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Asking Patients to Close the Loop on Diagnostic Imaging Test Results

By Susan Carr, Senior Writer

This article is the second part of a two-part feature on Act 112. Catch up on the first part in the March 2019 issue of ImproveDx.

> *Claims of difficulty in contacting the treating or referring physician will garner little sympathy from the public when they are able to reach any one of their friends in mere seconds…they will not accept that you cannot do the same.*
>
> — Michael Raskin, MD, JD[1]

To prevent missed and delayed diagnoses, the state of Pennsylvania requires imaging providers to directly notify patients when an unexpected test result, though not an emergency, warrants being reviewed by a physician.

Patient notification is one way to keep diagnostic test results from falling between the cracks, especially when unexpected findings indicate a new health problem, but it is arguably a workaround for a persistent patient safety problem. Pennsylvania's Patient Test Result Information Act, or Act 112[2], which went into effect in December 2018, is arguably just such a workaround.

Act 112 was inspired by stories of patient harm due to lost test results and delayed diagnosis. It requires patients be notified within 20 days following certain imaging exams if an abnormal finding indicates they should seek medical advice within 90 days. Organizations in Pennsylvania, including the medical society and hospital association, are working to clarify what the law requires. Meanwhile, a program at Penn State Health's Milton S. Hershey Medical Center illustrates the challenges and benefits of direct patient notification.

Backstops and Homing Pigeons

Patients may find it hard to understand why radiologists, in command of medicine's most amazing technologies, can't reliably deliver simple communications.[1] In fact, patients are sometimes used to solve the problem by providing an alternate channel or acting as a backstop for physician-to-physician communication.

Partnering with patients to close this communication gap is not a new idea.[3,4] Direct communication with patients offers benefits but will not simplify an inherently complicated process. Learning about a possible new health problem will motivate some but not all patients to see a physician. Some clinicians worry about patients discovering they may have a serious medical problem without an explanation or

support from a knowledgeable provider. Patients often don't understand the radiologist's role or the relationships among the clinicians involved. Abnormal findings come with different levels of certainty and concern. It may be difficult for any of the players involved to communicate across different provider networks. Last but not least, growth in the number of diagnostic tests means that primary care physicians, among others, receive more messages, alerts, and results than they can manage.

In emergency medicine, there may be neither a referring nor known primary care physician to receive notice about the incidental finding. The patient or a family member may be the only person available to receive the report and recommendation to seek follow-up. Michael Bruno, MD, who practices radiology in a large academic department in Pennsylvania, reflects on situations where there is no physician to whom the ED can send the incidental results. Bruno says we act effectively as if these patients were "homing pigeons," entrusted with delivering vital information that otherwise lacks a carrier.[5]

Communication is especially unreliable for results of outpatient diagnostic imaging exams that fall somewhere between critical and expected. Although there is no guarantee that a critical finding will be acted on immediately, results that indicate a potential problem, different from what was expected, are particularly prone to falling between the cracks.

Documentation Does Not Equal Communication

In a simpler time, sending a report to the ordering physician satisfied the radiologist's duty. Case law and analysis of recent malpractice claims show that is no longer enough. Transmission of a final report may fulfill the standard of care, but radiologists are now held responsible for knowing that communication has been received and had the desired effect, i.e., for closing the loop.[4,6]

In a 2005 revision of Practice Guidelines for Communications, the American College of Radiology (ACR) introduced the term "non-routine communications," to acknowledge that some situations fall outside predictable or traditional parameters. The current guidelines, revised in 2014, say the final report represents "definitive documentation" of the study results, not necessarily the definitive means of communicating those results.[1,7(p3)] Under "non-routine communications," the guidelines describe situations that warrant further action, proper documentation of non-routine transmission, and recommended methods for alerting the treating or ordering physician of concerning results. The ACR states that, "in certain situations [i.e., self-referred or third-party-referred patients], the interpreting physician may feel it is appropriate to communicate the findings directly to the patient."[7(p6)]

The process of communicating imaging results offers many opportunities for failure: Was the report or alert received by the intended physician? That receipt was documented doesn't necessarily mean the report was read. Knowing that the report has been read doesn't guarantee that the patient will know the results or receive further examination or care.

Make No Assumptions

Timothy Mosher, MD, chair of radiology at Penn State Health's Milton S. Hershey Medical Center, thinks that engaging patients in the process of test results and diagnosis in general will help. "Often, patients assume the lack of communication is an affirmation that there's nothing wrong. There's an education component to this."

Physicians, too, sometimes mistakenly assume the reporting process and alert systems are reliable. Mosher says, "There's an overreliance on the system. Patients may think no news is good news. Radiologists may think their report was received and read. Paraphrasing a classic quotation, Mosher points out, "The biggest problem in communication is assuming that it actually occurred."

Each health system in Pennsylvania will have to figure out how best to comply with Act 112, and each one will face challenges from its own perspective. Mosher's Hershey Medical Center already has experience with an innovative program designed to ensure proper follow up of unexpected findings. Hershey's radiology department still views Act 112 as challenging to implement, but the infrastructure it has in place gives it a leg up and may be helpful to other systems as they plan for Act 112.

Failsafe

Hershey Medical Center's approach to reliable communication of incidental findings, "Failsafe," uses significant information technology (IT) and human resources to ensure that patients receive follow-up care. Although now a large program used in all departments that offer imaging at Hershey Medical Center, Failsafe is finely tuned to solve a specific problem efficiently.

Radiologist Michael Bruno (of the earlier homing pigeon metaphor) wanted to improve communication about incidental findings for patients in the emergency department. He knew patients were often lost to follow-up for various reasons, including the reality that ED patients are focused on immediate needs and may not fully understand that a different health problem needs attention. The incidental finding should go to the patient's primary care physician (PCP), for follow-up. In Bruno's experience, many ED patients can't provide the name of their PCP, don't have one, or have more urgent things to think about.

Working with a team of emergency physicians, PCPs, department chairs, the chief quality and medical officers, plus an attorney, Bruno created Failsafe, which was first implemented in 2012. Initially, patients with incidental findings that warranted follow up but were not urgent enough to have been addressed in the ED received a letter instructing them to see a primary care physician. PCPs at Hershey pledged to see patients who did not have their own PCP. After the department had issued approximately 500 Failsafe letters, Bruno called a sampling of patients to ask for feedback and learned that the program had been ineffective, due largely to misunderstanding. Among the patients he was able to reach, some had ignored the advice to seek care and others had discarded the letter, assuming it was irrelevant or a bill.[8]

Adding personal contact by telephone transformed the program. Nicole Seger Swope, RN, manager of patient safety at Hershey, joined Failsafe in 2016 and began following up letters with personal phone calls to patients. Swope and Megan Rudy, who joined Failsafe in 2018, call patients to make sure they understand the letter and to encourage them to make an appointment to see a PCP. The letter includes a pre-populated release form to make it easy for patients to consent to have their health information sent to the PCP. Including the consent form does more than facilitate the process. Swope believes it provides visibility—a surprise benefit—and catches patients' attention. She says, "The yellow 'sign here' flag distinguishes our letter from others patients get from Hershey—bills, for example."

Contacting patients by phone provides other benefits: information, feedback, and relationship-building. Swope reports that very few patients among the hundreds she and Rudy have called report having been made anxious by the letter. They have been able to update contact information for patients, field complaints, triage immediate care needs, and connect patients to scheduling services. The calls are

scripted and a number of the situations they encounter—insurance questions, for example—have an algorithm for efficient response. Failsafe is not limited to one call. Swope and Rudy will call patients again to see if the they have seen a PCP and to learn if the diagnosis changed and how things turned out.

During each call, the nurses enter data and notes directly into an electronic system. Failsafe's IT component is handled through Hershey's safety-event reporting system. With programming provided by Andy Moyer, RN-BC, BSN, a clinical informatics specialist in Hershey's patient safety department, customizable modules in the system enable data acquisition and reporting, as well as automation of many parts of the process. When the system prompts the nurses that it's time to call a patient, they have the information they need and are confident that the call is necessary.

Preparing for Act 112

Hershey's work on Failsafe has provided some degree of readiness for Act 112, but the new law requires new systems to be developed and poses questions that will take some time to answer. Bruno reports, "Failsafe doesn't satisfy everything in the law, so we had to set up a parallel process."

As information services director for medical image management at Hershey, Jonelle Thomas, MD, works with a team to develop systems for both Failsafe and Act 112. Thomas is also involved in Failsafe daily. She helps to determine, for example, if patients have received follow-up care between the time they were entered in the Failsafe system and when the letters are mailed, which can be as much as one week later.

Thomas and a team that includes IT, radiology, cardiology, and obstetrics meet frequently to work on Act 112 implementation. With the first Act 112 letters expected to be mailed in May, this is still a new program. Some of the processes Hershey has in place for Act 112 provide a good start but may be replaced with more sophisticated approaches as time goes on. Thomas reports having looked into using natural processing to help sort Failsafe and Act 112 into separate worklists but found the cost was prohibitive for the moment.

Thomas sees value in patient engagement efforts such as Act 112:

> *It's important to encourage patients to take an active role in their care. This gives them that engagement in radiology. A lot of patients didn't really know that radiologists are physicians. Radiology has been kind of a black hole to them.*

Although Failsafe and Act 112 both address incidental findings by directly notifying patients, the two approaches are distinctly different. Act 112 is triggered by exam type. Failsafe is triggered by a radiologist's judgment. Act 112 requires an audit to demonstrate an organization has complied with the law. Failsafe is controlled by Hershey, goes above and beyond the standard of care, and does not require external validation. Act 112 excludes imaging provided in the ED. Failsafe's origins are in the ED and in Bruno's awareness that ED patients are especially prone to missing out on follow-up. Patients whose incidental findings are captured by Act 112 receive a letter with more detail (ordering provider, date of exam, etc.) than Failsafe patients, but they will miss out on the personal attention of a nurse who calls them at home. That is the most obvious and perhaps consequential difference between the two programs at Hershey.

Mosher and others at Hershey know from experience that Act 112's letter to patients will help close the communication loop but, in some cases, it still won't be enough. Looking to future improvement, Mosher says, "We recognize we must go beyond simple notification. We're going to comply with the law, but we want to go the next step longer term."

Another important difference is that Act 112 is new, requiring hospitals across Pennsylvania to develop new processes, workflows, and data-tracking systems. The original wording of the law has led to uncertainty and confusion. Failsafe is a mature program that has a track record and history of having learned from earlier implementation. Over the next few years, imaging providers will learn how best to implement Act 112, and some number of Pennsylvania citizens will receive important follow-up care and diagnoses they might otherwise have missed.

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Diagnostic Quality Heads ECRI's Patient Safety List

In 2018 ECRI Institute released its list of the *Top 10 Patient Safety Concerns for Healthcare Organizations* and named diagnostic errors as the number one concern. In the report ECRI noted that diagnostic errors are "challenging to measure and learn from because they often go undetected until after the patient leaves the hospital or emergency department (ED). Healthcare organizations should capture data on diagnostic errors and near misses. Sources may include the event-reporting system, malpractice and payment claims, patient complaints, patient surveys, autopsies, and record reviews. The organization can then make changes to address gaps. Discussing the topic in multiple forums, such as grand rounds and debriefings, can support ongoing analysis and learning for clinicians."

Each year, ECRI develops the Patient Safety Concerns list by reviewing events in the ECRI Institute Patient Safety Organization (PSO) database, PSO members' root-cause analyses, medical malpractice data, research requests, and finally, votes from a panel of experts from inside and outside ECRI Institute.

When ECRI released their list for 2019 last month, it was notably different than the 2018 list. Rather than identifying the broad topic of diagnostic error, the new list included specific aspects of diagnostic quality that lead to patient harm and diagnostic errors. Bill Marella, executive director of ECRI's PSO Operations and Analytics notes, "Diagnostic quality is an aspect of most everything on the list. Ensuring that accurate and timely diagnosis happens, and that it's communicated effectively, is so important. When that doesn't happen it's almost impossible for anything else to go right."

Among the diagnostic quality concerns on the 2019 list:

#1 Diagnostic Stewardship and Test Result Management Using EHRs

"When diagnoses and test results are not properly communicated or followed up on, the potential exists to cause serious patient harm or death… To help 'close the loop,' providers must not only fully utilize an EHR designed to meet their practices' unique needs, but also recognize the importance of clear communication, both among caregivers and between caregivers and patients."

ECRI's *Partnership for Health IT Patient Safety* developed a set of recommendations around safe health practices for closing the loop on test results.

#6 Detecting Changes in a Patient's Condition

"Failure to detect changes in a patient's condition is an ongoing patient safety concern across the continuum of care. Problems can arise within a care unit and during transitions of care within a facility and from one facility to another."

#8 Early Recognition of Sepsis Across the Continuum

"Healthcare workers throughout the continuum of care must be able to recognize sepsis… To facilitate timely diagnosis and management, healthcare organizations across the continuum should have protocols for response when sepsis is suspected, much as they do for chest pain. Organizations may use checklists, tools, or algorithms to support the response."

More than 5,000 healthcare institutions and systems worldwide—including four out of every five U.S. hospitals—are members of ECRI Institute and use their reports and product evaluations to guide their operational and strategic decisions. ECRI Institute joined the Coalition to Improve Diagnosis in 2018.

According to Marella, the ECRI Institute crafts its patient safety list with a C-suite audience in mind, "the list helps readers make the case internally with their C-suite that these are issues that are worth their attention." ECRI hopes the document gets distributed to the board of directors at healthcare organizations and that the board uses it to drive their quality agenda.

Paul Anderson, ECRI's director of risk management publications notes, "it's worth committing our time and energy to fighting the problem of diagnostic errors because we can improve patient safety, and if we're focusing on the top things on the ECRI lists maybe we can have a big impact."

Executive Briefs for the 2018 and 2019 *Top 10 Patient Safety Concerns for Healthcare Organizations* are available on ECRI's website.

Patient Voices Make a Difference

Last June, more than 40 congressional staffers assembled at a briefing on Capitol Hill to listen to heartbreaking stories from three people whose lives were drastically changed as a result of diagnostic errors. Sue Sheridan, director of patient engagement at the Society to Improve Diagnosis in Medicine (SIDM), shared the story of her late husband, Pat, whose untimely death was caused by a failure to communicate the results of a pathology report that showed a malignant tumor. Ciaran Staunton spoke about his young son, Rory, whose scraped arm and strange symptoms quickly turned into sepsis, which was not diagnosed quickly enough to save him. Mick Night told the story of his son, John Michael, who suffered a stroke that left him permanently unable to speak or move his limbs, a condition which could have been prevented with timely diagnosis and administration of a one-cent aspirin.

While there were many speakers at the event, the personal stories of harm and the toll taken on these families showcased for attendees the imperative to do all we can to improve the diagnostic process.

All three families, touched by diagnostic error, came together to share their stories and advocate for increased research funding in diagnostic quality and safety. For Sue, Ciaran, and Mick, the stories were difficult to share, but they were connected and inspired by a desire to make sure the errors that impacted their families do not happen again.

As psychologist Julian Rappaport explains, "people who seek either personal or community change often find that it is very difficult to sustain change without the support of a collectivity that provides a new communal narrative." Stories elevate the work that we do; they are an essential tool in any social movement. At the core of SIDM's mission is the need to incorporate patients not only as storytellers, but also as active participants in the diagnostic process and partners in research, policymaking, education and quality improvement.

With this in mind, SIDM showcases families who have been harmed by missed or delayed diagnosis through an online story bank. These stories span the spectrum of diagnostic errors in medicine and underscore the fact that these errors happen to men, women, children, seniors—all people, regardless of race or socioeconomic status. The stories that families are willing to share cover different types of breakdowns in the diagnostic process, such as delays in diagnostic testing, incomplete history-taking, communication failures, and cognitive biases. The stories also demonstrate that diagnostic errors can involve any disease or chronic condition, from sepsis to lung cancer, missed stroke, and Lyme disease.

The SIDM Story bank ensures the voices of patients and their families inform diagnostic improvement efforts and brings the magnitude of the issue to life. SIDM seeks to highlight stories that illustrate the physical and emotional harm caused by preventable errors during the diagnostic process. Dr. Rappaport notes that "the goals of empowerment are enhanced when people discover, or create and give voice to, a collective narrative that sustains their own personal story in positive ways." Many of the individuals profiled in the story bank have become advocates themselves, participating in Patient Family Advisory Councils, joining SIDM Patient Partners, and working on behalf of organizations promoting improved diagnosis in a specific condition.

In addition to using patient stories to highlight the need to improve diagnosis, it is also imperative to include patients and families as active partners in program design, implementation, and evaluation.

Together with patients, SIDM hopes to find solutions that increase diagnostic accuracy and timeliness and ultimately ensure the best possible health outcomes for patients.

From the Field: Call for Abstracts

The Society to Improve Diagnosis in Medicine (SIDM) is seeking submissions for high-quality posters and oral abstracts that contribute to and advance the field of diagnostic quality for DEM2019.

Join us in the Nation's Capitol for the Society to Improve Diagnosis in Medicine (SIDM)'s 12th International Diagnostic Error in Medicine Conference (DEM2019). We will come together to showcase developments in the field of diagnostic quality and safety, and focus on the unique role of public policy in driving advances in research, quality improvement, and medical education.

This year's theme is: *Shaping Policy, Improving Practice.*

The DEM2019 Program Planning Committee seeks submissions for scientific, education, clinical vignette, or practice improvement abstract proposals. The deadline to submit abstracts is **June 14, 2019 at 11:59pm EST**.

Abstract submissions should contribute to and advance the field of diagnostic quality and be relevant to SIDM's Strategic Priorities. DEM2019 is a self-accredited Patients Included conference especially

interested in innovative, patient-centered abstracts that are co-developed and delivered with patients and family members.

DEM2019 brings together physicians, patients, nurses, healthcare professionals, researchers, institutional leaders, policymakers, educators, students, and residents to highlight and share recent innovations to improve the diagnostic process.

Oral presenters will be chosen and notified by the review committee from the pool of abstract submissions by late August. All accepted presenters will be required to register for DEM2019. To review the abstract submission guidelines, visit our webpage. For any additional questions about submissions, contact SIDM at DEMSpeaker@improvediagnosis.org.

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