PATIENT AND FAMILY ADVISORY COUNCIL

Guide for Hospital and Health System Leaders
For Diagnostic Quality and Safety

SOCIETY to IMPROVE DIAGNOSIS in MEDICINE
PURPOSE OF THIS GUIDE

This document is intended to serve as a compendium of best and promising practices in diagnostic quality and safety for use by hospital and health system leadership. These care settings focus on a host of quality and safety issues, the information here will focus specifically on guidance for preventing diagnostic errors, and uniquely, on the key role of patients, families, and Patient and Family Advisory Councils or “PFAC”s in pursuing diagnostic safety and quality improvement activities. This compilation is based on insights and knowledge shared at the joint Society to Improve Diagnosis in Medicine (SIDM) and National Academy of Medicine (NAM) PFAC convening held in December of 2019, data and guidance from the Health Research and Educational Trust (HRET) Hospital Improvement Innovation Network (HIIN)/SIDM Improving Diagnosis in Medicine Change Package,¹ and most importantly, from the lived experience and learnings of many patients and families impacted by diagnostic error.

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INTRODUCTION

Why Diagnostic Errors Matter

The complexity of diagnosis is easy to take for granted, but without an accurate, timely, and communicated diagnosis, every clinical step that follows could be unnecessary, inappropriate, or even harmful. While physicians* are largely known as the diagnosticians in health care, other team members, frequently play a role. In fact, the multifactorial, multi-person nature of diagnosis is one of the reasons errors and delays occur.

A diagnostic error means that the patient will not receive the correct or timely treatment for the problem, or may receive inappropriate treatment for a problem that does not exist. Or the patient may never discover the true problem, so treatment never begins, and the underlying condition worsens. These errors can lead to serious harm or even death. Errors in diagnosis also increase costs to the healthcare system and society at large and comprise a significant fraction of avoidable healthcare costs.

Sadly, diagnostic errors are common. Studies in primary care clinics found that 1 in 20 adult patients will experience a diagnostic error every year, and roughly speaking, 10 percent of suggested diagnoses are probably wrong. Most diagnostic errors will arise in ambulatory care settings, where most medical care is delivered, but there are also many that arise in the emergency room, and in hospital settings.

The National Academies of Sciences, Engineering, and Medicine (NASEM) concluded that,

“It is likely that most of us will experience at least one diagnostic error in our lifetime, sometimes with devastating consequences.”

Fortunately, the vast majority of diagnostic errors do not cause serious harm, but a small percentage do, and given the millions of diagnoses rendered in the US every day, the aggregate harm is appreciable. Autopsy studies suggest that 40,000 to 80,000 hospital deaths annually are attributed to diagnostic errors, which would rank in the top 10 for all causes of death. Studies of malpractice claims support the findings that diagnostic errors are the most common cause for serious harm, accounting for the highest costs per case, and the most catastrophic outcomes. The “Big 3” categories of cancer, vascular events, and infections account for the largest fractions of cases in these studies.

There are also, too commonly, appreciable delays in diagnosing other common, chronic, ambulatory conditions, such as asthma, anemia, diabetes, hypertension, and early forms of kidney disease. More timely intervention in these conditions could help improve long-term outcomes.

Diagnostic errors are very costly – patients harmed may suffer disability, pain, unnecessary interventions, reduced productivity, and in extreme cases, loss of life. For example, a delayed sepsis diagnosis can result in longer hospitalization, more expensive care in specialty units, and long-term consequences such as amputation of an affected body part. These complications lead to additional costs such as rehabilitative therapy and

*Physician assistants, nurse practitioners, nurse midwives, nurse anesthetists, and others also diagnose illnesses and conditions.

THE MISSED TEST

Julia Berg was a perfectly healthy 15-year-old from Minnesota enjoying her summer vacation and looking forward to the fall swim season. As July was winding to a close, she began to feel under the weather. She was lethargic, had a sore throat and a fever. When her nose started bleeding and wouldn’t stop, her parents took her to an urgent care clinic.
assistive devices and may affect the ability of the person to continue in their current job, resulting in lost wages. As the cost of health care increase, the financial impact of diagnostic errors rises as well.\textsuperscript{11}

**The Process of Diagnosis**

The diagnostic process figure from NASEM is an instructive tool for digesting and diagramming where and how diagnostic errors occur. (See Figure 1.)

As Figure 2 shows, failures can occur from the time patients attempt to engage with the healthcare system all the way through to communication of the diagnosis – or lack thereof – and treatment for the suspected issue. They can occur when patients neglect to mention an important symptom they are experiencing or omit relevant history, or in the clinician’s own collection of data. They can occur as clinicians begin to process and integrate the collected information, or when clinicians attempt to communicate the diagnosis but do so in a way that is not understandable to patients. They can also occur when clinical systems are not designed to ensure accurate and timely diagnosis – such as when test results are not communicated. Similarly, when patients see specialists after a referral from their primary care physician, it is not uncommon for important information to be lost in the transition or unavailable because of firewalls or lack of interoperability between clinics, hospitals, or health systems.

The process map can serve as an important conversation facilitator for clinicians and clinical teams as they contemplate the complexity of the diagnostic process. Similarly, as patient safety advocates have become more versed and vocal in the diagnostic quality space, they too have incorporated the NASEM process map to better analyze where missteps occurred in their diagnostic process and what changes – institutional, policy, or educational – may be required to prevent future harm. Advocates refer to this as defining their “what ifs”.

**FIGURE 1. The Diagnostic Process**

[Diagram of the diagnostic process]

Used with permission from the National Academies of Sciences, Engineering, and Medicine’s *Improving Diagnosis in Medicine* report.
Cal Sheridan’s experience is illustrative. Cal was born two weeks early. He developed jaundice soon after birth; nurses noted this finding several times in their notes. However, the finding was not communicated to his parents, and lab tests to assess the severity and cause were not conducted. He was discharged 33 hours after birth with a recommendation to follow up in two weeks.

On day four after birth, Cal was floppy and difficult to awaken. His parents called the hospital to report the concerning symptoms. Their concerns were dismissed because the nurse considered the first-time mom to be overreacting. The parents then took Cal to the pediatrician, where their concerns were also dismissed. They finally took Cal to the hospital. A bilirubin test was drawn; the level was the highest ever recorded at the hospital. There was no referral to the NICU, and an abnormal result on brain MRI was not communicated to Cal’s parents.

Cal received standard phototherapy and was discharged home. He continued to have difficulty breastfeeding and displayed frequent startle reflex to noise. At 16 months Cal was diagnosed with classic kernicterus due to blood type incompatibility. Today, he lives with permanent neurologic disabilities caused by a condition that could have been prevented if correctly diagnosed at the time.

There are several sources of failure that led to diagnostic error in Cal’s case. Consider how these could have been prevented:

- What if there had been a systematic, universal pre-discharge bilirubin test required for all newborns, to replace the less accurate visual assessment?

**FIGURE 2. Focusing on Four of the Errors in Cal Sheridan’s Diagnostic Journey**

*Used with permission from the National Academies of Sciences, Engineering, and Medicine’s Improving Diagnosis in Medicine report.*
• What if Cal’s parents had been empowered members of the care team and:
  • had been equipped with discharge information about the risks of newborn jaundice and the availability of a bilirubin test,
  • had been heard and believed, so that the symptoms they were reporting were integrated into the diagnosis, and
  • had been provided access to his medical records and medical notes (e.g., OpenNotes®) via a patient portal so that they were able to see critical information that wasn’t verbally shared?

• What if Cal’s parents had access to and were aware of a rapid response team that they could activate when they were concerned about changes or signs of a problem?

• What if there were an alert system in place that would trigger an automatic NICU transfer for extremely high bilirubin levels?

**Improving Diagnostic Quality and Safety**

Because of the complexity of diagnosis, attempting to eliminate diagnostic errors and related harm must be a collaborative and cross-function effort. SIDM, in collaboration with the Health Research & Educational Trust (HRET) Hospital Improvement Innovation Network (HIIN) recently produced a consensus set of the five key drivers necessary to the improvement of diagnostic quality and safety in practice. These include the need to:

- Engage patients and family members
- Improve teamwork in diagnosis
- Improve the reliability of the diagnostic process
- Optimize clinical reasoning
- Improve learning about and from diagnostic errors

Each of these drivers encompasses a body of associated activities and more detailed information about how hospitals and health systems can move toward these changes is described below.

As a hospital or health system leader, you can play a valuable role in improving the quality and safety of diagnosis and reducing the adverse effects of diagnostic error on patients and their families. You are uniquely positioned to provide top-down institutional awareness and mobilization, as well as to create a culture that embraces partnership with patient and family advisors. What follows is practical, tangible guidance for better understanding the current diagnostic quality and safety performance of your institution, identifying methods for forming effective team-based diagnostic solutions, providing training and capacity-building opportunities for all clinical team members, combatting common and often innate reasons for diagnostic errors, and perhaps most logically, better incorporating PFACs, patients, and families into your improvement efforts at systemic and individual levels.
ENGAGE PATIENTS AND FAMILIES

The active involvement of patients and families is critical for reducing diagnostic errors, though it is important to understand that two levels of engagement are required: engagement of individual patients and families within their own diagnostic journey, and engagement of PFACs, patients, and families in systemic or institutional diagnostic improvement efforts. The actions needed and investment required in patient and family engagement are dependent on this distinction, and the drivers and recommended actions from the SIDM/HRET Change Package delineate accordingly.

It is often instructive to think about improving the engagement and involvement of patients and families in their diagnostic journeys “through” the work done in partnership with a PFAC. In other words, the only way to build solutions and processes effective for patients and families is by co-creating them with patients and families. Often it is patients or family members of patients affected by diagnostic error who become active in PFACs, aiming to prevent for other patients, the harm they experienced. Increasingly, hospitals and health systems are employing PFACs in a variety of capacities to address safety and quality. Therefore, in the diagnostic realm, they can play a crucial role in delivering feedback about risks, errors, and possible solutions. However, not all hospitals and clinics have PFACs, and those that do sometimes fail to ask for their input on safety matters.

Leadership in clinical institutions with effectively integrated patient and family advisors and PFACs tend to demonstrate a set of important behaviors. These include:

- Modeling the belief and practice that patients and families have unique expertise and knowledge.
- Ensuring staff and other infrastructure support for PFACs and patient or family advisors.
- Inviting patients, family advisors, and PFACs to identify priorities, provide feedback on safety issues and concerns, and participate in “walkabouts” to tour the organization and give feedback on possible safety concerns.

FROM A SMALL SCRAPE TO SEPSIS

Rory Staunton was a 12-year-old boy with the dream to grow up to be a pilot—he had fallen in love with the story of “Sully” and the miracle landing of the disabled jet on the Hudson River. Rory was diving for a ball in the school gym one day. He got the ball but scraped his arm.

Used with permission from the National Academies of Sciences, Engineering, and Medicine’s Improving Diagnosis in Medicine report.
### EXEMPLARY PFACS—BEST PRACTICES

**PFAC structure and membership**

- The PFAC has an executive sponsor and staff liaison.
- There is a defined relationship between the PFAC and the hospital/health system leadership and board of directors.
- More than 50% of PFAC members are PFAs: PFAs are representative of the patient populations served.

**Recruitment**

- Recruitment is an ongoing program rather than a one-time event.
- Recruitment strategies are designed to ensure that the PFAs reflect the diversity of communities served.
- Clinicians and staff members help identify potential PFAs; other contacts and resources available through the hospital are used (e.g., support groups, relationships with community organizations).

**Onboarding and orientation**

- Onboarding and orientation are provided to all PFAC members, covering the key elements of the role of a PFA and helping orient PFAs to hospital quality and safety work.

**PFAC operations**

- The PFAC meets regularly, approximately 10 times per year.
- There is an agenda for each PFAC meeting, ideally developed by a PFA chair or co-chair, or by the PFAC.
- Language/translation services, childcare, parking/transportation, and even stipends are provided to encourage participation, especially among disadvantaged populations.

**Opportunities offered to PFAs**

- The hospital offers a variety of ways to serve as PFAs, including virtual opportunities and full membership on key committees, quality improvement and safety teams, and governing boards.

**Feedback, evaluation, and reporting**

- PFAs receive feedback about the impact of their work.
- There is an annual PFAC evaluation that measures the outcomes and impact of PFAC activities and initiatives.
- An annual report is prepared to summarize PFAC accomplishments and future plans and shared broadly with the health system and the community.

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Used with permission from NYS Health Foundation’s Strategically Advancing Patient and Family Advisory Councils in New York State Hospitals report.
These attributes are essential to facilitate the successful involvement of PFACs and patient and family advisors in improving safety. One study found that hospitals that had PFACs achieved better quality and safety scores than those without PFACs. In addition, there are recognized best practices that have been shown to make PFACs themselves more effective. (See Figure 4.) Hospitals with PFACs that followed best practices achieved better results on Centers for Medicare & Medicaid Services (CMS) quality and safety measures than hospitals with PFACs that did not.

PFACs have the capacity to improve safety for several reasons:

- Patients and families observe care across all settings (for example, outpatient clinics, emergency departments, post-surgical recovery units), while care providers and hospital and health system leadership often see care provided within a limited or narrow context. The observations of PFAC members provide valuable information about areas of risk.
- PFACs are powerful at driving change. When PFAC members share personal stories about diagnostic error, care providers and leaders better understand the impact of errors and the urgent need to prevent them.
- PFACs have access to the local community. PFAC members can effectively share information with community members to help them navigate their healthcare experiences.
- The role of PFACs is expanding due to CMS requirements and the Patient-Centered Outcomes Research Institute’s current research agenda. This means that PFACs will have even more opportunities to give input about errors in the future.
- Organizations that use best practices related to PFACs achieve significantly higher patient satisfaction scores.

The **SIDM/HRET Change Package** provides specific suggestions for involving PFACs in the cultural shift toward broad and integrated patient and family engagement (Figure 5 below) and outlines numerous steps to better incorporate patients and families as partners in their own diagnostic journeys (Figure 6 below).

<table>
<thead>
<tr>
<th>FIGURE 5. PATIENT AND FAMILY PARTNERSHIP IN DIAGNOSIS IMPROVEMENT, GOVERNANCE, AND POLICY</th>
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<tr>
<td>Incorporate diagnostic errors work on patient and family advisory councils, quality improvement teams, and governance</td>
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<tr>
<td>Include patients, families, and/or representatives from patient and family advisory council in root cause analysis of diagnostic error cases</td>
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<tr>
<td>Provide orientation and training about diagnostic safety and quality to healthcare personnel, patients, and family members that enables their participation in governance (patient and family advisory councils, practice improvement teams, board representatives)</td>
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<tr>
<td>Adapt PfP Health Equity Roadmap methods to ensure equity in healthcare quality and safety</td>
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Michael McGinnis engages PFAC leadership to learn how to drive patient engagement in hospitals and health systems to improve diagnostic quality and safety.
### FIGURE 6. PATIENT AND FAMILY MEMBERS ON THE DIAGNOSTIC TEAM

<table>
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<th>Activity</th>
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<tr>
<td>Facilitate patient and family engagement in the diagnostic process, aligned with their needs, values, and preferences</td>
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<tr>
<td>Adapt PfP preadmission checklist to orient patients to the diagnostic process (inviting them to participate in the diagnostic process)</td>
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<td>Provide relevant patient education materials and access to credible resources (i.e., SIDM The Patient’s Toolkit for Diagnosis, medical libraries, trusted websites)</td>
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<tr>
<td>Ensure processes and culture support patients and their families to share feedback and concerns about diagnostic errors and near misses</td>
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<tr>
<td>Ensure patients have access to electronic health records, including clinical notes and diagnostic testing results, to facilitate their engagement in the diagnostic process and their review of health records for accuracy</td>
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<tr>
<td>Adapt shift change huddles/bedside reporting with patients and families for improving diagnosis</td>
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<tr>
<td>Provide understandable discharge information informing patients of symptoms to report and to whom and when</td>
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<tr>
<td>Implement a rapid response system for patients to activate when a serious change in their medical condition occurs (Code HELP)</td>
</tr>
<tr>
<td>Create processes that make patients and family members feel comfortable requesting specialty expertise and second opinions</td>
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<tr>
<td>Adapt Patient Activation Measure (PAM) or similar tool to measure patient activation and motivation</td>
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<tr>
<td>Implement teach-back for diagnosis and diagnostic uncertainty</td>
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<tr>
<td>Engage in shared decision making about goals related to diagnosis and care throughout the informed consent process</td>
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<tr>
<td>Clarify health literacy and language preference; use translator or advocate when necessary in clinical encounters</td>
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The role of PFACs, patients, and families is not limited to these activities; PFACs can play an important role in a host of key diagnostic quality and safety activities. Similarly, patients and families can be integrated in a variety of ways to create a culture of inclusivity and partnership. The remaining sections will explore in more detail the way that hospital and health system leaders can partner with PFACs, patients, and families throughout nearly every facet of diagnostic quality improvement.
Teamwork can be improved by making sure the team includes a diversity of care providers, as well as patients and families. Adopting a team-based framework for diagnosis is believed to help catch many diagnostic errors before there is harm, as ‘fresh eyes’ help catch mistakes. To be most effective, these teams must implement best practices, such as using “diagnostic timeouts,” where any team member can halt the diagnostic process to voice a concern.

Hospitals and health systems can partner with PFACs in the promotion of effective teamwork in a number of ways, such as:

- Seeking PFAC ideas for increasing the implementation of more patient family engagement (e.g., bedside huddles)
- Co-developing with PFAC members communication tools for patients and families at risk of diagnostic error (e.g., a diagnostic charter or consent for clinical care)
- Working with the PFAC to define and implement full transparency of clinical documentation for patients, families, and caregivers (e.g., OpenNotes)

By seeking guidance and input from PFACs, hospitals and health systems can involve individual patients and families in their own diagnostic process by:

- Working in diagnostic teams that include patients and family members as defined in the NASEM Report on *Improving Diagnosis in Health Care*
- Teaching the diagnostic process to all disciplines, patients, and families and routinely discuss diagnosis and expected clinical course with all team members
- Educating team members, including patients and family members, about their roles in the diagnostic process and their diagnostic responsibilities
- Providing learning opportunities for patients, families, and caregivers to learn about the diagnostic process (e.g., diagnostic toolkit, diagnostic uncertainty questions)
- Teaching patients and families the importance of accuracy and thoroughness when giving health history and physical information
IMPROVE THE RELIABILITY OF THE DIAGNOSTIC PROCESS

Creating a reliable diagnostic process requires that structures within the care setting (hospital, clinic, etc.) exist to prevent diagnostic errors. It also requires that the flow of clinical services and information work well. For example, there must be a dependable way for care providers to follow up with patients who have been seen in the emergency department. Specialists must be available to see patients when indicated. Systems must be in place to ensure that test results are communicated reliably and in a timely manner.

Hospitals and health systems can partner with PFACs in improving the reliability of the diagnostic process in a number of ways such as:

- Involving the PFAC in identifying methods to improve follow-up (lab/radiology/clinical process management systems) and closing of the loop.
- Co-designing with the PFAC, processes for connecting and reporting test results that do not come back until after discharge (e.g., D/C summary contains list of pending test results)
- Asking for input from the PFAC about how to optimize how staff are aligned and work to improve diagnosis (e.g., care tracks; preplanned workflows; how to minimize patient trips, “swarming” – the whole team meets the patient at the onset of care)
- Asking the PFAC to use and evaluate patient communication devices such as whiteboards, iPads, OpenNotes, and patient portals to determine what is most effective in improving communication with patients and their families
- Co-creating with the PFAC systems for patients and families to give ongoing feedback during the course of illness
- Discussing with the PFAC ideas for creating an environment and processes that make patients and family members feel comfortable requesting specialty expertise
- Involving the PFAC in the plan for creating a culture, structure, and process that encourages and supports patient and family engagement in the diagnostic process as well diagnostic improvement efforts and governance

Ultimately, each of these system improvements would involve individual patients and families in their unique diagnostic and care process, and even extend into the days, weeks or months after. No matter how well intended, initiatives meant to engage and involve patients and families that are created for, rather than with, patients and families—typically PFACs and PFAC members—tend to fall short of their envisioned purpose or are not as effective as they could be. Take, for example, a feedback reporting mechanism that uses language familiar and comfortable to clinicians, rather than language proposed and endorsed by patients and families.
OPTIMIZE CLINICAL REASONING

Perhaps the most critical step in the diagnostic process is the work done by the clinicians who synthesize the available information to arrive at the most relevant diagnostic possibilities. Clinical reasoning can be defective if information is incorrect or missing, if the clinician’s knowledge base is limited, or by any number of factors that detract from optimal decision-making, including stress, distractions, pressure of time, and other factors. Among the most promising methods that can improve cognitive performance is the use of clinical decision support, which can help clinicians arrive at the most appropriate set of diagnostic possibilities. Other options include using reflection during the clinical reasoning process, or asking others (usually peers, or consultants) to provide second opinions on a case. The functionality of the electronic medical record in use is another key element that influences the reliability of the clinical reasoning process.

It may be difficult to envision a way to involve patients and families in the work to optimize the cognitive processes of clinicians, but as with most activities, patients and families can be valuable partners. A fundamental step for hospital and health system leaders dedicated to improving diagnostic quality and safety is to provide ample, multi-stakeholder educational opportunities to improve clinical reasoning. Education guided by emerging evidence should be offered to all members of the team including PFAC members, quality improvement committees, and boards on topics such as:

- The mechanics of clinical reasoning
- Common cognitive causes of diagnostic error
- The role of uncertainty in the diagnostic process
- Common biases
- Potential methods of reducing cognitive error, including cognitive debiasing, checklists, and timeouts

By educating PFAC members on topics like this, they may be able to formulate approaches to support clinical reasoning, or to support patients and families going through the diagnostic process. For example, are there particular questions patients and families could pose to clinicians that would draw out and help to minimize the presence of bias? Could PFAC members and clinicians co-create discussion guides or decision aids for addressing and discussing uncertainty? If patients and families going through a diagnostic process are aware of the more common pitfalls in clinical reasoning, might they be more apt to take action when something feels amiss, and ask question such as “what else could this be?”
Diagnostic performance can improve when hospitals and health systems seize the opportunity to learn from adverse diagnostic events, as well as from diagnoses that go well. Engaging patients, families, and providers to provide feedback is a critical first step to identify both diagnostic errors and successes. Hospitals can increase awareness of diagnostic errors by instituting or promoting systems for reporting errors, and by providing educational opportunities such as workshops for care providers, board members, and hospital executives.

Hospitals and health systems can work with PFACs to:

- Create a process for simple and anonymous reporting of diagnostic errors by all members of the diagnostic team, including patients and clinicians outside of the specific healthcare system
- Develop reliable and routine timely feedback processes for communicating diagnoses to emergency departments, patient and family members, providers, and diagnostic team (e.g. murmurs)
- Develop a process for obtaining and reviewing patient experience feedback in order to assess diagnostic performance
- Implement a patient-centered approach for early disclosure of adverse events and a method to achieve an amicable and fair resolution for the patient, family, and involved healthcare providers (e.g., CANDOR)
- Increase awareness of diagnostic harm and errors through patient and family participation in grand rounds, board of trustee and senior management education, visiting professor rounds, faculty development conferences, and other venues
Diagnostic errors occur too often and can have devastating consequences for patients, families, clinicians, and the institutions and health systems in which they occur. There are recognized methods for reducing these errors. Hospital and health system leaders are essential in establishing cultural norms and institutional practices that uphold diagnostic quality and safety. Equally important, leadership must partner with PFACs in identifying and working to prevent or learn from diagnostic error, and in setting the expectation that patients and families are team members in their own diagnostic processes. Multifactorial, multi-person challenges require multifactorial, multi-person solutions. By leading by example, and embracing a culture and practice of patient and family engagement, hospital and health system leaders can pursue the eradication of diagnostic error and create a world where no patients are harmed by this preventable cause.

**TAKE HOME POINTS**

Diagnostic errors occur too often and can have devastating consequences for patients, families, clinicians, and the institutions and health systems in which they occur. There are recognized methods for reducing these errors. Hospital and health system leaders are essential in establishing cultural norms and institutional practices that uphold diagnostic quality and safety. Equally important, leadership must partner with PFACs in identifying and working to prevent or learn from diagnostic error, and in setting the expectation that patients and families are team members in their own diagnostic processes. Multifactorial, multi-person challenges require multifactorial, multi-person solutions. By leading by example, and embracing a culture and practice of patient and family engagement, hospital and health system leaders can pursue the eradication of diagnostic error and create a world where no patients are harmed by this preventable cause.

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