RECOGNIZING EXCELLENCE IN DIAGNOSIS
Recommended Practices for Hospitals
July 2022

THE LEAPFROG GROUP
Giant Leaps for Patient Safety

Funded by:

GORDON AND BETTY
MOORE
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Recognizing
Excellence in
Diagnosis
A Program of The Leapfrog Group

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FOREWORD

Leah Binder, President & CEO of The Leapfrog Group

The Leapfrog Group was founded in 2000 by business leaders inspired by *To Err Is Human*, a landmark report from the Institute of Medicine (now the National Academy of Medicine) that exposed the problem of medical errors and launched the modern patient safety movement to address them.

Over the decades, Leapfrog has expanded and improved reporting on patient safety by harnessing the burgeoning fields of health services research and measurement science. This report represents a breakthrough in that research: the emerging recognition of diagnostic errors as one of the nation's most significant sources of patient harm. In 2015, the National Academy of Medicine (NAM) issued a call to action to improve diagnosis, warning that virtually every American will suffer the consequences of a diagnostic error at least once in their lifetime and noting that every year 250,000 hospital inpatients will experience a diagnostic error.[1] Experts have found diagnostic errors to be the leading cause of medical malpractice claims,[2] accounting for as many as 17% of all hospital adverse events.[1]

Leapfrog and researchers at The Johns Hopkins University conducted a small study and found that hospitals were aware of the problem of diagnostic errors, but unsure where to start to solve it.[3] This report intends to help hospitals and other stakeholders get started.

The report is a distillation of best-in-class, evidence-based, practical steps hospitals can start implementing today. Identifying these practices has been a complex journey. We are grateful for funding from the visionary Gordon and Betty Moore Foundation, guidance from the Society to Improve Diagnosis in Medicine (SIDM) and Johns Hopkins Medicine, leadership from two world-renowned experts who devoted their careers to diagnostic excellence — Hardeep Singh, MD, MPH and Mark Graber, MD, FACP — and the determination and diligence of a diverse array of experts and stakeholders.

We are often asked why Leapfrog focuses on the quality of care delivered at facilities instead of individual clinicians. Our answer is that no individual clinician practices in a vacuum: the quality of care they deliver depends heavily on the team surrounding them and the systems in place to support them, including procedures, protocols, and rules that undergird a hospital or other setting for care, and the army of caregiving partners, sometimes invisible to the patient, who must work together in concert. No physician, no matter how skilled, can save a patient from harm if the whole team doesn't come together to benefit the patient. Problems of patient safety are solved by re-organizing systems of care. We assume all people working in health care will make mistakes because they are human, but we rely on systems to prevent those errors from harming the patient.

Similarly, the issue of diagnostic errors is a systems issue. We assume errors will be made at every stage in the diagnostic process, but systems should be in place to prevent those human errors from causing harm to the patient. This report features recommended practices for building great systems.

This report is possible because of an exceptionally high-functioning team, beginning with the talented and passionate team at Leapfrog. We are proud to do our part for giant leaps in diagnostic excellence, and we invite you to join us.

Leah Binder
President and CEO, The Leapfrog Group

ABOUT THE LEAPFROG GROUP

The Leapfrog Group is a nonprofit watchdog organization that serves as a voice for health care consumers and purchasers, using their collective influence to foster positive change in United States (U.S.) health care. Leapfrog is the nation's premier advocate of transparency in health care—collecting, analyzing, and disseminating data to inform value-based purchasing and improve decision-making.

Through the annual Leapfrog Hospital Survey and Leapfrog Ambulatory Surgery Center (ASC) Survey, Leapfrog sets national standards for safety and quality, and publicly reports hospital and ASC progress on meeting those standards. In addition, Leapfrog issues the biannual Leapfrog Hospital Safety Grades in which an A, B, C, D, or F is assigned to all general hospitals and represents their track record for keeping patients safe from accidents, errors, and infections. Thousands of employers and other purchasers, along with coalitions of consumer advocates use Leapfrog ratings to make good decisions. Employers and purchasers also use Leapfrog's ratings to structure health benefits to reward excellence.

In 2015, Leapfrog joined a coalition led by the SIDM who expanded our awareness of diagnostic errors as a major patient safety problem. In 2020, the Gordon and Betty Moore Foundation awarded funding to The Leapfrog Group for this project, in partnership with SIDM and leading experts, to advance diagnostic excellence in hospitals. This report is the first milestone of the project, which called for the publication of an evidence-based national report of recommended practices that hospitals should implement to address diagnostic excellence. In the future, Leapfrog plans to work with SIDM and other partners to ensure hospitals have tools to support them in implementing recommended practices and, ultimately, to include the recommended practices in the Leapfrog Hospital Survey and publicly report hospitals' progress towards implementation.

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BACKGROUND & OVERVIEW

The report is funded by the Gordon and Betty Moore Foundation as part of a larger four-year project, titled *Recognizing Excellence in Diagnosis*. It is led by The Leapfrog Group in partnership with the Society to Improve Diagnosis in Medicine; Hardeep Singh, MD, MPH, a patient safety researcher at the Center for Innovations in Quality, Effectiveness and Safety based at the Michael E. DeBakey VA Medical Center and Baylor College of Medicine; Mark L. Graber, MD, FACP, Founder and President Emeritus of SIDM and Matthew Austin, PhD, Associate Professor at the Johns Hopkins Medicine Armstrong Institute for Patient Safety and Quality.

Goals of the Recognizing Excellence in Diagnosis Recommended Practices for Hospitals Report

Safe, high-quality hospital care begins with patients receiving the right diagnosis, communicated accurately and in a timely manner. In practice, this process too often fails. Communication breaks down, diagnoses are inaccurate or informed by incorrect information, and patients suffer. Experts estimate that nearly every American will be harmed by at least one diagnostic error in their lifetime.[1] Over the past two decades, our knowledge of how to improve diagnosis in different health care settings has grown substantially, driven in large part by a deeper understanding of how diagnostic errors arise and the realization that many can be prevented.

The Leapfrog Group convened this team of experts and stakeholders because the problem of diagnostic errors is a dramatic yet largely overlooked patient safety problem. This report aims to deploy lessons learned from the patient safety movement to offer hospitals practical, evidence-based guidance on addressing diagnostic errors. Leapfrog's next step is development of standards for excellence which will inform future content in the Leapfrog Hospital Survey and other quality initiatives.

For this report, a comprehensive literature review dating back to the 2015 NAM report was conducted, *Improving Diagnosis in Health Care*, and searching for interventions ideally suited for the hospital setting and studies on the incidence and etiology of diagnostic errors. This information was reviewed and synthesized and supplemented with recommendations from subject matter experts. We identified over 300 potential practices, and with input from the Recognizing Excellence in Diagnosis Advisory Group, achieved consensus on a smaller set of 29 recommended practices and two promising practices that can substantially improve diagnostic processes and outcomes.

The 29 practices in this report are organized by a measurement framework that represents areas of diagnostic care that could benefit from performance measurement and improvement. The framework identifies two broad areas where all hospitals should focus their attention to reduce harm to patients from diagnostic errors: Organizational Leadership & Systems and the Diagnostic Process.

The report is meant to be used by hospitals, including the senior administrative leaders, physicians, radiologists, pathologists, nurses, pharmacists, and others involved in the diagnostic process, as well as patient safety officers, quality directors, risk managers, and others who can benefit from reviewing the practices included in this report and working across departments and roles to implement them. The recommended practices are meant to be implemented in high-risk areas throughout the hospital

where diagnostic errors are common, including the emergency department (ED), inpatient units (e.g., labor and delivery units, critical care units), and departments central to the diagnostic process such as radiology, laboratory medicine, and pathology. Each practice reflects the latest evidence on what hospitals can and should do to improve diagnostic safety and quality, which has been guided and refined with input from a multistakeholder Advisory Group.

The resources and strategies that accompany each practice serve as concrete examples for those working to implement the practice, but hospitals should not be limited to the specific examples in this report. The examples are intended to provide a "jumping off" point for hospitals to begin this work. It is recommended that hospitals start by identifying a small set of practices that are most feasible and/or most impactful for them and begin there. Additional practices can be added to the initial set as time goes on.

Although the primary audience for this report is hospitals, both patients and purchasers can leverage their roles as stakeholders in the health care system to improve diagnostic safety and quality. Patient engagement is intentionally included in our measurement framework as a separate subdomain because patients are key partners in the diagnostic process. When visiting a hospital, patients should be aware of their options to seek an escalation of care when needed, prepare for their visit using patient guides supplied by the Agency for Healthcare Research and Quality (AHRQ), make use of their electronic patient portals, and even report their diagnostic concerns directly to the hospital.

As purchasers, employers can recognize and reward hospitals that implement these recommended practices to improve diagnostic quality and safety. Purchasers and payors can promote dialogue about diagnostic excellence by educating patients and calling attention to the importance of choosing hospitals that are committed to diagnostic excellence and are undertaking a visible effort to improve performance in this dimension of health care quality. Importantly, purchasers can continue to apply pressure on hospitals to be transparent about their implementation of practices chosen to improve diagnostic safety and quality, and report results on measures of clinical outcomes in diagnosis.

Diagnostic errors and strategies to improve diagnosis in health care have been understudied and under-resourced to date, which makes this report a vital resource for hospitals. It provides a series of recommended practices that hospitals can choose from and offers examples of how other hospitals have implemented the practices.

Definition of "Diagnostic Error"

The Advisory Group agreed on the following definition of a diagnostic error: An event where one or both of the following occurred, with harm or high potential of harm to the patient:
- Delayed, wrong, or missed diagnosis: At least one missed opportunity to pursue or identify an accurate and timely diagnosis based on the information that existed at that time.
- Diagnosis not communicated to the patient: Accurate diagnosis was available but was not effectively communicated to the patient or family.

The definition is adapted from the 2021 AHRQ *Common Formats for Event Reporting – Diagnostic Safety*. The Advisory Group selected the AHRQ definition because it reflects the most current thinking from leading experts in diagnosis[4] and builds upon previously articulated definitions of diagnostic

error, including the one advanced by NAM in 2015. This definition also reflects the Advisory Group's input to ensure that diagnostic errors are clearly defined for patients, their family caregivers, hospital leaders, clinicians, and others involved in the diagnostic process.

The Advisory Group did modify the AHRQ definition by adding "with harm or high potential of harm," in place of "whether or not the patient was harmed." This update clarifies the goals of this project, to focus on diagnostic errors that have the highest impact on patient safety. The Advisory Group also added the word "effectively" to the definition of "diagnosis not communicated to patient" to indicate the importance of clearly communicating diagnoses in terms that patients understand, and that are actionable for the patient as they seek continuing care.

Other definitions of key terms used in this report are listed in Appendix A.

Incidence and Etiology of Diagnostic Errors in Health Systems

In 2015, NAM published *Improving Diagnosis in Healthcare*, a landmark report that summarized all the research in the field to that point and proposed a roadmap for reducing diagnostic errors in health care.[1] The NAM report concluded that diagnostic errors are ubiquitous, surprisingly common, and cause inordinate harm. Roughly one in ten diagnoses is incorrect, and one in twenty outpatients in the US will experience a diagnostic error every year. Diagnostic errors contribute to an estimated 40,000 – 80,000 deaths annually, according to autopsy studies. The NAM concluded that "…. most of us will experience at least one diagnostic error in our lifetime, sometimes with devastating consequences." Studies published since the NAM report are consistent with NAM's conclusions. Diagnostic errors dominate malpractice lawsuits in most specialties and cause the most harm to patients.[5] This problem is not limited to just the United States. The incidence of diagnostic error in ambulatory settings in the United Kingdom is comparable to the U.S.,[6] and diagnostic error has been recognized as a major global concern.[7]

A systematic review of diagnostic errors involving hospital inpatients found a quarter million will experience a harmful diagnostic error annually in the United States.[8] Another systematic review examined diagnosis-related harm in U.S. adult intensive care units and found an estimated 40,000 deaths annually.[9] A systematic review of diagnostic error in pediatric critical care units reported an incidence of 10%-23% based on autopsy studies, and 8%-12% based on chart reviews.[10]

While the aggregate harm related to diagnostic error in hospital EDs is not yet known, the ED is considered the *petri dish* for diagnostic errors and the incidence will very likely exceed that in ambulatory and inpatient care settings. Diagnostic errors are the primary cause for malpractice suits involving patients seen in the ED.[2] A systematic review of diagnostic errors in the ED has been commissioned by AHRQ and expected availability is late 2022.[11]

The NAM 2015 report identified three main etiologic factors contributing to diagnostic error:

Diagnosis is complex: There are roughly 200 symptoms but over 10,000 diseases. Only a fraction of these diseases (roughly 1,000) is covered in medical education. Even common conditions can present in a variety of ways, depending on the patient and the stage of disease. Although "rare" diseases are indeed rare, there are so many rare diseases that an estimated 1 in 15 individuals worldwide has a "rare" condition, according to the World Health Organization.

Human cognition is fallible: Although all physicians are taught the essence of clinical reasoning, they generally receive little or no training in critical thinking, they rarely use optimal strategies for decision-making, and they share many cognitive and affective (emotion-related) biases that are common in human decision-making in every setting. Production pressure, interruptions, distractions, fatigue, illness, burnout, and many other factors also degrade clinical decision-making.

Our health care systems are imperfect and error-prone: There are potential breakdowns in every step of the diagnostic process. Follow-up processes are often rudimentary while safety monitoring and improvement are typically secondary priorities below financial stability and productivity in most organizations. The patient-practitioner clinical encounter is the foundation of correct diagnoses. Nevertheless, research suggests that nearly 80% of diagnostic errors can be traced back to a process breakdown in the encounter, and a majority of these are related to history-taking.[12]

Addressing the problem

Although we have learned a great deal about diagnostic error, very little has been done by health care organizations to address the problem. Aside from a handful of pioneering hospitals, most health systems are still on the sidelines, despite data on the magnitude of the problem and recommendations from the NAM report to address the problem.[13] [14] A survey administered by Leapfrog found that while most hospitals who responded were aware of the diagnostic error problem, their commitment to change was limited.[3]

A host of interventions have been considered and recommended to reduce the risk of diagnostic error, or to minimize harm to patients, but essentially none of these interventions have been implemented or even trialed. There are two key barriers that explain why health systems do not approach this problem with the urgency it deserves. First, many hospitals do not know where to start. There is no clear consensus on the specific best practices, measures, or performance standards that all hospitals should consider when striving for diagnostic excellence. Second, they don't know why they need to start. Hospitals do not get a clear signal from the public, private payors, regulators, or accreditors that diagnostic safety and quality is a priority.

Nevertheless, there are some clear next steps for all hospitals. Improving patient engagement is a core recommendation from The Joint Commission, AHRQ, NAM,[1] Institute for Healthcare Improvement (IHI),[15] and other organizations. As well, promoting teamwork in the diagnostic process was the number one recommendation in NAM's *Improving Diagnosis in Health Care* report,[1] based on abundant evidence from other high-reliability professions where teamwork has proven to be a cardinal feature of high-performing, safe systems. Many diagnostic errors involve deficiencies or breakdowns in the team-based aspects of diagnosis, and communication-related issues are particularly common.

The goal of the Recognizing Excellence in Diagnosis project, and this report specifically, is to start to address the first key barrier by giving hospitals a clear set of recommended practices they can start implementing today to reduce and prevent harm to patients caused by diagnostic errors.

THE MEASUREMENT FRAMEWORK

Creating a Measurement Framework

Creating a measurement framework was a critical first step to organizing the recommended practices drawn from the literature, subject matter experts, and the Advisory Group. The framework was developed by the Advisory Group to identify gaps and organize the recommended practices included in this report.

The Advisory Group determined that the National Quality Forum's (NQF) *Diagnostic Quality and Safety Framework*[16] could be effectively adapted to create the measurement framework for use in hospitals because it focuses on organizational and policy opportunities and the diagnostic process and outcomes.

The Advisory Group refined the NQF *Diagnostic Quality and Safety Framework* to focus on the two domains most relevant to improving diagnostic safety and quality in hospitals: Organizational Leadership & Systems and the Diagnostic Process. Each domain includes several subdomains (examples in the bulleted lists), with patients, families and caregivers, health information technology (IT), and health care disparities key cross-cutting areas that were considered for each practice across all subdomains (Figure 1). Subdomains represent discrete areas where measurement can lead to improvements in the diagnostic process and outcomes for patients.

For other measurement frameworks evaluated, see [Appendix B: Other Measurement Frameworks](#).

Figure 1: The Recognizing Excellence in Diagnosis Measurement Framework

To reduce and prevent harm to patients from diagnostic errors...

- Senior leaders are held accountable for diagnostic safety and quality
- The hospital's culture support diagnostic safety, quality, and transparency
- Processes and structures are in place to:
  » Engage patients in their care
  » Identify risks and hazards in the diagnostic process
- Financial, technological, and staffing resources are allocated to support learning and improvement activities

To reduce and prevent harm to patients from diagnostic errors...

- Processes and structures are in place to:
  » Gather accurate and complete information from patients and other sources
  » Enable correct interpretation and synthesis of information
  » Effectively communicate diagnostic information to patients and ensure timely and complete hand-offs during transitions of care

IMPLEMENTATION OF RECOMMENDED PRACTICES

Achieving excellence in diagnosis is a laudable goal and will save countless lives. Yet most health care organizations are at the very beginning of this journey: aware of the need to reduce the harm associated with diagnostic error but unsure where or how to start.[3] This section outlines general implementation principles to clarify next steps.

> **"....urgent change is needed to address the issue of diagnostic error, which poses a major challenge to health care quality. Diagnostic errors persist throughout all settings of care..."**
>
> -National Academy of Medicine, Improving Diagnosis in Health Care, 2015

General Principles

It starts at the top. If hospital leaders demonstrate that diagnostic safety and quality is a priority for the organization, it will be a priority. AHRQ has published an Issue Brief, *Leadership To Improve Diagnosis: A Call to Action*, for organizations who are ready to address diagnostic safety and quality that identifies clear first steps for hospital leaders.

Culture is the key. Establishing a culture of safety in hospitals has been on the forefront of successful patient safety and quality initiatives for years. Hospitals should continue to build on that foundation as they embark on their journey to improve diagnostic safety. When hospital staff feel safe to speak up and are encouraged to listen to others on the care team, when patients and family caregivers feel like they are listened to, when transparency is embraced, change can happen.

Hospitals know how to do this. Since the seminal report *To Err is Human* estimated 98,000 lives lost to preventable medical errors each year, hospitals have been working to reduce medical errors and preventable patient harm. Reducing harm to patients from diagnostic errors is no different. Hospital leaders must commit to organizational engagement, conduct a risk assessment to identify critical problems, incorporate measurement, use rapid-learning Plan-Do-Study-Act (PDSA) cycles, and listen to patients about their problems and recommendations for solutions.

The problem is urgent. Thousands of patients are harmed by diagnostic errors every day. There is never going to be a better time to *start* than now. The recommended practices in this report focus on senior administrative leadership and their commitment and local risk assessment (using the Safer Dx Checklist) to help hospitals select practices that are most relevant to their patients and diagnostic safety gaps. Clinicians and other staff as well as patients and family caregivers should be engaged in making decisions about which of the selected practices to implement first.

Be transparent. This report aims to engage hospitals across the U.S. in the hard work of reducing harm to patients from diagnostic errors. We encourage hospitals to be transparent about their gaps, both internally and externally, and to initiate or join collaboratives to share experiences and learn from others. In practical terms, hospitals should consider joining a Patient Safety Organization (PSO) and voluntarily reporting data – in return, PSOs will provide feedback to help health care organizations

learn from past adverse events and diagnostic errors and take steps to prevent recurrence. Likewise, hospitals can take advantage of AHRQ's recently published *Common Format for Event Reporting – Diagnostic Safety (Version 1.0)*, which will facilitate collecting and reporting information about diagnostic errors in a standardized way. Finally, hospitals should disclose diagnostic errors to patients and family caregivers when harm occurs.

Monitor progress. Track progress after implementing recommended practices and continually analyze the data collected and try to identify gaps or trends that offer a clear indication of potential issues in the quality of care that led to diagnostic errors. Immediately following publication of this report, The Leapfrog Group will launch a pilot survey of hospitals to assess initial nationwide progress in implementing these practices. In subsequent years, a hospital's progress in implementing these recommended practices will be scored and publicly reported as part of the Leapfrog Hospital Survey. Hospitals interested in participating in the pilot or in Leapfrog's programs should contact The Leapfrog Group directly.

Additional Resources

AHRQ Issue Briefs on Diagnosis. As the lead Federal agency addressing diagnostic quality and safety, AHRQ commissioned a series of white papers addressing key issues:

- Improving Education—A Key to Better Diagnostic Outcomes (PDF Version, 1.8 MB)
- The Contribution of Diagnostic Errors to Maternal Morbidity and Mortality During and Immediately After Childbirth: State of the Science (PDF, 1.4 MB).
- Leadership To Improve Diagnosis: A Call to Action (PDF, 2.3 MB).
- Health Information Technology for Engaging Patients in Diagnostic Decision Making in Emergency Departments (PDF, 2.6 MB)
- Evidence on Use of Clinical Reasoning Checklists for Diagnostic Error Reduction (PDF, 971 KB).
- Telediagnosis for Acute Care: Implications for the Quality and Safety of Diagnosis (PDF, 1.1 MB).
- Operational Measurement of Diagnostic Safety: State of the Science (PDF, 1.9 MB).
- Bridging the feedback gap: a sociotechnical approach to informing clinicians of patients' subsequent clinical course and outcomes.

Several strategies for detecting diagnostic errors have demonstrated "proof of concept" and are ready for wider implementation. AHRQ's MeasureDX is a resource to help health care organizations prepare to learn about diagnostic safety events in their facilities. Measure Dx outlines a step-by-step approach with suggestions for engaging people in the organization, selecting a measurement approach that fits the organization's capabilities, systematically detecting and analyzing diagnostic safety events, and using this information for learning and improvement.

AHRQ Resource List of Publications: Improving Diagnostic Safety in Medical Offices: A Resource List for Users of the AHRQ Diagnostic Safety Supplemental Items. This is a list of 30+ helpful publications and websites on various topics. Though many focus on ambulatory care, hospitals can leverage many of these resources at their facilities.

The Society to Improve Diagnosis in Medicine (SIDM) Website and the Coalition to Improve Diagnosis: SIDM is the only organization focusing solely on diagnostic quality and safety. The SIDM website provides access to resources and tools for organizations, clinicians, and patients to improve diagnosis, and offers links to register for the SIDM newsletters and publications. The Coalition to Improve Diagnosis includes over 60 organizations committed to improve diagnosis outcomes, including leading health care organizations.

Pioneering Organizations

Several organizations have already started work to improve diagnostic quality and safety. Examples include:

- Kaiser Permanente's SureNet system is a pioneering effort to proactively monitor electronic health records (EHRs) for delays in follow-up of tests and in addressing abnormal test results in a timely fashion.
- Geisinger Health (Danville, PA) has implemented pilot program for organizational and personal learning.[17] The program models leadership commitment, learning from cases, and optimizing health IT resources for diagnosis.
- Johns Hopkins Medicine models various aspects of a learning organization.[18]

IDENTIFICATION, SELECTION, AND PRIORITIZATION OF RECOMMENDED PRACTICES

Environmental Scan of Practices

To identify practices that have been trialed or recommended to improve diagnosis, we conducted an environmental scan that combined information from several different sources described below, including input from Advisory Group members:

- **An English-language literature search** of articles published between 2014 and early 2021 reporting on diagnostic error or interventions to address it.
- **A hand-search of** over 3,000 publications related to diagnosis and diagnostic error.
- **Authoritative organizational reports** such as the NAM report on *Improving Diagnosis in Health Care* provided a wide range of recommendations. Additional candidate practice recommendations were found in other major reports, including:
  - 2017 NQF: *Measure Concepts - Improving Diagnostic Quality & Safety*[19]
  - 2018 Health Research & Educational Trust (HRET): *Improving Diagnosis in Medicine – Diagnostic Error Change Package*[20]
  - 2019 NQF: *Advancing Chief Complaint-Based Quality Measurement*[21]
  - 2020 NQF: *Improving Diagnostic Quality & Safety/ Reducing Diagnostic Error: Measurement Considerations*[22]
  - 2021 AHRQ: *Operational Measurement of Diagnostic Safety: State of the Science*[23]
- **Systematic reviews of interventions to improve diagnosis,** published before the 2015 NAM report, on both cognitive[24] and system-related[25] interventions found a dearth of effective interventions. Another early review by McDonald and colleagues identified 14 randomized intervention trials, 11 of which improved diagnostic outcomes.[26] More recently, Abimanyi-Ochom and colleagues conducted a systematic review of general interventions,[27] and Lambe reviewed interventions related to clinical reasoning.[28]
- **Review of items from leading hospital evaluators** including The Leapfrog Hospital Survey,[29] The Joint Commission 2022 National Patient Safety Goals[30] and their publication on the Most Commonly Reviewed Sentinel Event Types.[31] The IHI Safer Dx Checklist, an organizational self-assessment for diagnostic excellence, was also reviewed.[32]
- **Interviews with subject matter experts** also yielded relevant practice examples, and experts from the following diagnostic-related specialties were interviewed:
  - Risk Management and Patient Safety: Becky Jones, RN (Pennsylvania Patient Safety Authority), Anne Gaffey, RN, MSN, CPHRM, DFASHRM, (Healthcare Risk and Safety Strategies, LLC), Tejal Gandhi, MD (Press Ganey), and Dan Sullivan, MD, JD, FACEP (The Sullivan Group)
  - Hospital Medicine: Robert M. Wachter, MD (UCSF), Andrew Olson, MD, FACP, FAAP (University of Minnesota Medical Center)
  - Emergency Medicine: David Meyers, MD, MBE, FACEP, Prashant Mahajan, MD, MPH, MBA (University of Michigan Medical School), Thomas Benzoni, MD (Des Moines University and UnityPoint Health-Iowa Methodist Medical Center), and John Sather, MD (Yale School of Medicine and Yale-New Haven Health System)
  - Laboratory Systems: Michael Laposata, MD, PhD (University of Texas Medical Branch, Galveston), and Brian Jackson, MD (ARUP Laboratories, and University of Utah School of Medicine)
  - Radiology: Len Berlin, MD, FACR (Rush University)
  - Health IT: Dean Sittig, PhD (UTHealth School of Biomedical Informatics)

o   <u>Medical Specialties</u>: Helen Burstin, MD, MPH, MACP (Council of Medical Specialty Societies), Sarah Sampsel, MPH (Independent Health Care Consultant)

From these sources, a preliminary list of over 300 potential practices were compiled and organized according to the domains and subdomains established in the Recognizing Excellence in Diagnosis Measurement Framework. In turn, the Framework was revised to accommodate new areas of diagnostic safety and quality not fully integrated into the extant domains and subdomains, even as those domains and subdomains identified gap areas for additional study and searches for potential practices.

Selection of Recommended Practices

The compilation of over 300 potential practices was gradually narrowed down to approximately 60 using three guiding principles:

- Strength of evidence
- Practice relates to organizational leadership, structures, or systems
- Practice has been successfully implemented in health care systems

The Advisory Group met over three successive meetings to refine the practice statements for clarity and specificity and select the 29 practices most aligned with the guiding principles. For details on the prioritization and selection process, see Appendix C.

RECOMMENDED PRACTICES FOR ACHIEVING DIAGNOSTIC EXCELLENCE

Domain 1: Organizational Leadership & Systems

Subdomain	Practice
1.1 *Senior leaders are held accountable for diagnostic safety and quality*	A – Establish goals for patient engagement, communication, and teamwork B – Convene a multidisciplinary team to promote diagnostic safety and quality C – Communicate progress of diagnostic safety programs
1.2 *The hospital's culture supports diagnostic safety, quality, and transparency*	A – Demonstrate commitment to diagnostic excellence through CEO leadership B – Promote teamwork C – Target training and education to nurses, pharmacists, and allied health professionals D – Make it easy for hospital staff to report diagnostic errors and concerns E – Openly communicate diagnostic errors to patients
1.3 *Processes and structures are in place to engage patients in their care*	A – Help patients and their family caregivers communicate complete and accurate information B – Make it easy for patients and family caregivers to report diagnostic errors and concerns C – Empower patients and family caregivers to escalate care D – Encourage patients to use patient portals
1.4 *Processes and structures are in place to identify risks and hazards in the diagnostic process*	A – Conduct a risk assessment B – Measure and monitor diagnostic safety outcomes C – Optimize the electronic health record to support accurate and timely diagnosis
1.5 *Financial, technological, and staffing resources are allocated to support learning and improvement activities*	A – Dedicate time for analysis and learning

Domain 2: The Diagnostic Process

Subdomain	Practice statement
2.1 *Processes and structures are in place to gather accurate and complete information from patients and other sources*	A – Train clinicians and others involved in the diagnostic process to collect accurate health information B – Correct inaccurate diagnosis and data in the EHR C – Ensure medical interpreters are available
2.2 *Processes and structures are in place to enable correct interpretation and synthesis of information*	A – Ensure access to radiology experts B – Jointly review diagnostic discrepancies C – Provide needed diagnostic expertise for patients admitted to the emergency department D – Provide knowledge resources to clinicians E – Train clinicians to recognize and minimize cognitive errors F – Implement and monitor adherence to diagnostic guidelines
2.3 *Processes and structures are in place to effectively communicate diagnostic information to patients and ensure timely and complete hand-offs during transitions of care*	A – Manage diagnostic uncertainty at handoffs B – Communicate clear instructions to patients discharged with an uncertain diagnosis C – Communicate clear instructions to patients discharged with pending test results D – Implement "closed loop" communication

RECOMMENDED PRACTICES FOR DOMAIN 1: ORGANIZATIONAL LEADERSHIP & SYSTEMS

Practice 1.1A – Establish goals for patient engagement, communication, and teamwork

Senior administrative leaders establish separate goals for engaging patients, improving communication between patients and their care team, and promoting better communication and teamwork between members of the care team to improve diagnosis and:

- Share these goals with the Board and throughout the organization.
- Communicate progress towards meeting these goals at least annually to the Board.
- Includes progress towards meeting these goals in the senior administrative leaders' annual performance reviews, incentives, or compensation.

Rationale

Several studies and national reports have highlighted the importance of the three pillars of diagnostic safety: patient engagement, communication between patients and clinicians, and communication and teamwork within the care team.

Improving patient engagement is a core recommendation from The Joint Commission, AHRQ, NAM[1], IHI[15], and other organizations. Systematic reviews report strong evidence for engaging patients in their own care and in patient safety initiatives at the organizational level, report positive effects on patient safety, financial performance of hospitals, patient experience scores, medical record accuracy, and adverse event reports.[33] [34] [35] An AHRQ-sponsored environmental scan found that "both patients and clinicians support patient and family involvement and participation in their own care and recognize that it can lead to better patient experiences and improved outcomes."[36]

The patient-practitioner clinical encounter is the foundation of correct diagnoses. Nevertheless, research suggests that nearly 80% of diagnostic errors can be traced back to a process breakdown in the encounter, and a majority of these are related to the history-taking portion.[37]

Promoting effective teamwork in the diagnostic process was the number one recommendation in the 2015 NAM report *Improving Diagnosis in Health Care,*[1] based on abundant evidence from other high-reliability professions where teamwork has proven to be a cardinal feature of high-performing, safe systems. Many diagnostic errors involve deficiencies or breakdowns in the team-based aspects of diagnosis, and communication-related issues are particularly common. Teamwork brings fresh eyes to a problem, as an effective way to catch errors and biases. Effective teamwork promotes care coordination, an especially important factor in determining patient satisfaction with their care, and the outcomes of that care.

When senior administrative leaders set goals for patient engagement, communication, and teamwork to improve diagnostic safety, they share these goals with the Board and staff and regularly report their progress towards meeting the goals to the Board. This transparency sends a clear message to the entire organization that diagnostic safety is an organizational priority that deserves both staff and financial resources. The AHRQ Issue Brief, *Leadership to Improve Diagnosis: A Call to Action*, emphasizes that hospital leadership is responsible for implementing a collective accountability framework that includes opportunities for both formal and informal learning opportunities.[38]

Resources and Strategies

- Senior administrative leaders set goals to partner with the hospital's Patient and Family Advisory Council (PFAC) to identify and work towards resolving diagnostic safety and quality issues, including implementing PFAC recommendations on engaging patients in their own
- diagnosis (e.g., following up on pending test results at discharge, interacting with the patient portal, reporting diagnostic concerns). Leaders can refer to SIDM's *PFAC Guide for Hospital and Health System Leaders,* which includes best and promising practices for structuring, recruiting, onboarding, and operating a PFAC.
- Senior administrative leaders set a goal to involve a PFAC member in another hospital-wide or departmental committee working on improving diagnostic safety and quality.
- Senior administrative leaders use *AHRQ's Guide to Patient and Family Engagement or AHRQ's Toolkit for Engaging Patients to Improve Diagnostic Safety* to set goals related to implementing recommended strategies that align with organizational priorities and needs related to patient engagement.
- Senior administrative leaders use the American Institutes for Research *Roadmap for Patient and Family Engagement in Healthcare* or the Patient Safety Foundation's *Actionable Patient Safety Solution: Person and Family Engagement* to design and implement programs to improve patient engagement at the hospital.
- Senior administrative leaders use *AHRQ's TeamSTEPPS® for Diagnosis Improvement* to set goals for staff training and implementing strategies that align with organizational priorities and needs related to communication and teamwork between members of the care team.
- Senior administrative leaders establish goals to measure and improve nurse and clinical pharmacist perceptions of being a valued member of the diagnostic team. For example, the rate at which nurses and clinical pharmacists actively participate on rounds could be measured.
- Senior administrative leaders monitor and display (e.g., internal newsletter or intranet) run-charts that track percentage of staff trained using one or more of the AHRQ resources listed above or track other established goals.

FEATURED IMPLEMENTATION EXAMPLE - PRACTICE 1.1A

Patient and Family Advisory Councils (PFACS)

Leaders at hospitals looking to meaningfully engage with patients in their community and reinforce community trust can start by establishing a Patient and Family Advisory Council (PFAC). PFACs are a low-cost, low-tech intervention that sits at the intersection of the hospital's or health system's efforts to achieve high patient satisfaction and uses the patient experience to improve the quality and safety of care. As a result, PFACs serve as a lynchpin facilitator of two-way communication, relationship management, and improvement work.

Marty Hatlie, a formal civil rights attorney, and longtime patient safety advocate, recommends hospitals turn to their PFACs if struggling with next steps in

Martin J. Hatlie, JD, President & CEO, Project Patient Care

reducing patient safety events, improving diagnostic quality and safety, or avoiding readmissions. This partnership can take the form of offering opportunities to Patient and Family Advisors to co-create solutions at regular PFAC meetings and serve on hospital committees or working groups, thereby creating a communication pipeline directly from users of care to organizational leadership and governance. Marty credits a strong institutional vision and leadership, active engagement by hospital board members, and a commitment to transparency in sharing safety and quality information with the patient community in his analysis of PFAC engagement to achieve sepsis reduction at MedStar Health.

Marty recommends that hospitals be creative about the role PFACs can play in contributing to improvement work. For example, PFAC members can be powerful advocates for change by sharing their stories about care delivery, bring patient experience and insight to the co-creation of improvement interventions, and be acute observers when rounding with hospital leaders. At the same time, PFACs can advance outward-facing improvement work, helping shape external communication and outreach about the importance of speaking up about safety concerns, using patient portals and following-up with discharge instructions, among other dimensions of being an engaged and activated patient.

Practice 1.1B – Convene a multidisciplinary team to promote diagnostic safety and quality

Senior administrative leaders convene a multidisciplinary team led by the Chief Medical Officer, or other senior administrative leader, to oversee a diagnostic safety and quality team that meets all the following criteria:

- At a minimum, the team includes representatives from nursing, pharmacy, laboratory medicine, radiology, and the ED.
- The team leader communicates regularly with the Board and other senior administrative leaders on issues related to diagnostic safety and quality.
- The team leader convenes staff from key clinical departments (including at least, if applicable, ED, hospital medicine, pediatrics, surgery, radiology, and obstetrics, intake or transfer coordinators, case management, pathology, radiology, and laboratory) quarterly to discuss diagnostic safety and quality issues and any lessons learned from specific patient cases.
- Designated members of the team collaborate with others involved in the diagnostic process to ensure diagnostic errors identified by the hospital undergo a root cause analysis and ensure the findings are shared with the staff involved in the case. If the patient was harmed, actions to prevent future similar errors are shared with the patient (and/or family caregiver).
- Designated members of the team collaborate with other staff to evaluate the implementation of programs (e.g., AHRQ's TeamSTEPPS) aimed at improving diagnostic safety and quality and to make recommendations for further training.

Rationale

There have been multiple calls for leaders of health care organizations to take action to address diagnostic error.[13][14][39] Leaders have the responsibility and opportunity to create a shared sense of purpose that drives everything forward in their organizations. "Whole system quality" is a new concept that describes the leadership principles, values, and patterns of behavior that set the foundation for all quality and safety-improvement efforts.[40] One comparative study found that hospitals where leadership emphasized a specific focus on quality improvement and health care excellence, fostered broader engagement with their board of directors by effectively communicating goals and progress.[17]

Resources and Strategies

- Geisinger pioneered a Learning and Exploration of Diagnostic Excellence (LEDE) program, with a physician dedicated full-time to the effort. Key elements of their 5-point action plan included a top-level virtual organizing committee, a focus on measurement for improvement, engagement of frontline clinicians in performance improvement efforts, and learning from identified opportunities to improve diagnosis in the framework of an "accountable culture."[41]

Geisinger's Committee to Improve Clinical Diagnosis (CICD)

Divvy Upadhyay, MD, MPH, Division of Quality and Safety, Geisinger

At Geisinger, Dr. Divvy Upadhyay's full time job is focused on coordinating and improving diagnostic safety as part of the system's Committee to Improve Clinical Diagnosis (CICD) and the Safer Dx Learning Lab. His main role is to gather information when diagnostic errors occur, and share lessons learned across the Geisinger's health system to drive improvement, including providing feedback to individual providers and departments. Typically, he directly receives cases from clinicians, patient experience department and risk management. He works with the Chair of the Committee and member clinicians from various departments in the health system to review cases and create "learning opportunities".

Dr. Upadhyay says the CICD at Geisinger garnered institutional leadership support and created a formal charter to develop innovative approaches to identify and analyze diagnostic missed opportunities and provide recommendations. "The CICD aims to pursue diagnostic excellence", he says, "while promoting learning and a culture of safety". The CICD's tasks are constantly evolving in an effort to create a learning health system, but it is slowly changing the local culture to encourage acknowledging, reporting, and learning from missed diagnostic opportunities.

"We encourage our providers to share learning opportunities because we believe that is a reflection of the commitment to our patients who trust us to continuously improve our processes and advance patient care".

Focusing staff resources on improving diagnostic safety, and providing feedback on diagnostic performance directly to providers, will help directly improve patient care, clinician satisfaction and subsequently the hospitals' quality and safety performance measures and reputation, which Upadhyay believes is the "hidden ROI."

Geisinger Committee to Improve Clinical Diagnosis (CICD) Creating Learning Opportunities*
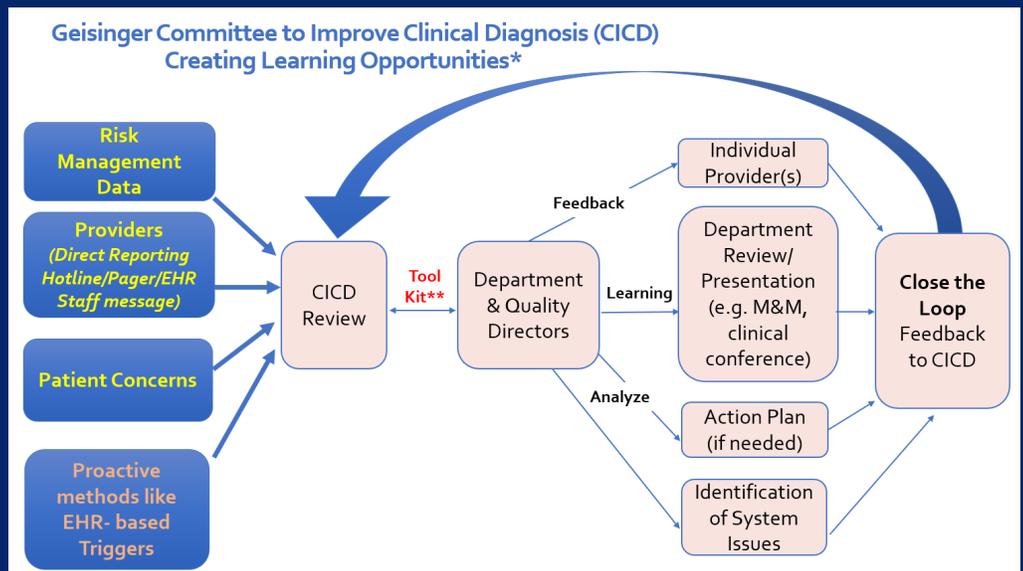
Practice 1.1C – Communicate progress of diagnostic safety programs

Senior administrative leaders communicate information regarding incidences of diagnostic errors, efforts to improve diagnostic safety and quality, and the outcomes of those efforts both internally and externally (e.g., hospital staff, hospital committees, patients and family caregivers, the community, other institutions), and to the board of directors. This includes specific activities related to diagnostic safety improvement, the results of interventions and solutions that have been implemented, and lessons learned from analysis of diagnostic errors.

Rationale

While diagnostic errors in hospitals are common, they have not received the same level of attention as other medical errors such as healthcare-associated infections or medication errors. Senior administrative leaders should send a clear message to hospital staff, patients and family caregivers, and the community that diagnostic safety and quality are organizational priorities and efforts are underway to reduce harm to patients from diagnostic errors. This public commitment is an important first step for quality improvement and public accountability.[42] [43] [44]

Resources and Strategies

- Senior administrative leaders share information and updates on the hospital's diagnostic safety learnings, goals, and programs through a monthly internal newsletter or the organization's intranet.
- The hospital publishes information on its diagnostic safety learnings, goals, and programs on its website or through a community newsletter or annual report.
- The hospital highlights programs initiated to improve diagnosis in press releases or at community events.
- The hospital shares information on their efforts to improve diagnostic safety with other hospitals and organizations through quality reports or research results published in scientific journals.

Practice 1.2A – Demonstrate commitment to diagnostic excellence through CEO leadership

The hospital CEO demonstrates a commitment to diagnostic excellence through a written or verbal commitment delivered to all staff, stating that the advancement of diagnostic excellence is a priority for the organization.

Rationale

The pursuit of diagnostic excellence requires extensive planning, resource allocation, and execution that must be spearheaded by the leader of the organization. Leaders have the responsibility and opportunity to create a shared sense of purpose that drives everything forward in their organizations. In *Safe Practices for Better Healthcare–2010 Update*, NQF stated that leaders are responsible for "personally reinforcing the principles of patient safety regularly and continuously to staff at all levels of the organization."[45] A systematic review found managerial support for medical leaders was a key component of success.[46] Additionally, having senior administrative leaders set the direction of health care organizations and execute the strategic plans were posited as key components in quality and safety.[47] This call for hospital CEOs to take a leading role in sponsoring improvements to diagnostic safety is echoed in AHRQ's *Leadership to Improve Diagnosis: A Call to Action*.[38]

Resources and Strategies

- The CEO, in partnership with the hospital's PFAC, sponsors an all-staff event to announce new goals or a new initiative to advance diagnostic excellence.
- The CEO participates in a series of 'town hall'-style talks on diagnostic excellence.
- The CEO identifies or designates 'champions' of diagnostic excellence in high-risk departments (e.g., the ED, radiology, laboratory medicine, critical care) and introduces them to the organization as leaders of diagnostic-improvement projects.
- The CEO writes a newsletter that is distributed to all staff or a blog on the intranet to share their commitment to diagnostic excellence.

Practice 1.2B – Promote teamwork

Senior administrative leaders continuously promote effective teamwork in diagnosis by putting policies or protocols in place to ensure:

- Diagnostic input and second opinions from clinician peers.
- Diagnostic input from nurses, pharmacists, and other clinical staff who touch the patient.
- Communication among clinicians and others involved in the diagnostic process and staff in radiology and the clinical lab regarding test selection and test result interpretation.

Rationale

Examples abound where breakdowns in teamwork led to diagnostic errors. In the case of Thomas E. Duncan, the first patient in the U.S. diagnosed with the Ebola Virus disease, the nurse who triaged the patient obtained and documented his history of recent travel to an endemic region in West Africa. However, the physician who saw the patient did not obtain this history, read the nurse's note, nor communicate with her, resulting in a delayed diagnosis and unnecessarily exposing many people to Ebola.[48]

Second opinions change the diagnosis in at least 10% of cases,[49] and increasing evidence suggests that groups considering a diagnosis more quickly and accurately arrive at a diagnosis compared to an individual.[50][51]

Promoting teamwork in the diagnostic process was the leading recommendation in NAM's *Improving Diagnosis in Health Care* report[1] based on abundant evidence from other high-reliability professions where teamwork has proven to be a cardinal feature of high-performing, safe systems.

Teamwork should begin by engaging nursing staff as critical members of the diagnostic team.[52][53] Nurses are ideally situated to monitor the diagnostic process and know if communication between the patient and physician was effective and complete. In many organizations, nurses participate in patient rounds and are encouraged to engage in discussions and decisions.

Including pharmacists on patient rounds can promote consideration of drug interactions and side effects as explanations for new symptoms. Pharmacists, physical therapists, and other members of the clinical staff have valuable insights when they share observations that could contribute to an accurate and timely diagnosis.[54][55] Leading researchers in the diagnosis field have published calls to improve collaboration between frontline clinicians and radiologists and laboratory professionals to reduce diagnostic errors.[56][57][58]

Resources and Strategies

- The hospital designates individuals to be trained as facilitators using AHRQ's *Facilitator's Implementation Roadmap*. Trained facilitators then teach the *TeamSTEPPS for Diagnosis Improvement* course to small teams of clinicians and others involved in the diagnostic process.
- The hospital practices interdisciplinary patient rounding in inpatient and critical care units. As part of the practice of interdisciplinary rounding, nurses, pharmacists, and allied health professionals engage in the discussions and contribute to decisions about the patient's diagnosis. Broadening the practice of interdisciplinary rounds to occur across all settings and be inclusive of all care team members can promote diagnostic excellence as each member offers insight relevant to their discipline. For example, including a pharmacist adds a lens for possible drug interactions or side effects contributing to new symptoms and a physical therapist can explain unexpected changes in mobility.

- Physicians in the ED consult with colleagues, including nurses, pharmacists, radiologists, and laboratory staff before discharge or admission to get input on key diagnostic information. At Boston Children's Hospital, the regional communications center connects clinicians at outlying centers to ED or intensive care unit physicians to briefly discuss complex cases to provide advice or consider transfer.
- The hospital has a standard process in place where patients with an uncertain diagnosis at a specific timepoint (48 to 72 hours after admission) automatically get a second review by a different clinical team.
- The hospital has a policy to include radiologists on tumor boards and in multidisciplinary conferences. [56]
- The hospital has a policy encouraging pathologists to provide feedback to other clinicians about test selection choices and successes and failures in interpretation of results. [57]

Practice 1.2C – Target training and education to nurses, pharmacists, and allied health professionals

The hospital targets training and education to nurses, pharmacists, and other allied health professionals.

Rationale

While it is important to train those commonly in the position of making a diagnosis, targeted training around the diagnostic process for nurses, pharmacists,[54] physical therapists,[55] and other allied health professionals is also an important step. Targeted training not only provides education to allied health professionals on the crucial part they play in the diagnostic process, but it also emphasizes to all health professionals that accurate and timely diagnosis takes a team. There are multiple critical places where allied health professionals contribute to the diagnostic process.[59] Patient engagement, information collection, interpretation, and communication, treatment and outcomes each rely substantially on allied health professionals. Targeted training ensures that allied health professionals understand all areas where they contribute to the diagnostic process, and how they are a part of achieving optimal diagnostic outcomes.[60]

Resources and Strategies

- The hospital ensures that nurses, pharmacists, and other allied health professionals are included in AHRQ's *TeamSTEPPS for Diagnostic Improvement Training*.
- The hospital examines current educational courses and includes content and resources specific to the diagnostic process. For example, courses on interdisciplinary communication, identification of sepsis, and when to call a rapid response team (RRT) are commonly given at hospitals and are relevant to the diagnostic process. Making modifications to these existing courses to explicitly link the course content to the diagnostic process can ensure that nurses, pharmacists, allied health professionals, and staff from radiology and laboratory medicine understand their role in the diagnostic process.
- The hospital ensures that targeted training to nurses, pharmacists, and allied health professionals is utilized through interprofessional patient rounds where all individuals participating in interprofessional rounding actively participate in the discussions and contribute to decisions about the patient's diagnosis.

Practice 1.2D – Make it easy for hospital staff to report diagnostic errors and concerns

The hospital has a formal process in place for staff to report diagnostic errors and concerns (e.g., breakdowns in communication, breakdowns in the diagnostic process). The process encourages psychological safety and staff adoption (the process is safe and easy to use) and should include all the following:

- Staff training on how and when to report diagnostic errors and concerns.
- A formal protocol for investigating and responding to staff-reported diagnostic errors, concerns, or questions.
- A formal protocol for notifying clinicians involved in the patient's care.
- A formal protocol for non-punitively including involved clinicians in investigations.
- An emphasis on transparency.
- A formal protocol for soliciting feedback from hospital staff on the psychological safety and usability of the process.

Rationale

Individual members of the care team are an important source of diagnostic error reporting because they experience and witness first-hand the diagnostic errors and breakdowns in the diagnostic process. However, members of the care team can be reluctant to report these incidents to others. Voluntary or "passive" staff reporting pathways are notorious for underreporting. Fewer than 6% of undesirable events are ever reported, and of these, almost none of the reports are made by physicians nor concern diagnostic errors. [61] Nevertheless, these reporting systems are important because some errors may only be identified through this mechanism. Several interventions have been shown to improve passive reporting systems, including adding pathways to reporting, mandating self-reporting as hospital policy, educating clinicians on what is considered reportable, and allowing anonymous reporting.[61] Interventions to increase reporting by medical students and trainees, including a trainee-led monthly conference to review adverse event reports,[62] and a curriculum for trainees on reporting procedures and integrating these into daily activities[63] were effective in increasing the number of reports and reducing patient harm.

Resources and Strategies

- The hospital establishes an easy-to-use system to facilitate reporting of diagnosis-related concerns, either through a mobile application[64] or hotline.
- The hospital expands the use of its incident reporting system to include diagnostic errors and concerns, regularly reminds clinicians and other staff to use the system and reports out on usage statistics on a regular basis.
- Senior administrative leaders regularly review the number and type of incidents being reported and provides retraining opportunities, reminders, and incentives to encourage reporting of diagnostic errors and concerns by clinicians and others involved in the diagnostic process, if gaps in usage are identified.
- The hospital considers the terms and language used in the reporting process. For example, on an electronic reporting form, the term "diagnostic error" could be rephrased as an "opportunity to make a more accurate or timely diagnosis" to encourage a broader range of reporting. One study found that this update increased physician reports from a baseline of 0 up to 2 per hundred admissions within 6 months.[65]
- The hospital pairs an easy-to-use electronic reporting system with a clinician champion who reinforces the importance of event reporting. One study found that when the hospital added a

desktop icon in the EHR for hospitalists to report a possible case involving diagnostic error and had a hospitalist peer championing use of the reporting system, 36 valid reports were submitted in the first 6 months, none of which would have been identified through the organization's existing risk management program.[14]

- The hospital provides training for medical students and trainees, including a trainee-led monthly conference to review adverse event reports,[62] and a curriculum on reporting procedures and ways to integrate these into daily activities, to increase the number of reports.[63] The conferences introduce trainees to patient safety investigations and quality improvement work and illustrate how they could participate in these initiatives.

Practice 1.2E – Openly communicate diagnostic errors to patients

The hospital has a formal process in place for identifying and notifying patients and/or their family caregivers when diagnostic errors occur resulting in harm.

Rationale

Disclosing certain egregious medical errors like wrong site surgery or transfusion of the wrong blood type, often referred to as "never events," to patients and family caregivers is now more common due to efforts from The Leapfrog Group, The Joint Commission, AHRQ, and other organizations. However, there are many types of medical errors that also result in harm that are not part of an existing disclosure policy or mandated by state or federal agencies, including harm from diagnostic errors.

Disclosing the medical error to patients and family caregivers when harm occurs is associated with less intense emotional impacts on patients and less avoidance of the health care facilities and clinicians involved in the error.[66] Additionally, while hospital concerns over litigation often prevent disclosure of medical errors, studies show that the AHRQ *CANDOR (Communication and Optimal Resolution) program* has reduced the number of malpractice suits arising from unexpected outcomes while improving case reporting.[67] [68]

Resources and Strategies

- The hospital enhances its existing communication and disclosure policy to include "diagnostic errors," as defined in this report, with a particular focus on cases of delayed, wrong, and missed diagnoses resulting in harm.
- The hospital has a standard process to identify potential diagnostic errors and refers these cases for risk management review. Risk management applies a standard protocol to identify cases where the patient was harmed from a diagnostic error, and then initiates a root cause analysis. Staff trained in the AHRQ *CANDOR* program communicate with the patient and family caregiver throughout the process of disclosure, response, and resolution.
- The hospital joins the Pathway to Accountability, Compassion and Transparency (PACT) Collaborative, or has implemented a Communication and Resolution Program consistent with the guidelines promulgated by the Collaborative for Accountability and Improvement.

Practice 1.3A – Help patients and their family caregivers communicate complete and accurate information

The hospital provides patients and their family caregivers with tools to help them communicate complete and accurate personal health information to the care team.

Rationale

The initial interview with the patient provides key information for diagnosis and is the foundation for establishing effective relationships between the care team and the patient. Communication breakdowns during the initial interview are commonly cited sources of diagnostic errors.[69] [70] Moreover, communication is a cardinal element of effective patient care and the key to patient satisfaction.[71] It helps ensure that patients are ready to play an active role as members of the care team. For example, they can ask "What else could this be?" throughout the diagnostic encounter.

Resources and Strategies

- The hospital uses the Toolkit Implementation Roadmap from the AHRQ Toolkit for *Engaging Patients to Improve Diagnostic Safety*, which includes deploying *Be The Expert On You*, a patient-facing strategy that prepares patients and their families to tell their personal health stories in a clear, concise way.
- The hospital includes links to evidence-based tools on its public website, including the SIDM *Patient's Toolkit for Diagnosis*, a patient-designed toolkit available in English or Spanish, that helps patients clearly communicate their symptoms and health information.

Be The Expert on You Toolkit

Chris Goeschel, ScD, MPA, MPS, RN, FAAN, Assistant Vice President of the MedStar Institute for Quality and Safety

As part of a contract with the AHRQ, the MedStar Health Institute for Quality and Safety worked with patients and providers to develop the Be the Expert on You Toolkit, a strategy hospitals and ambulatory care sites can use to help patients seeking care to clearly communicate and share information during the patient-clinician encounter.

Care sites looking to use the Be the Expert on You Note Sheet have many options for successful implementation. During field testing, some hospitals chose to provide the resource in-person upon patient arrival, by front desk staff; alternatively, some organizations distributed the Note Sheet via e-mail or through the patient portal. Hospitals can use the implementation worksheet included as part of the Toolkit to choose the appropriate path for them.

One hospital reported distributing the Note Sheet after the initial encounter with the nurse, with an opportunity for the nurse to explain the form. A successful implementation of the Toolkit will involve training physicians, nurse practitioners, medical assistants, and front desk staff, to ensure most staff can assist patients with questions about the form. The completed form serves as an important way for patients and families to make sure the provider has information relevant to the patient visit.

Practice 1.3B – Make it easy for patients and family caregivers to report diagnostic errors and concerns

The hospital provides patients and family caregivers with multiple channels (e.g., grievance process, ombudsman, patient-generated incident reporting, patient portal, patient survey) to report diagnostic errors and concerns and the hospital has a formal process in place to investigate and respond to the patient-reported diagnostic errors and concerns.

Rationale

As experts in their personal care, patients are well-positioned to identify diagnostic errors or potential threats to diagnostic safety. Patients can detect and report a wide range of patient safety concerns relevant to diagnosis, including inaccurate histories, notes written on the wrong patient, and erroneous diagnoses. An analysis of patient complaint data and a corresponding medical record review identified patterns of failures in the diagnostic process reported by patients and families.[72] Health systems could systematically analyze available data on patient complaints to monitor diagnostic safety concerns and identify opportunities for learning and improvement.

Resources and Strategies

- The hospital surveys patients to ask if they have identified errors in their electronic health record visit notes.[73] At Geisinger, researchers contacted patients identified as being at risk of a diagnostic error and asked them to complete an instrument designed to assess their experience with and assessment of the diagnostic process. [74]
- The hospital maintains a patient experience department that educates and encourages patients to report diagnostic errors and concerns via telephone, e-mail, or in-person visits, contacts patients who file a concern to follow-up, and logs the concern in an incident reporting system.[72]
- The hospital analyzes patient concerns submitted in free text fields from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey.

Kelly Gleason, PhD, RN Assistant Professor, Johns Hopkins University School of Nursing

A Patient Survey on Diagnostic Care

Kelly Gleason's team at Johns Hopkins has been refining a patient-reported feedback loop for diagnostic excellence. To reach patients with a recent diagnostic experience, they send patient portal messages to persons who were seen in the ED. To identify patients, they use a report in Epic that finds patients who received care in an ED within the Johns Hopkins Health System in the last 7 days and who have an active patient portal. The patients in that report are automatically sent invitations to complete a survey on their diagnostic experience.

They additionally invite people without a patient portal to complete the survey over the phone to ensure representative feedback.

The survey includes questions that directly capture patient-perceived accuracy, patient-reported health trajectory after discharge, and the patient's experience receiving an explanation of their health problem. It asks patients to rate their agreement, on a scale of 1 to 5, to statements about their experience with the diagnostic process, including: "I felt that the explanation of my health problem I was given was true"; "The explanation described what to expect of my health problem, regardless of whether it worsened, stayed the same, or resolved";

Rationale given in free-text component:	Patient response to question about whether diagnosis was true:					
	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Overall
General beliefs/logic						
Due to team's process						
Due to team's attitudes						
Due to health trajectory after discharge						
Due to not being given an answer						
Test results						
Medical knowledge						
Other doctor's input						
Matched symptoms at time						
Overall						

take the next steps after the visit." The survey additionally asks for free-text input to explain why they agreed or disagreed with the statements: "I felt the explanation of my health problem was true" and "The explanation described what to expect of my health problem."

Practice 1.3C – Empower patients and family caregivers to escalate care

The hospital has a standard, hospital-wide process that allows patients and family caregivers to escalate care that includes all the following:

- A written policy specifying that a patient or family caregiver can initiate the escalation of care.
- A formal process for notifying patients and family caregivers, verbally or in writing, about the policy and how to activate the process for an escalation in care.
- Training for clinicians and others involved in the diagnostic process, so they know how to respond to a patient or family caregiver once the process for the escalation of care has been activated.

Rationale

Accurate and timely diagnosis is important in the care of every patient but can have fatal consequences if not accomplished in rapidly deteriorating patients. [75] Evidence indicates that patients and family caregivers often recognize signs and symptoms of a worsening condition or diagnosis even before the care team does. [76] [77] Therefore, allowing patients and family caregivers to activate an escalation of care is one way to help prevent problems encountered when hospital staff are not available or unresponsive to a patient's deterioration.

In many hospitals, the escalation of care occurs when patients can activate an RRT. An RRT is a small multidisciplinary, trained team that can quickly assess a patient after a triggering event and initiate initial treatment and triage. RRTs have been widely adopted to accelerate the timely evaluation of rapidly deteriorating patients, and these programs have been effective in reducing out-of-ICU cardiac arrests and preventing clinical deterioration.[78] [79] Patient activated RRTs have proved feasible and valuable in expediting patient evaluations and interventions for deteriorating inpatients.[77]

Resources and Strategies

- The hospital has a policy on the escalation of care and the use of RRTs that allows patients and family caregivers to initiate the process. Information about activating the process is shared with patients when they are admitted to the hospital, and staff are trained on how to respond once the process has been initiated.
- Activation of RRTs is logged and regularly reviewed to identify patterns of activation that could identify opportunities for local system improvement.

Practice 1.3D – Encourage patients to use patient portals

The hospital ensures that patients use the patient portal to review their test results and other diagnostic related information by doing all the following:

- Providing patients with written instructions on how to access the portal during and after their hospital visit.
- Providing patients with access to the patient portal on tablets or other hospital-owned devices during their hospital visit (if applicable).
- Giving patients access to all the health information in their electronic medical records without a fee and without delay.
- Regularly tracking patient use of the portal.
- Periodically soliciting feedback from patients on the usability of the portal.
- Identifying barriers to use of patient portals and working to address them (e.g., language barriers, access to devices or internet).

Rationale

The 21st Century Cures Act requires hospitals and other health care organizations to give patients access to their medical information, including visit notes written by their clinician, visit summaries, and test results free of charge and without delay. Many hospitals have met this requirement using patient portals. These are secure websites managed by the hospital that allow patients to review information about their visit, including test results, discharge summaries, and care notes, among other functions, which vary based on the portal, such as the ability to schedule appointments or message their clinician. These portals have been found to be effective in improving both patient engagement in their care and elements of the diagnostic process.[80] However, hospitals have not always taken advantage of this opportunity. The Office of the National Coordinator for Health IT (ONC) reports that over a fifth of patients were not encouraged by providers to use their portals, contributing to underutilization, as patients are 48% more likely to use their portal when encouraged.[81] The use of patient portals has the potential to improve bidirectional communication between patients and clinicians and reduce diagnostic errors while promoting early error detection. In one study, one in five patients who had used their patient portal reported problems with their care, most commonly regarding diagnosis.[73]

Additionally, researchers have identified three ways in which sharing visit notes with patients might enhance diagnostic processes:[82]

- Avoiding delays and missed diagnoses by enhancing timely follow-up of recommended tests, results, and referrals.
- Identifying documentation errors that may undermine diagnostic accuracy.
- Strengthening patient-clinician relationships, thereby creating stronger bidirectional diagnostic partnerships.

Resources and Strategies

- The hospital actively encourages patients to use the patient portal and develops a strategy for clinicians to recommend using the patient portal during and after the hospital visit to access progress notes, discharge summaries, and test result notifications.[83]
- The hospital trains both administrative (e.g., registration staff) and clinical staff on use of the portal so they can assist patients who seek help.
- The hospital monitors use of the patient portal (e.g., how often patients read information about their test results) and seeks input from patients to improve use.
- The hospital partners with its PFAC to discuss strategies to improve patient use of the portal. This includes the hospital Chief Information Officer, or an equivalent, attending PFAC meetings

- to discuss this topic and giving the PFAC avenues to communicate with patients in the broader community. The OpenNotes Initiative [has additional information](#) for PFACs and hospitals on potential strategies to improve utilization of the patient portal.
- The hospital partners with its patient portal vendor to build mechanisms for patients to report symptoms, outcomes, and electronically request modifications to the clinical information in the medical record, if these features are not already available.
- One safety net hospital responded to socioeconomic disparities in their patient portal use by implementing a universal access policy, a mobile version of the patient portal, and a Spanish language version of the application.[84]

Practice 1.4A – Conduct a risk assessment

The hospital conducts an annual risk evaluation using a standardized risk assessment tool to identify gaps in staffing and clinical expertise, tools and technology, and communication and teamwork that contribute to diagnostic errors.

Rationale

Breakdowns in system-related components of care are common.[85] System-related factors have been identified in approximately 65% of diagnostic error events,[86] and system-related factors commonly degrade the cognitive aspects of the diagnostic process.[87] The NAM has detailed several system-based factors (technical or organizational barriers such as problems with communication and care coordination; inefficient processes; technical failures; and equipment problems) relevant to diagnosis and emphasized their criticality in enabling overall quality and safety.[1] A systematic risk assessment will provide organizations with a structured approach to identify and prioritize gaps that lead to diagnostic errors and to start to address these issues.

Resources and Strategies

- The hospital identifies a small team of clinicians and others involved in the diagnostic process from the major clinical services (e.g., emergency department, inpatient, radiology, laboratory medicine) to complete the Safer Dx Checklist.[3232] Results from the checklist are used to develop goals and inform process improvements.
- As an alternative to the Safer Dx Checklist, hospitals can conduct a hospital-wide assessment of diagnostic errors resulting in harm, including the frequency and severity assessment of each of those errors using a severity scale such as the National Coordinating Council for Medical Error and Reporting Index.
- To supplement the standardized risk assessment, the hospital conducts annual qualitative interviews with clinicians, including nurses and pharmacists, allied health professionals, and others involved in the diagnosis process to identify systemic problems in the diagnostic process.

The Safer Dx Checklist

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Hospitals should conduct a self-assessment using the Safer Dx Checklist of 10 recommended practices that can help achieve diagnostic excellence. This checklist can help hospitals understand the current state of their diagnostic practices, identify areas to improve upon, and track progress towards diagnostic excellence over time. After obtaining leadership support, a multidisciplinary team of individuals from various clinical and non-clinical disciplines should assemble and invite in quality and safety professionals, patient representatives, medical educators, and trainees. The team should first review every practice and rate how well it is implemented at the hospital using this scale: Full, Partial, Not Implemented.

After completing the checklist, the team should develop an action plan to implement practices that are not currently fully implemented and set defined metrics and roles and responsibilities to ensure progress. This team should meet regularly to review and analyze the current state of diagnostic safety until all 10 high-priority practices are fully implemented. When hospitals have incorporated all of the practices into the organization, they should continue to review the checklist annually and revise the action plan as needed.

Hospitals wanting to promote diagnostic excellence through the Safer DX Checklist can access it here.

Checklist Responses

For each of the 10 checklist items, team members from the organization (either individually or as a group) should select the **Implementation Status** that best represents the current state of their organization's practices:

- **Full**: A well-known and well-documented practice that occurs reliably in the organization.
- **Partial**: The practice occurs in the organization sometimes. While it is well-documented, the practice is not well known or it may be implemented inconsistently across the organization.
- **Not Implemented**: This practice does not occur in the organization.

The Safer Dx Checklist:
10 High-Priority Practices for Diagnostic Excellence
(Scenarios are examples of actions to improve the practices)

Implementation Status (Current state of organization's practices)

		Full	Partial	Not Implemented
1	Health care organization leadership builds a "board-to-bedside" accountability framework that includes structure, capacity, transparency, time, and resources to measure and improve diagnostic safety. Scenario 1: Senior leadership/C-suite establish a multidisciplinary team (e.g., diagnostic safety committee) charged with identifying and addressing opportunities to reduce errors at the institutional level. The team includes department leaders and clinical champions. Scenario 2: Senior leadership/C-suite consistently share diagnostic safety data with the governance board. This includes quantitative data to measure and track diagnostic safety as well as narrative patient stories, patterns, and action plans.		☐	☐	☐
2	Health care organization promotes a just culture and creates a psychologically safe environment that encourages clinicians and staff to share opportunities to improve diagnostic safety without fear of retribution. Scenario: Ensure non-punitive conditions that encourage clinical and non-clinical staff to report missed opportunities, harms, "good catches," tips, and lessons related to diagnostic safety. Close the loop and share information on corrective actions or steps taken to prevent recurrence in a timely and effective manner.		☐	☐	☐

Practice 1.4B – Measure and monitor diagnostic safety outcomes

Senior administrative leaders put processes and structures in place to identify, track, and analyze diagnostic errors, including errors that result in harm or death, with a focus on high-risk areas of the hospital (e.g., EDs, labor and delivery units, critical care units), and regularly communicate performance and progress on improvement initiatives with their board of directors.

Rationale

The NAM designated the improvement of diagnostic safety a national priority in 2015.[1] Nevertheless, health care organizations generally are not capturing these events, and calls to make diagnostic safety a priority have largely been ignored.[13][14][88] Hospitals need to address this problem by systematically identifying the incidence of diagnosis-related harm in their own patients. This can only be accomplished when senior administrative leaders prioritize measurement and monitoring activities. Many hospitals have processes in place to identify and measure treatment-related quality and safety but no such infrastructure for measuring diagnostic safety. Outcome measurement is a key step toward improving safety, generally, and is specifically needed to improve diagnosis. AHRQ's *Operational Measurement of Diagnostic Safety: State of the Science* offers practical guidance for hospitals seeking to use measures to enhance diagnostic safety.[89] Hospitals can also look to AHRQ's MeasureDx publication, a resource to help health care organizations prepare to learn about diagnostic safety events in their facilities. Measure Dx outlines a step-by-step approach with suggestions for engaging people in the organization, selecting a measurement approach that fits the organization's capabilities, systematically detecting and analyzing diagnostic safety events, and using this information for learning and improvement.

Resources and Strategies

- Senior administrative leaders can deploy electronic trigger tools to mine EHRs for diagnostic errors and opportunities for improving the diagnostic process. Electronic trigger tools are algorithms that identify patients who may have experienced a diagnostic error based on information in their EHR; for example, a return visit with a new diagnostic/therapeutic intervention.[90][91] Children's Hospital Colorado has adopted a systematic, non-voluntary approach to identify instances of ED diagnostic errors through rigorous electronic trigger tools followed by structured expert case review.[92] Error rates and outlier signals are systematically identified and actions are taken.
- Senior administrative leaders ensure that hospital staff are trained to identify diagnosis-related harm from incident reports, patient complaints, malpractice suits, and autopsies.
- Senior administrative leaders take action to encourage both patient and staff-reported diagnostic errors and concerns and put systems in place for safe and easy to use reporting.
- Senior administrative leaders can regularly monitor performance on nationally endorsed measures of diagnostic safety and quality (see Figure 2: Select Measures of Diagnostic Safety and Quality from the National Quality Forum and the Centers for Medicare and Medicaid Services Quality Measures Inventory).
- Geisinger pioneered a LEDE program, which includes using e-trigger tools to identify potential diagnostic errors, followed by individual case analysis.[41]
- Nationwide Children's Hospital developed a new approach to identifying diagnostic concerns, including root cause analyses, cases discussed at morbidity and mortality (M&M) conferences, and a trigger tool for patients with abdominal pain. Cases were then reviewed by an interdisciplinary team to extract lessons learned.[93]

Figure 2: Select Measures of Diagnostic Safety and Quality from the National Quality Forum and the Centers for Medicare and Medicaid Services Quality Measures Inventory

Measure Title	Description	Source
Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury	Performing cystoscopy at the time of hysterectomy for pelvic organ prolapse to detect lower urinary tract injury.	NQFID #2063
Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients Who Received Head CT or MRI Scan Interpretation within 45 minutes of ED Arrival	This measure calculates the percentage of acute ischemic stroke or hemorrhagic stroke patients who arrive at the emergency department within two hours of the onset of symptoms and have a head computed tomography (CT) or magnetic resonance imaging (MRI) scan interpreted within 45 minutes of arrival. The measure is calculated using chart abstracted data, on a rolling, quarterly basis and is publicly reported, in aggregate, for one calendar year.	NQFID #0661
Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older	Percentage of patients aged 50 years and older treated for a hip, spine, or distal radial fracture with documentation of communication with the physician managing the patient's on-going care that a fracture occurred, and the patient was or should be tested or treated for osteoporosis.	CMIT Ref. No. 267
Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description	Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in the institution's computer systems.	CMIT Ref. No. 2283

Practice 1.4C – Optimize the electronic health record to support accurate and timely diagnosis

The hospital has a process in place to identify and address features of the EHR that contribute to diagnostic errors.

Rationale

The EHR is central to most clinical activities in the hospital today. The EHR's configuration and the practices governing its use play a major role in every step of the diagnostic process.[94] Many features of the EHR can contribute to improved diagnosis,[95] [96] but there are several specific vulnerabilities in the EHR design that, if remain uncorrected, can detract from diagnostic safety and quality.[97]

Clinicians who use the EHR in daily practice have an excellent sense of EHR strengths and weaknesses and can identify specific vulnerabilities that lead to diagnostic errors. Examples of vulnerabilities include clinical information that is unavailable when using the EHR system, an overwhelming number of messages that can "bury" important notifications such as newly available test results, even incorrect pre-populated data.[98] [99] However, organizations must heed these suggestions and assign Health IT staff to work with clinicians to study any identified problems.[100]

Acknowledging the central role of the EHR in diagnosis and care delivery, the ONC has provided authoritative advice on EHR-related safety,[101] and organizations will be expected to attest to annual self-assessments using the ONC-sponsored Safety Assurance Factors for EHR Resilience (SAFER) Guides beginning in 2022 to meet CMS regulations.[102]

Resources and Strategies

- On an annual basis, the hospital actively seeks formal input from clinical staff on their satisfaction with the EHR and their recommendations to improve features that will reduce diagnostic errors and improve the diagnostic process. Some of these activities could be performed as part of annual self-assessments based on the ONC-sponsored SAFER Guides that most hospitals will be conducting starting in 2022.[103]
- The hospital establishes a workgroup or small committee of both health IT and clinical staff that meets at least quarterly to discuss active concerns with the EHR's configuration and how to address them.
- In setting the annual IT budget for the hospital, administrators and budget managers meet to include items that correspond to initiatives to resolve diagnostic safety issues identified in the EHR, and regularly review the items to ensure those funds are being disbursed.
- Just-in-time decision support systems are used, when available, to support diagnosis for common medical complaints or scenarios. For example, the *Pediatric Emergency Care Applied Research Network (PECARN) Clinically Important Traumatic Brain Injury* decision tool is integrated within the emergency department's EHR to help make decisions about neuroimaging for head trauma in children in the emergency department.

Practice 1.5A – Dedicate time for analysis and learning

Clinicians and others involved in the diagnostic process have protected time to participate in activities that help improve performance in diagnosis including, at a minimum:

- Analyzing patient-reported concerns and diagnostic safety outcomes data.
- Documenting and sharing what is learned with others.
- Using the documented information learned to develop and implement improvement activities.

Rationale

Involving clinicians and others involved in the diagnostic process in efforts to pursue diagnostic safety and quality will ensure that the most important problems are targeted, and real-world improvements are achieved. A valuable model for performance improvement centers is the "learning health system," where observations of ongoing practice outcomes serve as the basis for subsequent improvement efforts.[104] [105] This concept can be applied to improving diagnostic safety and quality.[106]

Resources and Strategies

- One or more clinicians from the hospitalist service or ED are allocated dedicated time to diagnostic improvement activities. These individuals work with the safety, quality, and risk management staff to evaluate reports of diagnostic concerns, help conduct and analyze diagnostic safety checklists and surveys, and collaborate in developing improvement programs.
- Clinicians and others involved in the diagnostic process have protected time to participate on interdisciplinary diagnostic safety teams and participate in team activities.
- Clinicians and others involved in the diagnostic process have protected time to participate in training and educational programs.

RECOMMENDED PRACTICES FOR DOMAIN 2: THE DIAGNOSIS PROCESS

Practice 2.1A – Train clinicians and others involved in the diagnostic process to collect accurate health information

Clinicians and others involved in the diagnostic process are trained in the use of evidence-based tools and strategies to collect complete and accurate personal health information from patients and family caregivers to facilitate a timely and accurate diagnosis.

Rationale

Clinicians and others involved in the diagnostic process who are trained to practice deep and reflective listening and effectively minimize interruptions can do a better job gathering the information needed to make an accurate diagnosis. Five key practices have been recommended to improve the gathering of personal health information from patients and family caregivers[107] including:

- Prepare with intention (take a moment to prepare and focus before greeting a patient).
- Listen intently and completely (sit down, lean forward, avoid interruptions).
- Agree on what matters most (find out what the patient cares about and incorporate these priorities into the visit or conversation).
- Connect with the patient's story (consider life circumstances that influence the patient's health; acknowledge positive efforts; celebrate successes).
- Explore emotional cues (notice, name, and validate the patient's emotions).

Resources and Strategies

- The hospital trains clinicians and others involved in the diagnostic process to use the Toolkit Implementation Roadmap from the AHRQ Toolkit *Engaging Patients to Improve Diagnostic Safety*, including the *60 Seconds To Improve Diagnostic Safety* training, which prepares clinicians to practice deep and reflective listening for one minute at the start of a patient encounter.

Practice 2.1B – Correct inaccurate diagnoses and data in the EHR

The hospital ensures that their EHR captures the correct diagnosis by having a process in place to review and correct inaccurate diagnoses on "problem lists" and elsewhere in the EHR.

Rationale

The EHR is one of the first places clinicians look when making a new diagnosis. Unfortunately, problems in documentation such as outdated or inaccurate problem lists, copy and paste errors, and inaccurate data in visit notes can lead to delays and inaccurate diagnoses.

For example, clinicians often look to the problem list when reviewing the medical record of a new patient. Ideally, the problem list will give them an accurate summary of the patient's major medical issues and past medical history, which is highly relevant to making a new diagnosis because new problems are often old, recurring problems or now manifesting in a new way. Additionally, the treatment for a current condition may be causing a new problem. A well organized, accurate problem list is often the starting place for exploring a patient's history and serves as the framework for the problem-oriented medical record, the de facto standard for documentation in advanced health care organizations internationally.

Unfortunately, the problem list is not always correct. Information that is missing or wrong can derail the diagnosis process from the beginning. Inaccuracies in documentation are common.[108] A recent study of EHRs found that 40% of important diagnoses (found in progress notes) were not included in the patient's problem list.[109] Patients reviewing their own medical records frequently identify inaccuracies, and errors regarding their diagnoses are among the most common problems reported.[73]

In a meta-analysis, researchers offered a list of recommendations for managing problem lists including frequent reviews of the problem list and a clear organizational policy on what should be included.[110]

Resources and Strategies

- Clinicians at the hospital encourage their patients to review their problem list online to identify errors that need correction and provide instructions for patients to report errors and have them corrected.[110]
- The hospital has a policy on what information to include in the problem list (and what should be left out), what to do with outdated data, who is responsible for the list's accuracy, and whether the accuracy of the list should be part of a clinician's evaluation.[110]
- Clinicians in inpatient units, including critical care units, review problem lists with patients while on rounds and make corrections in real-time in the EHR.
- The hospital deploys an EHR capable of linking a problem on the problem list to its supporting progress notes, administrative data, and clinical data such as test results and symptom documentation.[110]
- Hospitals use evidence-based guides to instruct clinicians on the proper use of copy and paste, such as the *Toolkit for the Safe Use of Copy and Paste* developed by the Emergency Care Research Institute (ECRI),[111] and follow other available guidance for appropriate use of problem lists.[112] [113]

Practice 2.1C – Ensure medical interpreters are available

Patients and family caregivers whose preferred language for medical information differs from their care team are provided with a professional medical interpreter (available 24 hours a day, 7 days a week), either on-site, via telephone, or via videoconferencing, to assist with:

- obtaining complete and accurate health information from the patient, and
- communicating complete and accurate information back to the patient.

Rationale

Language barriers put the health of many patients who are non-English speakers at risk by affecting their ability to communicate with their clinicians.[114] [115] [116] The ultimate diagnosis derives primarily from the patient's history, in most cases.[117] [118] Without this history, the diagnostic evaluation is less focused, more costly, and less likely to arrive at the correct diagnosis in a timely manner.

Misunderstandings in the patient's history are uncommon, and these have a high likelihood of leading to inappropriate tests and wrong, missed, or delayed diagnoses. Professional medical interpreters improve patient safety processes and outcomes.[119] [120] [121]

Resources and Strategies

- If available, the hospital matches patients whose preferred language for medical decision-making is not English with a certified bilingual clinician during diagnostic encounters.
- If certified bilingual clinicians are not available, the hospital ensures that the clinicians responsible for the patient's diagnosis have immediate access to professional medical interpreters to assist with obtaining the patient's medical history and communicating further plans and the diagnostic information back to the patient.
- The hospital contracts with a medical interpreter service vendor that offers phone and video interpretation 24 hours/7 days a week. Clinicians can access the service through a phone number or through a secure app on their personal device or a hospital-provided device.
- The hospital makes video interpretation devices highly accessible to clinicians by making them widely available throughout the hospital, thus raising the likelihood of use.
- The hospital employs virtual translation services such as *Connected Care*, *CyraCom*, or *Provider Solutions* to provide medical interpretation when interpreters are not available.

Practice 2.2A – Ensure access to radiology experts

The hospital has access to a radiologist 24 hours a day, 7 days a week, either onsite or via teleconferencing, to read and interpret urgent and emergent imaging studies and provide input on imaging test selection.

Rationale

Hospitals need access to appropriate radiology coverage 24/7, 365 days a year to avoid diagnostic errors. However, some U.S. hospitals must rely on radiology residents or ED physicians to interpret urgent and emergent imaging requests on night shifts, weekends, and holidays. These staffing arrangements can potentially lead to interpretative errors and delays in diagnosis. Discrepant and delayed readings of imaging studies have been amply documented in specialty imaging (pediatrics, neuroimaging, trauma).[122] [123] For example, 11% of trauma imaging studies disclosed a serious discrepancy between the original reading done by a resident and the subsequent 'official' reading by a staff radiologist.[122]

Essentially, all U.S. hospitals utilize digital imaging and have appropriate resources to enable teleradiology. One national survey of radiologists found that "teleradiology is widespread throughout modern radiology practice, helping practices achieve geographic, after-hours, and multispecialty coverage; reducing turnaround times; and expanding underserved access. Nonetheless, quality assurance of offsite examinations remains necessary."[124]

Resources and Strategies

- The hospital has intramural teleradiology arrangements (staff radiologists are available to read and interpret images from home) in place for all routine imaging whenever a staff radiologist is off-site to allow for 24 hours/7 days a week access to a radiologist. For general hospitals, the service is available for all routine adult imaging. For hospitals above a certain pediatric volume threshold, the service is available for all routine pediatric imaging. The service is accessed, as needed, at the discretion of the care team.
- The hospital has extramural teleradiology arrangements (contracted radiologists are available to read and interpret images) in place for all neuroimaging and specialty imaging (pediatric imaging at a general hospital) that allows for 24 hours/7 days a week access to a radiologist.
- The hospital has a program of ongoing review to evaluate the accuracy of readings and any diagnostic discrepancies, with feedback to the teleradiology provider.

Practice 2.2B – Jointly review diagnostic discrepancies

The hospital, at least quarterly, has a process by which radiologists and pathologists identify and jointly review cases where a biopsy, cytology, or autopsy result are discrepant with clinical and imaging impressions, and an interdisciplinary process to reconcile discrepant results.

Rationale

The first recommendation from the 2015 NAM report *Improving Diagnosis in Health Care* was to improve teamwork in diagnosis, and this applies directly to radiologists and pathologists;[1] "…pathologists, radiologists, and treating health care professionals should work collaboratively to improve diagnostic testing and imaging processes."

The feedback from pathologists on cases where there is a discrepancy between pathology results and imaging impressions provides a valuable opportunity for radiologists across all levels of experience to learn from these cases, improve their skill, and improve patient care.

Several researchers have provided evidence that joint review of radiology and pathology findings identifies resolvable discrepancies in diagnosis and care plans, and improves quality.[125] [126] [127] In cancer diagnosis, for example, the rate of discordance between radiologic and pathologic interpretations ranges from 1%-6% in a population where the malignancy incidence in cases thought to be benign has reached up to 25%-30%.[128] To quote one breast cancer study, "Determining imaging-pathology concordance after US-guided breast biopsy is essential. Discrepant cases and further diagnostic steps need to be discussed with an interdisciplinary approach".[129] Recent advances in informatics and artificial intelligence have facilitated joint radiology/pathology review processes.

The value of jointly reviewing cancer cases has prompted the suggestion of added value in more fully integrating the quality assurance programs in radiology and pathology.[130]

Resources and Strategies

- At the University of Kansas Medical Center in Kansas City, a weekly conference is held where pathologists and radiologists review all breast biopsies and produce a single integrated report.[131]

Practice 2.2C – Provide needed diagnostic expertise for patients admitted to the emergency department

Based on a risk assessment, the hospital ensures that the ED has access to the clinical expertise and technologies needed to ensure timely and accurate diagnosis of high-risk conditions (conditions that are commonly misdiagnosed and result in harm or death to the patient) identified by the department.

Rationale

The ED is a high-risk area for diagnostic error and presents many opportunities to improve diagnosis.[132] [133] Although there is now appreciable data on the conditions most likely to be involved,[134] [135] cases encountered locally are the most motivating to local clinicians. One example of a priority condition in adults is missed stroke, a serious cause of misdiagnosis-related harm in the ED.[136] An example of a priority condition in children is appendicitis.[137] [138]

Resources and Strategies

- Johns Hopkins Medicine provides consistent, rapid access to experts in stroke diagnosis and appropriate diagnostic technologies. The hospital maintains 24 hours a day, 7 days a week access to neurological consultants (on-site or teleneurology) and neuroimaging especially MRI. The hospital deploys novel diagnostic tests such as video-oculography that have been shown to facilitate major improvements in posterior stroke/dizziness diagnosis,[139] leveraging these[140] or related technologies[141] to facilitate remote eye movement assessment[142] for posterior strokes.[143] [144] Finally, they offer postdischarge access to specialists for short-term follow-up related to stroke diagnosis.
- The American Academy of Neurology's Telemedicine Work Group has found that teleneurology has a strong case for use in the diagnosis of epilepsy. This approach would enlist experienced specialists in epilepsy and neurophysiology in reading EEG records in real-time at rural hospitals that otherwise would not have access to this expertise.[145]

Practice 2.2D – Provide knowledge resources to clinicians

The hospital integrates knowledge resources into the clinical workflow to help clinicians improve their diagnosis in real-time for cases where there is diagnostic uncertainty and incentivizes clinicians to use these resources.

Rationale

Although most diagnostic errors involve breakdowns in clinical reasoning, many reflect deficiencies in knowledge. Clinical questions arise in practice and most go unanswered. Knowledge-related questions arise in roughly one third of cases in general practice, and physicians fail to pursue the answer in more than half of these situations.[146] In cases of diagnostic error, probably the most common reason for missed diagnosis is simply that "It never crossed my mind," as reported by internists with an average of four diagnostic errors in the past year.[147]

Providing knowledge resources and decision support tools for differential diagnosis can help address these common problems in care delivery. Decision support resources for differential diagnosis hold promise to address knowledge gaps in clinical practice and improve the likelihood of a correct diagnosis. However, decision support tools do have limitations and are often underused. AHRQ's systematic review of clinical decision support for diagnosis concluded, from exploratory studies, that these tools provide a useful adjunct to clinical decision-making and improve diagnosis and compliance with evidence-based recommendations.[79] Similar conclusions have been reached in other studies and systematic reviews.[148] [149] [150]

Resources and Strategies

- The hospital provides all clinical staff with online access to UpToDate, Micromedex, or equivalent medical knowledge resources. Ideally these are all EHR-integrated.
- The hospital ensures that clinical decision support is available for clinicians considering which, if any, diagnostic tests or imaging studies may be appropriate.
- The hospital ensures that all clinical staff have access to one or more decision support resources for a differential diagnosis.
- The hospital has a program to incentivize the use of medical knowledge and clinical decision support resources and monitors the efficacy and use of that program.

Practice 2.2E – Train clinicians to recognize and minimize cognitive errors

The hospital trains clinicians to optimize clinical reasoning in the diagnostic process. This includes training on critical thinking, avoiding and recognizing cognitive and affective bias, and utilizing organizational resources (team input, second opinions, decision-support tools for diagnosis) to improve diagnostic performance.

Rationale

The NAM report details how most diagnostic errors involve breakdowns in clinical reasoning, but most organizations have yet to take any specific steps to improve this cognitive aspect of diagnosis.[114] Most clinicians have little training in critical thinking, how to optimize clinical reasoning, or how to avoid or recognize cognitive bias. Some clinicians cannot access this training. Implementing an organization-wide educational program to address cognitive errors presents a timely opportunity to tackle this ubiquitous problem.

Training should include two elements:
- Practical advice on steps clinicians can take <u>on their own</u> to improve clinical reasoning, including reflection, and using tools to promote critical thinking.[151] [152] [153]
- Information on organizational resources to use and <u>getting help from others</u>. This includes taking input from team members, seeking second opinions and consults,[154] and having ready access to decision-support resources.[79]

AHRQ's systematic review of diagnostic error interventions concluded that "training on metacognitive skills may improve diagnostic accuracy, particularly as clinical experience increases" and that "online training, either didactic or via simulation, can be successfully used as a mode of delivery for educational interventions targeting clinical reasoning and diagnostic safety." Safety training to improve critical thinking is "feasible, well received, and effective."[79]

Resources and Strategies

- The hospital develops a training program that highlights the importance of clinical reasoning and the cognitive process, and includes some of the checklists, mnemonics, and decision support tools to improve clinical reasoning that are published on SIDM's [website].
- To encourage reflection and critical thinking in the diagnostic process, the Clinical Excellence Commission (New South Wales, AU) implemented the "[Take 2: Think Then Do]" program in all hospitals, emphasizing the value of a two minute "time out" for reflection to improve diagnosis.[155] Similarly, the Child Health PSO's (www.childrenshopsitals.org) *Diagnostic Safety Toolkit* includes directions and a template for a "time out" for reflection.[156]

Practice 2.2F – Implement and monitor adherence to diagnostic guidelines

The hospital deploys clinical pathways for diagnosis to help clinicians consistently implement evidence-based guidelines for care in the ED and measures the impact of implementing the guidelines on diagnostic performance (e.g., post-ED hospitalizations).

Rationale

Guideline-concordant care generally improves the quality and safety of health care processes and reduces variation in care provision. The American College of Emergency Physicians (ACEP) issues guidelines for diagnosing a wide range of high-risk clinical conditions commonly encountered in the ED. Many other ED-relevant guidelines are available from major medical centers or professional societies. These include guidelines for diagnosing stroke,[157] sepsis,[158] appendicitis,[159] and spinal abscess.[160] Promoting use and monitoring adherence to published guidelines can improve the diagnostic process for patients.

Resources and Strategies

- The hospital engages ED staff to review and adopt one or more published national guidelines that address high-risk conditions and monitor the quality of care before and after via the ACEP Clinical Emergency Data Registry.
- The hospital has protocols in place to ensure ED staff follow appropriate evidence-based guidelines for stroke diagnosis, particularly posterior circulation stroke, such as the ACEP guideline on evaluation of adult patients with suspected transient ischemic attack (TIA).[161]
- The hospital deploys clinical care pathways that help clinicians consistently implement such guidelines and implements measures of stroke hospitalizations following ED treat-and-release visits to facilitate ongoing monitoring of diagnostic performance.[162] [163]
- The hospital shares clinical pathways with other hospitals in their region. For example, a large pediatric referral center with an abundance of local pathways shares these pathways through active collaboration with general hospitals in the region. The regional centers in turn share feedback with the referral center.
- The hospital has protocols in place to ensure that staff follow appropriate evidence-based guidelines for diagnosing sepsis, such as the *Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021*.[164]

Practice 2.3A – Manage diagnostic uncertainty at handoffs

The hospital has a written policy that outlines the steps care team members should take when handing off patients with diagnostic uncertainty to the care team assuming responsibility for the next phase of care, including different units within the same hospital (e.g., emergency department to inpatient unit, hospital to skilled nursing facility, general hospital to free-standing pediatric hospital, hospital to primary care physician, to and from intensive care units, between specialty services).

Rationale

Uncertainty in diagnosis needs to be acknowledged and managed in everyday practice, and failure to address uncertainty is a major issue in cases of diagnostic error.[165] This is particularly true during handoffs and transitions in care. Critical elements of the handoff to convey to the care team assuming responsibility for the next phase of care are what has already been done, and what still needs to be done or considered. These facts need to be well documented, along with the degree of certainty or uncertainty regarding them. New tools to manage uncertainty are appearing and are especially useful at handoffs. [166] [167] [168]

Handoffs are prone to errors. Problems with handoffs are commonly cited in cases of diagnostic errors, which include failure to follow-up on abnormal test results. Failure to mention key items and to explain issues or complexities clearly are commonly-encountered causative factors in cases of diagnosis-related error and harm.[169] [170] [171] Safer patient handoffs are a major recommendation from NAM[1] and HRET,[20] **Error! Bookmark not defined.** and is one of the 10 key items on the *Safer Dx Checklist.*[32]

Resources and Strategies

- The hospital implements evidence-based tools and resources to improve both verbal communication (e.g., *TeamSTEPPS® for Diagnosis Improvement* or IPASS) and electronic communication (e.g., based on a self-assessment from the *ONC-sponsored SAFER Guide for Clinician Communication*).[172]
- The hospital takes the lead in convening a group of clinicians and administrators from neighboring facilities (e.g., nursing homes, primary and specialty care offices) to review and improve documentation and communication of uncertainty in diagnoses so the receiving facility can take the appropriate next steps.
- The hospital has a written policy of steps to transition the patient's care to a primary care team that includes written communication of the most likely diagnosis and its degree of certainty.

Practice 2.3B – Communicate clear instructions to patients discharged with an uncertain diagnosis

For patients discharged home from the hospital or the ED with an uncertain diagnosis, or where potential diagnoses involve high-risk conditions, the hospital should have a policy that ensures patients receive both of the following:

- Discharge summary notes with available test results and any test results that are pending.
- Explicit, condition-specific instructions for the patient and family caregiver on what to watch out for, when to return to the hospital, or how to get timely follow-up care, if needed.

Rationale

Many patients have a preliminary diagnostic evaluation in the ED or during their hospital admission that requires follow-up and further evaluation in an ambulatory setting. However, patients leaving the ED or hospital are often unclear on how or when to re-engage with care if their symptoms change or progress.[173]

Resources and Strategies

- The hospital has amended their patient discharge policy to add specific elements for uncertain or potentially high-risk diagnoses, which outlines the steps and instructions described in the practice statement.
- The hospital periodically conducts patient focus groups to ensure their policy, as executed, is effective in helping patients and their family caregivers obtain test results that were pending at discharge and understand how and when to seek the next phase of care. The hospital PFAC could lead this initiative.
- The hospital has amended their patient discharge policy to ensure discharge instructions are made available to the patient in the patient and/or family caregiver's primary language.

Practice 2.3C – Communicate clear instructions to patients discharged with pending test results

The hospital has a process and protocol in place to ensure that patients are discharged from the ED or hospital with 1) a list of their lab and imaging test results and 2) a list of any pending test results and written instructions to obtain those results.

Rationale

A test result is a critical piece of diagnostic information. Missed test results can lead to a missed diagnosis, or a missed opportunity to correct an erroneous diagnosis. The risk of a missed test result is magnified for patients in transition from hospital to home.[174] [175] A systematic review of 12 studies concluded that up to 16% of patients released from the ED and 23% of patients discharged from inpatient care will have laboratory test results pending.[176] In one study, 41% of medical inpatients had one or more test results (laboratory or imaging) pending at discharge, over 40% of the results were abnormal, and 9% required action, importantly, the patients' physicians were unaware of 62% of the test results.[177]

Often, test results pending at discharge are not mentioned in the discharge summary. The clinician(s) who assume the patient's care in the post-discharge ambulatory setting may not be aware that these tests were ordered and will not see the results because they are routed back to the hospital-based physician. It is critical to ensure patients know where and when to obtain these results.

Resources and Strategies

- The hospital implements a rigorous follow-up system for test results pending at discharge with a clear hierarchy of clinicians responsible for acting on results as they come in.
- The hospital develops a standard set of clear instructions for patients to obtain pending test results, using input from patients and family caregivers, representatives from Laboratory Medicine and Radiology, and representatives from the ED and other relevant hospital departments (hospitalists).
- The hospital monitors test results pending at discharge before and after implementation of the new discharge instructions to ensure more patients are obtaining their pending test results once they are discharged home.
- The hospital implements an automated email or text message system that notifies patients when their pending test results are ready. Discharge instructions note that patients can expect the email notification.[178]

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To mitigate this patient harm risk, the hospital partnered with the ED and Service Excellence Department to implement a protocol wherein clinically trained staff, including nurses and pharmacists, call the patient to close the loop and notify them of any test results that were pending at discharge and communicate the appropriate next steps. The Service Excellence Department developed scripting to communicate test results and enhance standard message delivery.

In addition, the success of this program also depended on collaboration with the Registration Department. The team refined their process to ensure the accurate collection of telephone numbers and email addresses, they helped patients register for the patient portal. Kirsten Edler led the FMEA team in the implementation of the new protocol.

Calling Patients for Test Result Follow-Up

During the height of the COVID-19 pandemic, ED staff at Frederick Health Hospital noticed a dangerous pattern: patients afraid of being exposed to COVID-19 were leaving the ED after tests were performed, but before they saw a physician who could give them their test results and appropriate discharge instructions. In response, the hospital conducted a Failure Mode and Effects Analysis (FMEA) and identified that one issue with patients leaving the unit before an official discharge was not knowing what tests(s) had been completed, what the results were, and where to find pending test results.

- ○ **Process Map - Activity**: A step in a process.
- ○ **Key Process Input**: The source of variability at each process step.
- ○ **Potential Failure Mode**: The ways that the process can fail for each key input. An input can have multiple failure modes.
- ○ **Potential Failure Effects**: The output results of each failure mode. A failure mode can have multiple failure effects.
- ○ **SEV** (severity rating): The severity of the output on each step. Use a 1 to 10 scale, where 10 is high severity and 1 is low severity. To mitigate potential legal issues, carefully define high severity outputs.
- ○ **Potential Causes**: The causes of the failure mode.
- ○ **OCC** (occurrence rating): How frequently the cause is likely to occur. Use a 1 to 10 scale, where 10 is highly frequent and 1 highly infrequent.
- ○ **Current Controls**: The way that the failure cause or mode is detected or controlled (for example, a poka-yoke device).
- ○ **DET** (detection rating): The ability of each control to detect or to control the failure cause or mode. Use a 1 to 10 scale, where 10 is poor detection or control (the cause is almost never detected before the failure) and 1 is high detection or control (the cause is almost always detected before the failure).

Evaluate the RPN to identify the risks.

- ○ **RPN:** The product of the **SEV**, **OCC**, and **DET** scores. A high **RPN** score indicates a more severe, more frequent, or less controlled problem. Always investigate a failure effect that has a high severity, regardless of its **RPN** value.
  - ▪ After you correct the failure, enter new **SEV**, **OCC**, and **DET** values to recalculate the **RPN**. You can record up to two sets of improvements, which is adequate for most situations.

Practice 2.3D

Subdomain 2.3: Processes and structures are in place to effectively communicate diagnostic information to patients and ensure timely and complete hand-offs during transitions of care

Practice 2.3D – Implement "closed-loop" communication

The hospital has a written policy that outlines the responsibilities of each care team member to ensure all critical and subcritical test results, including those pending at discharge, are viewed by the care team and communicated to the patient in a timely manner.

Rationale

Closed-loop communication means that every test result is sent, received, and addressed in a timely manner, and the patient is notified of the results and next steps. Test result follow-up is a longstanding problem that leads to delays in diagnosis and treatment. Breakdowns in communicating important test results to patients are common, even with modern EHRs. Delays and breakdowns in communicating abnormal radiologic findings are the second most common cause of a malpractice suit in radiology, and communication breakdowns are twice as likely to result in potential harm.[179] [180] In a study of alerted abnormal lab results, 6.4% were not followed-up within 30 days.[181]

These omissions can lead to patient harm and are encountered with some frequency in every study of diagnostic error. Tests pending at discharge, tests sent to outside labs, and revised test reports are especially problematic for communicating results to patients.

Several solutions have been advanced, but "Closed loop communication"[182] is a strong recommendation from a wide range of authoritative sources including NAM,[1] The Joint Commission,[183] AHRQ[79] and ONC.[184] Each of these resources provides guidance on addressing breakdowns in test result communication.

Resources and Strategies

- The hospital models the U.S. Department of Veterans Affairs national policy for the safe communication of test results to patients and clinicians. This policy includes national standards on timeliness of test result communication and informs performance measurement and quality improvement programs widely implemented across the VA health care system.[185]
- The hospital investigates and replicates Kaiser Permanente Southern California's "SureNet" system, which uses an algorithm to proactively identify patients that are overdue for a follow-up of abnormal tests.[186]
- The hospital reviews and adopts recommended practices on test result communication and follow-up found in the ONC-sponsored *SAFER Guides*.
- The hospital utilizes ECRI's *Closing the Loop Toolkit* to communicate all patient data and health information requiring an action to the correct individuals so the appropriate next step can occur.
- The hospital manages incidental findings through the tracking and follow-up of clinician recommendations and replicates efforts such as the *Backstop recommendation tracking system program* piloted by the University of Rochester.
- The hospital adheres to the safety actions outlined in The Joint Commission *Quick Safety Issue 52* to improve communication of test results and ensure patients understand any required next steps based on their results (e.g., optimize your organization's health IT capabilities, improve your organization's patient portal).[187]

FEATURED IMPLEMENTATION EXAMPLE – PRACTICE 2.3D

SureNet Identifies Missed Follow-Ups

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To minimize breakdowns in communication, the Kaiser Permanente health system created a "safety net" program, called SureNet, to track and resolve missing follow-ups of test results. SureNet works by regularly, electronically scanning the entire electronic medical record database, across all 12 million patients in Kaiser's health system, and checking for over fifty different possible scenarios of missed follow-ups and potential medication safety issues. When a missing follow-up is identified, the physician, facility and, in some cases, the patient is alerted and encouraged to complete the missing test.

Although most of these tests are designed for missing results in an ambulatory setting, some are applicable to hospitals, especially in the ED. For example, if an elevated creatinine is found in a patient's blood, and a follow-up blood test is not completed 3 months later to potentially diagnose chronic kidney disease, the system sends an alert to conduct the test. Another example is a follow-up alert with patients who reported suicidal ideation during an ED visit.

Dr. Kanter recommends hospitals identify what data they can access (claims data, data in the EHR), identify a gap in follow-ups, and design an intervention to periodically scan patients' EHRs to identify these missing follow-ups. Although every system will have different capabilities and limitations, most hospitals are not currently engaged in this kind of work. Dr. Kanter also cautions that when designing a system, hospitals should be careful to not contribute to provider burden or alert fatigue, and ensure alerts are only delivered to clinicians when they are both highly specific and actionable. The SureNet program should create its interventions such that the physician's workload is minimized.

PROMISING PRACTICES

There are two practices that may not be ready for widespread implementation by hospitals nationwide, but still show considerable promise: (1) provide feedback to clinicians on their diagnostic performance and (2) join a Patient Safety Organization to submit reports on diagnostic safety events. High-performing hospitals that have implemented many of the 29 Recommended Practices described in this report should look to these two practices, which require greater resources to support adoption, as the next frontier in improving diagnostic safety and quality.

Provide feedback to clinicians

The hospital provides clinicians with feedback on their diagnostic performance. The hospital should follow specific best practices when providing feedback to clinicians including timeliness, preparing the clinician before receiving the feedback, and fostering a learning environment and constructive dialogue.

Rationale

The 2015 NAM report *Improving Diagnosis in Health* cited "limited feedback to clinicians about diagnostic performance" as a key root cause of diagnostic errors, even though feedback "is essential for improved diagnostic performance".[1] The emphasis on the importance of systematic feedback goes back decades further,[188] but little progress has been made since. As Meyer and Singh argue, "clinicians must learn about the ultimate accuracy of their diagnoses, as well as the processes that led them to those diagnoses…or why diagnostic performance was suboptimal."[189]

Interventions are available to provide feedback to clinicians consistently and in a manner carefully targeted to enable continuous improvement. On promising model is the Diagnosis Learning Cycle, in which researchers engaged in a deliberate process drawing from learning in other fields, developing a model of diagnostic reasoning to enable the provision of regular feedback to clinicians.[190]

Resources and Strategies

- At Geisinger, the hospital tested a program to deliver performance feedback to clinicians on missed opportunities in diagnosis.[191] The program first identified potential cases from risk management, clinician reports, and patient complaints. Next, the hospital developed a guide to ensure the feedback sessions were structured, supportive, and nonpunitive. After training with a clinical psychologist, department leaders served as facilitators of feedback sessions, which generally lasted 20 to 30 minutes and reviewed both individual and system-based root causes of the diagnostic missed opportunity under discussion.
- At University of California San Diego, the *Post-Handoff Reports of Outcomes (PHAROS) project* uses the EHR to create an individual summary for clinicians that lists patients recently under their care and highlights outcomes after the patient was handed off to another clinician.

Participate in Patient Safety Organizations (PSO)

Hospitals should participate in a PSO, report diagnostic safety events using the AHRQ *Common Formats for Diagnostic Error Reporting and* participate in any opportunities for shared learning offered by the PSO.

Rationale

PSOs collect and analyze voluntarily reported data from health care providers, including hospitals, to help improve patient safety and health care quality. PSOs then provide feedback to promote learnings across the industry and prevent future errors. Information shared with PSOs and reported by PSOs is confidential to protect patients, providers, and hospitals. AHRQ released the Common Format for Diagnostic Safety Event Reporting in 2022 to help standardize reporting and key learnings related to diagnostic errors.

A benefit of PSOs is they provide useful information to hospital leaders that helps them better prioritize where they need to focus on improvement. Although PSOs may not be available to all hospitals and disciplines, the variety of available organizations means many hospitals will be able to find an appropriate fit and immediately begin to leverage the benefits of learning from diagnostic errors and other patient safety events. Although only half of hospitals are currently working with a PSO, 80% of those who do, find the learnings from participating in a PSO have helped prevent recurrences of safety events.[192]

Resources and Strategies

- Hospitals interested in working with a PSO can review the benefits of doing so and the steps needed by accessing AHRQ's [PSO homepage](#). This homepage includes a resource for searching for PSOs by area and specialty.

GAPS IN AVAILABLE RESEARCH

These practices reflect the best evidence and thinking available at the time of the report's publication, but evidence and reasoning in health services and clinical research continually evolves over time. Leapfrog plans to perform an environmental scan of literature published since 2021 and may issue updates to this report in 2024. Those working from this report are urged to monitor new advances in the field.

This report focuses on structures and processes that have evidence linking them to improved diagnostic safety and quality. It does not specifically focus on diagnostic outcome measures. As detailed in Practice 1.4B – Measure and Monitor Diagnostic Safety Outcomes, hospitals would benefit from identifying valid, reliable, and feasible diagnostic outcome measures that help them assess the impact of implementing these practices. However, these outcome measures are, at best, under development; none are in widespread use in federal public reporting programs, nor have they been reviewed by the NQF for endorsement.

Moreover, this report does not address ambulatory care settings, where most diagnoses are made. The focus of this report is acute care and emergency care in hospitals. Some of the practices included in the report may have applicability to ambulatory care, and specific recommendations for ambulatory care may follow in subsequent editions of this report. Finally, this report does not address the problem of overtesting and overdiagnosis. Overdiagnosis occurs when unnecessary diagnostic tests are performed and can increase the likelihood of false positive test result that create unnecessary and sometimes invasive care. We acknowledge that one unintended consequence of efforts to improve diagnosis may be over testing or overdiagnosis.

The field of diagnostic performance would benefit from additional work and studies to help quantify how well the practices included in this report drive improved diagnosis in the hospital setting. Many of the practices included in this report reflect a practice that has been trialed with a specific patient population or in a limited number of sites. Therefore, a broader understanding of their impact as adoption of the practice spreads would be beneficial for understanding where resources should be invested and where adoption should be encouraged. Documenting lessons learned in implementing these new practices would be valuable to the field, and we encourage the reporting of these lessons.

APPENDIX A: DEFINITIONS OF KEY TERMS USED IN THIS REPORT

Diagnostic error: An event where one or both of the following occurred, with harm or high potential of harm to the patient:

- Delayed, wrong, or missed diagnosis: At least one missed opportunity to pursue or identify an accurate and timely diagnosis based on the information that existed at that time.
- Diagnosis not communicated to the patient: Accurate diagnosis was available but was not effectively communicated to the patient or family.

(Adapted from the definition of a "diagnostic safety event" from the [2021 AHRQ *Common Formats for Event Reporting – Diagnostic Error*](#).)

Measurement framework: A tool to organize recommended practices related to diagnostic safety and quality in hospitals. Measurement frameworks are used in health care quality measurement as conceptual models that create an organized structure for different ideas about what is most important to measure in each area of health care.

Recommended practices: Practices for which there is some clear rationale (recommended by subject matter experts and/or peer-reviewed literature) that links the practice to improvements in the diagnostic process and/or diagnostic outcomes in hospitals. For the purposes of this report, these are practices that were identified and prioritized by the Advisory Group, and generally represent practices that have been implemented and assessed in one or more organizations.

Senior administrative leaders: Individuals responsible for hospital-wide departments or services (e.g., Chief Executive Officer, Chief Administrative Officer, Chief Nursing Officer, Chief Medical Officer).

Clinicians: Healthcare professionals qualified for clinical practice (providing direct care to patients). Clinicians include physicians, nurses, pharmacists, or other allied health professionals (adapted from [CMS](#)).

Care teams: Care teams are groups of healthcare professionals who collectively take responsibility for a set of patients. Care teams blend multidisciplinary skills, focusing insights of several people rather than a single clinician on each patient's problems (adapted from [AHRQ](#)).

Others involved in the diagnostic process: Healthcare professionals that include, but are not limited to radiologists, pathologists, laboratory personnel, and others.

Family caregiver: Any relative, partner, friend or neighbor who has a significant personal relationship with, and provides a broad range of assistance for, a person receiving medical care or long-term care services such as an older person, a child, or an adult with a chronic or disabling condition. These individuals may be primary or secondary caregivers and live with, or separately from, the person receiving care (adapted from the [Family Caregiver Alliance](#)).

Purchasers: Private and public sector employers and health plans who pay for health care services on behalf of their employees or members.

APPENDIX B: OTHER MEASUREMENT FRAMEWORKS

We conducted an environmental scan for other recently published diagnostic frameworks to determine whether frameworks either in their current form or in combination with one another, could be used to establish a logical framework to identify and organize recommended practices for hospitals aiming for diagnostic excellence.

The environmental scan sought frameworks developed by national workgroups (NAM, NQF) or recent additions to the space (the Safer Dx Framework). The following four frameworks were identified and reviewed:

The National Quality Forum Diagnostic Quality and Safety Framework: This framework (Figure 3) measures diagnostic quality and safety within three major domains, shown in the circle. The framework envisions the patient and their care as the focal point of diagnosis. Thus, the first domain (green) includes elements of patient engagement, patient satisfaction, and patient-based health outcomes. The second domain (orange) includes the various steps of the diagnostic process. The third domain (purple) captures organizational decisions, such as the environment of care and the role of leaders in setting priorities, providing resources, and establishing a safety culture. This framework formed the basis of the Recognizing Excellence in Diagnosis Measurement Framework.

Figure 3: National Quality Forum's Diagnostic Quality and Safety Framework
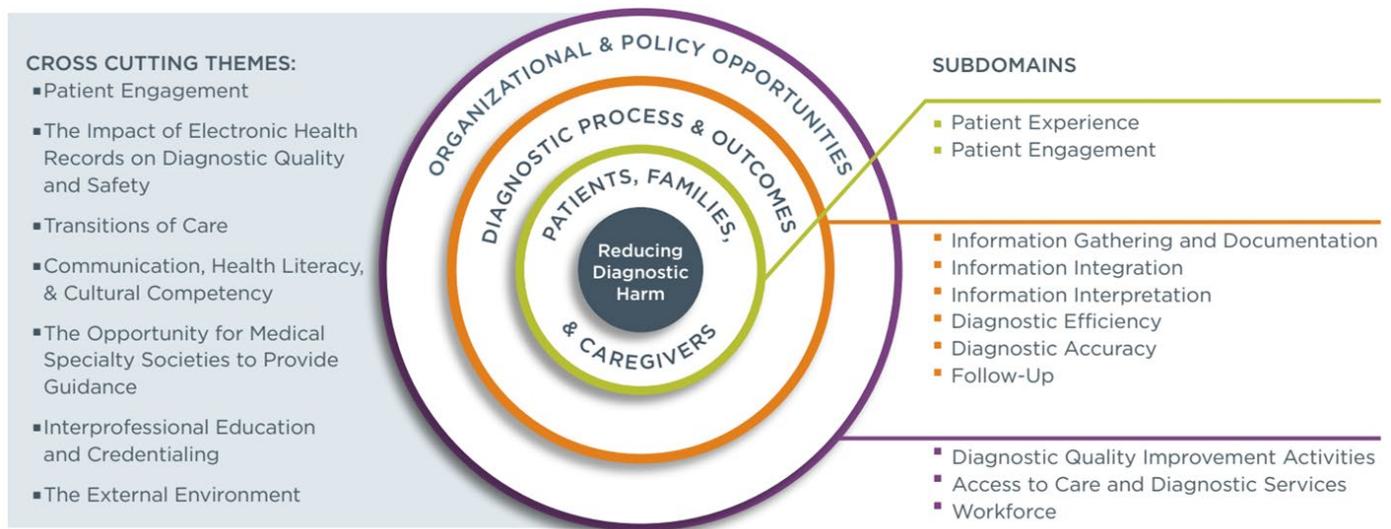
The Safer Dx framework: This framework (Figure 4) establishes a robust groundwork for measurement and monitoring techniques to ensure diagnostic safety.[193] As noted in Singh and Sittig, "the framework accounts for the complex adaptive sociotechnical system in which diagnosis takes place (the structure), the distributed process dimensions in which diagnoses evolve beyond the doctor's visit (the process) and the outcomes of a correct and timely 'safe diagnosis' as well as patient and health care outcomes (the outcomes)." We adopted many of the ideas specific to the Diagnostic Process and

incorporated the changes in policy as recommended practices in our Recognizing Excellence in Diagnosis framework.

Figure 4: The Safer Dx Framework
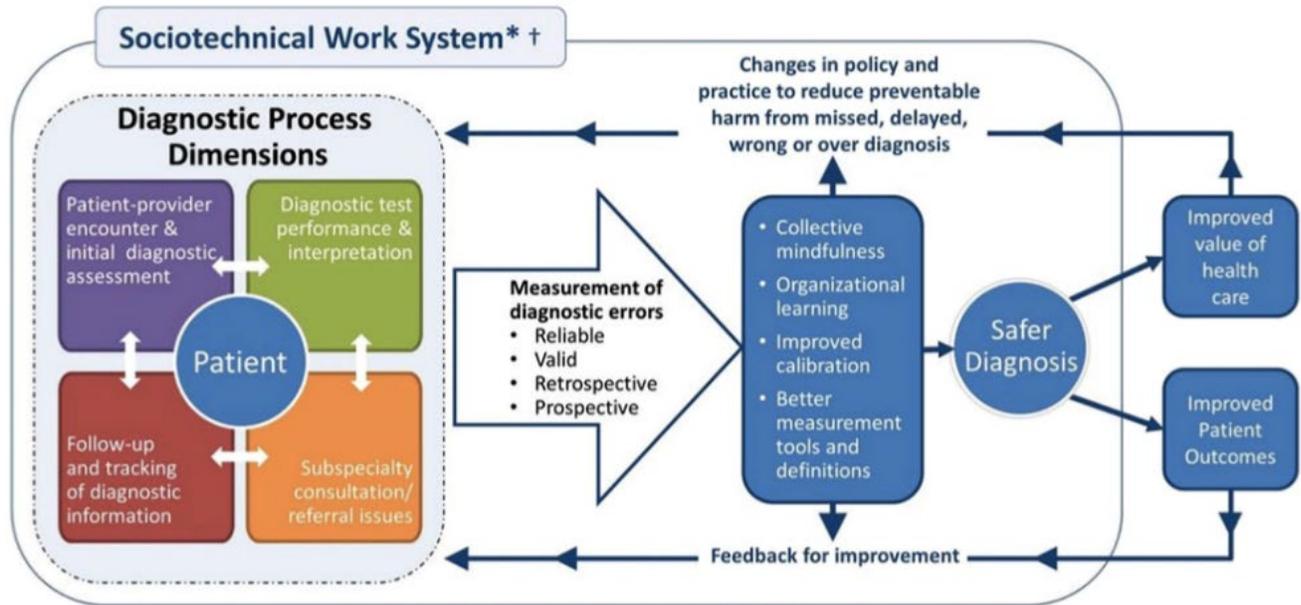
Re-used with permission from the British Medical Journal of Quality and

National Academy of Medicine Improving Diagnosis in Health Care Framework: This framework (Figure 5) aims to address the dual goals of reducing diagnostic errors and improving diagnosis and emphasizes each individual step of the diagnostic process and its evolution.[1] As with the Safer Dx framework, many of these elements, especially consideration of the "work system" and the critical importance of communicating the diagnosis, were incorporated as subdomains into the Recognizing Excellence in Diagnosis Measurement Framework, or included as recommended practices.

Figure 5 National Academy of Medicine's Improving Diagnosis in Health Care Framework
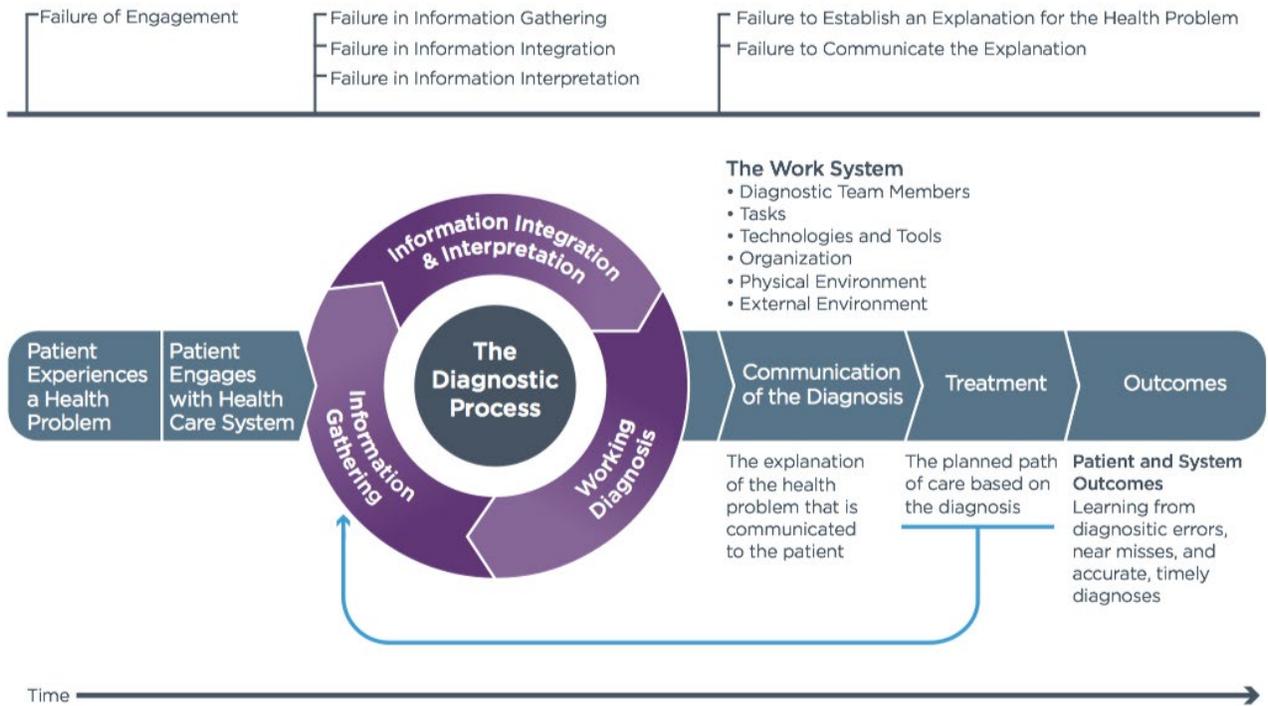
Re-used with permission from the National Academies of Medicine

The "situativity" framework: This framework (the image is publicly available and can be accessed at DeGruyter) derives its name from considering diagnosis as being *situated* in a particular context, in which diagnosis is not just a cognitive activity "in the head," but a pursuit "in the world", where success will depend on many other factors beyond just clinical reasoning skills.[194] This framework approaches the complexity of diagnosis by considering social, ethnographic, and phenomenological perspectives that are not fully accounted for in prior frameworks, which are primarily derived from a human-factors/organizational safety viewpoint. The "situativity" framework provides an appropriate framework for understanding and addressing the equity and disparity issues in diagnosis that are increasingly evident, and these concepts have been incorporated in the cross-cutting areas of the Recognizing Excellence in Diagnosis Framework.

APPENDIX C: PRIORITIZATION OF RECOMMENDED PRACTICES

Prioritization of Recommended Practices

The Advisory Group used the following four prioritization criteria to narrow down the final set of recommended practices:

- Impact of reducing diagnostic harm to patients, based on an estimate of the potential for the practice to reduce harm.
- Feasibility of implementation, based on an estimate of both the cost and time required to implement the practice.
- Usable to patients and purchasers choosing between hospitals for care, based on the utility of publicly reported data comparing hospital performance on a measure of the rate of implementation of the practice.
- Ability to distinguish between high and low performers, based on an estimate of the national distribution of hospital performance in implementing the practice.

Following the prioritization exercise, scores were tallied for each recommended practice. In addition, subject matter experts rated the evidence base supporting each practice. The Advisory Group met again to discuss the scores, reviewing practices with a low score to recommend either that the practice be revised to address the concerns of the Advisory Group, or be removed from consideration for inclusion in this report. The culmination of this process yielded the 29 practices described in this report.

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