^{10,11} of the diagnostic process where errors occur are:

- *Lab and radiology testing*, including ordering the correct tests, accurate and timely result reporting process, and interpretation of information relative to diagnoses.
- *Clinical assessment*, including sufficient hypothesis generation, appropriate prioritization, and recognition of urgencies and complications.
- *History taking*, including adequate, iterative discussions with patient and/or family, contact with primary care provider and/or specialists, and sufficient review of medical records.
- *Physical exam*, including completeness, and repeated as needed with new information, change in condition or unclear diagnosis.
- *Referral or consultation*, including adequate communication between providers, and prompt processing or action on consultant recommendations.

There are two basic decision-making processes that providers use routinely. Analytic deductive reasoning with hypothesis testing is the methodical and academic process that is generally more accurate but is time consuming and resource intensive. The second system involves the use of cognitive shortcuts or heuristics that allow the rapid processing of varied inputs. Biases can

⁸ Graber, ML, et al. Diagnostic Error in Internal Medicine. Arch Intern Med 2005; 165(13):1493-99.

⁹ CRICO/RMF. Optimizing Physician-Nurse Communication in the Emergency Department: Strategies for minimizing diagnosis-related errors. CRICO/RMF Strategies Emergency Medicine Leadership Council White Paper, 2011:1-9.

¹⁰ Pennsylvania Patient Safety Authority. Diagnostic Error in Acute Care. PA Pt Safety Advisory 2010; 7(3):76-86.

¹¹ Schiff GD, 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. 05-00212. 2005:255-78.

categorize incoming information to allow the heuristic process to cut through background noise and distractions and function more efficiently¹². Usually all of these elements work together, switching between decision-making processes as needed, to provide rapid and accurate diagnoses, but each component can also contribute to diagnostic errors:

- a. *Analytic decision-making process* – errors can result when providers have insufficient information, have faulty reasoning or when the process is overloaded with input.
- b. *Heuristics* – helpful for generation of differential diagnosis and rapid decision-making in acute situations, cognitive shortcuts do not allow for methodical processing of complex inputs and can be misled by biases.
- c. *Biases* – biases are universal, numerous and diverse, and therefore must be accounted for in the diagnostic process to help prevent skewed results. More common biases impacting the diagnostic process include:
 - i. *Social* - assumptions based on patient's economic status, education level, race/ethnicity, cognitive function, history of substance abuse and English fluency are some examples.
 - ii. *Availability heuristic*- tendency to accept a diagnosis due to ease of recalling similar event or case.
 - iii. *Anchoring* - tendency to stay with a diagnosis despite evidence to the contrary.
 - iv. *Premature closure* - narrowing the differential diagnosis too quickly.
 - v. *Satisficing*- acceptance of less than ideal or seeking merely a satisfactory solution.
 - vi. *Confirmation bias* - tendency to seek out data that confirms diagnosis rather than validating contradictory data.
 - vii. *Context errors* - provider biased by patient history or other factors, diagnosis is made in the wrong context.
 - viii. *Status quo bias* - always easier for clinicians to continue to make decisions as they've done in the past.
 - ix. *Bias blind spot* - belief that a provider is not vulnerable to biases.
- d. *Overconfidence* – a mismatch between perceived and actual diagnostic accuracy, overconfidence can be the result of the lack of consistent and timely feedback about diagnostic errors.¹³ Clinical guidelines and decision-support tools that can validate diagnoses are often underused.

Inadequate diagnostic error surveillance and provider feedback. While hospital systems vary widely, diagnostic error surveillance processes are often neither systematic nor timely. When errors are detected, root cause analyses may not be carried out to identify all possible system and individual components. Aggravating factors may include:

- Metrics for diagnostic error are either inadequate or nonexistent, making it challenging to systematically scan records and quickly detect diagnostic errors.
- Management response to diagnostic errors may follow a more punitive than educational strategy, reducing incentives for reporting errors.

¹² Croskerry, P, et al. Bias: a normal operating characteristic of the diagnosing brain. *Diagnosis* 2014; 1(1):23-27.

¹³ Berner, ES. Op.cit.

- Self-reported errors are critical for surveillance and timely feedback to other providers.
- In general, there are fewer autopsies done, more malpractice experiences are sealed, and hospital stays are shorter, limiting opportunities for provider education about ultimate diagnoses.
- Diagnostic errors may be reviewed as an individual provider issue rather than one clinical piece in the larger hospital context. This view reduces opportunities for system improvement and broader education efforts about diagnostic pitfalls.

Potential improvement activities and resources

The complexity of the diagnostic process and potential errors requires multi-faceted, multi-level approaches to improvement. The basic tenets of diagnostic process improvement activities¹⁴ should include: a non-punitive, collaborative and systematic approach to the diagnosis process; leverage of Health Information Technology (HIT) through clinical documentation and feedback; and utilization of lists of “don’t miss” diagnoses/red flag symptoms.

Individual provider level. Improvement of the diagnostic process requires a willingness and ability to reflect on one’s own thinking processes, assumptions, beliefs and conclusions.^{15,16} Providers should:

- Develop strategies for stepping back from immediate problems to examine their thinking process (metacognition).
- Avoid predictable biases (cognitive forcing functions) and potential pitfalls of heuristics; decrease reliance on memory for working or final diagnosis.
- Recognize fatigue and other personal factors (affective forcing functions). Take frequent time-outs during the diagnostic process, and with changes in patient status, to review data and diagnoses. Involve all clinical team members and the patient in iterative reassessments.

If a diagnosis is not considered then it cannot be ruled out, hence the value of a collaborative approach to diagnosis and the use of decision-support systems.

System/hospital level. System level contributions to diagnostic error include reporting and follow up of test results, transitions of care, staff education and clinical care team dynamics and communication. There are numerous proposals for quality improvement in the literature, some of the most fundamental strategies are listed below.

- Engage patients and families on many levels as meaningful partners in the diagnostic process.¹⁷

¹⁴ Schiff, GD. Presentation to IOM Committee on Diagnostic Error in Health Care 8/7/14. Accessed 5/14/15 at

<http://www.nationalacademies.org/hmd/~media/Files/Activity%20Files/Quality/DiagnosticErrorMedicine/August%20Meeting/Schiff.pdf>

¹⁵ Ely, JW, et al. Checklists to Reduce Diagnostic Errors. Acad Med 2011; 86:307-13.

¹⁶ Gillon, SA, et al. Zebra in the Intensive Care Unit: A metacognitive reflection on misdiagnosis. Crit Care Resusc 2012; 14(3):216-221.

¹⁷ Schiff GD, et al. Diagnosing Diagnostic Error, op.cit.

- Improve the diagnostic error surveillance system in order to provide meaningful and timely feedback to providers. Discover new ways to uncover errors.
- EHRs (Electronic Health Records) can improve or disrupt provider workflow and access to information.¹⁸ Speed and ease of information searches, effective problem and medication list management, fail-safe test result management, and seamless communication across transitions of care are critical fundamental functions for hospital system EHRs.
- Diagnostic decision support systems. Diagnosticians can use these tools to complement their experience and judgment to ensure full, objective consideration of possible diagnoses. Some systems have been shown to improve provider performance but not necessarily patient outcomes,¹⁹ and may disrupt workflow, therefore identification and implementation of effective and provider-accepted HIT systems is critical to their success.
- Incorporate diagnostic checklists into EHRs to assist providers.^{20,21} A variety of existing and developing lists can help providers to check the completeness of their diagnostic process, expand differential diagnoses and consider common pitfalls.²²
- In the ED, with its unique role and often chaotic setting, some key ED recommendations²³ are centered around structuring communication between physician, mid-level providers and nurses throughout each patient stay, particularly during the diagnostic process.

The Institute of Medicine's 2015 report, *Improving Diagnosis in Health Care*, is a significant milestone for quality improvement and patient safety and will contribute to local, national and global efforts to improve the diagnostic process. The report provides detailed reviews and analyses of the diagnostic process and references and recommendations for improvement that may assist providers, health care facilities and organizations, policy makers and other stakeholders in their collaborative patient safety and diagnostic improvement work. The adoption of communication and resolution programs such as those currently in use at several Massachusetts hospitals (MACRMI, Massachusetts Alliance for Communication and Resolution following Medical Injury uses the CARE approach, Communication, Apology and Resolution) is also recommended.²⁴

Conclusion

Diagnostics errors are frequently the result of multiple factors at the individual provider and hospital systems levels. Diagnosticians can work to improve their understanding of their own diagnostic processes, biases and heuristics to help avoid common pitfalls. Increasing the use of a collaborative diagnostic process and available HIT decision-support systems and checklists can

¹⁸ Schiff, GD, et al. Can Electronic Clinical Documentation Help Prevent Diagnostic Errors? NEJM 2010; 362(12):1066-69.

¹⁹ Gillon, ibid.

²⁰ The Joint Commission. Preventing Delays in Treatment. Quick Safety, 2015; 9. Accessed 5/24/15 at http://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Nine_Jan_2015_FINAL.pdf

²¹ Schiff, GD, et al. How Can We Make Diagnosis Safer? Acad Med. 2012; 87:135–138.

²² Ely, JW, op.cit.

²³ CRICO/RMF. op.cit.

²⁴ <http://www.macrmi.info/#sthash.NZwB6iJc.dpbs>

also be effective. Hospitals need to ensure a collaborative, non-punitive environment exists for the reporting and review of diagnostic errors.

Administrative efforts that improve communication between all staff levels, disciplines and departments, and empower staff and patients to take a greater role in the diagnostic process, can effectively reduce diagnostic error and improve the quality of patient care.

Resources

The Institute of Medicine, Improving Diagnosis in Health Care.

<http://iom.nationalacademies.org/reports/2015/improving-diagnosis-in-healthcare>

2014 Annual Benchmarking Report: Malpractice Risks in the Diagnostic Process. CRICO Strategies. Good statistics about diagnostic errors by diagnosis, specialty and cause. Focused on ambulatory setting but elements applicable to all settings.

http://www.rmfsstrategies.com/~media/Files/Strategies/Reports/crico_benchmarking_ambdx_final.pdf

Clinical Reasoning Toolkit, Society to Improve Diagnosis in Medicine. Provides multimedia tools and references to help providers learn about the cognitive processes that underlie diagnostic reasoning. The Society works to make diagnosis accurate and timely.

<http://www.improvediagnosis.org/?ClinicalReasoning> for toolkit,

<http://www.improvediagnosis.org> for Society homepage.

Pennsylvania Patient Safety Advisory Diagnostic Error in Acute Care, 2010. Has numerous and detailed recommendation at the provider and system levels.

[http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Sep7\(3\)/Pages/76.aspx](http://www.patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2010/Sep7(3)/Pages/76.aspx)

Preventing Delays in Treatment. The Joint Commission Quick Safety, 2015; 9.

http://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Nine_Jan_2015_FINAL.pdf

Patient Safety Net primer on diagnostic error, Agency for Healthcare Research and Quality

<http://psnet.ahrq.gov/primer.aspx?primerID=12>

AHRQ's Web M&M: Morbidity and Mortality Rounds on the Web. Excellent case reviews involving a variety of issues including diagnostic error.

<http://webmm.ahrq.gov>

Myths and Facts about Diagnostic Error. A useful and easily read fact sheet for physicians from the Society to Improve Diagnosis in Medicine and the National Patient Safety Foundation that can be used to explain the issues around diagnostic errors.

<http://www.improvediagnosis.org/?page=Facts>