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WELCOME TO THE SPECIAL ISSUE

Regina Hoffman, MBA, BSN, RN, CPPS

It is with great pleasure that I present to you the first special edition of the Pennsylvania Patient Safety Advisory. This issue is intended to bring awareness of the challenges involved in the diagnostic process. Beyond that is the hope of sparking creative solutions as we embrace these challenges.

Often in life, we are faced with not just one problem but many. Focus divided, we turn to multitasking and reprioritization, only to be ultimately left with feelings of frustration and failure. As mortal beings, we simply cannot do it all. We must be selective with the mantles we don if we aspire toward success. Choosing a problem that is as complex as healthcare itself is not a first choice for many. However, these are the types of problems that we must address—these are the ones that matter most.

Whether you are a physician, nurse, allied health provider, or healthcare leader, my plea to you is to choose improving diagnosis as one of your top priorities. Our healthcare facilities can have all the luxuries of a five-star hotel, the most helpful and kindest staff on the planet, the best food, the quietest environment, and the shortest wait times, but none of that truly matters if we cannot positively affect the health outcome for the patient.

Providing a correct diagnosis provides the basis for appropriate treatment options, informed choices, quality of life, quality of care, and ultimately, satisfaction with the healthcare system and the people who make up that system.

When something goes wrong in the diagnostic process, we remember. These are the stories that we relive and replay over and over, trying to find where a wrong turn was taken. This is the middle-aged woman who is surely just having another episode of anxiety accompanied by tightness in her chest. This is the older gentleman who fell off a ladder and has a fractured rib and a suspicious shadow on his chest radiograph that may or may not be followed up by someone. This is my mother-in-law who passed away from oral cancer that went undiagnosed for more than a year. We remember these events. They change us.

Improving diagnosis is a complex issue that is best tackled through a multifaceted approach that considers multiple perspectives, to build a foundation for improvement. We need innovative solutions to both new and age-old problems, embracing not only a culture of safety but a culture of creativity and inclusion, as well. In this issue, we bring some of these perspectives together—the patient, the data, thought leaders, healthcare facilities, and patient safety experts. All are necessary and vital to success.

My hope is that this issue serves as a catalyst for you to engage in this important work. Only after securing a proper foundation are the tallest skyscrapers built. The hard work begins at the foundation and it begins with all of us.

Regina Hoffman
Executive Director, Pennsylvania Patient Safety Authority
The Pennsylvania Patient Safety Advisory provides timely original scientific evidence and reviews of scientific evidence that can be used by healthcare systems and providers to improve healthcare delivery systems and educate providers about safe healthcare practices. The emphasis is on problems reported to the Patient Safety Authority, especially those associated with a high combination of frequency, severity, and possibility of solution; novel problems; and problems in which urgent communication of information could have a significant impact on patient outcomes.

This special issue of the Advisory is a publication of the Patient Safety Authority’s Center of Excellence for Improving Diagnosis.

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Identifying and Learning from Events Involving Diagnostic Error: It’s a Process

Rebecca Jones, MBA, BSN, RN, CPHRM, CPPS & Mary C. Magee, MSN, RN, CPHQ, CPPS

Abstract: Diagnosis involves a complex system with many team members and numerous interdependent steps, all of which can make it challenging to identify and learn from failures in the process. The Pennsylvania Patient Safety Authority sought to explore this by analyzing events involving patient harm. We queried the Pennsylvania Patient Safety Reporting System for Serious Events likely to involve diagnostic error or the diagnostic process reported during calendar year 2016. The query yielded 1,212 reports, from which we identified 138 diagnostic process failure events. We modified the diagnostic error evaluation and research (DEER) taxonomy and classified events according to process step and failure point. In the event reports, failure points in testing were involved most frequently (68.1%, n = 94 of 138) and the surgical/procedural care area predominated (21.0%, n = 29 of 138). Although the monitoring/follow-up process step accounted for just 13.0% of all events, it represented nearly half of those that resulted in death. Healthcare facilities can act now by using the modified DEER taxonomy to classify events from various sources, identify vulnerabilities in the diagnostic process, and prioritize areas of opportunity for learning and improvement. Pa Patient Saf Advis 2018 Oct 31;15[Suppl 1]:3-15.

According to the National Academy of Medicine (NAM), everyone is likely to experience at least one diagnostic error during his or her lifetime,1 and studies estimate that 12 million adults in the United States could be subject to diagnostic error each year.2,3 Diagnostic error has been identified as the leading cause of medical malpractice claims,4,6 with the majority of occurrences being classified as high severity and more than one-third resulting in death.6 Diagnostic errors are a major problem in both outpatient and inpatient care settings in the United States, but are more likely to result in death in the inpatient environment.4 Attention and action toward the problem of diagnostic error has been lacking, in part due to the difficulty in measuring errors and failures.5-10 In recent years,
multiple national organizations have acknowledged that improving diagnosis is a priority for patient safety and have started to take action.

In 2015, NAM released its report, *Improving Diagnosis in Health Care*, noting that quality and patient safety have neglected diagnostic error and diagnostic process failures because of the lack of effective measurement related to the diagnostic process and diagnostic outcomes.\(^1\) In its 2017 annual report, "Transition to the Quality Payment Program," the Centers for Medicare and Medicaid Services (CMS) recommended initial measure development in the area of diagnostic accuracy for several medical specialties.\(^11\) That same year, the National Quality Forum (NQF) convened a multistakeholder expert committee that released a measurement framework including a set of "prioritized measurement areas" to inform and guide future work to improve diagnostic quality and safety.\(^12\)

Consensus is lacking and challenges persist about defining the terms associated with diagnostic error.\(^7,8,10,13\) The term *diagnosis* can relate to the process or to the outcome of the process\(^1,13\) and researchers agree to disagree on whether various types of occurrences should be labeled as diagnostic errors.\(^10,13,15\) Some people do not think a diagnostic error has occurred unless a clear error in assigning the correct diagnosis to the patient’s condition was the proximate cause of harm or death, even when the occurrence arose from a problem during the diagnostic process.\(^8,16\) For example, a delayed diagnosis caused by a laboratory result that was not communicated to the ordering physician may be viewed by some as a diagnostic error and by others as a communication error.

The many paradigms of diagnosis—such as severity, complication, and recurrence\(^15\)—depend on the expertise of, and interactions between, various members of the diagnostic team and the larger sociotechnical healthcare system.\(^17\)

Our objectives for this study were to use a clear, structured approach to mitigate the challenges associated with measuring and defining diagnostic error and to classify and analyze events reported by Pennsylvania healthcare facilities to identify priority areas for learning and improvement.

**Methods**

**Database Query**

We queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) database\(^6\) for Serious Events\(^1\) likely to involve diagnostic error or the diagnostic process reported from January 1, 2016, through December 31, 2016. Key terms were used within pertinent event types and subtypes of the PA-PSRS taxonomy.

Terms included grammatical and synonymic variations of the following words: accurate, appreciate, detect, deterioration, diagnosis, discover, discrepancy, failure, follow-up, identify, incidental, incorrect, interpretation, misread, notify, and retrospective.

This query yielded 1,212 PA-PSRS reports, which provided the basis for our manual analysis.

**Taxonomy**

Initially, we attempted to create an operational definition to identify PA-PSRS reports resulting from diagnostic error and sort them as either diagnostic errors or not. We applied definitions outlined by NAM\(^1\) and others\(^8,19,20\) and ultimately determined the type and amount of information needed to satisfy criteria for a single definition could not be extrapolated from many of the PA-PSRS reports.

Because of challenges associated with classifying the PA-PSRS reports using the term *diagnostic error*, we explored approaches to classify them according to failures in the diagnostic process as defined in the *diagnostic error evaluation and research (DEER)* taxonomy\(^14,20,21\) and the NAM report (e.g., failure in information gathering, failure to establish an explanation [diagnosis]).\(^1\) The DEER taxonomy was the best fit based on the type and amount of information provided in the PA-PSRS reports.

We then modified the DEER taxonomy originally developed by Schiff and colleagues in 2005\(^14\) and adapted by the Pennsylvania Patient Safety Authority ("the Authority") in 2010\(^21\) to more completely capture the multidisciplinary nature of the diagnostic process and to allow for more precise classification of certain events. Modifications included the following:

- Renaming process steps—the term *physical examination* became *physical examination/assessment*, *assessment* became *hypothesis generation*, and *follow-up* became *monitoring/follow-up*
- Expanding the testing process step to include types of testing beyond laboratory and radiology—for instance, eye-pressure test, electrocardiogram
- Adding failure points for the testing process related to specimen delivery problems and for the monitoring/follow-up process related to monitoring and communication

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\(^1\)PA-PSRS is a secure, web-based reporting system through which Pennsylvania hospitals, ambulatory surgical facilities, abortion facilities, and birthing centers submit reports in accordance with mandatory reporting laws outlined in the Medical Care Availability and Reduction of Error Act (Act 13 of 2002).\(^18\)

\(^2\)A “Serious Event” is an event, occurrence, or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient.\(^18\)
- Relocating failure points related to recognizing urgency and complications from the former assessment process step to the monitoring/follow-up process step.

See Table 1 for the full modified DEER taxonomy.

**Definitions and Inclusion Criteria**

We each independently manually reviewed and analyzed the PA-PSRS report narratives, recommendations, and contributing factors to identify events related to diagnostic process failure. We then compared our findings and resolved discrepancies through joint analysis and consensus. Subject matter medical experts were consulted as necessary.

We created term definitions and inclusion criteria as follows:

- Diagnostic process failure—a process step and failure point from the modified DEER taxonomy must be identified. A diagnostic process failure can occur without definitive information about the accuracy or timeliness of the diagnosis itself.

- Unable to determine—the PA-PSRS report may relate to the diagnostic process but there is insufficient information to determine that a diagnostic process failure occurred or the process step during which it likely occurred.

- Not a diagnostic process failure—the PA-PSRS report does not relate to the diagnostic process, no diagnostic process failure is identifiable, or it relates to a different event type altogether. The information provided in the PA-PSRS report does not meet the term definition/inclusion criteria for “diagnostic process failure” or “unable to determine.”

**Event Classification and Analysis**

After identifying diagnostic process failure events, we reviewed narratives and other free-text fields to classify the events, determine the medical conditions involved, and identify events in which patients may have contributed to the process failure.

We classified each event in accordance with the modified DEER taxonomy based on the step in the diagnostic process during which it occurred (“process step”) and specific failure that occurred during the process step (“failure point”). Although many events involved more than one process step or failure point, at times it was challenging to differentiate them from one another, and researchers have questioned whether there is value in doing so.20 For that reason, we identified only the most critical failure point for each event.

We also analyzed the events based on data in discrete fields such as harm score22 and care area. We combined like care areas into categories; for example, ambulatory surgery, hospital operating rooms, and procedural areas like interventional radiology and invasive cardiology were combined into a surgical/procedural care area category.

**Results**

Of the 1,212 PA-PSRS reports analyzed, 138 (11.4%) events met the inclusion criteria and were defined as “diagnostic process failure” events (“events”). A determination could not be made for 20 (1.7%) of the reports, which were defined as “unable to determine.” The remaining 1,054 (87.0%) were excluded and defined as “not a diagnostic process failure.”

**Process Step and Failure Point**

**(Modified DEER Taxonomy)**

More than two-thirds of the events (68.1%; n = 94 of 138) involved failures in the testing process. Of the 11 failure points under testing, misread and misinterpreted tests accounted for about one-third (33.0%; n = 31 of 94) of the events.

The monitoring/follow-up process step accounted for 13.0% (n = 18 of 138) of all events, with failures or delays in recognizing urgency or complications being identified most frequently (33.3%, n = 6 of 18).

Figure 1 shows the percentage of diagnostic process failure events by process step, along with the percentage of testing process events by failure point.

**Table 2** includes examples of event narratives from each of the seven process steps.

**Harm Score**

Harm scores were identified by healthcare facilities at the time of reporting. The majority of events involved temporary harm: harm scores E and F accounted for 73.2% (n = 101 of 138) of all events (Table 3). Events that contributed to or resulted in death accounted for 10.9% (n = 15).

Although failures in the monitoring/follow-up process accounted for just 13.0% (n = 18 of 138) of all events, this step represented nearly half of all events that resulted in death (46.7%; n = 7 of 15).

**Care Area**

Care areas designated by reporting healthcare facilities were aggregated (Figure 2). The top two care areas identified in the events were surgical/procedural (21.0%, n = 29 of 138) and emergency department (ED; 16.7%, n = 23). Reports from discrete outpatient clinics and physician practices comprised 5.8% (n = 8) of all events; only practices and clinics under a hospital license are mandated to report into PA-PSRS. For context, of all PA-PSRS Serious Events reported during calendar year 2016, 2% (n = 152 of 7,548) were from outpatient clinics and physician practices. (continued on page 9)
Table 1. Modified DEER Taxonomy*

<table>
<thead>
<tr>
<th>DIAGNOSTIC PROCESS STEP</th>
<th>FAILURE POINT</th>
</tr>
</thead>
</table>
| 1. Access/Presentation  | A. Failure or delay in patient seeking care  
                          | B. Failure or denial of access to care  |
| 2. History              | A. Failure or delay in providing or eliciting a piece of history data  
                          | B. Inaccurate or misinterpreted piece of history data  
                          | C. Suboptimal weighing of a piece of history data  
                          | D. Failure or delay in acting on or following-up on a piece of history data  |
| 3. Physical Examination/Assessment | A. Failure to perform a physical examination or assessment  
                                     | B. Inaccurate or missed physical examination or assessment finding  
                                     | C. Suboptimal weighing of a physical examination or assessment finding  
                                     | D. Failure or delay in acting on or following-up on a physical examination or assessment finding  |
| 4. Testing (Laboratory/Radiology/Other) | A. Failure or delay in ordering needed test(s)  
                                      | B. Failure or delay in performing needed test(s)  
                                      | C. Suboptimal test sequencing  
                                      | D. Wrong test(s) ordered  
                                      | E. Test(s) ordered the wrong way  
                                      | F. Identification failure (e.g., sample mix-up, mislabeled specimen, or test performed on the wrong patient)  
                                      | G. Technical or processing error (equipment problem, poor processing of specimen/test, or skill issue)  
                                      | H. Specimen delivery problem (e.g., specimen never sent, delayed delivery, or lost specimen)  
                                      | I. Misread or misinterpreted test(s)  
                                      | J. Failure or delay in transmitting or communicating test result to healthcare provider  
                                      | K. Failure or delay in acting on or following-up on test result (including results not communicated to the patient)  |
| 5. Hypothesis Generation | A. Failure or delay in considering correct diagnosis  
                              | B. Suboptimal weighing or prioritizing  
                              | C. Too much weight given to lower probability or priority diagnosis  |
| 6. Referral/Consultation | A. Failure or delay in ordering a referral or consult  
                                   | B. Failure or delay in obtaining or scheduling an ordered referral or consult  
                                   | C. Failure or delay in communicating consultation findings  |
| 7. Monitoring/Follow-Up  | A. Failure or delay in monitoring (e.g., failure to routinely check vital signs, failure to apply monitor, technical issue)  
                          | B. Inaccurate or missed physiologic monitoring finding (e.g., misinterpreted fetal monitor strip)  
                          | C. Failure or delay in recognizing urgency of condition or complication  
                          | D. Failure or delay in communicating findings among healthcare team members  
                          | E. Failure to refer the patient to appropriate setting or for appropriate monitoring  
                          | F. Failure or delay in timely following-up with or rechecking the patient  |

Figure 1. Percentage of Diagnostic Process Failure Events by Process Step (N = 138)

PERCENTAGE OF EVENTS

- Access/Presentation (n = 5)
- History (n = 3)
- Physical Exam/Assessment (n = 5)
- Testing (n = 94)
- Hypothesis Generation (n = 12)
- Referral/Consultation (n = 1)
- Monitoring/Follow-Up (n = 18)

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Percentage of Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access/Presentation</td>
<td>3.6%</td>
</tr>
<tr>
<td>History</td>
<td>2.2%</td>
</tr>
<tr>
<td>Physical Exam/Assessment</td>
<td>3.6%</td>
</tr>
<tr>
<td>Testing</td>
<td>68.1%</td>
</tr>
<tr>
<td>Hypothesis Generation</td>
<td>8.7%</td>
</tr>
<tr>
<td>Referral/Consultation</td>
<td>0.7%</td>
</tr>
<tr>
<td>Monitoring/Follow-Up</td>
<td>13.0%</td>
</tr>
</tbody>
</table>

Note: Serious Events reported through the Pennsylvania Patient Safety Reporting System, January 1, 2016, through December 31, 2016.
Table 2. Pennsylvania Patient Safety Reporting System Event Narrative Examples

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Event Narrative</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Access/Presentation</strong></td>
<td>Six weeks after knee surgery, patient complained of leg pain. Patient was instructed to go to the ED [emergency department] immediately. The patient expired after arriving at the ED a few days later.* Patient underwent a D&amp;C [dilation and curettage] and ablation. Patient had continued bleeding afterwards, which was treated with medication and she was discharged. Later that day, patient called due to continued bleeding and was instructed to return to the hospital. She did not return but called again the next day due to worsening bleeding and clots. Patient was again instructed to return to the hospital. Patient was subsequently diagnosed with a significant laceration requiring closure.*</td>
</tr>
<tr>
<td><strong>History</strong></td>
<td>Patient became diaphoretic and ashen during a procedure under local anesthesia. In the recovery area, she developed nausea and then vomited and became bradycardic. Upon further questioning, she conceded to not disclosing several days of shoulder and arm pain before the procedure. Patient was transferred to the ED for further evaluation.* Post procedure, the patient complained of increased abdominal pain. Patient’s temperature was slightly elevated. Patient conceded having the pain before the procedure but not informing the provider. Provider ordered a CT [computed tomography] scan, the results of which [differed from] what was seen during the procedure. Because of continuing symptoms, the patient was admitted for further treatment.*</td>
</tr>
<tr>
<td><strong>Physical Exam/Assessment</strong></td>
<td>Family member relayed patient’s complaints of pain in the arm and leg to the provider. Provider told family member there was no need to examine the arm or leg. Two days later, family member informed a different provider about the patient’s continued complaints. Patient was examined and x-rays were ordered showing fractures and DVTs [deep vein thromboses]. Patient was admitted to the medical unit from the ED with a diagnosis of UTI [urinary tract infection]. Staff on the medical unit immediately noticed significant facial droop and flaccid limbs on the right. Patient’s wife said that’s why she brought him to the hospital. A stat [urgent] CT was ordered and patient was transferred for further treatment.</td>
</tr>
<tr>
<td><strong>Testing</strong></td>
<td>A bronchoscopy specimen was collected during a surgical procedure and sent to the lab. Two months later, when the patient called for the results, it was discovered that the order for testing had not been entered. The patient had to have a repeat procedure. Patient underwent a chest x-ray in the ED, which revealed a 4 cm lung nodule. A CT was recommended, but follow-up did not occur at the time. One year later, the patient underwent a chest CT, which revealed the same lung mass. Subsequent testing confirmed metastatic squamous cell carcinoma. Patient returned for follow-up appointment one week after medication abortion. US [ultrasound] was performed and interpreted by provider as [no evidence of pregnancy]. Patient returned 7 weeks later due to symptoms of ongoing pregnancy. US showed pregnancy of 16 weeks gestation. The morning after lobectomy procedure, patient was transferred to ICU [intensive care unit] due to shortness of breath. Provider ordered serial cardiac enzymes [blood tests]. Troponin result was positive, but provider was not notified for 5 hours. Once notified, provider ordered an EKG [electrocardiogram] as routine and not stat. Repeat troponin results continued to show elevated levels with each draw. EKG was not performed until the next day and showed ST-segment elevation [in the heart rhythm]. Patient immediately sent to cardiac cath lab for intervention. Patient was seen in ophthalmology clinic after cataract surgery. Right eye pressure was [much higher than normal]. Patient not scheduled to return until one year later. Patient returned in 10 months due to decreased vision in right eye. Eye pressure [continued to be elevated]. Patient’s worsening vision resulted from undiagnosed glaucoma.</td>
</tr>
</tbody>
</table>
Process Step  Event Narrative

**Testing (continued)**

Patient underwent D&C due to miscarriage. Patient had recurrent pregnancy losses so provider ordered both pathology and genetic analysis of products of conception. Specimens should have been sent to both departments but were sent only to pathology. They had already been fixed, so genetic analysis could not be performed.

Patient presented to ED due to rapid onset of confusion. Head CT was interpreted as negative and patient was discharged. Patient returned to the ED 2 days later due to worsening neurologic condition. A repeat head CT showed a stroke. Review of images from 2 days prior revealed a failure to appreciate stroke on the initial CT.

Patient had abnormal colonoscopy results requiring follow-up colonoscopy in 6 months. Follow-up colonoscopy was not ordered. Patient returned 3 years later and was diagnosed with metastatic colon cancer.

Preoperative biopsy results indicated adenocarcinoma of the lung, for which the patient underwent a lung resection. Postoperatively the final confirmed biopsy results showed no adenocarcinoma.

**Hypothesis Generation**

Teenage male presented to the ED with complaints of left lower pelvic pain and vomiting. Patient was diagnosed with a groin sprain and discharged. Patient went to his PCP [primary care physician] the next day due to continued pain. PCP ordered a testicular US which showed torsion of the left testicle with no blood flow. Patient was admitted to the hospital and underwent surgery to remove the left testicle.

Patient presented to ED with complaints of chest pain, hypertension, and sweats. Cardiac indicators were negative for MI [myocardial infarction] and patient was admitted for monitoring and non-urgent cardiac work-up. Patient continued to complain of chest pain and developed lower abdominal pain. Patient’s condition deteriorated, he went into cardiac arrest, and resuscitation attempts failed. Autopsy revealed thoracic aortic dissection.

**Referral/Consultation**

Patient’s death was the result of a delayed surgical consult resulting in a delayed diagnosis.

**Monitoring/Follow-up**

The patient experienced bradycardia leading to cardiac arrest requiring intubation and a round of meds. Prior to this event, the patient showed signs of hypoxia, which were not recognized. Upon investigation it was discovered that staff were unaware the monitors could be adjusted in order to see tracings from multiple rooms.

The patient returned from [radiology] after having a thrombectomy and was noted to be weaker and unable to move without significant assistance from staff. House staff was notified. Overnight, the patient reported she was unable to move her extremities on one side. This continued to worsen but the nurse did not report these findings to the provider. In the morning, the patient was found to have experienced an acute neurological event with hemi-paresis.

Patient taken to ED via EMS [emergency medical services] due to complaints of diarrhea and fever. Upon arrival to the ED, triage nurse performed EKG which was negative for STEMI [ST-segment elevation myocardial infarction] and sent patient to the waiting room. Later, another triage nurse called for patient on two occasions and presumed he eloped due to lack of response. Several hours later patient was found unresponsive in the waiting room and resuscitation efforts were unsuccessful.

Patient was taken off monitor, assisted to the BR [bathroom], and [left alone in BR without monitoring]. When staff returned to check on patient, she was unresponsive. Resuscitation efforts were unsuccessful.

Patient suffered multi-organ system failure and subsequent death due to hours of low perfusion state following a complex heart surgery. Investigation revealed lack of communication between healthcare team members about patient’s declining condition.

Maternal and fetal heart rate tracings were confused. Once this became clear, a stat C-section [cesarean delivery] was performed due to fetal bradycardia. Infant was transferred to NICU [neonatal intensive care unit] and placed on a therapeutic hypothermia protocol due to hypoxic-ischemic encephalopathy.

Note: Data reported through the Pennsylvania Patient Safety Reporting System from January 1, 2016, through December 31, 2016

The details of the Pennsylvania Patient Safety Reporting System event narratives have been modified to preserve confidentiality.

*Patient contributed to the event (e.g., patient did not disclose health information to the provider).
Table 3. Diagnostic Process Failures in Serious Events by Harm Score (N = 138)

<table>
<thead>
<tr>
<th>HARM SCORE</th>
<th>PERCENTAGE</th>
<th>NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>E—An event occurred that contributed to or resulted in temporary harm and required treatment or intervention.</td>
<td>48.6</td>
<td>67</td>
</tr>
<tr>
<td>F—An event occurred that contributed to or resulted in temporary harm and required initial or prolonged hospitalization.</td>
<td>24.6</td>
<td>34</td>
</tr>
<tr>
<td>G—An event occurred that contributed to or resulted in permanent harm.</td>
<td>12.3</td>
<td>17</td>
</tr>
<tr>
<td>H—An event occurred that resulted in a near-death event (e.g., required intensive care unit care or other intervention necessary to sustain life).</td>
<td>3.6</td>
<td>5</td>
</tr>
<tr>
<td>I—An event occurred that contributed to or resulted in death.</td>
<td>10.9</td>
<td>15</td>
</tr>
</tbody>
</table>

(continued from page 5) Failures in testing accounted for nearly three-quarters (72.4%, n = 21 of 29) of events reported from surgical/procedural areas, and more than half (52.2%, n = 12 of 23) reported from the ED.

Medical Condition

Figure 3 displays events by medical condition. In five instances, more than one condition was identified. Cancer was identified most frequently (22.5%, n = 31 of 138) and, of the cancers identified, lung cancer predominated (22.6%, n = 7 of 31). The conditions classified as “other” included hypoad hyperglycemia, subdural hematoma, ectopic pregnancy, and esophageal diverticula. Vascular events included stroke, myocardial infarction, and pulmonary embolism. Infectious disease conditions included sepsis, appendicitis, and meningitis. Complications included those resulting from treatment or after a procedure, such as retained surgical items missed on imaging, pneumothorax, perforation, and retroperitoneal bleeding. Orthopedic conditions included fractures and dislocations.

Failures in testing accounted for 100% (n = 31 of 31) of the events related to cancer. Seven of the 11 failure points in the testing process step were involved (Figure 4). Misread or misinterpreted diagnostic tests accounted for 29.0% (n = 9) of the events.

Patient Involvement

We identified nine instances (6.5% of 138 events) in which patients contributed to the event. For examples, refer to event narratives marked with an asterisk in Table 2.

Discussion

Using our modified version of the DEER taxonomy, we classified and analyzed events reported through PA-PSRS to identify areas of opportunity for improvement and future research related to the diagnostic process. More than two-thirds of the events involved the testing process step, and surgical/procedural areas were frequently involved. Monitoring/Follow-up failures were found to be an area of high risk, accounting for nearly half of all events resulting in death.

Testing

Our finding that failures in the testing process accounted for the largest proportion of events is consistent with other research in the field based on various methodologies. For example, a survey of physicians showed that 44% of the cases of diagnostic error involved a failure related to radiology/laboratory testing.20 In addition, in a review of 10,618 closed medical professional liability claims from 2013 through 2017, Hanscom, Small, and Lambrecht found that 52% of diagnostic error claims related to diagnostic/laboratory testing steps.6

It is unclear, based on our results, whether events in the category of testing contribute most often to diagnostic process failures or if these events are just more likely to be recognized and reported. The PA-PSRS taxonomy includes specific categories for reporting events related to testing, which may play a role. In addition, testing results, as well as the tasks associated therewith, tend to be more discernible in medical records and through various sources of data than are failures related to many of the other diagnostic process steps. Regardless, many of the failure points associated with testing can be considered “low-hanging fruit” and ripe for improvement efforts.

Surgical/Procedural Care Area

The surgical/procedural care area was the most frequent care area identified in this study. Although surgical/procedural areas do not typically rise to the top in studies of diagnostic error across provider types, such as those involving medical malpractice claims,5,6 care areas identified by reporting healthcare facilities do not necessarily reflect the healthcare provider or team “responsible.”
Note: Serious Events reported through the Pennsylvania Patient Safety Reporting System (PA-PSRS), January 1, 2016, through December 31, 2016; only practices and clinics under a hospital license are mandated to report into PA-PSRS.

Note: Serious Events reported through the Pennsylvania Patient Safety Reporting System, January 1, 2016, through December 31, 2016; the conditions total more than the 138 diagnostic process failure events because some events described more than one condition.

* Includes hypo- and hyperglycemia, subdural hematoma, ectopic pregnancy, and esophageal diverticula
† Includes retained surgical items missed on imaging, pneumothorax, perforation, and retroperitoneal bleeding
For example, for specimen delivery problems originating from surgical/procedural areas, some healthcare facilities listed the location as operating room, while others selected the laboratory. Moreover, the surgical/procedural care area in our study includes events from hospitals and ambulatory surgical facilities, which likely contributed to this care area predominating.

Within the surgical/procedural care area, failures in the testing process step were most common. Because so many tests originate in surgical/procedural areas, testing processes and teamwork within these areas and across other departments and disciplines are vital to improving the diagnostic process and may be a great place to begin improvement work.

**Monitoring/Follow-Up**

Although every step in the diagnostic process depends on contributions from the entire diagnostic team—including nurses, technologists, respiratory therapists, social workers, and others—these contributions are most visible during the testing and monitoring/follow-up process steps. We have already identified opportunities for improvement work related to testing; given that more than one-third of the events classified as failures in the category monitoring/follow-up resulted in patient death, this area may warrant further attention as well.

We chose to use the term *monitoring/follow-up* for clarity, although the contributions made by healthcare team members during this step of the process go well beyond monitoring. Traditionally, reference to a *diagnostic error* meant there was a mistake in identifying the primary cause of a patient’s signs and symptoms; in other words, an inaccurate or delayed diagnosis of a new condition. However, especially in acute care settings, complications can arise from treatment or after a procedure for the original problem, or a separate clinical issue can present during the course of care. The entire healthcare team must be vigilant about monitoring the patient, recognizing and communicating changes in a timely manner, and following up as appropriate.

**Patient Involvement**

Patients also play a role as key members of the diagnostic team. Although the patient does not bear sole responsibility for a successful diagnostic process, during certain process steps, the patient’s participation is vital. In our study, we identified nine events in which the patient contributed to the process failure, the majority of which involved the process steps of access/presentation or history.

**Hypothesis Generation**

The process step hypothesis generation accounted for 9% of the events in our study. Although not a direct comparison in terms of methodology or definitions, studies based on data from medical record reviews and provider interviews, malpractice claims, and
Table 4. Resources to Improve Aspects of the Diagnostic Process

<table>
<thead>
<tr>
<th>RESOURCE</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnostic Team</td>
<td>This article discusses an expanded diagnostic team—including nurses and allied health professionals, as well as the patient—that supports the diagnostic process.</td>
</tr>
<tr>
<td>Patient involvement strategies for diagnostic error mitigation</td>
<td>This article contains a list of patient tactics for preventing and detecting diagnostic errors, including telling your story well, being an informed patient, and ensuring follow-up on testing. The authors encourage patients to report diagnostic error.</td>
</tr>
<tr>
<td>Nurses in diagnostic error prevention</td>
<td>This article defines a framework for nursing engagement in the diagnostic process and includes an approach to addressing barriers to nurses participating as full members of the diagnostic team.</td>
</tr>
<tr>
<td>Patient’s toolkit for diagnosis</td>
<td>This toolkit helps patients prepare for a visit with their healthcare provider by providing a format with prompts for telling their story clearly.</td>
</tr>
<tr>
<td>Testing</td>
<td></td>
</tr>
<tr>
<td>Lost surgical specimens, lost opportunities</td>
<td>This article presents risk reduction strategies, including specimen retrieval, reducing reliance on memory, and chain of custody.</td>
</tr>
<tr>
<td>In vitro hemolysis: delays may pose safety issues</td>
<td>This article presents risk reduction strategies including timely and accurate testing processes such as phlebotomy site selection and analysis of adverse events.</td>
</tr>
<tr>
<td>Health IT and laboratory testing</td>
<td>This article presents risk reduction strategies including assembling a multidisciplinary team to evaluate and improve the total testing process, simplifying test names in order menus, monitoring the display of results, and establishing a communication plan for incomplete specimens, cancelled specimens, and amended results.</td>
</tr>
<tr>
<td>Hypothesis Generation</td>
<td></td>
</tr>
<tr>
<td>Diagnostic reasoning toolkit</td>
<td>This toolkit shares resources as an introduction to clinical reasoning.</td>
</tr>
<tr>
<td>Monitoring/Follow-up</td>
<td></td>
</tr>
<tr>
<td>Alarm interventions during medical telemetry monitoring: a failure mode and effects analysis</td>
<td>This is a comprehensive failure mode and effects analysis on telemetry monitoring, with detailed mitigation strategies about alarm management.</td>
</tr>
<tr>
<td>Connecting remote cardiac monitoring issues with care areas</td>
<td>This article presents risk reduction strategies to enhance communication about remote cardiac monitoring of patients in noncritical care areas.</td>
</tr>
<tr>
<td>Physiologic alarm management</td>
<td>This article identifies potential contributing factors to patient deaths associated with physiologic alarm monitoring and includes mitigation strategies.</td>
</tr>
<tr>
<td>Managing patient access and flow in the ED to improve patient safety</td>
<td>This article includes strategies to increase patient safety and improve quality during the emergency department (ED) visit from point of arrival through diagnostic evaluation.</td>
</tr>
<tr>
<td>Patient flow in the ED—diagnostic evaluation through disposition decision</td>
<td>This article includes general principles to enhance patient safety related to the diagnostic process in the ED setting.</td>
</tr>
<tr>
<td>Patient flow in the ED—disposition through departure</td>
<td>This article includes strategies to enhance patient safety related to monitoring, communication, and a reference from the Agency for Healthcare Research and Quality on a feedback mechanism about a patient’s ED diagnosis versus final diagnosis.</td>
</tr>
<tr>
<td>Warming blankets and patient harm</td>
<td>This article includes strategies to enhance patient monitoring practices while using warming devices.</td>
</tr>
<tr>
<td>Early warning systems: the next level of rapid response</td>
<td>This article describes the use of an early warning system, based on physiologic signals, to assist staff in recognizing high-risk patients before they deteriorate.</td>
</tr>
<tr>
<td>Failure to rescue and nursing surveillance</td>
<td>This article defines and outlines nursing surveillance as a strategy to prevent the inability to save a patient’s life when he or she experiences a complication (i.e., failure to rescue).</td>
</tr>
<tr>
<td>Hospital and patient characteristics associated with death after surgery</td>
<td>This article coins the phrase “failure to rescue” and identifies patient characteristics associated with adverse occurrences.</td>
</tr>
</tbody>
</table>
voluntary reports from ED physicians appear to reflect a much higher proportion of occurrences involving this process. However, it is challenging to distinguish the cognitive aspects of hypothesis generation from not only the cognitive aspects involved in other steps of the process, but from all of the organizational, environmental, and other work-system factors that might have impacted cognition at the time.

Although these findings represent a lower-than-expected rate of reporting for events involving hypothesis generation, we cannot be sure whether a lack of reporting by physicians contributed, because PA-PSRS reports do not capture the role of the reporter. However, some experts in the field have recognized insufficient incident reporting by physicians and emphasize that physician reports of diagnostic errors can call attention to occurrences that may otherwise go unidentified.10

**Improvement Opportunities**

Clearly, there is no shortage of opportunities to improve the diagnostic process. We have identified some priority areas of focus based on data collected across Pennsylvania, and healthcare facilities can use the modified DEER taxonomy locally to identify trends, set priorities, and create improvement strategies. Sources of information that can serve as a starting point for identifying occurrences to classify include incident reports, employee and patient surveys, patient and family complaints and grievances, medical record reviews, morbidity and mortality and peer reviews, malpractice claims, insurance claims, and clinical surveillance. These sources are complementary and can be combined for the most complete understanding.1,10,31

In addition, Table 4 lists a number of resources that may help to address some of the process issues identified in this study.

**Limitations**

This analysis is based on facility-reported Serious Events and does not quantify diagnostic error in Pennsylvania. Despite mandatory reporting laws, the data are subject to the limitations of self-reporting and the complexities of the reporting system. The Authority’s findings might have differed had the analysis included Incidents.9

There is no explicit taxonomy available in PA-PSRS for reporting diagnostic errors or diagnostic process failures. PA-PSRS reports were analyzed based on information in the free-text narratives and structured fields. Reports were neither discussed with associated caregivers nor correlated with medical records.

**Conclusion**

Although the diagnostic process is extensive and complex, this study provides key insights and areas worth exploring further. While the Authority has access to a breadth of valuable data from PA-PSRS events reported by healthcare facilities across the Commonwealth, hospitals and health systems have much deeper and richer sources of data related to each unique event. Using the modified DEER taxonomy as a starting point, the Authority, along with healthcare facility leaders, healthcare providers, and all interested stakeholders, can work together to create an effective and reliable system for measuring events involving diagnostic process failures, thus strengthening our ability to recognize patterns and prioritize areas of opportunity for learning and improvement both at the facility level and broadly across Pennsylvania and beyond.

Notes


*An “Incident” is an event, occurrence, or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient.18
Beyond the Lab
The Link between Health IT and Laboratory Test Problems
Kim Liberatore, MSN, RN, CPHQ

Abstract: Laboratory testing plays an important role in the diagnostic process; thus, timely and accurate laboratory testing processes are essential to delivering safe patient care. Health information technology (health IT) has been introduced as a mechanism to reduce error and improve efficiency throughout the laboratory testing process. Yet, health IT was indicated as a contributing factor to laboratory-test problems in 775 evaluable events reported January 2016 through December 2017 through the Pennsylvania Patient Safety Reporting System. The pre-pre analytical phase, involving test ordering, drawing, and transportation to the laboratory, accounted for the largest number of events. Problems due to incorrect human data entry (i.e., wrong input) and incorrect machine output or display of data (i.e., output/display error) were most common. Risk reduction strategies include assembling a multidisciplinary team to evaluate and improve the total testing process, simplifying test names in order menus, monitoring the display of results, and establishing a communication plan for incomplete specimens, canceled specimens, and amended results. Pa Patient Saf Advis 2018 Oct 31;15[Suppl 1]:16-24.

Laboratory results are an integral part of decision making during the diagnostic process. Health information technology (health IT) has been introduced throughout the laboratory testing process to improve the accuracy and efficiency of tasks once reliant on paper, manual effort, phone calls, and couriers. Health IT has transformed the laboratory test process, from ordering and collection of tests through the communication and interpretation of results. As the role of health IT in the laboratory testing process has advanced, so too has the possibility for patient safety to be compromised in new and unexpected ways.1 The introduction of health IT throughout the laboratory testing process has complemented an evolving appreciation of the complex, interrelated processes that extend beyond the walls of the laboratory. Regulatory guidelines, patient safety priorities, and a focus on patient-centered care have supported
this broader, systems approach to evaluating and improving patient care.2-4

Recognizing the importance of studying the effects of health IT on patient safety and the diagnostic process, this analysis evaluates reports that associated health IT with laboratory test problems submitted by Pennsylvania healthcare facilities over a two-year period.

Methods
Pennsylvania Patient Safety Authority analysts queried the Pennsylvania Patient Safety Reporting System (PA-PSRS) for events submitted from January 1, 2016, through December 31, 2017, that were submitted under the event subtype “laboratory test problem” and indicated health IT was a contributing factor.a Analysts manually reviewed all reports and categorized the phase of laboratory testing and health IT problems. The phase of laboratory testing was categorized using the five phases of laboratory testing described by Plebani.2 The steps within each phase are outlined in Table 1.

The health IT problems described in event narratives were categorized using a health IT-specific taxonomy developed by Magrabi and co-authors.5 This taxonomy classifies problems as being human- or machine-related, and occurring at the point of data input, transfer, output, or at a broader general technical level (Figure 1). When specifically reported in the event narrative, contributing factors from the Magrabi taxonomy were also applied. A single event could be tagged with multiple categories from the Magrabi taxonomy. Reports were excluded from the analysis based on the following criteria: description of a non-laboratory diagnostic test problem, insufficient detail to categorize the phase of laboratory testing, or insufficient detail to categorize the health IT problem.

After categorizing all evaluable reports using adaptations of both the Plebani and Magrabi taxonomies, the events were analyzed by reported harm score, phase of the laboratory testing process, and health IT problem. Analysts conducted a review of the literature to ascertain background on laboratory testing errors, the role of health IT in laboratory testing, and strategies to reduce risk.

Results
The query identified 864 reports, of which 6 described non-laboratory test problems, and 83 had insufficient detail to categorize the phase of testing or health IT problem. The remaining 775 evaluable events are described below.

Harm Score
More than 99% of events were reported as Incidents (Figure 2). The most common harm score in all phases of the laboratory testing process was C (i.e., event reached the individual but did not cause harm and did not require increased monitoring).7 Three events resulted in patient harm (i.e., Serious Events): one pre-analytical event involved a test ordered but not performed, one analytical event involved wrong results, and one post-analytical event involved wrong results. The pre-analytical event, in which an ordered test was not performed, was associated with the patient’s death (i.e., harm score I).

Laboratory Testing Phase
Based on the Plebani taxonomy addressing the phases of laboratory testing,2 the pre-pre analytical phase was associated with the largest number of events involving laboratory test problems. The analytical phase was associated with the fewest (Figure 3).

Health IT Problems
Based on the Magrabi taxonomy addressing health IT defects,1 review of the 775 PA-PSRS events identified 917 problems (Table 2). Human-computer interactions were involved in more than half (54.7%)

---

Table 1. Location and Phases of Laboratory Testing

<table>
<thead>
<tr>
<th>Outside the laboratory</th>
<th>Within the laboratory</th>
<th>Outside the laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-pre analytical</td>
<td>Pre-analytical</td>
<td>Analytical</td>
</tr>
<tr>
<td>• Test request</td>
<td>• Log-in</td>
<td>• Sample analysis</td>
</tr>
<tr>
<td>• Patient and specimen identification</td>
<td>• Centrifugation</td>
<td></td>
</tr>
<tr>
<td>• Blood drawing</td>
<td>• Aliquotting</td>
<td></td>
</tr>
<tr>
<td>• Sample collection and handling</td>
<td>• Pipetting</td>
<td></td>
</tr>
<tr>
<td>• Transportation of sample to laboratory</td>
<td>• Dilution</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Sorting specimens into batches</td>
<td></td>
</tr>
</tbody>
</table>

Figure 1. Magrabi Classification of Reports Related to Health Information Technology

HUMAN
Contributing factors
- 1.2.1 Wrong input
- 1.2.2 Missing data
- 1.2.3 Didn’t do
- 1.2.4 Fail to alert

5. Contributing factors
- 5.1 Staffing/training
- 5.2 Cognitive load
- 5.3 Fail to carry out duty
- 5.2.1 Interruption
- 5.2.2 Multi-tasking
- 5.3.1 Fail to log-off

MACHINE

1.1 Data capture down or unavailable

1. Input
2. Transfer
3. Output

2.1 Network down or slow
2.2 System interface issues

3.4 Data retrieval error
3.3 Output/display error
3.2 Record unavailable
3.1 Output device down or unavailable

4. General technical

4.1 Computer system down or too slow
4.2 Access problem
4.3 Software not available
4.4 Software issue
4.5 Data loss

4.4.1 Functionality
4.4.2 System configuration
4.4.3 Device interface
4.4.4 Network configuration

Note: Revised classification for health information technology problems (new categories for software issues are underlined).

Figure 2. Reported Health Information Technology Events by Harm Score (N = 775)

NUMBER OF REPORTS

<table>
<thead>
<tr>
<th>Incident (99.6%, n = 772)</th>
<th>Serious Event (0.4%, n = 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reports of events that did not reach the patient (33.8%, n = 262)</td>
<td>Reports of events that reached the patient (66.2%, n = 513)</td>
</tr>
<tr>
<td>A</td>
<td>E</td>
</tr>
<tr>
<td>107</td>
<td>1</td>
</tr>
<tr>
<td>B1</td>
<td>F</td>
</tr>
<tr>
<td>22</td>
<td>1</td>
</tr>
<tr>
<td>B2</td>
<td>G</td>
</tr>
<tr>
<td>133</td>
<td>0</td>
</tr>
<tr>
<td>C</td>
<td>H</td>
</tr>
<tr>
<td>408</td>
<td>0</td>
</tr>
<tr>
<td>D</td>
<td>I</td>
</tr>
<tr>
<td>102</td>
<td>1</td>
</tr>
</tbody>
</table>

Note: As reported to the Pennsylvania Patient Safety Authority, January 2016 through December 2017.
Figure 3. Reported Health Information Technology Events by Phase of Laboratory Testing (N = 775)

Note: As reported to the Pennsylvania Patient Safety Authority, January 2016 through December 2017.

An urgent urinalysis was ordered by the physician. The order entry indicated the specimen was already collected. The specimen had not already been collected and should have been entered as pending to activate a collection workflow. Followed up with physician regarding correct order entry.

Specimen collection status was set to “unit collect.” Patient did not have a central device that would permit a unit collection. Nurse changed the collection status to “lab collect.”

Examples of event reports categorized as wrong inputs in the post-analytical phase are as follows:

*When entering manual differential results into the LIS [laboratory information system], tech accidentally inverted two results.*

Test was negative but tech entered result as positive.

Output/Display Error

Data output/display errors were identified in the second largest number of event reports (19.7%; n = 181 of 917). More than half of these errors occurred in the pre-pre analytical phase (55.2%; n = 100 of 181) and a third occurred in the post-analytical phase (32.6%; n = 59 of 181). The types of technology involved in output/display errors included electronic health records (EHR), laboratory information systems (LISs), printers, and mobile applications.

*The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.

of categories assigned; the remaining 45.3% were machine-related. Problems involving information input were most common (46.5%; n = 426 of 917), with 72.3% occurring during the pre-pre analytical phase (n = 308 of 426). Problems involving information output were the next most common (34.8%; n = 319 of 917).

At a more granular level, the most common event report categories assigned were problems due to wrong input, output/display error, system interface issues, and (humans) didn’t do (Table 2).

Wrong Input

Problems related to wrong input were identified in the largest number of event reports (32.0%; n = 293 of 917), with 73.4% occurring in the pre-pre analytical phase (n = 215 of 293). Wrong input problems in the post-analytical phase were the next most common (18.8%; n = 55 of 293). Wrong inputs during test ordering and resulting were both mechanical (e.g., typing errors, wrong drop-down menu selection) and cognitive in nature (e.g., acting upon incorrect information, misinterpreting information).

Examples of event reports categorized as wrong inputs in the pre-pre analytical phase are as follows:*

Incorrect provider was entered into the electronic orders system as ordering provider. Surgical report was sent to wrong provider.

Blood culture submitted. Source listed on requisition was “Arterial Catheter, Blood.” Per collector, source was actually “Umbilical Artery.” Sample was reordered with corrected source and processed.

An urgent urinalysis was ordered by the physician. The order entry indicated the specimen was already collected. The specimen had not already been collected and should have been entered as pending to activate a collection workflow. Followed up with physician regarding correct order entry.

Specimen collection status was set to “unit collect.” Patient did not have a central device that would permit a unit collection. Nurse changed the collection status to “lab collect.”

Examples of event reports categorized as wrong inputs in the post-analytical phase are as follows:

*When entering manual differential results into the LIS [laboratory information system], tech accidentally inverted two results.*

Test was negative but tech entered result as positive.

Output/Display Error

Data output/display errors were identified in the second largest number of event reports (19.7%; n = 181 of 917). More than half of these errors occurred in the pre-pre analytical phase (55.2%; n = 100 of 181) and a third occurred in the post-analytical phase (32.6%; n = 59 of 181). The types of technology involved in output/display errors included electronic health records (EHR), laboratory information systems (LISs), printers, and mobile applications.

*The details of the PA-PSRS event narratives in this article have been modified to preserve confidentiality.
Table 2. Application of the Magrabi and Plebani Taxonomies to Evaluable Reports (N = 775*)

<table>
<thead>
<tr>
<th>Magrabi Taxonomy</th>
<th>Problem Categories</th>
<th>Pre-pre-analytical</th>
<th>Pre-analytical</th>
<th>Analytical</th>
<th>Post-analytical</th>
<th>Post-post-analytical</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Information input problem (n = 426)</strong></td>
<td>1.1 Data capture down or unavailable</td>
<td>11</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>0</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>1.2.1 Wrong input</td>
<td>215</td>
<td>20</td>
<td>1</td>
<td>55</td>
<td>2</td>
<td>293</td>
</tr>
<tr>
<td></td>
<td>1.2.2 Missing data</td>
<td>29</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>1.2.3 Didn’t do</td>
<td>44</td>
<td>10</td>
<td>0</td>
<td>6</td>
<td>3</td>
<td>63</td>
</tr>
<tr>
<td></td>
<td>1.2.4 Fail to alert</td>
<td>9</td>
<td>6</td>
<td>0</td>
<td>5</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td><strong>Information transfer problem (n = 71)</strong></td>
<td>2.1 Network down or slow</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>2.2 System interface issues</td>
<td>23</td>
<td>21</td>
<td>0</td>
<td>24</td>
<td>1</td>
<td>69</td>
</tr>
<tr>
<td><strong>Information output problem (n = 319)</strong></td>
<td>3.1 Output device down or unavailable</td>
<td>27</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>3.2 Record unavailable</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>3.3 Output/display error</td>
<td>100</td>
<td>15</td>
<td>4</td>
<td>59</td>
<td>3</td>
<td>181</td>
</tr>
<tr>
<td></td>
<td>3.4.1 Wrong record retrieved</td>
<td>22</td>
<td>3</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>3.4.2 Missing data</td>
<td>11</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>3.4.3 Didn’t look</td>
<td>30</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>33</td>
</tr>
<tr>
<td></td>
<td>3.4.4 Not alerted</td>
<td>29</td>
<td>7</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>39</td>
</tr>
<tr>
<td><strong>General technical (n = 79)</strong></td>
<td>4.1 Computer system down or too slow</td>
<td>12</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>4.2 Access problem</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>4.3 Software unavailable</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>4.4.1 Software issue—functionality</td>
<td>13</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>4.4.2 Software issue—system configuration</td>
<td>24</td>
<td>5</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>4.4.3 Software issue—device interface</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>4.4.4 Software issue—network configuration</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>4.5 Data loss</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td><strong>Contributing factor (n = 22)</strong></td>
<td>5.1 Contributing factor—staffing/training</td>
<td>15</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>5.2.1 Contributing factor, cognitive load—interruption</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>5.2.1 Contributing factor, cognitive load—multitasking</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>5.3.1 Contributing factor, fail to carry out duty—fail to log off</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>623</td>
<td>101</td>
<td>8</td>
<td>171</td>
<td>14</td>
<td>917</td>
<td></td>
</tr>
</tbody>
</table>


*Event report categories total more than the 775 PA-PSRS reports due to some events describing more than one health IT problem.
Examples of event reports categorized as data output/display errors in the pre-pre analytical phase are as follows:

Specimen sent to lab with incomplete patient information due to printer malfunction - cut off patient data.

STAT CBC [complete blood count] ordered by physician in computer. When nurse went in to review orders, the order was erroneously displayed as Routine. Help desk ticket entered to correct computer programming.

In the post-analytical phase, rule-based computer interventions such as autoverification and result flags were linked to output/display errors. Examples of such event reports are as follows:

Patient’s blood cultures were positive. Result was not flagged in red font color in EHR.

BHCG [beta-human chorionic gonadotropin] result autoverified prior to autodilution.

System Interface Issues

System interface issues were identified in the third largest number of event reports (7.5%; n = 69 of 917), with all but one occurring in pre-pre analytical, pre-analytical, and post-analytical phases. Described as information that did not “cross over” or could not be “seen,” such problems required additional communication between clinicians and the laboratory to resolve.

An example of an event report categorized as a system interface issue in the pre-pre analytical phase is as follows:

Order for potassium lab entered. Nurse called phlebotomy who stated that the order was not transferred to them.

An example of an event report categorized as a system interface issue in the pre-analytical phase is as follows:

Urinalysis ordered, collected, and sent to Laboratory. Per the Laboratory, the order could not be seen and thus the sample was not processed.

An example of an event report tagged as a system interface issue in the post-analytical phase is as follows:

Result did not transfer from lab system to clinical system in physician office.

Didn’t Do

Failure to update information (i.e., didn’t do) was the fourth most common category applied to event reports (6.9%; n = 63 of 917), with 69.8% occurring in the pre-pre analytical phase (n = 44 of 63). Examples of didn’t do problems included orders not being released (e.g., a standing order that was not clicked off for completion), tests not being marked as collected, and orders not being discontinued. Five of these events involved default values in laboratory test orders not being updated to reflect the intended test, collection date, or collection frequency.

General Technical

Although not among the most common categories applied to event reports, the latent patient safety risks associated with new software functionality and system configurations make examination of the general technical category important. Collectively, general technical problems accounted for 8.6% of all categories applied to reports (n = 79 of 917).

Problems involving software issues, particularly system configuration and functionality, were the most common, followed by computer systems being down or too slow. Examples of system configuration problems include duplicate order rules misfiring, incorrect test order menus, and incorrect reference ranges. Examples of functionality problems include the laboratory being unable to see all fields of laboratory test orders, nonfunctional forms, and incomplete labs ordered in the emergency department being unable to cross over to the inpatient record. Eighteen events described problems during computer system downtime such as specimen labeling errors and labs not being drawn or processed.

Discussion

The majority of event reports that associated health IT with laboratory test problems involved processes occurring before the specimen reached the laboratory. Problems due to wrong inputs and output/display errors were most common. While fewer than 1% of events resulted in patient harm, every event in this analysis had the potential to affect patients and staff in the form of inconvenience, rework, and delay or inaccuracy in the diagnostic process.

The Total Testing Process

Laboratory leaders have historically been on the forefront of quality control and quality assurance efforts, typically focusing on processes within the laboratory to improve efficiency, accuracy, and turnaround. An expanded definition of laboratory errors that encompasses the continuum of processes, beginning with order placement and extending through communication of results, has been supported by agencies such as The Joint Commission, College of American Pathologists Laboratory Accreditation Program, and the International Organization for Standardization.

Regulatory requirements have made the monitoring of pre-pre analytical and post-post analytical quality indicators a priority for laboratory leadership. This more comprehensive, patient-centered approach introduces new opportunities for improvement, along
with governance, measurement, and perspective challenges that only a multidisciplinary team approach can overcome.\(^2\,^3\,^10\)

The distribution of laboratory testing errors has been studied extensively. Variation in the definitions of testing phases makes comparison difficult.\(^3\)

This analysis applied the phases of testing defined by Plebani to capture the transfer of information between locations, people, and IT systems. Filtering laboratory test problems to only events involving health IT, the results of this analysis align with Plebani’s finding that pre-pre analytical errors are most frequent.\(^11\)

**Entering Orders**

Computerized provider order entry appears to be a particularly vulnerable step in the pre-pre analytical phase. Reasons may include the variety of people completing the task, the frequency of the task, staff training and competency, or reliance on human recall of patient-specific nuances. Orders entered as “nurse collect” instead of “phlebotomy collect,” and specimen “collected” instead of “pending collection,” were reported. The downstream effects of such errors included electronic collection workflows not being generated, causing specimen collection to be delayed or completely omitted.

The growing complexity of laboratory test menus may be another factor complicating order entry. Test menus on order screens may contain multiple abbreviations, similar-sounding options, inappropriate names, or new, less familiar additions.\(^12\,^13\,^15\)

Whether built by non-clinicians, natural products of evolution, or with the intent of being accommodating and comprehensive, complex test menus set the stage for confusion, error, and inefficiency.\(^12\,^13\,^15\)

Multidisciplinary committees charged with reviewing, refining, and approving additions to laboratory test menus can facilitate improvements in user experience as well as use and cost.\(^12\,^16\)

**Specimen Readiness for Processing**

Delays in the pre-analytical phase were frequently caused by specimens arriving to the laboratory with incomplete information. Event narratives highlight diverse sources of such error, including interface issues, incorrect orders, unreleased orders, missing requisitions, and label problems. The quality of communication about specimen problems between clinicians and the laboratory was variable—from proactive and timely to reactive and delayed. On the collection end, processes such as specimen time-outs integrated into surgical or clinical checklists may help to ensure information completeness and accuracy before specimen delivery.\(^17\)

Within the laboratory, procedures for how long to hold specimens with incomplete information can reduce the risk of specimen loss.\(^17\) An accompanying communication plan to ensure clinicians are notified of specimen problems in a timely manner may decrease downstream delays in care.

The status of a specimen in the EHR is intended to be a mechanism of tracking and communication. Clear, well defined specimen statuses can prevent delayed recognition of problems, such as waiting hours for the results of a “pending” specimen only to learn it had not been collected. In an article on the benefits and challenges of an interfaced EHR and LIS, Petrides and co-authors recommend that facilities evaluate specimen statuses in order to proactively manage the risk of duplicate orders spurred by confusion.\(^18\)

In an article by Schreiber and co-authors, two unique instances in which duplicate orders were canceled by the LIS but appeared as pending in the EHR are highlighted.\(^19\) Solutions that leverage health IT, such as provider cancellation notices sent through an LIS-EHR interface,\(^19\) may reduce the risk of critical tests or irretrievable specimens being lost.

**Displaying Results**

Input problems in the post-analytical phase were far less common than in the pre-pre analytical phase, yet their closer proximity to the end point of the laboratory testing process—clinical decision making, based on results—makes these errors more concerning.\(^11\) Event narratives highlighted clerical errors, such as entering positive instead of negative values and time as 12:01 instead of 00:01, which were attributed to drop-down menu misclicks, number inversion, and keying errors. Many facilities have replaced manual entry of results with some degree of autoverification to reduce such errors and free staff to perform more specialized tasks.\(^9\,^20\) It is important to recognize that autoverification is not a flawless solution; quality control remains essential.\(^20\)

Regardless of the cause, when results must be amended, a process for “immediate and proactive”\(^21\) communication with the clinician may mitigate the risk of patient harm.

**Intuitive, accurate display of laboratory test results sets the stage for interpretation and action. The variety of ways results are now received by providers and patients—computers, devices, and paper printouts—makes ongoing quality control essential.\(^22\)**

The output/display errors in the post-analytical phase of this analysis represent such challenges. These events highlighted unexpected errors stemming from automatic computer-driven processes, such as autoverification, result flags, reflex orders, and quality control hard stops. Routine monitoring of result outputs, as well as targeted assessments...
with system upgrades, provides an opportunity to evaluate system performance and connect with end users to identify opportunities for improvement.²²,²³

Limitations
Despite mandatory reporting laws, PA-PSRS data is subject to the limitations of self-reporting, including the complexities of selecting the appropriate event subtype and harm score. The indication of health IT as a contributing factor in the event is subject to the reporter’s interpretation and understanding of health IT. Analyst ability to categorize events is limited by the information provided in the event report, and reflects the analyst’s interpretation of laboratory testing, health IT, and the Plebani and Magrabi taxonomies. The Plebani taxonomy, used in this analysis to differentiate the phases of laboratory testing, does not explicitly outline the role of the patient in the diagnostic process; this may represent a potential future enhancement.

Risk Reduction Strategies
The following risk reduction strategies come from event reports and from the literature:

- Engage a multidisciplinary team to evaluate and improve the laboratory testing process as it relates to health IT.⁴,¹⁰
- Periodically reassess system configuration decisions to optimize processes based on experience using the system.
- Monitor trends in test order errors (e.g., wrong collector, wrong source) to identify opportunities for improvement, such as provider training or order screen configuration.¹⁴
- Evaluate and refine the menu of laboratory tests in electronic orders to reduce erroneous and inappropriate selections.¹²⁻¹⁴
- Customize lab labels to include draw instructions, such as the number and color of tubes.¹⁴,²⁴
- Perform a time-out before sending specimens, to ensure all orders, paperwork, specimens, and labels are complete and accounted for.¹⁷
- Leverage the power of a bidirectional EHR-LIS interface to allow the laboratory to monitor pending orders and help proactively manage missed or lost specimens.⁹
- Establish a procedure for handling specimens that arrive to the laboratory with incomplete information, including how long to hold the sample, and a mechanism for communicating the problem with the care team.¹⁷
- Evaluate the different specimen statuses that display in the EHR (e.g., pending, collected) to identify opportunities to enhance their clarity and utility.¹⁴,¹⁸,¹⁹
- Create a closed-loop process to communicate specimen cancellations. Consider ways to leverage IT, such as developing the ability to send cancellation notices and acknowledgments across a LIS-EHR interface.¹³,¹⁹
- Use autoverification to automatically send results to the LIS and EHR in order to decrease reliance on manually transcribing results.⁹,²⁰,²²
- Establish a procedure to ensure that amended results are communicated in a timely and proactive manner²¹ and that the corrected information flows into all appropriate result displays.
- Set up automatic alerts to notify the laboratory when ordering providers do not acknowledge receipt of test results.²⁵
- Conduct routine monitoring of the result displays—in all the different mediums being used by providers and patients—to evaluate information accuracy and utility.²²,²³ Engage clinicians and patients in the process to gain their perspective and ideas for improvement.
- Include focused assessments of laboratory-result displays as part of system upgrade procedures.²²

Conclusion
Well designed and correctly used health IT can add efficiency and accuracy to the laboratory testing process. This analysis demonstrates how flaws in human-computer and machine performance—in all phases of the testing process—can impact the diagnostic process and patient care. The most common vulnerabilities highlighted in this analysis include steps in the pre-pre analytical phase and those throughout the testing process where there is potential for wrong inputs or output/display errors. Facilities seeking to leverage the power of health IT to improve the laboratory testing process may benefit from focusing efforts in these areas of opportunity.

Acknowledgments
Erin Sparnon, MEng, Engineering Manager, Health Devices, ECRI Institute, was consulted for her expertise and knowledge of health information technology during the development of this article.

Supplemental Material
The Office of the National Coordinator for Health Information Technology (ONC) Safety Assurance Factors for EHR Resilience (SAFER) Self-Assessment Guide, Test Results Reporting and Follow-Up, is a tool for healthcare organizations to evaluate their implementation of strategies to improve the safety and safe use of EHR technology.²⁶

https://www.healthit.gov/sites/default/files/safer_test_results_reporting.pdf
Kim Liberatore
Patient Safety Analyst
Pennsylvania Patient Safety Authority

Notes
15. Hawkins R. Managing the pre- and post-analytical phases of the total testing process. Ann Lab Med. 2012 Jan-Feb;19(1):5-16. Also available: http://dx.doi.org/10.3334/alm.2012.32.1.5. PMID: 22529773

idiosyncrasy. J Am Med Inform Assoc. 2017 Sep 1;24(5):958-63. Also available: http://dx.doi.org/10.1093/jamia/ocw188. PMID: 28339629
A Roundtable Discussion with some of the Nation’s Leaders in Improving Diagnosis

Abstract: In the spring of 2018, the Pennsylvania Patient Safety Authority convened an expert panel to discuss issues in diagnostic error and strategies for improvement. The 10 invited speakers were Paul Epner (Society to Improve Diagnosis in Medicine [SIDM]), Dr. Mark Graber (SIDM), Sue Sheridan (SIDM), Dr. Chris Goeschel (MedStar Health), Dana Siegal (CRICO), Dr. Hardeep Singh (Department of Veterans Affairs), Dr. Timothy Mosher (Milton S. Hershey Penn State Medical Center), Helen Haskell (Mothers Against Medical Error), Dr. Joyce Knestrick (American Association of Nurse Practitioners [AANP]), and Dr. Michael Consuelos (Hospital and Healthsystem Association of Pennsylvania [HAP]). The panel was moderated by Caitlyn Sidrane of the Pennsylvania Patient Safety Authority. Pa Patient Saf Advis 2018 Oct 31;15[Suppl 1]:25-36.

What is diagnostic error? How does fear of malpractice claims influence provider judgment? What is the one thing facilities could do today to prevent a misdiagnosis? In the spring of 2018, the Patient Safety Authority convened a panel of the nation’s top experts on diagnostic error to answer these questions.

The 10 invited speakers were (in the order in which they spoke) Paul Epner, Mark Graber, Sue Sheridan, Chris Goeschel, Dana Siegal, Hardeep Singh, Timothy Mosher, Helen Haskell, Joyce Knestrick, and Michael Consuelos. The panel was moderated by Caitlyn Sidrane. What follows are excerpts from the discussion.

CAITLYN SIDRANE: While diagnostic error is common and causes significant harm, leading to as many as 80,000 preventable U.S. deaths each year,2 there is still no consistent, universally accepted definition. There's general agreement on the concept but difference on how to best operationalize it.2 What is diagnostic error, and at what point is something considered delayed or a misdiagnosis?

PAUL EPNER: A layman’s definition is whenever the diagnosis is wrong—i.e., I’m told one thing and it's really something different—or when it’s avoidably delayed, and there are questions about that, certainly.

MARK GRABER: First, the definition in the IOM report is terrific, and it has been very well received. So for everyday purposes, I think we should all be trying to use that one. It’s patient-focused, it emphasizes timeliness and accuracy issues and the importance
If someone asked what they could do to improve diagnosis, what would you tell them?

Get started.
of communication, so it really has a lot going for it. Another thing is that patients have a lot of trouble recognizing that term and understanding that what happened to them is really a diagnostic error. We’ve done focus groups and we asked patients, “Who’s had a diagnostic error?” and just a few hands go up. But if you explain, “This is about a diagnosis that should have been made a lot earlier, or a diagnosis that was wrong and was later found to be something else,” then, all of a sudden, a lot more hands go up. So we have a problem with people understanding what a diagnostic error really is.

“We have a problem with people understanding what a diagnostic error really is.”
-Mark Graber

The question about at what point something is delayed is an excellent one, because it points out that we really have no standards or guidelines or appreciation in medicine today of how long it should take to diagnose anything.

There is a study about how long it takes to diagnose iron deficiency in women, and the answer is two years. That’s crazy. How long does it take to document a diagnosis of asthma in children who are wheezing? Seven clinic visits.

We really see that there’s a lot of work that needs to be done, and it can be done productively to get a better grip on how long diagnosis takes.

SUE SHERIDAN: I agree about the definition that was created by the IOM. It’s not too complicated or academic; it’s understandable, patient-centered, and I’m hoping that everybody will use that as a definition going forward. Many, many patients have experienced diagnostic error, and I myself, despite the severity of both the diagnostic errors in my family, didn’t fully appreciate that they were both diagnostic errors until I got to know Mark [Graber]. Then I started to realize how what happened to my family fits in the IOM definition of diagnostic error.

CHRIS GOESCHEL: One of the things that we grappled with in our work that I believe is important is when a diagnosis is communicated to the patient. When do you know what you know, and when is it shared with patients? Timely communication is critical.

DANA SIEGAL: I have the very far end of this journey, and the malpractice claims I study provide all the hindsight in the world to look at diagnostic error. When we look back on these cases, we’re able to see the initial missteps that resulted in a wrong initial diagnosis that then links to the delay of getting the right diagnosis. Because we code these cases for educational purposes, we agonized for years over whether it was wrong, delayed, or missed, but ultimately, we focused on the opportunity to better identify vulnerabilities and interventions for the broader diagnostic process, providing more clarity on what the common issues were, regardless of a delayed versus wrong initial diagnosis.

The critical piece that we see in the medical malpractice claims is that, more often than not, we have the right information, and to Chris [Goeschel’s] point, it just wasn’t communicated. That may be to the patient, or it may be to another provider who had accountability to move the ball forward. And that’s where so much of the vulnerability is, not in the cognitive or clinical judgment process, but in the communication and delivery of information.

HARDEEP SINGH: After doing more than a decade of research in this area, we’re still struggling with how to define this correctly. In our work, we have found there’s not a lot of distinction between missed, delayed, or wrong diagnosis, so we try not to use those as buckets. They overlap almost all the time.

“We need to think of [diagnostic error] as a phenomenon that is beyond a single provider’s thinking.”
-Hardeep Singh

The concept that’s most useful to us has been that of a missed opportunity; was there something different I could have done when I was seeing the patient at that time? We need to understand that this is not a black-and-white sort of a thing, it’s really gray. Diagnosis evolves over time. There’s a lot of uncertainty involved. We need to think of this as a phenomenon that is beyond a single provider’s thinking. And when we take it from a more systems perspective, the definition becomes a little better and is more operational.

MR. EPNER: It also depends on the issue of whether there’s a symptom that we’re reacting to. If the U.S. Preventive Services Task Force has a guideline for...
screening and the patient is asymptomatic but skips an appropriate screening, and if that screening would have shown something, is that a diagnostic error with the error being attributed to the patient for not completing appropriate screening?

I’m not saying it is, but the notion of whether there’s a symptomatic impetus to initiating the diagnostic process or a public health strategy that’s not being followed, one could say from a public health perspective that either one could be a basis for describing a diagnostic error.

And then one also needs to consider, even if someone is symptomatic, if having a simple explanation for the symptom is sufficient, or does the patient’s context—their genotype, their phenotype, other socioeconomic attributes, social determinants—need to be included in the diagnosis because of the potential implication for care? And then is failure to identify those social determinants a diagnostic error as well? So, again, if you want to go very broad, these are other things that should be considered.

**MS. SIDRANE:** Paul [Epner] brings up an interesting point about the public health aspect of this. Medical errors are a leading cause of preventable death, and misdiagnoses are a leading cause of medical error. Are there broad-based interventions that can and should be implemented?

**TIMOTHY MOSHER:** One of the things that I look at when viewing diagnostic error from a public health standpoint is the need to focus on what are systemic factors that are addressable that we can extrapolate across the whole healthcare system. And we’re finding that there are quite a few.

Concepts such as human factors engineering. The way we’re setting up the health system that drives cognitive error and leads to errors in communication. The lack of ability to get information between different electronic medical records and other information systems. The lack of good registry data to be able to look at where diagnostic errors are occurring. There are a lot of things that need to be addressed at the public health level for us to be able to really leverage what we’re learning about what’s occurring in diagnostic error at the individual patient provider level. So for us to really be able to move this forward, we have to raise this to the level of a public health problem.

**HELEN HASKEL:** Well, IHI [the Institute for Healthcare Improvement, where Ms. Haskell sits on the board of directors] is doing that. We’re coordinating a national action plan on patient safety as a public health issue, and certainly diagnosis will be part of that, to actually have strategies and measurements on a broad scale that can be followed. When I think about public health, one of the things that’s near and dear to patients’ hearts is the idea of public education campaigns, making signs and symptoms of common ailments part of general education, not just heart attack and stroke—although that’s certainly needed—but also acute illnesses like sepsis. That has begun, but it needs to be more broadly disseminated.

**DR. SINGH:** I agree with Helen [Haskell] about the context of putting this broadly. If you look at it from that perspective, there are lots of things we could do with broader healthcare issues such as access and workforce competency and high quality diagnostic testing, the use of health IT [information technology] involving patients and improving the way we deliver care in our clinics or emergency rooms, and letting doctors spend more time with patients. All of that is good and all of that can be put into the context of public health, but what it means for diagnosis specifically is also strengthening the overall health system, improving primary care, improving emergency room care, and working on broader delivery system issues, not just the thinking around making a diagnosis.

**We’re wasting $765 billion a year in healthcare... There’s a public health imperative to ensure patients are actively engaged.**

-Paul Epner

**MR. EPNER:** So let me take a slightly contradictory stand on that. According to the National Academy of Medicine, we’re wasting $765 billion a year in healthcare. But that probably doesn’t include things like the advanced stages of disease that require more expensive treatments versus early detection, lost employment, productivity, etc.

So if we’re saying that public health implies that we’re not focused on an individual patient but that we’re trying to ensure that everyone has the best opportunity to be healthy and productive, and that society’s resources are best used to help society, then there is a public health imperative to ensure patients are actively engaged and the systems are actively engaged in trying to find detectable health problems, even when someone may not have entered the health system yet.

**MS. HASKEL:** That sort of intervention can be really onerous, and it’s something that I would be hesitant
to advocate for, to go and seek out people, except in the cases of perhaps an acute or contagious illness.

**DR. SINGH:** I agree. We are not doing a very good job in diagnosing disease in patients who are presenting to us with symptoms that are fairly obvious and have red flags, so going out and looking for asymptomatics with disease that might present in 20, 25 years is probably not the way patient safety ought to move right now.

**MR. EPNER:** I’m certainly not suggesting that we go out and look for patients who have nothing wrong but maybe will in 20, 25 years, but certainly, diabetes is an underdiagnosed problem. There are many other infectious diseases, such as HIV, et cetera, where there is a public health value to screening, and that has been well demonstrated and well published. There are other kinds of areas where, again, having people understand when they should access the system, and if the U.S. Preventive Services Task Force is right about appropriate screenings, it’s in the interest of society and healthcare to reduce the economic and human burden in the long term.

**MS. SIDRANE:** What about patients and their responsibility in all of this? What role do you think patients should play? And what do you wish patients knew about the diagnostic process?

**DR. GRABER:** Given the complexity of diagnosis, it’s amazing that we do get it right almost all the time. The diagnostic error movement and activities are not meant to beat up on doctors or on healthcare organizations: it’s to think about how we can do a better job. And what patients don’t appreciate is how complicated it is and how many pitfalls there are.

**SUE SHERIDAN:** What I wish patients and family members knew about the diagnostic process is that it is a process, it’s not a static event, and there are many potential pitfalls and breakdowns in that process. I wish that patients and family members knew the magnitude and impact of diagnostic errors.

Unfortunately, patients believe healthcare systems are infallible, and patients need to understand that they are not. I’d like patients to know that no news is no news, regarding test results, regarding their diagnoses. Never assume anything just because you haven’t heard anything.

**JOYCE KNESTRICK:** I don’t know what other people have been seeing, but I’ve noticed that patients are becoming more active members about their diagnosis. I see more people bringing things in from the internet. “I think I have this, what do you think?” But it’s also important to make sure that you can develop that trusting relationship with the patient so that they tell you everything that they need to tell you to help you to make a good diagnosis. And I think that is the biggest part that they could play, and sometimes it’s difficult because they don’t want to tell you everything.

**It’s important to develop that trusting relationship with the patient so they tell you everything that they need to tell you to help you to make a good diagnosis.**

-Joyce Knestrick

Regarding the responsibility of the patient, that’s the wrong question. It all starts with the clinician. I struggle with the concept of “patient responsibility” regarding getting the right diagnosis. A lot of times it’s very hard for patients to step into this diagnostic process. That clinician needs to issue an invitation to the patient to join the doctor in the diagnostic process.

And so the question is not what’s the role of the patient, but has the clinician informed the patient and family member about the diagnostic process, so that he or she is crystal clear about the importance of the history and physical, and what symptoms to look for, how to report them, to whom they should report them, and within what time frame. It’s better framed as, what can clinicians do to encourage them to participate in their diagnostic process?

The clinician also needs to encourage the patient to collect his or her documents, use the portal, ask questions, and be informed as much as possible. Knowledge is power. Patients will go to the web, and we want them to, so clinicians can help identify the most credible websites where their patients and family members can do their research.

**JOYCE KNESTRICK:** I don’t know what other people have been seeing, but I’ve noticed that patients are becoming more active members about their diagnosis. I see more people bringing things in from the internet. “I think I have this, what do you think?” But it’s also important to make sure that you can develop that trusting relationship with the patient so that they tell you everything that they need to tell you to help you to make a good diagnosis. And I think that is the biggest part that they could play, and sometimes it’s difficult because they don’t want to tell you everything.
MS. SIDRANE: There was a recent study by *U.S. News & World Report* that quantifies how much patients really don’t want to tell us. They found that up to 30 percent of patients have either told a white lie or intentionally withheld information from their healthcare provider.5

MS. HASKELL: It’s really important that patients understand the concept of uncertainty. Tests and providers don’t necessarily have all the answers. Diagnoses can change. They really have to be part of the process and bring in their own information. It’s critical for patients to do research. And in terms of the information that they give to the provider, I take a pretty different perspective on this. The obligation goes one way. Medicine is a service industry. Healthcare providers have an obligation to do their best to help patients and to inform them, but patients don’t have an obligation to tell everything to their healthcare providers.

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"It’s really important that patients understand the concept of uncertainty. Tests and providers don't necessarily have all the answers."

-Helen Haskell

Patients are concerned that their information isn’t secure, and with insurance being so up in the air, it could even be used against them. And while they might be happy for their providers to have it, they don’t know what’s going to happen to it after that. Doctors and advanced care practitioners aren’t always aware of how little control they have over that information and where it might go after them. Patients need to know what information to convey to a clinician about what they think they might have. They’re not going to share everything, so they need to know what they need to convey.

MR. EPNER: The notion for patients to decide by themselves what’s important would require them to know everything the physician knows that’s going into establishing the diagnosis. We do have a lack of trust and lack of control of private information, and that is a problem that does need to be solved. But to say that the physician needs to read the mind of the patient or it’s okay if you don’t give them enough clues; the ultimate consequence of a wrong diagnosis because of insufficient information will be felt by the patient.

MS. HASKELL: I agree with your last statement, but what I meant was that doctors’ offices collect a lot of information on patients, a certain amount of which is not necessarily relevant to any given situation. Similarly, patients may provide too much information because they are not sure what is important, and they want to be sure nothing is missed. While all this information should in theory be grist for the mill, in practice it can create a high noise-to-signal ratio that is fertile ground for diagnostic error. The fact that it also may not be secure is simply icing on the cake.

The point I was trying to make is that clinicians should be more targeted about what they collect, and patients should be more targeted about what they communicate. Doctors are concerned about this, too. Dr. John Ely has a tool, “Eight Characteristics of a Symptom,” that is intended to help with exactly this problem of imprecise communication.

MS. SIDRANE: How does the payment system impact diagnostic error? How much influence do payers have in this, and what changes need to be made to the payment system?

DR. GRABER: The payment system has a major impact on diagnostic quality in big ways and in little ways. Our current payment systems aren’t focused on quality, they’re focused on productivity, and that’s an enormous problem. The biggest complaint we hear from doctors is they just don’t have enough time for diagnosis. It takes time to get a history and do a physical and think about what might be going on, and if you only have 10 or 15 minutes to see a new patient with 15 problems, that’s not going to be good for diagnosis. We would like to see a payment system that rewards quality and accuracy and timeliness, and we don’t have that at all now.

And there are little things. For example, if you’re seeing a patient, there’s pressure to assign a code so that encounter can be billed. So before you’re even sure what’s going on, the patient is now labeled, and the next person seeing that patient may not think it through completely, and that’s bad, too. Premature labeling is one of the major problems we see in terms of what causes diagnostic errors.

MS. SHERIDAN: I agree with Mark [Graber]. Our payment system has a tremendous impact on diagnostic errors. Case in point, when my husband’s malignant pathology failed to be communicated to the ordering doctor, I asked the pathologist why in the world didn’t he pick up the phone and call the doctor. And he said, “Sue, we’re not paid for that. That’s not my job.” We need to ensure that we have a payment system, as Mark [Graber] said, that incentivizes quality communication and teamwork.
Also, it is important to remove financial incentives that inadvertently delay the diagnosis and appropriate treatment, especially when diagnostic delays can result in serious patient harm. I’ll give you an example regarding newborn jaundice management. During the peak of managed care in the 1990s, bundled payments to hospitals for procedures—such as newborn delivery—gave hospitals incentives to limit their costs for those procedures. A negative consequence was that many hospitals discontinued routine laboratory bilirubin tests for newborns and instead relied on less expensive and less effective visual assessment of jaundice levels, delaying accurate diagnosis and treatment of newborn jaundice.

Furthermore, hospitals received an additional payment when newborns would be readmitted for eventual bilirubin testing and appropriate treatment. This delay in diagnosing and treating newborn jaundice resulted in the reemergence of kernicterus [brain damage from jaundice] in the USA. I think that has changed, but we have to really look at how our payment models are structured to ensure that there are no incentives that could inadvertently delay a diagnosis or actually harm the patient.

MICHAEL CONSUELOS: I have a question for the group. Physicians have been under an RVU-based [Medicare’s Relative Value Units] or production-based model for decades unless you’re in some sort of salaried position. Is it more about the regulatory stuff to make sure there’s documentation for billing or is it really the productivity piece?

DR. GRABER: That’s a good point and I think it’s a little of both. To pile on the problems with the current payment system, there are no more autopsies in the United States, by and large, and that’s completely because it’s not paid for anymore by CMS [the Centers for Medicare and Medicaid Services] or by private insurance. You have to pay for it out of pocket, and that has led to a problem with feedback.

There’s a lot of overconfidence out there, and that’s a problem. There used to be somebody called a clinical pathologist in every laboratory who the clinicians could call up and say, “Hey, what’s the best diagnostic workup for my patient who’s jaundiced?” and get some advice on how to interpret tests or come up with the best strategies. That person is gone, and again, it’s because it’s not paid for, it’s not covered in any modest payment model. Very bad for diagnosis to have lost that individual.

DR. CONSUELOS: Organizations should be able to spend their time and effort and resources to find out where their greatest risks are, and where diagnostic error is most likely to occur. To really look for solutions. And maybe the money should be spent around allowing physicians and other providers to spend more time thinking about the patient’s diagnosis and treatment plan and freeing them up from the burdens that are not related to patient care.

MS. SIDRANE: Speaking about burdens on physicians, what about medical malpractice? Do you think that provider judgment is influenced by concerns about malpractice?

MS. SIEGAL: That sounds like that’s coming right at me. This is a question we’ve asked often. On the one hand, there is always the question about over-diagnosis and are we doing too much, and are we getting into trouble by the more we do? I’m not sure that over-diagnosis or even just doing more tests—that might seem appropriate to some but not others—is always driven by the fear of malpractice. Our providers truly have a desire and a commitment to do the right thing by their patient and to get the right answer as quickly as they can.

Providers truly have a desire and a commitment to do the right thing by their patient and to get the right answer as quickly as they can.

-Dana Siegal

That said, I do think that there are providers who would have trusted their gut and said, you know what, I’m not sure we need that MRI [Magnetic Resonance Imaging Scan] right now, let’s hold on this for a little bit longer. But then, they decide to do it anyway, for fear that they are missing a positive finding and might be sued. I do believe there is some unavoidable fear of retribution, or of being sued for not doing everything possible in the moment, that drives the volume of testing providers do.

If anything, we might be reducing diagnostic error if they were going all-out for everything they thought would be helpful. I’m just not convinced fear of lawsuits is the only thing driving that.

DR. GRABER: The goal of malpractice originally was to ensure that the quality of medical care is at a high standard, and from my perspective, it has failed pretty miserably in achieving that goal. It’s not good for learning; almost every case is concluded with settlements that are sealed. You can’t really find out what happened. There’s very little learning that derives from this.
It’s certainly not good for patients. If you talk to patients who have gone through the malpractice mill, even the ones who win their case, they’re disappointed because they didn’t ever really get an apology; they didn’t really find out what happened. There was usually very little commitment from the organization to fix things that are broken, so it’s a disappointment to them. And in terms of getting them compensation, it’s horrible. There are so many people who are harmed from diagnostic error, but just the very tiniest minority get any compensation from the current malpractice system.

And it’s not even good at identifying bad doctors. There are a few out there, and we could do a much better job at finding them and finding different things for them to do besides trying to diagnose patients.

MS. SIEGAL: Thanks, Mark [Graber]. I do think there are many challenges in the litigation process, but I would have to disagree with your comments about limited learning opportunities. Yes, with reference to the laws and litigation processes, I would completely agree with you about its vulnerabilities. But with respect to the learning that’s available from studying malpractice cases, it is far more valuable than you’ve credited it for.

Perhaps an opportunity exists for us to expose the data more and begin to see the value we can gain from studying the malpractice claims in large volumes that show the repeated system failures, communication failures, patterns of behavior failures that contribute to diagnostic failure. There’s much to be learned, and perhaps we haven’t positioned it yet in a way that people can hear and benefit from it. But I would beg to differ with you on what there is to learn. We are learning valuable lessons. Our entire risk management programs are driven by our learnings from our malpractice cases.

DR. GRABER: You’re absolutely right, and we can learn so much from closed claims analyses and the deep kind of learning that you all are doing at CRICO and other organizations. I was talking about all those cases that are finalized with nondisclosure agreements and are taken off the market in terms of learning.

MS. SIEGAL: They may be off the “public” market, but they all live in our claims management systems; and for those insurers that share in our national malpractice database [CRICO’s Comparative Benchmarking System (CBS)], we have every claim—open and closed, dismissed, or settled—available for analysis.

MS. GOESCHEL: Dana [Siegal], I agree with you, but something that you said at the end is critically important. For people who know to look at CRICO or to search for things, there’s wealth of learning. But there is a larger audience. And you talked about positioning the information differently, leveraging it differently. There is a significant need to do that for the betterment of people who have interacted with healthcare and of those who have not yet had the fortune or misfortune to do so.

MS. SHERIDAN: I doubt that patients really know about what you learned in your database. Given confidentiality agreements that patients sign, it is hard for the public to benefit from the lessons learned. This is a problem. However, there are more and more patients who are refusing to sign such agreements in hopes of driving change and improvement across the healthcare system. Studies show that is the number one thing that patients want after experiencing harm in our healthcare system. Also, there’s a really nice phenomena going on where patients who are engaged in litigation are sitting down with the hospital and the providers and agreeing to improvements and new policies in that hospital to prevent similar events, and they share it with other hospitals.

That’s something that we can foment and encourage. And, frankly, I was one of the litigants 15 years ago, and it wasn’t all about money. This is about policy change, and it did happen in both healthcare systems. We need to encourage that dialogue more and more—that we don’t fear it and hide it. All the kernicterus cases that came before my son had been sealed and I was never aware of them. The fact that newborns were suffering brain damage from the failure to test jaundice levels never rose to the public eye, and that’s what we need to make sure happens.

MS. SIEGAL: There is a difference between learning from the malpractice cases, which are somewhat removed from the event, and something else Mark [Graber] mentioned that’s really critical. And, Sue [Sheridan], you’re alluding to it in some way, too: the movement for apology and disclosure has got to go bigger, broader, and more aggressive, because we are still not embracing our patients as openly and as honestly as we should.

And to your point, allowing them the opportunity to participate in individual events that we can better learn from in real time is essential. We’re so afraid of the litigation that we’re not having honest, transparent conversations. And that’s a problem. But apology and disclosure are a very different way and a very important way of learning in real time, versus the hindsight of data analysis that tells us where to go back and look in our systems. We need both.

MS. SIDRANE: A frequently cited concern regarding diagnostic error is the difficulty of quantifying it and the lack of adequate forms of measurement.7

DR. GRABER: Measurement is our weakest link. It’s true that there’s not a single healthcare organization
in the country that’s measuring their rate of diagnosis error, and that’s because the tools that healthcare organizations use now to monitor patient safety problems don’t readily find or detect diagnostic errors.

We need new ways to find these errors, and it isn’t going to be that difficult. All we have to do is more effectively ask the patient, did we get it right at an appropriate point in time after they’ve been through a diagnostic experience, or ask the doctors.

I’m very impressed by a study that Bob Trowbridge did at Maine Medical Center. He’s a hospitalist. He just told his hospitalist colleagues that he was interested in diagnostic error and could they bring cases to his attention. In a six-month period, they collected 36 cases of diagnostic error, not a single one of which would have been detected by the ongoing patient surveillance tools that the hospital used. That’s a model for how we can find diagnostic errors going forward, in terms of getting physicians more interested in reporting them.

Beyond that, there are many ways to start measuring different aspects of the diagnostic process. Take timeliness. How long does it take between when you present with a lung nodule and a biopsy is done? How long does it take to diagnose anemia? There are all sorts of things we could start looking at, in terms of timeliness. It has also been pointed out by many people that even if you can’t measure it, there are many opportunities to try different kinds of improvement efforts. And until we have good measurements, there are a lot of simple things that could be put in place now that would improve the safety and quality of diagnosis.

MR. EPNER: It also depends on if we’re talking about what I call macro or micro measures. Macro measures are national measures that help guide policy—what’s the total burden to patients, the total harm, the total cost?—so we know how to prioritize the allocation of resources. And then at the patient level or the physician level or the health system level, the micro level, how do we know whether there’s been a suboptimum outcome for a patient at the real frontline level? There’s a lot more work for both types. We’re making progress, but we’re not there yet.

DR. SINGH: I agree with Mark [Graber] that measurement is our weakest link. But something that is getting closer to maturing as a possible safety indicator in this area is how often abnormal test results are followed up within an institution. It’s very quantifiable. We’ve done some work to figure out how we can use health IT and electronic health record data to try to identify patients who have missed follow-up. That could become, with a bit more time and thinking towards implementation, one measure where we could actually try to figure out how we’re doing. But again, I want to emphasize, this is going to be hard because we have to balance the many measures that are being sprung on clinicians and hospitals. Some of them are just not worth anything, and we’re often still measuring stuff just for the sake of measurement. It’s not actionable measurement, it doesn’t lead to anything concrete or any improvement.

We need to be looking at actually trying to improve the process, and not simply measuring the process.

- Timothy Mosher

DR. MOSHER: To follow up on Hardeep [Singh’s] comment that we need measures that actually drive improvement: In radiology, we have American College of Radiology’s (ACR) RADPEER, which is a national program in which we do double reads, and we look at discrepancy rates between readers. We have good data on national discrepancy rates (between one and three percent for what we consider clinically significant errors). And although that might sound like we’re being quantitative and robust about it, we’re finding that it doesn’t drive change. It gives you the zone of quality that everybody else is demonstrating—therefore, I’m good. And we’re also finding that physicians aren’t buying into it because they realize it has very little value on improving their practice.

The trend now is really to focus on participation in group learning. Where are the opportunities where we see we’re making mistakes? Let’s be more focused and deliberate on trying to learn from those mistakes as opposed to simply trying to quantify them. I would just say, we need to be looking at actually trying to improve the process, and not simply measuring the process.

MR. EPNER: And just one more point to emphasize for this issue of measurement. Just Wednesday morning, I was in San Francisco for a meeting with [a donor], and I made the point that not all things that are important can be measured. And [he] said, “Yeah, we can’t solve all important issues, so we’re only going to focus on the ones that can be measured.” So measurement is going to be an important issue in driving change, because I think his views reflect the views of many others as well.

MS. SIDRANE: A recurring topic in the literature is the importance of following up on test results
and how the care team can prevent information from falling through the cracks.  

DR. SINGH: We’ve developed several best practices in the area. The problem is implementation of these best practices and adoption of these best practices among healthcare systems. One example is the Office of the National Coordinator for Health IT’s (ONC) Safety Assurance Factors for EHR Resilience (SAFER) Guides that we developed back in 2014. They were updated last year again. They are available on HealthIT.gov’s website. They’re free, but few health systems use them.

In addition to closing the loop on test results, there is one on improving communication, which might be relevant to diagnosis. We’ve also developed several tools within the VA [Veterans Administration] that offer best practices, policies, procedures, and workflows that are fairly generalizable and worth disseminating. And AHRQ [Agency for Healthcare Research and Quality] has developed an outpatient testing process toolkit that is also available freely on their website. So there are definitely lots of best practices, especially in the area of test results and communication, but the issue is adoption and implementation.

MR. EPNER: Sometimes we try to make this too difficult. That’s not to say implementation is easy, but Amazon and FedEx and UPS—they don’t have the problems with closing the loop on delivery. And they know how to do it, they know how to keep the people informed along the way, they know when to raise the alarms when things are missing and don’t happen along the way.

So it’s not a technology discovery, it’s an application issue. It’s development, not research that’s needed to just use the same tools that are already used in other industries to ensure that information flows, gets to the appropriate spot, and is acted upon. And there may be multiple appropriate spots, both healthcare professionals as well as patients, to do that if we just develop the will to do it. It’s not a big leap, technologically.

MS. HASKELL: That’s a great point, Paul [Epner]. Having test results go to the patient automatically, unless the patient has requested otherwise, is a big aid in this. Patients won’t always see them, they won’t always look, but it can help make sure that things don’t get missed.

DR. KNESTRICK: Patients want to have their results, whether they’re positive or negative, so it’s important to let them know that it’s OK to call and say, “I haven’t gotten my results, what were they?” We have a lot of systems in place now with patient portals and other devices to do that, but not everybody is able to access information that way. So we need to leave the door open for the patient to be involved with their test results.

DR. MOSHER: One of the things that we found, regarding the closing the loop on incidental findings test results, is the real need to be proactive and actually have a nurse coordinator who really manages all of those test results and communicates with the patient.

We verify then that any follow-up studies have been ordered, and make sure that the provider is in the loop. We found that if we took a more passive role, that while we were communicating to the patient by sending them letters, that loop wasn’t actually being closed. So if I were to say one thing as far as the best practice, it is that you really need verification, along the lines of what Amazon and FedEx have, of making sure that loop is actually truly being closed by somebody who manages and oversees that cycle.

MS. SIDRANE: What happens when the loop is closed but before a provider has an opportunity to discuss it with the patient, especially for something that’s a more sensitive diagnosis, like cancer? Is that a situation in which it would be better for the providers to have a conversation ahead of time with the patient, or should all diagnoses be treated the same?

DR. KNESTRICK: The loop isn’t closed just because the patient saw that information on the patient portal. I had that happen to me with someone who had a brain tumor and saw it on the patient portal before—over the weekend, and no one was there to talk to her about what the testing was. As soon as I realized that she had accessed that information, we called her right away and got her in for an appointment. But she had fretted all weekend about that information and not knowing, was looking things up on the internet.

In some ways I’m happy that she had access to it, but other ways holding off a little bit before it was posted there would have been better. But I still think we have the responsibility to make sure that feedback loop is closed. Just because she got the information didn’t mean that the feedback loop was closed.

MR. EPNER: There are two key points here. One is that we should not be patronizing to patients in deciding what’s good for them or bad for them. However, information that’s out of context is not necessarily good for them. And I think what most systems do is embargo the results for 48 or 72 hours or something, and in some cases it’s only for specific results, such as sexually transmitted diseases or potentially life-threatening things.

But, at the same time, if we don’t at some point make sure the patient has access, we run the risk of something falling through a crack and patients feeling the consequence. That’s why I recommend allowing a physician or a clinician, clinical team, to have 24, 48 hours to create context and contact the patient, but then at the end of that period if nothing has happened, then the communication goes directly to
the patient. That seems to be the right balance of responsibility in making sure patients do have the opportunity to know what’s going on.

**DR. SINGH:** We’ve found that patients may get anxious and have negative emotions even with normal results. It’s a very anxiety-provoking experience, more than we think. And there are no national best practices on what the best timing of releasing test results is. When do you release abnormal imaging? When do you release labs?

We’ve heard anecdotally of patients getting abnormal results and taking detrimental action, including somebody who made funeral plans before they talked to the doctor based on what they saw on the test results. This is not an easy thing, just directly releasing all test results to patients and expecting them to follow up and interpret and manage them on their own. We’re going to need to develop strategies to make sure we’re doing this right. We recently called for a national platform of creating some best practices and standards in this area. I don’t think we need to have different standards in Rochester versus Houston on when we should release imaging results that are abnormal to patients.

**MS. SIDRANE:** If someone called you tomorrow and asked what they could do to improve diagnosis in their own facility, what would you tell them?

**MR. EPNER:** Get started.

**DR. KNESTRICK:** Include all members of the team.

**DR. GRABER:** My number one recommendation to healthcare organizations is that they should start to identify and learn from diagnostic errors in their own patients. These errors are happening every day in every hospital, and there’s a lot of harm. We estimate that there’s 10 deaths every year in every hospital, and if places started to see that it’s affecting their own patients, it would make it real, and it would also show them that this is an actionable problem. There’s a lot that could be done to address this.

**MS. GOESCHEL:** I second that. And the thing that I would add is to acknowledge and to be transparent about it, not only within their own organization but outside of the organization. Patient safety picked up traction when everybody started saying, yeah, it happens here too. When we begin to own that this stuff happens everywhere, some of the leverage of folks who want to point fingers or say we’re better than that will dissipate. Owning that this really is ubiquitous, that it does happen everywhere.

**MS. SIEGAL:** I couldn’t agree more. And having been a clinician some years ago and on the teaching side now, if I had one message for leadership within organizations it’s exactly that; talk about it openly and honestly, talk about it at your board meetings, talk about it at your staff meetings, talk about it when you’re doing your rounds. It’s up to leadership to make sure that everyone in the organization knows that it’s a critical topic.

If you never hear about the diagnostic issues that we’re having, or never hear that you’re part of a diagnostic team, you will never begin to embrace it yourself. They’ve got to start talking about it at every level in their organization. Leaders need to lead the charge in order for everyone else to recognize that that’s a direction they need to walk in.

**DR. CONSUELOS:** The prior folks have captured it. It’s about the conversations with our leadership. And the one thing I would add is that I would ask our leaders to hire for this. This should be part of the ever-growing softer side of healthcare leadership and hiring for their junior staff based on their philosophy around this issue and quality and other important patient care aspects. It’s not just about productivity, it’s not just about research. Hire for these kind of competencies; hire leaders who think this way, who talk about improving quality and reducing errors.

**MS. HASKELL:** People should adhere to the principles of a high-reliability organization. In a facility, so much happens that is between providers, and my concern there is care coordination. So you have people making sure that the voice of the patient is heard, and that things are being followed up on and things are being noticed, so that when there are changes it doesn’t fall through the cracks.

**DR. MOSHER:** I’d say one of the things that we need is to push it down to specific work units, where people are working around common symptoms or common problems, and they need to determine where there are opportunities to improve diagnosis. Start off with where you have a large degree of variability in diagnosis.

Give you an example in ours, I’m a musculoskeletal radiologist, and we found that we were having high variability when we were talking about our diagnosis of osteomyelitis in diabetic feet using an MRI. That

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*Be transparent. Patient safety picked up traction when everybody started saying, yeah, it happens here too.*

- Chris Goeschel
gave us an opportunity to really come together, and by having a focused area that was a target opportunity for us to work in, we were able to see some real changes in a relatively short period of time.

It’s easy to go in and say, look at this big massive problem, and you’re quickly going to become overwhelmed. Focus on the day-to-day practice. What matters to you, what matters to your patients. Focus on those because then you’re going to have the motivation to really carry these through to completion.

MS. GOESCHEL: And to Sue [Sheridan’s] point earlier, it’s crucial to raise the awareness of diagnostic challenges not only in our own organizations, but outside of our organizations, to embrace our patient community, foster very active patient and family advisory committees, and to be sure that our thought process constantly recognizes that as we build our teams and our partnerships for a safer world that our patients are key leaders in that journey as well.


Hire for this. It’s not just about productivity, it’s not just about research. Hire leaders who talk about improving quality and reducing errors.

-Michael Consuelos

Notes
Misdiagnosis Can Cause Guilt for Those Seeking Resolution

From the Bedside to the Courtroom, the Perspective of a Clinician Turned Malpractice Attorney

Veronica Richards, RN, MSN, CRNP, JD

It would be reasonable to expect that victims of medical malpractice would be motivated by anger or a desire to seek revenge on the guilty. However, in my experience, anger is rarely the emotion that dominates my clients who are victims of medical malpractice. Almost without exception, the emotion that overwhelms my clients is guilt. The most common sentiment that is expressed to me is, “I am not the type to sue anyone, let alone a healthcare professional.”

When I talk about guilt, I refer to a negative emotion generated from a past event. In this context, the event was seeking medical care due to concern about illness or injury. Whether guilt is manifested as a fleeting stomach pang or a crippling roadblock to regaining a sense of peace and acceptance, this emotion will not change the past. Nothing can.

As professionals, how can we seek to prevent delayed or missed diagnoses and protect patients and practitioners from the poisonous consequences of diagnostic error and the accompanying guilt? How can we improve patient safety in the process?

As a former nurse practitioner, I had the privilege of serving people of diverse educational, ethnic, and social backgrounds. For the past 30 years, I have been a medical malpractice lawyer. I have defended healthcare professionals, and I have represented patients and families in catastrophic medical malpractice cases. The word catastrophic describes the impact on both patients and the practitioners who became defendants in a court of law. Whether my work was in a hospital or a courtroom, I embraced the unique challenges of each and I always appreciated the fact that without the patient, there was really no need for me. Your patients, some of whom may become my clients, are consumers of professional services. As consumers of healthcare, they seek to make informed choices about their health, which starts with getting an accurate diagnosis.

Formulating a Diagnosis

Let’s start with a key part of the diagnostic process: developing a differential diagnosis. It is a fundamental concept and skill that is taught in medical school and used daily by every medical practitioner who provides direct patient care. In its simplest form, the process consists of three steps: (1) collect information, (2) synthesize the information, and (3) make the diagnosis. The differential diagnosis process is dynamic because, as new information is acquired, the diagnosis may change. It is time-sensitive because it is critical to first rule in or out any potential diagnoses that could be life-threatening or life-altering.

Both the patient and the practitioner have mutually important, interdependent roles in the differential diagnosis process. The patient is responsible for seeking medical care, answering questions honestly, completing any diagnostic testing in a timely manner, and following up on test results. There was a time when it was almost solely the healthcare provider’s responsibility to follow up after testing. Those days are past. In today’s healthcare system, the patient’s mistaken belief that “no news is good news,” is dangerous.

The practitioner is responsible for collecting information. An important source of information is the patient history, a key determinant of the plan of care. A history is obtained by asking questions, listening to the patient, and asking appropriate follow-up questions. Information is also gathered from reviewing prior medical records, performing a physical exam, ordering indicated diagnostic tests, and analyzing the results. Communicating test results and proposing a plan of treatment is the responsibility of the practitioner.

Medical malpractice occurs when preventable error causes harm. If there is an error and no harm or if the delayed or missed diagnosis was not preventable, it is not medical malpractice. In medical malpractice cases, failing to listen to the patient or ask appropriate follow-up questions is often the beginning of a cascade of missteps that results in a delayed or missed diagnosis.

**Seeking Resolution**

The shock of the fact that the delay of a correct diagnosis led to death or serious injury and was preventable sends the soul searching for answers. For many of the patients I’ve represented, their first thought pattern is predictable: “What did I do wrong?”

Patients often share that practitioners change their behavior toward the patient and family, once a diagnostic error is discovered. Healthcare providers scamper in and out of the hospital room and eye contact ceases. Patients and families develop feelings of fear, mistrust, and isolation. They hesitate to ask questions. Further, the questions they muster the courage to ask are left unanswered or the answers provided are evasive. Bewildered and confused, they do not know where to turn for answers. As a last resort, they call me.

Yet, the very act of calling a lawyer becomes another source of guilt. They never thought that one day they’d be sitting in the plaintiff’s chair.

From the practitioner’s point of view, the initial knowledge that a diagnosis has been delayed or missed may not be known for months or years. This phenomenon can occur because the correct diagnosis may have been made later by another practitioner or at a different healthcare institution.

Additionally, delayed and missed diagnoses historically have not been tracked or studied and no system is in place to provide feedback to the original practitioner. This issue was raised to national prominence with the National Academy of Medicine’s 2015 publication, “Improving Diagnosis in Health Care.”

In addition, I’ve had many practitioners tell me the first time they learned they were allegedly responsible for a delayed or missed diagnosis was when they were served with the lawsuit. Although practitioners' reactions vary, the emotion of guilt is quite common.

When patients come to me seeking representation, they most frequently request two things. First, they want to know why it happened. I’m fairly confident that we can give our clients answers to the first question by reviewing the medical records, policies, and procedures and analyzing the system that failed both the patient and the practitioner. The second request, preventing someone else’s life from being forever altered by a similar preventable medical error, is more challenging. No one person alone can achieve that request. We must work together.

What can patients and practitioners do to prevent a delayed or missed diagnosis from occurring? It is critical for patients, as consumers, to understand that the performance of a differential diagnosis is a process. Discuss your diagnostic system with your patients and explain what their role is in the process. Teach patients that the process of formulating an accurate and timely diagnosis requires their participation and input. Seek to engage patients in the process.

Information available on the internet is not a threat to the practitioner, but instead, is an opportunity. Direct patients to reliable internet resources and encourage them to formulate questions. Incorporate the differential diagnosis process and reliable internet sites into discharge planning and the written documentation provided to patients.

Recognize that by welcoming and encouraging participation, you are empowering the patient. Embrace the fact that an empowered patient is your ally. How we address the human dimension of medical errors so that practitioners and patients find closure is imperative to patient safety. As a team, the practitioner and patient can avoid the inevitable guilt associated with diagnostic error and its aftermath, by working through the differential diagnosis process together to improve patient safety.

**Notes**


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The Star of the Diagnostic Journey: Assessing Patient Perspectives

Kelly Gipson, BSN, RN, CPPS

Abstract: Delayed or incorrect diagnosis is a commonly identified medical error, and awareness of this issue has increased. Improving diagnosis is a pillar of the strategic plan for the Pennsylvania Patient Safety Authority. Insight into how Pennsylvania residents want to be engaged during the diagnostic process was obtained during a recent telephone survey. Survey results indicate that 42.3% of 606 adult respondents always call their doctor when a medical test is ordered but no one has called them with results. It also showed that in-person communication to receive a diagnosis was preferred by 87.7% and potentially important information was withheld by 7.1% of respondents. Education and communication related to the diagnostic process are essential and can be facilitated through engagement. Although a partnership with patients and families is critical, healthcare professionals should be aware that not everyone may want to assume an active role in this process. The needs of every patient may be different; still, healthcare professionals should view the patient and family as a focal point in the journey to diagnosis. Pa Patient Saf Advis 2018 Oct 31;15(Suppl 1):39-45.
The diagnostic process includes communication of the health problem to the patient. Traditionally, patients have received diagnostic communication during face-to-face visits with their doctor. With transformations in healthcare delivery, many new and different options are available for receiving a diagnosis. From specialty care to walk-in clinics and from patient portals to telemedicine, convenience and access are priorities for patients today.

In a survey, healthcare consumers across the nation identified diagnostic error as one of the most common medical errors. To help understand the impact in Pennsylvania and inform the work to improve diagnosis, the Pennsylvania Patient Safety Authority (“the Authority”) sought input from Pennsylvania residents to understand how patients envision their role in the diagnostic process through questions related to use of basic self-advocacy, preference about how a diagnosis is received, and transparency of information during the diagnostic process.

Methods
The Authority sponsored questions in a spring 2018 consumer survey by the Center for Survey Research, Penn State Harrisburg. The survey was administered via telephone from February 19, 2018, through April 19, 2018, to adult Pennsylvania residents.

The consumer survey methodology is described in the September 2018 Pennsylvania Patient Safety Advisory article, “Speaking Up for Safety—It’s Not Simple.” The following questions were included to inquire about the patient perspective and participation related to the diagnostic process.

- How often do you call your doctor when you have a medical test ordered, but no one calls you with the results?
  - Respondents could choose from the options of Always, Often, Sometimes, or Never. Some individuals did not respond and said the question does not apply to them, they do not know, or they declined to answer.
  - They were then asked an open-ended question: Why do you [always/often/sometimes/never] call your doctor when you have a medical test ordered but no one calls you with the results?

- When dealing with an illness or new health problem, how would you prefer to receive your diagnosis? The following options were provided:
  - In-person discussion with my physician
  - Communicating with a physician or medical professional over video call such as Skype, Face Time, or Teledoc
  - Technology that does not require direct interaction with a medical professional such as a smartphone app or mail-order testing kit
  - Visiting the closest walk-in or express clinic or urgent care

Some individuals did not respond to the question and said they do not know or they declined to answer.

- Have you ever withheld information from a doctor, nurse, or other healthcare worker that could have been important? The available responses were Yes or No. Some individuals did not respond to the question and said they do not know or they declined to answer.

Results
Demographics
Responses were obtained from 606 Pennsylvania residents; 51.6% of participants were female. The respondents’ ages were as follows:

- 107 (17.7%) were 18 to 34 years of age
- 301 (49.7%) were 35 through 64
- 198 (32.7%) were age 65 or older

To ensure that results were not biased toward any demographic group and to prevent over- or under-representation, the results were checked against two known demographic characteristics of the population. The weights were applied to give each case a value that was representative of the known percentage in the population. The weighted value better represents the population in age and sex to ensure equal representation but may not total 100%.

When No One Calls with Results
Of the total respondents, 42.3% of the weighted response set (n = 606) reported that they always call their doctor when a medical test is ordered but no one has called them with results. See Figure 1.

When asked why, respondents gave narrative answers. Respondents who said that they always call the doctor when a medical test is ordered but no one has called them with results. See Figure 1.

When asked why, respondents gave narrative answers. Respondents who said that they always call the doctor gave response themes such as entitlement, concern, curiosity, importance of information sought, and error prevention. Their responses show a sense of self-empowerment. Imagine the thought process of the individual who stated to the surveyor, “I am the star.”

"I am the star.
-Patient Survey Respondent
Other quotes received are listed here:

- “Results affect me.”
- “I care about my health.”
- “I need to know.”
- “I have a right to know and make my own decision on my healthcare.”
- “I deserve to know my results. If you don’t call me I want to know why.”
- “I know doctors are busy, but we have to own our healthcare, and we have to look out for ourselves.”

A smaller number of respondents, 12.0% of the weighted response set (n = 606), reported that they never call their doctor when a medical test is ordered but no one has called them with results. Dichotomous responses were received from this group and ranged from a sense of empowerment to passiveness. A portion of the responses referenced use of patient portals, emails, and online access. Other responses were more passive or suggested minimal patient involvement. This was evident in comments that referred to an assumption that a lack of contact from the medical team indicated a negative result, the opinion that it is the responsibility of healthcare professionals to communicate results, a willingness to wait for disclosure of results at a follow-up appointment, and general apathy. A few of the participant comments are listed.

- “Because the standard practice is that they call you if something is wrong.”
- “I do not care about the results.”
- “They always call me.”
- “No news is good news.”

- “If there were reason for concern, the doctor would call.”
- “Too much going on in life.”
- “I get an email advising that the results are available online.”
- “The results are always available at the next visit.”

Receiving a Diagnosis

In-person communication to receive a diagnosis was preferred by 87.7% of the weighted response set (n = 606) of respondents. See Figure 2 for total responses. Although most respondents prefer to receive a diagnosis in person, a smaller number of respondents prefer to use methods such as video conference, walk-in clinics, and other technology. Responses were similar across the three age groups, with majority of respondents selecting in-person discussion (Figure 3). In the 18-to-34-year age group, 6.2% of the weighted response set (n = 606) chose the closest walk-in or express clinic or urgent care, compared with 2.5% and 3.8% in the two older age groups.

Withholding Medical Information

Of the individuals surveyed, 7.1% of the weighted response set (n = 606) reported withholding potentially important information, as shown in Figure 4.

Discussion

When No One Calls with Results

An open-ended question in the survey generated diverse responses about how much patients want to be involved in the diagnostic journey. The responses could be categorized into three themes: those who do not call and, instead, wait for follow-up; those who do not call and, instead, use other resources;
Figure 2. When Dealing with an Illness or New Health Problem, How Would You Prefer to Receive Your Diagnosis?

- In-person discussion with my physician: 87.7%
- Communicating with a physician or medical professional over a video call, such as Skype, FaceTime, or Teledoc: 4.3%
- Visiting the closest walk-in or express clinic or urgent care: 4.1%
- Technology that does not require direct interaction with a medical professional, such as a smartphone app or mail-order testing kit: 2.1%
- Don’t know: 1.7%
- Declined to answer: 0.2%


Note: Total does not equal 100% because of weighting of respondent groups.

Figure 3. When Dealing with an Illness or New Health Problem, How Would You Prefer to Receive Your Diagnosis? (By age)

- Visiting the closest walk-in or express clinic or urgent care:
  - 18-34 years: 6.2%
  - 35-64 years: 3.8%
  - 65 or older: 2.5%
- Technology that does not require direct interaction with a medical professional, such as a smartphone app or mail-order testing kit:
  - 18-34 years: 2.0%
  - 35-64 years: 2.3%
  - 65 or older: 1.8%
- Communicating with a physician or medical professional over a video call, such as Skype, FaceTime, or Teledoc:
  - 18-34 years: 3.5%
  - 35-64 years: 5.7%
  - 65 or older: 2.5%
- In-person discussion with my physician:
  - 18-34 years: 88.2%
  - 35-64 years: 88.3%
  - 65 or older: 93.2%


Note: Total does not equal 100% because of weighting of respondent groups.
and those who call. Those who do not call and await follow-up may prefer passive involvement in healthcare. Those who do not call but who use available resources refer to patient portals and emails. This may lead to less direct communication with the healthcare team but expedite providing test results to patients and family in a convenient manner.

Others are inclined to interact with the healthcare team, as they appear to seek a more assertive and collaborative role in their healthcare. As noted earlier, one respondent states, “I am the star.” This quote may indicate a sense of empowerment. A patient who embodies this thought process would likely engage as an active participant in the diagnostic process; however, this may not be a realistic expectation for some individuals.

Healthcare professionals can be aware of the diverse perspectives and needs of individuals and develop diagnostic processes that accommodate various preferences. To improve the diagnostic process and other safety and quality initiatives, healthcare professionals must be open to the patient perspective and ensure their involvement. With the development of a partnership, healthcare professionals can learn individual needs and preferences, and thus improve the journey to diagnosis.

Receiving a Diagnosis

Survey respondents prefer to receive a diagnosis during an in-person discussion with their physician. This may validate the necessity of a risk reduction strategy, which is for physicians to maintain long-term continuity of care with patients. The other response options to this question are related to convenience and with fewer of these options selected, this may indicate a priority on relationship rather than someone assigned by manner of convenience. While diagnoses will continue to be delivered in unconventional ways or settings, they may not be preferred by patients for an initial diagnosis.

One might surmise that younger respondents would have a different outlook on how to receive information, because communication preferences and technology use vary among generations. But this was not the case. Response distribution was similar across the three age groups. The in-person discussion with a physician was the way most respondents said they preferred to receive a diagnosis, but the younger individuals might be more inclined to use the closest walk-in or express clinic or urgent care. When caring for diverse populations, we must consider unique patient needs and preferences.

Withholding Medical Information

About 7% of survey respondents reported that they intentionally withheld information that could have been important, which has potential for negative sequelae. Other surveys have found that up to 50% of individuals admitted that they lied or deliberately mislead a physician during an encounter. In addition, patients may not realize that they have withheld information. Patients may withhold information for many reasons. The electronic health record has been referred
to as a double-edged sword; it can improve quality, but concerns exist about privacy and security, which may culminate in nondisclosure to protect personal information.\textsuperscript{7} Additional reasons for nondisclosure include absence of physician inquiry, anticipation of physician disapproval, patient perceptions of relevance and importance, perceived physician disinterest, a fear of being judged, aversion to being lectured to, or fear of being viewed negatively.\textsuperscript{6,8} This may explain why patients lie or stretch the truth about topics such as diet, exercise, smoking, sex, alcohol intake, recreational drug use, and adherence to doctor’s orders.\textsuperscript{6}

Other reasons for withholding information may be that patients perceive that the healthcare team does not take problems seriously, dismisses their complaints, or does not listen to concerns about serious symptoms or deterioration.\textsuperscript{3} Correct diagnosis depends on a complete and accurate medical history; therefore, it is vital that patients are transparent. Development of meaningful relationships may create an environment where patients are less likely to withhold information.

A few strategies can be used to encourage patient disclosure of health information. Consider using open-ended questions or questions that inquire about the last time something was done.\textsuperscript{9} Communicate with patients the benefits of the electronic health record,\textsuperscript{7} use of the electronic health record to engage with personal health information, the consequences of nondisclosure and the benefits of full disclosure, and privacy and security issues with an emphasis on confidentiality and a safe environment.\textsuperscript{6} Consider behaviors that establish a personal connection, such as introductions, eye contact, and a sitting at eye level.

\textbf{Patients as Partners}

Although survey results indicate that Pennsylvania residents would rather receive a diagnosis from a physician with whom there is an established relationship, individuals have different needs and expectations when it comes to obtaining test results.

Inclusion of patients as active participants in the diagnostic process has been identified as a patient education strategy.\textsuperscript{4} The Authority interviewed a panel of experts and their comments make up the article, “Ask the Experts: A Roundtable Discussion with some of the Nation’s Leaders in Improving Diagnosis,” in this edition. In comments made during the expert panel but not included in the article, Sue Sheridan, a patient safety leader and advocate, stated that an invitation from the clinician or the clinical team to join them in the diagnostic journey is going to be vital. This is a role that some patients will not accept, and conversations about partnership development are needed. As survey results indicate, some patients may not want to embrace this role and prefer a more passive degree of involvement.

Patient partnerships have not historically been supported by medicine, but there has been a shift away from the “doctor knows best” culture with assistance from patient engagement initiatives,\textsuperscript{10} also described as a shift from a paternalistic to a patient-centered approach.\textsuperscript{8} The \textbf{National Academy of Medicine (NAM)} encourages healthcare professionals and organizations to partner with patients and families as diagnostic team members via engagement through alignment of needs, values, and preferences.\textsuperscript{1}

NAM lists ways for healthcare professionals to engage patients and families, such as the following: provide opportunities for patients and family to learn about the diagnostic process, create comfortable environments to engage patients and families, ensure electronic health record access and active engagement, and include patients and families in efforts to improve diagnosis.

Patient partnerships may also occur through education about diagnosis. The Joint Commission has resources that can be found with the Speak-Up™ program, with a goal of helping patients and their advocates become active care participants.\textsuperscript{11} A toolkit, “The Patient’s Toolkit for Diagnosis,” was developed for patient use by the \textbf{Society to Improve Diagnosis in Medicine (SIDM)} and includes four areas of focus: preparing patients for an appointment, symptoms or pain, medications, and next steps after the doctor visit.\textsuperscript{12} The toolkit approaches healthcare as a patchwork of brightly colored fabrics. The patient’s role is to stitch together the pieces to secure the quilt. It can help patients prepare for healthcare encounters, through inspiration to speak up and ask questions. Ideally, patient-provider partnerships will empower patients.

\textbf{Limitations}

A limitation to this study is that after the open-ended response for the question about calling when no one calls with results, there was no additional inquiry to provide insight about the response. The additional insight would be beneficial to determine strategies for the three themes of patient preferences.

The survey did not explore the reasons individuals have preferences about the ways they receive a diagnosis. In an effort to ensure accessibility today, healthcare organizations are using unconventional methods of care delivery. Because of a preference for in-person discussion with a physician, there may be potential for healthcare organizations to develop diagnostic processes specific to these unconventional methods. Another opportunity would be to
explore whether individuals in search of a diagnosis will defer medical care in cases in which they have access only to unconventional care delivery. A strong driver of healthcare today is insurance, or third-party payers. This component was not explored in relation to the three survey questions.

After the question about withholding information, this survey did not ask additional questions of those who answered yes. Inclusion of what information was withheld or why the information was withheld would be beneficial to healthcare teams in development of strategies.

Conclusion

Healthcare professionals need to engage patients, focus on their individual needs, and include them as active participants in the diagnostic process. Two key components to the diagnostic process include communication and education. These components help build the patient-provider partnership, which is paramount to the process. While most individuals surveyed prefer to receive a diagnosis in person, patients may have different needs and preferences that might require individualized approaches. Including the patient perspective in this important work is key to long-term success in improving diagnosis.

Notes


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Failures in the Diagnostic Process When Assessing Suicidal Intent

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Abstract: Identifying suicidal intent in patients is difficult; in behavioral health, valid and reliable objective measurements and physiologic testing in the diagnostic process are lacking. The first indication of error in assessing depressive symptoms and suicide risk may be an injury or death resulting from a suicide attempt. Potential failures in the diagnostic process were identified in events reported from May 1, 2015, through April 30, 2018, through the Pennsylvania Patient Safety Reporting System (PA-PSRS) database. A review of PA-PSRS data found that about 20% of suicide-attempt event reports mentioned the patient had been assessed as being at low risk of suicide. A complete assessment explores not just the patient’s first statements of suicidal ideation but delves deeper into other plans that the patient may have been withholding and the evolution of those plans over time. In addition, information gathering for patient assessment appeared to be inconsistent or incomplete in several event reports. Improving information gathering at all stages of the patient’s crisis and ensuring that relevant data is communicated throughout the continuum of care can contribute to a more accurate diagnostic process. Pa Patient Saf Advis 2018 Oct 31;15[Suppl 1]:46-50.

The diagnostic process is impacted by key cognitive and psychological factors on the part of both the diagnostician and the patient, especially during the stages of history, assessment, and monitoring/follow-up. However, accurate and timely identification and treatment of behavioral health disorders may be more challenging than in general medicine, and failures in the process could be more difficult to identify. The diagnostic process in behavioral health relies on identifying symptoms from patient reports and clinician observations without access to objective laboratory tests or biomarkers. This lack of valid and reliable confirmation makes it difficult to identify errors in the diagnostic process before they cause harm. The first indication of error in uncovering depressive symptoms and suicide risk may be an injury or
Gathering accurate information is vital, particularly when assessing suicidal intent. Some patients may openly share their intent to attempt suicide, even if they are uncertain or the interviewer is ineffective. However, a skilled, detailed discussion and review of past documentation is often needed to gain an accurate portrait of a patient’s true suicidal intent. Consideration should be given not just to a patient’s stated intent, but also to reflected and withheld intent.

“...”

Of the 9.8 million adults in the United States who reported having had serious thoughts of suicide in 2016, 2.8 million reported having made a suicide plan and 1.3 million attempted suicide.

“...”

Of the 9.8 million adults in the United States who reported having had serious thoughts of suicide in 2016, 2.8 million reported having made a suicide plan and 1.3 million attempted suicide. Of the adults who attempted suicide, 77% reported having made plans prior. A methodical suicide risk assessment presents the opportunity to understand and refine the diagnostic process and reduce the likelihood of diagnostic error resulting in unforeseen suicide attempts. Not just in behavioral health, but in medicine generally, chances are high that patients will experience at least one meaningful diagnostic error in their lifetime.

Methods
The author reviewed the PA-PSRS database events reported by Pennsylvania healthcare facilities as “Suicide Attempt – Injury” that resulted in an unanticipated injury requiring additional healthcare services or events reported as “Suicide – Death” that occurred during a three-year period from May 1, 2015, through April 30, 2018. The author manually reviewed the total resulting set of 70 event report narratives to identify reports describing the results of the latest completed suicide risk assessment. The events were also grouped by method of injury and reported level of harm resulting from the suicidal actions.

Results
Of the 70 events, 81.4% (n = 57) were reported as “Suicide Attempt – Injury” and 18.6% (n = 13) were reported as “Suicide – Death.”
In 18.6% (n = 13 of 70) of event report narratives, it was mentioned that the patient either denied suicidal ideation or had been assessed as being of low risk for suicidal behaviors prior to the event. Information gathering appeared to be inconsistent or incomplete in several event reports.

Of method of injury among event report narratives that indicated a low-risk assessment, 38.5% (n = 5 of 13) involved self-mutilation (e.g., cutting), 15.4% (n = 2) involved a jump from height, and one each involved hanging, gunshot, intentional overdose, car traffic, and train tracks. One narrative did not mention the method of injury.

In 38.5% (n = 5 of 13) of the events involving patients assessed as low risk, the injury occurred after the patient was discharged from the reporting facility, indicating that a diagnosis of suicidal intent may have been missed during the latest assessment. Of the 13 events, 69.2% (n = 9) resulted in an unanticipated injury that required additional healthcare services, and the remaining events resulted in the death of the patient.

**Discussion**

The review of 70 event reports revealed that nearly one-fifth specifically mentioned the patient was assessed as being at low risk for suicide due to lack of stated intent or result of assessment. In more than one-third of those instances, the patient was then discharged from the facility to a lower level of care where the suicide attempt occurred.

Accurately assessing risk for impulsive actions and suicidal intent is especially important prior to care transitions, oftentimes because the patient’s ability to execute suicide plans increases as their psychotic or depressive symptoms improve. The patients involved in those events may have had a level of suicidal intent or risk of impulsive actions but did not state their intent to the clinician during the most recent assessment. This may indicate that a greater weight is given to a patient’s stated intent during the assessment process than other underlying risks, or plans may have been overlooked.

In many areas of medicine, symptom-based diagnostic systems have been replaced with objective measurements and physiologic testing of physical data. This conversion has been slow within the behavioral health field. Although the DSM gives behavioral health providers a definition of symptoms (criteria) for the diagnosis of various conditions, it does little more to guide the diagnostic process. Limited information is available on valid biomarkers and other differential testing for behavioral health disorders. Standardized screening and assessment tools for suicide risk suffer from the same limitations. As such, behavioral health is anchored in determining diagnoses and providing treatment based on symptoms, which often have multiple potential causes. Unfortunately, treatment based on symptoms alone often fails to effectively address underlying issues completely.

These issues are perpetuated by the limits of identifying diagnostic errors and adjusting the process accordingly. Consensus of experts, a common method for determining error in behavioral health, is problematic. To recognize an error, agreement must be reached about which diagnostic prototype fits a patient’s symptoms and clinical presentation. In addition, most behavioral health diagnostic errors are discovered long after the error has been made. For example, a patient in whom schizophrenia or depression has been diagnosed may emerge as having bipolar disorder, but not until several years later, revealing the initial misdiagnosis.

When assessing a patient’s risk for suicidal actions, it is critical to gather information directly from the patient about his or her intent to die by suicide. However, the information gathered at that time may not be truthful or complete. A patient may not share accurate information for a variety of reasons. Although most of these reasons are from conscious decisions, there may also be instances when a patient implements unconscious defense mechanisms, such as denial, rationalization, or intellectualization. Conscious reasons that patients may choose to misrepresent suicidal intent identified by The Training Institute for Suicide Assessment & Clinical Interviewing include the following:

- The suicide attempt may be a result of impulsivity without extensive suicidal ideation.
- Patients may purposely choose to not relay suicidal ideation or may withhold the method of choice because they do not want to be stopped from completing the plan.
- Patients may believe that suicide is a sign of weakness or is an immoral act.
- Patients may be worried that they will be perceived as crazy or will be shamed.
- Patients may fear that they will be hospitalized if suicidal ideation is shared.
- Patients may believe that their suicidal ideation cannot be helped.
- Patients may have trouble recognizing or describing emotional pain.

Additionally, information gathering may be inconsistent throughout the diagnostic process. During the
initial intervention, the patient may be emotionally charged—with either positive or negative feelings—and be more willing to share the truth. It is extremely important that as much data is gathered at that time as possible and equally important the information is passed along to subsequent healthcare providers. This relayed information can often greatly affect the level of suicide risk identified. Past documentation and information from prior providers can be weighed with current evaluations to assess suicidal intent accurately.

Although stated intent is important, withheld and reflected intent are vital pieces often not weighed as heavily during the diagnostic process. Patients may relay their suicidal intent in stages, based on how the provider responds. This is also true of information the patient may have shared, but reevaluated based on a perceived negative reaction with a previous provider during either the current episode or prior episodes. When patients with strong suicidal intent are asked about a plan, they often choose not to share their method of choice even when asked directly and might reveal abandoned methods first. For example, a patient may share a plan to shoot herself, but hold back on her true method of choice, such as to overdose on drugs, for fear the pills will be removed as an option. If that shared method is addressed by the provider, and the gun is removed, there may be a false belief that the risk of suicide is sufficiently mitigated, resulting in the patient’s true suicidal intent being grossly underestimated.

Overlooking reflected intent may lead to erroneous assumptions about a patient’s potential for suicidal actions. As Shea states, “Those patients most likely to die by suicide are those patients least likely to relate their intention to do so.”

Motivational theory supports the importance of reflected intent. When looking at the motivation to do something that is hard to do but beneficial, such as substance-abuse counseling, the extent of the patient’s goal-directed thinking and subsequent actions may be much better indicators of intent to proceed than stated intent. Although motivation is typically used to discuss initiating difficult-to-do actions for positive change, it can be equally effective for initiating a difficult-to-do action that is harmful, such as suicide. Therefore, exploring the “amount of time a patient spends thinking, planning, and practicing a suicide attempt” by examining the patient’s history, previous clinical interactions, and statements made outside of crisis periods, may be a more accurate indicator of imminent danger than a patient’s current words.

Behavioral health patients are especially vulnerable to diagnostic errors related to clinical reasoning, including perceptions, failed critical thinking processes, and cognitive biases. There is a tendency for clinicians to be more judgmental with behavioral health patients and blame them for their own illnesses, potentially skewing data to fit preconceived expectations. This is also true for patients with substance abuse disorders, which are common comorbidities with depression and suicidal ideation. The provider’s cognitive constructs can affect how criteria are selected and weighed when assessing for suicide risk. These cognitive errors are pervasive and predictable and require providers to take action. Croskerry provides strategies to help counteract these cognitive errors, including the following:

- Increase awareness of cognitive biases by describing attitudes towards and among individuals with mental health disorders.
- Force consideration of alternative etiologies for symptoms so all possibilities are explored.
- Provide opportunities to step back from a problem and reflect on the thinking process.
- Use cognitive aids such as algorithms, mnemonic devices, and handheld technology, to improve the accuracy of judgments and decrease reliance on memory.
- Develop simulation opportunities to observe triggers of cognitive bias and their consequences.
- Construct training materials to compare biased and debiased approaches.
- Develop strategies to avoid anticipated bias when discussing sensitive issues such as suicidal intent.
- Make information available in a concise, clear, well-organized format.
- Minimize time pressures and provide adequate time for complete history gathering and assessment.
- Communicate clear accountability for decisions and establish a process for follow-up.
- Provide feedback as soon as possible so that errors are quickly recognized and corrected.

Because of the reliance on history taking and assessment during interviews, behavioral health providers are in a unique position to contribute to the study and improvement of the diagnostic process in all areas, not just behavioral health diagnoses and suicide risk assessment. Described or observed behaviors and responses of patients, family members, and providers may contribute to missed or incorrect diagnoses. Understanding the source and reason
for those behaviors and reactions can contribute to decreased errors during the history and assessment stages of the diagnostic process.

Diagnostic reasoning, acknowledging and learning from mistakes, communicating with patients and families, and using motivational techniques to gather information are processes with strong roots in behavioral healthcare that can help improve the diagnostic process.

Limitations
This study is limited by the type and number of reports collected, which depend on the degree to which facility reporting is accurate and complete. Other limitations include scant detail in some of the PA-PSRS reports and potential misinterpretation of information in the narrative descriptions.

Suicide attempts that do not result in an unanticipated injury requiring additional healthcare services might be reported as Infrastructure Failures, which are not reported to the Pennsylvania Patient Safety Authority through PA-PSRS. Events reported as “Self-mutilation” or “Ingestion” and not as “Suicide Attempt” were not included in the review, as well as potentially applicable events reported as “Other/miscellaneous.”

The sample size of event report narratives reviewed is too small for statistical analysis.

Conclusion
The diagnostic process for behavioral health, specifically in the assessment of suicide risk, is different from most other areas of medicine. This difference presents both unique challenges and opportunities. Review of PA-PSRS event reports indicates a potential overreliance on stated intent during this assessment process. Recognizing how suicidal intent can be more thoroughly assessed and discovered, then communicated to all providers, is an important step in reducing the harm from associated failures of the diagnostic process.

Notes
From Virtual Autopsies to Expedited Stroke Detection
How Facilities are Improving the Diagnostic Process

Listening to Reason: Strategies for Instilling a Culture of Clinical Reasoning
University of Pittsburgh Medical Center
VA Pittsburgh Healthcare System

Although misdiagnosis often has multiple causes, due to both cognitive and systems-based factors, errors in clinical reasoning have been increasingly recognized as important contributors. As a result, a growing consensus in the medical community points toward the need for better training in medical decision-making at all levels.

Despite this need, explicit instruction regarding clinical reasoning principles is often lacking. Furthermore, the optimal timing and methods for such education have not been established. As outlined in a recent systematic review, the majority of reported curricular interventions are brief (not longitudinal) and are isolated both in terms of learner level and in terms of venue (not incorporated into existing educational structure).

Implementation of such isolated curricular interventions, in our experience, does not lead to lasting change. Instead, we have found that use of a top-down and bottom-up approach (targeting faculty, residents, and medical students) while incorporating curricula into existing educational venues creates a culture in which clinical reasoning concepts are at the forefront.

We developed a comprehensive, multipronged approach for the creation of a culture of clinical reasoning within our Division of General Internal Medicine by disseminating the common language that governs clinical reasoning, role-modeling a systematic approach to case solving, and creating an environment in which errors can be freely discussed. We have implemented the various components of this program incrementally over the past five years.

This issue is important because in a 2015 report, the National Academy of Medicine identified diagnostic error as major threat to patient safety.

Clinical Reasoning Education Program Overview

Our clinical reasoning program includes longitudinal programmatic initiatives, as well as other efforts individualized to our various learner levels. On the programmatic level, we instituted a monthly "Clinical Reasoning Case Conference" at all three of our training sites. This conference, described in more detail below, allows for role modeling of decision-making and for discussion of diagnostic error and cognitive biases, and it is delivered to a diverse audience that includes students, residents, fellows, and faculty.

At the faculty level, we developed a training and development series that includes discussion of the incidence and impact of diagnostic error and review of clinical reasoning terminology. It provides a practical framework for teaching clinical reasoning in the clinical setting as well as for remediation of errors in clinical reasoning. We deliver this series, which includes interactive and case-based exercises, during time set aside for faculty development.

Our residents and medical students similarly learn these concepts through interactive online modules (which are described in more detail below) and case-based workshops tailored to each distinct learner level. We continuously reinforce this content in the real clinical setting through several initiatives, including widely disseminated posters and pocket cards containing key concepts.

Finally, we have incorporated education regarding clinical reasoning topics into existing educational venues, including morning report (through dedicated clinical reasoning training of our chief residents) and noon conferences.

Clinical Reasoning Case Conference

Early experimental evidence supports the use of example-based learning (EBL), wherein a skill is learned through observing examples of that skill, such as for teaching clinical reasoning. However, use of this approach requires that clinical teachers possess the skills to make their own reasoning processes explicit, limiting broad application. To address this educational...
challenge, we developed an interactive conference with a focus on discussion of clinical reasoning principles through inclusion of a “clinical reasoning moderator” and following the principles of EBL.

Our monthly “Clinical Reasoning Case Conference” includes sequential delivery of clinical information from a real patient case to an expert discussant, who in turn describes his or her approach to the case as it unfolds, in a “think-out-loud” format. Cases are challenging and present opportunities for discussion of diagnostic uncertainty. The conference is facilitated by a “clinical reasoning moderator,” who, in keeping with EBL principles, provides explicit commentary regarding the clinical reasoning processes being used and prompts the audience to engage in active learning. This monthly conference has sustained high attendance for nearly three years since its introduction.

In this conference series, a focus on the clinical reasoning process has contributed to the development of a shared clinical reasoning vocabulary within our training program. Furthermore, this format has allowed us to leverage the skills of a small group of clinical reasoning educators across a large and diverse group of learners and to effectively employ EBL principles. The clinical reasoning moderator—who delivers teaching points, probes the discussant’s thoughts, and provides commentary regarding reasoning processes being used—plays a key role in dissemination of broadly applicable clinical reasoning concepts.

Key steps for consideration in conference development include achieving buy-in from key programmatic stakeholders, identifying the ideal venue and timing to maximize attendance and participation, and recruiting and training skilled “clinical reasoning moderators.”

Online Clinical Reasoning Modules

With a goal of being able to efficiently deliver clinical reasoning content to a large group of diverse learners, we developed an interactive online curriculum that teaches the language, theory, principles, and process of medical decision making. We created 11 interactive modules based on extensive review of the literature and expert consultation. Modules are multimedia with video-discussant, interactive patient videos, text, multiple choice and short-answer questions, and branching logic.

Topics covered include diagnostic error, intuitive and analytical reasoning, key steps in the clinical reasoning process, and heuristics/cognitive biases. In addition, the last five modules are dedicated to introduction and training in the use of a cognitive analytic tool developed for use as a bedside decision-making tool.

These modules have become a standard component of the educational program for all internal medicine residents as well as for all medical students when rotating through our department. We received written feedback regarding the modules from about 80% of learners, the substantial majority of which were very positive.

Lessons Learned

Since the implementation of these efforts, we have observed increased use of clinical reasoning vocabulary at all levels as well as an increasing frequency of spontaneous discussion of biases and clinical reasoning at core educational sessions and as part of submissions to national meetings. Requests for dissemination to other departments are another marker of our success.

As we have worked to promote a culture of clinical reasoning within our division, a number of principles have emerged as essential. First, dissemination of a common language to all levels is an important first step. Next, use of a centralized and bidirectional approach has been critical; previous scattered and isolated efforts were met with resistance and did not lead to lasting change. Finally, introduction of a systematic approach for decision-making allows for skill-specific education and remediation.

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Accurate Identification of Obstetric Sepsis Using E-record Tools

UPMC Magee-Women’s Hospital

Sepsis accounts for 10% to 15% of all maternal deaths worldwide and is the leading cause of preventable maternal death. Early sepsis recognition and management protocols developed by the Centers for Medicare and Medicaid Services (CMS) have been implemented since fall 2015. However, the recommended CMS Systemic Inflammatory Response Syndrome (SIRS) guideline parameters for adult patients, based on the CMS Inpatient Quality Reporting Measure, do not factor in normal physiologic changes during pregnancy.

To avoid overuse of resources, the authors developed adjusted SIRS parameters, organ dysfunction parameters, and obstetric (OB) criteria recommended by local obstetric experts and National Perinatal Information Center (NPIC) research, to accurately identify and manage sepsis in OB patients.

The adjusted parameters are used for inpatients who are pregnant or immediately postpartum (within 6 weeks after delivery). The authors developed a screening report in the electronic health record menu to identify OB patients with any of the following:

1. OB Adjusted SIRS Criteria (patient must meet 2):
   - Temperature greater than or equal to 38°C (100.4°F) or less than 36°C (96.8°F)
   - Heart rate greater than or equal to 110 beats per minute
   - Respiratory rate greater than or equal to 20 breaths per minute
   - White blood cell (WBC) count greater than or equal to 15,000/mm3 or less than 4,000/mm3 or greater than 0.5 K/uL bands
   - Fetal heart rate (FHR) baseline greater than 160 beats per minute

2. Organ dysfunction (patient must meet 1):
   - Lactic acid level greater than 2 mMol/L or less than 4 mMol/L
   - Hypotension: Systolic blood pressure less than 85 mmHg or mean arterial pressure less than 65 mmHg
   - Creatinine level greater than 2.0 mg/dL
   - Bilirubin greater than 2 mg/dL
   - Platelet count less than 100,000 mm3
   - International normalized ratio (INR) greater than 1.5
   - Activated partial thromboplastin time (aPTT) greater than 60 seconds

The sepsis screening report automatically prints out on each unit for review by the charge nurse/clinician at 6 a.m. and 6 p.m., to provide a quick alert to the bedside nurse for patients with possible sepsis. Nursing then uses the Magee-Womens Hospital of UPMC Nursing Sepsis Screening Form as a guideline for monitoring and notifying the multidisciplinary team to implement CMS’s recommended sepsis interventions.

The Sepsis Screening Report, Nursing Screening Form, and staff education were implemented over the last three quarters of 2017. From January 2018 through June 2018, the hospital has decreased the number of OB patients who did not meet CMS SEP-1 guidelines to zero.

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Closing the Loop on Critical Stroke Results Reporting

UPMC Pinnacle Hanover

Whether a potential stroke patient is received via inbound emergency medical services or walks through the front door, time is of the essence: time is brain! As a primary stroke center, UPMC Pinnacle Hanover recognizes that communication is key in providing this prompt care.

After identifying that the patient could be having a stroke, it is critical to diagnose the type of stroke (e.g., ischemic, hemorrhagic) correctly in order to render the appropriate treatment. Interventions within a specific time constraint for potential stroke patients are considered critical, and treatment with
alteplase, a tissue plasminogen activator (tPA), cannot be rendered unless the computed tomography (CT) scan result is negative for hemorrhagic stroke.

In early 2017, the facility implemented an approach to enhance and close the loop on communicating stroke CT-scan results. Previously, stroke CT results were reported to the provider by telephone only when the results of the scan were positive for bleed or infarct. But there can be a delay in treatment and/or a negative patient outcome when stroke CT results are not known as soon as they are available. With the new approach, the radiologist calls the emergency department (ED) or ordering provider with the results of all stroke protocol CT scans, regardless of the results.

At the time of the call, the provider may have all the other information needed to make the crucial decision of whether to administer tPA. Having the radiologist contact the provider by telephone helps to eliminate a time delay for the ED provider reviewing the report. Moreover, the physician-to-physician call is an additional safeguard to help prevent a CT report being left unread prior to tPA administration.

Representatives from the emergency medicine, quality improvement, and radiology departments worked together to develop the process and monitor for compliance. This effort did not come without reluctance, and there were challenges to work through.

First, outsourced radiology providers did not immediately embrace the process, because they did not have to do this at the other hospitals they covered. To overcome this challenge, the facility re-educated radiology providers and made clear the expectation of the CT scan communication. The facility then monitored compliance per individual radiologist and reported results to the radiology administrative team and the vice president of medical affairs, who followed up as needed.

Another challenge was related to providers incorrectly ordering the stroke protocol CT for patients who did not meet criteria or who were outside of the stroke window for thrombolitics (such as alteplase) or endovascular therapy, as defined by hospital protocol. The ED team was explicitly educated to use this CT only for patients who meet stroke-alert criteria.

Together, these efforts improve the diagnostic process by reducing delay in communicating critical results for stroke patients, which ultimately may reduce harm to patients with time-sensitive conditions. In addition, monitoring orders for the stroke-protocol CT to protect against its overuse improves diagnosis by eliminating waste and preventing treatment delay.

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Closing the Safety Gap on Pulmonary Nodule Incidental Findings

WellSpan Health

WellSpan Health started an initiative in 2015 to develop a systematic response to the patient safety issue of patient and treating physician unaddressed imaging findings and related follow-up recommendations, by defining and developing a Pulmonary Nodule Incidental Findings registry. The goal of the program is to identify pulmonary nodules/incidental findings and ensure follow-up.

The tracking registry began with limited imaging studies that identified pulmonary nodules that were incidental to the primary reason for the ordered study. When an incidental finding is identified, the radiologist adds specific wording to his or her report that allows the case to be identified by the nodule registry team. Working with the oncology team, a database was built to accommodate tracking, monitoring, and follow-up for these incidental findings.

The incidental finding care coordinator (IFCC) registered nurse reviews each imaging study finding entered into the database and the corresponding electronic medical record, to assess for planned follow-up according to Fleischner Society guidelines and related radiologist recommendations. If there is no identified notation to indicate that the physician or primary care physician (PCP) is aware of the nodule finding or has planned the recommended follow-up, the IFCC will contact them by sending an electronic task or by placing a phone call and having a discussion with the office staff, physician, or PCP. If there is no PCP documented, the IFCC will contact the patient by phone or certified letter.

The IFCCs are making positive care impacts by identifying patients whose imaging study findings require follow-up that may be unknown to the patient’s physician or practitoner. From July 2017 to June 2018, the IFCCs received and reviewed 5,119 patients for pulmonary nodules. All 5,119 patients were identified by a radiologist as needing follow-up. In 12% of all imaging reports reviewed, the PCP (and as a result, the patient) was unaware of or had not followed up on the pulmonary nodule that had been identified in the imaging study. Appropriate follow-up would include notifying the patient of the nodule, planning or scheduling follow-up imaging studies, and scheduling appointments.

As a result of the Pulmonary Nodule Incidental Findings registry review and workflow safety net, 51 patients per month, on average, were made aware of an incidental finding pulmonary nodule that otherwise might have been missed in treatment planning and follow-up. The IFCC Program is functional at the four
Decreasing Diagnostic Error in a Neonatal Intensive Care Unit

Einstein Medical Center Philadelphia

The Finnegan Neonatal Abstinence (FNA) scoring tool is widely used in neonatal intensive care units (NICUs) to guide the diagnosis and treatment of neonates born addicted to opiates. The FNA tool’s severity score, or diagnostic score, is important because it leads the NICU team to the most appropriate treatment protocol; inconsistency in scoring can lead to a longer length of stay and less effective opiate weaning.

NICU nurses at Einstein Medical Center Philadelphia identified several concerns with scoring, so an interprofessional team—comprised of nurses, physicians, pharmacists, social workers, and administrators—was formed to focus on increasing uniformity in assessment and diagnosis. The team identified inconsistency among caregivers in assessing and scoring using the FNA tool, including variability in differentiation of moderate tremors from severe tremors, identification of feeding trouble, and differentiating which skin breakdown is an indicator of feeding disturbance.

The process for identifying solutions to decrease diagnostic errors began with a literature review that revealed useful tips and key points for those responsible for scoring. Based on findings from the search, the team created a written competency and a return demonstration skills checklist (returning in a physical demonstration what was taught). These were completed by all NICU staff members.

The NICU team also implemented interobserver reliability training to help newer staff with scoring. A review of the items the infant is consistently being scored for is reported during crib-side handoff, so oncoming nurses know which items require more focused attention during scoring.

These interventions resulted in greater uniformity in staff assessment and scoring using the FNA tool. This supported a more consistent diagnostic process to guide application of opiate-withdrawal protocols and, because of the tool’s precision and uniformity in communicating the care plan, improved parental understanding of the treatment process.

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The Diagnostic Safety Program at Children’s Hospital Colorado

Children’s Hospital Colorado

Children’s Hospital Colorado formally began addressing patient harm due to diagnostic errors in December 2016. The diagnostic safety program focuses on three main topics: knowledge, culture, and measurement.

Over the past five decades, cognitive psychology has provided great insight into the processes of human decision-making, but that knowledge has not always been incorporated into medical education. The hospital’s educational strategy provides clinicians with basic knowledge of decision-making processes to build awareness of clinicians’ reliance on them in the diagnostic process.

Building on this educational campaign, Children’s Colorado is beginning to address the culture surrounding diagnostic error by systematically redesigning the structure of its clinical case review process (classically known as the morbidity and mortality review, or M&M). This will include M&M facilitator training focused on creating a safe environment in which to discuss diagnostic errors and their connection to system improvement.

Children’s Colorado is also developing a repository of articles about the current science of clinical reasoning and a handbook on best practices for the successful development and execution of M&M conferences. Establishing a scientific understanding of human judgment and creating a culture supportive of discussing flaws in judgment that lead to diagnostic errors will allow clinicians to identify opportunities for reducing harm from such errors.

Another component of the strategy is to identify larger trends in diagnostic error that may be amendable to system-wide solutions. Although patients in a subspecialty or clinical unit may suffer harms unique to their medical circumstances, it is unlikely that the underlying diagnostic reasoning failures are unique. If improved understanding of these underlying failures remains isolated in the knowledge of a single unit, it deprives learning at an institutional level to uncover where, when, and how these diagnostic errors are occurring.
Collecting this knowledge centrally will allow systematic measurement of the frequency and type of diagnostic errors encountered. To that end, Children’s Colorado has created a novel diagnostic error reporting and tracking database that will permit compiling M&M cases from across the hospital to discover trends in diagnostic error. This will foster the study and implementation of improvement strategies that can prevent harm in a much larger proportion of the hospital’s patient population.

Over the past year, progress has been slower than hoped. Openly discussing diagnostic errors creates significant discomfort in diagnosticians. Bringing the harms that result from faulty diagnostic reasoning into the light challenges the diagnosticians’ defining characteristic—to get the diagnosis right. Yet, it is vitally important to ensure the trust and cooperation of diagnosticians because the diagnostic process is so often obscure.

The approach taken to build that trust and cooperation involves a strategy rooted in partnership and establishment of shared goals. For example, the redesign of the M&M process started with one-on-one conversations between the Diagnostic Safety Program leader and M&M facilitators to understand their unique challenges, followed by a retreat with several facilitators to define shared goals, expectations, and components of clinical case review. Similarly, the database developed for tracking case-review details and outcomes is being tested by select clinical units that already have robust case review processes. Feedback is used to refine the database to ensure that it serves both the local case review process within the unit and supports the larger institutional mission.

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Ensuring Follow-Up of ED Radiologic Incidental Findings

Tyrone Hospital providers and staff were challenged by the desire to ensure adequate and accurate patient education about incidental findings. They were eager to participate in the Hospital and Healthsystem Association of Pennsylvania (HAP) Hospital Improvement Innovation Network (HIIN) pilot project. The Pennsylvania Patient Safety Authority and the Health Care Improvement Foundation led the project, and the goal was to decrease diagnostic error.

As part of this project, a team was formed at the hospital to ensure interdepartmental coordination of care, including the chief radiologist, chief nursing officer, emergency department (ED) nurse manager, radiology department director and secretary, and quality director. The team reviewed the electronic medical record for documentation issues and tracking abilities. After project-related meetings and education, the team discussed proposed practice changes for feasibility and implementation.

The changes addressed incidental findings on ED imaging scans. For example, a computed tomography scan of the abdomen and pelvis may be ordered to evaluate for acute appendicitis. However, an incidental finding might be revealed, such as a renal mass or lung nodule. This incidental finding might need further evaluation to assess for malignancy. In addition, the prevalence of preliminary radiologic interpretations for ED cases (performed overnight at many institutions) means that final interpretations may occur when the ordering clinician is off duty.

The following imaging-tracking practice was refined after engagement with the HIIN project. If the radiologist determines that the incidental finding may be clinically significant, he or she flags the case for the department secretary, who then obtains the patient’s contact information and identifies the primary care clinician. The secretary prints the report and drafts a cover letter to the patient and primary care clinician explaining that an abnormality identified by imaging requires follow-up. The radiologist then contacts the patient to discuss imaging findings and recommendations. This educational conversation either takes place in person or by telephone. The related documents are either hand delivered or mailed to the patient. In addition, the report is forwarded to the primary care clinician.

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result in appropriate diagnosis and treatment in the timeliest manner possible. The team is driven by their passion to improve community health and wellness and provide patients potentially lifesaving treatment.

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**Faster Imaging for Earlier Stroke Diagnosis and Treatment**

**Einstein Medical Center Montgomery**

To maintain our certification as a primary stroke center at Einstein Medical Center Montgomery (EMCM), we work diligently to follow standards outlined by Joint Commission. A multidisciplinary committee—which is chaired by the stroke coordinator and includes representatives from the emergency department (ED), diagnostic testing, radiology, laboratory services, case management, neurology, and a community member—meets monthly.

The committee’s primary goal is to improve patient outcomes through case review and to determine how the hospital can safely and efficiently improve processes with an emphasis on rapid diagnosis and treatment. The committee reviews all charts of patients who presented as a stoke alert either to the ED or as inpatients and pays particular attention to cases in which the patient received a lytic medication or endovascular thrombectomy.

In the fall 2015, after a review of evidence-based practices for stroke care, recommendations were received from the stroke committee to make significant changes to our stroke-alert process in the ED. Knowing that rapid diagnosis is a precursor for successful patient outcomes, EMCM reached out to local emergency medical services (EMS) organizations that transport patients to our facility to determine whether arriving crews would take patients directly to the radiology department for a computerized tomography (CT) scan on the EMS stretcher.

This is an atypical practice for EMS, although doing so would save precious time by avoiding the patient first being placed on an ED stretcher and then transported for a CT scan. EMS’s notifying EMCM prior to the arrival of a potential stroke patient allows early communication and treatment collaboration with the CT technician as well as the other members of the stroke team. Effective implementation of the practices was agreed upon by all parties.

In spring 2017, recognizing that vital time was being lost when a stroke patient had to return to CT scan for a **computed tomography angiography** (CTA) scan after having a noncontrast imaging study allowed for a change in practice in which a patient undergoes both CT and CTA in rapid succession. Stroke patients now undergo a noncontrast CT that is first read by a radiologist; then, if deemed safe and clinically appropriate, the patient undergoes a CTA without ever being moved from the CT table. The results of the CTA will provide information that will determine whether a patient is eligible for a mechanical thrombectomy.

Patients who present within 3 to 4.5 hours of the start of stroke symptoms are eligible to receive a **tissue plasminogen activator** (tPA) in an attempt to dissolve the clot that is causing the obstruction to the brain, thereby leading to improved blood flow to the affected area. The standard for ED presentation to tPA administration is 60 minutes. Completion of a noncontrast CT is necessary to determine a patient’s eligibility for receiving this medication.

By decreasing the time it takes for the CT to be completed and read we have significantly decreased our administration time for tPA. From August 2015 through July 2016, 50% of eligible patients received tPA within 60 minutes of presentation to the emergency department. For 2017, that had grown to 87% of eligible patients receiving tPA within 60 minutes.

By improving our processes and delivering treatment more quickly, we improved our outcomes by improving our patients’ quality of life and limiting the degree of disability as a result of their stroke.

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HIV and Hepatitis C Virus: Improving Diagnosis through Electronic Medical Record–Driven ED Testing

Temple University Hospital

The number of acute hepatitis C infections identified in Philadelphia between 2012 and 2016 has increased ten-fold. Philadelphia County also has the highest 12-year incidence rate of hepatitis C virus (HCV) in the state. And Philadelphia has had more new human immunodeficiency virus (HIV) cases than all other counties in Pennsylvania combined (31,986 cases from 1980 to 2016 in Philadelphia, compared with 28,621 cases for all other Pennsylvania counties). Yet, Philadelphia County comprises only 12% of the total population of the state.

Temple University Hospital, in Philadelphia, serves a high-risk, inner-city population, and many of its residents lack access to primary care. To facilitate early diagnosis and to establish timely follow-up and initiation of care, the hospital has implemented a novel screening program for HCV and HIV through the emergency department (ED), using the electronic health record (EHR).

When patients enter the ED at the main hospital and a community affiliate, a best practice alert in the EHR is triggered if the patient’s medical record indicates that criteria for HCV testing is met, based on current guidelines from the Centers for Disease Control and Prevention (CDC). The alert instructs the provider to offer HCV testing, which can then be ordered by nurses or physicians. A similar program has been implemented at the affiliate site for HIV screening. All patients arriving in the ED, age 18 through 65, are offered HIV testing and consent for testing is obtained in triage if they accept.

The results from these screenings are collected in a registry within the EHR. Navigators then use the registry to contact patients with positive results for appropriate follow-up. Attempts to contact patients are documented in the chart and the results are tracked within the registry. If patients who were not reached by phone or certified letter return to the hospital, the on-site navigators are notified by means of EHR and text messages so the patients can be informed of their results. Once informed of the diagnosis, patients are scheduled for a follow-up appointment with the appropriate specialist.

Since August 2017, more than 4,000 patients have been screened for HCV; testing for 7.4% demonstrated chronic infection. Thirty-three percent of patients with positive HCV test results have been linked to care with an HCV specialist. Of the 1,825 patients who have been screened for HIV, 0.4% had positive test results. All aspects of the process, including triggering of the best practice alert, resultant testing or dismissal of the alert, and patient follow-up, are being tracked to further refine the process to increase the number of patients tested and linked to care.

Early diagnosis of HCV and HIV using this type of EHR-driven testing program can increase the number of patients screened and linked to care. Ultimately, this screening program may lead to improved diagnosis, supporting a decrease in disease transmission and associated morbidity and mortality.

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Improving Diagnosis by Monitoring Serial Procalcitonin Levels

Summit Health

Rapid determination of the pathogenic organism type—bacterial, viral, or fungal—presents a challenge in the diagnosis and treatment of infectious diseases. Until this information is known, treatment remains empiric and largely requires the use of broad spectrum, and potentially unnecessary, antimicrobials. This, in turn, could result in adverse drug effects, increased hospitalization costs, and an adverse effect on local antimicrobial susceptibility patterns.

Summit Health uses the biomarker procalcitonin to identify bacterial infections in a timely manner. Procalcitonin is undetectable in the absence of a bacterial pathogen. Obtaining and monitoring serial procalcitonin levels is especially helpful in determining whether an infection is bacterial and if it should be treated with an antibacterial agent. Further, serial...
procalcitonin levels may predict a satisfactory response to antimicrobial therapy, which could enable de-escalation of antimicrobials in a timely manner.2

The pharmacy department partnered with the pulmonology, infectious disease, hospital medicine, infection prevention, and pathology departments to initiate a procalcitonin protocol for patients admitted with bronchitis, pneumonia, chronic obstructive pulmonary disease, or congestive heart failure diagnoses. The protocol included drawing a procalcitonin level at admission and every 48 hours thereafter. The orders for procalcitonin were hard-coded into the computer-physician order-entry order sets. The clinical pharmacist was notified each time a procalcitonin level test result was completed by the laboratory.

When baseline and successive procalcitonin levels were less than 0.1 ng/mL, the case was referred for review by the antimicrobial stewardship team, which included an infectious disease physician. Using procalcitonin level results in combination with other biomarkers such as C-reactive protein, presence or absence of leukocytosis, chest radiography, and temperature trends, the infectious disease physician determined whether communication with the attending physician was warranted to advise the attending physician that an infectious process was unlikely to be bacterial in nature and that discontinuation of antimicrobials should be considered.3

Because of serial procalcitonin measurements, many patients admitted with select diagnoses (e.g., bronchitis, pneumonia) were determined not to have bacterial infections and thus were spared full courses of antimicrobial therapy.

Monitoring serial procalcitonin levels in a subset of patients suspected of having a respiratory bacterial infection can be useful in ruling out a bacterial cause; procalcitonin provides a beneficial tool to improve antimicrobial stewardship.

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Improving Post-Mortem Diagnosis in Unexpected Neonatal Demise Using Virtual Autopsy

Abington Memorial Hospital

Congenital anomalies are a leading cause of neonatal death worldwide.1 These lesions may not be detected by ultrasound during routine antenatal surveillance but can have significant, and even lethal, implications during the neonatal transitional period.2 A neonatal loss has a profound impact on patients, families, and care providers, and often a traditional autopsy is not pursued by the family because of the delicate nature of the situation and the invasiveness of the procedure. Virtual autopsy or “virtopsy” has been validated through multiple studies as a minimally invasive means of objectively documenting cause of death.3,4 Virtual autopsy is often a composite of imaging, including ultrasound, computed tomography (CT) and magnetic resonance imaging (MRI). Although virtopsy has been studied in adults, it has only recently been studied in neonates.3

At Abington Memorial Hospital, a 30-year-old primagravida presented to labor and delivery with preterm, premature rupture of membranes. She was admitted, given prophylactic antibiotics, and expectantly managed. She had an uneventful labor course, and fetal monitoring was reassuring throughout the night. She quickly progressed to complete dilation; however, after two hours of pushing, there was no descent of the fetal head. A cesarean delivery was recommended. After a difficult delivery, resuscitative measures were unsuccessful, which resulted in a neonatal death. Like many others, the patient and her husband were opposed to a traditional autopsy. A virtual autopsy was offered to the family as an alternative.4

A CT, MRI, and ultrasound were performed, and diagnostic imaging clearly demonstrated an imperforate thin membrane across the trachea distal to the vocal cords, making it impossible for air to flow through the respiratory tract into the lungs despite extensive resuscitative measures.

Imaging demonstrated fluid throughout the tracheobronchial tree and the absence of air in the lungs. The presence of a tracheal air fluid level suggestive of an upright presentation while the infant was supine is particularly compelling for this case. Virtopsy provided noninvasive documentation of findings, which could be analyzed and independently verified with preservation of tissues. The finding of a tracheal web at virtopsy explains why resuscitation efforts were ineffective. Obtaining answers in situations like these is of critical importance to prevent inappropriate assignments of guilt and blame for patients and family, as well as providers. In this case, it was particularly instrumental in diagnosing a cause of death and providing closure to all involved.
Virtopsy provided noninvasive documentation of findings that could be analyzed and independently verified, while preserving tissues. However, although virtopsy allows for structural and tissue analysis, it does not provide molecular or genetic information, suggesting that there are still roles for traditional post-mortem evaluation techniques.

As evidenced by this case, using virtopsy to identify a cause of death can be critically important in the process of coping and healing after a loss, and it allows the study of disease through a different lens from that of traditional autopsy. The hope in applying this technique broadly is to provide a minimally invasive way to gain insight and in-depth information that might be unobtainable otherwise.

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Safer Dx Learning Lab at Geisinger: A Partnership between Researchers and Health System Leaders for Improving Diagnostic Safety

Geisinger Medical Center

Diagnostic errors—missed opportunities to make timely and accurate diagnoses—are major contributors to patient harm but are hard to tackle because they are difficult to identify and measure. Progress in reducing diagnostic errors hinges upon our ability to overcome several unique measurement-related challenges, including operationally defining diagnostic error in real-world settings. Compounding these challenges is the fact that diagnostic errors typically emerge across multiple episodes of care. Although recent studies1 show that misdiagnosis affects at least one in 20 U.S. adults each year in the outpatient setting, health systems have yet to develop a systematic approach to improving diagnostic performance in either inpatient or outpatient settings.

This compelling need to demonstrate how to identify and reduce diagnostic errors led to the creation of the Safer Dx Learning Lab. Funded by the Gordon and Betty Moore Foundation, clinical leaders at Geisinger and researchers at Baylor College of Medicine have formed a unique learning health system for improving diagnosis. The lab is taking a systematic approach to learn how healthcare systems can enhance the safety and accuracy of the diagnostic process. This collaboration combines Baylor’s multidisciplinary research expertise and Geisinger’s innovative approach to clinical operations, allowing translation of research into meaningful care improvements.

The Safer Dx Learning Lab—Dx stands for diagnosis—uses multiple data sources from the health system (risk management, electronic triggers), providers, and patients to identify missed opportunities in diagnosis. After an initial rigorous review by the Learning Lab team, missed opportunities are then reviewed by the Committee to Improve Clinical Diagnosis (CICD) to further understand how to uncover contributory factors and provide feedback to individuals, teams, and entire divisions.

This analytic process is all about how and what we can learn from the opportunity. We look at five dimensions in the diagnostic process derived from the Safer Dx framework2: (1) patient-provider interactions, (2) diagnostic test performance and interpretation, (3) the referrals process, (4) appropriate follow-up of test results, and (5) patient factors.

Geisinger has harnessed a wealth of electronic data and will leverage it to provide actionable information to improve clinical diagnostic quality. Together with Baylor, the group will use a multidisciplinary, socio-technical approach to improve the measurement and feedback of diagnostic errors.

The unique CICD at Geisinger advises and closely collaborates with the Safer Dx Learning Lab. Its members include senior physicians, clinical and operational leadership, and key stakeholders from quality and safety, risk management, patient experience, medical informatics and information technology. The CICD has an extensive agenda, but in general seeks to identify and assess diagnostic errors while making every error an opportunity for broad-based learning in an open and constructive environment. This project is in its early stages but offers a unique opportunity to address challenges posed by diagnostic errors.
A Standardized Approach to Defining and Rapidly Recognizing Diarrhea

Select Medical

Diarrhea is a common occurrence in critically ill patients. Up to 38% of patients in the intensive care unit have at least one episode of diarrhea. These episodes may be noninfectious (i.e., associated with nutritional interventions such as enteral feeding) or attributable to insidious hospital-acquired *Clostridium difficile* infection. Diagnosis and management of diarrhea is especially critical in this patient population because of the impact on the patient’s long-term recovery and nutritional status. However, the lack of standardized definitions of diarrhea, inconsistent approaches to troubleshooting the underlying cause, and the potential for over-use of laboratory *C. difficile* testing make diagnosis and management challenging.

Recognizing these challenges, Select Medical’s long-term acute care hospital (LTACH) division embarked on a diagnostic stewardship mission to promote rapid identification and resolution of diarrhea. The approach was to use a standardized diarrhea definition and interdisciplinary management.

Senior leaders from the clinical, dietary, and pharmacy disciplines collaborated to define diarrhea by two criteria, only one of which is required to meet the definition: the presence of three or more watery stools in 24 hours or less or a significant change from patient’s baseline stool consistency.

The leaders also developed a diarrhea management algorithm to guide staff through appropriate diagnostic steps after a new onset of diarrhea. The algorithm includes assessment of underlying medical causes, evaluation of potential fecal impaction, and medical record reviews by nursing, pharmacy, and dietary staff to identify any other possible contributing factors to diarrhea prior to ordering tests for *C. difficile*.

Assessment of other clinical or pharmaceutical causes for diarrhea was expected to reduce routine *C. difficile* testing when clinical indications of infection were not present. Additionally, limiting *C. difficile* testing to patients with acute signs and symptoms of infection was expected to reduce the risk of false-positive tests in cases of asymptomatic colonization.

The diarrhea management program was tested in pilot programs at five Select Medical LTACH sites from March 1 through September 30, 2017. Participating sites reported an increase in the number of diarrhea cases identified and improved multidisciplinary collaboration for diarrhea management.

Preliminary results of the program were shared with Select Medical’s National Medical Advisory Board, which approved the roll-out of the strategy to all facilities in the LTACH division in early 2018. Education of clinical leaders at each hospital was completed through a series of structured webinars, and in-service sessions for all staff members on the standardized definition and management protocol were completed in March 2018.

Notes

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The problem of diagnostic error is not new to healthcare, yet it still has not received its due attention. In its 2015 report, the National Academy of Medicine (NAM) concluded that “most people will experience at least one diagnostic error in their lifetime, sometimes with devastating consequences.” Despite a recognized need for more work in this area to improve processes and prevent harmful events, the breadth of the issue makes it challenging to find a place to start. Solutions are rarely “one size fits all,” and in some cases they may not yet exist.

The Institute for Healthcare Improvement (IHI) recommends approaching challenges with a comprehensive Model for Improvement to guide efforts from goal-setting through iterative small changes using Plan, Do, Study, Act (PDSA) cycles. This model provides a tested, standard method for performance improvement work.

Daunting patient safety challenges can be viewed as learning journeys that invoke a spirit of welcoming new and creative ideas and allow room for experimentation. With this approach, hospital project leaders and change agents (“project leaders”) set the creative context and help the team move to action more quickly through small trials, with an expectation of learning and adaptation along the way.

In this article, we share a conceptual framework that can be used to tackle any big patient safety challenge. This is not an alternative to the IHI Model for Improvement and PDSA but a supportive framework that can be used in conjunction with them. We also share our story of working together to decrease diagnostic error in Pennsylvania as an example of our conceptual framework in action (see “The Conceptual Framework in Action to Decrease Diagnostic Error in Pennsylvania” beginning on page 64).

Understand the Nature of the Challenge

With a broad, complex patient safety challenge, attempting to clarify every detail can impede progress.
Instead, teams can first focus on understanding the nature of the challenge. In “The Practice of Adaptive Leadership: Tools and Tactics for Changing Your Organization and World,” Heifetz and colleagues explain that challenges can be technical or adaptive in nature, and in some instances, have elements of both. For technical problems, solutions and expertise already exist; the work is in applying and implementing known solutions. Conversely, adaptive challenges require shifting of attitudes and priorities, adopting new habits, and letting go of old beliefs that support the status quo. The people experiencing the challenge must take action to solve their problem and not rely on others to provide solutions.

One key skill of a project leader is the ability to diagnose technical challenges versus adaptive ones. The approach and tools best suited to address the challenge may differ. Coaching and supporting improvement teams is greatly enhanced when they can assess the nature of the challenge as technical or adaptive and bring the best tools to the table to accelerate change. Without this early phase of understanding the nature of the challenge, efforts can be impeded as teams take an ill-suited approach. Attempting to solve adaptive challenges with technical solutions can bring frustration and inertia to performance improvement efforts.

An ideal place to start in making this determination is to look at the current state and what is happening daily in the context of the challenge. In this stage, we can step back and look at the steps in a process, how individuals relate and communicate, as well as positive attributes—what is working well? All the observations and additional information gathered will support efforts of the team in understanding the nature of the challenge and determining their best strategy.

Ensure All Voices are Heard

If we view a challenge in terms of the process steps involved, we can more easily identify the individuals who should be included. When forming a project team, a broader discussion provides perspectives across different roles from which the problem is viewed. At the unit level, physicians and nurses are rarely overlooked when requesting participation. On the other hand, support staff, who contribute greatly to unit culture, are often not asked to participate yet can offer an important perspective. For example, environmental services staff may have relevant, valuable input for keeping hallways clear or improving infection control practices.

Everyone looks at aspects of the process through their own lens and may “see” barriers or assets missed by others. Ensuring diverse representation from all interested stakeholders will provide the best opportunity to unleash new ideas.

Most people are familiar with conventional team meetings, which have a set agenda and a meeting leader who speaks at the participants. These familiar environments may not help generate creative thinking and fresh ideas. It can also be intimidating for some individuals to speak up and offer their perspective. How the environment of the meeting itself is designed and structured by project leaders can accelerate the move toward new, actionable ideas. Project leaders can benefit from building their own skills in designing and running meetings. These skills (continued on page 66)
In 2016, the Pennsylvania Patient Safety Authority (PPSA) and the Health Care Improvement Foundation (“project team”), under the Hospital and Healthsystem Association of Pennsylvania (HAP) Hospital Improvement Innovation Network (HIIN), launched a multiyear project focused on diagnostic error related to imaging in the emergency department (ED). In year one, the project team developed a set of measures to be tested in year two with a group of Pennsylvania hospitals. Now approaching the end of year two, the project team has identified important insights for healthcare organizations seeking to address the problem of diagnostic error.

Understand the Nature of the Challenge
The project team focused on imaging in the ED because of the many challenges and opportunities for improvement in these clinical areas. The ED is an inherently risky environment with many distractions and coordination challenges. Imaging is often critical to accurate and timely diagnosis, yet radiologists may not be engaged as full members of the diagnostic team. In addition, silos often exist between the ED and radiology, and processes between the two departments involve individuals in many roles located in different parts of the hospital. The project team sought to understand the nature of the challenges related to diagnosis in these clinical areas. Given the disparate nature of the process and necessary coordination between individuals and departments, it was clear the project would involve some adaptive, nontechnical challenges, thus requiring different approaches to find solutions. The project team anticipated and planned its work throughout the project to create the space and interactions needed to challenge assumptions and unleash new ideas along the way.

Determine the Current State
The project team focused on narrowing the scope to specific clinical areas. A project team leader visited several Pennsylvania hospitals to observe processes in the ED and radiology in real time and obtain frontline staff members’ perspectives. The project team leader sought to identify areas of variation or discrepant understanding of the process. The following themes emerged:

- The pitfalls and opportunities to improve the diagnostic continuum identified by ED physicians and advanced practice providers were very different from those identified by radiologists.
- Many of the ED nurses did not view their roles as being significant to the diagnostic process (although some said they should “trust their gut” and speak up more often when they have concerns).
- Not only did the observations and interviews provide valuable information, but they allowed new relationships to be formed with hospital teams for future participation in the project.

Ensure All Voices are Heard
Collaboration is essential to spark new ideas and foster sharing across disciplines, as well as refine scope and prioritize areas for further study and evaluation. The project team gathered diverse stakeholders including radiologists, emergency medicine physicians, radiologic technologists, nurses, a patient representative, patient safety experts, invited expert speakers, professional organization leaders, and department leaders from hospitals across Pennsylvania for a full-day collaborative event.

In planning the meeting, the project team focused on who should be invited and what was to be accomplished. By viewing diagnosis as a multifaceted process, they identified key players with direct knowledge of different aspects of the process. The project team also used interactive methods to achieve the objectives. After presentations by invited subject matter experts, facilitated and interactive discussion allowed for connection and deeper discovery of themes in creative ways.

"For this project, an incidental finding is defined as “an imaging finding that is unrelated to the patient’s presenting complaint(s) or to the clinical indication(s) for the imaging examination that was performed.”"
Many participants commented that they learned things that day that challenged their assumptions about processes in other departments. The activity was captured by a graphic recorder (Figure 1). By the end of year one, the project team achieved consensus among participants, deciding to focus on communication of incidental findings.* The goals were to improve providers’ communication with patients about incidental findings and verify patients’ understanding of follow-up recommendations. The project team developed a preliminary toolkit that included a data-collection tool and resources to help hospital team leaders with implementation.

**Overcome Inertia**

In year two, 12 hospital teams piloted the measures as a demonstration project. Participating hospitals represented all regions of the state, including metropolitan and rural, teaching and non-teaching, and profit and not-for-profit hospitals. Upon enrollment, hospital teams agreed to implement a process to identify patients whose ED imaging studies reflected incidental findings requiring follow-up or treatment; to test measures through data collection and submission; and to provide input on the toolkit and data collection tools. Program activities, such as webinars, one-on-one calls, and collaborative check-ins, provided additional support and assistance to hospital teams. The project team took care to maintain the context for hospital teams moving into year two—that trying new things might not always unfold smoothly nor go as planned but learning and adapting to new information would continue, through collaborative activity, on the road to change.

During early collaborative discussions, hospital teams described their intended processes for capturing data on the measures. During the months that followed, hospital teams shared process modifications to improve data capture, reduce burden, and improve communication between departments. During that time, the project team regularly supported hospital teams to understand and express to their staff that ongoing learning and adaptation is an expectation and not a sign of failure.

Hospital team leaders shared challenges related to process variation among clinicians in reporting of incidental findings in radiology reports and communication between departments. These discussions allowed the groups to share new ideas and interventions to address local barriers.

**Learn and Adapt**

Some key findings among hospital teams included inconsistency in use or location of the term *incidental finding* in radiology reports, causing concern that this important information is not easily seen. This led some hospital teams to standardize use of the term. Others standardized the format of their radiology reports.

Hospital teams also identified gaps in communication between departments and among providers. Some hospitals in the project have deployed strategies to decrease final radiology report turnaround time, so ED providers can communicate results to patients prior to discharge. Another hospital implemented a voice recognition service that has improved the speed at which final reports are completed and made available to the ordering physician.

Processes and methods of communicating incidental findings to patients vary across hospitals and may be based on resources and workflow; methods include electronic, paper, in-person, and by telephone. In one hospital, the radiologist has face-to-face conversations with the ED providers about all incidental or other significant findings, while others have chosen to use real-time electronic communication between departments that allow for immediate follow-up on any issues. Reaching patients after discharge remains a challenge, so the ideal aim is to communicate this information before patients are discharged from the ED.

The next step in this journey is to explore potential measures to determine whether the patient follows and receives recommended follow-up. The project team continues to expand this work in Pennsylvania and is planning collaborative efforts with hospital teams to address the next steps in this challenging yet rewarding process.

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(continued from page 63) are just as important, and should be as foundational to improvement work, as knowledge of policies and best practices.

Skills in utilizing many tools and techniques for developing this expertise can be taught and many are available publicly with directions on implementation. One set of techniques, coined "Liberating Structures," is described by its creators as, "Easy-to-learn microstructures that enhance relational coordination and trust. They quickly foster lively participation in groups of any size, making it possible to truly include and unleash everyone."

Overcome Inertia

With information gathered to this point, project leaders can coach the team to narrow the focus. To get started, identify a piece of the overall process where it is possible to take actionable steps and identify short-term opportunities for intervention.

By acting, rather than continuing to simply discuss the issue in committees, the team forms an iterative process from which to learn and shape next steps (the Do phase of the PDSA method). New information will reveal new opportunities as the improvement work advances.

Project leaders should anticipate hesitation to act among the team when there is lack of clarity on the path forward. Teams often become “stuck” in the development phase and may feel unready to launch or roll out changes. The key is to gather just enough information to get started and then move to action with small but meaningful tests of change, making sense of what is learned, and continuing to adapt and move forward down a path with bends and curves.

Learn and Adapt

At this stage, teams begin to straighten out the bends in the path to change, by processing what they have learned and deciding what to do next (the Study and Act phases of the PDSA method). Improvement work is an iterative process. Project leaders should allow time for analyzing data and studying themes that have been observed in small tests and interventions. These discussions should be lively and held in an environment that encourages interactive dialogue and creative problem solving. Although untraditional structures may give the false impression of being "too loose," it is up to the project leader to allow for fun and excitement while maintaining focus on the objectives—action, learning, and new possibilities.

In addition, returning to the front line ("go and see") where the work is occurring provides the best understanding of the effects of small process changes. Teams can also broaden the assessment to ask what is working well and capitalize on existing solutions that might have already been unrecognized. With new understanding, the team focuses on establishing the next steps, rather than the final steps, as the cycles continue.

Conclusion

This conceptual framework can overlay any improvement process in any discipline, offering wider context for tackling complex challenges. Getting started—somewhere, on some piece of the process, where even small but meaningful change can occur—builds momentum for the journey. The skills needed throughout the framework can be taught and built upon. We recommend professional development for anyone in the role of project leader, change agent, or coach.

This framework is laid out in stages, each building on the previous and offering new information to overcome inertia by focusing on what needs to be done next rather than the long, looming road ahead. What ties the steps together, and perhaps can be seen as the peak of a hill, is bringing diverse voices together and capitalizing on the synergy when real face-to-face conversations occur.

Project leaders create the environment and extend the invitation to frontline experts—who may already have solutions for aspects of the larger challenge—building a culture that promotes learning and adapting to new information and creative ideas as possibilities for sustainable change.

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Acquiring Diagnostic Skill
Understanding the decision making processes used by experts

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How is an art expert certain that a famous painting is not an elaborate forgery?

How can an antiquities expert determine that an artifact is more contemporary than claimed?

Experts use a combination of rapid recognition and deliberate analysis, described as System 1 and System 2 thinking.\textsuperscript{1} System 1 thinking, also called “fast” thinking or intuition,\textsuperscript{2} involves pattern recognition as skilled practitioners quickly recognize typical situations. An art expert can rapidly recognize common forgeries and copies that appear genuine to the untrained eye.\textsuperscript{3} Even more baffling, an art expert may recognize a subtle anomaly that many others miss, noting something that just doesn’t seem right in a high-quality copy.

This ability to recognize the typical and detect anomalies is key to diagnostic skills in the clinical domain as well as in the art domain. This is that “gut feeling”\textsuperscript{2} or “Spidey sense” that clinicians describe when they walk into a room and “just know” that this patient is sick.

In some situations, however, System 1 thinking is not enough. When clinicians engage in a more deliberate analytic process to diagnose a patient’s condition, Kahneman refers to this as System 2 or “slow” thinking.\textsuperscript{1} Clinicians often generate hypotheses and
seek information to confirm or rule out each hypothesis, particularly when faced with a novel presentation, uncertainty, or complexity.

Determining the correct diagnosis for a patient has always been essential in healthcare, but recent attempts to understand how the diagnostic process occurs have received increased attention. Under what circumstances is immediate recognition of a pattern, an intuitive process, a good thing? Does it reflect experience and knowledge? Or is it error-prone, subject to bias and presumptions?

Conversely, when is a methodical approach more appropriate? Should the clinician work through an organized algorithm to ensure a thorough review of all potential diagnoses? Or is this process unnecessarily laborious when the correct diagnosis might be obvious?

**Novice and Expert Decision-Making in Diagnosis**

Both System 1 and System 2 thinking can be appropriate, depending on the experience level of the clinician, the complexity or rarity of the medical condition, and the time and resources available. However, descriptive studies suggest that novice and expert clinicians use different processes to develop diagnoses.

Novice clinicians tend to depend more on quantifiable, verifiable objective data, such as vital signs and laboratory test results. They seek affirmation from other members of the healthcare team—explicitly or implicitly—to verify their assessments.

Experts generally have more confidence in their assessments. They develop hypotheses based on both objective data and less quantifiable information, such as changes in mental status, abnormal skin temperature or color, or an “ill appearance.” They respond to their own gut feelings. Experts sequentially test and revise their assessments and refine their diagnoses based on the patient’s response to interventions, as an ongoing process. Experts are sensitive to circumstances in which test results or the patient’s evolving medical condition violates their expectations.

For experts, even System 2 thinking is driven by their own experiences, as they develop and test hypotheses based on recognition of typical and anomalous data. An expert’s experience informs what he or she considers relevant and useful data to assess, track, and test to form hypotheses. Studies of expertise across a range of domains suggest that exposure to many cases or a “deep experience-base” is needed to develop these critical skills.

Although experts appear to move between System 1 and System 2 thinking seamlessly, it is sometimes assumed that the methodical, systematic approach to diagnosis is inherently the better process. Indeed, that is how medical students and residents are taught. For novices, this may be necessary because they have not yet built up a repository of clinical experiences to support a sufficient variety of patterns needed for recognition. Training and testing for physicians often involves developing an extensive and thorough “differential diagnosis” with justification or rebuttal of a wide variety of possible diagnostic options (e.g., congenital, traumatic, infectious, neoplastic). The stepwise exercise may be valuable for a novice, but it can be frustrating for an expert when faced with an immediately recognizable condition she has seen and treated many times before.

**Helping Clinicians Improve their Skills**

If experiences can help novices develop expertise, can opportunities for experiences be optimized? Can educational experiences help novices deepen both System 1 and System 2 knowledge? Conversely, can experts develop techniques to avoid premature diagnostic closure?

Simulation, or training and practice in lifelike situations, can be a useful option.

Broadly, simulation offers the ability to provide directed practice during experiences that support identifying and managing a variety of medical conditions at the relative convenience of the learners and faculty, without direct risk to patients. Simulation is effective enough to have gained recognition as “a central thread in the fabric of medical education.”

Simulation-based education ranges from practice for isolated skills to participation in complex immersive scenarios. Simulators (e.g., simulation devices) may be high or low technology, physical, virtual, human, or combinations. Simulators are incorporated into simulations. Current limitations in the ability of simulators to demonstrate evolving changes in a patient’s mental status, skin color, or lesions and rashes may be mitigated with the growth of simulation incorporating augmented reality.

Simulation-based facilitated experiential learning, including debriefings, is typically implemented in safe and supportive environments that have been proven to help students learn better. Simulations can therefore provide opportunities to increase the learners’ exposure to recognizable and retrievable diagnostic patterns, as well as opportunities for faculty to elicit and reinforce correct diagnostic assessments.

For example, trainees at the Children’s Hospital of Philadelphia participate in simulations designed to help them distinguish different types of shock and cardiac arrhythmias. Trainees at the ORL Emergencies Boot Camp participate in simulations designed
to help them recognize and manage “cannot intubate, cannot ventilate” patient care emergencies; one participant published a testimonial that the lessons he learned saved a patient’s life. Much contemporary literature focuses on strategies intended to prevent erroneous diagnoses, with the implication that the weaknesses of humans attempting to achieve correct diagnoses can be overcome if sufficient constraints are implemented. But it seems obvious that a focus on teaching learners what their limitations are might not result in enhancing their strengths. Investigators have demonstrated that the performance of learners who are debriefed about their successes as well as their failures improves significantly compared with the performance of learners who are debriefed only about failures. Other research suggests that debriefing strategies that help novices see what experts noticed and how experts made sense of the situation support skill acquisition. Contemporary Safety-II principles, which seek to “enable things to go right more often,” align with the premise that providing appreciation and reinforcing successful identification of diagnostic patterns will improve the diagnostic process. Simulation-based training can promote effective use of System 1 and System 2 thinking because it provides an opportunity to extend a clinician’s experience base and encourages reflection with timely feedback and exposure to expert perspectives.

Developing Expertise

Determining the correct diagnosis for a patient may be extremely easy or incredibly difficult. Simulation provides a mechanism that supports directed practice. The debriefing provides a mechanism to amend incorrect diagnoses, optimize correct diagnoses, and expose the learner to expert diagnostic processes. Reinforcing correct diagnoses and providing a view into expert thought processes are important components of helping novices develop expertise and helping experts fine-tune their skills.

Notes

Improving Diagnosis: Action and Insights

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The articles in this special issue of the Pennsylvania Patient Safety Advisory offer a glimpse into the depth, breadth, and complexity of the diagnostic process. From a discussion with subject matter experts about how to define the term diagnostic error to an analysis reflecting all potential failure points along the continuum of the diagnostic process, the content illustrates how some aspect of diagnosis is involved in nearly every healthcare encounter.

Theory and conceptual understanding of this topic are important, but they are not enough. Understanding must be translated into actions that lead to solutions to improve diagnosis and reduce harm and death from diagnostic error.

The following highlights from articles in this issue provide actions you can consider taking to improve diagnosis in your setting:

- Use the modified DEER taxonomy to classify failures in the diagnostic process using existing sources of data, such as incident reports, patient complaints, quality reviews, and malpractice claims. Identify patterns of failure to focus on and prioritize aspects of the process for learning and improvement.

- Understand that while health information technology (health IT) can improve efficiency and reduce the risk of error, it can also contribute to problems in processes such as laboratory testing. Engage a multidisciplinary team of experts to identify and correct potential health IT-related hazards in your laboratory testing processes.

- Acknowledge that some patients still believe that “no news is good news” when it comes to their test results. Engage patients as members of the diagnostic team, educate them about their roles, and empower them to follow up with you if they do not receive their results.

- Recognize the importance of gathering and communicating information related to suicide risk assessment. Assess your processes for collecting complete information from patients and ensuring thorough communication between providers. Improvements in these two areas are crucial for a more accurate and timely diagnostic process for this vulnerable patient population.

- Review processes for communicating incidental radiology findings among providers and with patients to ensure that recommended testing and treatment are pursued in a timely fashion. Incidental findings can be a source of significant patient harm or death if missed or not communicated properly.

The opportunities are limitless. Become curious and seek to understand the vulnerabilities in your diagnostic processes. Trial small tests of change—you will gain insights by trying something new that you would not have gained by simply thinking about the problem.

Acknowledging that a concerted focus on this issue is long overdue, the Pennsylvania Patient Safety Authority recently launched the Center of Excellence for Improving Diagnosis (CoE) to catalyze awareness and action throughout Pennsylvania. Through our key objectives of knowledge, connection, and action, the CoE team will lead, guide, and support healthcare facilities and systems, providers, patients, and all interested stakeholders to improve diagnosis in Pennsylvania and beyond. The desired future of a more accurate and timely diagnostic process begins with all of us.

Think of one way you can make a difference. Now do it.

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