Measure DX:

A Resource to Identify, Analyze, and Learn From Diagnostic Safety Events

Agency for Healthcare Research and Quality

PATIENT SAFETY

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Measure Dx

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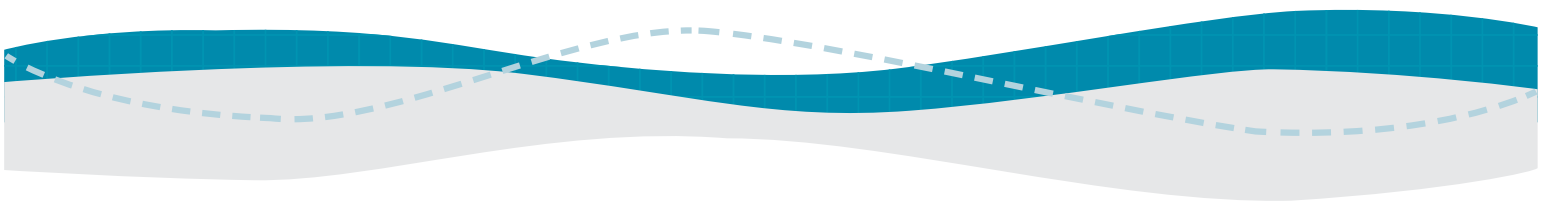

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Introduction

Diagnostic errors often involve missed opportunities related to various aspects of the diagnostic process, including recognition of key signs, symptoms, and test results. Unfortunately, as noted in the 2015 National Academies of Sciences, Engineering, and Medicine (NASEM) report *Improving Diagnosis in Health Care*,[1] tragic outcomes are not rare. The case of Rory Staunton (sidebar) is one example. Diagnostic errors are major contributors to patient harm, but their complexity and intertwined cognitive and systems origins make them difficult to identify and measure.

Measurement begins with a definition. NASEM defined diagnostic error as "the failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient." Singh and colleagues proposed the concept of "missed opportunities" in diagnosis.[2] The Agency for Healthcare Research and Quality (AHRQ) adapted and applied concepts from both definitions and defined a **diagnostic safety event**[3] as the occurrence of one or both of the following (whether or not the patient was harmed):

- **Delayed, Wrong or Missed Diagnosis**: There were one or more missed opportunities to pursue or identify an accurate and timely diagnosis (or other explanation) of the patient's health problems based on the information that existed at the time.
- **Diagnosis Not Communicated to Patient**: An accurate diagnosis (or other explanation) of the patient's health problems was available, but it was not communicated to the patient (includes patient's representative or family as applicable).

As of now, reliable, valid, and usable measures of diagnostic safety are still under development. Still, simply identifying and analyzing diagnostic safety events is useful because the measurement process itself can bolster learning and improvement. NASEM recommended that accrediting organizations require healthcare organizations (HCOs) to "monitor the diagnostic process and identify, learn from, and reduce diagnostic errors and near misses in a timely fashion."[1]

Measure Dx has been developed to help HCOs detect diagnostic safety events and learn from them to gain actionable insights for improvement. In the long term, the strategies described in this resource can be used to "promote a nonpunitive culture that values open discussion and feedback on diagnostic performance" and create HCOs that value Learning and Exploration of Diagnostic Excellence (LEDE organizations).[4] LEDE organizations use safety surveillance methods to create a continuous learning and feedback cycle, and their leaders act on data to prevent diagnostic harm (Figure 1). Few HCOs currently apply this systematic approach to improve diagnostic safety.

Figure 1. Learning and Feedback System for LEDE Organizations

Case Example

Sepsis in a 12-Year-Old Boy

A healthy 12-year-old boy, Rory Staunton, cut his arm during a basketball game at school. The next day, he woke up with symptoms of vomiting and leg pain. His parents brought him to the pediatrician, who attributed Rory's symptoms (leg pain, vomiting, fever) to possible gastroenteritis.

Rory was referred to the emergency department (ED), where he was also given a diagnosis of gastroenteritis and sent home. Rory had mottling of the skin that was not noted or acted on. His labwork showed leukocytosis, (white blood cell count 14.7, 54% band forms), but test results were returned only after Rory was discharged from the ED.

No action or plan was documented based on the abnormal findings, and no information was communicated to Rory's parents or his primary pediatrician. Rory continued to worsen and the following day returned to the ED, from where he was admitted to the intensive care unit. A few days later, he died of streptococcal sepsis thought to be related to his initial cut on the arm.

Adapted from Dwyer J. An infection, unnoticed, turns unstoppable. New York Times, 2012 Jul 11.

What is Measure Dx?

Measure Dx is a resource to help healthcare professionals and organizations detect, analyze, and learn from diagnostic safety events at their HCOs. Measure Dx includes:

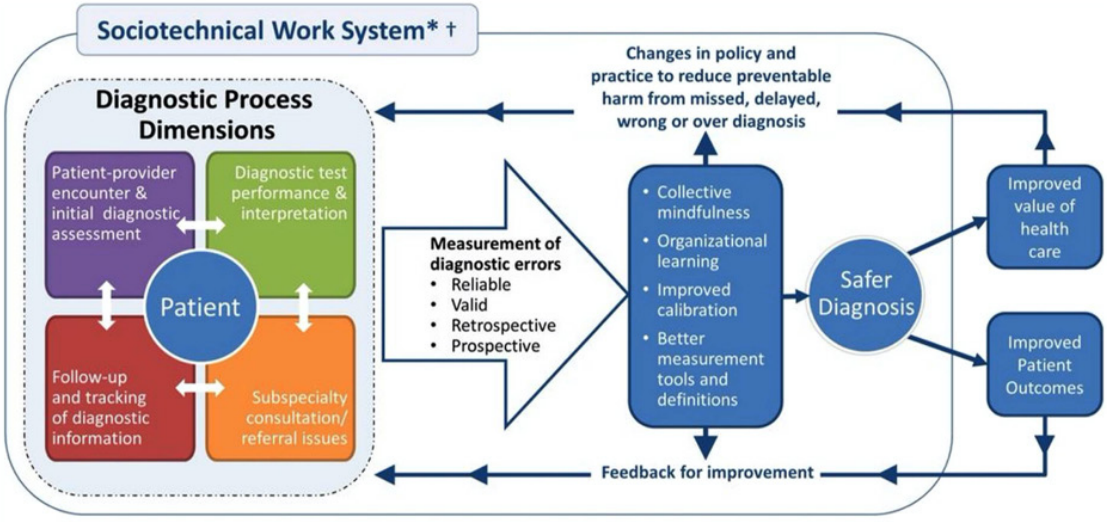
- A **Guide** (this document) that provides background and step-by-step instructions for developing, implementing, and sustaining diagnostic safety measurement strategies.
- **Appendixes** that include additional resources, tools, and instructions for various activities outlined in the guide.
- An **Infographic** that can be used to quickly orient various stakeholders to the significance and purpose of these activities.

Measure Dx can be used by any organization interested in promoting diagnostic excellence and reducing diagnostic safety events that can result in harm. The audience for this resource includes anyone interested in improving diagnostic safety. Users may include, but are not limited to, clinicians, quality and safety professionals, risk management professionals, health system leaders, clinical managers, and any organizations or entities engaged in quality and safety improvement.

In 2020, an AHRQ issue brief outlined the state of the science of operational measurement of diagnostic safety, informed by peer-reviewed scientific publications, innovations in real-world healthcare settings, and initiatives to spur further development of diagnostic safety measurement.[5]

Measure Dx translates recommendations from the issue brief[5] to provide practical guidance on implementing these innovations. The goal of these activities is to stimulate learning and identify targets for improvement. The strategies outlined in this resource do not prescribe specific metrics, but rather provide a foundation for HCOs to implement routine discovery, learning, and feedback in their daily operations.

Figure 2. Safer Dx Framework



* Includes 8 technological and non-technological dimensions
† Includes external factors affecting diagnostic performance and measurement such as payment systems, legal factors, national quality measurement initiatives, accreditation, and other policy and regulatory requirements.

Reprinted with permission from Singh H, Sittig DF. Advancing the science of measurement of diagnostic errors in healthcare: the Safer Dx framework. BMJ Qual Saf. 2015 Feb;24(2):103-10. doi: 10.1136/bmjqs-2014-003675. Accessed April 27, 2022.

The Safer Dx framework[6] (Figure 2) provides a conceptual framework for this resource, which addresses measurement of missed opportunities in diagnosis involving five key components of the diagnostic process.

1. The patient–provider encounter (history, physical examination, ordering of tests/referrals based on assessment)
2. Performance and interpretation of diagnostic tests
3. Followup and tracking of diagnostic information over time
4. Subspecialty and referral-specific factors
5. Patient-related factors

How to use the Measure Dx Guide

This guide is organized into four sections that reflect the general sequence of activities needed to begin and sustain measurement of diagnostic safety. However, these steps are not "one size fits all" and should be considered iterative: as new learning emerges, you will most likely find it useful to revisit and refine your strategy.

- Part I proposes strategies to engage people in your organization to ensure that you have adequate resources to implement measurement and learning activities, as well as support from leaders and other stakeholders. A case example illustrates the process of bringing in additional stakeholders over time. This section also addresses the importance of psychological safety and the need to ensure that activities are carried out in compliance with HIPAA[i] and other relevant laws related to privacy, confidentiality, and privilege protections.
- Part II is a self-assessment to gauge both overall organizational readiness and guidance for choosing one or more of four types of strategies that you can consider for measurement of diagnostic safety at your HCO.
- Part III provides guidance for implementing diagnostic safety measurement strategies, including step-by-step recommendations and case examples. For the purpose of this resource, a measurement strategy is a process that includes case finding and systematic analysis of cases for learning opportunities. Strategies can be used in combination for more robust learning and apply both to missed opportunities and to cases that went well. The choice of measurement strategy depends on your diagnostic safety team's goals, expertise, technical capabilities, and available human and data resources.
- Part IV provides recommendations for systematically reviewing and analyzing the gathered data and translating your findings into useful insights for local learning and improvement. It also includes guidance for training reviewers and using structured case review tools.
- References to **Appendixes** and the **Infographic** are provided when relevant as additional materials to facilitate measurement activities.

[i] Health Insurance Portability and Accountability Act

Overview of the Resource

1 Preparing Your Organization for Diagnostic Safety Measurement

Essential conditions for using measurement for learning and improvement include engaging leadership and other stakeholders throughout the organization, building a team, and fostering psychological safety.

→ **Case study: Building a Diagnostic Safety Program**

2 Organizational Self-Assessment

A checklist to ensure that sufficient resources are available to support diagnostic safety measurement activities and self-assessment questions to guide selection of one or more measurement strategies.

→ **General Organizational Readiness Checklist**

→ **Selecting a Measurement Strategy**

3 Measurement Strategies

Strategies and practical guidance for identifying potential missed opportunities in diagnosis for the purposes of learning and improvement.

Strategies are selected both for potential yield of actionable information and readiness for implementation. Case examples illustrate application in real-world settings.

→ Strategy A
Use Quality and Safety Data Already Collected by the Organization

→ Strategy B
Solicit Reports From Clinicians and Staff

→ Strategy C
Leverage Patient-Reported Data

→ Strategy D
Electronic Health Record-Enhanced Chart Review

4 Reviewing and Analyzing Cases of Interest

A process to systematically review and analyze cases is a key step for learning and improvement. This section describes existing tools and processes for case review and data gathering, recommendations for training case reviewers, and guidance for synthesizing findings into useful feedback to stakeholders.

→ **Prepare reviewers to gather data**

↓

Analyze cases using tools provided

↓

Identify opportunities for improvement

I. Preparing Your Organization for Discovery and Action

Step 1

Ensure a foundation of psychological safety. It is crucial to carry out diagnostic safety measurement activities in a way that safeguards the privacy and confidentiality of involved clinicians and patients and minimizes harm to everyone involved in these activities. Good intentions are necessary but not sufficient.

Activities described here should be integrated with routine quality and safety activities of an organization. In addition, before engaging in the activities described in this resource, check with, or include on your team, the appropriate point of contact in your organization who can help ensure compliance with the HIPAA Privacy and Security Rules and any requirements related to confidentiality and privilege protections.

Note that if confidentiality and privilege protections for this kind of activity are available and desired, they will likely only apply if specific requirements are followed. For instance, certain steps may need to be taken in advance, the activities may need to be conducted in a certain way, and information related to these activities may need to be stored in a certain location. Also, be clear about how information related to your activities might be shared and used within your organization and for what purposes.

More information is available in AHRQ's fact sheet on privacy and confidentiality, available at https://www.ahrq.gov/sites/default/files/wysiwyg/patient-safety/resources/resources/PS-privacy-factSheet.pdf.

Motivators for Engagement

Outreach and collaboration are essential to catalyze interest and motivation for engagement (Table 1). Some possible motivators to engage other team members include:

- Preventing harm and consequences of harm.
- Reducing opportunities for legal claims/lawsuits.
- Achieving clinical excellence and professionalism.
- Optimizing patient flow/utilization and value.
- Building a culture of safety.
- Creating opportunities for clinicians to receive feedback and "close the loop" on patients they were concerned about.
- Responding to patient concerns and demands for enhanced safety practices.
- Participating in external initiatives to enhance safety (e.g., Oro 2.0 High Reliability Organizational Assessment).[8]

Step 2

Engage leadership. Start by engaging leaders at the unit, department/division, facility, or enterprise level, depending on the scale of your initiative. Prepare an "elevator pitch" based on this resource that emphasizes the significance of the risk at your HCO and why leadership should support your efforts to improve diagnostic safety. Use the **Infographic** to provide a quick overview to stakeholders. The NASEM report has additional suggestions for engaging leadership.[1]

Discuss intended uses and protections, if any, for information that might be generated as a result of the initiative. For example, clarify concepts related to the confidential or nonpunitive intent of the program and ensure consistency with policies, procedures, and any applicable laws or regulations.

Step 3

Build your team. Develop a diagnostic safety team consisting of a centralized group or a "virtual hub"[2] to help gather, analyze, and learn from safety events. Learn not just about safety events (Safety-I thinking) but also "good catches" and situations when things went exceptionally well (Safety-II thinking).[7] The team should be responsive to the local context and needs of the organization. The ultimate goals of the team should be to review and analyze safety data and disseminate actionable feedback to improve the safety of the diagnostic processes throughout the organization. No single team structure best fits all organizations. Team structure should be agile and scalable. The team may begin with a single champion and exist within a single department or be institutionwide. It may constitute a separate entity, or it may be a subgroup within an existing entity such as a quality and safety committee. The initial configuration may be a workgroup that evolves to a more formal structure within the organization. **A recommended basic minimum team composition includes a clinician (diagnostician) and a patient safety professional.** Patient representatives should also be considered.

Although knowledge or prior experience in diagnostic safety is helpful, a willingness to learn and develop is more important. **Appendix A** includes resources to develop team members' knowledge and skills in diagnostic safety. The team should define specific goals based on organizational priorities. **Appendix B** provides an example of a high-level summary of team functions (from Geisinger's Committee to Improve Clinical Diagnosis).

Step 4

Engage related stakeholders. Engaging a broad coalition of stakeholders and collaborators can yield insights into factors that may increase the value and impact of diagnostic safety measurement in the organization. While leadership engagement and support are essential, do not overlook other stakeholders, such as clinical directors, educators, patient representatives, and information technology/informatics specialists. **Table 1** includes suggestions on engaging these groups.

As with other innovations, application of a change management strategy is recommended.[9] Consider outreach through presentations to stakeholder groups in the organization. Explaining real but deidentified and anonymized cases of harmful diagnostic safety events (preferably from the same organization), stimulating discussion of individuals' personal experiences of diagnostic error, and highlighting pockets of excellence can also foster engagement. Any such discussions of actual safety events should be careful to maintain patient privacy and provider confidentiality.

Step 5

Disseminate information about your work. Promote awareness of diagnostic safety in the context of routine educational and operational functions (e.g., electronic health record [EHR] upgrades and training, patient safety reviews, training and curricular offerings, peer review, morbidity and mortality conferences, quality improvement programs).

Table 1. Considerations for Engaging Key Stakeholders in Diagnostic Safety

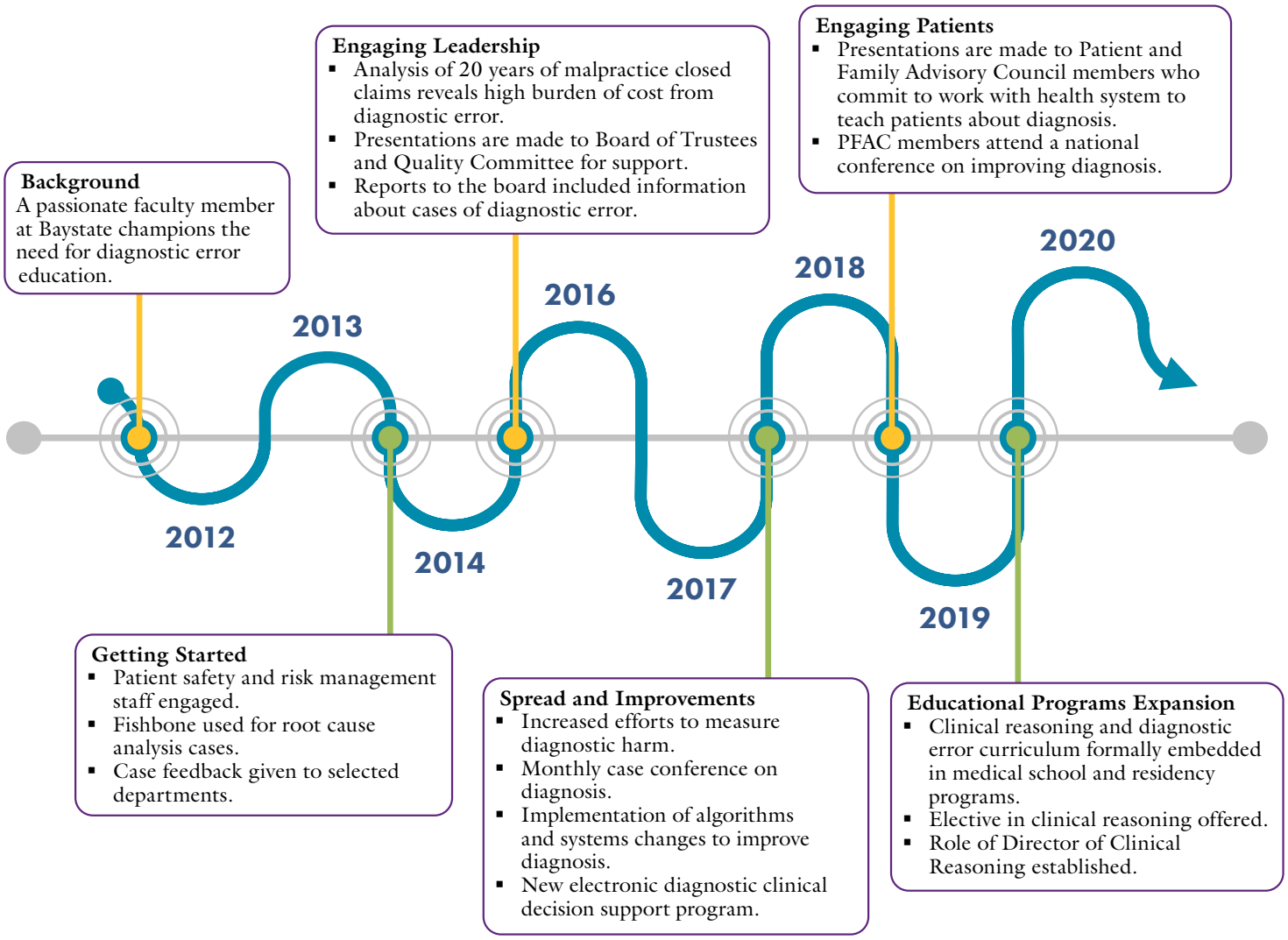
Stakeholder	Needs this stakeholder may have that you can help them fulfill
Member of the Board of Trustees	▪ Fulfilling fiduciary duty to ensure quality and safety of care ▪ Improving local and national reputation of the organization
Hospital/Health System Administrator	▪ Strategy and tactics for improving patient safety to avoid claims ▪ Engagement of physicians/clinicians to partner in patient safety work ▪ Potential to drive efficiency/cost containment in care by avoiding increased length of stay and unnecessary diagnostic testing
Clinical Operations	▪ Meaningful data for dashboards or metrics to track safety
Nursing Leadership	▪ Ways to ensure that, as the largest employee group in most HCOs, nurses are engaged as key members of the diagnostic team
Information Technology/ Informatics	▪ Opportunities to put data to use in improving quality and safety
Department Chair/Division Chief/Medical Director	▪ Research programs that allow faculty to speak and publish work ▪ Demonstrated contributions to patient safety for hospital administration
Risk Manager/Quality Director	▪ Expert guidance at analyzing diagnostic errors ▪ Solutions that can be implemented proactively or in response to safety events
Clinical/Medical Educators	▪ High-quality curriculum and mentoring for students and residents ▪ Scholarly projects for residents to complete
Patient and Family Advisory Council	▪ Opportunity to participate in impactful patient safety work ▪ Improved patient care
Patients	▪ Ways to identify healthcare organizations that value patient safety ▪ Opportunity to contribute their unique insights to improve healthcare delivery and address gaps in care

CASE EXAMPLE

Building a Diagnostic Safety Program

Baystate Health's diagnostic safety program began as an effort to embed dedicated diagnostic safety activities into the organization's existing patient safety infrastructure. Through outreach and collaboration, awareness of diagnostic safety has reached beyond the areas of risk management and patient safety to groups responsible for academic, operational, patient/family relations, and governance functions.[10]

Growth of Diagnostic Safety Program at Baystate



II. Organizational Self-Assessment

General Organizational Readiness Checklist

Before selecting specific diagnostic safety measurement strategies, ensure that sufficient resources and supportive mechanisms are available not only to collect information about diagnostic safety but also to respond effectively when learning opportunities are discovered. Check the following items as you develop your plan for measurement:

Clear objectives

- ☐ The diagnostic safety team has identified specific motivations and expected outcomes of measurement activities that foster nonpunitive learning and improvement.

Leadership engagement

- ☐ Leaders at the appropriate level of the organization have committed support to learning from diagnostic safety events.

Designated team

- ☐ One or more team members are able and willing to commit time and effort to lead a diagnostic safety measurement and improvement program.
- ☐ Team members have support from others at your organization who are also willing to learn in pursuit of diagnostic excellence. These could include physicians/clinicians, nursing staff, risk management/legal staff, representatives of diagnostic specialties (if available), and information technology and informatics staff (if available).

Safety culture

- ☐ Your organization demonstrates commitment to safety culture (e.g., by conducting periodic surveys of safety culture,[11] reviewing and learning from the findings, and implementing strategies to address findings).
- ☐ Your organization has a mechanism to share learning from case review/analysis.

Quality and safety resources and infrastructure

- ☐ Patient safety and quality infrastructure is available to support your efforts. This could include basic safety measurement and reporting infrastructure or resources that support more advanced data gathering and analysis.

Results

None to few items checked: Start small. Consider using one strategy in a limited capacity (e.g., pilot test on a single unit).

Several items checked: Consider using one or more of the strategies below, or focus on broad implementation of a single measurement strategy.

Most/all items checked: You seem well positioned to use multiple measurement strategies from the list below.

Selecting a Measurement Strategy

Assuming leadership support and sufficient commitment of time and effort, most HCOs will at least be able to use a strategy based on learning from cases that have already been identified by risk management, quality and safety, or another entity in the organization (**Strategy A**). However, some teams will opt to solicit information about diagnostic safety directly from clinicians (**Strategy B**) or use information provided by patients (**Strategy C**). Others will leverage the capabilities of EHRs (**Strategy D**) to identify previously undetected diagnostic safety events. Although a robust measurement program incorporates multiple strategies, most organizations new to this work should begin with only one and expand their portfolio of strategies over time.

Questions	If YES, then consider...
Does your HCO collect patient safety data for quality improvement purposes?	Strategy A
Does your HCO perform root cause analyses or other forms of case reviews for specific safety events or adverse outcomes (e.g., mortality, sepsis, trauma)?	
Does your HCO have an event reporting system for receiving input from frontline clinicians that includes (or could be modified to include) a dedicated category for diagnostic safety?	Strategy B
Does your HCO collect and aggregate any patient experience data through routine surveys, a hotline, or another mechanism?	Strategy C
Does your HCO have an EHR data warehouse or equivalent system for EHR queries?	Strategy D
Is there a person who can access the data warehouse and can support the team with EHR queries?	
Is there a team member who understands clinical data quality/validation?	
Does the HCO have a coordinated process for requesting EHR data, running queries, and generating reports?	

III. MEASUREMENT STRATEGIES

Strategy A

Use Quality and Safety Data Already Collected by the Organization

Cases that have already been reviewed or investigated in the organization may be able to be re-reviewed for information and learning opportunities specific to diagnostic safety. An ideal approach for learning leverages multiple data sources with both new/evolving events and resolved/archived events.

Who Can Use This Strategy?

Most organizations that collect quality and safety event data as long as the team can access complete case materials for review.

What To Do

Step 1

Develop a partnership with the quality/safety department and risk management and include one or more individuals as members of the diagnostic safety team. Some risk management data may not be immediately available as primary sources (e.g., ongoing/pending claims), but risk managers may be able to refer closed cases for review[12] and may also have valuable perspectives on other data sources in the organization. Others in the quality/safety department will have the content knowledge of other existing quality/safety data sources throughout the HCO.

Step 2

Take inventory of existing data sources that could be used for further learning and improvement (see "**Data Sources for Diagnosis Review**"). Look for specific cases that have been reviewed or investigated within the organization. Determine which may be used for new improvement activities consistent with applicable requirements related to patient and clinician privacy, confidentiality, and privilege protections.

For example, review of autopsy reports may reveal autopsy-identified diagnoses that differ significantly from those made during the diagnostic process. Similarly, evaluation of sepsis review cases may identify those with significant delays in arriving at the diagnosis or completely missed sepsis diagnoses. Further review of such cases may yield insights to help clinicians better understand and possibly modify the factors that led to missed diagnosis. Multiple data sources are needed for a more comprehensive picture of diagnostic safety. The number of data sources to use and cases to gather and analyze may depend on feasibility, data protections, and available resources.

Step 3

Use review tools (Part IV) to identify improvement opportunities. In addition:

- Develop relationships with those who gather and maintain source data (e.g., risk management, quality and safety) and invite them to join the diagnostic safety team, which will lay the groundwork for productive collaborations.

Case Example

Learning From Every Death

In 2003, a small multidisciplinary group of frontline doctors and nurses at Mayo Clinic developed a case-based learning methodology focused on learning from deaths. This multidisciplinary, consensus-driven approach to case reviews augmented existing quality and safety work within the organization by: (1) identifying opportunities not previously identified through traditional safety and quality mechanisms; and (2) recognizing that this methodology identified four times more omissions of care than traditional safety commissions.

These omissions brought to light previously unmeasured delayed or missed diagnoses, delayed recognition of the severity of illness, absence of goals of care conversations, and delays in treatment. The Mayo Clinic team published their lessons learned from their 7,500 consecutive case reviews in 2014.[13]

The robust learning from this effort prompted a pivot toward a broader strategy of learning from every patient experience, not just deaths. This case-based learning methodology has since been replicated in other healthcare systems with similar findings of identifying and quantifying the previously unmeasured omissions of care.

- Go beyond the usual sources such as closed claims and closed investigations of safety events and find department- and discipline-specific initiatives or ad hoc learning bodies created to address specific problems (see **Data Sources for Diagnosis Review**).
- Conduct outreach to other groups at your HCO that might cross-refer cases or events for learning.[14] Consider giving a presentation that highlights the importance of diagnostic safety in general and in ways that are relevant to your HCO.
- Consider targeting a specific cohort that your HCO is already prioritizing (mortality, readmission, sepsis diagnosis) and help your HCO leaders identify diagnosis-related opportunities for improvement that were previously not visible.

Data Sources for Diagnosis Review

Organizational Data Sources To Consider

Direct case referrals to risk management by one or more sources

- Clinicians and staff
- Patient experience/patient advocacy departments
- Legal/compliance and regulatory/accreditation teams
- Patients or families

Serious safety events and incident reports related to diagnosis

- Safety event/root cause analysis reports
- Risk management (at some organizations, events may be called "claims" even if not identified in litigation)
- Quality improvement (QI)/safety data

Resolved malpractice claims (closed)

- Risk management
- Aggregate data from insurers

Hospital-acquired conditions data

- Records of preceding care (evaluate to detect delayed/missed diagnosis)

Ongoing or focused professional practice evaluation

- When diagnosis-focused

Morbidity and mortality conferences

- May be a source of cases but may also be an output/action in response to a case review

Autopsy cases

- Underused data sources that reveal useful patterns of diagnostic discrepancies

Institution- or clinic-wide QI/safety initiatives

- Mortality reviews (often completed independent of/prior to autopsy)
- Diagnosis specific (e.g., sepsis, cancer)
- Reviews of unexpected admissions, transfers to intensive care, codes, rapid response
- Department-specific review processes such as ED or primary care case review (e.g., unexpected return to ED)
- Radiology discrepancies and internal lab QI/safety reviews

Peer review data

- Formal or informal

Emerging Data Sources

Nursing data

- Nursing data re activation of rapid response teams
- Data that may exist independent of QI/safety processes

Pharmacy data/clinical pharmacists

- Database of changes to medication orders
- Changes to orders that may signal missed opportunities in diagnosis

Strategy B

Solicit Reports From Clinicians and Staff

Clinicians and staff are valuable sources of data about diagnostic safety events but need to be engaged to share what they know. Soliciting brief comments about potential diagnostic safety events from clinicians and staff can alert the diagnostic safety team to systemic problems that might not be identified or captured through other safety mechanisms. You may choose to solicit:

1. Cases where it took longer than expected to make a correct diagnosis regardless of whether the delay had an adverse outcome,
2. Cases with potential problems related to the diagnostic process or decision making,
3. Cases that could be exemplars for teaching or learning about how to get better at diagnosis, and
4. Cases where some system factor interfered with the diagnostic process.

Who Can Use This Strategy?

Organizations that have experience implementing a system for clinicians and staff to report safety events can use this strategy to augment their existing system or create a new reporting mechanism specific to diagnostic safety events.

What To Do

Step 1

Decide whether to capture diagnostic safety events through a general safety event reporting system versus a dedicated (parallel) system dedicated only to diagnostic safety events. General safety event reporting systems are seldom designed with diagnostic events in mind and may need to be modified. Although dedicated systems have some advantages, they require commitments of personnel and time for regular review of incoming reports, as well as collaboration with patient safety leadership and risk management staff to ensure that any serious safety or harm events are evaluated by all appropriate groups. The advantages and disadvantages of each approach are summarized in **Table 2**, along with case examples.

Step 2

Engage support from stakeholders in risk management, quality improvement and patient safety leadership, nursing leadership, clinical informatics, patient and family advisory councils, and clinical leadership. Many clinicians are not comfortable discussing diagnostic errors.[15] A challenge to establishing a successful diagnostic safety event reporting program is creating a safe reporting culture that is not viewed as punitive.[16] Having clinical leaders share their own experiences with diagnostic errors and being thoughtful about language and messaging can help promote psychological safety.

Invite case submissions across a unit or the entire organization by using regular communication channels. To ensure this process works effectively over time, provide frequent reminders for case submissions.

Tips for Implementation

- Ensure that your reporting mechanism is **readily accessible and simple**. When possible, offer multiple reporting mechanisms (e.g., telephone hotline, smartphone app, dedicated EHR inbox).
- **Solicit the minimum information needed from frontline reporters.** Solicit the minimum amount of information needed to locate the records and information about the event that will be needed for later case review.
- **Cultivate a safe reporting culture**. Careful consideration of language can enhance safety culture (e.g., "diagnostic learning opportunities"[17] as opposed to "diagnostic errors"). Review existing policies and legal protections that will apply to information developed for this activity. Verify that the information will not be used to blame or criticize individuals and will be focused on identifying opportunities for improvement at the system level.
- **Provide transparency** about how safety report data are accessed, evaluated, and used and by whom.
- **Provide feedback** by regularly sharing learning and system changes put in place in response to reported events.

Step 3

Create an operational definition and approach to help clinicians and staff identify reportable events. It may be harder to judge presence or absence of diagnostic errors when case details are evolving over time or when there is ongoing natural progression of disease. Framing the report as a learning opportunity could help (see example from Cincinnati Children's Hospital Medical Center in **Table 2**). Also consider soliciting "good catches," examples of what is working well, and pockets of excellence.

Step 4

Implement a two-stage process for event reporting and review. Reporting processes should be designed to minimize reporter burden, capturing only the minimum information needed to identify the involved patient and collect a very brief summary of the incident (**Figure 3**). The diagnostic safety team can then conduct a more detailed review and investigation of submitted reports. Use one or more of the review tools in Part IV to identify improvement opportunities.

Table 2. Approaches to Soliciting Diagnostic Safety Information From Clinicians and Staff

Mechanism	Advantages	Disadvantages	Case example
General safety event reporting system	▪ Already familiar and accessible to clinicians ▪ Builds on existing infrastructure and processes for reviewing events (but may need additional expertise in diagnostic safety)	▪ Diagnostic safety signals often buried within other reports ▪ May be difficult to flag or categorize diagnostic safety events due to system constraints	While Maine Medical Center* initially maintained a dedicated diagnostic safety event reporting system,[18] the transition to a new institutionwide general safety event reporting system presented an opportunity to integrate their two systems. Local diagnostic safety experts collaborated with risk management staff, information technology specialists, and the software developer to create a diagnostic safety event category and streamline the reporting form itself (including reducing the number of required fields).
Dedicated diagnostic safety event reporting system	▪ Highly customizable ▪ Able to solicit events through multiple channels (e.g., hotline, web-based reporting forms, EHR inbox)	▪ Requires greater initial investment of technological resources and personnel, including one or more champions ▪ Needs dedicated process for reviewing events and cross-referral to other entities (e.g., risk management)	At Cincinnati Children's Hospital Medical Center, few diagnosis-related safety reports were filed through their general safety event reporting system. The Division of Hospital Medicine used quality improvement methods to develop and evaluate a dedicated system to increase physician reporting of diagnostic safety events, initially targeting attending pediatric hospitalists.[17] Key steps included: 1. Creation of a simple, customized web-based reporting form (see example below) 2. Cultivating psychological safety through messaging (e.g., calling reported events "diagnostic learning opportunities") 3. Providing transparency on how these reports are used to generate divisionwide learning about diagnostic safety

* Acknowledgment: Dr. Robert Trowbridge, Maine Medical Center.

Figure 3 is an example of a diagnostic safety event ("diagnostic learning opportunity") reporting form.

Figure 3. Sample Diagnostic Learning Opportunity Report

Diagnostic Learning Opportunity (DLO) Report
Definition of a DLO: During the patient's current illness, either prior to or during admission, there was a potential opportunity to make a better or more timely diagnosis.

Please contact xxx@xxx.org with any questions or concerns.

Date of DLO:	Initial diagnosis/presenting symptoms:
Patient Medical Record Number:	Final diagnosis (if known):
Patient first name:	Brief clinical course:
Patient last name:	What do you think we can learn from this patient? (optional)

Acknowledgment: Dr. Trisha Marshall, Cincinnati Children's Hospital Medical Center.

Emerging Methods and Future Directions

Successful safety event reporting systems provide feedback to clinicians and staff. An innovative way to provide feedback to frontline physicians would be to develop a secure case-sharing website or smartphone/web-enabled application that allows sharing of summative learning and highlights system changes that have been implemented from previously reported cases. It could also serve as a platform to share diagnostic conundrums and receive real-time, crowd-sourced feedback. Organizations should consider potential privacy, confidentiality, privilege, and security issues when designing and deploying such systems.

Strategy C

Leverage Patient-Reported Data

Patients and families are an important source of unique insights that may be used for learning and diagnostic safety improvement. Learning healthcare systems may apply multiple methods, both passive and active, to find cases of patient-perceived breakdowns in the diagnostic process.

Who Can Use This Strategy?

Organizations that are already engaged in soliciting feedback from patients and family members for learning and improving may consider leveraging their existing infrastructure for responding to patient complaints and safety events involving diagnosis.

What To Do

Step 1

Identify sources of patient feedback in your organization. Potential sources of feedback about diagnostic concerns include:

- Patient reporting systems (akin to event reporting systems for clinicians and staff), such as websites and telephone hotlines.[19,20]
- Routine patient experience surveys,[21] including free-text comments.
- Patient complaints, claims, and other open-ended patient data.[22-26]

Step 2

Determine data sources and operationalize data use. Identify:

- Data source or sources that best fit with your organizational resources dedicated to diagnostic measurement.
- People within your organization you will need to work with or get permissions from to access the data.
- Policies and procedures that govern data access, storage, confidentiality, and security at your organization.
- Infrastructure (e.g., staff, coding taxonomies, data standards) available to support your diagnostic safety measurement activities.

Step 3

Decide on an approach to identify cases for further review. Methods to classify diagnostic safety events using patient-reported data are still being developed. Your team may opt for a qualitative review of free-text patient comments, complaints, emails, web reports, and other narrative descriptions.[22] Alternatively (or additionally), you could use a structured taxonomy to classify the nature of patient concerns (such as a taxonomy by Reader, et al.)[24] and then delve deeper into diagnosis-related concerns. Selected cases should then be further investigated through chart review.

Step 4

Use one or more of the review tools in Part IV to identify improvement opportunities if you find diagnosis-related concerns. Develop a plan to manage feedback to patients and families, as well as the involved clinical teams, after analysis.

Tips for Implementation

You can engage patients in reporting efforts by bringing them in at the planning stage. Consider reaching out to your patient and family advisory council for help.

Regardless of which data sources you select to identify patient-reported breakdowns in the diagnostic process, consider how to optimize outreach and solicitation of reports from underrepresented patient populations. These groups may be based on sex, race, ethnicity, age, and languages or other patient-level characteristics that may result in underreporting.

When possible, coordinate with leaders of community health/health equity within your organization and community to synchronize efforts to reach underrepresented patient populations. Some strategies may include

- Work with members of your underrepresented communities to codesign the reporting system, questions on surveys, or marketing materials used to "get the word out" and encourage a reporting culture.
- Work with members of your communities to codesign any local adaptations to the coding taxonomy and categories used.
- Use your patient-level data to help identify gaps in reports from your patient communities. These gaps may go beyond simple race, ethnicity, sex, age, and language data and extend to reports from patients in certain geographic areas served by your healthcare system. Once you identify who is not reporting or responding, work with community members to bolster reporting.
- Create a feedback loop to those who submit data.

Case Example

MedStar Health's We Want to Know™ Program

With funding from AHRQ, the MedStar Health system designed, developed, implemented, and evaluated a program to solicit patient and family reports on care breakdowns. This program included a telephone hotline, program email, web-enabled reporting portal, and active solicitation of events from frontline staff through a patient-family notepad and inclusion of We Want to Know™ questions on the interdisciplinary team rounding checklist. Reports are managed either by the frontline care teams or by a real-time response navigator who monitors reports for the 10-hospital health system.

The navigator initiates a response first by reaching out to the patient/family (the reporter) to obtain details of the event, recommendations for improvement, and any requested restitution. The navigator then activates a local team at the hospital through an emailed summary of the report. The navigator also documents the report in the patient safety event reporting system as a We Want to Know™ report.

The local team activates the appropriate level of response based on the patient/family concern. The final resolution is shared with the patient/family, local response team, and the navigator and is documented in the reporting system.

The system-level navigator receives 5 to 10 reports weekly across the 10-hospital system. These reports are not usually captured through any other patient or safety reporting mechanisms and range from experience issues to patient safety events, including diagnostic safety events.

Case Example

MedStar Health's Patient Experience Survey

MedStar Health uses a structured question on their hospital patient experience surveys to aid in the detection and monitoring of patient-perceived breakdowns in care.[21] The question includes a Likert scale and is designed to be congruent with the scoring methodology of the Hospital Consumer Assessment of Healthcare Providers and Systems survey completed by rigorously sampled patients after hospital discharge. The question, "How often did you feel comfortable speaking up if you had any problems in your care?" has four responses: (1) no problems, (2) always felt comfortable, (3) usually/sometimes, (4) never [felt comfortable speaking up].

Patients who respond usually/sometimes and never felt comfortable speaking up were correlated with lower responses to the composite scores for nursing and physician communication, overall rating of the hospital, and a patient's likelihood to recommend the hospital. The health system uses responses to this question as part of its patient experience and safety dashboard for leaders and monitors the impact of the We Want to Know™ program.

Emerging Methods and Future Directions

- Adding structured diagnostic safety-related questions to existing surveys completed by patients and family members may be a robust source of data health systems can use to measure and assess patients at risk for diagnostic breakdowns. Similar to the case example described above (MedStar Health's Patient Experience Survey), organizations can develop, pilot test, and implement items that signal a need for further review of the diagnostic process.
- Analysis of patient complaints can give useful information about diagnostic concerns. In a study done at Geisinger in Pennsylvania, complaint analysis and corresponding record reviews revealed useful patterns of patient/family-reported concerns in the diagnostic process.[22] This study was facilitated by Geisinger's patient/family advocate program that helps navigate and resolve concerns. As more health systems develop infrastructure for analyzing complaints, they can use a similar approach.
- Soliciting patient reports through a patient portal can provide health systems with insights on opportunities for diagnostic improvement. Implementation of the 21st Century Cures Act in 2021 facilitates patients' access to their health record. Patients have previously reported safety concerns such as medication issues and incorrect information in the medical record while accessing their providers' notes online (e.g., open notes) through secure web-based portals. For example, in a prior study, one in five patients who read their own clinical notes identified mistakes, some of which were related to the diagnostic process.[27,28] In another study, patients could identify diagnostic concerns based on a structured evaluation of their own visit notes.[29] Despite increased focus on transparency and access, low utilization of patient portals and disparities in portal use will need to be addressed to fully leverage this strategy.

Strategy D

Electronic Health Record-Enhanced Chart Review

With appropriate systems, personnel, and resources in place, electronic health record (EHR) data can be used to systematically track and identify diagnostic process breakdowns. Search queries applied to EHR-based data can filter clinical and administrative data to identify groups of patients at risk for diagnostic safety events. Records flagged by these tools can then be reviewed to identify improvement opportunities and facilitate organizational learning.

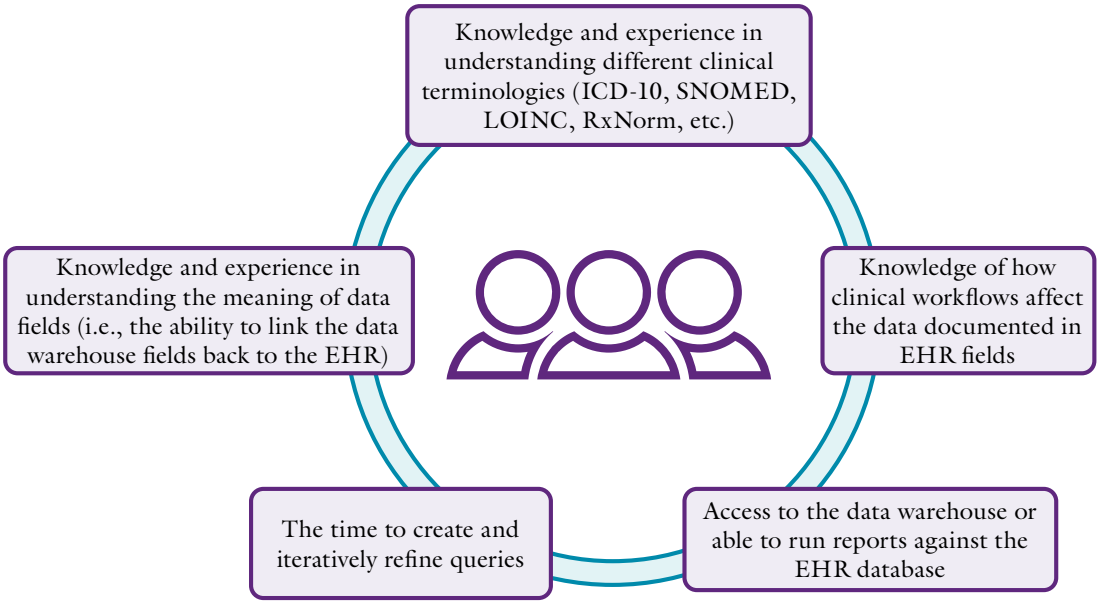
Who Can Use This Strategy?

Any HCO that uses an EHR that can be queried can use this strategy, provided the diagnostic safety team has access to the corresponding data. Some EHRs include built-in reporting and searching functionality that allows sufficient data access and querying capabilities when only a few simple criteria are required to identify the sample (e.g., patient age, gender, abnormal test results).

More advanced searches that rely on multiple inclusion and exclusion criteria or involve more complex calculations (e.g., times between events) will often require access to an EHR data warehouse to be effective. Such data warehouses provide a repository of historical data in a centralized location and often allow use of more advanced tools to analyze the data.

HCOs interested in developing the capacity to implement more advanced queries (such as the triggers described in Table 3) will need a team that includes the abilities and domains of expertise depicted in **Figure 4**. Team members may include clinical informaticists, information technology professionals, patient safety professionals, and clinicians, all working closely to overcome development and implementation challenges. In some cases, one person may fulfill multiple needs.

Figure 4. Team Composition for Advanced EHR Strategies



Case Example

Case Finding Through the EHR

Two healthcare organizations implemented programs to learn from events identified using their EHRs and other information systems. Both sites developed trigger tools to identify cases based on processes or outcomes encoded in the EHR or other system. Examples included triggers for unexpected deaths, deaths followed by autopsy, readmissions within 48 or 72 hours, and rapid response team activation.

A panel of six to eight clinicians reviewed triggered records using previously published frameworks and methods to identify missed opportunities and contributing factors. The average time for each case review process, including feedback to the involved care team members, was 2 to 4 hours.

Over a 1-year period, Site 1 (Regions Hospital, St. Paul, MN) identified 184 cases, of which 34 percent were found to have opportunities for improvement, and Site 2 (University of California, San Diego) identified 346 cases, of which 19 percent had opportunities for improvement.

Although the highest yield of opportunities for improvement came from cases referred or reported by staff, certain triggers, such as rapid response team activation and ED visit within 7 days, were also associated with improvement opportunities in one out of five cases.

The authors describe a 5-step process for implementing similar case review programs at other organizations:

1. Implement criteria to trigger case review.
2. Establish a review panel.
3. Develop a system to conduct reviews.
4. Perform reviews.
5. Feed lessons learned back to the provider and the system.[30]

What To Do

Step 1

Define an area of interest. Choose a diagnostic safety target (see **Table 3** for examples). Consider organizational priorities, available resources, and availability of structured data relevant to your team's goal.

Step 2

Develop queries. The structure and complexity of queries is determined by the available data and the target of measurement.

Simple queries of EHR databases use a few parameters (e.g., dates of service, diagnosis) to create a cohort of records to review for learning opportunities. For example, your team might decide to review all cases in the past year of a diagnosis known to be frequently missed or delayed. High-yield examples could include cases of spinal epidural abscess,[31] cancer (especially colorectal or lung), and deaths associated with certain common diagnoses.[32]

Some EHR systems support relatively simple end user-generated queries, reducing the need for information technology support. For instance, you could extract the last 25 patients diagnosed with colon cancer or all patients diagnosed with spinal epidural abscess in the past year and review them for missed opportunities.

Electronic triggers ("e-triggers") are algorithm-based computer programs designed to scan vast amounts of electronic data, such as in a data warehouse, to flag cases at high risk of a missed opportunity. They might focus on high-risk clinical scenarios (e.g., test results pending at discharge) or query for unusual care patterns that may signal a potential breakdown in the diagnostic process.

E-triggers provide a method to detect diagnostic missed opportunities that would otherwise be too resource-intensive to find using consecutive or random chart reviews. While initially developed via research in the Department of Veterans Affairs, they are being increasingly applied in practice elsewhere.[33]

Table 3 describes examples of potential e-triggers to identify potential cases of missed opportunities. The Safer Dx Trigger Tools Framework (**Appendix C**) and additional readings in **Appendix A** provide further guidance for developing and refining e-triggers.

Tips for Implementation

An integrated EHR database provides a longitudinal view of the patient's diagnostic journey, including outpatient and inpatient encounters and data from urgent/emergency care, laboratories, radiology reports, referrals, and progress notes. Absence of multiple diagnostic data points makes the e-trigger less useful. For instance, a query for "missed test results" could identify any of the following steps in the testing process:

- Results that were not correctly communicated to the provider
- Results that were communicated but never received or reviewed by the provider
- Results that were reviewed by a provider, but followup action not recommended
- An appropriate recommendation the provider made, but followup action (e.g., referral) not carried out

Query performance should be assessed and refined to minimize false positives. For example, if after an abnormal fecal test result, the recommended followup colonoscopy was done at a different health system than the one where the EHR is being queried, the e-trigger will falsely detect followup was "missed."

Advanced Applications

Several e-triggers detect potential diagnostic events retrospectively and, if implemented correctly, will allow HCOs to monitor events, identify contributory factors, and inform improvements and organizational learning.

Some e-triggers (e.g., "Abnormal test results lacking evaluation"; see **Table 3**) can be used to monitor potential care gaps prospectively and help identify patients at high risk for a subsequent safety event. This approach can enable clinicians, patients, and safety personnel to take preventive actions proactively.

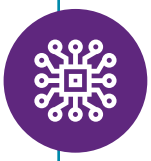
Step 3

Use one or more of the review tools in Part IV to identify improvement opportunities. Queries cannot confirm that a missed opportunity occurred, why it occurred, or whether it was preventable. Thus, all events identified through a query or trigger should be reviewed manually by a clinician for confirmation of learning opportunities.

Emerging Methods

Natural language processing (NLP) for unstructured data. NLP systems have shown promise in replacing manual chart review of narrative text to identify clinical diagnoses and events.[34]

Predictive models. Machine learning-enabled predictive models can be used to facilitate earlier detection of adverse clinical outcomes. Predictive models could be developed to identify patients who are at elevated risk of diagnostic safety events and integrated into clinical decision support tools.



Patient-reported outcome (PRO) measures. The integration of PRO measures into EHRs presents an opportunity to develop indicators for quality improvement purposes. In certain situations, significant changes in PRO scores may indicate a potential missed or wrong diagnosis.

Table 3. Examples of EHR-Based Triggers for Record Review

Example	Red flag (inclusion) criteria	Clinical exclusion criteria	Data requirements
Tests pending at discharge from hospital or emergency department (ED)[35, 36] Test results that return after a patient is discharged from the hospital or ED are at high risk for delays in followup, especially for tests with long turnaround times, such as send-out labs.			
Missed diagnosis of urinary tract infection at discharge	Abnormal urine culture (i.e., >100,000 colony-forming units and growth of ≤2 organisms) that result after date/time of hospital discharge	**Clinical Exclusion** ▪ Deceased at discharge or code status of comfort measures only at the time of discharge **Appropriate Followup** ▪ Antibiotic prescribed at time of discharge to which organism found to be susceptible	▪ Coded urine culture reports (i.e., results and antibiotic sensitivities) ▪ Standard medication coding system used for antibiotic sensitivities and medications
Abnormal test results lacking timely evaluation[37, 38] Triggers can identify cases when certain high-risk test results have not received expected followup in the outpatient setting (such as after an office visit or diagnostic procedures). Many of these test results remain "unacknowledged" in providers' EHR inboxes for extended periods, which is another way to identify them.			
Missed abnormal findings that warrant colorectal cancer evaluation	Positive fecal immunohistochemical test (FIT)	**Clinical Exclusion** ▪ Terminal illness; prior colectomy or known colorectal cancer **Appropriate Followup** ▪ Gastrointestinal exam or colonoscopy within 60 days	▪ Access to patient demographics ▪ Coded diagnosis/problem list data (ICD-10) ▪ Coded lab results (FIT and FOBT) ▪ Access to schedule of visits ▪ Coded procedures (CPT)
Unanticipated escalations of care[39, 40] Unexpected escalations in care may indicate the presence of a diagnosis that was missed early on, leading to unexpected worsening in patient's condition.			
Missed appendicitis with bowel perforation	Child transferred to intensive care unit (ICU) unexpectedly from acute care floor after a rapid response and required vasoactive medications or endotracheal intubation due to decompensation within 24 hours	▪ Expected transfer to surgical ICU after an elective surgery	▪ Access to data on medication use ▪ Access to data on intubation ▪ Access to admission/discharge/transfer (ADT) data ▪ Access to RRT call/response data
Missed diagnosis of deep venous thrombosis and subsequent pulmonary embolus	Patient age <65 when admitted to an adult inpatient service and Charlson Comorbidity Index <2 with transfer to ICU after activation of RRT	▪ Transfers for postprocedure care ▪ >2 prior hospitalizations in the past year ▪ Transfer to hospice or palliative care in 6 months prior to hospitalization	▪ Access to ADT data ▪ Ability to calculate Charlson Comorbidity index ▪ Access to RRT call/response data
Unexpected hospitalization after an ED or primary care visit[41,42] An unscheduled return visit may signal a possible deviation from expected care. Previous studies have linked return ED visits, particularly those resulting in hospital admission, to diagnostic error.			
Missed diagnosis of new-onset stroke	Unexpected hospitalization with new stroke within 10 days of being seen in primary care or ED	▪ Patients with known stroke and no new stroke diagnoses between admission and discharge	▪ Access to ADT data
Incomplete referrals[43, 44] When referrals for certain conditions are not followed up on a timely basis, delays in diagnosis can occur in the outpatient setting.			
Delay in lung cancer diagnosis due to delayed referral	Referral to pulmonary clinic for evaluation of abnormal chest imaging not completed	▪ Referral scheduled within 30 days	▪ Access to referral-related ICD-10 or CPT structured codes ▪ Access to referral data

ICD-10 = International Classification of Diseases version 10; CPT = Current Procedural Terminology; RRT = rapid response team; FOBT = fecal occult blood test

IV. Reviewing and Analyzing Cases of Interest

Case analysis including review of clinical details is essential to understand and address diagnostic safety events. However, it is complex and involves a lens of clinical reasoning as well as systems-related concepts.

Uncertainty is the norm. Many diagnoses evolve with time, so it may be hard to determine if a diagnosis was indeed timely, especially when a patient presents with undifferentiated symptoms. Reviewers may not necessarily agree on findings. The medical record is both a useful and accessible source of information to examine the diagnostic process for remote events, but for more recent events, also consider interviews and discussions with the involved patients and staff.

Using structured case review tools helps standardize the review process and can help identify process breakdowns and improvement opportunities. Regardless of how a potential diagnostic safety event is initially identified, a systematic process for case review followed by analysis and case representation will help to ensure consistency in your team's approach.

Using Case Review Tools for Analysis and Classification of Diagnostic Safety Events

The flowchart below outlines a series of steps for using structured case review tools for analysis of diagnostic safety events. For most situations, it is recommended that teams initially review cases of interest to **determine whether a missed opportunity occurred**. The Revised Safer Dx Instrument (**Appendix D**) was designed to increase confidence in these determinations. The Safer Dx Process Breakdown Supplement (**Appendix E**) can guide a more comprehensive assessment of the five diagnostic processes outlined in the Safer Dx Framework[6] based on review of the patient's medical record.[45]

Detailed guidance on how to use the Safer Dx Instrument is freely available in an open-access publication.[46] **Appendix F** includes a tip sheet to facilitate reviewer training. This sheet can be used as a standalone guide for clinicians whose involvement in diagnostic safety activities focuses primarily on performing case reviews.

The Revised Safer Dx Instrument defines diagnostic errors as "missed opportunities to make a correct or timely diagnosis based on the available evidence, regardless of patient harm."[2,47] However, for selected situations that do not involve assessing complex clinical reasoning, such as missed test results, the approach may involve a simpler data collection instrument that uses more objective criteria to determine if and why a potential followup delay occurred (see **Appendix G**, for example).

Flowchart for Case Review

Identify a case for review

- Use Strategies A-D in Part III for case detection
- Ensure that pertinent clinical documentation is available

↓

Is there a missed opportunity?

Use Revised Safer Dx Instrument to determine presence or absence of missed opportunity (see tips for reviewers, Appendix E)

↓

Review further for contributing factors

- Consider collecting additional case details using Common Formats for Event Reporting - Diagnostic Safety
- Other review and analysis tools include the DEER taxonomy, fishbone diagram, etc. (**Table 4**)

↓

Determine opportunities for immediate improvement or intervention

Compile data over time to look for trends

If initial review shows evidence of a missed opportunity, further analysis can help identify contributing factors, contextual factors, and other important aspects of the case to consider for tracking over time and planning a response. In addition to standard root cause analysis (RCA), several diagnosis-specific review tools and techniques have been used to analyze and represent diagnostic safety events. Features, strengths, and limitations of case review tools are listed in **Table 4**.

As your team becomes more experienced, explore additional review tools, especially if you have in-house safety analyst expertise to develop these. Understanding the "why" issues requires considering both the system-related and cognitive elements that might have contributed; most diagnostic safety events have elements of both. A taxonomy that distinguishes the major cognitive and system-related root causes can also be consulted to assist in this analysis.[48]

Table 4. Case Analysis and Representation Tools for Diagnostic Safety Events

Review tool	Purpose	Description	Strengths	Limitations
Revised Safer Dx Instrument (**Appendix D**)[46]	Increase confidence in determination of a missed opportunity in the diagnostic process	Twelve items, rated from "strongly disagree" to "strongly agree," that assess the adequacy of the diagnostic process for a given episode of care and help identify a missed opportunity to make a correct and timely diagnosis	▪ Comprehensive view of the diagnostic process ▪ Applied in multiple research studies and health systems ▪ Evidence for good interrater agreement ▪ Safer Dx Process Breakdown Supplement (**Appendix E**) offers additional insights	Requires initial training to use (see **Appendix F** for reviewer training materials)
Diagnostic Error Evaluation Research (DEER) taxonomy (**Appendix H**)[49]	Classify breakdowns in the diagnostic process	A taxonomy of potential breakdowns, organized by steps in the diagnostic process (e.g., history, physical exam, tests) that is used to identify primary and secondary contributing factors in a diagnostic error	▪ Comprehensive view of the diagnostic process ▪ Applied in multiple studies	Many overlapping and interdependent categories
Modified fishbone diagram for diagnostic errors[50]	Identify system-related versus cognitive contributing factors to a diagnostic safety event	A diagram that breaks down complex safety events into categories of various system-related, cognitive, and contextual contributing factors	▪ Visual representation ▪ Adaptation of a tool already commonly used in RCAs	Requires experience or education in understanding cognitive contributions
Common Formats for Event Reporting - Diagnostic Safety (CFER-DS) [51]	Classify contextual and contributory factors and adverse consequences associated with diagnostic safety events	Standardized language and definitions for diagnostic safety events for aggregation across multiple cases, sites, and organizations	▪ Early version field tested for usability ▪ In the public domain ▪ Can be used for reporting events through federally listed patient safety organizations (PSOs) to the national Network of Patient Safety Databases	New - released mid-2022 Requires users to understand and apply CFER-DS-specific concepts to case analysis

Reviewer Training

Reliable and accurate case analysis is imperative to ensure diagnostic performance is appropriately evaluated. Therefore, once your team has chosen one or more case review instruments, your next step is to train reviewers to analyze cases of interest. Reviewers can include different types of interested clinicians, including trainees.

- ☐ **Step 1: Select appropriate reviewers.** Reviewers should be clinicians familiar with the diagnostic processes being evaluated and have adequate baseline clinical knowledge, especially when reviews involve understanding decision-making processes.[52]
- ☐ **Step 2: Pilot test case review procedures (see Appendix F) and refine instructions as needed.** Reviewers should perform several test reviews (e.g., 10-20 reviews) to become familiar with the review tools and identify any unclear or ambiguous terminology.[41,53] Ambiguous language should be clarified, and if necessary, tools could be slightly refined to improve clarity for your local situations. Reviewers should generally be asked to judge diagnostic performance based on the data that were reasonably available to the treating clinicians at the time. Their findings are key to subsequent analysis.
- ☐ **Step 3: Maintain rigor in the review process.** To ensure the flow of high-quality knowledge from case reviews, findings from two or more reviewers should be compared after training and periodically thereafter to ensure reasonable agreement. If disagreement is high, efforts should be made to build a shared mental model and resolve the underlying cause of the ambiguity, including modification of review procedures and retraining. This process should repeat iteratively with a new set of reviews until a reasonable level of agreement is reached.

Exemplar cases can be used to build a shared mental model and also as reference standards to train future reviewers.[52] Periodically comparing a small percentage of chart abstractions across reviewers may enable continued monitoring of review reliability and validity.[54]

For clinicians whose role on the team is limited to case reviews, a reasonable set of training materials includes the Measure Dx **Infographic**, **Appendix F**, the Revised Safer Dx Instrument (**Appendix D**) and accompanying open-access manuscript,[46] and any additional selected case review tools.

Adapting Review Tools for Specific Diagnoses and Care Settings

The review tools listed in Table 4 apply to a broad range of settings. If your learning and improvement efforts focus on a narrow range of clinical situations, consider using an adapted tool more specific to your setting. Published adaptations of the Revised Safer Dx Instrument, for example, include versions for use in stroke,[55] pediatric critical care,[56] neonatal intensive care unit,[57] and psychiatric diagnosis.[58] Teams are **cautioned** against ad hoc adaptations of this or any other review tools. In general, adaptation of existing tools is not recommended outside of research settings.

Using the AHRQ Common Formats for Diagnostic Safety

Consider using the AHRQ Common Formats for Diagnostic Safety[51] to structure the capture of diagnostic safety event data, whether through a general event reporting system or in developing a dedicated system for diagnostic safety events. Having a common frame of reference and standardized data elements makes shared learning possible at the local, regional, and national levels.

Generating Useful Feedback for Improvement

It is critical to close the loop on measurement and learn from the data. For instance, if you find missed followup of certain abnormal test results to be a consistent problem, you can use Plan-Do-Study-Act (PDSA) cycles within a specific setting or larger improvement initiatives across the entire institution. You may find several systems or process issues that need to be addressed at the HCO level.

Keep a database to help track cases and learning. You may ultimately analyze anywhere from one to several cases of diagnostic safety events every month. Make sure to also solicit "good catches" or situations when things were done exceptionally well. Based on your activities, the diagnostic safety team should not only look for signals for what could have been done differently in individual cases but also glean patterns at an aggregated level.

You may find certain types of situations, settings, or patients especially vulnerable. For instance, you may find patterns suggesting that diagnostic safety events affect medically underserved patients disproportionately or other signals suggesting that you should further explore and seek to remedy disparities in care or outcomes. Consider proactively analyzing patterns according to known health disparities in your HCO or surrounding community.

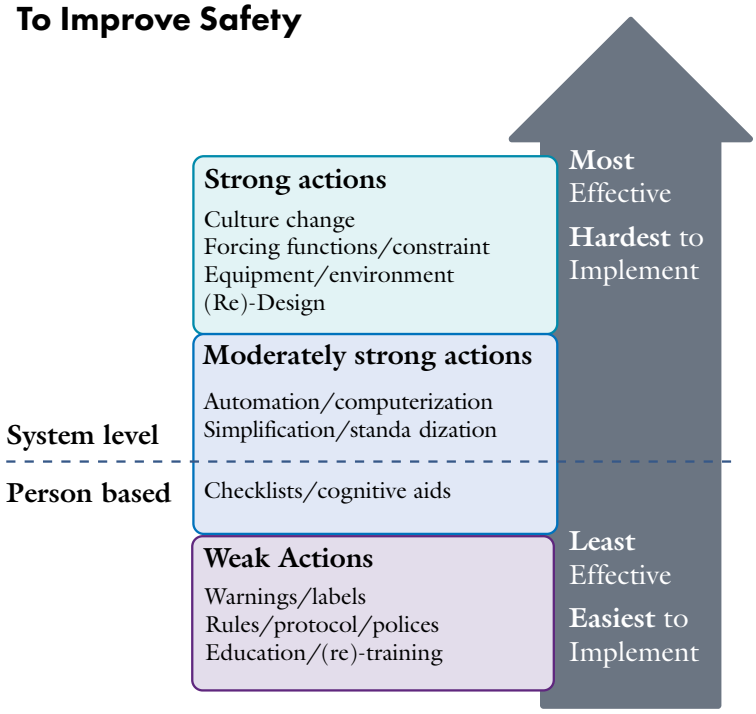
Based on analysis, provide regular feedback to your organizational leaders and related stakeholders that includes:

1. A brief description of the team's mission and goals as a reminder.
2. Measurement methods and processes used.
3. Summary findings (e.g., top risks identified, percentage of cases examined with diagnostic process breakdowns).
4. Recommendations for improvement. Effective recommendations are tied to underlying factors that affect system performance and allow opportunities for a range of solutions.[59,60]

Organizational feedback should inspire change. Based on the data your team has gathered, devise and implement improvement strategies by leveraging the relationships you have developed in your organization (e.g., informatics, radiology, lab, other specialties).

When describing potential solutions, consider sensitivity to operations and potential for effectiveness. Certain lessons should also be distributed more widely across the institution. As depicted in **Figure 5**, informational and educational interventions are generally easier to implement, but they are less effective than system-focused changes such as redesign, automated processes, engineering controls, and standardized processes.[59,61]

Figure 5. Hierarchy of Effectiveness of Actions To Improve Safety



Adapted from: Trbovich P, Shojania KG. Root-cause analysis: swatting at mosquitoes versus draining the swamp. BMJ Qual Saf 2017;26:350-3.

As you become more advanced in your measurement, you may also consider providing individual feedback to involved clinicians. For example, Geisinger developed a formal program using trained facilitators to deliver feedback to clinicians involved in diagnostic safety events.[62] They developed a toolkit to assist department and quality directors in providing feedback to clinicians on learning opportunities that had been identified and reviewed by the diagnostic safety team. The feedback was intended to be constructive and nonthreatening as part of an open dialogue to facilitate learning. Recommendations for individual feedback are provided in **Appendix I**. Clinicians may find it helpful to adopt additional reflective practices to develop their diagnostic decision skills and learning over time.[63]

Measurement in Action: Case Examples

Two health systems have implemented learning and improvement initiatives based on multiple data sources discussed here and have begun their learning and exploration of diagnostic excellence, i.e., the LEDE journey. Their stories are discussed as case examples for other HCOs.

Case Example 1

Geisinger/Baylor Safer Dx Learning Lab[4,62]

The "Safer Dx Learning Lab," a unique partnership between researchers at Baylor College of Medicine (Houston, Texas) and Geisinger (central Pennsylvania) was funded by the Gordon and Betty Moore Foundation in 2017 to develop a learning health system for reducing diagnostic error. The lab applies a systematic approach to learn how healthcare systems can enhance the safety and accuracy of the diagnostic process and help translate research into meaningful care improvements.

Several strategies outlined here were also tested as part of the lab. The lab used several sources of data, including existing risk management data, clinician reporting, patient reporting, and e-triggers that harnessed a wealth of electronic data for analysis. The data were then used to provide actionable information to improve diagnostic quality.

The Committee to Improve Clinical Diagnosis at Geisinger provided advice and worked closely with the Safer Dx Learning Lab. Committee members included senior physicians, clinical leadership, the patient safety officer, and key stakeholders from quality and safety, risk management, patient safety, patient experience, medical informatics, and information technology. As of 2021, more than 500 cases have been identified and analyzed, and findings of learning opportunities have been shared across Geisinger. The lab also created a program to deliver nonpunitive, confidential, and constructive feedback to clinicians and intervened to address system and process problems identified through analysis. Other organizations can similarly begin their journeys to learn and explore diagnostic excellence.

Case Example 2

The Diagnostic Error Index at Nationwide Children's Hospital[64]

Nationwide Children's Hospital, a quaternary pediatric hospital in Columbus, Ohio, developed a diagnostic error index as a practical method to identify and measure serious diagnostic errors. This tool was championed by a multidisciplinary diagnostic error QI team that identified five key drivers based on the team's charge and on recommendations from the NASEM report:

1. Improving communication and collaboration among healthcare providers;
2. Creating a supportive environment for review and discussion of diagnostic error;
3. Providing feedback to clinicians;
4. Creating a culture of transparency; and
5. Training clinicians.[1]

The team used five sources to identify cases of potential diagnostic errors: (1) autopsy findings; (2) institutional root cause analyses; (3) voluntary reporting through an electronic risk management system; (4) morbidity and mortality conferences; and (5) an abdominal pain EHR trigger. Cases were reviewed by a multidisciplinary QI team to determine if a diagnostic error occurred. They found 105 confirmed errors representing a variety of diagnoses. Confirmed diagnostic errors were represented as a diagnostic error index, a composite of the number of monthly confirmed diagnostic errors identified from the five data sources. This QI initiative informed the use of potential interventions and provides a useful example for other HCOs to measure and reduce diagnostic errors.

Conclusion

Measure Dx aims to provide you with the knowledge and resources to develop a diagnostic safety program at your organization. The NASEM report highlights why improving the diagnostic process is "a moral, professional, and public health imperative." This resource provides options for everyone – from organizations just starting their journeys to understand their experience with diagnostic errors to organizations that have already begun a measurement approach to improve diagnostic safety and quality. The pragmatic recommendations and innovations outlined here can help translate some of your aspirations into action and help jumpstart your organization's LEDE journey to reduce preventable patient harm, improve diagnosis, and achieve diagnostic excellence.

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APPENDIXES

Appendix A – Selected Diagnostic Safety Resources

Appendix B – Suggested Approaches to Developing a Virtual Hub Based on Functions of Geisinger's Committee to Improve Clinical Diagnosis

Appendix C – Safer Dx Trigger Tools Framework

Appendix D – Revised Safer Dx Instrument

Appendix E – Safer Dx Process Breakdown Supplement

Appendix F – How To Review a Case for Diagnostic Learning Opportunities

Appendix G – Sample Instrument to Collect Data on Test Result Followup Delays

Appendix H – Diagnostic Error Evaluation and Research (DEER) Taxonomy

Appendix I – Feedback Guide for Clinicians

Reminder
Before accessing patient records and generating new data or other records using these materials, review all privacy, confidentiality, and privilege protections that apply to your organization, and be aware of any specific requirements to ensure compliance with the HIPAA Privacy and Security Rules and other relevant laws.

Appendix A. Selected Diagnostic Safety Resources

Closing the Loop: A Guide to Safer Ambulatory Referrals in the EHR Era

http://www.ihi.org/resources/Pages/Publications/Closing-the-Loop-A-Guide-to-Safer-Ambulatory-Referrals.aspx

This publication recommends ways to help standardize how primary care practitioners activate referrals to specialists and then track the information over time. The guide describes a nine-step, closed-loop process in which all relevant patient information is communicated quickly to the correct person through the appropriate channels. The process involves significant collaboration among all stakeholders, so the guide includes both general recommendations and recommendations specific to each step in the process and each stakeholder group.

Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families

https://www.ahrq.gov/patient-safety/reports/engage.html

AHRQ developed this guide as a resource to help primary care practices partner with patients and their families to improve patient safety. The guide is composed of materials and resources to help primary care practices implement patient and family engagement to improve patient safety.

Implementation Approaches for Closing the Loop

https://www.ecri.org/hit/implementation-approaches-closing-the-loop

Working directly with healthcare organizations, the Partnership for Health IT Patient Safety explored ways to close the loop on diagnostic evaluations. Clinicians used their existing technology and modified their practices to better track key information.

Improving Diagnosis in Health Care

https://www.ncbi.nlm.nih.gov/books/NBK338596/

The National Academies of Sciences, Engineering, and Medicine posted resources to facilitate communication between patients and clinicians, including videos, checklists, and additional report resources.

Improving Your Laboratory Testing Process: A Step-by-Step Guide for Rapid-Cycle Patient Safety and Quality Improvement

https://www.ahrq.gov/hai/tools/ambulatory-care/lab-testing-toolkit.html

The tools in this step-by-step guide can increase the reliability of the testing process in medical offices by helping providers examine how tests are managed. This guide describes how to assess an office testing process, assess patient experience and documentation, plan for improvement, implement change, and reassess to determine if the office has improved.

Reducing Diagnostic Error: Measurement Considerations

https://www.qualityforum.org/ProjectDescription.aspx?projectID=90704

The National Quality Forum convened a multistakeholder committee to identify recommendations for the practical application of the Diagnostic Process and Outcomes domain of the 2017 Diagnostic Quality and Safety Measurement Framework, measuring and reducing diagnostic error, and measuring and improving patient safety. This report outlines the recommendations through a series of four use cases that depict resolutions to specific types of diagnostic errors, as well as broad-scope, comprehensive recommendations with applications to multiple populations and settings.

The final report can be found at: https://www.qualityforum.org/Publications/2020/10/Reducing_Diagnostic_Error__Measurement_Considerations_-_Final_Report.aspx.

Safer Dx Checklist: 10 High-Priority Organizational Practices for Diagnostic Excellence

http://www.ihi.org/resources/Pages/Tools/safer-diagnostic-checklist.aspx

The Safer Dx Checklist is an organizational self-assessment tool with 10 recommended practices to achieve diagnostic excellence. It can help understand the current state of diagnostic practices, identify areas to improve, and track progress toward diagnostic excellence over time.

Society to Improve Diagnosis in Medicine Resource Center

https://www.improvediagnosis.org/resources-for/

The Society to Improve Diagnosis in Medicine features educational resources for trainees, practitioners, and educators on clinical reasoning, critical thinking, and system factors that underlie diagnostic error, as well as strategies to improve diagnostic performance.

SureNet

https://permanente.org/reducing-diagnostic-errors/

The SureNet program identifies test results or signs and symptoms that generally require followup for which the patients do not appear to have had the needed followup. It thus potentially prevents diagnostic errors by preventing patients from "falling through the cracks." It is limited to diseases with a course of progression slow enough that one can take a few weeks to identify the cases and intervene.

TeamSTEPPS® for Diagnosis Improvement

https://www.ahrq.gov/teamstepps/diagnosis-improvement/index.html

TeamSTEPPS® is an evidence-based program built on a framework composed of four teachable, learnable skills—communication, leadership, situation monitoring, and mutual support. TeamSTEPPS for Diagnosis Improvement applies the TeamSTEPPS framework to the specific problem of diagnostic error.

Toolkit for Engaging Patients to Improve Diagnostic Safety

https://www.ahrq.gov/patient-safety/resources/diagnostic-safety/toolkit.html

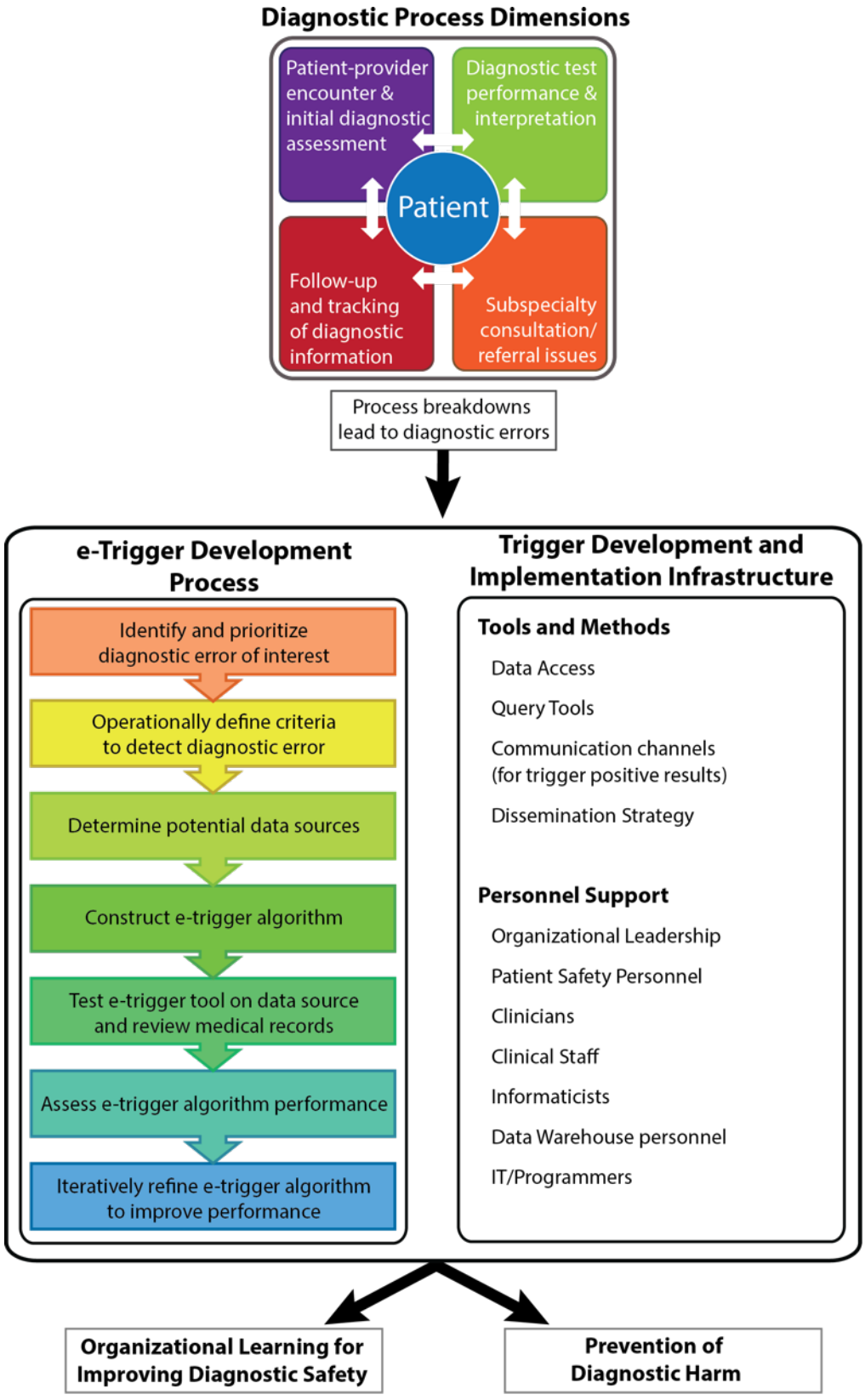
AHRQ developed this toolkit to help patients, families, and health professionals work together as partners to improve diagnostic safety. The toolkit includes two strategies ("Be The Expert On You" and "60 Seconds To Improve Diagnostic Safety") that, when paired together, can enhance communication and information sharing within the patient-provider encounter to improve diagnostic safety.

Appendix B. Suggested Approaches to Developing a Virtual Hub Based on Functions of Geisinger's Committee to Improve Clinical Diagnosis

Suggested Approaches	Examples
Create virtual hub goals	▪ Develop innovative approaches and a formal review process to identify diagnostic errors and near misses and strategies to address them ▪ Work constructively with clinical and health care system leaders to develop a culture that values transparency and encourages the reporting of diagnostic errors as part of individual and organizational professional responsibility
Partner with patient safety and risk management	▪ Work collaboratively with patient safety and risk management to conduct reviews and root cause analyses on diagnostic errors with potential for significant patient harm or morbidity ▪ Collaborate with risk management in cases where there is harm or potential for litigation so that the health care system proceeds with the usual course of action while still learning from missed opportunities ▪ Focus on the learning opportunities and expand the lessons learned to other clinicians
Review and monitor diagnostic errors	▪ Categorize diagnostic errors in a systematic fashion and identify major areas of emphasis ▪ Provide feedback to clinic and hospital leaders on major patterns of missed opportunities
Prioritize action	▪ Develop recommendations to address high-volume, high-risk, and high-morbidity/mortality missed opportunities and communicate them to clinic and system leaders
Create learning	▪ Create learning opportunities and implement feedback process for clinicians guided by principles that include providing the feedback in person in a nonthreatening/nonpunitive fashion and that support transparency and a learning culture
Promote education	▪ Identify resources that can be used in patient care to enhance critical thinking, clinical reasoning, and the diagnostic process ▪ Develop strategies and programs to enhance the educational process for staff, residents, and clinicians

Reprinted with permission from Singh H, Upadhyay DK, Torretti D. Developing health care organizations that pursue learning and exploration of diagnostic excellence: an action plan. Acad Med. 2020;95:1172-78. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7402609/. Accessed April 1, 2022

Appendix C. Safer Dx Trigger Tools Framework



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Appendix D. Revised Safer Dx Instrument

The Safer Dx Instrument: Items for Determining Presence or Absence of a Diagnostic Missed Opportunity

Rate the following items for the episode of care under review:
1—2—3—4—5—6—7

1 = Strongly Disagree 7 = Strongly Agree

Item	Score
1. The documented history was suggestive of an alternate diagnosis, which was not considered in the diagnostic process.	
2. The documented physical exam* was suggestive of an alternate diagnosis, which was not considered in the diagnostic process.	
3. Data gathering through history, physical exam, and review of prior documentation (including prior laboratory, radiology, pathology or other results) was incomplete, given the patient's medical history and clinical presentation.	
4. Alarm symptoms or "red flags" (i.e., features in the clinical presentation that are considered to predict serious disease) were not acted upon.	
5. The diagnostic process was affected by incomplete or incorrect clinical information given to the care team by the patient or their primary caregiver.	
6. The clinical information (i.e., history, physical exam, or diagnostic data) should have prompted additional diagnostic evaluation through tests or consults.	
7. The diagnostic reasoning was not appropriate, given the patient's medical history and clinical presentation.	
8. Diagnostic data (laboratory, radiology, pathology, or other results) available or documented were misinterpreted in relation to the subsequent final diagnosis.	
9. There was missed follow-up of available or documented diagnostic data (laboratory, radiology, pathology, or other results) in relation to the subsequent final diagnosis.	
10. The differential diagnosis was not documented OR the documented differential diagnosis did not include the subsequent final diagnosis.	
11. The final diagnosis was not an evolution of the care team's initial presumed diagnosis (or working diagnosis).	
12. The clinical presentation at the initial or subsequent presentation was mostly typical of the final diagnosis.	
13. In conclusion, based on all the above questions, the episode of care under review has a missed opportunity to make a correct and timely diagnosis.	

* Physical exam includes vital signs.

Additional information - please check "Yes" if applicable:

1. Care episode involves a management error. ☐ Yes
2. Care escalation (e.g., hospitalization at subsequent visit) was related to worsening of an original correctly diagnosed condition that the patient initially presented with (rather than from something being missed initially). ☐ Yes
3. Patient initially refused admission or additional evaluation. ☐ Yes

Brief description of missed diagnostic opportunity or management error and any relevant thoughts and observations that helped with your decision (for or against).

Appendix E. Safer Dx Process Breakdown Supplement

Study ID: Reviewer: Review Date: Index Visit Date:

What was the missed diagnosis?	
What was the chief complaint or presenting symptoms at initial presentation?	
Was the chief complaint related to the diagnostic error?	☐ Yes ☐ No

Provider Characteristics

Please identify all setting/personnel involved in the error(s) and rate the importance of their contribution.

Setting Involved (code list, setting code)	Personnel Type (code list, pages 1-2)	Personnel Involved (code list, specialty codes)	Contributory Role Rating (code list, scoring scale)
1.			
2.			
3.			
4.			

What factors prompted the error discovery? (select all that apply)

☐ Discovered as part of planned follow-up	☐ Fresh eyes looking at the original picture
☐ Failure of original symptom or signs to resolve	☐ Information after patient died (i.e., family alleges diagnostic error)
☐ New symptoms or signs	☐ Text/Other, please describe:
☐ Evolution of the original symptoms or signs	☐ Not able to be determined
☐ Patient insistence/persistence on pursuing another diagnosis	☐ Patient admitted to hospital, please select:
☐ New data	☐ Parent facility ☐ Outside facility

In the episode of care most closely associated with the error, was any differential diagnosis documented?	
If "Yes", was the differential diagnosis acted upon?	
Was the correct diagnosis considered in the differential diagnosis at the initial presentation of the health problem?	

Timeline

How many visits (Outpatient/Inpatient) did the patient make before the correct or final diagnosis was made? (including visit that prompted the correct diagnosis)	
i. Outpatient visit number:	ii. Inpatient visit number:
With the benefit of hindsight, what date would have been the first opportunity to begin the process of making this diagnosis had the patient come in at first symptom? (including visit that prompted the correct diagnosis)	
Date:	☐ Not able to be determined
When did the patient first present with symptoms related to the diagnostic error?	
Date:	☐ Not able to be determined
When was the final diagnosis made? (Note the earliest date found)	
Date:	☐ Not able to be determined

Outcome

What was the potential severity of injury associated with delay or missed diagnosis? (select one)

Harm
Impairment of the physical, emotional, or psychological function or structure of the body or financial distress and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

No Harm

☐ Category A- Circumstances or events that have the capacity to cause error

Error, No Harm

☐ Category B- An error occurred but the error did not reach the patient (An "error of omission" does reach the patient)
☐ Category C- An error occurred that reached the patient but did not cause patient harm
☐ Category D- An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm

Error, Harm

☐ Category E- An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention
☐ Category F- An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization
☐ Category G- An error occurred that may have contributed to or resulted in permanent patient harm
☐ Category H- An error occurred that required intervention necessary to sustain life

Error, Death

☐ Category I- An error occurred that may have contributed to or resulted in the patient's death

Dimensions (select all that apply)	
1) Patient Related	☐ Delay in seeking care ☐ Lack of adherence to appointments ☐ Other, please specify:
2) Patient-Provider Encounter	☐ Problems with history ☐ Problems with physical exam ☐ Problems ordering diagnostic tests for further work up ☐ Failure to review previous documentation ☐ Problems with data integration and interpretation ☐ Other, please specify:
3) Diagnostic Tests	☐ Ordered test not performed at all ☐ Ordered tests not performed correctly ☐ Performed tests not interpreted correctly ☐ Misidentification ☐ Other, please specify:
4) Follow-Up & Tracking	☐ Problems with timely follow-up of abnormal diagnostic test results ☐ Problems with scheduling of appropriate and/or timely follow-up visits ☐ Problems with diagnostic specialties returning test results to clinicians ☐ Problems with clinicians reviewing test results ☐ Problems with clinicians documenting action or response to test results ☐ Problems with notifying patients of test results ☐ Problems with monitoring patients through follow-up ☐ Other, please specify:
5) Referrals	☐ Problem initiating referral ☐ Lack of appropriate actions on requested consultation ☐ Communication breakdown from consultant to referring provider ☐ Other, please specify:

Reprinted with permission from Singh H, Khanna A, Spitzmueller C, Meyer AND. Recommendations for using the Revised Safer Dx Instrument to help measure and improve diagnostic safety. Diagnosis 2019;6(4):315-23. https://doi.org/10.1515/dx-2019-0012. Accessed April 6, 2022.

Appendix F. How To Review a Case for Diagnostic Learning Opportunities

Important: Before analyzing cases, reviewers should read the original manuscript that describes the development and use of the Revised Safer Dx Instrument, which is freely available:

Singh H, Khanna A, Spitzmueller C, Meyer A. Recommendations for using the Revised Safer Dx Instrument to help measure and improve diagnostic safety. Diagnosis (Berl). 2019;6(4):315-23. doi:10.1515/dx-2019-0012.

What you will need to begin:

- Approval to access medical records and patient identifiers for conducting this improvement activity
- Revised Safer Dx Instrument
- Additional case review tools (optional)

1 Ensure that you and any other reviewers have a shared understanding of diagnostic error

- Keep the fundamental question in mind: could something different have been done to make the correct diagnosis earlier?
- Make your judgments about clinicians' decision making and diagnostic reasoning based on the information they had available to them at the time.
- Look for missed opportunities not only by clinicians but also by the care team, system, and patients.

2 Identify the episode of care to evaluate

- Usually involves all the care a patient received over a given period of time for a specific health problem they present with.
- Can span multiple encounters, including inpatient and outpatient visits, or focus on a sole encounter such as a hospitalization.

3 Review the chart with a focus on diagnostic process rather than the ultimate outcome

- Start by evaluating the clinical encounter (history, exam, tests ordered), as well as the initial presumed diagnosis or working differential diagnosis.
- Read through the chart to understand how the diagnostic processes and reasoning evolved rather than focusing on the ultimate accuracy of the diagnosis or any potential adverse outcome.
- Also look at progress notes, test results, referrals, consultant notes, and other documents that informed the diagnosis.
- Use current literature or guidelines to evaluate the diagnostic process.

4 Answer the prompts in the Revised Safer Dx Instrument to make a determination about missed opportunities

- Prompts 1-12 ask you to evaluate the diagnostic processes at various stages such as history taking, physical exam, diagnostic testing, consulting, and clinical reasoning.
- The higher you score each prompt, the more likely you think there was a missed opportunity for diagnosis at this stage of the process.
- Prompt 13 asks you to look at the case as a whole and come to a final judgment as to whether there was a missed opportunity for diagnosis.
- Do not try to add up the numbers of each question to make any type of overall score. The questions are only to help you think through each item so you can make an overall assessment at the end with prompt 13.
- Write a few sentences to add context and explain your reasoning for your answer to prompt 13.

5 Analyze cases with missed opportunities

- Cases with scores >5 on question 13 generally suggest there was a missed opportunity, and it may be good for a second reviewer to look at the case. If there is disagreement between the first two reviewers, it may help to have a third reviewer or discuss the case among the clinician team members. Depending on your resources, you can take a second look at scores of 4 or more.
- If missed opportunities are confirmed, in consultation with the diagnostic safety team, use additional tools, such as the Safer Dx Process Breakdown Supplement, DEER taxonomy, fishbone diagram, and CFER-DS, to identify process breakdowns, contributing and contextual factors, and level of harm to the patient.
- Refer to quality and safety personnel for further review if missed opportunities can be linked to system failures.

Appendix G. Sample Instrument to Collect Data on Test Result Followup Delays

Example Test Result Delay Data Collection Instrument

Site: _____ Reviewer Initials: _____ Review Date: _____

1. Patient and Provider Characteristics

Patient MRN: _____ Date of Birth: _____

Test Name: _____ Test Date: _____

Reason for Test: _____

Patient's PCP: _____ Is the ordering provider the patient's PCP? ◉ Yes ◉ No

(If "No," specify Ordering Provider's Name and Sub-specialty code below)

PCP Type: ◉Physician ◉ PA ◉ NP

Ordering Provider Name _____ Ordering Provider Sub-specialty Code _____

2. Is there documentation of any of the following WITHIN the 14 days AFTER test was performed?

1) Patient notified of the test results? ◉ Yes ◉ No → If "Yes" → _____ Date

→ If "No" → _____ Date:

2) Patient referred to another provider or specialist ◉ Yes ◉ No → If "Yes" → _____ Date

3) Another follow-up test ordered? ◉ Yes ◉ No → If "Yes" → _____ Date

- ○ Follow up care received at an outside site.
- ○ Follow up was refused by patient.
- ○ Patient was already receiving appropriate care for the condition for which the provider was alerted.
- ○ None of these were documented.

4) ☐ Other action(s) taken.

5) ☐ Multiple providers notified → # of providers: ◉1 ◉2 ◉3

6) Additional Verbal Communication: ◉ Yes ◉ No → (If Yes, Describe below)

7) Anticipated impact if report was to be lost to follow-up:

- ◉ None
- ◉ Inconvenience
- ◉ Very Minor Harm/little or no remediation
- ◉ Minor Harm/remediation or treatment
- ◉ Considerable Harm/remediation or treatment
- ◉ Very Serious Harm/danger of permanent damage
- ◉ Serious Permanent Damage
- ◉ Immediate and Inevitable Death

8) Did patient receive follow up action after 14 days? ◉ Yes ◉ No → If "Yes" → _____ Date

If "No" → **Take appropriate Action**

Acknowledgment: Dr. Daniel Murphy, Baylor College of Medicine and Department of Veterans Affairs. Used with permission.

Appendix H. Diagnostic Error Evaluation and Research (DEER) Taxonomy

Where in the Diagnostic Process	What Went Wrong
1. Access/Presentation	a. Failure/delay in presentation b. Failure/denied care access
2. History	a. Failure/delay in eliciting critical piece of history data b. Inaccurate/misinterpreted/overlooked critical piece of history data c. Failure in weighing critical piece of history data d. Failure/delay to follow-up critical piece of history data
3. Physical Exam	a. Failure/delay in eliciting critical physical exam finding b. Inaccurate/misinterpreted/overlooked critical physical exam finding c. Failure in weighing critical physical exam finding d. Failure/delay to follow-up critical physical exam finding
4. Tests (Lab/Radiology)	*Ordering (traditionally called "pre-analytic phase")* a. Failure/delay in ordering needed test(s) b. Failure/delay in performing ordered test(s) c. Error in test sequencing d. Ordering of wrong test(s) e. Tests ordered wrong way
	Performance (traditionally called "analytic phase") f. Sample mix-up/mislabeled (e.g., wrong patient/test) g. Specimen delivery problem h. Technical errors/poor processing of specimen/test i. Erroneous lab/radiology reading of test j. Failed/delayed reporting of result to clinician
	Clinician Processing (traditionally called "post-analytic phase") k. Failed/delayed follow-up of (abnormal) test result l. Error in clinician interpretation of test
5. Assessment	*Hypothesis Generation* a. Failure/delay in considering the diagnosis
	Suboptimal Weighing/Prioritizing b. Too little consideration/weight given to the diagnosis c. Too much weight on competing/coexisting diagnosis
	Recognizing Urgency/Complications d. Failure/delay to recognize/weigh urgency e. Failure/delay to recognize/weigh complications of a diagnosis
6. Referral/Consultation	a. Failure/delay in ordering referral/consult b. Failure/delay in obtaining/scheduling ordered referral c. Error/suboptimal quality in diagnostic consultation performance d. Failed/delayed communication/follow-up of consultation
7. Follow-up	a. Failure/delay in timely follow-up/rechecking of patient b. Failure to refer patient to close/safe setting/monitoring c. Failure/delay in needed monitoring or lab (BP, INR, repeat CXR) d. Failure/delay in communicating findings among healthcare providers

Acknowledgment: Dr. Gordon Schiff, Harvard Medical School. Used with permission.

Appendix I. Feedback Guide for Clinicians

A GUIDE TO GIVING FEEDBACK TO CLINICIANS

Providing Feedback on Diagnostic Performance

1) SCHEDULE THE DEBRIEFING IN A TIMELY MANNER

- Ensure that the debriefing occurs soon after the event to promote a learning environment rather than a punitive one

2) PLAN AND PREPARE FOR THE DEBRIEFING

- Encourage the recipient(s) to review the case before the debriefing.
- Consider including more than one person (e.g. care team) as recipients

3) SET A FLEXIBLE TIME FRAME

- Schedule 10-20 minutes for debriefing
- Allow for more time with a larger group

4) SET THE STAGE FOR A LEARNING ENVIRONMENT

- Take a non-judgmental stance
- Explain the context, including goals and objectives
- Be aware of non-verbal cues

5) SEEK INPUT AND ALLOW FOR EXPLANATION

- Discuss specific actions or decisions
- Do not infer motives
- Explore unclear issues with curiosity
- Include what went well

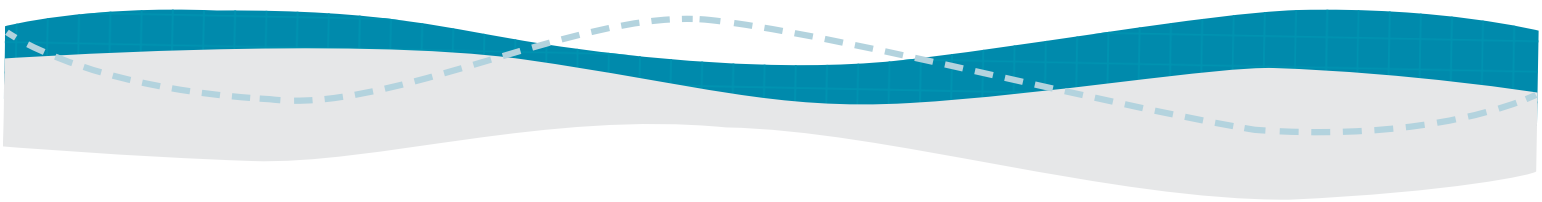
6) HAVE RECIPIENT(S) IDENTIFY LEARNING OBJECTIVES

- Emphasize learning for the individuals, the care team, the department, and the system

7) END WITH APPRECIATION

- For their input
- For their time
- For their willingness to help improve clinical decision making at the facility/system.

Reprinted with permission from Meyer AND, Upadhyay DK, Collins CA, Fitzpatrick MH, Kobylinski M, Bansal AB, Torretti D, Singh H. A program to provide clinicians with feedback on their diagnostic performance in a learning health system. Jt Comm J Qual Saf 2021;47:120-26. https://pubmed.ncbi.nlm.nih.gov/32980255/. Accessed April 6, 2022.



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