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

FINAL 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: Patients, Families, and Caregivers; Diagnostic Process and Outcomes; 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 and develop this report.

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 four use case topics selected—including missed subtle clinical findings (Use Case 1), communication failures (Use Case 2), information overload (Use Case 3), and dismissed patients (Use Case 4)—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. The solutions within the use cases reflect opportunities for stakeholders to reduce diagnostic error in the subdomains of the Diagnostic Process and Outcomes domain of the 2017 Measurement Framework, allowing for stakeholders to drive improvement in multiple areas—including, Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, Diagnostic Accuracy, and Follow-up. 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. Each use case concludes with a description of the impact of the identified solutions on patient safety, as well as a section on measurement considerations. The measurement considerations highlighted include possible measurement approaches and measure concepts.

This report concludes with comprehensive, broad-scope, actionable, and specific recommendations for applying the Diagnostic Process and Outcomes domain of the 2017 Measurement Framework, and for measuring and reducing diagnostic error. Recommendations for applying the Diagnostic Process and Outcomes domain of the 2017 Measurement Framework highlight implementing quality improvement activities to identify and reduce diagnostic errors from occurring, including specific recommendations related to engaging patients, educating clinicians, developing and deploying clinical protocols, leveraging technology, supporting a culture of teamwork, and improving information sharing. Each recommendation for applying the 2017 Measurement Framework aligns with a specific recommendation for measuring and reducing diagnostic error and improving patient safety. These measurement-focused recommendations are centered around using patient-reported measures; assessing, providing, and obtaining feedback on clinician diagnostic performance and adherence to protocols; evaluating the impact of technology and leveraging technology to reduce errors; measuring communication and teamwork; assessing the appropriate use of laboratory testing and radiology; and, measuring the total cost, time, and impacts of diagnostic odysseys. Each recommendation has related actions for diverse stakeholders to measure and evaluate current processes and outcomes in order to reduce diagnostic error and ultimately improve patient safety.

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; an estimated 12 million Americans will experience a diagnostic error each year in this setting.[2] Diagnostic errors persist throughout 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 Centers for Medicare and Medicaid Services (CMS), 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 Process and Outcomes domain, including specific use cases to demonstrate how the framework can be operationalized in practice, as well as detailed recommendations for measuring and reducing diagnostic error and improving patient safety.

Diverse stakeholders, including healthcare organizations, clinicians, patients, payers, EHR vendors, policymakers, and others, can use the practical guidance and recommendations in this report to apply the Diagnostic Process and Outcomes domain of the 2017 Measurement Framework and to measure and reduce diagnostic errors. 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. Diverse stakeholders can implement the broad-scope, comprehensive recommendations included within this report to apply the Diagnostic Process and Outcomes domain of the 2017 Measurement Framework, measure and reduce diagnostic errors, and measure and improve patient safety.

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.

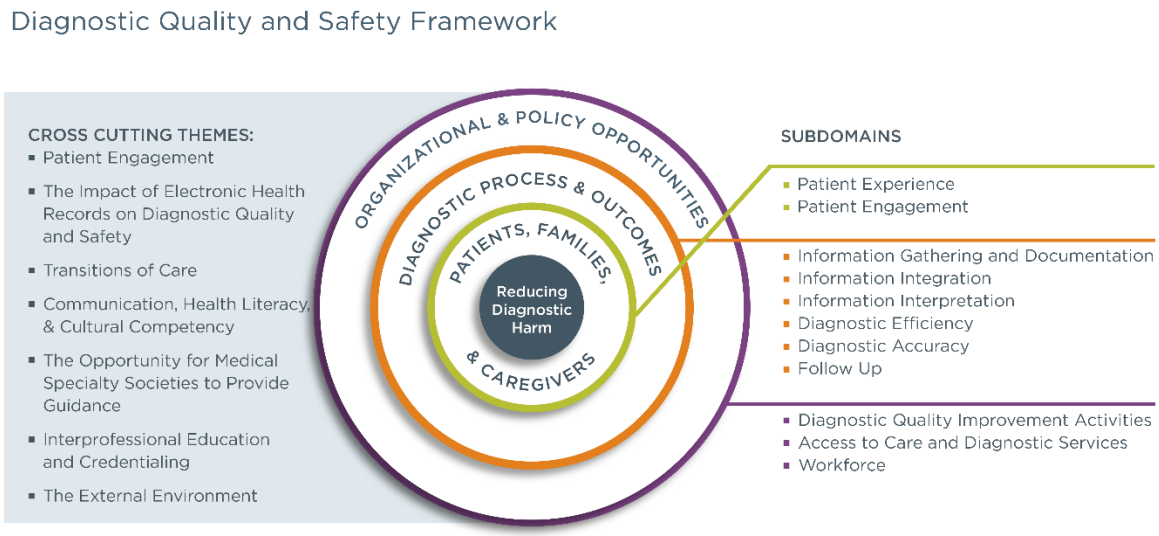
Table 1. Diagnostic Quality and Safety Measurement Framework

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 are as follows:

- 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: 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.[7,8]

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 informational technology (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 (i.e., alert fatigue). 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 the teach-back method.[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 12 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 new measure concepts can be found in Appendix B. Additional measures can also be found in Appendix F of the 2017 *Improving Diagnostic Quality and Safety* report.

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. The use cases then include 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. 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. 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.

As measurement for diagnostic error is an evolving area, the measure concepts and approaches included in the use cases range in the level of research and science. Measure concepts that are earlier in their research stages are best suited for internal quality improvement and can be use on a case-by-case basis, depending on the population served and the individual quality improvement focus areas identified. 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. Any measure concepts included in the measurement considerations section should be fully specified, developed, and tested, including scientific acceptability and feasibility testing, before full implementation, and especially prior to use in an accountability or payment program.

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 them 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. 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. Although the symptoms themselves may not be subtle, their association with the diagnosis

may be considered that way. 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 people 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: **system factors, condition/disease factors, and clinician factors.**

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.[21] 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.[22] Limited interoperability, challenging user interfaces, and the manner in which the EHR displays results and information all present barriers to accurate and timely diagnoses.[22] Lastly, internal quality initiatives related to judicious resource use may impact a clinician's ability to improve diagnostic efficiency. Unnecessary testing and consultations can lead to unintended harm, and certain quality initiatives focused on resource use may impact a clinician's decision to proceed or not proceed with certain diagnostic tests or supportive consults.

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 one of its symptoms 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.

Lastly, the two primary **clinician factors** contributing to these types of diagnostic errors are failures of expertise and cognitive biases.[23] 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 [24] and others finding that errors in clinical reasoning are the dominant explanation.[25,26]

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.[27] 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.[28] 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: [29]

- 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. [30,31,32,33] 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.

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

Assumptions	• Diagnostic errors are complex and 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 missed subtleties. These errors 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	• **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
	  ○ Competing quality initiatives regarding judicious resource utilization
	• **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
	• **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
	  ▪ Implicit bias
	  ▪ Overconfidence
	  ▪ Premature closure bias
	  ▪ Representativeness
	  ▪ Search satisficing

Potential Solution #1	**Employ a teamwork approach and emphasize the value in diverse opinions and clinical teams[34]**

Process	• Engage clinician consultants with specialized expertise
	  ○ Increase access to consultants and specialists through consultations, "curbside" second opinions, or through telemedicine[35]
	  ○ 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 [36]
	• Foster a culture where all team members take shared ownership of the diagnosis
	  ○ 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[37]
	  ○ Create expectations and a safe environment 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 #2	**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][38]) 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 computerized tomography scan (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[39] ○ Deploy AI-enhanced diagnostics to detect subtle symptoms through machine learning or other technologies
Potential Solution #3 ***Process***	**Enhance clinician expertise through education, training, standardized processes, and feedback for learning** • Create policies, protocols, and educational materials 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[40] ○ 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 ○ Perform simulation-based training to ensure clinicians understand new protocols [40] • 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., revisits, adverse events, deaths) ○ Illuminate missed subtleties on specific cases through Morbidity and Mortality reviews[41]

	○ 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[39] • Use metacognitive "forcing" strategies ○ Form diagnostic error checklists that ask the clinician to consider bias and ask, "What else?" before confirming diagnoses[42] ○ Initiate diagnostic time-outs with diagnostic error checklists[39] ○ Create processes that initiate a second opinion once a patient returns for the same complaint multiple times[43]

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 a busy ED with vertigo (i.e., a sensation of movement) and vomiting for three hours since awakening. Of note, the ED has recently been focusing on improving throughput and reducing waiting times. 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 two to three 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 clinician was balancing a busy ED and various competing demands; and his many cognitive pressures were likely exerted by the ED's operational priorities of improving throughput and reducing waiting time, amongst the other normal cognitive load from

managing patients, adhering to guidelines, and using the EHR. 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. While the patient was instructed to follow up with his PCP in two to three days, the ED clinician did not specify a contingency plan with the patient and family to indicate the patient should return sooner if his clinical condition worsens or if his symptoms become inconsistent with the current diagnosis. 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]

There are specific solutions that would have helped prevent this error:

- **Providing education to support clinicians in engaging patients and families as part of the diagnostic team (*from potential solution #3*):** Staff from the patient education department should 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.[36] 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.

- **Creating opportunities to share feedback as a learning mechanism (*from potential solution #3*)**: 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.

- **Engaging clinician consultants with specialized expertise (*from potential solution #1*):** 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 (information technology) 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.

- **Identifying opportunities for novel technology to support identification of subtle symptoms *(from potential solution #2)*:** 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, 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 diagnosis 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.

There are specific solutions that would have helped prevent this error:

- **Creating policies, protocols, and educational materials based on the findings of the quality improvement activities performed (*from potential solution #3*):** 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.

- **Fostering a culture where all team members take shared ownership of the diagnosis (*from potential solution #1*)**: 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.

- **Leveraging the EHR to support recognition of subtle findings (*from potential solution #2*):** 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) as well as 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.

There are specific solutions that would have helped prevent this error:

- **Creating policies, protocols, and educational materials based on the findings of the quality improvement activities performed (*from potential solution #3*):** 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.

- **Using metacognitive "forcing" strategies (*from potential solution #3*):** As protocols are developed, administration could encourage including the use of metacognitive 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.

- **Leveraging the EHR to support recognition of subtle findings (*from potential solution #2*):** 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 (U.K.) are required to review more than 10 times the annual mammograms compared to U.S. 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 U.S. compared to the U.K., 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.[5050] 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. Prior to implementation, measurement approaches and concepts should be fully specified, developed, and tested.

Table 5. Measurement Considerations for Cognitive Error – Missed Subtle Clinical Findings

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 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 • 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	• 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

Measurement Approach	Measure Concepts	Rationale
	paroxysmal positional vertigo [BPPV][59])	

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[38]
	• Possible measure concepts using symptom-disease pairings include:
	  ○ Diagnoses of stroke linked to prior visits for 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
		• 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[38] to understand the potential harms from misdiagnosis

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? 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: **systems factors, condition/disease factors, and clinician factors.**

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.[66]

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.

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.

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.[67]

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.

The use case in Table 6 is focused on opportunities to prevent and overcome diagnostic errors that occur when there are communication failures. It 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

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.
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	• **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
	• **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

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[37]
	  ○ 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
	  ○ 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)
	• 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)
	  ○ Introduce redundancy in interpreting test results through independent reviews by clinicians at various stages in the process from reporting through result interpretation[69]
	• Identify best practices, create procedures and expectations, and deploy clinician education on the use of multiple modes of communication with patients
	  ○ Leverage the EHR to require multiple types of contact information from patients (e.g., multiple phone numbers, email address, mailing address) and ask patients their preferred method and times for communication
	  ○ 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 teach back techniques to support closed-loop communication with patients
	  ○ 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
	  ○ Provide direct-to-patient result reporting and confirm that a patient can access the patient portal when scheduling the initial appointment or before discharge[37]
	  ○ 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 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), who has 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 two to three 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).

There are specific solutions that would have helped prevent this error:

- **Identifying best practices, creating procedures and expectations, and deploying clinician education on the use of multiple modes of communication with patients *(from potential solution #1):*** Administrators can create a policy to ensure that multiple modes of communication (e.g., working phone number, email 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 understand 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.

There are specific solutions that would have helped prevent this error:

- **Assembling 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 a 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.

- **Creating 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 onsite medical interpreters and/or 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]

- **Creating 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 four-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 two to three 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.

There are specific solutions that would have helped prevent this error:

- **Enhancing 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.

- **Creating 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 with 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.

- **Creating 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 one 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 help ensure closed-loop communication and prevent 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. Prior to implementation, measurement approaches and concepts should be fully specified, developed, and tested.

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 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: ○ 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 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	• 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

Measurement Approach	Measure Concepts	Rationale
quality on patient surveys		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 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: **systems factors, condition/disease factors, and clinician factors.**

Systems factors 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 a 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 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. 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.

Several **clinician factors** contribute to these types of errors, with one of the key underlying causes 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]

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

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 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	• **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)
	• **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

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, invasive device usage)
	  ○ Educate clinicians on the capability of EHRs to perform data visualization methods and trend analyses
	  ○ Leverage clinical decision support software as a tool to help synthesize and organize clinically complex or ambiguous information
	  ○ 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
	  ○ Re-evaluate the relevance of EHR notifications on an ongoing basis and/or at repeated intervals after the initial evaluation
	  ○ 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
	  ○ Use simulation training to prepare clinicians for managing situations with high cognitive load and large amounts of information
	  ○ 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 have 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 educational 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 nonspecific 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 her overlooking this finding and making a diagnostic error.

There are specific solutions that would have helped prevent this error:

- **Increasing 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 user experience for entering radiographic reports to ensure all pertinent findings are highlighted in the final impression.

- **Employing 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]

- **Increasing 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.

There are specific solutions that would have helped prevent this error:

- **Enabling 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.

- **Developing 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. For 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.

- **Employing 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.

There are specific solutions that would have helped prevent this error:

- **Enabling 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.

- **Creating 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. Some of these tools could be 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.

- **Ensuring 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 the most important information for clinical decision making.[89] Dashboards and other electronic tools can assist in managing this complex information. For 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. Prior to implementation, measurement approaches and concepts should be fully specified, developed, and tested.

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 manage 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 heard, and he/she is part of the diagnostic team

Measurement Approach	Measure Concepts	Rationale
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, nonspecific, 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: **systems factors, condition/disease factors, and clinician factors.**

Systems factors 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 social determinants of health (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.

Nonspecific 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 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.

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.

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

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 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	• **System Factors:**
	  ○ Lack of interoperability across EHRs
	  ○ Overemphasis 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
	  ○ Nonspecific 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)
	• **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
Potential Solution #1	**Empower patients to raise concerns and share their perspectives**
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 ○ Create contingency plans with clear instructions on returning to medical care if their condition changes or becomes inconsistent with the current diagnosis ○ 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, 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 #2 ***Process***	**Identify opportunities for technology and data to recognize potential diagnostic odysseys** ● 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 clinical decision support software as a tool to help clinicians overcome cognitive biases and minimize over adherence to protocols ○ 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

Potential Solution #3:
 	
Process
	Enhance opportunities for patient engagement through education and training
	
	• 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 ignored

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, 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 nonspecific nature of symptoms of celiac disease also contribute to the diagnostic delay experienced by this patient.

There are specific solutions that would have helped prevent this error:

- **Encouraging clinicians to act early on the concerns voiced by patients and families *(from potential solution #3):*** 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.

- **Inviting patients to be part of the diagnostic team *(from potential solution #1):*** 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 noticed 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.

- **Engaging patients who have experienced diagnostic odysseys to help prevent diagnostic errors in the future *(from potential solution #1)*:** 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.

- **Using data to understand the impacts of diagnostic odysseys *(from potential solution #2):*** 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 nonspecific 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.

There are specific solutions that would have helped prevent this error:

- **Supporting clinicians in overcoming common biases they may limit their ability to hear the perspectives of patients *(from potential solution #3):*** 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 metacognitive forcing strategies and other approaches.

- **Inviting patients to be part of the diagnostic team *(from potential solution #1):*** 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 provide opportunity for feedback on the diagnostic process, questions, and input.

- **Using data to understand the impacts of diagnostic odysseys *(from potential solution #2):*** 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 nonspecific nature of intermittent headaches also contributes to the misdiagnosis.

There are specific solutions that would have helped prevent this error:

- **Supporting clinicians in overcoming common biases that may limit their ability to hear the perspectives of patients *(from potential solution #3):*** 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.

- **Engaging the PFAC *(from potential solution #1):*** Healthcare organizations could engage PFACs to make recommendations aimed at reducing misdiagnosis in vulnerable populations, including those with mental illness or homelessness. PFACs 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, it 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.

- **Inviting patients to be part of the diagnostic team *(from potential solution #1):*** 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. Prior to implementation, measurement approaches and concepts should be fully specified, developed, and tested.

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

Measurement Approach	Measure Concepts	Rationale
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 of homeless patients to care	• 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 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. Within the 2017 Measurement Framework, 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 explain the patient's health problem. 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. To apply the framework, stakeholders should measure diagnostic error using the measures, measure concepts, and measurement opportunities outlined throughout this Report and in the 2017 *Improving Diagnostic Quality and Safety* report. When measuring diagnostic errors, stakeholders should identify in which subdomains they have the greatest opportunity for improvement and reduction of diagnostic error. Stakeholders can then leverage the solutions throughout the use cases and the recommendations for applying the framework. Ultimately, by linking specific errors to recommended measurement approaches and targeted solutions, organizations can drive meaningful change given their own organizational context, resources, and patient populations.

It is also important that approaches to reduce diagnostic error do not merely involve increasing testing rates. Rather, by thoughtfully identifying specific situations where diagnostic testing can be applied in more precise ways, through protocols, education, and other approaches, it is possible to reduce error without increasing aggregate testing. It is also important for measurement approaches to include balancing measures that monitor testing rates. For example, for measures that evaluate the misdiagnosis rates for life-threatening conditions that sometimes have subtle presentations (e.g., pulmonary embolism, subarachnoid hemorrhage, and stroke), it is important to assess the testing rates for these conditions as a measure of the precision of interventions to improve diagnostic accuracy.

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. These recommendations also align with the cross-cutting themes reinforced and identified by the Committee, including: patient engagement; impact of EHRs on diagnostic quality and safety; transitions of care; communication, health literacy, and cultural competency; the opportunity for medical specialty societies to provide guidance; interprofessional education and credential; external environment; and the importance of advancing science in diagnostic error.

When implementing the recommendations, stakeholders must consider which measurement focus areas align with their needs. As measurement for diagnostic error is an evolving area, measure concepts and approaches included throughout this report, both within the use cases and the recommendations, range in their level of research and science. Measure concepts that are in the earlier stages of research are best suited for internal quality improvement and use on a case-by-case basis depending on the population served and individual quality improvement focus areas identified. 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. Any measure concepts used in accountability or payment programs should be fully specified, developed, and tested prior to implementation.

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

1. **Implement quality improvement activities to identify and reduce diagnostic errors from occurring:** Implementing quality improvement activities to identify and remediate diagnostic errors occurring in the healthcare organization/practice will drive improvement in the subdomains of Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, Diagnostic Accuracy, and/or Follow-up depending on the type of error identified. Quality improvement programs should include multidisciplinary teams of clinicians and administrators who work longitudinally to identify errors, their root causes, develop specific strategies to mitigate future errors, and measure the results of improvement activities. When healthcare organizations and clinicians assess and understand the type of diagnostic errors occurring in their facility, they are better able to identify the contributing factors, and develop and deploy targeted interventions included in this report to help improve and prevent the error in the future.

2. **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 facilitating systems to involve patients in the co-creation of diagnostic processes. This should include 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, organizations can create and use 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 an integral 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 telephone or computer software.

3. **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 Information Integration, Diagnostic Efficiency, and Diagnostic Accuracy. 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 that are especially prone to diagnostic error, such as chest pain or dizziness, to help train clinicians on how to prevent common diagnostic errors. Education and training can also include information on 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.

4. **Educate clinicians about the science of diagnostic error, including practicing clinicians as well as students in undergraduate, graduate, and post-graduate training programs:** Deploying education on the diagnostic error and ways to reduce errors for practicing clinicians, as well as students, will drive improvement in the subdomains of Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, Diagnostic Accuracy, and Follow-up. A Consensus Curriculum project led by the Society to Improve Diagnosis in Medicine (SIDM) recently identified 12 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.

5. **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 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 will reduce the presence of a single clinician's bias in the diagnostic process.[111]

6. **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 help remediate errors.

7. **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 future likelihood. EHR vendors should develop EHRs with the capabilities for organizations and practices to facilitate the integration of their clinical protocols and workflows within the EHR; and education needs to be built around the deployment of clinical protocols so that clinicians understand their rationale.

8. **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. Additionally, clinicians should leverage the use of wearable diagnostic devices, where evidence

supports their use, for continuous monitoring to improve diagnostic accuracy as well as continuously evaluate emerging diagnostic testing technology to improve the diagnostic process.

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:

1. **Use measurement as a mechanism for continuous quality improvement in the diagnostic process and to improve diagnostic outcomes:** Continuous quality improvement is an important concept in healthcare and is a critical mechanism to identify and prevent diagnostic errors. A central part of the continuous quality improvement process is the use of measurement. Organizations, healthcare administrators, and clinicians should use specific healthcare quality measures and measure concepts to assess current diagnostic processes and outcomes. These data should be used to inform interventions targeted at specific subdomains of errors and measure their effectiveness over time. Measures should be designed to be specific, relevant, and actionable. Since the goal is to drive better care for patients and reduce diagnostic errors, stakeholders should ideally measure outcomes of care. Alternatively, when outcome measures are not feasible, stakeholders should measure processes and/or structures that are tightly linked to improved outcomes which can subsequently drive local quality improvement.

   One particular approach to diagnostic error measurement and quality improvement that follows Donabedian's Structure-Process-Outcomes model is described in Singh and Sittig's Safer Dx Framework.[112] This approach includes the complex, adaptive sociotechnical dimensions where a diagnosis occurs (i.e., the structure), the process dimensions where a diagnosis evolves outside of a single clinician visit (i.e., the process), and the outcomes of a correct and timely diagnosis (i.e., the outcome).[113] In this approach, there is a continuous cycle of measurement, organization learning, and improved collaboration, which ultimately leads to safer diagnoses and improved outcomes.

   Healthcare organizations need to invest in deploying teams that engage in clinical quality improvement and provide systems to measure errors across a variety of data sources including patient- and clinician-reported errors and objective data sources, such as the EHR and health plan claims, to detect errors. In particular, 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. One example of this is the Geisinger Health System that has identified a five-point action plan for learning and exploration of diagnostic excellence (LEDE).[114] This involves: 1) implementing a virtual center that identifies risks and prioritizes interventions across departments, 2) participating in diagnostic research to translate evidence into practice, 3) focusing on measurement, 4) engaging clinicians in activities for improving diagnosis, and 5) developing a culture of accountability. Another approach for measuring and monitoring safety is used by the National Health System in the United Kingdom. This approach involves five elements: 1) looking into the past for safety events, 2) assessing the reliability of diagnostic processes, 3) focusing on operations and whether care is currently safe, 4) anticipating future safety events, and 5) integration and learning, ensuring that the system is responsive.[115]

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.

2. **Integrate patients into the diagnostic process and use patient-reported measures to inform quality improvement and reduce diagnostic errors:** To support accurate and timely diagnosis, clinicians must develop partnerships with patients to engage them in improving the diagnostic process. These partnerships are critical in all patient encounters and diagnoses, but are especially important in preventing, measuring, and reducing diagnostic errors related to communication failures, information overload, and dismissed patients. Moreover, assessing the role of patients and integrating patients into the diagnostic process in meaningful ways will support improvement in various subdomains related to diagnostic error, including Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, Diagnostic Accuracy, and Follow-up.

   Clinicians must make deliberate efforts to engage patients, families, and caregivers as they advance through the diagnostic process. Patients and families are critical partners in sharing key information about their own health condition and also informing how the diagnostic process itself can be improved to reduce diagnostic errors. In today's healthcare environment, patients often receive care from multiple clinicians across multiple settings. Gathering information directly from a patient, family, or caregiver may be the most optimal way to measure communication quality and avoid possible diagnostic errors in a fragmented system and/or when only the patient is aware of a miscommunication across clinicians and settings.

   Empowering patients to report errors can be a key step in the measurement process. Organizations should consider developing systems for patients to be able to report errors that occur or collecting information from patients about whether errors have occurred. Because most organizations have not developed such a process, opportunities exist for researchers to identify the best ways to seek this information from patients. However, information, particularly when collected systematically, provides a useful way to prioritize activities to remediate those

errors though clinical quality improvement. This may involve reporting processes through multiple modes including phone, email, or through patient portals. In particular, the presence of patient portals as a two-way communication device is an opportunity to include patients as part of the team, allowing them to see their results and help participate in the interpretation of test results.

Healthcare organizations should assess if patients are empowered to participate as part of the diagnostic team. Organizations can use NQF #0166 *Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)* surveys to evaluate the patient experience with communication with the healthcare team about medications and their discharge and care transition plans. Such surveys could be used to assess whether diagnostic errors have occurred. Additionally, organizations can be measured on whether they have patient portals and among those that do, whether their patients participate in them. As a more specific measure of patient communication, organizations can measure the rate of use of interpreter services when English is not a patient's preferred language. Organizations can use NQF #1821 *Patients receiving language services supported by qualified language services providers,* which assesses the percentage of limited English-proficient (LEP) patients receiving both initial assessment and discharge instructions supported by assessed and trained interpreters or from bilingual providers and bilingual workers/employees assessed for language proficiency. While patient-reported outcomes are an emerging science, organizations need to remain engaged in the evolution of and innovations in this area. 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 and barriers to participation in the diagnostic process, and patient-reported experience with the diagnostic process.

3. **Assess and provide feedback on clinicians' diagnostic performance and adherence to diagnostic protocols, and obtain clinician feedback to optimize diagnostic processes and outcomes:** Deploying education and training to students and practicing clinicians on the science of diagnostic error, common types of diagnostic errors, and diagnosis-related competencies can decrease diagnostic errors. In addition, delivering education on specific diagnostic errors, and measuring diagnostic performance and diagnostic protocol adherence may improve Information Integration, Diagnostic Efficiency, and Diagnostic Accuracy. As clinicians learn more about the science of diagnostic errors and contributing factors, clinicians may improve in the subdomains of Information Gathering and Documentation and Information Interpretation as well.

   Protocols, clinical decision support tools, and other electronic diagnostic tools serve as cognitive forcing strategies that, when used appropriately, guide a clinician through specific diagnostic steps and processes. These tools may help reduce diagnostic errors by reducing the risk of clinicians missing a subtle or uncommon, yet significant, clinical sign. Healthcare organizations should measure adherence of protocols that exist with the diagnostic process. Organizations can use chart review to measure the rate of protocol use for cases that fall under a particular clinical syndrome (e.g., chart review of chest pain cases that used the HEART score). To operationalize this, organizations should identify which clinical syndromes currently have protocols, clinical decision support tools, and other electronic diagnostic tools in place already. Conducting chart,

image, and/or video review can identify cases where protocols and/or decision support were not adhered to and will support sharing this information with clinical teams. Organizations may also consider using these data and measures as part of the ongoing professional practice evaluation (OPPE) of staff. Measure developers can focus on related measure development opportunities and prioritized measure concepts, including evaluating compliance of existing protocols with e-trigger tools.

Healthcare systems can focus on assessing clinician performance after education and training is deployed through post-training evaluations, assessments during simulations, and/or through annual continuing education/competency assessments. Opportunities also exist for measure developers to assess whether organizations have implemented such training, and whether it has been effectively integrated into clinical practice.

When assessing clinician performance and adherence to protocols (e.g., rate of clinical decision support used), organizations must also share feedback with clinicians to support further reduction of diagnostic error. When leadership shares feedback with clinicians on diagnostic performance and adherence to protocols, they are not only supporting transparency, but the information sharing is an intervention within itself to drive improvement. To provide this feedback, organizations could include a dashboard that assesses clinician-level adherence to protocols within the EHR or actual rates of diagnostic errors (i.e., misdiagnosis) or other diagnostic issues identified (e.g., delays in diagnoses) through the EHR, e-trigger tools, or chart review. As an example, organizations may have protocols in place that require a 12-lead electrocardiogram for non-traumatic chest pain to reduce the risk of misdiagnosis of heart attack. To measure the use of these protocols, organizations could use NQF #0090 *Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain*. Additional protocol-related measures exist for other clinical presentations, such as NQF #0577 *Use of Spirometry Testing in the Assessment and Diagnosis of Chronic Obstructive Pulmonary Disease (COPD)* to assist in the diagnosis of COPD. Measure development opportunities also exist to support measuring clinician feedback, such as clinician-reported measures on receiving feedback on diagnostic performance and adherence to protocols.

While providing feedback to clinicians on diagnostic performance and protocol use is critical, so is obtaining feedback directly from clinicians and frontline staff on these processes. Healthcare administrators and leadership should engage clinicians in improving this feedback loop to ensure that the correct measures are chosen, dashboards are useful and clear, protocols are designed properly, and that education is delivered in an appropriate manner to optimize diagnostic performance. As the science of providing feedback on diagnostic performance as well as protocol adherence continues to evolve, organizations will also need to learn and improve organizational learning and improvement in their processes of delivering feedback to clinicians and developing interventions to optimize diagnosis, in particular with balancing overdiagnosis and underdiagnosis.

4. **Evaluate the impact of technology on diagnostic error and leverage technology to improve an organization's ability to detect and reduce diagnostic errors:** Recognizing the impacts of the technology on the diagnostic process, measure developers, and other healthcare stakeholders,

should assess how technology itself both reduces and contributes to diagnostic errors. Since technology is a powerful tool for improving diagnostic processes and outcomes, measuring its impact and leveraging technology to support detection of diagnostic errors offers an opportunity for improvement related to the subdomains of Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, Diagnostic Accuracy, and Follow-up.

Healthcare organizations should assess the usability of the EHR by measuring clinician-reported assessments of usability and addressing specific issues that arise. Healthcare organizations can also measure the presence of data visualization methods within the EHR to assess if their current EHR assists the clinical team with displaying and managing complex clinical information and if there are opportunities to improve usability. In assessing the use of technology, stakeholders must also monitor and measure for unintended consequences, such as over adherence to protocols leading to an increase in a different diagnostic error. While clinical decision support tools and AI also have the potential to decrease diagnostic errors, developers of these tools should evaluate their ability to assist clinicians in diagnosing uncommon diseases that present in atypical ways.

Organizations and stakeholders can leverage technology to detect diagnostic errors across settings. While e-trigger tools are still at a research stage, they may be powerful ways to identify and remediate diagnostic errors in real time. For example, an e-trigger tool may identify if an important clinical finding, such as radiographic diagnosis of cancer, was not followed up by additional diagnostic testing or clinician visits. Measure development opportunities exist to evaluate the proportion of diagnoses where an e-trigger tool is used.

Another way to leverage technology to reduce diagnostic error is to measure participation in health information exchanges and other data sharing programs. As patients increasingly receive care in various settings, data sharing and open communication during the diagnostic process become even more essential. If organizations do not have data sharing infrastructure in place, patients may be more likely to experience diagnostic errors related to communication failures, missed subtle clinical findings, and dismissed patient concerns. Processes must be in place to support data and information sharing across clinicians and settings in a HIPAA compliant manner.

Measuring the current use and limitations of interoperability of health information and information sharing across settings will help reduce communication issues and support technical vendors in developing future interoperability to reduce diagnostic errors. To evaluate if critical information is shared across organizations, measure developers should focus efforts on measuring the interoperability of health information technology. One existing measure to assess EHR interoperability is NQF #0489 *The Ability of Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data Elements*, which assesses the ability of an organization's EHR to have direct electronic transmission of data from one or more laboratories. Additional measure development opportunities include assessing the presence of interoperability and data sharing across EHRs and communities, and identifying the rates and percentages of health system participation in health information

exchanges and other data sharing programs, as sharing of information across settings improves the ability of clinicians to consider all information in caring for patients and reducing diagnostic errors. In NQF's 2016 report *Identification and Prioritization of Health IT Patient Safety Measures,* several measure concepts were proposed to assess interoperability and usability, including measuring the number of times diagnostic test results were not available, transmitted or displayed for a clinician or patient group as expected as a result of a problem at the interface of two different clinical HIT systems, and the extent to which meaningful external data is available to make diagnosis or management decisions.

5. **Measure the use of and communication between specialists, second opinions, and teamwork throughout the diagnostic process:** The healthcare system is complex, and clinicians consistently engage with multiple clinicians and consultants from subspecialties over the course of a single patient's diagnostic journey. The advancements in testing and imaging over the past several decades have enabled clinicians to obtain increasing amounts of data to inform the diagnostic process. As clinicians order more diagnostic tests, they must communicate and coordinate with more individuals to facilitate testing and follow-up on results, often across care settings and health systems. The communication and coordination of clinicians play an integral role in accurate and timely diagnoses, and measuring these interactions will enable an organization to identify improvement opportunities related to Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, Diagnostic Accuracy, and Follow-up. In particular, measuring and understanding these communication and teamwork processes among clinicians will help reduce systematic errors related to communication failures, as well as cognitive errors related to missed subtle clinical findings and clinician biases.

   In measuring the use of specialists, second opinions, and teamwork, organizations should identify opportunities to improve the consultation and second-opinion process to promote efficiency and teamwork, particularly when it comes to diagnoses that are prone to error or when a misdiagnosis may lead to a poor patient outcome. This is particularly relevant in rural settings where specialists may be less frequently available. As an example, acute stroke care is often challenged in rural settings by lack of presence of a neurologist to help make decisions regarding thrombolytics or other advanced stroke treatments. This type of care can be facilitated by the presence of a telemedicine program to facilitate immediate access to neurology consultation, which could serve as a potential measure concept of quality care for measure developers to explore.

   The timely and thorough follow-up on laboratory and radiology results is also critical, and without good processes and supports in place for this, diagnostic errors related to communication failures may occur. When ordering laboratory tests and radiology studies, clinicians must ensure closed-loop communication occurs so that results and next steps are properly shared to all pertinent care team members and to the patients themselves. A lack of follow-up on test results may lead to delayed diagnoses or patients undergoing repeat tests or imaging, particularly when information on reported tests results is unavailable across settings. To support closed-loop communication, healthcare organizations must measure how information is shared across clinicians when ordering, performing, and following up on radiology

and laboratory results. Organizations can use existing measures that evaluate closed-looped communication processes, such as NQF #0645 *Biopsy Follow-Up*, which allows for the assessment of new patients whose biopsy results have been reviewed and communicated to the primary care or referring physician and patient by the physician performing the biopsy. Organizations can also use NQF #0491 *Tracking of Clinical Results Between Visits* to understand the extent to which a provider uses a certified/qualified EHR to track pending laboratory tests and diagnostic studies. This includes provider reminders when clinical results are not received within a predefined timeframe, which helps support follow-up and closed-loop communication. Measure developers can focus measure development efforts on assessing the appropriate use of laboratory and diagnostic testing and appropriate communication of test results and sharing of laboratory testing and radiology information across settings.

Furthermore, opportunities exist to measure care coordination and teamwork across settings. For example, NQF #0291 *Emergency Transfer Communication Measure* assesses the proportion of patients transferred to another healthcare facility whose medical record documentation indicated that required information was communicated to the receiving facility prior to departure or within 60 minutes of transfer. To measure the presence of teamwork and effective hand-off procedures, organizations should audit charts to evaluate the proportion of pre-specified "high-risk findings" where verbal handoffs between clinicians occurred. For example, organizations can measure whether a verbal handoff occurred for high-risk radiographic diagnoses, such as aortic dissection or pulmonary embolism which require immediate treatment between a radiologist and a treating clinician. Another way healthcare organizations can measure the use of specialists and teamwork is to use existing disease-specific quality measures that incorporate specialized exams being performed with documented communication to the physician who manages the ongoing care of the patient (e.g., NQF #0089: Diabetic Retinopathy *Communication with Physician Managing Ongoing Diabetes Care* or NQF #0045: Osteoporosis *Communication with the Physician Managing Ongoing Care Post-Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older)*. Although current measures focus on documentation of communication occurring, to measure effective communication between clinicians and stakeholders, measures should focus on the content of the communication, ensuring a thoughtful dialogue occurs to convey essential information.

Measures of relational coordination, such as the Coordination of Care Index (COCI), which focus on coordination and communication of teams, can serve as a proxy for measuring if the entire clinical team is successfully coordinating care across clinicians and transitions in care. Teamwork and coordination of care are critical components of an accurate diagnosis, as communication errors and incomplete information lead to inaccurate or delayed diagnoses. Additionally, using team-based approaches to diagnosis, such as second opinions and expert consults, may help reduce the likelihood of a single clinician's biases closing off potential diagnostic pathways and/or dismissing patient concerns and perspectives. Prioritized measure concepts include assessing when team-based approaches are initiated, such as measuring for the presence of a protocol for escalation of the diagnostic approach (e.g., second opinions, consults, and/or additional testing) for patients with continuous undiagnosed symptoms). 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 results transparently with staff to create a learning and feedback system. In measuring the use of specialists, second opinions, and teamwork, balancing measures are also important to ensure that clinical teams are using diagnostic resources appropriately and following established protocols.

6. **Assess the appropriate use of laboratory testing and radiology during the diagnostic process:** Clinicians often use laboratory and radiology testing as mechanisms to confirm or rule out a diagnosis. Despite increased availability of diagnostic tests, clinicians must continue to thoughtfully order the appropriate test in the context of a patient's entire care process. When considering the appropriate use of testing, clinicians and measure developers must be aware that the term "appropriate" is bidirectional, and thus includes a desire to reduce over testing as well as undertesting. Measuring the use of laboratory testing and radiology enables an organization to improve their processes and outcomes related to the subdomains of Diagnostic Efficiency, Diagnostic Accuracy, and Follow-up.

   While misdiagnoses may be caused by a test not being ordered, clinicians sometimes may overuse diagnostic tests. When this occurs, clinicians and organizations experience increased costs and resources, and patients experience unnecessary burden, costs, worry, and treatment. Additionally, the overuse of testing may also result in additional testing due to incidental findings and patient anxiety through the workup process. Healthcare administrators and clinicians should implement programs that support using evidence-based diagnostic tests that are free from harm, truly necessary, and not duplicative of other tests[116]. Organizations and clinicians can leverage existing tools, such as those aligned with the Choosing Wisely program, to support appropriate use of testing.[117]

   Organizations and stakeholders can measure appropriate test use through protocol adherence as described in the recommendations above, or more broadly, through measures of testing rates and balancing that with measures of misdiagnosis. To understand current usage of laboratory and radiology diagnostic resources, healthcare organizations can assess the appropriate use of laboratory testing and radiology by measuring imaging and radiology for specific conditions.

   Of note, promulgating measures of misdiagnosis may lead to an increase in the use of diagnostic resources. To evaluate the unintended consequences of quality improvement efforts focused on identifying, measuring, and reducing diagnostic errors, organizations should use balancing measures to evaluate over testing, overuse, and incidental findings. Using these types of balancing measures will help ensure clinical teams are using diagnostic resources appropriately while following established protocols. For example, appropriate use can be measured by assessing imaging rates for headache, abdominal pain, or cancer screening (e.g., CMIT ID 2553: Overuse of Imaging for the Evaluation of Primary Headache, CMIT ID 2539: Appropriate Follow Up Imaging for Incidental Abdominal Lesions, NQF #0508 *Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms*, and NQF #0389 *Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients*).

7. **Measure the total cost, time, and/or other impacts of diagnostic odysseys:** Patients may experience diagnostic delays through long process of often iterative testing, also called a "diagnostic odyssey" that ultimately lead to a rare or complex diagnosis. These odysseys can have wide-reaching impacts on patients, families, clinicians, and healthcare organizations, including costs, time, and other impacts (e.g., excess biopsies and testing, complications from diagnostic procedures). Measuring the impact of these diagnostic odysseys provides an opportunity to identify and improve diagnostic processes and outcomes across all subdomains, including Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, Diagnostic Accuracy, and Follow-up.

   Diagnostic delays and/or odysseys can lead to harm from failure to treat the correct diagnosis or adverse effects from unnecessary treatment related to an incorrect diagnosis. Healthcare organizations and clinicians should engage patients who have undergone diagnostic odysseys to evaluate their experiences with the diagnostic process. Currently, there is a paucity of measures that exist to capture the extent or effect of diagnostic odysseys on patients. In addition, there is little science that describes how long it should take to diagnose a rare condition, and when a diagnostic process turns into an odyssey. Measure developers can focus measure development efforts on assessing the total cost, time, and/or other impacts of diagnostic odysseys through measuring diagnostic processes and defining specific time thresholds for what constitutes an odyssey for specific conditions.

   Measurement opportunities exist for developers to develop measures that assess the time to detection of important clinical events and the rate of accurate diagnosis of commonly misdiagnosed conditions. When measuring the time to diagnosis, prioritized measure concepts may include measuring the amount of days from the original, related patient chief complaint or related diagnosis until a final, accurate diagnosis occurs. To assess rates of delayed diagnosis, measure developers can develop measure concepts that assess delay in action upon critical action lab values and the time and/or number of visits from first symptom to diagnosis for conditions that commonly result in diagnostic odysseys (e.g., celiac disease and rare cancers). To assess the health impacts of diagnostic odysseys, developers can also assess the frequency of late-stage or emergency presentations in patients who have sought care before (e.g., late-stage or emergency cancer presentations for a patient who has visited the clinic multiple times) and healthcare organizations can conduct root cause analyses of delays to identify solutions to remediate identified problems. 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.

Figure 2. Summary of Recommendations

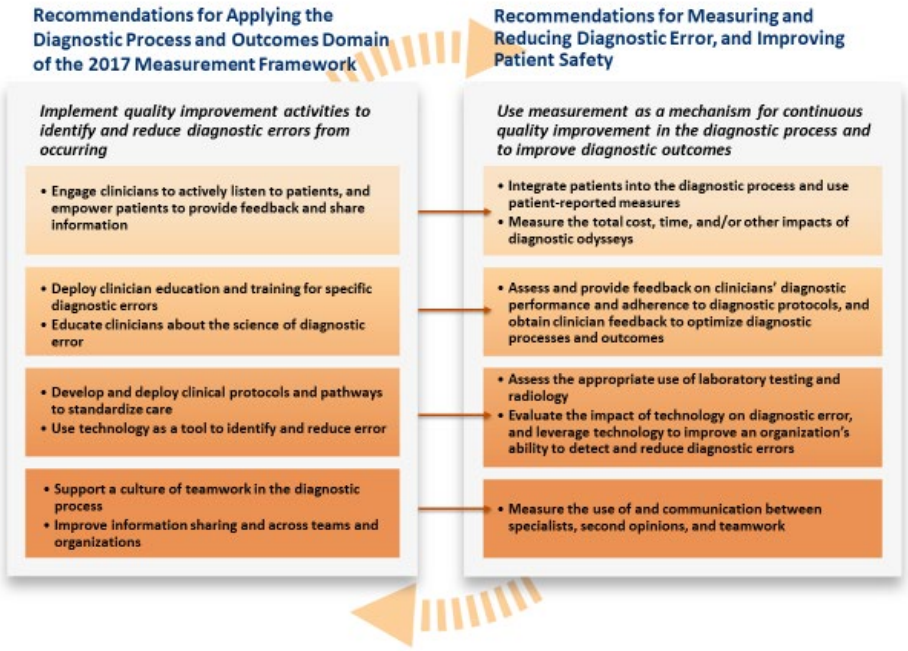


Figure 2 depicts the relationship between the recommendations for applying the Diagnostic Process and Outcomes Domain of the 2017 Measurement Framework and the related recommendations for measuring and reducing diagnostic error and improving patient safety. These recommendations for applying the 2017 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 stakeholders 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, this 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 offer a set of actions that diverse stakeholders can take to apply the Diagnostic Process and Outcomes domain of the 2017 Measurement Framework, and to measure and reduce diagnostic errors, ultimately improving the quality of care patients receive.

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 and NQF Staff

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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
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

Source	Description	Classification
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

The measures included below are additions to the measure inventory. Additional measures can also be found in Appendix F the 2017 *Improving Diagnostic Quality and Safety* report.

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

NQF ID or Source	Title	Type	Classification
CMS Quality Measures Inventory	Diagnostic report timeliness, completeness and accuracy - impact on patient outcomes and management	Process	Diagnostic Efficiency
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

Appendix D: Public Comments

For Use Case 1: Cognitive Error— Missed Subtle Clinical Findings, are there any additional causal factors or challenges that should be included?

Commenter Name	Comment	Response
Nicholas Kuzma St. Christopher's Hospital for Children	Provide education to support clinicians in engaging patients and families as part of the diagnostic team: Contingency plan. The physician made a diagnosis that turned out to be incorrect and it took the family many hours to return to medical attention. Only instructions given were to follow up with PMD in 2-3 days. Patient may return sooner if specific contingency plan was provided using "if... then..." language. for example, "I think the best diagnosis is labyrinthitis. However, if [something] happens, then you should return to the ED as that is not consistent with this diagnosis".	Thank you for your feedback. We have included information about creating contingency plans as a solution to address the challenges outlined in the Use Case 1.
Bob Hussey RGH Health Consulting	Wolters Kluwer supports the numerous references in the draft report that cite CDS as a tool to improve clinical decision-making and reduce diagnostic error. For example, increasing real-time access to diagnostic decision support systems can help a clinician understand the full clinical picture, particularly symptoms that may be subtle (page 17 of the report). An electronic protocol and checklist could be deployed in the electronic health record (EHR) to help treat patients with a chief complaint of vertigo (page 19). CDS can also be used to suggest diagnostic alternatives, applied across a broader range of complaints and findings (page 22). While these references properly give CDS its due, such software can also assist in Use Case #1 to enhance clinician expertise through education and training (page 15). Regular use of Wolters Kluwer's UpToDate software, for example, may qualify clinicians for continuing medical education credits.	Thank you for your comments. We appreciate your thoughtful feedback on the recommendations in the report.

Commenter Name	Comment	Response
Brenna Rabel **Battelle Memorial Institute**	In general, the use cases provide reasonable illustration of some types of diagnostic errors and the contributing factors leading to those errors. However, while the report lists Diagnostic Efficiency as a Diagnostic Process and Outcome subdomain, it does not provide enough discussion on competing national quality initiatives regarding judicious resource utilization (i.e., Choosing Wisely) and control of the cost of medical care. It is important to acknowledge that minimizing diagnostic error to the level of zero may not be achievable or even regarded as the sole driver of quality in the current context. Clinicians and systems, in practice, are often as concerned by the risks/costs of over-testing and over-consulting as they are of the risk of diagnostic error. For example, patients with small sub-segmental pulmonary emboli who are diagnosed with acute pulmonary embolism and placed on long term anti-coagulant medications (when they may not have been needed) may experience another type of unintended harm – unnecessary exposure to radiation, risk of anticoagulation, and increased healthcare cost following an accurate diagnosis of an insignificant pathology. Overall, the report should acknowledge this real-world balance that exists in a clinician's cognitive framework regarding the risk of missed diagnosis with risks of over-testing and over-diagnosis. Failure to address this concept risks missing a major driver of diagnostic error, i.e. the conscious (and perhaps conscientious) choice to not chase a rare diagnosis or unusual presentation.	Thank you for your feedback. We have expanded the causal factors in Use Case 1 to include competing quality initiatives regarding judicious resource utilization. We have also included additional information regarding competing demands as a contributing factor to the first snapshot in Use Case 1.

For Use Case 1: Cognitive Error— Missed Subtle Clinical Findings, do the solutions effectively address the casual factors and challenges in an actionable and specific way?

Commenter Name	Comment	Response
Bob Hussey **RGH Health Consulting**	Wolters Kluwer supports the development of a new measure related to the rate of clinical decision support use, but with some changes from what is proposed in the draft report.	Thank you for your feedback. We have modified the language in the measure concept about the rate of clinical decision support in Use Case 1.

Commenter Name	Comment	Response
	That measure concept (page 24) currently reads as “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.” As drafted, we are concerned such a measure would only capture use of CDS triggered by an alert. Any measure that tracks CDS use should encompass both so-called “push” technology, in which a CDS alert is triggered based on input into the EHR, and “pull” technology, in which the clinician affirmatively makes the decision to consult CDS at any point in the patient consultation or diagnostic process. UpToDate and other clinical knowledge systems are examples of “pull” technology, and given the more than 80 research studies that associate the use of such systems with improved outcomes, they should be included in any new quality measure tracking use of CDS. We therefore recommend the final report edit the new measure concept on page 24 to simply read “rate of clinical decision support use.” This would encompass all types of CDS, and reflect all manners of how a clinician may interact with the software. If the Committee feels the measure concept should be more prescriptive, it might also read “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	

Commenter Name	Comment	Response
	the EHR or for cases when a clinician consults with a clinical decision support tool to help answer a clinical question." We prefer the simpler, shorter version. We also support development of a process measure that tracks rate of protocol use that fall under a particular syndrome (page 23).	

For Use Case 2: System Error—Communication Failure, do the solutions effectively address the casual factors and challenges in an actionable and specific way?

Commenter Name	Comment	Response
Bob Hussey RGH Health Consulting	We agree patients should be empowered to play a more active role in the diagnosis of their condition. Use Case #2: Systems Error – Communications Failure makes a compelling case that one of the solutions is to engage patients as active partners in information communication and follow-up. Integral to this is for clinicians to use education materials to support patients participating as active partners in diagnosis and follow-up (page 29). Such materials can also be integrated into the EHR and discharge workflow (page 32). We also agree that through education about their condition, patients can help their care team avoid information overload issues by being more fully engaged in the diagnostic process (i.e. understanding the diagnostic tests being performed or when certain diagnoses have been ruled out (page 42)).	Thank you for your comments. We appreciate your thoughtful feedback on the recommendations around patient empowerment, education, and engagement.

Bob Hussey RGH Health Consulting	Time is a critical factor in successfully diagnosing many diseases in which rapid progression of the underlying condition can impact the range of treatment options and the eventual outcome. As such, we strongly agree with those measure concepts cited on page 37 of the draft report that track the rates of delay in acting upon critical action lab values, the time or number of visits from first symptoms to diagnosis of various cancers, the number of missed opportunities in diagnosis antecedent to cancer diagnosis, the frequency of late-stage or emergency cancer presentations (all found on page 37). Measures that utilize patient-reported data also merit development, including patient-reported understanding of diagnosis and/or diagnostic uncertainty after discharge (page 37).	Thank you for your comments. We appreciate your feedback on the measure concepts.

For Use Case 3: Cognitive Error—Information Overload, do the solutions effectively address the casual factors and challenges in an actionable and specific way?

Commenter Name	Comment	Response
Bob Hussey RGH Health Consulting	In Use Case #3, Cognitive Error – Information Overload, we recommend adding CDS software as a solution to help synthesize and organize clinically complex or ambiguous information that a clinician may encounter when addressing a difficult diagnosis (page 40).	Thank you for your feedback. We have expanded the solutions outlined in Use Case 3 to include the use of clinical decision software to help organize and synthesize clinically complex or ambiguous information that clinicians may encounter.

Commenter Name	Comment	Response
Bob Hussey RGH Health Consulting	In Use Case #3: Cognitive Error – Information Overload, alert fatigue is cited as a possible contributor to diagnostic error (page 38). We agree. The draft report alludes to a best practice we strongly recommend to clinicians and developers when configuring any alert system (page 41). Each institution should have a committee responsible for configuring alert filters to achieve a suitable balance of precision and recall. Without any filter settings, too many alerts would be generated, which could result in important alerts being missed (i.e. alert fatigue). If filter settings are too restrictive, some important alerts could be filtered out, possibly compromising patient safety. The decision on how to configure the alert filters should be revisited at least annually. After the initial implementation, the institution should review both alert log data and adverse event data on a regular basis to see if refinements should be made to the filter settings.	Thank you for your feedback. We have expanded the current solutions in Use Case 3 to reiterate that evaluating EHR notifications and identifying opportunities to increase the clinical salience of the notifications should be an ongoing activity that is reevaluated after initial implementation.
Bob Hussey RGH Health Consulting	For their final report, NQF and the Committee may want to review a recent study published this year that provides additional insight into the performance of medication alert software.[1] In the study, researchers reviewed whether hospital CPOE EHR systems correctly generated an alert, warning, or soft or hard stop after a test order had been entered that could have caused a serious adverse drug event (ADE). While performance of both basic and advanced CDS medication alerts improved over the study's 10-year period, there remained room for improvement in all categories. In addition, there was significant variability across and within EHR systems. The authors attribute the lackluster results to variations in how the hospital implemented the software, whether customization was involved, the technology acumen of the hospital staff, and the organization's safety culture. In one instance, a flawed process was cited when hospitals overly relied on dispensing pharmacists to avoid therapeutic duplication contraindications. The study includes recommendations for improving medication	Thank you for your feedback. We appreciate the information you have provided.

Commenter Name	Comment	Response
	alert software performance, several of which may help reduce diagnostic error. Though it is more common for medication alerts to be triggered during treatment rather than diagnosis, alert fatigue can contribute to missed or ignored alerts related to diagnosis. The study recommendations include hospital adoption of annual and periodic CPOE safety evaluations, and greater sharing between hospital and EHR vendors of best practices for safety and software implementation to lessen variability in both areas. We agree with these recommendations. We also recommend that more attention be given to incentivize hospital systems to adopt advanced CDS, which can help avert ADEs. Similar incentives should be considered for EHR vendors. At present, patient safety gaps may exist not because of faults in the available CDS but because of failure to adopt and optimally deploy existing capabilities. *[1] Classen, David C., MD, MS et al National Trends in the Safety Performance of Electronic Health Record Systems from 2009 to 2018, JAMA Network Open. 2020;3(5):e205547. doi:10.1001/jamanetworkopen.2020.5547*	
Bob Hussey RGH Health Consulting	As discussed in an earlier comment, time is a critical factor in successfully diagnosing many diseases in which rapid progression of the underlying condition can impact the range of treatment options and the eventual outcome. We therefore agree with the measure concept cited in the draft report on page 48 that tracks the time it took to detect an important clinical event such as sepsis.	Thank you for your comments. We appreciate your feedback on the measure concepts.

For Use Case 4: Cognitive Error—Dismissed Patient, are there any additional causal factors or challenges that should be included?

Commenter Name	Comment	Response
Nicholas Kuzma St. Christopher's Hospital for Children	Similar to case 1, a contingency plan was not created. The patient may have returned sooner if clear instructions were given on when to return to medical. (as opposed to follow up in 2-3 days).	Thank you for your feedback. We have included information about creating contingency plans as a solution to address the challenges outlined in the Use Case 4.

For Use Case 4: Cognitive Error—Dismissed Patient, do the solutions effectively address the casual factors and challenges in an actionable and specific way?

Commenter Name	Comment	Response
Bob Hussey RGH Health Consulting	As we mentioned in an earlier comment, time is a critical factor in successfully diagnosing many diseases in which rapid progression of the underlying condition can impact the range of treatment options and the eventual outcome. As such, we strongly agree with the measure concept cited in the draft report that tracks days from original patient chief complaint until final, accurate diagnosis (page 60). With regard to measures that utilize patient-reported data, we also support a new measure for patient-reported satisfaction with the diagnostic process (page 60).	Thank you for your comments. We appreciate your feedback on the measure concepts.
Bob Hussey RGH Health Consulting	In Use Case #4, Cognitive Error – Dismissed Patients, we recommend adding CDS software as a solution to help clinicians overcome cognitive biases and minimize over-emphasis and over-adherence to static protocols that cannot account for every clinical scenario (page 51).	Thank you for your feedback. We have expanded the solutions outlined in Use Case 4 to include the use of clinical decision support software to help organize and synthesize clinically complex or ambiguous information that clinicians may encounter when addressing a difficult diagnosis.

Do the broad-scope, comprehensive recommendations outline clear, actionable recommendations for various stakeholders to apply the Diagnostic Process and Outcomes domain of the 2017 Measurement Framework and measure and reduce diagnostic error?

Commenter Name	Comment	Response
Nicholas Kuzma St. Christopher's Hospital for Children	Yes	Thank you for your feedback.
Bob Hussey RGH Health Consulting	Wolters Kluwer is a leading global provider of information, business intelligence and point-of-care solutions for the healthcare industry. Key solutions include UpToDate®, Medi-Span®, Lexicomp®, Facts & Comparisons®, Pharmacy OneSource®, Health Language®, Emmi® and POC Advisor®. Wolters Kluwer had annual revenue in 2019 of €4.6 billion. We generally support the draft report and strongly commend the National Quality Forum (NQF) and its multi-stakeholder expert Committee for the work done to date on developing new measurement concepts to improve diagnostic quality and reduce diagnostic error. Such work is long overdue, as attested by the figures cited in the draft report that 12 million Americans annually suffer a diagnostic error, resulting in an estimated 40,000-80,000 deaths. As a developer of software solutions that deliver evidence-based solutions at the point of care, Wolters Kluwer is dedicated to improving the accuracy and effectiveness of medical decision-making. We therefore agree with the draft report's recommendations that technology such as clinical decision support should be leveraged to identify and reduce diagnostic error, clinical protocols and pathways should be developed and deployed to standardize care, and patients should be empowered to become more active participants in the diagnostic process.	Thank you for your comments. We appreciated your thoughtful feedback on the solutions outlined in the report.

Commenter Name	Comment	Response
Brenna Rabel Battelle Memorial Institute	Thank you very much for the opportunity to review this report. As the Technical Assistance Contractor for the Gordon and Betty Moore Foundation's Quality Measures to Improve Diagnosis grant program, we are delighted to see the complex and important topic of diagnostic performance at the forefront of this document. We shared this report with the grantees in our cohort and have compiled their comments below. General Comments- Content In general, the report provides sufficient information about committee history and explanation of environmental scan methodology. Further, the measurement consideration tables—which seem to make-up the core of the report—are well-arranged and easy to understand. However, the use cases and recommendations are much broader than measurement. We suggest narrowing the focus on considerations for measurement, rather than on clinical suggestions in general (e.g., education). Also missing from this report is any discussion about new or emerging measurement methodologies that might better enable measures of diagnostic performance, such as machine learning. We would be interesting in seeing further exploration of novel approaches in a future report.	Thank you for your comments. We appreciate your thoughtful feedback on the report.
Bob Hussey RGH Health Consulting	The draft report recommends the development and deployment of clinical protocols and pathways to standardize care (page 63), a point on which we wholeheartedly agree. Unfortunately, clinical care in the United States is characterized more for its variability than standardization. Such variability is widespread, expensive and often leads to diagnostic error. Reducing variability by embracing solutions and processes that standardize evidence-based care and best	Thank you for your comments. We appreciate your thoughtful feedback on the recommendations outlined in the report.

Commenter Name	Comment	Response
	practices is essential to improving patient safety, diagnostic quality and clinical outcomes. Helping standardize care and reduce variability is the driving force behind Wolters Kluwer's new UpToDate Advanced solution, which offers evidence-based clinical decision pathways on common medical conditions with well-established variability in care. UpToDate Advanced also provides assistance in interpreting abnormal test results, another common source of variations in care that can result in unnecessary testing and missed diagnoses.	

Are there any additional comprehensive, broad-scope recommendations that should be included to measure and reduce diagnostic error?

Commenter Name	Comment	Response
Koryn Rubin American Medical Association	The American Medical Association (AMA) appreciates the opportunity to comment on this draft report. Understanding and addressing those factors that contribute to diagnostic errors remains critical to ensure physicians provide the best possible care to their patients and we appreciate the work of the committee. That said, it is essential that the report include only those measure concepts for which there is clear evidence that the structure or process can impact patient outcomes, are appropriate for performance measurement, and are feasible to collect and report. We note that many of the measurement approaches and concepts outlined in each of the use cases have not been sufficiently evaluated on the underlying evidence that would support the process or outcome nor does the report adequately discuss the barriers to the development and implementation of these measures.	Thank you for your feedback. We have made modifications to various sections of the report to clarify that the measurement concepts outlined are potential approaches, reiterating that any subsequent quality measures still need to be thoroughly specified, developed, and tested for feasibility and scientific acceptability. We clarified that measure concepts and approaches throughout the report, including in the use cases and in the recommendations, range in their level of research and science. We clarified that measure concepts in the earlier stages of research are best

Commenter Name	Comment	Response
		suited for internal quality improvement and use on a case-by-case basis, and that any measure concepts used in accountability or payment programs should be fully specified, developed, and tested prior to implementation.
Koryn Rubin American Medical Association	Cont'd: It is imperative that the measure concepts focus on structures, processes, and outcomes that will be useful for performance measurement and not just become a documentation burden. Many of the proposed measure concepts are not well suited for even quality improvement initiatives and it is critical that the concepts included in this report be evidence-based, clearly linked to improving outcomes and that their value outweighs the resources required to collect and report the information. We request that this committee reconsider many of the measure concepts included within each of these use cases on the basis of the evidence to support its focus and the ability of physicians, facilities, and health systems to use the resulting information in a meaningful way. The AMA also recommends that additional discussion on the feasibility and scientific acceptability of measuring many of these concepts be incorporated into the report.	Thank you for your feedback. We have included language to clarify that the measurement concepts outlined in the report are potential approaches, reiterating that measures would need to be thoroughly specified, developed, and tested for feasibility and scientific acceptability before being fully implemented.

Please also share any general comments or feedback on the Draft Report.

Commenter Name	Comment	Response
Randal Moseley	This document is spectacular in its breadth and depth, packed with wisdom on the topic of diagnostic error in general. However, the title is not really consistent with the content. This paper goes far beyond "measurement considerations", and that additional content distracts from the measurement topic. I think what we need in practice is clear guidance on what to measure and how. Elements of this are buried within this document, but I will find it very challenging to use in my local organizational efforts to improve and standardize the measurement of diagnostic error.	Thank you for your feedback. We have included additional information and detail in the measurement-related recommendations in the report.
Nicholas Kuzma St. Christopher's Hospital for Children	The content in this paper is well-thought-out and comprehensive. Discussions about discharge instructions, including when to return to medical attention, was the area I found to be most lacking. Many of the example cases included instructions for follow up in 2-3 days, but lacked specific discharge instructions. Contingency plans are often used in pediatrics to help families plan for the unexpected, and I feel are a crucial part of any discharge plan. This concept is briefly discussed on page 35, but I think could be more emphasized. Additionally, discharge instructions can be difficult to understand and remember (https://pediatrics.aappublications.org/content/140/2/e20164165). Using teach-back to ensure closed-loop communication is recommended by the AHRQ for these situations (https://www.ahrq.gov/patient-safety/reports/engage/interventions/teachback.html). The concept of closed loop communication and/or teach back could be included in the " Engage patients as active partners in information communication and follow-up" solution. Additionally, several recent studies and reviews have brought into question the	Thank you for your feedback. We have included information around creating contingency plans as a solution to address the challenges outlined in Use Case 1 and 4. We have also included information about closed-loop communication/teach-back as a solution in Use Case 2.

Commenter Name	Comment	Response
	importance of cognitive biases. These papers generally suggest that these biases are best explained by deficits in knowledge. (https://journals.lww.com/academicmedicine/fulltext/2017/01000/the_causes_of_errors_in_clinical_reasoning_.13.aspx). I would consider deemphasizing the importance of these biases as explanations for errors.	
Gerard Castro Society to Improve Diagnosis in Medicine	I commend the committee on the substantive work in advancing diagnostic quality and safety. The "use cases" make explicit the contributing and causal factors, potential harm to patients, and examples of how to address the identified contributing and causal factors to improve diagnostic quality and safety. Please consider the following general comments and suggestions: Page 2 – In the Executive Summary consider making more explicit the relationship between the Use Cases and the 2017 Diagnostic Quality and Safety Measurement Framework and how the identified solutions can drive improvement. In the Executive Summary, it is stated the Use Cases are intended to "support the practical application" the Diagnostic Process and Outcome Domain of the framework and "identify comprehensive resolutions to specific types of diagnostic error." Consider adding language similar to that on page 11 where the relationship to the framework is described: "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." Page 12 – Use Case 1 describes cognitive errors associated with "Missed Subtle Clinical Findings." According to the description, subtle clinical findings include both "symptoms that mimic other common conditions" and "non-classic presentation." It is important to make	Thank you for your feedback. We have included additional language in the Executive Summary to clearly define the relationship between the use cases and the 2017 Diagnostic Quality and Safety Measurement Framework. We also added "implicit bias" to the Use Case 1 table and expanded the titles of the potential solutions referenced in your comment to ensure they adequately capture to sentiment of the solution.

Commenter Name	Comment	Response
	the distinction between these types of findings and perhaps specify which solutions are more effective at addressing the different types of subtle findings.	
Gerard Castro Society to Improve Diagnosis in Medicine	Cont'd: Page 15 – Under the list of cognitive biases, "implicit bias" is included in the list on page 13 but missing in the list on page 15. Page 15 – Potential Solution #1, "Enhance clinician expertise through education and training" description is narrow in scope relative to the processes listed. Inherent to the processes listed are organizational structures such as the process "Create opportunities to share feedback as a learning mechanism" on page 16. Consider a broader concept such as "Enhance clinician expertise through education, training, standardized processes, and feedback for learning." Education alone is considered a weaker safety intervention unless it is within the context of a learning health system, elements of which is what is described in the solution. Page 32 – The specific solution "Provide clinician education on best practices, procedures, and expectations (from potential solution #1)" seems incongruent with most of the activities described which calls for creation of policies, coordination with IT to collect data, and then finally educate clinicians. Consider expanding the description of the solution.	Thank you for your feedback. We have included additional language in the Executive Summary to clearly define the relationship between the use cases and the 2017 Diagnostic Quality and Safety Measurement Framework. We also added "implicit bias" to the Use Case 1 table and expanded the titles of the potential solutions referenced in your comment to ensure they adequately capture to sentiment of the solution.

Commenter Name	Comment	Response
Brenna Rabel	The Moore Foundation grantees noticed a handful of formatting issues that impact the readability and usefulness of the report. While none of these are significant problems, our grantees did feel that minor changes could go a long way toward improving the document's readability and navigability. Consider adding a table of contents/list of figures and tables for clearer navigation Consider highlighting the snapshots with a colored background/border. Also, some longer snapshots could benefit from being broken into paragraphs. Consider reformatting some of the tables. For example, Tables 4, 6, 8, and 10 are difficult to understand due to the header row. The structure indicates it should be read vertically, but it is to be read horizontally. Further, there are rows for Potential Solution 1, 2, and 3, which are really headings, not elements, entries, cases, observations, etc. in a table. The repeating of stakeholders that are nearly identical takes up quite a bit of space. Perhaps a matrix of 4 use cases by 8 possible stakeholders will be more readable. Lastly, as a minor issue, many rows break over pages. In brief, this table is used in ways that people do not usually use tables. Consider plain text headings (Assumptions, Causal Factors, Solution process 1, solution process 2, and solution process 3) to make it clearer.	Thank you for your feedback. We have added a table of contents to the report and have modified the tables to improve readability. We have also expanded the language in the executive summary to more explicitly reference the recommendations.
Brenna Rabel Battelle Memorial Institute	Cont'd: We also suggest reformatting the potential solution sections. Rather than listing three bulleted potential solutions, we suggest creating potential solutions for each stakeholder group. For example, on page 19 the potential solution "Engage consultants with specialized expertise," would benefit from more clearly identify roles or specific actions that healthcare administrators, clinicians, patients, payers, EHR vendors, and	Thank you for your feedback. We have added a table of contents to the report and have modified the tables to improve readability. We have also expanded the language in the Executive Summary to more explicitly reference the recommendations.

Commenter Name	Comment	Response
	policymakers should take to implement such a solution. The executive summary seems discordant with the rest of the report. Half of it specifies the background and history of this report, without much space devoted to the actual contents or recommendations. Use cases should be bold or numbered in the executive summary. We suggest including examples of measurement approaches or measure concepts (from tables 5, 7, 9, 11) in the executive summary as well.	
	Cont'd: The snapshots provide a good illustration of the discussed diagnostic errors. However, none of the snapshots sufficiently illustrate the totality of cognitive pressures clinicians face at the moment of diagnosis. We suggest modifying some snapshots to illustrate the complexity of the cognitive process of diagnosis, including the cognitive pressures exerted by operational measures (e.g., throughout, utilization), malpractice concerns, guideline adherence, and EHR requirements. These concepts can best be addressed in Use Cases 1 and 4. For example, in the case of the missed stroke, a real-world scenario might include a clinician who considered stroke but did not order the CTA/MRI or consult neurology because of the related impact on length of stay or utilization metrics that their department uses to assess clinician performance.	Thank you for your feedback. We have expanded the causal factors in Use Case 1 to include competing quality initiatives regarding judicious resource utilization. We have also included additional information regarding competing demands as a contributing factor to the first snapshot in Use Case 1.
Paul Epner Society to Improve Diagnosis in Medicine	It is great to see the work continue on this important problem. Each new report adds to the body of knowledge and the depth of analysis. A couple of comments: The committee has proposed to use the term "subtle" in reference to symptoms or findings not typically associated with the disease that should be under consideration. Specifically, the report says, ""Subtle" refers	Thank you for your feedback. We have included language in the report to reiterate that though symptoms may not be subtle, their association with the diagnosis may be subtle. We appreciate your feedback about creating illustrative numerators and denominators

Commenter Name	Comment	Response
	to the concept that the finding or symptom is not clinically obvious or “classic” as it would appear in a medical textbook." While the linkage between a disease and a symptom might be subtle, the symptom itself can be anything but subtle. Dizziness is not a subtle symptom even though its association with stroke may be atypical. Peripheral arm pain is not a subtle symptom even though its association with MI may be atypical. Since diagnosis is about symptoms and findings with a disease or condition as an outcome, I suggest the committee consider a word or phrase that recognizes one might fail to appreciate the significance of a symptom rather than suggest the symptom is hard to detect. While the report is entitled Measurement Considerations, there is not a clear connection between the use cases, the possible solutions and measures. The use cases could be enhanced by the addition of an illustrative numerator and denominator that would be sensitive and specific to the use case. Applying measures to the use cases might be more helpful to the committee's work and stakeholder utilization than the listing of possible solutions which are very generalized and with insufficient detail to offer help in selection or implementation; understandably beyond the scope of this report.	in the use cases but, unfortunately, that is out of scope for this report. However, we have included additional information in the measurement recommendation section to offer additional details and resources on measurement.
Carlos Higuera-Rueda	It is a well written and clear document. I do not have any changes.	Thank you for your feedback.

References

[1] Leape LL, Berwick DM, Bates DW. Counting deaths due to medical errors (in reply). J Am Med Assoc 2002;288:2404–5.

[2] Singh H, Meyer AN, Thomas EJ. The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations. BMJ Qual Saf 2014;23:727–31.

[3] Shojania KG, Burton EC, McDonald KM, Goldman L. Changes in rates of autopsy-detected diagnostic errors over time: a system- atic review. J Am Med Assoc 2003;289:2849–56.

[4] Singh H, Sittig DF. Advancing the science of measurement of diagnostic errors in healthcare: the Safer Dx framework. BMJ Qual Saf. 2015;24(2):103-110.

[5] Donabedian A. Evaluating the Quality of Medical Care. Milbank Q. 2005;83(4):691-729.

[6] Giardina TD, Haskell H, Menon S, et al. Learning From Patients' Experiences Related To Diagnostic Errors Is Essential For Progress In Patient Safety. *Health Aff Proj Hope*. 2018;37(11):1821-1827.

[7] Kwan JL, Singh H. Assigning responsibility to close the loop on radiology test results. *Diagn Berl Ger*. 2017;4(3):173-177.

[8] Bell SK, Delbanco T, Elmore JG, et al. Frequency and Types of Patient-Reported Errors in Electronic Health Record Ambulatory Care Notes. JAMA Netw Open. 2020;3(6). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7284300/. Last accessed July 2020.

[9] Campione JR, Mardon RE, McDonald KM. Patient Safety Culture, Health Information Technology Implementation, and Medical Office Problems That Could Lead to Diagnostic Error. J Patient Saf. 2019;15(4):267-273.

[10] Santhosh L, Lyons PG, Rojas JC, et al. Characterising ICU-ward handoffs at three academic medical centres: process and perceptions. *BMJ Qual Saf*. 2019;28(8):627-634.

[11] Guide to Improving Patient Safety in Primary Care Settings by Engaging Patients and Families. http://www.ahrq.gov/patient-safety/reports/engage.html. Last accessed July 2020.

[12] Eichbaum Q, Adkins B, Craig-Owens L, et al. Mortality and morbidity rounds (MMR) in pathology: relative contribution of cognitive bias vs. systems failures to diagnostic error. Diagnosis (Berl). 2019;6(3):249-257.

[13] Olson A, Rencic J, Cosby K, et al. Competencies for improving diagnosis: an interprofessional framework for education and training in health care. Diagnosis (Berl). 2019;6(4):335-341.

[14] Itri JN, Patel SH. Heuristics and Cognitive Error in Medical Imaging. *AJR Am J Roentgenol*. 2018;210(5):1097-1105.

[15] O'Sullivan ED, Schofield SJ. Cognitive bias in clinical medicine. *J R Coll Physicians Edinb*. 2018;48(3):225-232.

[16] Berenson R, Singh H. Payment Innovations To Improve Diagnostic Accuracy And Reduce Diagnostic Error. Health Aff (Millwood). 2018;37(11):1828-1835.

[17] Hoffman JM, Keeling NJ, Forrest CB, et al. Priorities for Pediatric Patient Safety Research. Pediatrics. 2019;143(2).

[18] Merkebu J, Battistone M, McMains K, et al. Situativity: a family of social cognitive theories for understanding clinical reasoning and diagnostic error. Diagnosis. 2020;1(ahead-of-print). https://www.degruyter.com/view/journals/dx/ahead-of-print/article-10.1515-dx-2019-0100/article-10.1515-dx-2019-0100.xml. Last accessed July 2020.

[19] Cognitive Errors in Clinical Decision Making - Special Subjects. Merck Manuals Professional Edition. https://www.merckmanuals.com/professional/special-subjects/clinical-decision-making/cognitive-errors-in-clinical-decision-making. Last accessed July 2020.

[20] Schiff GD, Hasan O, Kim S, et al. Diagnostic error in medicine: analysis of 583 physician-reported errors. Arch Intern Med. 2009;169(20):1881–1887. doi:10.1001/archinternmed.2009.333

[21] Bernstein SL, Aronsky D, Duseja R, et al. The effect of emergency department crowding on clinically oriented outcomes. Acad Emerg Med. 2009;16(1):1–10. doi:10.1111/j.1553-2712.2008.00295.x

[22] Graber ML, Siegal D, Riah H, et al. Electronic Health Record-Related Events in Medical Malpractice Claims. J Patient Saf. 2019;15(2):77-85.

[23] Croskerry P. From Mindless to Mindful Practice - Cognitive Bias and Clinical Decision Making. New Engl J Med. 2013;26:2445-8

[24] Sherbino J, Norman GR. Reframing diagnostic error: maybe it's content, and not process, that leads to error. *Acad Emerg Med.* 201421(8):931-933.

[25] Graber ML, Franklin N, Gordon R. Diagnostic error in internal medicine. Arch Intern Med. 2005;165(13):1493-1499.

[26] Croskerry P. The importance of cognitive errors in diagnosis and strategies to minimize them. Acad Med. 2003;78(8):775-780.

[27] Ericsson KA, Charness N, Feltovich PJ, et al., eds. *The Cambridge Handbook of Expertise and Expert Performance.* New York, NY: Cambridge University Press; 2006.

[28] Cognitive biases in health care. https://www.jointcommission.org/resources/news-and-multimedia/newsletters/Newsletters/quick-safety/quick-safety-28/Cognitive biases in health care. Last accessed July 2020.

[29] O'Sullivan ED, Schofield SJ. Cognitive bias in clinical medicine. J R Coll Physicians Edinb. 2018;48(3):225–232. doi:10.4997/JRCPE.2018.306

[30] Monteiro S, Sherbino J, Sibbald M, et al. Critical thinking, biases and dual processing: The enduring myth of generalisable skills. *Medical Education*. 2020;54(1):66-73.

[31] Dhaliwal G. Premature closure? Not so fast. *BMJ Qual Saf.* 2017;26(2):87-89.

[32] Norman GR, Monteiro SD, Sherbino J, et al. The causes of errors in clinical reasoning: cognitive biases, knowledge deficits, and dual process thinking. *Acad Med.* 2017;92(1):23-30.

[33] Croskerry P, Singhal G, Mamede S. Cognitive debiasing 1: origins of bias and theory of debiasing. BMJ Qual Saf. 2013;22 Suppl 2:ii58-ii64.

[34] Middleton LP, Feeley TW, Albright HW, et al. Second-opinion pathologic review is a patient safety mechanism that helps reduce error and decrease waste. *J Oncol Pract*. 2014;10(4):275-280.

[35] Schiff, Gordon D. “Minimizing Diagnostic Error: The Importance of Follow-up and Feedback.” The American Journal of Medicine 121, no. 5 (May 1, 2008): S38–42. https://doi.org/10.1016/j.amjmed.2008.02.004.

[36] Verna R, Velazquez AB, Laposata M. Reducing Diagnostic Errors Worldwide Through Diagnostic Management Teams. Ann Lab Med. 2019;39(2):121-124.

[37] Graber Mark L., Rusz Diana, Jones Melissa L., et al. The new diagnostic team. *Diagnosis*. 2017;4(4):225.

[38] Liberman AL, Newman-Toker DE. Symptom-Disease Pair Analysis of Diagnostic Error (SPADE): a conceptual framework and methodological approach for unearthing misdiagnosis-related harms using big data. *BMJ Qual Saf*. 2018;27(7):557-566.

[39] Obermeyer Z, Cohn B, Wilson M, et al. Early death after discharge from emergency departments: analysis of national US insurance claims data. BMJ. 2017;356. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6168034/. Last accessed June 2020.

[40] The Diagnostic Error in Medicine 12th Annual International Conference. *Diagnosis*. 2019;6(4):eA1–eA96.

[41] Schiff, Gordon D. “Minimizing Diagnostic Error: The Importance of Follow-up and Feedback.” The American Journal of Medicine 121, no. 5 (May 1, 2008): S38–42. https://doi.org/10.1016/j.amjmed.2008.02.004.

[42] Ely JW, Graber ML, Croskerry P. Checklists to Reduce Diagnostic Errors. *Academic Medicine*. 2011;86(3):307–313.

[43] Payne VL, Singh H, Meyer AND, et al. Patient-initiated second opinions: systematic review of characteristics and impact on diagnosis, treatment, and satisfaction. Mayo Clin Proc. 2014;89(5):687-696.

[44] Newman-Toker DE, Della Santina CC, Blitz AM. Vertigo and hearing loss. Handb Clin Neurol. 2016;136:905-921.

[45] Omron R, Kotwal S, Garibaldi BT, et al. The Diagnostic Performance Feedback "Calibration Gap": Why Clinical Experience Alone Is Not Enough to Prevent Serious Diagnostic Errors. AEM Educ Train. 2018;2(4):339-342.

[46] McDonald KM, Bryce CL, Graber ML. The patient is in: patient involvement strategies for diagnostic error mitigation. BMJ Qual Saf. 2013;22(Suppl 2):ii33-ii39.

[47] Berger ZD, Brito JP, Ospina NS, et al. Patient centred diagnosis: sharing diagnostic decisions with patients in clinical practice. BMJ. 2017;359. https://www.bmj.com/content/359/bmj.j4218. Last accessed March 2020.

[48] Saber Tehrani AS, Kattah JC, Kerber KA, et al. Diagnosing Stroke in Acute Dizziness and Vertigo: Pitfalls and Pearls. Stroke. 2018;49(3):788-795.

[49] Ronicke S, Hirsch MC, Türk E, et al. Can a decision support system accelerate rare disease diagnosis? Evaluating the potential impact of Ada DX in a retrospective study. Orphanet J Rare Dis. 2019;14(1):69.

[50] Graber ML, Kissam S, Payne VL, et al. Cognitive interventions to reduce diagnostic error: a narrative review. *BMJ Qual Saf*. 2012;21(7):535-557.

[51] Abimanyi-Ochom J, Bohingamu Mudiyanselage S, Catchpool M, et al. Strategies to reduce diagnostic errors: a systematic review. *BMC Medical Informatics and Decision Making*. 2019;19(1):174.

[52] Smith-Bindman R, Chu PW, Miglioretti DL, et al. Comparison of Screening Mammography in the United States and the United Kingdom. *JAMA*. 2003;290(16):2129-2137.

[53] Fridriksson S, Hillman J, Landtblom AM, et al. Education of referring doctors about sudden onset headache in subarachnoid hemorrhage: a prospective study. *Acta Neurol Scand.* 2001;103:238e42.

[54] Ramnarayan P, Winrow A, Coren M, et al. Diagnostic omission errors in acute paediatric practice: impact of a reminder system on decision-making. *BMC Medical Informatics and Decision Making*. 2006;6(1):37.

[55] Graber ML, Sorensen AV, Biswas J, et al. Developing checklists to prevent diagnostic error in Emergency Room settings. *Diagnosis*. 2014;1(3):223-231.

[56] Arkes HR, Faust D, Guilmette TJ, et al. Eliminating the hindsight bias. J Appl Psychol 1988;73:305e7.

[57] Kattah JC, Talkad AV, Wang DZ, et al. HINTS to diagnose stroke in the acute vestibular syndrome: three-step bedside oculomotor examination more sensitive than early MRI diffusion-weighted imaging. Stroke. 2009;40(11):3504-3510.

[58] Newman-Toker DE, Kerber KA, Hsieh Y-H, et al. HINTS outperforms ABCD2 to screen for stroke in acute continuous vertigo and dizziness. Acad Emerg Med. 2013;20(10):986-996.

[59] Newman-Toker DE, Camargo CA, Hsieh Y-H, et al. Disconnect between charted vestibular diagnoses and emergency department management decisions: a cross-sectional analysis from a nationally representative sample. Acad Emerg Med. 2009;16(10):970-977.

[60] National Quality Forum (NQF). Advancing Chief Complaint-Based Quality Measurement Final Report. June 2019. http: //www. qualityforum.org /Publications/2019/06/Advancing_Chief_Complaint-Based_ Quality_ Measurement _Final_Report.aspx. Last accessed July 2020.

[61] Factors in Diagnostic Error. Society to Improve Diagnosis in Medicine. https://www.improvediagnosis.org/factors-in-diagnostic-error/. Last accessed June 2020.

[62] Grissinger M. Multiple Latent Failures Align to Allow a Serious Drug Interaction to Harm a Patient. P T. 2015;40(1):10-11.

[63] Privitera MR. Addressing Human Factors in Burnout and the Delivery of Healthcare: Quality & Safety Imperative of the Quadruple Aim. Health. 2018;10(5):629-644.

[64] Graber ML, Franklin N, Gordon R. Diagnostic Error in Internal Medicine. Arch Intern Med. 2005;165(13):1493-1499.

[65] Bhise V, Sittig DF, Vaghani V, Wei L, Baldwin J, Singh H. An electronic trigger based on care escalation to identify preventable adverse events in hospitalised patients. BMJ Qual Saf. 2018;27(3):241–246. doi:10.1136/bmjqs-2017-006975

[66] TeamSTEPPS Fundamentals Course: Module 3. Evidence-Based: Communication. http://www.ahrq.gov/teamstepps/instructor/fundamentals/module3/ebcommunication.html. Last accessed June 2020.

[67] Whitehead NS, Williams L, Meleth S, et al. Interventions to Improve Follow-Up of Laboratory Test Results Pending at Discharge: A Systematic Review. J Hosp Med. February 2018.

[68] Dingley, C., Daugherty, K., Derieg, M., et al. Improving Patient Safety Through Provider Communication Strategy Enhancements. Retrieved from https://www.ahrq.gov/downloads/pub/advances2/vol3/Advances-Dingley_14.pdf

[69] McDonald KM, Matesic B, Contopoulos-Ioannidis DG, et al. Patient Safety Strategies Targeted at Diagnostic Errors: A Systematic Review. *Annals of Internal Medicine*. 2013;158(5_Part_2):381-389.

[70] Ash J, Singh H, Sittig D. Test Results Reporting and Follow-up. 2016:37.

[71] Singh H, Vij MS. Eight recommendations for policies for communicating abnormal test results. Jt Comm J Qual Patient Saf. 2010;36(5):226-232.

[72] Yen PH, Leasure AR. Use and Effectiveness of the Teach-Back Method in Patient Education and Health Outcomes. Fed Pract. 2019;36(6):284-289.

[73] Murphy DR, Meyer AND, Bhise V, et al. Computerized Triggers of Big Data to Detect Delays in Follow-up of Chest Imaging Results. Chest. 2016;150(3):613-620.

[74] Interpretation of Diagnostic Imaging Tests. https://www.acep.org/patient-care/policy-statements/interpretation-of-imaging-diagnostic-studies/. Last accessed July 2020.

[75] Singh H, Naik AD, Rao R, et al. Reducing diagnostic errors through effective communication: harnessing the power of information technology. *J Gen Intern Med*. 2008;23(4):489-494.

[76] AHA. Focusing on Teamwork and Communication to Improve Patient Safety | AHA News. https://www.aha.org/news/blog/2017-03-15-focusing-teamwork-and-communication-improve-patient-safety. Last accessed June 2020.

[77] Diagnostic Error: Safe and Effective Communication to Prevent Diagnostic Errors. Patient Safety & Quality Healthcare. https://www.psqh.com/analysis/safe-and-effective-communication-to-prevent-diagnostic-errors/. Last accessed February 2020.

[78] Poon EG, Haas JS, Louise Puopolo A, et al. Communication factors in the follow-up of abnormal mammograms. *J Gen Intern Med*. 2004;19(4):316-323.

[79] Murphy DR, Wu L, Thomas EJ, et al. Electronic Trigger-Based Intervention to Reduce Delays in Diagnostic Evaluation for Cancer: A Cluster Randomized Controlled Trial. *J Clin Oncol*. 2015;33(31):3560-3567.

[80] Meyer AND, Murphy DR, Singh H. Communicating Findings of Delayed Diagnostic Evaluation to Primary Care Providers. *J Am Board Fam Med*. 2016;29(4):469-473.

[81] Stange KC. The problem of fragmentation and the need for integrative solutions. Ann Fam Med. 2009;7(2):100–103. doi:10.1370/afm.971

[82] Wyer Jr. RS. A theory of social information processing. In: Handbook of Theories of Social Psychology, Vol. 1. Thousand Oaks, CA: Sage Publications Ltd; 2012:156-177.

[83] Engineering I of M and NA of. Engineering a Learning Healthcare System: A Look at the Future: Workshop Summary.; 2011. https://www.nap.edu/catalog/12213/engineering-a-learning-healthcare-system-a-look-at-the-future. Last accessed July 2020.

[84] Fraser KL, Ayres P, Sweller J. Cognitive Load Theory for the Design of Medical Simulations. *Simul Healthc*. 2015;10(5):295–307. doi:10.1097/SIH.0000000000000097

[85] Melnick ER, Dyrbye LN, Sinsky CA, et al. The Association Between Perceived Electronic Health Record Usability and Professional Burnout Among US Physicians. Mayo Clin Proc. 2020;95(3):476–487. doi:10.1016/j.mayocp.2019.09.024

[86] Sanderson P, McCurdie T, Grundgeiger T. Interruptions in Health Care: Assessing Their Connection With Error and Patient Harm. Hum Factors. 2019;61(7):1025–1036. doi:10.1177/0018720819869115

[87] Cvach M. Monitor alarm fatigue: an integrative review. Biomed Instrum Technol. 2012;46(4):268–77. doi: 10.2345/0899-8205-46.4.268.

[88] Warner LS, Pines JM, Chambers JG, Schuur JD. The Most Crowded US Hospital Emergency Departments Did Not Adopt Effective Interventions To Improve Flow, 2007-10. *Health Aff (Millwood)*. 2015;34(12):2151-2159. doi:10.1377/hlthaff.2015.0603

[89] Furlow B. Information overload and unsustainable workloads in the era of electronic health records. The Lancet Respiratory Medicine. 2020;8(3):243-244.

[90] Ahmed A, Chandra S, Herasevich V, et al. The effect of two different electronic health record user interfaces on intensive care provider task load, errors of cognition, and performance*. Critical Care Medicine. 2011;39(7):1626–1634.

[91] Pickering BW, Dong Y, Ahmed A, et al. The implementation of clinician designed, human-centered electronic medical record viewer in the intensive care unit: A pilot step-wedge cluster randomized trial. International Journal of Medical Informatics. 2015;84(5):299-307.

[92] Aspesi AV, Kauffmann GE, Davis AM, et al. IBCD: Development and Testing of a Checklist to Improve Quality of Care for Hospitalized General Medical Patients. Jt Comm J Qual Patient Saf. 2013;39(4):147-156.

[93] Cunningham H. How Engaged Are Consumers in Their Health and Health Care, and Why Does It Matter. 2008. https://www.researchgate.net/profile/Judith_Hibbard/publication/23411858_How_Engaged_Are_Consumers_in_Their_Health_and_Health_Care_and_Why_Does_It_Matter/links/0912f50b4c6c464b19000000/How-Engaged-Are-Consumers-in-Their-Health-and-Health-Care-and-Why-Does-It-Matter.pdf.

[94] McDonald KM, Bryce CL, Graber ML. The patient is in: patient involvement strategies for diagnostic error mitigation. BMJ Qual Saf. 2013;22(Suppl 2):ii33-ii39.

[95] Pollack CE, Hussey PS, Rudin RS, Fox DS, Lai J, Schneider EC. Measuring Care Continuity: A Comparison of Claims-based Methods. Med Care. 2016;54(5):e30–e34. doi:10.1097/MLR.0000000000000018

[96] Sawyer SL, Hartley T, Dyment DA, et al. Utility of whole-exome sequencing for those near the end of the diagnostic odyssey: time to address gaps in care. Clin Genet. 2016;89(3):275–284. doi:10.1111/cge.12654

[97] Grier J, Hirano M, Karaa A, Shepard E, Thompson JLP. Diagnostic odyssey of patients with mitochondrial disease: Results of a survey. Neurol Genet. 2018;4(2):e230

[98] Carson A, Stone J, Hibberd C, et al. Disability, distress and unemployment in neurology outpatients with symptoms 'unexplained by organic disease. Journal of Neurology, Neurosurgery & Psychiatry 2011;82:810-813.

[99] RARE Facts. Global Genes. https://globalgenes.org/rare-facts/. Last accessed July 2020.

[100] Weis M. Clinical review of hereditary angioedema: diagnosis and management. Postgrad Med. 2009;121(6):113–120

[101] Zanichelli A, Magerl M, Longhurst HJ, et al. Improvement in diagnostic delays over time in patients with hereditary angioedema: findings from the Icatibant Outcome Survey. Clin Transl Allergy. 2018;8:42. Published 2018 Oct 12. doi:10.1186/s13601-018-0229-4

[102] Hennekam R.C.M. Care for patients with ultra-rare disorders. Eur. J. Med. Genet. 2011;54:220–224.

[103] Carmichael N, Tsipis J, Windmueller G, Mandel L, Estrella E. "Is it going to hurt?": the impact of the diagnostic odyssey on children and their families. J Genet Couns. 2015;24(2):325–335.

[104]Unexplained Symptoms: When Diagnostic Uncertainty Becomes a Diagnosis. Society to Improve Diagnosis in Medicine. https://www.improvediagnosis.org/improvedx-july-2019/unexplained-symptoms-when-diagnostic-uncertainty-becomes-a-diagnosis/. Last accessed June 2020.

[105] Using Speak Up in your organization. https://www.jointcommission.org/resources/for-consumers/speak-up-campaigns/using-speak-up-in-your-organization. Last accessed June 2020

[106] National Quality Forum (NQF). National Quality Partners Playbook™: Shared Decision Making in Healthcare. Washington, DC: NQF; 2018.

[107] Partnering With Patients to Improve Safety. https://www.acog.org/en/Clinical/Clinical Guidance/Committee Opinion/Articles/2011/05/Partnering With Patients to Improve Safety. Last accessed July 2020.

[108] Haun JN, Lind JD, Shimada SL, et al. Evaluating user experiences of the secure messaging tool on the Veterans Affairs' patient portal system. *J Med Internet Res*. 2014;16(3):e75. Published 2014 Mar 6. doi:10.2196/jmir.2976

[109] Fontaine P, Ross SE, Zink T, et al. Systematic Review of Health Information Exchange in Primary Care Practices. J Am Board Fam Med. 2010;23(5):655-670.

[110] Consensus Curriculum on Diagnosis and Diagnostic Error. Society to Improve Diagnosis in Medicine. https://www.improvediagnosis.org/consensuscurriculum/. Last accessed July 2020.

[111] Vidyarthi AR, Sharpe BA, Fox M, et al. A call for a nonprocedural “time out”. Journal of Hospital Medicine. 2011;6(4). https://www.journalofhospitalmedicine.com/jhospmed/article/127704/nonprocedural-time-out. Last accessed July 2020.

[112] Advancing the science of measurement of diagnostic errors in healthcare: the Safer Dx framework. http://psnet.ahrq.gov/issue/advancing-science-measurement-diagnostic-errors-healthcare-safer-dx-framework. Last accessed September 2020.

[113] Operational Measurement of Diagnostic Safety: State of the Science. http://www.ahrq.gov/patient-safety/reports/issue-briefs/state-of-science.html. Last accessed September 2020.

[114] Singh H, Upadhyay DK, Torretti D. Developing Health Care Organizations That Pursue Learning and Exploration of Diagnostic Excellence: An Action Plan. Academic Medicine. 2020;95(8):1172–1178.

[115] Health Foundation (Great Britain). A Framework for Measuring and Monitoring Safety: A Practical Guide to Using a New Framework for Measuring and Monitoring Safety in the NHS.; 2014.

[116] Our Mission. Choosing Wisely. https://www.choosingwisely.org/our-mission/. Last accessed September 2020.

[117] Am I Choosing Wisely? Choosing Wisely. https://www.choosingwisely.org/am-i-choosing-wisely/. Last accessed September 2020.