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

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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\(^13\)—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* 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

*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).\(^18\)

\(^{1}\)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.\(^\text{20}\) 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 score\(^\text{22}\) 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>
<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)

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>Access/ Presentation</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.*</td>
</tr>
<tr>
<td>History</td>
<td>Patient underwent a <strong>D&amp;C</strong> (<a href="#">dilation and curettage</a>) 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>Physical Exam/ Assessment</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.*</td>
</tr>
<tr>
<td>Testing</td>
<td>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 <strong>CT</strong> (<a href="#">computed tomography</a>) 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>
</tbody>
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**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.**

**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.**
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.

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

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.

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.
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 hypoglycemia, 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. 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.

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, care areas identified by reporting healthcare facilities do not necessarily reflect the healthcare provider or team “responsible.”
Figure 2. Percentage of Diagnostic Process Failure Events by Care Area (N = 138)

- Surgical/Procedural: 21.0% (n = 29)
- Emergency Department: 16.7% (n = 23)
- Laboratory: 10.1% (n = 14)
- Radiology: 10.1% (n = 14)
- Medical/Surgical Units: 8.7% (n = 12)
- Specialty Units: 7.2% (n = 10)
- Critical Care Units: 8.7% (n = 12)
- Outpatient Clinics & Practices: 5.8% (n = 8)
- Intermediate Units: 5.8% (n = 8)

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.

Figure 3. Number of Diagnostic Process Failure Events by Medical Condition (N = 138)

- Cancer: 31 events
- Other*: 28 events
- Vascular: 23 events
- Infectious Disease: 21 events
- Complication†: 20 events
- Unable to Determine: 11 events
- Orthopedic: 8 events

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><strong>Diagnostic Team</strong></td>
<td></td>
</tr>
<tr>
<td>The new 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><strong>Testing</strong></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><strong>Hypothesis Generation</strong></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><strong>Monitoring/Follow-up</strong></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>
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</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.

**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.

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.

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 a new 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.*
The next organizational challenge: finding and addressing diagnostic error.


9. Also available: https://doi.org/10.1515/dx-2017-0027. PMID: 29536936


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