NATIONAL QUALITY FORUM

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Improving Diagnostic Quality and Safety/Reducing Diagnostic Error: Measurement Considerations

DRAFT REPORT

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Executive Summary

The delivery of high-quality healthcare is predicated upon an accurate and timely diagnosis. Diagnostic errors, which are defined as the failure to establish or communicate an accurate and timely assessment of a patient's health problem, contribute to an estimated 40,000-80,000 deaths each year.[1] Approximately 12 million Americans suffer a diagnostic error each year, and the National Academies of Science, Engineering, and Medicine (NASEM) Committee on Diagnostic Error in Health Care suggested that most people will experience at least one diagnostic error in their lifetime.[2]

In 2017, NQF convened a multistakeholder expert Committee to develop a conceptual framework for measuring diagnostic quality and safety, and to identify priorities for future measure development. The 2017 Measurement Framework included three domains: Diagnostic Process and Outcomes, Patients, Families and Caregivers, and Organization and Policy Opportunities. To further advance patient safety and reduce diagnostic error, NQF convened a new multistakeholder Committee in 2019 to build on the previous Committee's work.

With guidance from the Committee, NQF conducted an environmental scan to refine the Diagnostic Process and Outcomes domain of the 2017 Diagnostic Quality and Safety Measurement Framework. The environmental scan reaffirmed the findings of the 2017 Measurement Framework, and based on a review of new literature published since the work of the former Committee concluded, the Measurement Framework did not require updates nor modifications to the subdomains.

Over a series of eight web meetings, this Committee designed four Use Cases to support the practical application of the Diagnostic Process and Outcomes domain of the 2017 Measurement Framework. The Use Cases were developed by the Committee as an opportunity to identify comprehensive resolutions to specific types of diagnostic errors. The Use Cases detail how wide-ranging stakeholders, including, but not limited to clinicians, administrators, patients, payers, professional societies, measure developers, and EHR vendors can take actionable steps to reduce and overcome common types of diagnostic errors. The Use Case topics selected – including missed subtleties, communication failures, information overload, and dismissed patients – reflect high priority problems and examples of diagnostic error that cause patient harm. Each Use Case describes the type of diagnostic error, its causal factors, key stakeholders who can help overcome and prevent the error, and global and granular solutions to the error. Use Cases also include snapshots of case exemplars to demonstrate how the specific solutions can be implemented in practice, offering an opportunity for readers to identify how to best prevent and overcome specific diagnostic errors in their own organization and practice. The case exemplars range across settings and populations, and readers can identify which case exemplar resonates most given their own unique circumstances and contexts.

This Report concludes with comprehensive, broad-scope, actionable and specific recommendations for applying the Diagnostic Process and Outcomes Domain of the 2017 Measurement Framework, as well as for measuring and reducing diagnostic error and improving patient safety. Recommendations are centered around three pillars of training, teamwork, and technology. Each recommendation includes actionable steps that diverse stakeholders can take to measure and reduce diagnostic error, and ultimately improve patient safety.

Final Report

Background and Project Objectives

A 2015 report of the National Academies of Sciences, Engineering, and Medicine (NASEM), *Improving Diagnosis in Health Care*, defines diagnostic error as the failure to establish or communicate an accurate and timely assessment of the patient's health problem.[1] When diagnostic errors occur, the correct diagnosis may be detected by a later clinical evaluation, diagnostic test or finding on autopsy, or it may never be detected at all. Diagnostic errors can lead to patient harm when the incorrect treatment or delayed treatment is delivered. For example, a patient may have subtle symptoms of a heart attack – or acute myocardial infarction (AMI) – but may be misdiagnosed and sent home from a clinic or hospital. This may lead to delayed treatment or even death because timely treatments are available for AMI. Timely and correct diagnoses rely on many factors including the knowledge, training and skills of clinicians delivering care, the resources available to them, and the supporting systems designed to reduce the frequency of or mitigate common diagnostic errors.

The NASEM Committee on Diagnostic Error in Health Care suggested that most people will experience at least one diagnostic error in their lifetime. Diagnostic errors are estimated to contribute up to 17 percent of adverse hospital events, and data from autopsy-detected diagnostic errors and total deaths in hospitals suggest that between 40,000-80,000 deaths related to misdiagnosis occur annually.[3,1] Diagnostic errors are especially common in primary care, as an estimated 12 million Americans will experience a diagnostic error each year in this setting.[2] Diagnostic errors persist through all care settings and can result in physical, psychological, or financial repercussions for the patient. The NASEM Committee noted that there is a lack of effective measurement in the area, observing that "for a variety of reasons, diagnostic errors have been more challenging to measure than other quality or safety concepts."

In follow-up to the NASEM report, the National Quality Forum (NQF), with funding from the Department of Health and Human Services (HHS), convened a multistakeholder expert Committee (the Diagnostic Quality and Safety Committee) to explore the complex intersection of issues related to diagnosis and reducing diagnostic harm. The Committee developed a conceptual framework for measuring diagnostic quality and safety, identified gaps in measurement of diagnostic quality and safety, and highlighted priorities for future measure development. This project resulted in the 2017 report *Improving Diagnostic Quality and Safety*.

In 2019, NQF convened a new multistakeholder expert Committee – the Improving Diagnostic Quality & Safety/ Reducing Diagnostic Error: Measurement Considerations Committee—to revisit and build on the work of the 2017 NQF report. The Committee first reviewed the Diagnostic Process and Outcomes domain of the 2017 Measurement Framework to identify any needed updates. The Committee also identified high-priority measures, measure concepts, current performance measures, and areas for future measure development that had emerged since the initial development of the 2017 Measurement Framework. Informed by these activities, the Committee developed practical guidance for the application of the Diagnostic Processes and Outcomes domain, including specific Use Cases to demonstrate how the framework can be operationalized in practice, as well as detailed recommendations for the reduction of diagnostic error.

Diverse stakeholders, including healthcare organizations, clinicians, patients, payers, EHR vendors, policymakers and others, can use the practical guidance in this Report to apply the Diagnostic Processes and Outcomes domain of the 2017 Measurement Framework. Stakeholders can use existing measures and measurement concepts, as well as future measurement approaches, to identify specific opportunities for reducing diagnostic error and improving patient safety. The implementation strategies and solutions within the Report can subsequently be used to drive improvement in diagnostic processes and outcomes. Organizations and stakeholders can also use existing measures, measure concepts, and future measurement approaches to measure the effectiveness of the interventions and solutions.

Environmental Scan Findings

An Environmental Scan was performed to identify any needed modifications related to the Diagnostic Process and Outcomes domain of the 2017 Diagnostic Quality and Safety Measurement Framework. The scan also reviewed cross-cutting themes identified in the previous report, as well as identified measure concepts to add to the measure inventory. In addition, the environmental scan identified new measure concepts and measures applicable to the Diagnostic Process and Outcomes domain of the framework.

The 2017 Diagnostic Quality and Safety Measurement Framework

In 2017, the Diagnostic Quality and Safety Committee developed the Diagnostic Quality and Safety Measurement Framework based largely on the NASEM committee's conceptual model of the diagnostic process, while also drawing on concepts from the literature, including Singh and Sittig's SaferDx Framework[4] and Donabedian's organizing concepts of structure, process, and outcome.[5] The goal of the Measurement Framework is to serve as a guide for future measure development efforts by any and all stakeholders attempting to improve diagnostic quality and safety.

The 2017 Diagnostic Quality and Safety Measurement Framework includes three domains: patients, families, and caregivers; diagnostic process and outcomes; and, organizational and policy opportunities. Table 1 specifies the three domains and 11 subdomains for categorizing measures of diagnostic quality and safety.

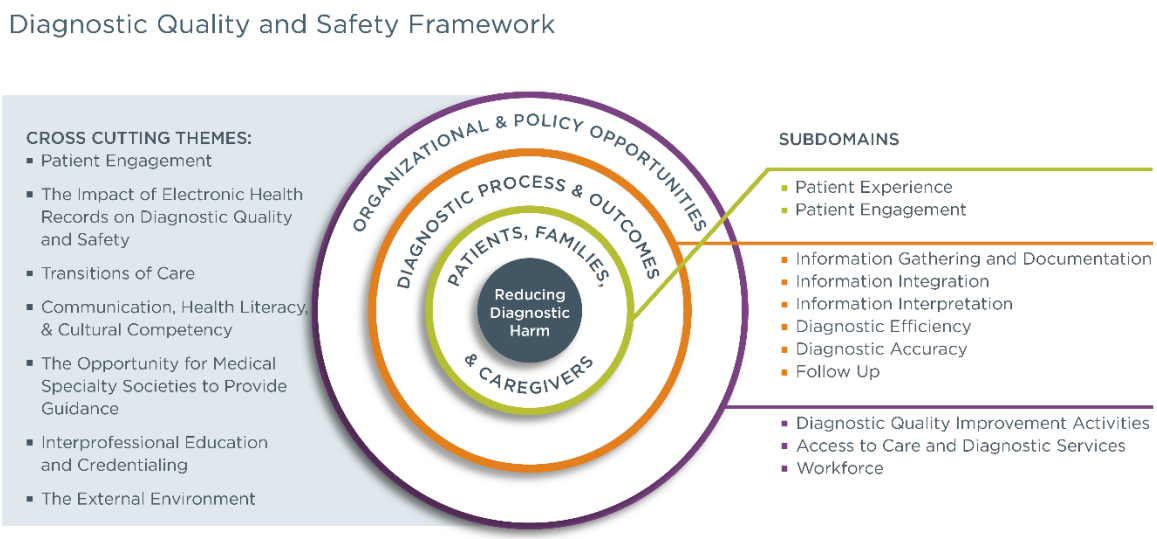
Table 1. Diagnostic Quality and Safety Measurement Framework

Domain	Subdomain
Patients, Families, and Caregivers	Patient Experience Patient Engagement
Diagnostic Process and Outcomes	Information Gathering and Documentation Information Integration Information Interpretation Diagnostic Efficiency Diagnostic Accuracy Follow-Up
Organizational and Policy Opportunities	Diagnostic Quality Improvement Activities Access to Care and Diagnostic Services Workforce

The Patients, Families, and Caregivers domain includes the patient's perception of the diagnostic process, inclusion, and communications among providers, patients, caregivers, and the system. The Diagnostic Process and Outcomes domain addresses the actions and processes that are carried out by the healthcare providers and/or teams to develop, refine, and confirm a diagnosis, or to discuss the patient's health problem. The Organizational and Policy Opportunities domain addresses organizational attributes that affect diagnostic performance. This includes organizational learning from diagnostic errors, diagnosis-related quality improvement activities, availability of diagnostic resources (e.g., organizational access to on call radiology services), and workforce sentiment. While the three domains are separate, there can be overlap when implementing the Measurement Framework (e.g., a facility policy may be needed to encourage patient engagement).

Based on a review of new literature published since the work of the former Committee concluded, the measurement framework did not require updates nor modifications to the subdomains. Figure 1 shows a graphic representation of the 2017 Diagnostic Quality and Safety Measurement Framework demonstrating the relationship between domains, subdomains, and cross-cutting themes.

Figure 1. 2017 Diagnostic Quality and Safety Measurement Framework



Diagnostic Process and Outcomes Domain

The Diagnostic Process and Outcomes domain of the 2017 Diagnostic Quality and Safety Measurement Framework addresses the actions and processes that are carried out by healthcare providers and/or teams to develop, refine, and confirm a diagnosis, or to discuss the patient's health problem. The Diagnostic Process and Outcomes subdomains include:

- Information Gathering and Documentation: The collection and documentation of diagnostic-related information
- Information Integration: The use of consultants, hand-offs, and care transitions between providers (e.g., provider-provider, provider-system communication)
- Information Interpretation: The use of decision support and best practices, cognitive processing, and machine computation

- Diagnostic Efficiency: The timeliness, efficiency, and appropriate use of diagnostic resources and tests
- Diagnostic Accuracy: Diagnostic errors, delay in diagnoses, and missed diagnoses
- Follow-Up: Appropriate and timely follow-up of labs, radiology, consultation notes, and other diagnostic findings

Although no updates were made to the Diagnostic Process and Outcomes domain, the environmental scan identified additional literature that supports the composition of the subdomains, and their continued relevance to reducing diagnostic error. The environmental scan identified a number of articles that add additional breadth to some subdomains, describing additional interventions and approaches that may be useful in reducing diagnostic error.

The environmental scan found that a patient narrative can be a useful source of information in identifying factors that lead to diagnostic errors. Reiterating the recommendations in the NASEM, literature has emphasized the potential value of improving teamwork in the diagnostic process. To promote learning from cases of diagnostic error, a new program using purposeful, non-random peer review of selected cases in radiology led to significantly more cases of error being identified, allowing trends to be identified for quality improvement.

A number of articles reviewed addressed issues related to clinical reasoning and cognitive bias, highlighting the important role of cognitive bias and other breakdowns in clinical reasoning as a contributing factor to cognitive errors. One study examined autopsy cases to identify discrepancies between autopsy and clinical diagnosis, finding a significant number of discrepancies. These discrepancies were associated with unexpected deaths, inadequate workups, and quality issues. Discrepancies identified in the autopsy may serve as a useful way to identify and measure quality and diagnostic error, particularly given the high discrepancy rate.

Several articles examined trigger tools, including the Institute for Healthcare Improvement's Global Trigger Tool. A novel framework was proposed that is relevant, the Safer Dx Trigger Tools Framework, which is intended to enable health systems to develop and implement e-trigger tools to identify and measure diagnostic errors using electronic health record (EHR) data. Specifically, e-trigger tools can detect potential diagnostic events and allow health systems to monitor event rates, as well as study contributory factors and identify targets for improving diagnostic safety. Some e-triggers can also monitor data prospectively and identify patients at high-risk for a future adverse event where preventive actions may be beneficial in reducing diagnostic errors.

Overall, the information found in the environmental scan did not contradict the previous work or require that any substantive changes be made to the original Diagnostic Process and Outcomes domain of the Diagnostic Quality and Safety Measurement Framework published by NQF in 2017.

Cross-Cutting Themes

At the time of the publication of the Diagnostic Quality and Safety Measurement Framework developed by the 2016-17 Diagnostic Quality and Safety Committee, the Committee identified a variety of issues and considerations applicable to measure development and the diagnostic process that were not necessarily addressed in any one domain. These "cross-cutting themes" were intended to be a part of any future discussion of applications of the measurement framework. As part of this current project,

NQF reviewed literature in order to identify any updates to the cross-cutting themes originally highlighted by the previous Committee. The updated environmental scan reinforced the previous cross-cutting themes and identified one additional theme: the Importance of Advancing Science in Diagnostic Error.

Patient Engagement: Engaging patients and using their knowledge of their own medical histories is a critical aspect of the diagnostic process. Incorporating the patient's perspective, engaging them in their care, and leveraging their knowledge to improve the diagnostic process will lead to fundamentally better outcomes. In tracing the causes of diagnostic error, one analysis revealed four principal categories: 1) ignoring patients' knowledge, 2) disrespecting patients, 3) failing to communicate, and 4) engaging in manipulation or deception.[6] The authors recommend new lifelong learning requirements to improve and maintain clinician communication skills.[6] Additionally, patient engagement was cited as a key component to improve the management of test results. By improving patient access to their own medical records, including through the use of open notes platforms, documentation errors may be more readily identified and remediated.[78]

Impact of Electronic Health Records (EHR) on Diagnostic Quality and Safety: Diagnostic quality and safety can be advanced significantly if EHRs have the capacity to collect key information related to diagnosis and are interoperable within and across organizations. Interoperability is particularly relevant to diagnosis given the frequent occurrence of errors when information fails to transfer easily across systems. One study of 925 medical offices found that a lower score on patient safety culture was significantly correlated with more frequently reported health IT problems, including unavailability of lab or imaging tests.[9] However, an increased reliance on electronic notification systems can lead to increased incidence of key diagnostic alerts being ignored by the recipient provider. One study recommended that institutional and system-level policies be created to assign a responsible entity for following-up on abnormal or critical test results, and that these policies be accompanied by structures to ensure accountability to promote adherence.[7]

Transitions of Care: Problems with transitions of care and errors during care transitions (e.g., loss of information critical to patient care) can be a direct cause of and have a significant impact on diagnostic errors. One study suggested that adverse events due to communication challenges were common, and that these could be attributable to the failure to document and convey important diagnostic information.[10]

Communication, Health Literacy, and Cultural Competency: Communication—between the provider and the patient, and between providers—is a key issue in diagnostic quality and safety. When communicating with patients about their diagnoses, healthcare professionals should be sensitive to the patients' health literacy and cultural needs or preferences. Clinicians can enhance communication and increase understanding by employing strategies like teach back.[11]

The Opportunity for Medical Specialty Societies to Provide Guidance: Improving diagnostic quality and safety will require medical specialty societies to engage and provide guidance as diagnostic measures are developed, in particular for conditions that are frequently misdiagnosed or can lead to serious harm in the event of a diagnostic error.

Interprofessional Education and Credentialing: Diagnostic quality and safety should become an important component of professional education, and credentialing organizations should ensure that their reviews emphasize diagnostic quality and safety. Following the NASEM report's recommendation to improve interprofessional education on the diagnostic process, a consensus group of educators outlined the potential for education to improve diagnostic outcomes, and identified a set of twelve key competencies that should be acquired during healthcare professional education. Several review articles underscored the importance of cognitive biases in leading to diagnostic errors, with one review finding that cognitive biases are widespread and contribute to over one third of fatal medical errors.[12] [13] Common biases identified included social and cultural biases, as well as biases such as confirmation bias, availability bias, and regret bias.[14] A review highlighted the importance of implementing procedures, such as checklists, as well as simply slowing down, in order to minimize the impact of biases on clinical decision-making.[15] The environmental scan highlighted the importance of including strategies to minimize the impact of cognitive biases in interprofessional education and credentialing.

External Environment: Issues related to the external environment, such as the alignment of payment incentives to promote timely and correct diagnosis, are less amenable to quality measurement but will have a significant impact on diagnostic quality and safety. An external factor highlighted in the cross-cutting theme description is the possibility of payment incentives to heighten accountability and strengthen diagnostic outcomes. One review describes new approaches to reducing diagnostic error having to do with heightening accountability via payment mechanisms. One is making reimbursement more flexible to account for clinician time that is not directly face-to-face and is instead concentrated on diagnostic processes, such as data gathering and interpretation, or even interprofessional coordination. Another is to champion alternative payment models that would support centers of diagnostic expertise and excellence, or increase accountability for diagnostic errors.[16]

Importance of Advancing Science in Diagnostic Error (NEW): Studies also identified research agendas in diagnostic error that may be relevant in the future development of quality measures. For example, Children's Hospitals Solutions for Patient Safety Network identified 49 research topics in the areas of high reliability, safety culture, open communication, and early detection of patient deterioration and sepsis.[17] Another advance is the novel application of social science techniques to study the diagnostic process, emphasizing concepts of "situativity" and the contextual aspects of diagnosis.[18]

Prioritized Measure Concepts

Purpose and Limitations of Measure Concepts

NQF distinguishes between a measure and a measure concept. A measure is defined as a fully developed metric that includes detailed specifications – to the point that the measure could be readily implemented in the specified care setting on the basis of these specifications alone – and generally will have undergone scientific testing to ascertain whether the measure, as specified, is both a reliable and valid measure of quality or cost. A fully developed measure identifies what should happen (i.e., what is being measured), who should be measured (i.e., population), where measurement should happen (i.e., setting), when it should happen (i.e., time), and how it should occur. A measure concept is an idea for a measure that includes a description of the potential measure, possibly including planned target and population.

The prioritized measure concepts are not intended to be differentiated by whether they would be appropriate for accountability programs, quality improvement, or both applications. When measures are used for accountability applications, performance results are used to make judgments and decisions as a consequence of performance. For example, performance results can be used for reward or recognition (e.g., certification programs), payment, or provider selection (e.g., public reporting). Measures used for quality improvement help organizations identify strengths and areas for improvement in healthcare delivery; organizations then use a systematic approach to make improvements in care. Benchmarking refers to the process of comparing the performance of accountable entities with that of their peers or with external best practice results.

New Measure Concepts

In order to identify new measure concepts, NQF reviewed new literature published since 2016, the date of the previous environmental scan for the Improving Diagnostic Quality and Accuracy project, including reports published by NQF. Two of these NQF reports, Advancing Chief Complaint-Based Quality Measurement and Population-Based Trauma Outcomes, yielded a variety of measure concepts across four components of the Diagnostic Process and Outcomes domain of the Improving Diagnostic Quality and Safety Measurement Framework.

Table 2 includes the count of measure concepts identified by subdomain. A full list of measure concepts can be found in Appendix B.

Table 2. Count of New Measure Concepts by Subdomain

Subdomain	Measure Concept Count
Information Gathering and Documentation: Includes the collection and documentation of diagnostic-related information	2
Information Integration: Includes the use of consultants, hand-offs, and care transitions between providers (e.g., provider-provider, provider-system communication)	0
Information Interpretation: Includes the use of decision support and best practices, cognitive processing, and machine computation	0
Diagnostic Efficiency: Includes timeliness, efficiency, and appropriate use of diagnostic resources and tests	8
Diagnostic Accuracy: Includes diagnostic errors, delay in diagnoses, and missed diagnoses	7
Follow-Up: Includes appropriate and timely follow-up of labs, radiology, consultation notes, and other diagnostic findings	0

High-Priority Areas for Future Measure Development

The previous Diagnostic Quality and Safety Committee agreed that all areas of measurement discussed above are important aspects of diagnostic quality and safety and should continue to be explored to help clinicians and healthcare researchers learn more about improving diagnostic performance. The environmental scan confirmed that the high-priority areas for future measurement development identified by the 2016-17 Committee – including timeliness of diagnosis, timeliness of test result follow-up, communication and hand-offs, patient-reported diagnostic errors, and patient experience of diagnostic care – remain critical to measuring and reducing diagnostic errors. The environmental scan

did not yield any additional high-priority areas for future measure development, nor were any revisions to the existing high-priority areas for future measure development required.

Measure Inventory

An environmental scan of performance measures specifically related to the Diagnostic Process and Outcomes subdomain was performed. These performance measures could be used either by stakeholders in order to reduce diagnostic errors in their care settings, or serve as models for other, similar performance measures where the original may be inapplicable. Measures were identified in the National Quality Forum Quality Positioning System (QPS) database, as well as in the CMS Measures Inventory (CMIT) database. The search for measures was limited to those that are in development, in testing, and in use, or were otherwise updated since the environmental scan was completed for the previous project in 2016.

Measures were classified based on the subdomains of the Diagnostic Process and Outcomes domain of the 2017 Diagnostic Quality and Safety Measurement Framework. In total, 19 measures were identified. These measures include both newly developed measures that were not in the inventory at the time of the 2016 scan, and measures that were endorsed prior to 2016 but not included in the original environmental scan. Table 3 summarizes the new measures by subdomain. A full list of measures can be found in Appendix C.

Table 3: Count of New Measures by Subdomain

Subdomain	Measure Count
Information Gathering and Documentation: Includes the collection and documentation of diagnostic-related information	0
Information Integration: Includes the use of consultants, hand-offs, and care transitions between providers (e.g., provider-provider, provider-system communication)	0
Information Interpretation: Includes the use of decision support and best practices, cognitive processing, and machine computation	0
Diagnostic Efficiency: Includes timeliness, efficiency, and appropriate use of diagnostic resources and tests	18
Diagnostic Accuracy: Includes diagnostic errors, delay in diagnoses, and missed diagnoses	1
Follow-Up: Includes appropriate and timely follow-up of labs, radiology, consultation notes, and other diagnostic findings	0

Use Cases: Comprehensive Resolution of Diagnostic Errors

To support the practical application of the Diagnostic Process and Outcomes domain, the Committee developed four Use Cases that depict specific diagnostic errors and solutions to overcome them.

Selection Process

NQF worked in collaboration with CMS and HHS liaisons to guide the process of conducting the environmental scan to identify measurement gaps related to diagnostic error in the healthcare setting. Upon identifying opportunities to address the measurement gaps identified, NQF proceeded to outline key topic areas to be discussed over the course of several months through Committee web meetings. To

promote practical application of the Diagnostic Process and Outcomes domain from theory into practice, NQF convened the Committee, with HHS' input, to identify and prioritize four key examples of diagnostic errors with viable solutions to inform the content of Use Cases.

The Use Cases below were developed by the Committee as an opportunity to identify comprehensive resolutions to specific types of diagnostic errors. The Use Case topics selected – including missed subtleties, communication failures, information overload, and dismissed patients – reflect high priority problems and examples of diagnostic error that cause patient harm. The Committee identified and refined the Use Cases over a series of eight Committee web meetings.

Approach

The Use Case approach is intended to support various stakeholders (e.g., clinicians, payers, measure developers, researchers, and others) in applying the Diagnostic Process and Outcomes domain of the 2017 Framework. The Use Cases reflect high priority examples of diagnostic error within the Diagnostic Process and Outcomes domain, and include both global and granular solutions to overcome and prevent these errors.

For background purposes, each Use Case describes the type of diagnostic error and its causal factors at the outset of the Use Case. The Use Cases then includes basic assumptions regarding the diagnostic error being described, key stakeholders who can help overcome and prevent the error, a summary of causal factors and diagnostic challenges, and various potential solutions within a table format. Each global solution includes a series of more granular solutions to support implementation of the broader solution by wide-ranging stakeholders.

The Use Cases also include snapshots of case exemplars to demonstrate how the specific solutions can be implemented in practice. The case exemplars range across settings and populations, and stakeholders can identify which case exemplar resonates most given their own unique circumstances and contexts.

The Use Cases conclude with an overview of the impacts of the solutions on overall patient safety, and a section outlining measurement considerations. The measurement considerations include potential approaches, possible measure concepts, and the rationale behind them. Stakeholders can look to the measurement considerations section to aid in assessing the degree to which the solutions are being implemented and are facilitating a reduction in diagnostic error.

Diverse stakeholders can review the Use Cases, and apply them directly to their respective setting, system, and/or population. The Use Cases describe a variety of options, and stakeholders can adapt the Use Cases to their own settings by understanding their organization's specific context, resources, and patient and staff needs. Solutions within the Use Cases reflect opportunities to reduce diagnostic error in multiple subdomains of the Diagnostic Process and Outcomes domain, allowing for stakeholders to drive improvement in multiple areas.

Stakeholders can also leverage the content within the Use Cases to design their own Use Cases. To do this, stakeholders can identify the assumptions, key individuals, causal factors and diagnostic challenges, and solutions that are most pertinent for them to focus on.

Use Case 1: Cognitive Error – Missed Subtle Clinical Findings

This Use Case focuses on a specific type of diagnostic error: one that occurs when a subtle clinical finding or symptom goes unrecognized or is misinterpreted, leading to a diagnostic error. "Subtle" refers to the concept that the finding or symptom is not clinically obvious or "classic" as it would appear in a medical textbook. Subtle findings can lead to misdiagnosis when, for example, a rare, serious illness may have similar symptoms to a more common illness and the subtle difference in symptoms or clinical examination findings goes unnoticed or is misinterpreted by the clinician. This is considered a cognitive error, which is a type of error that is made unconsciously.[19]

To illustrate, aortic dissection is a rare but deadly vascular condition with an incidence rate of 5-30 per 1,000,000 per year. It is a diagnosis that may be missed because it is uncommon, a challenge to diagnose at the bedside, and individuals with this condition often do not present with a uniform set of symptoms. Alternatively, a patient may have a relatively common condition, such as a stroke, but have uncommon or subtle symptoms that mimic other common conditions, such as benign positional vertigo. In both examples, clinicians can miss subtleties in the patient presentation that would enable them to accurately diagnose and treat the patient.

Broadly, diagnostic errors are detected when an adverse outcome occurs (e.g., a death or untoward clinical event occurs from a misdiagnosis), when a correct diagnosis is made and upon review it appears that other clinicians may have missed an opportunity to make an earlier diagnosis, and/or when a patient presents with certain clinical findings. Diagnostic errors due to missed subtle clinical findings are identified when the ultimate cause for the error is determined to be a non-classic presentation, or a subtle symptom or clinical finding. Errors that result in serious misdiagnoses commonly occur in hospital-based emergency departments where patients present with acute, undiagnosed complaints, but can also occur in any clinical setting, including outpatient clinics, inpatient settings, or other facilities.[20]

There are several causal factors that contribute to diagnostic errors resulting from unrecognized and/or misinterpreted subtle clinical finding or symptoms. These factors can be described in three broad groups: **clinician factors, system factors, and condition/disease factors.**

The two primary **clinician factors** contributing to these types of diagnostic errors are failures of expertise and cognitive biases.[21] Both factors are "cognitive" as they involve errors of thinking or perception. Studies that have examined the root cause of diagnostic errors are divided, some concluding that failures of knowledge and expertise are the dominant cause of diagnostic errors [22] and others finding that errors in clinical reasoning are the dominant explanation.[23] [24]

Underlying factors of failure of expertise include inadequate medical knowledge, insufficient training and practice, or lack of feedback. Clinicians are trained differently and have varied knowledge and experience. Clinicians with less experience, knowledge, or specialization may be less likely to detect subtle findings. By comparison, a specialist may be more likely to detect a subtle finding because of their training, experience, and focus on a particular area of the body (e.g., a neurologist or cardiologist as opposed to a primary care clinician).

Solving problems of expertise failure can be approached educationally through problem-specific solutions, deliberate practice, and prompt feedback.[25] Teamwork, access to colleagues with specific

expertise, and/or diagnostic decision support tools and systems, including the use of large datasets and artificial intelligence (AI) or machine learning, may also be used to provide greater expertise at the point of care, ultimately lowering the risk of diagnostic error. Cognitive biases, or flaws in judgement and/or decision making, and diagnostic errors are a complex concept, as more than 100 cognitive biases have been identified.[26] Diagnostic errors related to cognitive biases occur where the clinician uses a decision-making shortcut – also known as a "heuristic" – to make a diagnosis. A shortcut may include not fully evaluating symptoms or not performing a thorough clinical examination, which can lead to problems particularly when symptoms or clinical findings are subtle. Oftentimes, the shortcut ends up being the incorrect approach in a particular patient and can lead to misdiagnosis when subtle findings go unrecognized as a result of using the shortcut. Many different types of cognitive biases can occur in situations where clinicians miss a clinical symptom and a diagnostic error results, including, but not limited to:[27]

- Affective bias: Prioritizing negative events differently than positive events
- Availability bias: Favoring more recent and/or readily available diagnoses because of ease of recall and perceived importance
- Anchoring bias: Focusing, or "anchoring", on early information or an initial clinical impression
- Base rate neglect: Ignoring the underlying incidence rates of conditions and not applying them to the patient
- Confirmation bias: Interpreting or seeking information to fit a preconceived diagnosis
- Conjunction rule: Incorrectly believing that multiple diagnoses being true is greater than a single diagnosis; also known as "Occam's razor", where a simple unifying explanation is more likely than multiple unrelated ones
- Diagnostic momentum: Building on the momentum and continuing a clinical course of action started by previous clinician(s) without considering the information available
- Hindsight bias: Perceiving that events that have already occurred were more predictable than they actually were before the event already took place
- Implicit bias: Holding attitudes or stereotypes that unconsciously impact a clinician's understanding, actions, and decisions
- Overconfidence: Inflating the opinion of a clinician's own diagnostic ability
- Premature closure bias: Arriving at a diagnosis early in the case without having carefully explored all possible diagnostic options
- Representativeness: Misinterpreting the likelihood of a diagnosis considering the similarities of an individual's presentation to a general population
- Search satisficing: Ceasing to look for further information or alternative answers when a plausible diagnosis is identified

Many solutions can help address the detrimental impact of cognitive biases, including the use of standardized approaches, like using checklists or routinely creating a differential diagnosis, and through learning about cognitive bias as a source of error.[28,29,30] [31] System-based interventions can also be effective in addressing shortcomings in clinical reasoning, such as providing access to second opinions or decision-support tools to assist with differential diagnosis.

Systems factors contributing to these types of errors include the environment in which the clinician works and the resources available to a clinician. The environment can include the physical or virtual environment that care is delivered in. Notably, environmental factors can increase the likelihood of errors when there are subtle findings. For example, a hectic, crowded emergency department can increase the likelihood of errors because an overly busy clinician or chaotic environment may lead to a

rushed examination, or one that is performed in a hallway stretcher rather than in the privacy of a patient room.[32] The resources available to a clinician also contribute to diagnostic errors when clinicians miss subtle findings. Certain environments may have less access to specialists, standardized protocols, diagnostic tests, and other resources which may increase the likelihood of a misdiagnosis when there is a subtle presentation. Additionally, the EHR itself is commonly cited as a contributing factor in cases of diagnostic error.[33] Limited interoperability, challenging user interfaces, and the manner in which the EHR displays results and information all present barriers to accurate and timely diagnoses.[33]

Lastly, there are a number of **condition/disease factors** that increase the likelihood of a diagnostic error occurring, including "red herrings", subtle presentations, and rare diseases. The risk of misdiagnosis increases when there is a "red herring", or another prominent clinical finding or situation that distracts the clinician from detecting a subtle finding, overshadowing the correct diagnosis. For example, an older adult patient with underlying cardiac disease may present to the ED after a major motor vehicle accident. The primary focus of the initial evaluation is likely focused on detecting and treating injuries from the accident, but more subtle findings may be missed—such as a finding of an arrhythmia on the electrocardiogram representing long QT syndrome (LQTS) that was the cause of the crash in the first place, since a symptom of LQTS is sudden fainting.

The subtlety of a patient's presentation can also contribute to a diagnostic error. Clinicians are typically taught the classic symptoms of conditions. For example, "classic" symptoms and signs of stroke include slurred speech and unilateral (e.g., on one side of the body) weakness. For sepsis, patients classically have high fever and low blood pressure. When patients have more subtle symptoms – or symptoms do not follow the classical textbook pattern – the risk of diagnostic error increases. Therefore, the degree of subtlety of an individual patient's presentation itself is a risk factor, which may fall along a spectrum. Additionally, the rarity of a diagnosis also contributes to these diagnostic errors. Rare diagnoses can increase the likelihood of misdiagnosis, as clinicians tend to have less experience with rare diagnoses than with common diagnoses.

The Use Case in Table 4 is focused on opportunities to prevent and overcome diagnostic errors that occur when a subtle clinical finding or symptom goes unrecognized or is misinterpreted. The Use Case addresses multiple subdomains from the Diagnostic Process and Outcomes domain within the 2017 Diagnostic Quality and Safety Measurement Framework, including Information Gathering and Documentation, Information Integration, Information Interpretation, and Diagnostic Accuracy. Organizations, clinicians, and other healthcare stakeholders (e.g., payers, researchers, EHR vendors) can review the solutions included in the Use Case and identify opportunity areas that are most applicable to them given their organizational needs, resources, and context.

Table 4. Use Case 1: Cognitive Error – Missed Subtle Clinical Findings

Title	**Cognitive Error – Missed Subtle Clinical Findings**
Assumptions	• Diagnostic errors are complex and have a variety of root causes. Organizations and clinicians should convene multi-disciplinary quality improvement teams to understand and remediate the types of errors occurring within their organization and/or practice. • Organizations have performed quality improvement activities and identified that diagnostic errors are occurring due to missed subtleties. These errors

Title	**Cognitive Error – Missed Subtle Clinical Findings**
	often manifest when a subtle clinical finding or symptom goes unrecognized or is misinterpreted, ultimately resulting in a diagnostic error. "Subtle" refers to the concept that the finding or symptom is not a clinically obvious or "classic" as it would appear in a medical textbook.
Stakeholders	• Patients • Clinicians • Administrators (e.g., Chief Medical Officer, Chief Quality Officer, Chief Nursing Officer, Chief Technology Officer, Chief Financial Officer, Legal Counsel) • Professional societies • Payers • Others (e.g., EHR vendors)

Causal Factors and Diagnostic Challenges	• **Clinician Factors:**
	  ○ Clinician knowledge and experience
	  ○ Cognitive biases, such as:
	  ▪ Availability bias
	  ▪ Anchoring bias
	  ▪ Base rate neglect
	  ▪ Confirmation bias
	  ▪ Conjunction rule
	  ▪ Diagnostic momentum
	  ▪ Hindsight bias
	  ▪ Overconfidence
	  ▪ Premature closure bias
	  ▪ Representativeness
	  ▪ Search satisficing
	• **System Factors:**
	  ○ Busy and chaotic work environments
	  ○ Staffing shortages
	  ○ Limited resources to support access to specialists, protocols, tests, and other resources that support accurate diagnosis
	  ○ The display of results and information within the EHR
	• **Condition/Disease Factors:**
	  ○ "Red herrings" and other cognitive distractions or competing explanations
	  ○ The subtlety of the patient's presentation
	  ○ The rarity of the patient's diagnosis

Potential Solution #1	**Enhance clinician expertise through education and training**

Process	• Create educational materials and protocols based on the findings of the quality improvement activities performed
	  ○ Provide targeted education on subtle signs of disease
	  ○ Use simulation training to hone bedside skills in diagnosing uncommon causes of common, high-risk symptoms[34]
	  ○ Use protocols that require escalation of care for persistent vital sign abnormalities (e.g., for high-risk clinical conditions, such as thoracic aortic dissection risk scores, acute vertigo protocols, and spinal cord compression)
	  ○ Tailor protocols to high-risk symptoms that address known pitfalls

Title	**Cognitive Error – Missed Subtle Clinical Findings**
	○ Perform simulation-based training to ensure clinicians understand new protocols[34] • Provide education to support clinicians in engaging patients and families as part of the diagnostic team ○ Involve patients in the design of clinician training and education programs to advance clinician communication techniques, listening skills, and empathy ○ Develop educational programs to improve clinician communication techniques to detect subtleties in patient symptoms through active listening ○ Build and encourage clinicians' active listening skills through motivational interviewing training ○ Ensure clinicians ask patients and families if all of their specific concerns have been addressed ○ Teach patients how to prepare for a healthcare system visit through conversations and patient education materials ○ Educate patients on how to communicate with clinicians, particularly when describing symptoms • Create opportunities to share feedback as a learning mechanism[35] ○ Provide peer feedback on diagnostic performance through chart/artifact review or video review of whole encounters ○ Provide systematic feedback to clinicians on patient outcomes (e.g., re-visits, adverse events, deaths) ○ Illuminate missed subtleties on specific cases through Morbidity and Mortality reviews[36] ○ Support staff in attending conferences and other larger learning opportunities offered through professional associations ○ Establish partnerships between insurers and medical societies to share and use claims data to inform accurate and timely diagnosis[37] • Use meta-cognitive "forcing" strategies ○ Form diagnostic error checklists that ask the clinician to consider bias and ask "what else" before confirming diagnoses[38] ○ Initiate diagnostic time-outs with diagnostic error checklists[38] ○ Create processes that initiate a second opinion once a patient returns for the same complaint multiple times[39]
Potential Solution #2	**Employ a team approach and emphasize the value in diverse opinions and clinical teams[40]**
Process	• Engage consultants with specialized expertise ○ Increase access to consultants and specialists through consultations, "curbside" second opinions, or through telemedicine[40] ○ Create "phone-a-friend" hotlines for access to other clinicians within the same discipline and in other disciplines ○ Create symptom- or problem-specific consultation services or diagnostic management teams [41] • Foster a culture where all team members take shared ownership of the diagnosis

Title	**Cognitive Error – Missed Subtle Clinical Findings**
	○ Empower patients, nurses, and allied health professionals to be part of the diagnostic team by valuing their expertise and proactively engaging them ○ Seek frequent input and participation from diverse team members[42] ○ Create expectations for all team members to voice concerns about the diagnostic process or diagnosis ○ Include diverse team members from various disciplines in "diagnostic time-outs" before discharging patients ○ Assign tasks, particularly around verifying diagnoses and assessing protocol compliance, to other clinicians to reduce cognitive load on one specific clinician
Potential Solution #3	**Leverage technology to help understand the full clinical picture before making a diagnosis**
Process	• Promote information sharing through technology ○ Increase real-time access to computer-based diagnostic tools, knowledge repositories, online risk calculators, and diagnostic decision support systems (e.g., checklists, differential diagnosis generators, or virtual image databanks) ○ Leverage EHR vendors' capability to allow a single interface for data across multiple platforms to promote appropriate sharing of relevant patient data ○ Use regional information sharing infrastructure and organizations (e.g., Chesapeake Regional Information System for our Patients [CRISP][43]) to obtain out-of-network follow-up • Leverage the EHR to support recognition of subtle findings ○ Collaborate with administrators and Chief Technology Officers to understand the capabilities of structured and unstructured EHR data ○ Leverage the EHR to reduce cognitive distractors that take up valuable cognitive space ○ Create EHR alerts and/or rules to address specific known pitfalls in diagnosis (e. g., ordering CT rather than MRI for stroke with dizziness/vertigo) ○ Reduce unnecessary cognitive loading via user interfaces and data visualization tools (e.g., using trend analysis of lab data or displaying data on a body heatmap for related diagnoses) • Use the EHR as a tool to collaborate with patients on diagnostic planning ○ Leverage open notes platforms in EHRs for patient input and co-creation of the diagnostic plan ○ Use clear, jargon-free language in open notes platforms to support patient understanding and engagement ○ Establish electronic processes for a "diagnostic check-in" with patients on the accuracy of their diagnosis after their encounter • Identify opportunities for novel technology to support identification of subtle symptoms ○ Use EHR-based checklists to ensure protocol compliance[38] ○ Deploy AI-enhanced diagnostics to detect subtle symptoms through machine learning or other technologies

Case Exemplars – Snapshots

The snapshots below depict clinical cases where clinical teams miss subtle symptoms and/or clinical presentations, ultimately causing a diagnostic error. Each snapshot provides an overview of the case exemplar, outlines case-specific challenges and causal factors that likely contributed to the error, and includes granular solutions and implementation strategies for broad stakeholders to overcome the error.

Snapshot One

OVERVIEW OF CASE

A 55-year old man with a history of hypertension presents to the ED with vertigo (i.e., a sensation of movement) and vomiting for three hours since awakening. On examination, the patient has left-beating nystagmus (i.e., uncontrolled, rapid eye movements) that changes to slight right-beating when looking right, which goes undetected. These are subtle eye findings that are an indicator of stroke that go undetected by the clinician. The patient has difficulty walking but is able to ambulate. The neurological examination is otherwise normal. However, a Head Impulse Nystagmus Test of Skew (HINTS) examination— which would have helped detect this subtle finding – was not completed because the clinician had not been taught how to conduct this exam A non-contrast head CT is performed that demonstrates no acute stroke. The patient improves somewhat with oral meclizine which is used to help reduce vertigo symptoms. The family voices concern that the patient is having a lot of trouble with balance, which is dismissed by the team. The ED diagnosis is peripheral vertigo (i.e., labyrinthitis) which is a diagnostic error, and the patient is discharged on meclizine treatment and instructed to follow up with his primary care physician (PCP) in 2-3 days. The patient returns to the same hospital the next day and sees a different clinician in the ED. The patient receives the correct diagnosis of hemiplegia from a progressive brainstem stroke. The original diagnosing physician is never informed of the new, accurate diagnosis.

CASE-SPECIFIC CHALLENGES AND SOLUTIONS

This is an example of diagnostic error due to a missed subtle finding of stroke, which is a common condition. Specifically, the lack of a careful examination – driven by a lack of expertise on the part of the clinician – led the team to miss the subtle, direction-changing nystagmus that was an indicator of an early stroke. In addition, the negative head CT and improvement with oral meclizine were reassuring to the clinical team; however, it is known that head CT is not a sensitive test for acute stroke,[44] and the meclizine response is also non-diagnostic. The team also failed to address the family's concerns about the patient's difficulty walking. Together, the missed subtle clinical finding led to a subsequent series of additional problems that ultimately led to the misdiagnosis of peripheral vertigo, which is a more benign condition than stroke. If the patient had been admitted for observation or an MRI had been performed, it is possible that the ultimate cause of his illness (i.e., stroke) would have been detected earlier and he would have received treatment that could have prevented or adequately treated the larger stroke that came two days later. Finally, the original diagnosing clinician never received the feedback about this patient's misdiagnosis. Therefore, there was no opportunity to reflect on the misdiagnosis, which would have served as an impetus for learning or creation of a protocol to reduce the likelihood of misdiagnosis in the future.[45]

Specific solutions to help prevent this error include:

- **Provide education to support clinicians in engaging patients and families as part of the diagnostic team (*from potential solution # 1*):** Staff from the patient education department can provide clinician education on how to engage patients and families as meaningful members of the diagnostic team.[46] This includes enabling clinicians to recognize how patients are uniquely positioned to notice gaps or inconsistencies in practice, and to appreciate the unique expertise that patients and families bring to the diagnostic process.[41] Patient education team members and clinicians can share strategies on how to effectively take patient and family values and concerns into account, which in this case, would have enabled the clinician to value the family concerns about the patient's difficulty walking.[47] The specific patient education materials could be developed by the hospital, or they could use existing materials that have already been developed by patient advocacy groups, professional associations, and/or other stakeholders.

- **Create opportunities to share feedback as a learning mechanism (*from potential solution #1*)**: Hospital administrators and clinical leaders can implement a feedback system for misdiagnoses to ensure a clinician is aware of diagnostic errors. This feedback system can be used for quality improvement and provides clinicians an opportunity to improve their diagnostic skills and learn from the misdiagnosis. Any misdiagnoses should also be communicated back to original ED staff, as well as to the patient. The feedback system could be set-up to trigger from claims data, health information exchange data, and/or a trigger for patients who return to the same facility within a specific time period.

- **Engage consultants with specialized expertise (*from potential solution # 2*):** Hospital administrators can increase the availability of expert neurologists to consult either in-person or by telemedicine. This could be done by ensuring that neurologists are available and contractually obligated to consult on ED patients. For rural settings, administrators can collaborate with IT staff and frontline providers to have a technology platform that supports telemedicine consults. If telemedicine is used, IT staff should educate frontline clinicians and the consulting neurologists on how to use the platform, including identifying troubleshooting tactics and processes in case technical challenges arise.

- **Identify opportunities for novel technology to support identification of subtle symptoms *(from potential solution #3)*:** Clinical leaders can develop a protocol for patients with a chief complaint of vertigo in the EHR as a clinical decision support tool. To develop the protocol, quality leaders could convene a multidisciplinary team of frontline staff, including emergency medicine physicians, neurologists, and clinical leadership. The protocol would take clinicians through a checklist, which would include conducting a HINTS examination to detect subtle signs of stroke, and not to over-rely on a negative CT to exclude a diagnosis of stroke.[48] Once the protocol is developed, information technology (IT) staff would need to develop and deploy the protocol within the electronic system. The multidisciplinary team that developed the protocol, or a single, expert clinician, should educate clinicians on the new protocol elements (e.g., how to conduct a HINTS exam), and about the accuracy of CT head in stroke.

Snapshot Two

OVERVIEW OF CASE

A 65-year old woman with no prior medical history presents to an outpatient clinic with fever of 101 degrees Fahrenheit (F), diffuse muscle aches, and shortness of breath during influenza season. The clinician saw three patients earlier the same day who tested positive for influenza B. The patient reports that she did not get the influenza vaccine this year. An electrocardiogram (EKG) is performed that shows sinus tachycardia to 125 beats per minute (bpm) but is otherwise normal. Her initial blood pressure is

105/70. A chest x-ray is performed which is normal. No laboratory work is sent, except for an influenza swab that is negative for influenza A and B. The patient is given acetaminophen and her breathing somewhat symptomatically improves with an albuterol/ipratropium nebulizer, but the patient still feels very weak. Her fever reduces to 99 degrees F, but the tachycardia (fast heart rate) does not improve. The last set of vital signs demonstrates a heart rate of 122 bpm and a blood pressure that has decreased to 95/60. The patient is discharged with a diagnosis of swab negative influenza. She receives a prescription for oseltamivir to treat influenza and an albuterol metered-dose inhaler, and the clinician recommends acetaminophen for the fever. Later that evening, the patient continues to feel even weaker and calls an ambulance. Repeat chest x-ray demonstrates that infiltrates have developed, and the ultimate diagnoses is gram-positive sepsis due to pneumonia. The patient has an intensive care unit (ICU) stay and prolonged hospitalization.

CASE-SPECIFIC CHALLENGES AND SOLUTIONS

In this case, there were several findings that were not perceived to be relevant during the initial clinic visit, including the persistent tachycardia, falling blood pressure, continued weakness, and negative test for influenza. Although the patient did not appear acutely ill to the clinician, in combination together, these could have pointed to the correct diagnosis of sepsis and led to earlier initiation of antibiotics. A lack of expertise by the clinician, as well as cognitive bias—in particular, availability bias—may have contributed to the error and the missed subtleties in this case. Given the findings of tachycardia and falling blood pressure, laboratory testing should have been ordered and the patient should have been referred immediately to the ED. There were also no EHR trends or data visualization methods to help the clinician recognize the vital sign abnormalities or trends. Furthermore, the "red herring" in this case was that it was influenza season and that the three prior patients seen by the clinician had tested positive for influenza, resulting in the faulty assumption by the clinician that this patient's influenza test was a false negative. The clinician's availability bias, demonstrated by favoring the diagnosis of influenza because of ease of recall due to the recent cases, led to premature closure of the diagnosis where the clinician closed off other diagnostic possibilities and did not explore additional options.

Specific solutions that would have helped prevent this error include:

- **Create educational materials and protocols based on the findings of the quality improvement activities performed (*from potential solution #1*):** Clinical leaders who are experts in sepsis can develop targeted clinician education on the subtle signs of sepsis for clinicians working in outpatient settings. The education could be deployed as continuing medical education via in-person or an online training. The education team can post signage throughout the clinic that reminds clinicians of the signs of sepsis and encourages clinicians to "think sepsis". If in a rural setting or at a facility that does not have an expert in sepsis, administrators can engage medical specialty societies or can outsource the education development to external experts.

- **Foster a culture where all team members take shared ownership of the diagnosis (*from potential solution #2*)**: Clinic leadership can initiate a discharge "time-out" process prior to patient discharge where any team member can openly express concern about the diagnosis. This activity could be performed by multidisciplinary clinical team members, and will help overcome individual clinician-level biases, such as availability bias or confirmation bias. A discharge "time-out" would have been particularly useful during influenza season to ensure detection of subtle, more serious infections. Clinic leadership can collaborate with the IT team and the EHR vendor to develop a process for documenting the "time-out" in the EHR. After

educating clinical staff how to perform and document the "time-out", compliance could be monitored by pulling data from the EHR. The patient should also be included as an active member of the diagnostic team, and clinicians can use toolkits to aid patients in participating in the diagnostic process.

- **Leverage the EHR to support recognition of subtle findings (*from potential solution #3*):** With administrative support, clinical leaders can work with IT staff to implement data visualization methods and trends in the EHR. The trending could be used to support recognition and alert clinicians of subtle but persistent and concerning vital sign abnormalities, including persistent tachycardia. The alerts could be created by a multidisciplinary team of physicians and nurses (to ensure the alert is based on clinical guidelines) and IT staff (to ensure the EHR is capable of deploying the alert as intended). After the alerts are created, leaders from the multidisciplinary team should educate frontline staff on using them. Alternatively, decision-support tools that assist in formulating a differential diagnosis could also be incorporated into the EHR to support recognizing subtle findings.

Snapshot Three

OVERVIEW OF CASE

An 80-year old woman living independently with a history of hypertension and mild osteoarthritis of the knees presents to an outpatient primary care clinic with one week of new, bilateral (i.e., both sided) headache. After assessing that the symptoms are worse when the patient places her head between her legs, the clinician diagnoses a pressure phenomenon from sinusitis and prescribes antibiotics. No laboratory tests are obtained. The patient returns twice more, at weekly intervals, with persistent headache symptoms and general malaise. On the third visit, the clinician obtains a head CT to rule out a brain tumor. Within one week of the CT, the patient goes blind in both eyes from untreated temporal arteritis.

CASE-SPECIFIC CHALLENGES AND SOLUTIONS

In this case, the symptoms were ultimately caused by temporal arteritis, which is a rare, but serious, cause for headache. This was not a classic case of temporal arteritis, which is commonly unilateral (i.e., one-sided) and confined to the temple. However, the clinician missed subtleties that should have prompted a more thorough work-up and earlier involvement of specialists. This case demonstrates both a failure of expertise and cognitive bias. There was a failure of expertise because a new, persistent headache lasting longer than 72 hours in an elderly patient should have sparked consideration of temporal arteritis, even if the headache is bilateral, and should lead to measurement of an erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP). Another failure of expertise was that the clinician did not carefully examine the patient for temporal artery tenderness which may have provided an additional clue to the correct diagnosis. The clinician also exhibited the cognitive biases of premature closure and anchoring bias, as he appeared to not consider additional diagnoses beyond a brain tumor even in the face of continued symptoms and repeated visits. Even after the CT showed no sinusitis, the clinician remained anchored on the original diagnosis and did not reconsider that a diagnostic error may have occurred.

Specific solutions that would have helped prevent this error include:

- **Create educational materials and protocols based on the findings of the quality improvement activities performed (*from potential solution #1*):** Quality improvement activities that occur

after a diagnostic error can help identify educational opportunities for clinicians to prevent the error from reoccurring. In this case, focused clinician education on the less common causes of headache, including temporal arteritis, could be developed. If the facility has a headache specialist or a PCP with interest in this topic, they could develop the educational materials. In rural settings or small clinics, administrators could outsource the development of the educational materials to a consultant. Opportunities exist for clinicians to then share these findings with their respective professional societies to support including education centered on these findings in healthcare education and training programs for healthcare professional students.

- **Use meta-cognitive "forcing" strategies (*from potential solution #1*):** As protocols are developed, administration could encourage including the use of meta-cognitive forcing strategies. When patients continue to have visits with novel, incompletely evaluated, or potentially high-risk complaints, such as a headache, there could be escalation to involve specialists or referrals to the ED. The escalation pathway needs to be a multidisciplinary approach that involves the PCPs who would do the initial evaluation of patients, as well as the specialists and ED clinicians who would do the additional follow up. The "trigger" for starting the escalation pathway would need to be agreed upon by the multidisciplinary team for the pathway to be operational. If the pathway is protocolized in the EHR, IT would also need to be involved. In rural settings, administration would need to set up external contracts to involve appropriate specialists if they are not available onsite.

- **Leverage the EHR to support recognition of subtle findings (*from potential solution #3*):** Since older age is a risk factor for temporal arteritis, clinical leaders can create a protocolized approach to be deployed in the EHR to diagnose headache in older adults. With support of hospital and clinic administrators, the protocol would first be developed by a multidisciplinary team of PCPs and neurologists to ensure it contains the appropriate clinical content (e.g., EHR-based prompt to request or require an ESR and/or CRP measurement for new headache in patients over 50 years old with persistent headaches that are not improving). The multidisciplinary team would also include IT staff to provide expertise in the capabilities of the EHR to ensure the protocol can be utilized as intended. Alternatively, decision support resources to assist with differential diagnosis could be used to suggest alternative possibilities, and would be useful across a broader range of complaints and findings.[49]

Impact of Solutions on Patient Safety

To be effective, solutions to diagnostic errors from missed subtleties must be tailored to specific causes of errors and implemented in the context of a specific organization and clinical environment. Various context-specific solutions and interventions have demonstrated differing degrees of effectiveness in enhancing safety and preventing future errors.

Increasing medical knowledge, experience, and clinical reasoning techniques via training and consultation access has been shown to increase a clinician's awareness of potential subtle findings, questions to ask, and diagnoses to explore.[50,51] For example, to fulfill the Mammography Quality Standards Act requirements, radiologists in the United Kingdom (UK) are required to review more than ten times the annual mammograms compared to US physicians.[50] This training requirement potentially contributes to the fact that the frequency rate of radiologists interpreting mammograms with positive results and then negative open surgical biopsy rates are twice as high in the US compared to the UK, despite cancer detection rates being similar.[52] As another example, one study found that content-specific training on criteria for clinician referrals of sudden onset headaches to neurosurgeons led to a

reduction in subarachnoid hemorrhage miss rates by 77% among community-based physicians.[53] Similarly, other studies have shown that decision support tools, checklists, and computer-aided detection systems for medical diagnosis have successfully suggested difficult or obscure diagnoses often missed by clinicians.[50] These reminders work to improve clinical knowledge, and standardize the approach to specific medical complaints. This standardization is a forcing strategy that can reduce the impact of cognitive biases by focusing attention on steps where cognitive errors may be most likely to occur. For example, a checklist may include an intentional focus on a specific error-prone, high-risk clinical finding that may not be immediately obvious.

Web-based reminder systems for interns and residents have also significantly improved diagnostic workups and reduced diagnostic omission errors.[54] While the use of decision support tools prompt clinicians to expand their differential diagnoses and to focus on high-risk, subtle findings, their use may also have the unintended consequences of increasing testing, costs, and complications resulting from unnecessary testing and treatment.[55] Finally, some clinicians do not have an in-depth knowledge of medical errors or cognitive biases. Early studies have shown that increasing clinician's knowledge and awareness of these issues encourages reflective practice. Reflective practice is also called "active metacognitive review" and has been shown to have positive effects in addressing specific types of cognitive bias, in particular premature closure and hindsight bias.[50,56]

Measurement Considerations

There are a variety of potential approaches to measuring performance to ensure that clinicians and healthcare systems reduce the likelihood of diagnostic errors when there are subtle findings. Measurement approaches, potential measure concepts, and supporting rationale are included in Table 5. The goal of measuring performance is to help drive quality improvement and/or to hold clinicians and organizations accountable for reducing these types of diagnostic errors. Measure developers can use these concepts and approaches to develop and test new clinical quality measures, either as process measures to support diagnosis or as clinical outcome measures. Payers can use these measurement approaches to support and incentivize the adoption of diagnostic best practices and improve quality of care.

Table 5. Measurement Considerations for Cognitive Error – Missed Subtleties

Measurement Approach	Measure Concepts	Rationale
Ensure protocols are created and detect deviations from protocols	• Rate of protocol use for cases that fall under a particular clinical syndrome (e.g., chart review of chest pain cases that used the History, ECG, Age, Risk factors, and Troponin [HEART] score)	• Protocols are a cognitive forcing strategy that, when used appropriately, guide the clinician with specific steps and may reduce the risk of missing subtle signs or not considering uncommon, but important, diagnoses • Protocols are an important step in delineating the safest, most efficient approach and take into account known pitfalls (e.g., using protocols for the work-up of acute dizziness that suggest

Measurement Approach	Measure Concepts	Rationale
		specific clinical examinations, such as the HINTS exam, to detect more subtle signs of stroke[57,58]) • Conducting chart, image, and/or video review will identify cases where protocols and/or decision support were not adhered to and will support sharing this information with clinical teams
Use of clinical decision support	• Rate of clinical decision support use for cases in which clinical decision support tools are available once clinicians complete the necessary documentation and fields in the EHR • Proportion of existing protocols that use an e-trigger tool to monitor protocol compliance	• Using clinical decision support for high-risk and/or commonly missed diagnoses may help support accurate, timely diagnosis and reduce errors • Building clinical decision support into the EHR may facilitate the deployment of protocols
Link outcome measures with measures of utilization	• Utilization of consultation, CT imaging, MRI imaging, cardiac imaging, and/or hospital admission or observation units • Match/mismatch between process measures and specific diagnosis (e.g., rate of CT use for diagnosis of the inner ear disease benign paroxysmal positional vertigo [BPPV][59])	• Promulgating measures of misdiagnosis may lead to an increase in the use of consultations and/or testing for ultimately benign conditions • Using these types of balancing measures will help ensure clinical teams are using diagnostic resources appropriately and following established protocols
Measure short-term outcomes of acute care visits	• Rate of accurate diagnosis of commonly misdiagnosed acute care conditions using the Symptom-Disease Pair Analysis of Diagnostic Error (SPADE) method[43] • Possible measure concepts using symptom-disease pairings include: ○ Diagnoses of stroke linked to prior visits for	• Linking visits that are potentially related will allow for further review using the SPADE framework and methodology to understand if prior visits were a missed opportunity to diagnose a later, more serious condition, and to use big data[43] to understand the potential harms from misdiagnosis

Measurement Approach	Measure Concepts	Rationale
	vertigo, dizziness, or weakness[60] ○ Diagnoses of sepsis linked to prior visits for fever or influenza[61] ○ Diagnoses of acute myocardial infarction linked to prior visits for chest pain or shortness of breath	
Ask for patient feedback	• Patient-reported understanding of diagnosis and/or diagnostic uncertainty after discharge	• Engaging the patient to understand medical history, visits over time, and potential misdiagnoses may help overcome fragmented systems and records across settings

Use Case 2: Systems Error – Communication Failure

Clinical Context

The delivery of medical care is becoming increasingly complex with the advancement of medical technologies and treatments, where multiple care team members—sometimes in different specialties and disciplines—caring for the same patient may be dispersed over time and space. These increasingly complex care processes and teams are superimposed on rising requirements to interact with EHRs and other information technologies.

The complex healthcare system links countless processes, practices, technology, and individuals.[61] System errors, such as communication failures, occur when there is a failure in the healthcare system related to organizational, environmental, or technical factors.[62,63] Breakdowns in communication and teamwork are the most common system-related breakdowns in most diagnostic error cases, and they occur in approximately one third of diagnostic errors.[64] Increased complexity within and across healthcare systems can increase the risk of communication failure when an important test result goes unrecognized. As a result, communication failures may lead to a delay in diagnosis or a misdiagnosis.

Communication failures occur across all clinical settings, including in ambulatory, ED, inpatient hospital, ambulatory surgical centers, skilled nursing facilities, and others. The solutions to communication failures oftentimes include strategies to improve the system in which the communication error is occurring.

Effective communication systems are vital to reducing the risk of communication failures. An example of effective communication is closed-loop communication, which involves not only the sending of information but also an acknowledgement of information receipt and any follow-up action that will

occur. In the process of closed-loop communication, critical questions emerge such as: (1) who is responsible, and (2) what processes/IT systems may be deployed to ensure that the communication occurs, and no important information is lost or delayed. In addition, data mining and e-trigger tools may be used to detect potential communication failures in order to reduce the likelihood of delay in diagnosis or misdiagnosis.[65]

There are several causal factors that can contribute to diagnostic errors resulting from communication failures. These factors can be described in three broad groups: **clinician factors, systems factors,** and **condition/disease factors.**

Several **clinician factors** contribute to communication failures, stemming largely from the transformation of information and a lack of teamwork and coordination across clinical teams and disciplines. Information sharing is a critical piece of a handoff, and sometimes important information is either not communicated at all or communicated in such a way that it is not clear what additional clinical action should be taken. Furthermore, there may be important information that is handed off without clear assignment of responsibility, which is commonly known as “diffusion of responsibility”.

Patients often receive care from multiple providers and at different sites; careful coordination is necessary to ensure clinicians act and follow-up on results and information. Occasionally, test results may appear in a clinical information system without the clinician acknowledging them. This can occur when a test result comes back after the ordering clinician leaves their shift and no one communicates responsibility for checking the test result. This is especially problematic when the laboratory test or radiology result requires either immediate action (e.g., a positive blood culture) or delayed clinical action that requires additional subsequent testing (e.g., a radiographic finding of a pulmonary nodule). Without clinician acknowledgement of the test result, the subsequent action or testing may not occur. Test results still pending at the time patients are discharged from the hospital are also associated with an appreciable rate of deficient follow-up.[66]

A clinician’s ability and comfort connecting and communicating with the patient also contribute to communication failures. Communication failures may occur between the patient and the clinician when the patient does not have a complete understanding of the treatment pathway or next steps, and the clinician does not realize that the patient does not understand. Patients are active partners in the diagnostic process, and when clinicians fail to explain the diagnostic tests performed and/or needed, and the process for obtaining results, the patient’s participation in ensuring information is obtained and acted upon is greatly hindered. In addition, patient-clinician communication failures can occur in circumstances where the patient is communicating important information, but the clinician fails to recognize the importance of that information and does not take the appropriate next steps or actions.

Communication failures often are rooted in larger **systems factors** that healthcare leaders must address at an organizational level. The busy and chaotic work environments within healthcare systems can make it challenging for clinicians to communicate effectively and may make it more challenging to keep track of information and required next steps. Clinicians and care teams commonly rely on organizational policies and guidelines, and a lack of policies and procedures related to information sharing and follow-up responsibility creates challenges in caring for patients. A lack of closed-loop communication processes increases misunderstandings and leaves critical gaps where the information received may not be the same as the original intent of the information sent.[67]

These communication failures can be magnified even further when there are multiple care settings and providers involved in a patient's care. Communication failures can occur when systems are not designed properly to identify important results and ensure they are followed up appropriately. Human factors associated with the current design of EHRs and their inherent complexity can lead to errors. Successful EHR systems engage clinicians and patients in their initial design to ensure effectiveness and ease of use, thus ensuring they are a tool to facilitate communication.

Failures of communication also occur when information is not shared with the patient in a timely and appropriate manner. Occasionally, clinicians will face barriers related to contacting the patient, and a lack of an organizational protocol for collecting patient contact information and preferred follow-up processes contributes to critical diagnostic findings not being shared back with the patient.

Lastly, there are individual **condition/disease factors** that contribute to communications failures. Namely, these revolve around how complex it can be to engage patients as active partners in sharing information during the diagnostic process. The health literacy level of the patient may be a barrier to engaging and communicating with the patient. Additionally, as the level of clinical complexity increases, opportunities for information to be missed increase. The condition complexity and number of diagnostic tests required may make it more challenging for a clinical team to share all pertinent information with the patient. Language and communication barriers may exist based on the clinician's condition, such as a patient being too ill or short of breath to convey and/or understand important information.

The Use Case in Table 6 is focused on opportunities to prevent and overcome diagnostic errors that occur when there are communication failures. The Use Case addresses multiple subdomains from the Diagnostic Process and Outcomes domain within the 2017 Diagnostic Quality and Safety Measurement Framework, including information gathering, information integration, information interpretation, diagnostic accuracy, diagnostic efficiency, and follow-up. Organizations, clinicians, and other healthcare stakeholders (e.g., payers, policymakers, EHR vendors) can review the solutions included in the Use Case and identify opportunity areas that are most applicable to them given their organizational needs, resources, and context.

Table 6. Use Case 2: Systems Error – Communication Failure

Title	**Systems Error – Communication Failure**
Assumptions	• Diagnostic errors are complex and can have a variety of root causes. Organizations and clinicians should convene multidisciplinary quality improvement teams to understand and remediate the types of errors occurring within their organization and/or practice. • Organizations have performed quality improvement activities and identified that diagnostic errors are occurring due to communication failures. These errors often occur when closed-loop communication processes do not occur.
Stakeholders	• Patients • Clinicians • Administrators (e.g., Chief Medical Officer, Chief Quality Officer, Chief Nursing Officer, Chief Technology Officer, Clinical Informatics Officer, Chief Financial Officer) • Non-clinical staff (e.g., IT team members, Patient Education staff)

Title	Systems Error – Communication Failure
	• EHR Vendors • Policymakers • Payers

Causal Factors and Diagnostic Challenges	• **Clinician Factors:**
	  ○ Failure to acknowledge and interpret test results
	  ○ Incomplete handoffs
	  ○ Diffusion of responsibility across clinicians
	  ○ Lack of teamwork and coordination across clinician teams and disciplines
	  ○ Failure to explain to the patient diagnostic tests performed and/or needed, and the process for obtaining results
	  ○ Failure to recognize important information shared by the patient
	• **System Factors:**
	  ○ Busy and chaotic work environments
	  ○ Lack of closed-loop communication processes
	  ○ Multiple care settings and providers involved in the patient's care
	  ○ Complex EHR systems
	  ○ Lack of defined protocols for collecting patient contact information and follow-up process
	• **Condition/Disease Factors:**
	  ○ The health literacy level of the individual
	  ○ The number of diagnostic tests required
	  ○ Language and communication barriers with the patient (e.g., patient too ill or short of breath to converse, hard of hearing, dementia)
	  ○ The complexity of the condition

Potential Solution #1	**Ensure clear roles and responsibilities exist for follow-up activities**

Process	• Enhance interdisciplinary communication to promote closed-loop communication
	  ○ Update policies to create and enforce requirements for phone or face-to-face exchanges for critical results or actionable revised results
	  ○ Combat "electronic silos" by creating processes for clinicians, laboratory, and radiology professionals to interact through collaborative rounds and huddles[42]
	• Assemble multidisciplinary teams to standardize forms, protocols, and communication methods that outline clear responsibilities related to handoffs and transitions of care across settings
	  ○ Use multidisciplinary huddles and structure toolkits to support information sharing in a structured way[68]
	  ○ Create policies and an electronic system that assigns and tracks follow-up tasks to a specific team member (e.g., assigning a non-clinician team member or case manager to follow-up with the patient)

Title	**Systems Error – Communication Failure**
	○ Introduce redundancy in interpreting test results through independent reviews by clinicians at various stages in the process, from reporting through result interpretation[69] • Provide clinician education on best practices, procedures, and expectations for communication ○ Encourage clinician use of read-back and hear-back techniques (e.g., asking a patient to describe their understanding of what was said and ask if they need a re-explanation) ○ Integrate information in the required, standard risk education process that highlights how clinicians not receiving questions from a referring clinician does not mean that they have received and acted on a result ○ Outline organizational procedures and expectations around communication escalation protocols to identify sufficient attempts of communication when patients are unable to be reached
Potential Solution #2	**Engage patients as active partners in information communication and follow-up**
Process	• Create organizational policies that support engaging patients as active partners in follow-up of results ○ Confirm patient contact information prior to discharge to ensure clinicians have a way to follow up ○ Create policies that require the use of interpreter services to support communicating in a patient's preferred language ○ Develop a plan prior to discharge for how results will be communicated to the patient, caregiver, and/or family, and share the plan directly with them ○ Create specific escalation protocols when patients are challenging to contact ○ Encourage patients to bring advocates with them to healthcare encounters to assist patients in accurately telling their story, as well as to help patients recall information and instructions given during the encounter • Develop and use education materials to support patients participating as active partners in diagnosis and follow-up ○ Educate patients that "no news" is not "good news" ○ Use toolkits to educate patients on the type of information and communication they should expect ○ Develop educational materials to support patient understanding of their results and associated diagnosis, empowering them to ask questions about their diagnosis, test results, and any required follow-up • Implement patient portals to support communication between patients and clinicians ○ Ensure patient representation on teams that are designing patient portals to confirm ease of use and to address health literacy language barriers

Title	Systems Error – Communication Failure
	○ Provide direct-to-patient result reporting and confirm that a patient can access the patient portal when scheduling the initial appointment or before discharge[42] ○ Encourage patients to follow-up on results proactively through portals, emails, and/or phone calls if they have not heard anything in the expected time frame
Potential Solution #3	**Leverage technology, data, and EHRs to promote closed-loop communication and information sharing**
Process	• Create partnerships between EHR vendors and clinical informatics leaders for them to: ○ Define requirements for asynchronous and synchronous communication ○ Use flags or other electronic processes to highlight EHR inbox messages that contain test results, trends, and/or other actionable findings that require immediate attention ○ Automate clinical actions in the EHR based on high-risk results (e.g., automated scheduling of follow-up appointments and/or testing for recommended laboratory or diagnostic findings) ○ Use e-trigger tools to identify and remediate situations where the indicated follow-up did not occur (e.g., new iron-deficiency anemia not followed up by colonoscopy within a specified time frame) ○ Design systems to facilitate clear assignment of responsibility and tracking of follow-up ○ Ensure that the most complete available data is searchable and available to clinicians through improved interoperability and health information exchanges ○ Learn from peers and leaders in the field who have successfully created electronic systems that serve as safety nets to prevent communication failures, and replicate these solutions ○ Explore the use of AI technology, particularly for reading of radiographs • Engage health policy leaders to enable collaboration and data sharing across stakeholders and sectors ○ Create health policies that incentivize payers to serve as partners in “closing the loop” between encounters through data sharing or other electronic tools ○ Develop national programs that allow clinicians to access claims data and statewide systems to gather information about previous patient encounters that may not have been previously communicated to the clinician (e.g., location of visits, test results ordered, or quality flags) ○ Engage health policy leaders to promote partnerships between state agencies and commercial payers to enable claims information and data from diverse populations to be included in statewide information systems ○ Support policymakers and state agencies to encourage the use of available resources to incentivize clinicians for accessing

Title	Systems Error – Communication Failure
	existing information systems (e.g., state-wide systems, regional systems, and/or payer systems) ○ Develop partnerships between EHR vendors, clinical informatics leaders, and payers to create trigger alerts for when secondary follow-up encounters or tests that should have occurred are not billed for (and thus were not completed)

Case Exemplars – Snapshots

The snapshots below depict clinical cases where communication failures occurred, ultimately causing a diagnostic error. Each snapshot provides an overview of the case exemplar, outlines case-specific challenges and causal factors that likely contributed to the error and includes granular solutions and implementation strategies for broad stakeholders to overcome the error.

Snapshot One

OVERVIEW OF CASE

A 56-year old male with a history of treated human immunodeficiency virus (HIV) with an undetectable viral load three months prior and recent intravenous drug use presents to an ED with a two-day history of a sore throat and febrile illness. Laboratory tests are performed, including a complete blood count (CBC), blood chemistries, a throat swab, and blood cultures. Results show that the white blood cell (WBC) count is 15,000/mm^3, chemistries are normal, and the throat swab is negative for strep throat. The patient does not appear critically ill in the ED and has normal vital signs with no documented fever, although he took acetaminophen prior to his arrival at the ED. The patient is discharged with a plan for follow-up in 2-3 days with his PCP. The blood culture results are still pending when the patient is discharged; however, there was no communication with the patient that there was an outstanding test that he may receive a call about. The next day both blood culture bottles result positive for gram-negative rods. The laboratory calls the physician in the ED to alert her of the test result, and the ED physician calls the patient and leaves a message on his cell phone stating that the patient should return to the ED. There is no additional follow-up because the ED was busy that day, and there was a large volume of active issues. The patient did not listen to his cell phone message. The following day, the patient presented to another ED with increasing weakness and the diagnosis was made of gram-negative sepsis. He was treated with appropriate antibiotics in the ED. However, by the time the patient had arrived at the second ED, he was in septic shock and experienced a rocky course complicated by disseminated intravascular coagulation. He died five days later despite intensive care.

CASE-SPECIFIC CHALLENGES AND SOLUTIONS

The communication failure in this case was that the blood culture results were never received by the patient nor acted upon. The finding of gram-negative rods in both blood cultures was a red flag finding that indicated that the patient required immediate care. While there was one single attempt by the current ED physician to communicate this result to the patient, this was not sufficient, and she never reached the patient. Because the result represented an emergent finding, immediate additional steps should have been taken to find the patient, including making additional phone calls, attempting to contact family members or emergency contacts, and potentially enlisting community resources (e.g., police).

Specific solutions that would have helped prevent this error include:

- **Provide clinician education on best practices, procedures, and expectations for communication *(from potential solution #1):*** Administrators can create a policy to ensure that multiple modes of communication (e.g., working phone number, e-mail address, family and/or emergency contacts) are collected and confirmed by the patient during the initial visit or when first scheduling an outpatient visit. Administrators could require patients to provide at least two modes of communication to reach them. To create this policy, administrators could engage administrative staff, receptionists, and clinicians who are commonly involved in collecting this information from patients and who will likely have an understanding of what communication modes are preferable for sharing information with patients. Administrators could also collaborate with leaders in the IT department to identify opportunities to use the EHR to collect this information, as well as to ensure there are designated fields for data entry of this information. After developing the policy, administrators can roll out education to individuals who are responsible for collecting the information, as well as to frontline clinicians to ensure they know where to find the patient's contact information in the EHR.

- **Assemble multidisciplinary teams to standardize forms, protocols, and communication methods that outline clear responsibilities related to handoffs and transitions of care across settings *(from potential solution #1):*** Clinical leaders can design and deploy a specific escalation protocol for high risk, time-sensitive test results. To develop the protocol, leaders could convene a multidisciplinary team of frontline staff who commonly order and follow-up on test results, as well as individuals in the radiology and laboratory departments who often identify test results and/or findings. Together, this group could create a policy that outlines specific roles and responsibilities for high-risk, sensitive test results, building on existing resources and guidelines.[70] The protocol can also include additional resources that may be enlisted to assist with carrying out the protocol if the designated clinician is unable to complete the protocol, such as engaging the house supervisor or other pre-identified team members. Healthcare organizations could deploy a process and tracking system to follow-up on abnormal results. The tracking system could remain in place until successful contact and follow-up are made with the patient. With IT support, non-clinical staff could manage the tracking system to help reduce responsibilities on practicing clinicians with large patient loads.

- **Develop and use education materials to support patients participating as active partners in diagnosis and follow-up *(from potential solution #2):*** Patient education leaders can deploy specific education materials to educate patients that "no news" is not "good news". To develop these materials, Patient education staff could collaborate with clinicians, patients, and the Patient Education Committee. Leaders could then disseminate the materials with all clinicians so that they can share the materials with their patients. These materials could support discussions between clinicians and patients when identifying next steps and anticipated turnaround time for test results. Clinicians could share these materials with patients who are awaiting blood culture results and encourage patients to proactively follow-up with the clinician if they do not hear about the results in a designated time frame. Patient education leaders could also collaborate with IT leaders and EHR vendors to embed this education process into the EHR and discharge workflow as part of the standardized discharge patient information form.

- **Support policymakers and state agencies to encourage the use of available resources to incentivize hospitals to facilitate access to existing information systems (*from potential solution #3*):** To encourage the use of state-wide health information exchanges to review previous laboratory test and image results, as well as clinical notes, policymakers and state agencies can create financial incentives for healthcare facilities to integrate outside information into their existing EHR systems so clinicians can easily access it. Through access to additional

patient data, clinicians could have a more complete picture of prior test results and may be able to reduce errors, as well as reduced duplicate testing.

Snapshot Two

OVERVIEW OF CASE

A 70-year old Spanish-speaking female with atrial fibrillation (i.e., irregular heartbeat) on apixaban is admitted to a surgical service with appendicitis diagnosed on CT scan. Given the early stage nature of the appendicitis and the complicating challenge that she is on anticoagulants, she is treated with antibiotics as opposed to operatively. She clinically recovers after three days. However, on the CT report, a follow-up CT is suggested at three months to ensure resolution of the radiographic finding. The surgeon communicates this to the patient in non-fluent Spanish without a formal interpreter, and the surgeon assumes that the patient's PCP will order the follow-up test. The patient nods but does not understand, and she does not speak up because she does not wish to offend the surgeon. The discharge follow-up instructions are printed in English, rather than Spanish, and the patient cannot understand what is written. The PCP sees the report and assumes that the surgeon will order the test and follow-up with the patient. Two years later, the patient is diagnosed with large appendiceal carcinoma that has metastasized to the liver.

CASE-SPECIFIC CHALLENGES AND SOLUTIONS

There are several communication challenges and failures in this case. Specifically, there was a diffusion of responsibility about which clinician should order the follow-up CT, as it was unclear whether it should be the surgeon or the PCP. The second challenge was an incomplete understanding of the follow-up instructions because the patient did not receive the verbal or written instructions in her preferred language. Further, due to the power differential between the surgeon and the patient, the patient did not feel empowered to speak up and ask for an interpreter.

Specific solutions that would have helped prevent this error include:

- **Assemble multidisciplinary teams to standardize forms, protocols, and communication methods that outline clear responsibilities related to handoffs and transitions of care across settings *(from potential solution #1):*** Administrators, collaborating with clinical staff, can create a policy to assign explicit accountability for which clinical team member will follow-up with the patient at discharge.[71] To create the policy, administrators should engage various clinical team members from diverse departments to ensure each department is represented. After the policy is developed, individual department heads could educate their respective staff. This education could also include strategies for clinicians to proactively identify clear roles and responsibilities as they collaborate with team members from other departments and disciplines. After the policy is implemented, adherence could be monitored electronically, and compliance could be reviewed by non-clinician team members (e.g., case managers) to help reduce the burden on clinical staff.

- **Create organizational policies that support engaging patients as active partners in follow-up of results *(from potential solution #2):*** Administrators can create policies that require the use of interpreter services in a patients' preferred language. To support this policy, administrators will need to invest in ensuring that appropriate language services and options are available at the facility. This may include the use of on-site medical interpreters, telephonic, and online interpreter services. Department leaders would need to educate all of their staff, including clinicians, receptionists, and other care team members about how and when to initiate the use

of interpreter services. Clinicians could also use teach back and read back communication techniques to ensure patients understand the discussion and necessary follow-up.[72]

- **Create partnerships between EHR vendors and clinical informatics leaders *(from potential solution #3):*** Clinical Informatics and IT leaders can develop and implement an e-trigger tool that focuses on ensuring a follow-up test, such as a CT scan, is performed. IT Leaders could collaborate with clinical department heads and frontline staff to understand which EHR fields and responses are appropriate to use as triggers.[73] IT Leaders could create the tool so that when a necessary follow-up CT is not performed, a trigger alerts a designated individual (e.g., a case manager, PCP, or the patient) that follow-up is needed. IT Leaders could also explore the e-trigger tool being used to conduct automated scheduling of the follow-up test; however, communication and coordination with the patient would be needed to achieve this.

Snapshot Three

OVERVIEW OF CASE

A 4-year old female patient is seen in an urgent care clinic for left hip pain and a limp. The child does not appear toxic and is afebrile, and the examination is only significant for a slight limp. A hip radiograph is performed, as well as blood tests including a CBC, blood chemistries, CRP, and ESR. The blood tests are normal, and the left hip and knee radiograph are read as normal by the urgent care clinician. The possibility of a discrepant finding on later read is not communicated to the mother. After receiving a dose of ibuprofen, the child improves and can ambulate. The urgent care clinician calls the child's pediatrician with a provisional diagnosis of transient synovitis, and the clinician recommends follow-up in 2-3 days. The pediatrician agrees to this plan. The next day, the radiologist performs a formal read of the hip radiograph as possible Legg-Perthes-Calve disease, which involves an interrupted blood supply to the hip and early avascular necrosis. The radiologist writes this in his report and calls the urgent care center back, but it is after hours so the radiologist leaves a message on the voicemail. The next day, the receptionist listens to the voicemail but does not understand the importance of the finding. The finding is also sent through an EHR inbox message to the pediatrician, but it is not explicitly flagged as an important finding. The pediatrician receives 40-50 inbox messages per day and has a busy clinical schedule, so this message did not register as an important finding when she was scanning her inbox. The child sees the pediatrician two days later, and the pediatrician thinks the x-ray was normal, so she recommends that the patient continue ibuprofen for a presumed transient synovitis. Over the next three weeks, the child continues to have intermittent limping and finally follows up with an orthopedic physician who repeats the x-ray and diagnoses Legg-Perthes-Calve disease. By that time, there is progression of the condition and avascular necrosis of the hip, now untreatable.

CASE-SPECIFIC CHALLENGES AND SOLUTIONS

In addition to the cognitive error of a misread radiograph by the treating urgent care clinician, there are multiple downstream communication failures related to the non-real-time definitive read of the radiograph. The original clinical decision and diagnosis are rendered based on the original read, which is built upon incomplete information. This leaves open the possibility of discordant findings, and ultimately, increases the likelihood of a diagnostic error. There are several other factors in this case that contributed to the delay in diagnosis. Specifically, the process of the radiologist calling back and leaving a voicemail is not an ideal way to communicate such an important finding. In addition, while the final read was available in the pediatrician's EHR inbox, it was not explicitly flagged, and it was ultimately overlooked.

Specific solutions that would have helped prevent this error include:

- **Enhance interdisciplinary communication to promote closed-loop communication *(from potential solution #1):*** Administrators can create policies that require real-time radiology reads (e.g., contemporaneous reading of radiology films) and person-to-person communication between radiologists and treating clinicians for discrepant reads, or more broadly, for serious, novel diagnoses detected on radiology imaging.[74] To create this policy, administrators could collaborate with leaders of various clinical departments, including, but not limited to, radiology, medicine, surgery, oncology, and the emergency department. For facilities or clinics that outsource their radiology requests, administrators can also incorporate the requirement for a real-time radiology read in the contract. Systems could also build in redundancies, so a single misstep does not lead to a critical error.

- **Create organizational policies that support engaging patients as active partners in follow-up of results *(from potential solution #2):*** Administrators can develop specific patient discharge instructions and a process to communicate with patients or family members/guardians that test results may change. To implement this, clinicians would need to communicate clearly with patients, or their family members/guardians, about any pending test results or any results that are not considered final yet. Clinicians should include specific instructions for patients, or the family member/guardian, to proactively follow-up if they have not been contacted about the final radiology read in a predetermined time frame. The instructions could also include information to empower patients to understand their expected disease course, such as including specific instructions on what to expect and to return if the condition fails to improve as expected. Administrators could also collaborate with clinical informatics leaders to identify if this could be included in a pre-discharge checklist to increase clinician adherence.

- **Create partnerships between EHR vendors and clinical informatics leaders *(from potential solution #3):*** Clinical informatics leaders and EHR vendors can reduce alarm fatigue and develop an explicit way to flag high-importance EHR inbox messages that contain important patient data from the EHR. To do this, clinical informatics teams could partner with EHR vendors to create an inventory of the existing EHR alarms and/or flags, and the rules that enable them to trigger. Once the clinical informatics team has the full inventory of alarms and flags, they could facilitate a multidisciplinary workgroup to help identify any unnecessary alarms and/or flags that can be removed, as well as identify any that may be missing. The workgroup can categorize what is appropriate for alarm within the EHR and what is appropriate for a high-importance inbox flag. Clinical informatics leaders could then collaborate with EHR vendors to facilitate removing unnecessary alarms and adding missing alarms and high-importance flags. These efforts will help reduce alarm fatigue by ensuring that high-importance flags are only used for true, high-importance situations through smart system design and human factors engineering. After the alarms and flags have been launched in the EHR, administrators, in partnership with clinical informatics leaders and clinical department heads, could develop a system to ensure that the high-importance messages are addressed. This system could include monitoring by non-clinical staff or an automatic report of the resolution for high-importance flags.

Impact of Solutions on Patient Safety

There are myriad interventions ranging in intricacy levels aimed at helping systems and clinicians overcome communication failures, and overall many interventions have demonstrated effectiveness.[51,75] Yet, studies have also shown that no solution alone has been proven to solve all communication challenges. An organization's context, resources, and implementation processes can have a large impact on the effectiveness of solutions.[51,75]

Effective communication and collaboration across healthcare teams reduce the potential for diagnostic errors and adverse events, resulting in increased patient safety and improved quality.[76] A key method of improving communication in healthcare is through the engagement of patients, families, and caregivers.[76] Many strategies exist to support engaging patients as active partners in information communication and follow-up. Research has increasingly shown a correlation between increased patient and family engagement and fewer adverse events, thus demonstrating how improving communication and engagement with patients can result in higher quality of care.[76]

Solutions to overcome communication failures should pinpoint the most vulnerable points in time across the communication continuum where common communication failures may occur, whether at message transmission, reception, or acknowledgement stages.[77] Healthcare organizations and clinicians may leverage health information technology to support coordination and closed-loop communication, as solutions aimed at improving message transmission may commonly include technological interventions. Interventions aimed at improving the reception of information and follow-up actions have shown positive effects in preventing misdiagnosis and timely treatment.[51] For example, communication strategies for follow-up of abnormal mammograms found that documentation of the follow-up plan by the physician increased appropriate follow-up of test results.[78] As another example, escalation strategies that involved an e-trigger tool to send secure emails, make phone calls, and inform clinic directors when "red-flag" cancer-related findings were detected. [79] These e-triggers helped to ensure that red-flag findings were addressed, leading to more timely diagnostic evaluations and significantly improving follow-up – including reducing time to diagnosis of colorectal cancer-related triggers by 96 days.[79] Meanwhile, interventions aimed at message acknowledgement, such as effective translation of "red-flag"' findings to PCPs through a similar escalation strategy, showed that escalation is insufficient on its own.[80] The same study found that a team-based communication approach where nurses are given diagnostic information can be beneficial in ensuring closed-loop communication and preventing communication failures.[80]

Measurement Considerations

There are a variety of approaches to measuring quality to ensure that clinicians and healthcare systems reduce the likelihood of communication failures and missing important findings resulting in diagnostic errors. Measurement approaches, potential measure concepts, and supporting rationale are included in Table 7. As a general principle, the Committee thought it was important that all clinicians involved in communication have a shared responsibility for ensuring communication across settings. Measure developers can use these concepts and approaches to develop and test new clinical quality measures, either as process measures to support diagnosis or as clinical outcome measures. Payers can use these measurement approaches to support and incentivize the adoption of diagnostic best practices and improve quality of care. The measure concepts can be considered to drive quality improvement and/or accountability, as appropriate.

Table 7. Measurement Considerations for Systems Error – Communication Failure

Measurement Approach	Measure Concepts	Rationale
Measure the use of e-trigger tools	• Proportion of diagnoses where an e-trigger tool is used	• Using e-trigger tools, although still at a research stage, may be a valuable way to identify errors

Measurement Approach	Measure Concepts	Rationale
		across settings, and machine learning may eventually become a useful tool to surveil for diagnostic errors in real-time
Measure the use of language interpreter services in patient's preferred language	• Rate of use of interpreter services when English is not a patient's preferred language	• Ensuring that patients communicate in their preferred language is important to ensure understanding, and measuring the use of interpreters may help improve communication
Audit charts for high-risk findings to ensure follow-up and verbal handoffs occur	• Proportion of "high-risk finding" charts with recommended follow-up completed and with verbal handoffs between clinicians	• Auditing charts could be used as a measure of system performance to ensure that high-risk findings are communicated and followed up on appropriately
Measure interoperability of health information technology	• Percentage of systems that support closed-loop communication and safety nets for test results	• Understanding current interoperability of health information and information sharing across settings may help reduce communication issues and support EHR vendors in developing future interoperability and/or adverse event outcomes (e.g., late stage cancer presentations)
Assess rates of delayed diagnoses	• Possible measure concepts to assess delayed diagnoses include: ○ Rates of delay in acting upon critical action lab values ○ Time or number of visits from first symptoms to diagnosis of various cancers ○ Number of missed opportunities in diagnosis antecedent to cancer diagnoses ○ Frequency of late-stage or emergency cancer presentations	• Measuring communication delays and diagnostic delays makes it possible to then further assess the extent to which communication failures are responsible, as well as to understand the extent to which solutions prevent diagnostic delay and/or adverse event outcomes (e.g., late stage cancer presentations)
Ask about communication quality on patient surveys	• Patient-reported understanding of diagnosis and/or diagnostic uncertainty after discharge	• Gathering information from the patient may be the most optimal way to measure quality related to communication in instances where only the patient is aware of a miscommunication across clinicians and settings

Use Case 3: Cognitive Error – Information Overload

Clinical Context

Over the past two decades, there has been increasing complexity in both the content of clinical care (e.g., aging population, multiple chronic comorbidities, sicker hospitalized patients) and the delivery of that care (e.g., faster pace of care, more complex and disconnected teams, increased regulatory oversight, complicated EHR, novel technologies).[81] This comes in the context of an exponential expansion in the volume of new medical science that must be applied in healthcare. Meanwhile, the ability of humans to process large volumes of data has remained constant.[82] The sheer volume of information and how it is presented to clinicians can sometimes lead to errors, as clinicians may have difficulty distinguishing important information from unimportant information.[83] In addition, the requirement to process a high volume of information may lead clinicians to miss a diagnosis that otherwise would have been readily apparent to the clinician if there were not as many sources of information and task overload.

There are several causal factors that can contribute to diagnostic errors resulting from information overload. These factors can be described in three broad groups: **clinician factors, systems factors,** and **condition/disease factors.**

Several **clinician factors** contribute to these types of errors, with one of the key underlying causes for being the excessive cognitive load on the clinician. Cognitive load can be separated into intrinsic and extraneous loads. Intrinsic loads involve the complexity of the information itself.[84] For example, a clinician may experience high intrinsic load when caring for a multi-trauma victim in the ICU who is acutely hypotensive (i.e., low blood pressure). Even if the information is presented to a clinician simply and succinctly, sorting through the problem commands substantial cognitive energy. Extraneous load, by contrast, is the mental load imposed by the structure, organization, or presentation of the information and the mental processing capacity (i.e., working memory) it takes to reach the intended cognitive task. For example, extraneous load is high when EHRs are designed without considering human factors, such that finding relevant information (e.g., a pertinent radiographic test) requires searching in multiple locations.[85] Alternatively, there may be no graphical presentation of lab value trends, requiring clinicians to notice the trend from the numeric values alone. Humans have a finite ability to manage cognitive load, so burdening their working memory with extraneous load leaves less available for intrinsic load. Creating clinical contexts and tools that have high extraneous load risks wastes precious working memory on unnecessary tasks (e.g., navigating the EHR) at the expense of intrinsic, mission-critical tasks (e.g., considering the full differential diagnosis for acute hypotension). Individual clinicians may experience a decreased ability to handle high cognitive load due to limited clinical experience, older age, or other factors. Alternatively, additional cognitive load may be imposed on a clinician when a patient has searched for symptoms online, resulting in the need for the clinician to address a long list of concerning conditions that may have little clinical relevance to the accurate diagnosis.

Physical and mental fatigue also contribute to these diagnostic errors. Clinicians may experience physical fatigue due to continuous overnight shifts and lack of sleep, and mental fatigue may be caused by factors such as long shifts with many complex patients. Unnecessary tasks waste precious cognitive resources, but distractions and interruptions in the environment disrupt a clinician's focus,

effectively shrinking the clinician's overall cognitive capacity to address both extraneous and intrinsic tasks.[86] This too can leave insufficient resources for tasks critical to identifying an accurate diagnosis. A related phenomenon is alarm or alert fatigue – where clinicians receive so many warning signals or alarms (e.g., frequently beeping monitoring equipment or alert messages in the EHR) that they unconsciously or deliberately ignore them. For example, an alert for a true critical action lab value (e.g., a very high potassium level) might be ignored because there are similar alerts for all out-of-range lab results.[87]

Systems factors also contribute to diagnostic errors due to information overload, as a clinician's environment impacts their ability to process information. Interruptions, such as busy clinical environments with constant interruptions of new information and requests, can make it increasingly challenging for a clinician to process information relevant for a specific patient. As more patients shift to virtual care and telemedicine, new challenges arise for diagnostic accuracy. Navigating complex clinical systems and processes, such as EHRs with limited organization and data presentation, also take up valuable cognitive resources for a clinician. This is further amplified when an individual patient is seen in multiple care settings with multiple providers, as an added level of coordination of information is needed. Lastly, the sheer complexity of clinical information itself can contribute to diagnostic errors. When information is very detailed and complex, or if there is diverse and wide-ranging information available, clinicians may have a more challenging time identifying the most pertinent pieces of information. Ambiguous information also contributes to these errors, as higher levels of ambiguity require an increase in cognitive resources to discriminate between what is known and unknown.

Disease/condition factors contributing to these types of diagnostic errors include clinical complexity, as well as individual patient factors that limit an individual's ability to be engaged in the diagnostic process. A patient's complex clinical presentation may result in an abundance of clinical information, which may make it more challenging for a clinician to identify which pieces of information are related to the specific diagnosis in question. Additionally, a patient with advanced disease or severe illness may be unable to participate as an active partner in the diagnostic process.

Use Case 3 in Table 8 is focused on opportunities to prevent and overcome diagnostic errors that occur when there is information overload. This includes high intrinsic load, high extrinsic load, excessive distraction, or a combination of all of these. The Use Case addresses multiple subdomains from the Diagnostic Process and Outcomes domain within the 2017 Diagnostic Quality and Safety Measurement Framework, including Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, and Diagnostic Accuracy. Organizations, clinicians, and other healthcare stakeholders (e.g., payers, policymakers, EHR vendors) can review the solutions included in the Use Case and identify opportunity areas that are most applicable to them given their organizational needs, resources, and context.

Table 8. Use Case 3: Cognitive Error – Information Overload

Title	**Cognitive Error – Information Overload**
Assumptions	• Diagnostic errors are complex and can have a variety of root causes. Organizations and clinicians should convene multi-disciplinary quality improvement teams to understand and remediate the types of errors occurring within their organization and/or practice.

Title	**Cognitive Error – Information Overload**
	• Organizations have performed quality improvement activities and identified that diagnostic errors are occurring due to information overload, which may include high intrinsic load, high extrinsic load, excessive distraction, or a combination of all of these.
Stakeholders	• Patients • Clinicians • Administrators (e.g., Chief Medical Officer, Chief Quality Officer, Chief Nursing Officer, Chief Technology Officer, Clinical Informatics Officer, Chief Financial Officer) • Non-clinical staff (e.g., IT team members, Patient Education staff) • EHR Vendors • Policymakers • Payers

Causal Factors and Diagnostic Challenges	• **Clinician Factors:**
	  ○ Cognitive load, which is dependent on the sum of, unfamiliar tasks, simultaneous tasks, and/or competing priorities
	  ○ Decreased ability to handle high cognitive load due to limited clinical experience or clinician age
	  ○ Physical fatigue (e.g., overnight shifts, lack of sleep)
	  ○ Mental fatigue (e.g., long shifts with many complex patients)
	  ○ Distractions
	  ○ Alarm fatigue
	• **System Factors:**
	  ○ Poor organization of information and lack of data presentation within the EHR
	  ○ Process complexity (e.g., multiple steps and processes to find the correct consultant or on-call provider)
	  ○ Interruptions (e.g., busy environments with constant interruptions of new information and requests)
	  ○ Multiple care settings and providers involved in the patient's care
	  ○ Information complexity (e.g., information is very detailed and complex, or there is diverse and wide-ranging information)
	  ○ Ambiguous information (e.g., higher levels of ambiguity require higher levels of cognitive load to discriminate between what is known and unknown)
	• **Condition/Disease Factors:**
	  ○ Clinical complexity (e.g., findings are masked by the patient's complex clinical state)
	  ○ Individual patient factors that limit an individual's ability to be engaged in the diagnostic process (e.g., severity of illness)

Potential Solution #1	**Leverage technology as a tool to manage complex information**
Process	• Enable technology and telehealth to help manage information and identify important changes in clinical information ○ Collaborate with EHR vendors and IT teams to understand the capability of the EHR to perform data visualization methods and trend clinical values (e.g., vital signs, input and output, laboratory test results, pain medication utilization,

Title	Cognitive Error – Information Overload
	invasive device usage) ○ Educate clinicians on the capability of EHRs to perform data visualization methods and trend analyses ○ Use AI to recognize data patterns to support identification of clinically relevant findings • Increase the usability of EHRs ○ Build multidisciplinary teams to analyze current EHR notifications and make recommendations to reduce notifications that do not increase patient safety ○ Examine current EHR notifications and identify opportunities to increase clinical salience of the notifications ○ Partner with EHR vendors to identify future opportunities for data visualization methods that improve the usability of EHRs ○ Use a human factors engineering approach when designing EHRs and adding new features ○ Engage frontline staff and end-users in discussions and focus groups with EHR vendors to help understand how features are currently being used and to identify opportunities for improved usability ○ Request that vendors perform education with frontline staff to share strategies for maximizing the capability of the EHR
Potential Solution #2	**Support clinicians in managing large and/or complex patient loads**
Process	• Employ a team approach to help distribute and/or offset the cognitive load on a single clinician ○ Engage multidisciplinary team members with varied expertise to support clinical decision making ○ Manage fatigue by optimizing shift scheduling and considering circadian rhythms ○ Encourage accommodating clinical schedules based on clinician age, experience, and/or other factors that may impact a clinician's cognitive limits ○ Reduce the number of extraneous tasks performed when finding information to enable clinicians to focus on clinical tasks (i.e., task offloading) ○ Rotate or shift repetitive tasks at pre-identified scheduled intervals • Increase access to mechanisms and tools that help clinicians process complex clinical information ○ Develop diagnostic algorithms and/or protocols for specific clinical circumstances that address known pitfalls in diagnoses ○ Use simulation training to prepare clinicians for managing situations with high cognitive load and large amounts of information

Title	Cognitive Error – Information Overload
	○ Increase access to specialists through telemedicine, especially in rural settings ○ Provide access to online textbooks and/or online journals ○ Provide access to diagnostic tools, such as differential diagnosis generators or diagnostic reminder systems ○ Create an easily accessible tool that contains information for on-call clinicians and specialists that can assist with complex cases or large patient loads ○ Utilize telehealth tools to support information collection
Potential Solution #3	**Provide patients opportunities to help manage information**
Process	• Create opportunities for patients to highlight important clinical information ○ Encourage patients and families to actively monitor their own care and escalate issues as they arise ○ Engage patients repeatedly at defined intervals to ensure they have ample opportunity to provide input and share information • Ensure patients understand what diagnoses are being considered and what has been ruled out ○ Support a culture of shared decision making throughout the diagnostic process ○ Explain to patients what diagnostic tests are being performed ○ Communicate frequently with patients about updates to the differential diagnosis when certain diagnoses have been ruled out ○ Provide education materials that are suitable for patients and their families about their diagnosis. ○ Provide patients access to medical records

Case Exemplars – Snapshots

The snapshots below depict clinical cases where information overload ultimately causes a diagnostic error. Each snapshot provides an overview of the case exemplar, outlines case-specific challenges and causal factors that likely contributed to the error and includes granular solutions and implementation strategies for broad stakeholders to overcome the error.

Snapshot One

OVERVIEW OF CASE

An ED physician is working an overnight shift in a busy urban hospital. Her patient load includes multiple patients at different stages in their clinical workup. One is an 85-year old woman with a history of chronic obstructive pulmonary disease (COPD) with home oxygen use and diabetes who has shortness of breath, dizziness, and hypotension. She is awaiting laboratory and radiology results. Another patient is a 50-year old male with a history of diverticulitis and is three weeks post-operative colon resection surgery who presented with fever, nausea, vomiting, and abdominal pain for three days. He is awaiting his initial evaluation. The third patient is a 20-year old male with sickle cell anemia presenting with shortness of breath, chest pain, and fever, in addition to his typical sickle cell crisis pain in his bilateral legs. His chest x-ray shows a new infiltrate and his pain is uncontrolled. The fourth

patient just arrived via ambulance to the trauma bay with a gunshot wound to his chest. He is a 30-year old man who is hypotensive and confused. He requires an emergent central line and multiple blood transfusions. He is awaiting transport to surgery. Additionally, the physician is responsible for treating and evaluating low-acuity patients. She attempts to keep track of all of her patients and the multiple tests that result. She orders a CT scan for the patient with abdominal pain. The CT result suggests that there may be early signs of a small abnormality of "possible perforation" around an area of thickened bowel. However, this is written by the radiologist in the extensive, main text of the report rather than in the "impression", which suggests a more non-specific finding. Given she was so busy, the clinician did not take time to read the entire report and instead reads only the "impression". She communicates the incorrect result to the patient. In addition, on her reassessment, the patient reports his pain has lessened, and he is discharged home. He returns two days later in septic shock (e.g., a serious infection) with an intraabdominal abscess. His treatment requires immediate surgery to remove the infection, and a prolonged stay in the ICU.

CASE-SPECIFIC CHALLENGES AND SOLUTIONS

In this case, the clinician makes a diagnostic error due to the information overload she is experiencing. The cognitive load involved in this case is very high, as she is experiencing high intrinsic and extraneous loads. She is caring for many complex patients in the ED, and each patient requires valuable cognitive resources for her to make an accurate diagnosis. She may also be experiencing physical and mental fatigue from working a long, overnight shift with many complex patients. There are also many systems factors that are present. The busy, chaotic environment of an ED adds to the information overload the clinician is experiencing. Lastly, the CT report includes the finding of a possible perforation in the main text of the report rather than in the impression. The poor organization of this information, coupled with the fatigue and cognitive load experienced by the clinician, lead to the clinician overlooking this finding and making a diagnostic error.

Specific solutions that would have helped prevent this error include:

- **Increase the usability of EHRs *(from potential solution #1):*** Clinical informatics leaders and EHR vendors could engage radiologists in discussions to understand how radiographic results are currently being reported and displayed in the EHR. Leaders could also hold focus groups with other frontline clinicians to learn their process for reading results, which may highlight that opportunities exist to ensure key findings are always listed within the final impression field. Clinical informatics leaders could then collaborate with EHR vendors to identify opportunities to improve the user experience for entering radiographic reports to ensure all pertinent findings are highlighted in the final impression.

- **Employ a team approach to help distribute and/or offset the cognitive load on a single clinician (*from potential solution #2):*** Healthcare administrators can help reduce the cognitive load on clinicians in a variety of ways. To create a culture of teamwork and support, leaders and administrators could increase staffing to help with task distribution when economically feasible. Administrators could partner with clinicians to identify tasks that currently impact their cognitive load that could be performed by other team members. Once tasks are identified, administrators could identify and hire for these positions, or could engage staff members already employed by the organization. Non-clinician staff members could perform non-clinical duties that would help reduce cognitive load on a clinician, such as scribing information to help with charting. Administrators could hire other clinicians, such as advanced practice providers and pharmacists, and enable them to perform activities at the top of their license.

Administrators and human factors engineers could also improve flow in the ED and other clinical settings to minimize episodes of high cognitive load.[88]

- **Increase access to mechanisms and tools that help clinicians process complex clinical information *(from potential solution #2):*** ED administrators could use simulation training to prepare clinicians for the busy, chaotic environment. Engaging clinicians in training exercises that simulate real-world scenarios where they will need to manage complex patients may help clinicians successfully manage high cognitive load. To develop the simulations, administrators could catalog especially challenging shifts that actually occurred within their ED and then emulate them during the simulation trainings.

Snapshot Two

OVERVIEW OF CASE

A 65-year old man with a history of hypertension and atrial fibrillation undergoes mitral heart valve repair due to stenosis. The complex open-heart procedure requires cardiopulmonary bypass and multiple blood transfusions. Post-operatively, he goes to the ICU for extensive, invasive monitoring. The ICU is at 100% occupancy with complex patients and there is a shortage of nursing staff. The patient is placed on a cardiac monitor with continuous blood pressure monitoring via an arterial line and has a triple-lumen central line in his subclavian vein. He has laboratory testing performed daily, including a CBC count, comprehensive metabolic panel (CMP), and coagulation studies. His vital signs and heart rhythm are continuously monitored and remain stable. Post-operatively, he has a persistent leukocytosis (i.e., high white blood cell count) and subtly increasing heart rate that is attributed to the surgery and not a developing infection. However, five days after surgery, he becomes acutely febrile and tachycardic. The clinician obtains blood cultures, starts the patient on broad-spectrum antibiotics for bacterial sepsis, and removes his central line. Despite the antibiotics, the patient continues to be tachycardic and febrile, and blood cultures are obtained daily. Since the early indication of an infection was missed, the delay in appropriate treatment led to his bacteremia infecting the repaired mitral valve. The infected valve required additional surgery, which ultimately prolonged the patient's ICU stay.

CASE-SPECIFIC CHALLENGES AND SOLUTIONS

This case demonstrates how information overload can commonly occur when clinicians are caring for complex patients who require continuous monitoring. The clinician does not diagnose the infection in a timely manner, which results in an infected valve, additional surgery, and a prolonged ICU stay for the patient. The patient has lab results obtained daily, but notably there is no EHR trend analysis to assist the clinician in tracking the results. There was also no trend in the EHR to help alert the clinician to the persistent leukocytosis and subtle increase in heart rate. Without these data visualization tools and triggers, the clinician was so overwhelmed with information and clinical data points that he did not notice the increases. Additionally, the hospital did not have a protocol in place for considering multiple causes of persistent leukocytosis in a post-operative patient, which would have served as a forcing strategy for the clinical team to consider the possibility of the central-line associated bacteremia earlier in the clinical course.

Specific solutions that would have helped prevent this error include:

- **Enable technology and telehealth to help manage information and identify important changes in clinical information *(from potential solution #1):*** EHR vendors and clinical informatics leaders

could collaborate to develop and deploy EHR tools to identify subtle trends in EHR data that may reflect a clinically significant finding, such as leukocytosis or increasing heart rate. EHR vendors and clinical informatics leaders could engage frontline clinicians in focus groups to help understand which key trends would benefit most from EHR data visualization tools. When a clinical finding is identified that would benefit from data visualization tools, EHR vendors could develop modules to address it within the EHR that the organization uses. EHR vendors could then make this module available for installation at other organizations that use their software and EHR platform.

- **Develop diagnostic algorithms and/or protocols for specific clinical circumstances that address known pitfalls in diagnoses *(from potential solution #2):*** Clinical informatics leaders and clinicians could partner to identify common clinical circumstances that lead to diagnostic errors. To help inform these discussions, clinicians could use their own clinical experience, as well as guidance and literature from medical specialty societies. Once the common circumstances are identified, clinical informatics teams could work with EHR vendors to embed algorithms and protocols to serve as forcing strategies for clinicians to recognize when these circumstances are occurring. As one example, documentation consistent with persistent leukocytosis could trigger an EHR notification to the clinician. This notification could alert the clinician of the persistent leukocytosis and could include a brief description about how a similar situation led to a diagnostic error in the past. While the clinician may not necessarily need to act on each situation, the alerts, algorithms, and protocols could provide clinical clues about subtle trends and reduce the likelihood of errors occurring.

- **Employ a team approach to help distribute and/or offset the cognitive load on a single clinician *(from potential solution #2):*** Healthcare administrators could create a team-based culture where allied health professionals are empowered to take active roles in the diagnostic process. This could involve the expansion of advanced practice providers, pharmacists, registered nurses, respiratory therapists, and other disciplines within the healthcare team. To uphold the culture of teamwork and collaboration, multidisciplinary clinical teams can work together to address the various clinical needs of the patients. The members of these teams can change based on the needs of the individual patient, expanding roles to include all aspects needed to care for the patient (e.g., if a patient needs assistance with activities of daily living, the team could include an Occupational Therapist). The team can work together to support clinical decision making and task distribution, and could lead to more comprehensive, timely care for the patients.

Snapshot Three

OVERVIEW OF CASE

A 45-year old female presents with symptoms of intermittent generalized weakness to a PCP for her first visit to the practice. The patient has a very complicated history with multiple medical and mental health comorbidities. She has insulin dependent diabetes, takes three medications for hypertension, and is on biological agents for rheumatoid arthritis. She also has a longstanding history of pulmonary embolism, where she goes on and off anticoagulants due to trouble with intermittent bleeding. She has had multiple hospitalizations at different hospitals with multiple different imaging studies, including a brain MRI one year ago. During those hospitalizations, she saw different specialists and received multiple, sometimes conflicting, recommendations for treatment and additional diagnostic testing. There was turnover in her previous primary care practice and each time she returned, she saw a different clinician who attempted to integrate all the findings and recommendations. However, given the complexity of the information, no one was able to synthesize a coherent diagnostic approach. At

her new primary care practice, she brings all previous records, including past primary care and specialist clinic notes, hospital discharge summaries, and previous imaging study reports. The new PCP attempts to review all the information but is unable to process all of it. On examination, the patient appears chronically, but not acutely, ill. Over the next six months, the patient's symptoms increase, and she has multiple clinic visits and normal laboratory testing. The patient eventually has an evaluation by a neurologist who recommends a brain MRI. While reviewing the imaging study, the neurologist identifies and reviews her previous brain MRI via a health information exchange. He notes the patient has progressive demyelinating findings and diagnoses multiple sclerosis (MS). The older MRI results that showed some concern for demyelinating disease were included in the records she provided her new PCP, but the PCP did not review them due to the large amount of information provided. This resulted in a delay in follow up with a neurologist and a subsequent delay in diagnosing MS.

CASE-SPECIFIC CHALLENGES AND SOLUTIONS

In this case, the PCP delays the diagnosis of MS despite the patient previously receiving an MRI that indicates progressing demyelinating findings and MS. The patient sees multiple providers in multiple care settings over time, resulting in disjointed clinical information. The abundance of information available to the PCP leads to the diagnostic delay since she is unable to process all of the information available. Without a consistent PCP, no single clinician is able to successfully integrate all of the information available. In addition, the level of detail and complexity of the information contribute to the delay.

Specific solutions that would have helped prevent this error include:

- **Enable technology and telehealth to help manage information and identify important changes in clinical information (*from potential solution #1*):** EHR vendors and clinical informatics leaders could work together to develop helpful synthesis tools that would allow for the easier digestion of large volumes of information. These tools could include a series of filtered summary screens that could help highlight important, clinically relevant findings in the EHR. The screens could display the information so that clinicians can easily view and access specific results, enabling them to make clinical decisions based on the most important historical information available.

- **Create opportunities for patients to highlight important clinical information (*from potential solution #3):*** Clinicians can provide patients, families, and caregivers multiple and ongoing opportunities to share information about their prior clinical experiences, test results, and symptoms. To encourage this proactive behavior, patient experience teams could partner with the Patient and Family Advisory Council (PFAC) and frontline clinicians to develop tools that support clinicians repeatedly engaging patients during the clinical process. These tools could include a toolkit or resource list of questions to ask patients and caregivers to help elicit more information from them, which could include asking specifically about the patient's prior imaging results, laboratory results, and recent diagnosis related to the symptoms they are experiencing.

- **Ensure patients understand what diagnoses are being considered and what has been ruled out *(from potential solution #3):*** Administrators could collaborate with clinicians to add items to a discharge checklist that remind clinicians to review any pending test results with the patient. Sharing information with patients about what tests have been performed will help them understand what tests are still pending and what results are already known. To further support patients understanding what diagnoses are being considered and what has already been ruled out, health systems and clinicians can provide patient access to medical records. To provide patient access, administrators can identify patient portals that exist within their EHR system.

Health systems and administrators will need to create education and roll-out plans to deploy access to patients, which would include providing instructions in multiple formats. Health systems could also dedicate specific resources to support helping patients access their medical records (e.g., patient help desk phone numbers, webpages for support, video tutorials).

Impact of Solutions on Patient Safety

Support systems that manage cognitive load and the amount of information a clinician processes provide opportunities to improve patient safety. Technology can be an especially powerful tool for assisting clinicians with processing complex information, although the use of an EHR alone can contribute to information overload for clinicians.[89] When EHRs are designed to focus on information capture and not the usability information, the systems result in copious data points without reference for what is most important information for clinical decision making.[89] Dashboards and other electronic tools can assist in managing this complex information. As one example, the Mayo Clinic created an EHR dashboard, AWARE (Ambient Warning and Response Evaluation), to assist with information management at the bedside in an ICU.[90] The dashboard was created with input from the ICU providers to ensure the data included on the dashboard was clinically meaningful and to reduce the task load involved with filtering, extracting, and using the data in the existing EHR.[90] The dashboard's data presentation and efficiency of accessing the data allowed clinicians to significantly decrease the time spent gathering patient information before daily rounds by three minutes per patient.[91]

Checklists also assist clinicians in processing complex clinical information and have shown to increase patient safety by increasing adherence to various quality indicators. The University of Chicago Medical Center created a paper-based checklist to address care processes for pneumococcal vaccination, pressure ulcer prevention, urinary catheter-associated urinary tract infections, and deep vein thrombosis (DVT) prevention in their general medicine inpatient units.[92] The use of the checklist significantly increased adherence to these four indicators from 68% to 82%.[92] Unlike an EHR reminder or alert, a checklist is able to incorporate multiple aspects of clinical care and can encourage clinicians to ensure diagnostic options. Checklists have also been shown to have higher levels of quality improvement when compared to EHR reminders or alerts.[92]

Patient, family, and caregiver engagement in managing their health data can assist in alleviating the information overload on a clinician as patients, families, and caregivers take a more active role in their healthcare decisions. Engaged patients have decreased delays in care and report more positive healthcare experiences, working with their providers to make decisions and set healthcare goals.[93] The use of open notes platforms can help patients actively collaborate with clinicians in their care, and can help identify errors that may have downstream safety and quality impacts.[8] Additionally, when patients, families, and caregivers are engaged and provided copies of test results and medical records, they are able to serve as a backup during care coordination with multiple clinicians.[94]

Measurement Considerations

In order to ensure that clinicians and healthcare systems reduce the likelihood of misdiagnoses of complex or critically ill patients when the disease "signal" is too high, there are a variety of approaches to measuring quality. Measure developers can use these concepts and approaches to develop and test new clinical quality measures, either as process measures to support diagnosis or as clinical outcomes. Payers can use these measures in improvement and payment programs to incentivize adoption of diagnostic best practices and improve quality of care.

Table 9. Measurement Considerations for Cognitive Error – Information Overload

Measurement Approach	Measure Concepts	Rationale
Assess the usability of EHR platforms by users	• Clinician-reported assessments of usability • Presence of data visualization methods that meet quality standards within the EHR	• Measuring the usability of EHRs, such as the presence of data visualization methods and other tools to identify EHRs that are successful in managing information and those with opportunities to improve usability, in particular to display and management of complex information
Measure clinician productivity as a proxy for cognitive load	• Number of patients seen per hour by a clinician	• Gathering information on the number of patients seen by a single clinician in a given time frame and also during times of peak demand may serve as a proxy for understanding the burden, clinical load, and/or cognitive load on particular clinicians • Analyzing information on clinical load and diagnostic errors may help inform if certain thresholds should be in place to help manage cognitive load
Measure the time to identify important clinical events	• Time to detection of important clinical events (e.g., sepsis)	• Understanding the time it takes to detect important clinical events will help identify opportunities where misdiagnoses are occurring, as well as provide data for root-cause analysis and follow-up to pinpoint remediable causes of delays
Assess participation in a learning system that supports data sharing	• Rate of participation in a health information exchange • Participation in a learning system with other healthcare organizations	• Participation in a health information exchange supports the use of data to improve accessibility of information and reduce diagnostic errors
Assess patients' perceptions of if they are part of the diagnostic team	• Patient-reported perceptions of patient input and barriers to participation in the diagnostic process	• Gathering information directly from the patient may be a useful way to measure if a patient feels that his/her opinions are

Measurement Approach	Measure Concepts	Rationale
		heard, and he/she is part of the diagnostic team
Measurement Approach	• Coordination of Care Index (COCI)[95]	• Measures of relational coordination, which focus on coordination and communication of teams, could serve as a proxy for if information and tasks are being successfully addressed by the team

Use Case 4: Cognitive Error – Dismissed Patient

Clinical Context

Patients with uncommon conditions, or unusual presentations of more common conditions, often experience long diagnostic delays in the assessment of chronic symptoms that are mild, non-specific, or evolving slowly.[96] If an initial search identifies no "objective" abnormalities that correspond to the patient's symptoms, the patient may be labeled as having "medically unexplained symptoms" and the search may be terminated. If the patient or clinician insists on pursuing additional testing, the patient may begin a prolonged "diagnostic odyssey" in which the patient visits multiple specialists in search of a diagnosis.[97] If no diagnosis is found despite substantial amounts of testing, the patient may be dismissed as having functional symptoms, somatization, or hypochondriasis; alternatively, the patient may be placed in a "wastebasket" diagnostic category without definitive diagnostic tests (e.g., chronic fatigue syndrome).[98] After such a diagnosis is given, additional symptoms may be attributed to the original diagnosis or even ignored by subsequent clinicians.

There are several causal factors that can contribute to diagnostic errors resulting from dismissed patients and diagnostic odysseys. These factors can be described in three broad groups: **clinician factors, systems factors,** and **condition/disease factors.**

Clinician factors contributing to these types of errors include cognitive biases, such as implicit bias, confirmation bias, overconfidence bias, and affective bias. Clinicians may have a tendency to undervalue patients' knowledge and contributions to the diagnostic process, thus undermining or ignoring the pertinent clinical information that patients may share. Many patients also see numerous providers in various care settings, and patients who do not have a PCP synthesizing information from multiple sources may be at an increased risk of experiencing these types of diagnostic errors. Lastly, clinicians must support patients in being active partners throughout the diagnostic process. When a clinician fails to explain specific diagnostic tests previously performed, diagnoses that have already been ruled out, or changes in the diagnosis, the clinician limits the ability of the patient to be an active partner.

Systems factors also contribute to diagnostic errors resulting from dismissed patients. When there are multiple care settings and providers involved in a patient's care, there is an increased risk of information not being shared or heard. A lack of interoperability across EHRs also contributes to ongoing diagnostic odysseys. When organizations and systems overemphasize the use of protocols, clinicians may tend to over adhere to protocols, even if it is not indicated or appropriate. This can

contribute to patients being dismissed if the information they are sharing does not align with the protocol. Additionally, healthcare organizations may not always have the systems and resources in place to support the complex SDOH-related needs of their patients.

Several **condition/disease factors** contribute to these types of diagnostic errors. Some delays occur because a condition is rare and indolent, and therefore is unknown or unfamiliar to the patient's clinician. There are over 7,000 rare diseases, and it is estimated that over 30 million Americans have one or more rare diseases.[99] For example, hereditary angioedema (HAE) is a rare, genetic condition that involves periodic swelling of the face, airway, extremities, and abdomen, and has a prevalence of 1 in 50,000.[100] Diagnostic delays commonly occur in HAE patients, and the average time from first symptoms to diagnosis is greater than two years, with some delays in diagnosis taking up to 20 years.[101]

Diagnostic delays may also occur when a condition is not typically diagnosed with a common test, making it more difficult to obtain the accurate diagnosis. Similarly, non-classic manifestations of common diseases, such as migraine, may be known only in narrowly focused subspecialties (e.g., recurrent dizziness caused by vestibular migraine known to neuro-otologists), subsequently contributing to diagnostic errors when patients present in other settings.

Non-specific symptoms, such as fatigue or chronic low-grade abdominal pain, and slow disease progressions are especially prone to diagnostic odysseys because the symptoms cross many specialty lines and often multidisciplinary clinical communication is lacking. Additionally, patients may experience a constellation of unrelated symptoms that are mistakenly perceived to be part of one condition or disease, when in actuality, they are unrelated. Diagnostic delays can lead to harm from failure to treat an underlying disorder or from the adverse effects of empiric symptomatic therapies.[102]

Individuals with specific conditions or diseases may also have certain characteristics that increase disparities in care and impact their ability to access care. Factors such as social determinants of health (SDOH), a history of psychiatric illness, and homelessness often contribute to diagnostic odysseys. Some patients may be fearful or reluctant to obtain a diagnosis, which may further perpetuate the diagnostic odyssey. The odyssey itself can also exact a major psychological and financial toll on the patient, family, and/or caregivers.[103]

While most patients with symptoms deemed "medically unexplained" in the modern era do not develop an overt medical cause in follow-up, an estimated 1-5 percent do. Whether they turn out to be misdiagnosed or not, the psychological impact of this "non-diagnosis" diagnosis on patients can be substantial.[104] When patients do finally achieve a diagnosis, they often describe feeling dismissed or not listened to during their odyssey. In some cases, the key to the correct diagnosis was, in fact, something the patient tried to say but was not heard or appreciated by the clinician. In other cases, affective bias may have contributed. This may manifest as clinicians become angry or frustrated with the patient, failing to listen to or hear the patient, and/or giving up on the patient.

The Use Case in Table 10 is focused on opportunities to prevent and overcome diagnostic errors that originate in patients with chronic, unexplained symptoms. The Use Case addresses multiple subdomains from the Diagnostic Process and Outcomes domain within the 2017 Diagnostic Quality and Safety Measurement Framework, including Information Gathering and Documentation,

Diagnostic Efficiency, Diagnostic Accuracy, and Follow-up. Organizations, clinicians, and other healthcare stakeholders (e.g., payers, policymakers, EHR vendors) can review the solutions included in the Use Case and identify opportunity areas that are most applicable to them given their organizational needs, resources, and context

Table 10. Use Case 4: Cognitive Error – Dismissed Patients

Title	**Cognitive Error – Dismissed Patients**
Assumptions	• Diagnostic errors are complex and can have a variety of root causes. Organizations and clinicians should convene multi-disciplinary quality improvement teams to understand and remediate the types of errors occurring within their organization and/or practice. • Organizations have performed quality improvement activities and identified that diagnostic errors are occurring due to dismissed patients.
Stakeholders	• Patients • Clinicians • Administrators (e.g., Chief Medical Officer, Chief Quality Officer, Chief Nursing Officer, Chief Technology Officer, Clinical Informatics Officer, Chief Financial Officer) • Non-clinical staff (e.g., IT team members, Patient Education staff) • EHR Vendors • Policymakers • Payers

Causal Factors and Diagnostic Challenges	• **Clinician Factors:**
	  ○ Lack of PCP who synthesizes information from multiple sources
	  ○ Tendency to undervalue patients' knowledge and contributions to the diagnostic process
	  ○ Cognitive biases, including implicit bias, confirmation basis, overconfidence, and affective bias
	  ○ Failure to explain to the patient diagnostic tests previously performed and diagnoses that have already been ruled out
	• **System Factors:**
	  ○ Lack of interoperability across EHRs
	  ○ Over-emphasis and over adherence to protocols
	  ○ Multiple care settings and providers involved in the patient's care
	  ○ Inadequate system resources to meet the complex SDOH needs of patients
	• **Condition/Disease Factors:**
	  ○ Rarity of the condition
	  ○ Condition may not be diagnosable with commonly used tests

Title	**Cognitive Error – Dismissed Patients**
	○ Non-specific nature of symptoms or slow progression of disease ○ Appearance of a constellation of unrelated symptoms that are mistakenly perceived to be part of one condition or disease ○ Patient fear of knowing the diagnosis ○ Patient-level characteristics that may increase disparities in care and impact access to care (e.g., SDOH, history of psychiatric illness, homelessness)
Potential Solution #1	**Enhance opportunities for patient engagement through education and training**
Process	• Provide education to support clinicians actively engaging patients and families as part of the diagnostic team ○ Require clinician education on patient-centered diagnostic decision-making and shared decision making ○ Create diagnostic checklists with items that pertain to getting input from the patient and/or family and ensure patient and family concerns are addressed ○ Share information about diagnostic tests performed and diagnoses ruled in or out with patients to support their own understanding of the diagnostic process • Support clinicians in overcoming common biases that may limit their ability to hear the perspectives of patients ○ Educate clinicians on common types of biases that contribute to dismissing the perspectives of a patient (e.g., affective bias) ○ Share information with clinicians on mechanisms to identify and overcome bias, such as performing a "gut check" for feelings of anger, frustration, or hopelessness when managing a complex patient ○ Create protocols for initiating consultations and/or second opinions (e.g., repeated visits for the same symptom with no explanation) • Encourage clinicians to act early on the concerns voiced by patients and families ○ Support the use of early referrals for genetic counseling, specialist care, and other high-risk situations ○ Educate clinicians that protocols are a tool to support accurate diagnoses but that deviations from protocols may occur based on clinical presentation and/or patient needs ○ Engage patients to share stories with clinical teams where diagnostic errors occurred when patient concerns and input were not listened to
Potential Solution #2	**Empower patients to raise concerns and share their perspectives**

Title	Cognitive Error – Dismissed Patients

Process	• Invite patients to be part of the diagnostic team
	  ○ Use shared decision making to co-create a diagnostic plan together with patients and families
	  ○ Request input directly from patients and families when trying to understand the clinical picture
	  ○ Ask patients about specific barriers to adhering to the recommendations for follow-up (e.g., insurance coverage, ability to make a follow-up appointment) and partner to identify targeted solutions
	  ○ Provide repeated and frequent opportunities for patients and families to share important information and/or raise concerns
	  ○ Offer feedback to patients to reinforce how the information shared helps contribute to an accurate and timely diagnosis
	  ○ Use signage throughout the organization that encourages patients to speak up
	• Ensure patients understand what diagnoses are being considered and when the diagnosis changes
	  ○ Use clear and straightforward language, supplemented by visual information (e.g., graphics, charts) to make information as easy to understand as possible
	  ○ Explain to patients what diagnostic tests are being performed
	  ○ Communicate frequently with patients about updates to the differential diagnosis when certain diagnoses have been ruled out
	  ○ Provide patient access to medical records
	  ○ Provide and/or direct patients to reliable information related to their diagnosis and clinical course
	• Engage the Patient and Family Advisory Council (PFAC)
	  ○ Partner with the PFAC to identify and understand opportunities to increase patient engagement in the diagnostic process
	  ○ Identify new opportunities to engage the PFAC in co-designing activities that promote timely and accurate diagnoses
	  ○ Offer education (e.g., materials, online classes, support groups) for how patients can be their own advocate
	• Engage patients who have experienced diagnostic odysseys to help prevent diagnostic errors in the future
	  ○ Create processes to support patients initiating a retrospective case review, or root cause analysis,

Title	**Cognitive Error – Dismissed Patients**
	of diagnostic odysseys and/or errors ○ Connect patients who have experienced diagnostic odysseys to participate on PFACs and Quality Committees to facilitate continuous improvement and learning ○ Enable patients to participate in Morbidity and Mortality conferences to describe the impacts of their concerns being dismissed and the diagnostic error they experienced ○ Encourage patients with conditions that commonly experience diagnostic odysseys to participate in support groups with other patients to support learning and improvement
Potential Solution #3	**Identify opportunities for technology and data to recognize potential diagnostic odysseys**
Process	• Use technology as a learning tool ○ Perform data analytics to identify known diagnostic pitfalls ○ Use information on known diagnostic pitfalls to identify opportunities for targeted improvement opportunities ○ Use AI and/or machine learning to detect patterns for diagnostic odysseys in EHRs and/or claims data ○ Leverage AI analytics as learning opportunities and share feedback to clinicians, when possible • Use data to understand the impacts of diagnostic odysseys ○ Partner with payers to use claims data to retrospectively analyze the time and cost impacts of diagnostic odysseys ○ Use claims data to pinpoint opportunities for improvement in the diagnostic process ○ Harvest data obtained from patient experiences, concerns, and surveys to identify patterns and trends to inform organization-specific solutions ○ Partner with data-focused organizations to support measurement and data mining as a performance improvement tool • Increase information sharing and interoperability across EHRs and settings ○ Build and support regional health information exchanges ○ Ensure access to patient information across health systems through information sharing requirements

Case Exemplars – Snapshots

The snapshots below depict clinical cases in which patient concerns were dismissed, resulting in long diagnostic odysseys and diagnostic errors. Each snapshot provides an overview of the case exemplar, outlines case-specific challenges and causal factors that likely contributed to the error and includes granular solutions and implementation strategies for broad stakeholders to overcome the error.

Snapshot One

OVERVIEW OF CASE

A 23-year-old female has a longstanding history of three years of intermittent abdominal pain, bloating vomiting, and diarrhea. She is uninsured and goes to the ED when she has symptoms, and is followed by a busy, safety net clinic. Over the initial three years of her symptoms, she has had six CT scans that have been normal, and she has been admitted to the hospital twice for the condition, once for three days because of a persistent inability to tolerate food. In the hospital, she was seen by a gastroenterologist who felt her symptoms could be evaluated as an outpatient. Yet, there was no clear diagnosis or specific cause identified for her symptoms. Between her multiple visits, she explores the internet for information about her symptoms to try to identify what is causing them. She learns about celiac disease (i.e., a gluten allergy) and believes it perfectly fits her symptoms. She brings this up to her clinicians at subsequent appointments at the safety net clinic and even during one of her hospitalizations, but the clinicians continually disregard her self-diagnosis and respond that there are many causes of abdominal pain and they must explore all possible diagnoses. After each visit, she is referred to see a gastroenterologist as an outpatient but has never made it to an appointment because the clinicians have asked for payment upfront before she is seen, which she states she cannot afford. She finally is able to obtain health insurance through her new job and sees a gastroenterologist. The gastroenterologist conducts an endoscopy and additional blood testing, and she is ultimately diagnosed with celiac disease.

CASE-SPECIFIC CHALLENGES AND SOLUTIONS

The patient in this case experiences a long, diagnostic odyssey before she finally receives the accurate diagnosis of celiac disease. The clinicians she sees undervalue the patient's own personal knowledge, thus limiting her ability to contribute to the diagnostic process. Despite the patient suggesting celiac disease, the clinicians disregard her suggestion and continue exploring other causes for her symptoms. The clinicians do not engage her as an active partner, and do not attempt to find out if there are any barriers that limit the patient's ability to adhere to the follow-up recommendations of seeing a gastroenterologist. Additionally, the multiple providers she sees over time, coupled with her repeated visits to the ED and the clinic, lead to disjointed information and a lack of a designated clinician to synthesize all of the patient's clinical information. Lastly, the non-specific nature of symptoms of celiac disease also contribute to the diagnostic delay experienced by this patient.

Specific solutions that would have helped prevent this error include:

- **Encourage clinicians to act early on the concerns voiced by patients and families *(from potential solution #1):*** Healthcare administrators could partner with communications professionals to develop and deploy educational tools to support clinicians actively listening to patient, family, and caregiver concerns. These tools could include a series of case studies that illustrate how active listening occurs in the clinical setting and could demonstrate specific clinical situations where clinicians were able to avoid a diagnostic error due to acting on the concerns

voiced by patients and families. Education could also include information on the intended use of protocols, reiterating to clinicians that protocols are intended to support accurate diagnoses and optimal clinical practice. Education should highlight that deviations from protocols may occur based on clinical presentation and/or patient needs, and clinicians must actively listen and engage patients to help identify situations where protocol deviations may be necessary.

- **Invite patients to be part of the diagnostic team *(from potential solution #2):*** Clinicians could explicitly invite patients to be part of the diagnostic team by engaging them in the co-creation of a diagnostic plan. Clinicians could ask patients about specific barriers to adhering to the recommendations for follow-up to proactively identify any challenges that may result in the plan not being followed. In this case, the clinician could have identified that the patient was not able to afford to see the gastroenterologist, and they could have identified an actionable plan together. To encourage clinicians to ask these questions specifically, the question could be added to a discharge checklist.

- **Engage patients who have experienced diagnostic odysseys to help prevent diagnostic errors in the future *(from potential solution #2)*:** Healthcare administrators, clinicians, and quality improvement teams could recruit patients who have experienced diagnostic odysseys to help prevent future diagnostic errors. Clinicians could identify specific patients they have cared for who have experienced diagnostic errors and diagnostic odysseys, or clinicians could identify conditions that are commonly misdiagnosed to help identify patients to engage in improvement efforts. Patients could participate in Morbidity and Mortality conferences to share information about their specific circumstance and misdiagnosis, enabling multiple disciplines and clinicians to learn from the error. Patient safety and quality improvement experts could identify opportunities for improvement based on the information shared at the conferences, and these could be deployed throughout the clinical setting.

- **Use data to understand the impacts of diagnostic odysseys *(from potential solution #3):*** Healthcare stakeholders, including data scientists, clinical informatics teams, health plans, and quality improvement specialists, could leverage data to learn about diagnostic errors and pinpoint opportunities for improvement. Clinical informatics experts could use AI and other tools to assess patterns that may reflect specific underlying conditions or circumstances that lead to diagnostic errors. For example, a common pattern seen with celiac disease may be patients presenting for repeated visits with non-specific gastrointestinal symptoms and no specific diagnosis. Clinical informatics experts could use AI to identify these commonalities and could raise them to clinicians as possible diagnoses to consider. These data tools could be developed and deployed through the EHR by EHR vendors and clinical informatics leaders, or through a payer using claims data.

Snapshot Two

OVERVIEW OF CASE

A 40-year old female with no medical history developed widespread muscle pain, tenderness, and numbness with increased fatigue, vague abdominal pain, and depression. She sees her PCP who diagnoses her with fibromyalgia and prescribes anti-inflammatory and muscle relaxant medication. She also sees several other providers including a psychiatrist, a chiropractor, and a massage therapist. Her symptoms do not improve, and she decides to see a rheumatologist, as well a neurologist, who treat her symptoms as functional. Despite her presenting her history and medical records, neither specialist considers an alternative diagnosis and they agree with the PCP's diagnosis of fibromyalgia. One morning the patient wakes up with more severe abdominal pain, focused in her right lower quadrant.

She goes to the Emergency Department where she is evaluated for possible appendicitis with a CT. Instead of appendicitis, they find that she has metastatic ovarian cancer, which was the cause of her symptoms all along.

CASE-SPECIFIC CHALLENGES AND SOLUTIONS

There are several examples of clinician's dismissing the patient that result in a diagnostic odyssey and a diagnostic error in this case. The specialist exhibits implicit bias once they learn about the patient's history of depression, psychiatric care, and prior diagnosis of fibromyalgia. Despite the patient's persistent symptoms, none of the clinicians appear to value the patient's knowledge and personal experience. Additionally, the nonspecific nature of her symptoms contributes to the ultimate delay in diagnosis.

Specific solutions that would have helped prevent this error include:

- **Support clinicians in overcoming common biases they may limit their ability to hear the perspectives of patients *(from potential solution #1):*** Professional societies could develop and deploy education materials for clinicians focused on overcoming biases in care. These materials could describe specific biases, as well as clinical encounters and situations that they commonly manifest. Healthcare administrators and leaders could build on education materials available from medical specialty societies or could create their own materials based on the biases impacting care at their facilities. The education materials could also describe specific solutions for clinicians to overcome their own biases using meta-cognitive forcing strategies and other approaches.

- **Invite patients to be part of the diagnostic team *(from potential solution #2):*** Clinicians could explicitly invite patients to be part of the diagnostic team by providing repeated and frequent opportunities for patients, families, and caregivers to share information and/or raise concerns. Clinicians could engage patients repeatedly at defined intervals and on an ongoing basis. Patients could also be included in the diagnostic team through the use of a patient portal. Clinicians could use the patient portal to share laboratory and radiographic results, as well as the notes describing the rationale behind their interpretation. By including patients as part of the diagnostic team, clinicians could engage in shared decision making to co-create a diagnostic plan. Clinicians could create a time to walk through the results in the portal specifically to describe their results, and also give the opportunity for feedback on the diagnostic process, questions, and input.

- **Use data to understand the impacts of diagnostic odysseys *(from potential solution #3):*** Healthcare administrators could partner with clinical informatics experts and payers to use claims data to understand the cost and time implications of diagnostic odysseys. Payers could use claims data to retrospectively analyze the time and cost impacts of diagnostic odysseys for conditions that are commonly misdiagnosed and/or that result in a delayed diagnosis. This information could be shared back with frontline clinicians to help them understand the resource impacts of delayed diagnoses.

Snapshot Three

OVERVIEW OF CASE

A 45-year old woman with a history of anxiety and schizoaffective disorder presents to multiple EDs with reports of longstanding, intermittent headaches over a one-year period. She states she has a history of migraines. She is homeless, has been to this ED many times, and is often dismissed by the

clinicians due to her history and frequent visits. Each time she goes to the ED she usually receives a cursory physical examination, which is consistently normal, is given acetaminophen, and is referred to a social worker and told to follow-up with a PCP. One day, she presents after a fall with a scalp hematoma and receives a head CT. The head CT does not demonstrate intracranial bleeding but does demonstrate a moderate-sized brain mass in her medial temporal lobe and midline shift, which was the cause for her indolent headaches that was missed during her multiple ED visits.

CASE-SPECIFIC CHALLENGES AND SOLUTIONS

In this case, the clinical teams frequently dismiss the patient's concerns and perspective. The clinicians exhibit implicit bias and dismiss the patient based on her history of psychiatric illness and homelessness. These patient-level characteristics contribute to disparities in care and result in clinicians undervaluing her knowledge and contributions to the diagnostic process. The patient is also frequently referred to a PCP, but none of the ED clinicians ask the patient if she has a PCP or if there are any barriers to the patient following up with a PCP. The non-specific nature of intermittent headaches also contributes to the misdiagnosis.

Specific solutions that would have helped prevent this error include:

- **Support clinicians in overcoming common biases that may limit their ability to hear the perspectives of patients *(from potential solution #1):*** Healthcare administrators could deploy education campaigns focused on identifying and remediating bias in the clinical setting. Education could be in multiple forms, including printed materials, online courses, or interactive activities. Education could be aimed at common biases that clinicians have, such as implicit bias, and could offer strategies to help clinicians recognize their own biases. Education could also include strategies for overcoming bias and could offer various mechanisms for clinicians to share their own experiences and support one another's learning.

- **Engage the PFAC *(from potential solution #2):*** Healthcare organizations could engage PFACs to make recommendations aimed at reducing misdiagnosis in vulnerable populations, including those with mental illness or homelessness. PFACs themselves could also expand their membership to ensure vulnerable populations are represented. Once the PFAC identifies recommendations to support clinicians understanding the unique challenges of vulnerable populations, the PFAC could present this information back to the organization leadership and frontline clinicians. The PFAC could also help create education materials and opportunities, such as printed materials, signage, or support groups, to share information on how patients can be their own advocate during the diagnostic process.

- **Invite patients to be part of the diagnostic team *(from potential solution #2):*** Clinicians could ask patients about specific barriers to adhering to the recommendations for follow-up to identify specific issues that may result in the plan not being followed. This could help clinicians learn about challenges their patients are facing, such as not being able to see a social worker or PCP. If barriers are identified, the clinicians could utilize resources available to them in the ED to identify other possible supportive services, such as social work or case management.

Impact of Solutions on Patient Safety

Patients are a critical part of the diagnostic process, and engaging them in the co-creation of a diagnostic plan and repeatedly engaging them for input provides an opportunity to improve overall patient safety and experience. An important example of this is the Joint Commission's *Speak Up*

campaign, which provides resources for facilities to empower patients and engage them in decision-making, and provides specific materials that hospitals can use to launch such a campaign.[105]

Shared decision making, or the process of communication in which clinicians and patients work together to make optimal healthcare decisions that align with what matters most to patients, is critical to the diagnostic process.[106] Partnering with patients to improve this two-way communication and information sharing has resulted in increased patient satisfaction, increased diagnostic accuracy, and improved quality of care.[107]

In particular, expanding patient access to their own information through patient portals is an important way to share information in the diagnostic and treatment process. This also provides a line of communication for patient questions that can be answered asynchronously and has been successfully deployed in the Veterans Health Administration system.[108] In addition, in the complex healthcare landscape, patients often see many providers in multiple settings. Health information exchanges allow for secure transfer for electronic health information across various healthcare organizations. The sharing of information has the ability to decrease diagnostic errors through improved workflows and decreased cost associated with the ability to access previous laboratory results and imaging reports faster, without having to do unnecessary repeat testing.[109]

Measurement Considerations

In order to ensure that clinicians and healthcare systems reduce the likelihood of patients experiencing diagnostic odysseys, there are a variety of approaches to measuring quality. Measure developers can use these concepts and approaches to develop and test new clinical quality measures, either as process measures to support diagnosis or as clinical outcomes. Payers can use these measurement approaches to support and incentivize the adoption of diagnostic best practices and improve quality of care.

Table 11. Measurement Considerations for Cognitive Error – Dismissed Patients

Measurement Approach	Measure Concepts	Rationale
Assess when team- based approaches are initiated	• Presence of a protocol for escalation of the diagnostic approach (e.g., second-opinions, consults, and/or additional testing) for patients with continued undiagnosed symptoms	• Using team-based approaches to diagnosis, including second-opinions, expert consults, and more expansive testing will help reduce the likelihood of a single clinician's biases closing off potential diagnostic pathways and/or dismissing the patient's concerns and perspectives
Measure the structures in place to support accurate and timely diagnosis	• Presence of systems in place for clinicians to provide feedback on IT issues related to diagnostic error • Presence of systems that support referral	• Measuring the presence of structures and processes that support accurate and timely diagnosis (e.g., feedback mechanisms for issues, warm handoffs and/or referral systems) will help organizations and clinicians understand if they have

Measurement Approach	Measure Concepts	Rationale
	of homeless patients to care	mechanisms in place to support reductions of diagnostic errors, and will identify where improvement opportunities exist
Measure the time to diagnosis for rare conditions	• Days from original patient chief complaint until final, accurate diagnosis	• Measuring the time to diagnosis for rare conditions will help increase understanding of the delays that patients experience and will help identify changes and improvements over time • Understanding the diagnostic delays that occur and how they impact treatment delays may help identify specific opportunities for improvement and efficiency in the diagnostic process
Measure the total cost of the diagnostic odyssey	• Total cost of the diagnostic odyssey	• Measuring the total cost of a diagnostic odyssey experienced by the patient will help increase understanding of the impacts of delayed diagnoses and diagnostic errors
Measure the volume and impact on diagnostic testing	• Number of consultations and/or second opinions	• Using a balancing measure will help understand how new protocols and processes for escalation of care for patients with undiagnosed symptoms are impacting the volume of consultations, second opinions, and/or diagnostic testing
Assess patient experience with diagnostic odysseys	• Patient-reported satisfaction with the diagnostic process	• Gathering information directly from the patient may help understand the patient-level impacts of diagnostic odysseys and how these experiences share their perception of the healthcare system

Broad-scope, Comprehensive Recommendations for Applying the Framework, Measuring and Reducing Diagnostic Error, and Improving Patient Safety

A measurement framework highlights measurement gaps, and can serve as a template for prioritizing scarce resources towards efforts to reduce and prevent diagnostic errors. The Diagnostic Process and Outcomes domain of the 2017 Diagnostic Quality and Safety Measurement Framework includes the subdomains of Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, Diagnostic Accuracy, and Follow-Up. In identifying opportunities for

stakeholders to apply the conceptual framework, measure and reduce diagnostic error, and improve patient safety in a variety of systems and settings, the Committee identified a series of broad-scope, comprehensive, recommendations that apply across diverse systems and settings.

To apply the Diagnostic Process and Outcomes Domain of the 2017 Measurement Framework, the Committee recommends the following actions:

- **Engage clinicians to actively listen to patients, and empower patients to provide feedback and share information:** Engaging clinicians to actively listen to patients, and empowering patients to provide feedback and share information will drive improvement in the subdomains of Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, Diagnostic Accuracy, and Follow-up. Healthcare administrators and organizations must support engaging patients as active partners in the diagnostic process by creating a culture and expectation of involving patients in the co-creation of diagnostic processes through encouraging patient participation in patient safety workgroups and committees focused on improving diagnostic safety. Administrators should also create policies and procedures that support successful patient engagement and participation in the co-development of individual diagnostic plans. These processes include deploying education focused on enhancing clinician communication strategies to ensure effective communication between clinicians and patients. For example, this may involve the creation and use of visual aids to educate patients about diagnosis, toolkits for health systems to help empower patients, patient portals to share information on test results, and other mechanisms that ensure patients are part of the diagnostic team. Clinicians and organizations can leverage existing patient education materials developed by professional societies or other entities to empower patients to actively partner with clinicians in the diagnostic process. Clinicians should also engage in best practices for active listening and improving the effectiveness of patient-clinician interactions and seek to integrate feedback to improve their communication skills. This involves a longitudinal process of engagement and empowering patients to be part of the diagnostic team. Clinicians should also be sensitive to their patients' health literacy levels and cultural preferences to reduce disparities and improve health equity. As an example, organizations should have interpreter services available for multiple languages, ensuring their specific patient populations are able to effectively communicate with the clinical team either in person, or via a telephone or computer software.

- **Deploy clinician education and training for specific diagnostic errors:** Deploying clinician education and training for specific diagnostic errors will drive improvement in the subdomains of Diagnostic Efficiency, Diagnostic Accuracy, and Information Interpretation. Professional and credentialing organizations should build on existing, or develop new, curricula to enhance education and training on specific types of diagnostic errors and how to overcome and prevent them through adherence to guidelines, protocols, or other means. Educators should use varied modalities to ensure that clinicians understand these materials, including training modules, case review of relevant charts, and in-person simulations. Educators should focus efforts on specific types of error related to common complaints with wide differential diagnoses, such as chest pain or dizziness to help train clinicians on how to prevent common diagnostic errors related to misdiagnosis. Education and training can also include the role of other patient or population factors, such as SDOH, in diagnostic error. Healthcare organizations should measure clinician performance in adherence to clinical protocols surrounding error-prone complaints, as well as identify and deliver focused education to clinicians who do not adhere to protocols or may be practicing in a way that may lead to diagnostic errors.

- **Educate clinicians about the science of diagnostic error including practicing clinicians as well as students in undergraduate, graduate, and post-graduate training programs:** Including education on

the diagnostic error and ways to reduce errors for practicing clinicians, as well as students, will drive improvement in the subdomains of Diagnostic Efficiency, Diagnostic Accuracy, Information Gathering and Documentation, Information Integration, Information Interpretation, and Follow-up. A Consensus Curriculum project led by the Society to Improve Diagnosis in Medicine (SIDM) recently identified twelve key competencies to support diagnostic quality and safety.[110] These competencies included three key categories: individual, team-based, and systems-related competencies. While clinicians-in-training may have had more exposure to the science of diagnostic errors, it is also vital to ensure practicing clinicians engage in this material and are able to achieve these competencies. Healthcare organizations and administrators should provide such training to practicing clinicians and ensure they have integrated these principals into their practice. Training curriculums and continuing education should include information on the role of clinician bias in diagnostic error as well as how to mitigate bias. Such education is especially important for clinicians in settings and specialties caring for vulnerable or underserved populations. When highlighting systems-related competencies, healthcare organizations and educators should also integrate information on technology and its impact on care delivery and diagnostic error. Clinical informatics leaders, data scientists, and EHR vendors should partner with administrators of training programs and credentialing organizations to demonstrate the benefits and limitations of technology, and its role in improving patient care. This is especially important for clinicians without specialized expertise. Clinicians should learn early on about how technology workflows impact quality, safety, and potential diagnostic errors, and how the appropriate use of technology can facilitate high-quality care. This may include information about the use of protocols in the diagnostic process as well as emerging tools such as AI or e-trigger tools. Curricula should also include information about the unintended consequences of EHRs, and how to remediate systematic issues that are created by the use of technology.

- **Expand the clinical team to support a culture of teamwork in the diagnostic process:** Expanding the clinical team to support a culture of teamwork and collaboration will drive improvements in the subdomains of Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Accuracy, and Follow-up. While clinical diagnosis has been historically perceived as the responsibility of a physician, it is now increasingly recognized that diagnosis is a team-effort. Healthcare administrators should support clinicians bringing diverse disciplines into the diagnostic process, including identifying opportunities for physicians to partner with nurses, allied health professionals, mental health professionals, specialists, laboratory technicians, patients, and others. Expanding the team will also help reduce cognitive load on a single clinician, while enabling individuals to practice at the top of their license and seek out clinicians with specific clinical expertise. Clinicians should proactively ask other team members about the diagnosis, which also will reduce the presence of a single clinician's bias in the diagnostic process.[111]

- **Increase and improve information sharing and collaboration within and across teams and organizations:** Increasing information sharing within and across teams and organizations will drive improvement in the subdomains of Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, Diagnostic Accuracy, and Follow-up. Communication failures are a major cause of diagnostic error, and enhancing information sharing, communication, and collaboration can greatly improve patient safety, especially in situations where patients undergo multiple care transitions across different clinicians, or clinician types or across health systems. Policymakers should support a culture of information sharing by enhancing access to health information exchanges and offering incentives for their use. Healthcare organizations should engage patient safety and quality departments to assist with reviewing transitions in care and information sharing processes to identify opportunities for improvement. Healthcare systems should also work to enhance access to consultation with specialists in-person to drive collaboration. Healthcare organizations should promote diverse teams with clear roles and responsibilities to support information sharing across providers, departments, and organizations. Settings with limited

resources can especially benefit from the use of technology and telemedicine to improve access to specialists and virtual teams. Administrators should engage frontline clinicians in the technology development process by bringing together and aligning the goals of clinicians, clinical informatics departments, and EHR vendors. EHR vendors should seek out opportunities to partner with individual clinics and health systems to understand how technology can be a tool in reducing diagnostic error and improving safety. In particular, EHR vendors should share and deploy best practices in reducing errors and eliminating error-prone processes. Payers should partner with healthcare delivery organizations and clinicians to analyze and share claims data to help identify errors, provide feedback on errors that have occurred, and ideally help remediate errors.

- **Develop and deploy clinical protocols and pathways to standardize care:** Developing and deploying clinical protocols and pathways to standardize care will drive improvement in the subdomains of Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, Diagnostic Accuracy, and Follow-up. Clinical protocols should be developed for specific complaints and conditions that are common and/or particularly prone to diagnostic error. Such protocols may include conditions where there is a known rate of error (e.g., major cardiac events among patients discharged from the ED with chest pain), or other high-risk complaints or conditions. Medical societies should focus efforts on clinical guidelines that support such tools to assist clinicians and organizations in identifying conditions that may be prone to diagnostic errors. Healthcare administrators should partner with frontline clinicians to develop these protocols. Patient safety officers must also collaborate with clinicians to develop protocols when an error occurs as a way to reduce the future likelihood of such an error. EHR vendors should facilitate the integration of protocols into the clinical workflow, and education needs to be built around the deployment of clinical protocols so that clinicians understand their rationale.

- **Use technology as a tool to identify and reduce error:** Using technology as a tool will drive improvement in the subdomains of Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Accuracy, and Follow-up. Organizations and clinicians should leverage technology such as AI, machine learning, data visualization, and EHR applications to support analyzing patient data, and taking appropriate follow-up actions that identify near misses, errors, and high-risk patient problems to support timely and accurate diagnoses. EHR and AI vendors should leverage their technology directly to help overcome clinician biases, using forcing strategies and facilitating the deployment of electronic protocols. Technology vendors and educators should provide education on the use of their technology, as the utilization of AI and other technology will become more prevalent in healthcare settings in the future. The use of telemedicine plays an especially important role to increase access to care and specialists in settings where such resources are limited. Organizations should use technology to support performance improvement efforts, such as through the use of e-triggers and other electronic mechanisms for data analysis. Payers, EHR, and AI vendors should collaborate with health systems to understand their clinical needs and create solutions that support using technology as a tool to identify diagnostic errors and deploy interventions to improve patient safety. These solutions include opportunities to identify patients with care patterns that suggest a diagnosis has been missed or that follow-up was not appropriate. There are also opportunities to drive interoperability of data across settings and systems.

When applying these recommendations, it is essential for organizations and stakeholders to measure and evaluate current processes and outcomes in order to drive improvement. To measure and reduce diagnostic errors, as well as to measure and improve patient safety, the Committee recommends the following actions

- **Use patient-reported measures to understand, assess, and improve the role of patients in the diagnostic process:** Measure developers should focus and prioritize measure development on patient-reported measures, such as patient-reported understanding of diagnosis and/or diagnostic uncertainty after discharge, patient-reported perceptions of their input into the diagnostic process, and patient-reported experience with the diagnostic process. Healthcare organizations should assess if patients are empowered to participate as part of the diagnostic team; for example, by measuring the rate of use of interpreter services when English is not a patient's preferred language.

- **Assess the rate of understanding and/or use of protocols, clinical decision support tools, and other electronic tools that support accurate and timely diagnosis:** Recognizing the impacts of technology on the diagnostic process, stakeholders should assess how technology both reduces and contributes to diagnostic errors. Measure developers can focus measure development efforts on assessing the presence, use, and adherence of such protocols that assist with the diagnostic process. Healthcare organizations and clinicians should assess the presence and use of these electronic tools to ensure technology is being appropriately deployed as a tool to reduce diagnostic errors. In assessing the use of technology, stakeholders must also monitor and measure for unintended consequences, such as over adherence to a protocol leading to an increase in a different diagnostic error.

- **Measure the use of specialists, second opinions, and teamwork throughout the diagnostic process:** In measuring these processes, organizations will likely identify opportunities to improve the consultation and second-opinion process to promote efficiency and teamwork. Measure developers can identify opportunities related to measuring the percentage of systems that have protocols for closed-loop communication for test results and relational coordination. Healthcare organizations should share measurement information transparently with staff to create a learning and feedback system.

- **Measure the total cost, time, and/or other impacts of diagnostic odysseys:** Researchers and measure developers can focus efforts on measuring the total cost, time, and/or other impacts of diagnostic odysseys. Measure developers can also develop measures that assess the time to detection of important clinical events and the rate of accurate diagnosis of commonly misdiagnosed conditions. Healthcare organizations and clinicians should engage patients who have undergone diagnostic odysseys to evaluate their experiences with the diagnostic process. When measuring and quantifying the impacts of diagnostic odysseys, stakeholders must share this information with clinicians to support recognition of the wide-ranging effects of delayed or missed diagnoses.

- **Use measurement as a mechanism for continuous quality improvement in the diagnostic process:** Continuous quality improvement is an important concept in healthcare, and is a critical mechanism to continue advancing the science of diagnostic error. Healthcare organizations and leaders should partner with clinicians to understand how to elicit information on delayed diagnoses and subsequent harms based on medical records and electronic data. Medical specialty societies should provide guidance as diagnostic measures are developed, in particular for conditions that are frequently misdiagnosed or those that can lead to serious harm in the event of a diagnostic error. Measurement should also be deployed at a national level to hold facilities and clinicians accountable, such as through the use of pay-for-performance, conditions of participation, or accreditation programs.

- **Measure participation in health information exchanges and other data sharing programs:** To understand how critical information is shared across organizations, measure developers should

focus efforts on identifying the rates of health system participation in health information exchanges and other data sharing programs.

These recommendations for applying the 2017 Measurement Framework, measuring and reducing diagnostic error, and measuring and improving patient safety were informed by the Committee discussions and the development of the Use Cases. The Use Cases included in this report demonstrate how users can apply the Diagnostic Process and Outcomes domain of the 2017 Diagnostic Quality and Safety Measurement Framework to reduce diagnostic errors and improve patient safety in a variety of systems and settings. The Use Cases detail how wide-ranging stakeholders, including, but not limited to clinicians, administrators, patients, payers, professional societies, measure developers, and EHR vendors can take actionable steps to reduce and overcome common types of diagnostic errors.

Although the recommendations apply broadly, different settings and populations may benefit from specific recommendations and actions. For example, in rural settings, stakeholders may consider focusing on the recommendations related to technology-based tools, solutions, and measures. When facing resource constraints, stakeholders can use the potential solutions outlined in the Use Cases to identify which are most feasible at their own organization given organizational resources, context, and other constraints. Stakeholders can refer to the Use Cases for examples of how to implement these recommendations within their own organizations.

Within each Use Case, measurement considerations are included to support diverse healthcare stakeholders in identifying measurement opportunities focused on improving and reducing diagnostic errors. These considerations and approaches align with and build on the prioritized approaches identified in the original 2017 Diagnostic Quality and Safety Measurement Framework. Measure developers can use the concepts and approaches within the Use Cases to develop and test new clinical quality measures, and payers can use these measures in improvement and payment programs to incentivize adoption of diagnostic best practices and improve quality of care. Of note, not all of the measure concepts are based on existing evidence because of a lack of research in this area. However, those in the measure development community would be expected to implement a rigorous measure development process to produce fully formed measures that are linked to outcomes.

Conclusion

Approximately 12 million Americans suffer a diagnostic error each year, and the National Academies of Science, Engineering, and Medicine (NASEM) Committee on Diagnostic Error in Health Care suggested that most people will experience at least one diagnostic error in their lifetime. These diagnostic errors, including missed or delayed diagnoses, can have major safety and care implications for patients and their families.[2]

Building on the 2017 Diagnostic Quality and Safety Measurement Framework, the Committee identified four high priority areas related to diagnostic error that cause patient harm: missed subtleties, communication failures, information overload, and dismissed patients. The Committee developed comprehensive resolutions to these types of diagnostic errors by identifying contributing factors and key implementation solutions to overcome and prevent the errors. Although the Use Cases vary in their topics, focus areas, and clinical settings, the Committee identified actionable, broad-scope recommendations that apply across the Diagnostic Process and Outcomes domain of the 2017

Measurement Framework. These recommendations center around training, teamwork, and technology, and offer a set of recommendations that diverse stakeholders can follow to reduce diagnostic errors and improve the quality of care.

As the healthcare landscape continues to evolve and demands continue to increase, accurate and timely diagnoses remain a critical priority in medicine. Expanding training, building teamwork, and leveraging technology are critical steps in the pathway towards diagnostic safety. Diverse healthcare stakeholders – including clinicians, administrators, patients, EHR vendors, medical specialty societies, payers, and others – must come together to take actionable steps to improve accurate diagnoses and reduce diagnostic errors for the safety of all Americans.

Appendix A: Improving Diagnostic Quality & Safety/Reducing Diagnostic Error: Measurement Considerations Committee Roster

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Appendix B: New Measure Concepts Applicable to the Diagnostic Process and Outcomes Domain

Source	Description	Classification
Chief Complaint Framework	Prescription of over-the-counter or prescription cough medicine for young children with a presenting problem of cough	Diagnostic Accuracy
Chief Complaint Framework	Patients with a presenting problem of dizziness, weakness, or fall injury who receive a falls assessment	Diagnostic Efficiency
Chief Complaint Framework	Effective care and diagnostic process for infants with a presenting problem of fever	Diagnostic Efficiency
Chief Complaint Framework	Use of pelvic ultrasound for patients in early pregnancy with a presenting problem of abdominal pain	Diagnostic Efficiency
Chief Complaint Framework	Use of head CT in patients without focal neurological symptoms with a presenting problem of syncope	Diagnostic Efficiency
Chief Complaint Framework	The proportion of children with a CT scan ordered for a presenting problem of febrile seizure	Diagnostic Efficiency
Chief Complaint Framework	Pediatric patients with a presenting problem of cough and sore throat receiving antibiotics	Diagnostic Efficiency

Source	Description	Classification
Chief Complaint Framework	Rate of missed stroke diagnosis for patients with a presenting problem of dizziness/vertigo with or without headache	Diagnostic Accuracy
Chief Complaint Framework	Rate of missed sepsis diagnosis among patients with presenting problems of fever or upper respiratory tract infection, sore throat, or generalized weakness/fatigue	Diagnostic Accuracy
Chief Complaint Framework	Rate of missed myocardial infarction among patients with presenting problems of chest pain or shortness of breath	Diagnostic Accuracy
Chief Complaint Framework	Patients with a behavioral health presenting problem (e.g., depression, attempted suicide) that are discharged with a structured suicide risk assessment and suicide safety plan	Diagnostic Efficiency
Chief Complaint Framework	Rate of missed spinal abscess diagnoses in patients with a presenting problem of back or neck pain	Diagnostic Accuracy
Trauma Outcomes	Diagnosis and Management of injury in pregnant patients (EAST Guidelines)	Diagnostic Accuracy
Trauma Outcomes	Imaging in adult ED patients with minor head injury	Diagnostic Efficiency
Trauma Outcomes	Delirium Diagnosis	Diagnostic Accuracy
Trauma Outcomes	Delirium Screening	Information Gathering and Documentation
Trauma Outcomes	Use of Glasgow Coma Scale with reporting of all three components (eye, verbal and motor response)	Information Gathering and Documentation

Appendix C: Additions to the Measure Inventory Applicable to the Diagnostic Process and Outcomes Domain

NQF ID or Source	Title	Type	Classification
CMS Quality Measures Inventory	Discouraging use of MRI for Diagnosis of Carpal Tunnel Syndrome	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	Notification to the ordering provider requesting amylase testing in the diagnosis of suspected acute pancreatitis	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	Notification to the ordering provider requesting myoglobin or CK-MB in the diagnosis of suspected acute myocardial infarction (AMI)	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	MRI Lumbar Spine for Low Back Pain	Efficiency	Diagnostic Efficiency
CMS Quality Measures Inventory	Use of Imaging Studies for Low Back Pain (eCQM)	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	Coagulation studies in adult patients presenting with chest pain with no coagulopathy or bleeding	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	Non-recommended Prostate-Specific Antigen (PSA)-based screening in older men	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	New Corneal Injury Not Diagnosed in the Post-Anesthesia Care Unit/Recovery Area	Outcome	Diagnostic Accuracy
CMS Quality Measures Inventory	Appropriate use of imaging for non traumatic shoulder pain	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	Appropriate follow up imaging for non traumatic knee pain	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	Overuse Of Imaging for the Evaluation of Primary Headache	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	Overuse of Diagnostic Imaging for Uncomplicated Headache	Efficiency	Diagnostic Efficiency
CMS Quality Measures Inventory	Appropriate Use of DXA Scans in Women Under 65 Who Do Not Meet the Risk Factor Profile	Efficiency	Diagnostic Efficiency
CMS Quality Measures Inventory	Diagnostic report timeliness, completeness and accuracy -	Process	Diagnostic Efficiency

NQF ID or Source	Title	Type	Classification
	impact on patient outcomes and management		
CMS Quality Measures Inventory	Appropriateness: Follow-up Computed Tomography (CT) Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	Appropriate follow-up imaging for benign adrenal masses	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	Appropriate Use Criteria Mechanism for review, documentation and evaluation for clinical practice improvement	Process	Diagnostic Efficiency
CMS Quality Measures Inventory	Unnecessary Screening Colonoscopy in Older Adults	Efficiency	Diagnostic Efficiency

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