

SENTINEL EVENT NEWSLETTER

DIVISION OF LICENSING AND REGULATORY SERVICES,
MAINE DEPARTMENT OF HEALTH AND HUMAN SERVICES

ISSUE 8, MARCH, 2016

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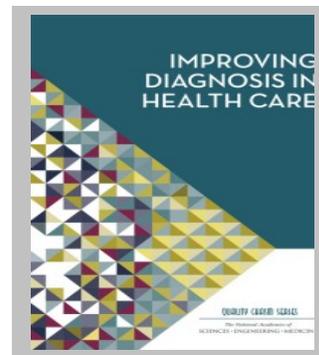
DIAGNOSTIC ERRORS

In 2015 the Institute of Medicine (IOM) published its report, "Improving Diagnosis in Health Care" as part of its ongoing series. (<https://iom.nationalacademies.org/Reports/2015/Improving-Diagnosis-in-Healthcare.aspx>) The report estimates that 5% of adults in the U.S. seeking outpatient care each year will experience a diagnostic error; that diagnostic errors contribute to approximately 10% of patient deaths; and diagnostic errors account for 6%-17% of adverse events in hospitals. The IOM defines diagnostic errors as "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." When a diagnostic error occurs it may result in the delay or withholding of a potentially beneficial treatment, or an unnecessary or inappropriate treatment being given.

Diagnostic errors are the leading type of paid malpractice claims and are almost twice as likely to have resulted in a patient's death, compared to other claims. In its 2014 report ("2014 CRICO Strategies"), CRICO, a national malpractice carrier, reviewed 4,140 cases asserted between 2009-2013 that resulted in \$1.0B in total incurred losses. CRICO findings were as follows:

- 58% of diagnosis-related cases originated in an ambulatory setting;
- General and emergency medicine accounted for 36% of cases and 39% of costs associated with diagnostic allegations;
- 60% of diagnostic-related cases resulted in high severity losses and drove 85% of total incurred costs; and
- Failure to establish a differential diagnosis (33% of cases) and its influence on test ordering (30%) had the most impact on diagnostic failures.

Diagnostic errors have always been prevalent. Khullar, et al in a 2015 article, in the *New England Journal of Medicine* ("Reducing Diagnostic Errors – Why Now?") posits that diagnostic errors are clinically and financially more costly today than ever before, because of more treatment options, advances in HIT and pay-for-performance metrics and risk-based contracts. As expensive



DIAGNOSTIC ERRORS, CONTINUED

treatments for advanced diseases become available; the costs of misdiagnosis and over-diagnosis will rise. Treatability of conditions for which effective treatment was previously unavailable means that diagnostic errors cost more in terms of lost life and quality of life. Khullar, et al also point out that the spread of multi-drug resistant pathogens means that failure to accurately and rapidly diagnose communicable infections can impact a wider network of people.

The IOM Report outlines the possible failures in the diagnostic process:

- Failure of engagement – patients who do not recognize when to access the healthcare system, or experience barriers to accessing healthcare;
- Failure in information gathering – failures to elicit key pieces of information, failure to order the right diagnostic test, or technical errors in handling, labeling and processing of samples;
- Failure in interpretation – inaccurate or failed attempts to interpret information gathered in the diagnostic process (tests, clinical history, referral/consultation information from other clinicians);
- Failure in integration – a) hypothesis generation: suboptimal weighting and prioritizing of information; b) failure to recognize or weight the urgency of clinical signs/symptoms;
- Failure to establish an explanation (diagnosis) – suboptimal weighting and prioritization of clinical signs and symptoms, delays in considering a diagnosis, or failing to follow up with patients; and
- Failure to communicate the explanation – no communication was attempted, communication was delayed or it did not align with the patient's health literacy and was not understood.

DIAGNOSTIC ERRORS, CONTINUED

Part of the challenge in addressing diagnostic errors is the difficulty in identifying and measuring them. In the Joint Commission Journal on Quality and Patient Safety, March, 2014, Graber, et al point out that there is no systematic measurement of the rate of diagnostic errors at either the local or national level. Current tools used by healthcare organizations to identify adverse medical errors (i.e., incident reports, autopsies, peer review, trigger tools) were not designed to detect diagnostic issues and rely heavily on voluntary reporting. The existing tools are ineffective in discovering diagnostic errors.

Graber, et al discuss innovative approaches to identifying diagnostic errors using facilitated physician reporting (Maine Medical Center), EHR-based triggers to identify diagnostic errors that have already occurred (Department of Veterans Affairs) and identifying missed opportunities related to diagnosis that can still be remediated (Kaiser Permanente).

Another approach is to ask patients if they have been misdiagnosed. The *British Medical Journal* article, "A Patient-Initiated Voluntary Online Survey of Adverse Medical Events: the Perspective of 696 Injured Patients and Families" (Southwick, et al, *BMJ Quality & Safety Online First*, June 19, 2015) highlights the potential efficacy of patient-initiated surveys for providing meaningful feedback and for guiding improvements in patient care. The leading category of error event in this survey was failure of diagnosis or treatment (30% of total number of events). 90% of responses expressed concern over a lack of provider accountability.

In their book, Medicine in Denial, Weed and Weed make the case that the current healthcare system does not support individual physicians in medical decision making. Physicians are educated to rely on their personal knowledge and judgement about what data to collect and what the data mean. However, in the absence of electronic information tools and standards of care for managing clinical information they lack the capacity and the time to consider all possible diagnostic possibilities and match them with individual patients' characteristics and symptoms. The process of matching general medical knowledge with patient-specific data and organizing the results is referred to as 'knowledge coupling', which the authors opine is fundamental to all of medical decision making.

IBM is also utilizing technology to harness the value of 'big data' with IBM Watson (Watson can read 40 million documents in 15 seconds, according to the IBM Watson website). Known as cognitive healthcare, IBM Watson uses natural language processing and machine learning to harvest large amounts of unstructured data. According to IBM, medical data is expected to double every 73 days by 2020, and 80% of health data is invisible to current systems

DIAGNOSTIC ERRORS, CONTINUED

because it is unstructured.

(www.ibm.com/smarterplanet/us/en/ibmwatson/health/)

For the past 4 years, IBM has been teaming with some of the world's leading healthcare institutions to advance Watson's ability to understand the science of medicine and draw conclusions from massive amounts of medical information. Doctors are able to access the cloud-based platform, Watson for Oncology (developed with Memorial Sloan Kettering Cancer Center), from any computer to analyze data and identify evidence-based treatment options.

While information technology may revolutionize medical diagnostics, it is not in common use at the time. The Society to Improve Diagnosis in Medicine is an organization that has been working since 2005 to bring focus to the significance of diagnostic errors, and to provide support and resources to ensure accurate, timely and efficient medical diagnoses. This website has an extensive list of both free and paid resources for healthcare clinicians and professionals.

(https://c.ymcdn.com/sites/improvediagnosis.site-ym.com/resource/resmgr/psaw_2014/diagnostic_errors_resource_1.pdf)

Dr. Mark Graber, identified the following steps that healthcare organizations can take to avoid diagnostic errors ("Minimizing Diagnostic Error: 10 Things You Could Do Tomorrow", *Inside Medical Liability*, First Quarter, 2014):

- Identify diagnostic errors: follow up with patients recently seen in the ER. Encourage inpatients to report errors;
- Provide clinicians with diagnosis-specific decision support tools;
- Identify physician volunteers interested in providing second opinions and advertise their services to their peers and to patients;
- Ensure there is radiology coverage to read stat films;
- Close the loop on diagnostic test results. Send results to patients. Monitor how many critical test results are acted upon within 30 days;
- Ensure that providers on vacation have designated a surrogate to review results;
- Encourage accurate problem lists, and a differential diagnosis;
- Establish ways for providers to receive feedback on their diagnoses;
- Encourage autopsies or vintopses (virtual autopsies);
- Ensure senior clinicians review all new cases with trainees in real time;
- Encourage and facilitate communication between front line clinicians and physician staff in radiology and the clinical laboratory;
- Use root cause analysis to identify remediable system-related contributions to diagnostic error; host Morbidity and Mortality Rounds with staff to review cases; and
- Empower nurses to become involved in improving diagnosis and patients to be proactive in their care.

IMPROVED SAFETY CULTURE, AN END IN ITSELF

In 2015, the National Patient Safety Foundation (NPSF) published the report of an expert panel, entitled “Free from Harm: Accelerating Patient Safety Improvement Fifteen Years after *To Err Is Human*”. The most important recommendation of the report, as defined by the expert panel, is the responsibility of leadership (boards/governing bodies as well as executives) to establish a safety culture as the foundation to achieving total systems safety. The report underscores that the importance of culture change needs to be brought to the forefront, rather than being treated as one among various safety activities, and that generating and maintaining the necessary large-scale culture shift requires strong leadership.

The report states that the process of transformation requires that hospital boards demand that leaders recognize a culture of safety as a priority and an activity for which they are responsible. This must include defining the goals and values of the organization, and healthcare leaders must clearly and relentlessly communicate that safe care is a primary, non-negotiable goal.

The importance of safety culture is illustrated by the example of the use of surgical checklists. Urbach, et al (2014) determined that superficial use of a surgical checklist was ineffective. However, a safety culture change initiative that *included* use of surgical checklists reduced mortality by 50% more than secular methods (Neily, et al 2010). A culture that demands patient safety is, therefore, not the means to an end, but an end itself.

The report lists four tactics that should be used to ensure that leadership supports a culture of patient safety:

- 1) Refocus the boards of organizations to guide and be accountable for patient safety through governance, goal setting, and ensuring that executives and all levels of management value and prioritize safety (e.g. ensure that safety data and stories are presented at every board meeting).
- 2) Ensure that leadership and governance bodies develop and implement robust processes to initiate and sustain transformation to a culture of safety and respect, specifically one that encourages honesty, fosters learning and balances individual and organizational accountability.
- 3) Develop and implement operational culture change “playbooks”, based on existing practices and operational experience with successful culture change efforts.
- 4) Create a new norm that every trustee, leader and regulator completes a foundational program in patient safety science (e.g., just culture, systems).

COMMUNICATION FAILURES

Communication or breakdown of communication is a common causal factor identified in RCAs. It was the third most prevalent common cause for sentinel events reported to The Joint Commission through 2015, and was the fifth most prevalent common cause for sentinel events reported to the SET in 2015.

CRICO recently published its annual benchmarking report for 2015 “Malpractice Risks in Communication Failures”, in which it explores the analysis of 23,000 medical malpractice claims and suits in which patients suffered some degree of harm. 3 out of 10 cases included at least one specific breakdown in communication. Some key CRICO findings are as follows:

- 7,149 cases involved failures in communication totaling \$1.7B incurred losses;
- 37% of all high severity cases involved a communication failure;
- 48% of failures occurred in an ambulatory setting, 44% occurred in inpatient settings, and 8% occurred in emergency departments;
- Provider-to-provider communication failures accounted for 57% of claims and 73% of incurred losses;
- Provider-to-patient communication failures accounted for 55% of cases and 43% of total incurred losses;
- There was overlap of 12% of cases and 16% of losses (communication failures in provider-to-provider and provider-to-patient);
- Common breakdowns included:
 - Miscommunication re: patient’s condition (26%);
 - Poor documentation (12%); and
 - Inadequate education re: risks of medications (5%).
- Among 951 general medical cases:
 - 45% reflect diagnosis errors (most commonly missed cancers);
 - 68% occurred in an ambulatory setting;
 - 60% resulted in a high-severity injury; and
 - 37% resulted in death.
- Among 380 obstetric cases:
 - 72% occurred in an inpatient setting;
 - 56% resulted in a high-severity injury; and
 - 23% resulted in either maternal or fetal death.
- Among the 647 nursing cases:
 - 24% reflect a patient monitoring error;
 - 75% occurred in an inpatient setting;
 - 45% resulted in a high-severity injury; and
 - 33% resulted in death.
- Among 1,959 surgery cases:
 - 50% involved outpatients;
 - 34% resulted in high severity injury;
 - 14% resulted in death.

The importance of effective and timely communication cannot be emphasized enough.

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UPDATES FROM THE SENTINEL EVENT TEAM

Reminder: the National Patient Safety Foundation's (NPSF) Patient Safety Awareness week is March 13 – 19. Check out activities and resources to help celebrate Patient Safety Awareness Week at the NPSF website:
http://www.unitedforpatientsafety.org/patient_safety_awareness_week

Staffing changes – We are pleased to welcome Madeline Orange, MSN, BS, RN, as the newest member of the SET. Madeline's nursing experience is in psychiatric care and nurse education. Her BS is in Criminal Justice, and she was a probation officer in California, where she worked with juveniles and court reports. Madeline's investigative skills combined with her clinical practice make her a valuable addition to the SET.

On-site reviews – The SET continues to conduct on-site reviews to determine if facilities are in compliance with the SE Rules and Statute.

Patient Safety Conference – in our ongoing efforts to promote patient safety and the importance of patient safety culture, the SET is pleased to announce that it will be holding a Patient Safety Conference on May 4, 2016. The Conference will be focused on the important role that leadership has in supporting a culture of patient safety. Keynote speaker will be international patient safety expert, Dr. Allan Frankel. Additional information will be forthcoming upon finalization of the agenda and venue. We are particularly interested in attracting senior leaders, board members and other members of management and leadership to this conference.

SENTINEL EVENT TEAM

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