



## **New Pennsylvania Law Requires Patient Notification for Abnormal Imaging Results**

By Susan Carr, Senior Writer, *ImproveDx*

*You are receiving this notice as a result of a determination by your diagnostic imaging service that further discussions of your test are warranted and would be beneficial to you. The complete results of your test have been or will be sent to the health care practitioner that ordered the test or tests. It is recommended that you contact your health care practitioner to discuss your results as soon as possible.*

*– Patient notification required by Pennsylvania’s Act 112*

The state of Pennsylvania wants to make sure patients who have a “significant abnormality” on an imaging exam are notified that they may require medical follow-up. A new law requires imaging service providers to notify those patients directly, in addition to sending the report to the health care practitioner (HCP) who ordered the exam.

The law—the Patient Test Result Information Act or [Act 112](#)—addresses a communication and patient safety problem that has been difficult to fix. A significant number of patients whose serious conditions are detected by imaging never get notified and may suffer the consequences of delayed diagnosis.

For years, people have tried different ways to “close the loop” and ensure that physicians receive test results promptly, especially when there is a “critical finding” that warrants prompt follow-up. Despite sincere efforts, the problem persists. With Act 112, legislators and citizens in Pennsylvania have sent a message to the imaging community and HCPs: patients have the right to know their results and may provide a solution to the communication problem.

Providing patients or a designated surrogate, such as a family member or friend, with direct access to their records—imaging results, laboratory tests, clinical notes, prescriptions, and more—is a growing trend. Pennsylvania’s new law is unusually proactive, potentially preempting the ordering HCP’s consultation with the patient. It’s one thing to make records available to patients, allowing them to choose when and whether to access the information. It’s another to push notification of problems to patients directly, without the counsel of a healthcare professional. If the law performs as intended, it will save lives and result in easier and more effective treatment for others. It is also causing the medical community to implement new systems and cope with legal uncertainty; Act 112 may also disrupt established professional relationships and patterns of practice.

Act 112 was signed into law by Gov Tom Wolf in October 2018, nearly four years after it was first introduced by state Rep Marquerite Quinn. When she filed the legislation, Representative Quinn [reported](#) that she did so because she knew “two situations in which abnormal test results were not communicated to the patient, resulting in the unnecessary death of both people.”

### **Grace Period Offered by Department of Health**

Acknowledging that Act 112 represents a sea change for providers, Pennsylvania’s Department of Health (DOH) announced shortly before the law went into effect on December 23, 2018, that it would offer a grace period to allow organizations to prepare to comply with the law. Although imaging facilities must begin to develop policies for compliance immediately, the department will not issue sanctions for non-compliance until after it has issued final “clarifying guidance,” expected later in 2019. Until that time, if the DOH finds a facility has not complied with the law’s requirements, including patient notification, it will issue a letter with helpful information instead of sanctions, the details of which have also not yet been determined.

The [Pennsylvania Medical Society](#) and the state’s [Hospital + Healthsystem Association](#) are working to create standardized guidelines to help clarify the legislation, which they will submit to the DOH for consideration.

### **What the Law Requires and Questions It Raises**

The implementation of Act 112 is in its infancy, and it is already clear that health care and imaging providers face many questions as they prepare to comply with the law. There was little coverage in local media or public debate of the proposed legislation as it worked its way through the state legislature. As implementation proceeds, and patients begin to receive notification, other questions may arise.

The scope of Act 112 is narrow, and its requirements are specific. In addition to the language quoted at the beginning of this article, entities must provide patients with the name of the HCP who ordered the test, the date of the test, the date when results were provided to the ordering HCP, and how the patient can obtain the full radiology report. Patients must receive that information either in person at the time of the exam or by mail, email, fax, or through access to a patient portal within 20 days of when the report was provided to the ordering HCP.

The Act’s exemptions have raised questions. Imaging services provided to inpatients and patients in the emergency department are exempt, as are “routine obstetrical ultrasounds” performed to monitor fetal development and “diagnostic radiographs,” understood to mean x-rays. It is not clear whether the Act applies to imaging for patients under observation in hospitals. The exemptions may have been an attempt to limit the burden of implementation on the healthcare system, but leaving all x-ray exams outside the scope of the Act means that many patients with incidental findings will not have the safeguard of direct notification. The status of nuclear medicine exams, endoscopy and echocardiograms needs to be clarified.

Act 112 states that the notification requirement is activated “when, in the judgment of the entity performing a diagnostic imaging service, a significant abnormality may exist.” According

to the legislation, a “significant abnormality or anomaly” is a finding that “would cause a reasonably prudent person to seek additional or follow-up medical care within three months.” Attorneys at Post & Schell, PC, a Pennsylvania-based law firm serving highly regulated industries, including health care, point out in a digital [news alert](#) that agreement among providers about what constitutes a “significant abnormality or anomaly” cannot be assumed. They see increased malpractice risk in situations where “the healthcare provider considers a finding significant, and the diagnostic imaging service entity did not report to the patient.”

Also in an online [alert](#) to providers, attorneys at White and Williams, LLP, a law firm with offices in six states, including Pennsylvania, point out that the law may reinforce a natural tendency for regulated individuals and organizations to err on the side of caution. If imaging entities protect themselves by expanding their definition of “abnormal,” more patients than necessary will be subjected to fear and anxiety.

The Act goes only as far as notification of the patient. There is no guarantee that patients will understand what the notification means and contact their HCPs for follow-up.

### **Result Reporting Systems Resist Improvement**

While no one expects Act 112 to be the silver bullet that solves all communication problems in radiology, it is a notable attempt.

Studies<sup>1,2</sup> performed at ambulatory clinics associated with the Michael E. DeBakey VA Medical Center in Houston demonstrate that making significant improvements in reporting test results is an ambitious goal.

A study published in 2007<sup>1</sup> evaluated the rate at which physicians received and acknowledged notification of critical imaging results in a system using alerts delivered through the sites’ electronic medical record (EMR). Although fewer critical results fell between the cracks than in studies performed at sites using non-computerized alerts, the DeBakey study still found that 4% of critical results had not been acknowledged four weeks after reporting. The authors were aware of at least one system that reported better results—2% lost to follow-up rate—by adding personal notification by telephone to automated alerts.

At the time of the 2007 study, primary care physicians in the relevant sites received up to 40 radiology reports per week, in addition to other results and reports. Providers across the institution were receiving between 20 and 60 alerts per day.<sup>1</sup>

The second study,<sup>2</sup> also performed at DeBakey and published two years later, measured how many reports of critical imaging test results received follow-up action as well as acknowledgement of the alert or report. HCPs were notified about critical results via an EMR alert or via access to the radiology report. The authors hypothesized that “...an EMR that facilitates the transmission and availability of critical imaging results through either automated notification or direct access of primary report would eliminate”<sup>2(p1579)</sup> the problem of reports being missed by HCPs,” which it did not. Automation with computerized alerts did not provide the reliability the authors were hoping for. In fact, they found that timely follow-up with

patients was a problem even in cases where the HCP acknowledged receiving the report. The second study found that 7.7% of critical results lacked follow-up vs 4% in the earlier study. This study included double reporting (two HCPs) of some alerts, which degraded rather than improved follow-up.

### **Pennsylvania's Center of Excellence for Improving Diagnosis**

Rebecca Jones, at the [Pennsylvania Patient Safety Authority](#), believes that “improving communication of test results is one of our biggest areas of opportunity when it comes to diagnostic excellence.” Jones serves as director of both the Authority’s innovation and strategic partnerships and its Center of Excellence for Improving Diagnosis. She reports that the Center is working with Pennsylvania hospitals to “develop a qualitative understanding of the current level of performance regarding diagnostic safety,” including their readiness for Act 112. Over time, the Center will help organizations identify areas of challenge and success. Jones expects hospitals and health systems that already have sound processes in place for notifying patients about incidental findings may be in good shape to fulfill Act 112’s requirements. The Center will encourage those organizations to share best practices and advise others to help improve diagnosis throughout the state.

*Stay tuned... the May issue of Improve Dx will feature further coverage of Pennsylvania’s Act 112, to include the perspective of patients and organizations about implementation.*

#### References

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2. Singh H, Thomas EJ, Mani S, et al. Timely follow-up of abnormal diagnostic imaging test results in an outpatient setting: are electronic medical records achieving their potential? *Arch Intern Med.* 2009;169(17):1578-1586.

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### **Learning Collaborative Applies QI to Diagnostic Error**

While quality improvement (QI) techniques have resulted in many changes in health care, using QI to drive improvements in diagnosis is a developing field. In partnership with the Institute for Healthcare Improvement (IHI), the Society to Improve Diagnosis in Medicine (SIDM) brought six leading medical centers together into the [SIDM/IHI Learning Collaborative](#) to apply QI to diagnostic quality and safety. With a grant from the [Gordon and Betty Moore Foundation](#), SIDM and IHI helped the centers apply [the IHI Breakthrough Series](#) methodology to develop specific interventions designed to reduce diagnostic error.

At [MedStar Health](#) in Washington, DC, clinicians utilize the CHEST guideline-based VTE Risk Advisor within Cerner’s MedConnect application. Despite a mandate requiring the use of this tool since 2016, rates of potentially preventable VTE are higher than expected. To improve VTE

risk assessment by internal medicine physicians at this large academic medical center, the MedStar team sought to improve clinician understanding of the VTE Risk Advisor risk assessment tool. Concordantly, they implemented small tests of change using a paper-based VTE risk assessment tool among surgeons at a community hospital where the VTE Risk Advisor was not yet in use.

At [University of Michigan's C.S. Mott Children's Hospital](#) in Ann Arbor, Michigan, the MDM portion of the EHR is the only surrogate that captures the cognitive aspects of decision-making. The Michigan team sought to field test a highly limited scope intervention in the form of a scripted, structured, patient problem-representation template. Their goal was to demonstrate that by structuring the MDM of the pediatric emergency department visit notes in a certain way through a template, the team could potentially influence, affect, or at least better monitor the “in the moment” diagnostic decision-making process of a pediatric emergency department patient encounter.

At [Nationwide Children's](#) in Columbus, Ohio, the team introduced a framework for diagnostic deliberation — the “diagnostic time-out” — during the collaborative in efforts to circumvent cognitive biases that may interfere with medical decision-making. The diagnostic time-out asks the medical team to pause and structures the discussion with two questions: 1) *What are the two or three most likely diagnoses for this patient?*, and 2) *What is at least one life threatening/more severe diagnosis that we must consider for this patient?* The team hypothesized that by fostering an environment to support active discussion regarding diagnosis, they would see improvement in the differential diagnoses.

At [Northwell Health](#) on Long Island, New York, the team predicted that using “teach-back” routinely during the patient encounter would improve communication and decrease diagnostic error. They developed and deployed PDSA trials to reduce diagnostic errors in ambulatory, emergency, and inpatient clinical settings by focusing on the roles of the patient, family and caregiver. The team effectively carried out enhanced patient communication using a scripted teach-back intervention where providers were asked to explain a diagnosis to a patient and have the patient repeat back what they understood about their diagnosis/diagnoses at the end of the encounter.

At the [University of San Francisco](#) in San Francisco, California, the team found they did not have a system for identifying or measuring diagnostic error beyond institution-wide incident reporting and the DHM Case Review Committee, both of which require provider suspicion of error and referral for review. The team needed to characterize the patients impacted by diagnostic error, identify systems failures contributing to diagnostic error, and examine the impact of diagnostic error on existing quality metrics. To do so, the team tested the following change ideas: 1) develop automated triggers to detect cases at high risk of diagnostic error, 2) complete two-person [SAFR-Dx/Deer Taxonomy](#) review of triggered cases, 3) develop infrastructure for provider feedback through a) automated programs that notify providers of patient readmission or death, and b) direct feedback on outcome of two-person review.

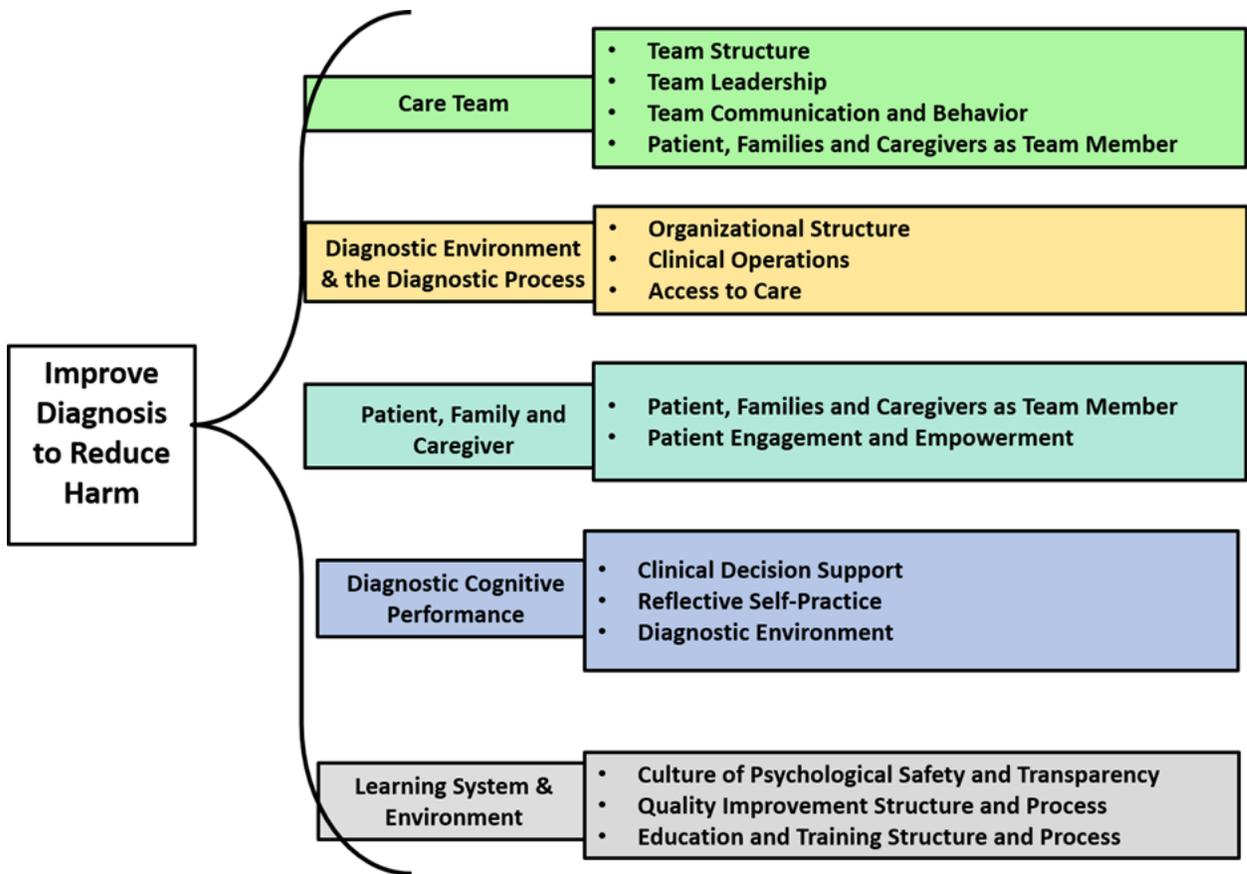
At [Tufts Medical Center](#) in Boston, Massachusetts, the team focused on testing the Outpatient Radiology Results Notification Engine. The Results Engine is designed to send notifications related to outpatient orders and results to Tufts Medical Center physicians who place these

orders. This is a potentially generalizable approach for identifying missed and delayed test results, even in health systems employing multiple EMRs. The workflow starts when a radiology order is placed for a patient and an appointment scheduled. The Results Engine sets a timer to expire 14 days from the time/date of the outpatient test appointment.

The Collaborative encountered a few key challenges and successes in the process of conducting quality improvement for diagnosis. The teams mapped their interventions to the diagnostic error reduction theory of change in the form of a driver diagram with primary and secondary drivers. These observations suggest that the drivers are generalizable across clinical settings and that the driver diagram is a solid tool to reduce the risk of diagnostic error. The six participating organizations used the driver diagram to identify areas to decrease diagnostic error and address those areas in an actionable and tactical way. Additionally, sites found that conducting quality improvement using IHI's methodology in conjunction with rapid PDSA cycles was an effective way to implement the interventions identified in the driver diagram and reduce diagnostic error. Time was intentionally devoted to this approach during the learning sessions because although the hypothesis is the same, the quality improvement methodology requires a paradigm shift from the traditional research study design methodology. Although both sciences, research and improvement science, aim to improve the quality of care, collecting, using, and evaluating data using quality improvement methods is distinctly different.

Despite the successes, there was one limitation that could not be overcome. The original goal was to develop a global outcome measure across all six pilot sites. But given the complexity of the diagnostic process and the diverse interventions, each team developed their own set of measures without significant overlap. This became especially challenging for the improvement teams in this Collaborative because an "apples-to-apples" comparison was not possible and therefore could not be used to validate many findings.

For more information on the SIDM/IHI Learning Collaborative or to learn more about a specific project described above, please visit the [Driving Quality Improvement Efforts Page](#) on the SIDM website or reach out to Diana Ruz, SIDM QI Program Manager, at [Diana.Rusz@Improvediagnosis.org](mailto:Diana.Rusz@Improvediagnosis.org).



Driver Diagram developed in the SIDM/IHI Learning Collaborative funded by the Gordon and Betty Moore Foundation. Project details are available [here](#).

### Applying the Real-World Wisdom of Patients and Families to Diagnosis

#### The Problem

According to the National Academy of Medicine, one in every ten diagnoses is wrong and one in every 20 patients will experience a diagnostic error each year. Furthermore, diagnostic errors cause an [estimated 40,000-80,000 deaths](#) in the U.S. annually. Not infrequently, symptoms of sepsis are dismissed as “the flu,” incidental findings and important patient information get buried in electronic health records, life-threatening test results are not communicated, and ominous symptoms are overlooked because of biases based on age, race, and gender—all resulting in [harm to patients and devastating losses for families](#).

Progress toward reducing harms from diagnostic error has been [frustratingly slow](#). Awareness of the magnitude and impact of harm from diagnostic error is [low in the patient/consumer](#)

[community](#) and, until recently, diagnostic improvement efforts have been led primarily by researchers, academicians, and policymakers with little input from the “users” of the U.S. healthcare system—the patients.

### The Solution

Based on their personal experiences, patients and family members could help fill the remaining gaps in knowledge, education, policy, and practice that lead to breakdowns in the diagnostic process. Their invaluable, real-world “pearls of wisdom” have the potential to help guide much needed improvements in the accuracy and safety of our diagnostic processes. Plus, the patient/family community brings a sense of urgency to this dialogue.

The Society to Improve Diagnosis in Medicine (SIDM), whose mission is “to create a world where no patients are harmed by diagnostic error,” has identified patient and family engagement as a key strategic priority. SIDM incorporates the “[human-centered design](#)” engineering approach to problem solving, which “starts with the people you're designing for and ends with new solutions that are tailor-made to suit their needs, preferences, values, and outcomes.” SIDM believes that this approach will lead to more timely, relevant, and patient-centered research, policy, education, and practice improvement strategies that will drive better diagnostic processes and outcomes for patients.

### Patient Engagement in Research

To enhance patients’ and families’ productive engagement in improving diagnostic processes, SIDM recently completed its “[PAtients Improving REsearch in Diagnosis](#)” (PAIRED) project. Funded by a Eugene Washington Award from PCORI, PAIRED brought patient leaders who had experienced diagnostic errors together with expert research mentors to integrate the patient perspective into research efforts to improve diagnostic processes. The project developed and evaluated an innovative curriculum to train [Patient Partners](#) to participate in the design, execution, and dissemination of research to improve diagnostic processes.

As a result of this training and collaboration, the patients and research mentors identified key research topics that mattered most to the patient community. Specifically, the patients identified the importance of researching the impact of age, race, and gender bias on missed and delayed diagnosis, biases that had personally affected some of the patients and family members. Based on this theme, SIDM is now conducting a two-year, funded research project entitled “Exploring and Addressing Diagnostic Error Disparities Related to Cognitive Reasoning Pitfalls,” in which some of the PAIRED patients are serving as advisors to a PAIRED research mentor.

The PAIRED project also identified a gap in many researchers’ knowledge and skills regarding methods for conducting patient-centered research in diagnostic safety, an approach that was unfamiliar to many traditionally trained researchers. This discovery led to a second PCORI award to SIDM to host a Diagnostic Researcher Workshop at the [DEM2019 conference](#).

These early positive results from collaboration among PAIRED patients, family members, and research experts are very encouraging:

- A new curriculum was developed to enable more patients to engage in diagnostic research as partners.

- Relevant, patient-centered research topics were identified.
- An activated patient/researcher community was created.
- New funding opportunities emerged.

### Patient Engagement in the Future

Building on lessons learned from the successful collaborations of the PAIRED project, SIDM now plans to engage and build capacity with patients and other stakeholders in SIDM’s other strategic priority areas including:

1. **Medical Education** - to prepare patients to participate in the co-creation and co-delivery of medical education, leveraging the ACCME’s new “patient engagement” criterion for accreditation and the AMEE’s new global theme, “Patients as Educators.”
2. **Advocacy/Policy** - to acquaint patients with the structure and processes of health care policymaking and equip them with skills needed for effective advocacy on Capitol Hill and for making public comments and participating on federal panels and advisory committees.
3. **Practice Improvement** - to help train patient advisors and Patient and Family Advisory Councils (PFACs) to be change engines for diagnostic improvement efforts within healthcare systems.

### Conclusion

The process of diagnosis is complex, with many layers, players, and systems that can result in significant patient harm and death. The solution will require an innovative, collaborative approach that engages the patient and family community, and other key stakeholders as problem solvers together.

SIDM has incorporated this approach by engaging and training patients and family members as well as leading experts in a research effort to improve diagnosis that, to date, has had encouraging results.

Going forward, SIDM is committed to this approach in future research, medical education, practice improvement, and policymaking efforts. We encourage others who are committed to improving diagnosis and incorporating the real-world wisdom of the patient community as collaborative problem solvers. That will help ensure that sepsis is diagnosed accurately; incidental findings and life-threatening test results are communicated in a timely, understandable manner; ominous symptoms are acted upon rather than misinterpreted due to biases; and patients and family members are safe from harm from diagnostic error.

#### Box A: [Patient and Family Engagement \(PFE\)](#)

“PFE is defined as patients, families, their representatives, and health professionals working in active partnership at various levels across the health care system—direct care, organizational design and governance, and policy making—to improve health and health care”

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## From the Field

The laboratory testing process begins at sample collection and, if successful, culminates with an accurate diagnosis. The March 2019 issue of *Diagnosis* explores how the collection and testing of the physiologic material, called the pre-analytic stage of the process, must be robust and accurate to generate high-quality data to aid diagnosticians. The issue introduction notes that, as samples are collected outside the controlled environment of the laboratory, poor sample quality has not been recognized sufficiently as a threat to safety. This reality provides context to certain vulnerabilities, including gaps in problem analysis, which have eluded systemized improvement efforts.

Alexander von Meyer of the German Institute for Laboratory Medicine and Microbiology, editor of this special issue, has engaged international contributors to examine the characteristics of each link in the chain, from sample collection to storage, and submit recommendations for improvement that speak to all actors across in the process. Notable topics covered include:

- overuse of laboratory tests as a deterrent to patient safety,
- current venous blood sampling guidelines as a baseline for best practice,
- reduction of sample value due to delays and poor transport processes,
- storage of samples to retain their usefulness as sources of information, and
- the potential impact of drug test interactions on the viability of diagnosis.

The issue highlights the need for the laboratory medicine community to mitigate the potential for missteps in the preanalytical phase and minimize downstream “holes in the swiss cheese” that degrade diagnosis.

Free access to each full issue of *Diagnosis*, the official peer-reviewed journal of the Society to Improve Diagnosis in Medicine, is a benefit of membership in the Society to Improve Diagnosis in Medicine.

Issue link: <https://www.degruyter.com/view/j/dx.2019.6.issue-1/issue-files/dx.2019.6.issue-1.xml>



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