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

Committee Web Meeting 8

September 14, 2020



Agenda

- Welcome, Review of Meeting Objectives, and Introductions
- Overview of Draft Report
- Discuss Broad-scope, Comprehensive Recommendations for Applying the Framework, Measuring and Reducing Diagnostic Error, and Improving Patient Safety
- Review and Discuss Public Comments
- Opportunity for Public Comment
- Next Steps
- Closing Comments

Welcome, Review of Meeting Objectives, and Introductions



NQF Project Staff

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Committee Roster

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- Colleen Skau, PhD
- Michael Woodruff, MD
- Ronald Wyatt, MD



Federal Liaisons

Nonvoting Committee Representatives

- Andrea Benin, MD
- David Hunt, MD
- Marsha Smith, MD, MPH, FAAP

Overview of Draft Report



Draft Report Outline

- Table of Contents
- Executive summary
- Background and project objectives
- Environmental scan findings
- Use Cases: comprehensive resolution of diagnostic errors
 - Selection process
 - Approach
 - Use Cases 1-4
- Broad-scope, comprehensive recommendations for applying the Framework, measuring and reducing diagnostic error, and improving patient safety
- Conclusion
- Appendices (e.g., Committee roster, measure inventory and concepts, public comments)



Background and Project Objectives

- The 2017 Diagnostic Quality and Safety Measurement Framework was developed to measure diagnostic quality and safety, and identify priorities for future measure development
- In 2019, NQF, with funding from the Department of Health and Human Services (HHS), convened a multistakeholder expert Committee to build on the work of the 2017 Diagnostic Quality and Safety Committee
- This Committee reviewed the Diagnostic Process and Outcomes domain of the measurement framework to identify any needed updates, identify high-priority measures, current measures, and areas for future measure development
- The Committee developed practical guidance for the application of the Diagnostic Processes and Outcomes domain, including specific Use Cases to demonstrate how the framework can be operationalized in practice and detailed recommendations for applying the framework, measuring and reducing diagnostic error, and improving patient safety



Use Cases

- Use Case 1: Cognitive Error Missed Subtle Clinical Findings
 - Subtle clinical presentations of dangerous conditions when the disease "signal" is too low
- Use Case 2: System Error Communication Failure
 - Failure to "close the loop" on communicating diagnostic test results for important conditions
- Use Case 3: Cognitive Error Information Overload
 - Information overload in complex, critically ill patients when the disease "signal" is too high
- Use Case 4: Cognitive Error Dismissed Patient
 - Prolonged diagnostic odyssey for chronic symptoms when the disease "signal" is almost nonexistent

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



The Diagnostic Process and Outcomes Domain of the 2017 Measurement Framework

- The Report outlines a series of broad-scope, comprehensive recommendations for applying the Diagnostic Process and Outcomes domain of the 2017 Measurement Framework, measuring and reducing diagnostic error, and measuring and improving patient safety across various systems and settings
- Each recommendation targets improvement in specific subdomains of the Diagnostic Process and Outcomes domain of the 2017 Measurement Framework
- The subdomains include:
 - Information Gathering and Documentation
 - Information Integration
 - Information Interpretation
 - Diagnostic Efficiency
 - Diagnostic Accuracy
 - Follow-Up



Recommendations for Applying the Diagnostic Process and Outcomes Domain of the 2017 Measurement Framework

- 1. Implement quality improvement activities to identify and reduce diagnostic errors from occurring
- 2. Engage clinicians to actively listen to patients, and empower patients to provide feedback and share information
- 3. Deploy clinician education and training for specific 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
- 5. Increase and improve information sharing and collaboration within and across teams and organizations
- 6. Develop and deploy clinical protocols and pathways to standardize care
- 7. Use technology as a tool to identify and reduce error



Implement Quality Improvement Activities to Identify and Reduce Diagnostic Errors From Occurring

Rationale

- Implementing quality improvement activities and remediating diagnostic errors will drive improvement in the subdomains of Information Gathering and Documentation, Information Integration, Information Interpretation, Diagnostic Efficiency, Diagnostic Accuracy, and/or Follow-up
- When healthcare organizations and clinicians assess the type of diagnostic error that occur in their facility, they are better able to identify contributing factors and deploy targeted interventions to prevent the error in the future

Implementation

• 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

Recommendations for Applying the Diagnostic Process and Outcomes Domain of the 2017 Measurement Framework

Implement quality improvement activities to identify and reduce diagnostic errors from occurring

- Engage clinicians to actively listen to patients, and empower patients to provide feedback and share information
- Deploy clinician education and training for specific diagnostic errors
- Educate clinicians about the science of diagnostic error
- Develop and deploy clinical protocols and pathways to standardize care
- Use technology as a tool to identify and reduce error
- Support a culture of teamwork in the diagnostic process
- Improve information sharing and across teams and organizations

Recommendations for Measuring and Reducing Diagnostic Error, and Improving Patient Safety

Use measurement as a mechanism for continuous quality improvement in the diagnostic process and to improve diagnostic outcomes

- Use patient-reported measures to understand, assess, and improve the role of patients in the diagnostic process
- Measure the total cost, time, and/or other impacts of diagnostic odysseys

• Measure clinicians' level of competency in diagnosis and adherence to protocols, and measure clinician feedback to support further reduction of diagnostic error

• Evaluate the impact of technology on diagnostic error, and leverage technology to improve the ability of detecting and reducing diagnostic errors

• Measure the use of and communication between specialists, second opinions, and teamwork

- Assess the appropriate use and follow-up of laboratory testing and radiology
- Measure participation in health information exchanges and other data sharing programs



Recommendations for Measuring and Reducing Diagnostic Error and Improving Patient Safety

- 1. Use measurement as a mechanism for continuous quality improvement in the diagnostic process and to improve diagnostic outcomes
- 2. Use patient-reported measures to understand, assess, and improve the role of patients in the diagnostic process
- 3. Measure clinicians' level of competency in diagnosis and adherence to protocols, and measure clinician feedback to support further reduction of diagnostic error
- 4. Evaluate the impact of technology on diagnostic error, and leverage technology to improve an organization's ability to detect and reduce diagnostic errors
- 5. Measure the use of and communication between specialists, second opinions, and teamwork throughout the diagnostic process
- 6. Assess the appropriate use and follow-up of laboratory testing and radiology during the diagnostic process
- 7. Measure the total cost, time, and/or other impacts of diagnostic odysseys
- 8. Measure participation in health information exchanges and other data sharing programs



Use Measurement as a Mechanism for Continuous Quality Improvement in the Diagnostic Process and to Improve Diagnostic Outcomes

Rationale

• Continuous quality improvement is a critical mechanism to continue advancing the science of diagnostic error, and the use of measurement is an essential part of the continuous quality improvement process

- Medical specialty societies should provide guidance as diagnostic error measures are developed
- Organizations, healthcare administrators, and clinicians should use specific healthcare quality measure concepts to assess current processes and outcomes
 - Data should be used to inform targeted interventions and measure their effectiveness over time
 - Measures should be specific, relevant, and actionable, and measure outcomes rather than process or structure
- Healthcare organizations should:
 - Deploy teams that engage in clinical quality improvement and provide systems to measure errors across a variety of data sources (e.g., patient- and –clinician reported data, EHR data, and health plan claims)
 - Partner with clinicians to understand how to elicit information on delayed diagnoses and subsequent harms
- Measurement should be deployed at a national level to hold facilities and clinicians accountable



Use Patient-Reported Measures to Understand, Assess, and Improve the Role of Patients in the Diagnostic Process (1 of 2)

Rationale

- Gathering information directly from a patient, family, or caregiver helps to measure communication quality and avoid possible diagnostic errors in a fragmented system and/or when only the patient is aware of a miscommunication
- Partnerships with patients are especially critical in preventing diagnostic errors related to communication failures, information overload, and dismissed patients

- Organizations should assess if patients are empowered to participate as part of the diagnostic team:
 - Measure the existence and use of patient portals
 - Develop systems for patients to be able to report errors, and a robust way to respond to and remediate those errors though clinical quality improvement
 - Evaluate patient experience with communication
 - Existing Measure: <u>NQF #1066</u>: Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) surveys
 - Measure the rate of use of interpreter services when English is not a patient's preferred language
 - Existing Measure: <u>NQF #1821</u>: Patients Receiving Language Services Supported by Qualified Language Services Providers



Use Patient-Reported Measures to Understand, Assess, and Improve the Role of Patients in the Diagnostic Process (2 of 2)

Implementation

• **Opportunities for measure developers** include prioritizing measure development of patient-reported measures (e.g., patient-reported understanding of diagnosis and/or diagnostic uncertainty after discharge, patient-reported perceptions of their input into the diagnostic process, and patient-reported experience with the diagnostic process)



Measure Clinicians' Level of Competency in Diagnosis and Adherence to Protocols, and Measure Clinician Feedback to Support Further Reduction of Diagnostic Error (1 of 2)

Rationale

- Deploying education and training to students and practicing clinicians on the science of diagnostic error and diagnosis-related competencies can decrease the occurrence of diagnostic error
- Protocols, clinical decision support tools, and other electronic tools can serve as cognitive forcing strategies to guide a clinician through the diagnostic process and can reduce the risk of diagnostic errors due to missed subtleties

- Organizations should:
 - Focus on ensuring that all clinicians receive training on diagnostic errors, and the tools available to prevent them (e.g., protocols)
 - Measure the ability of clinicians to make accurate diagnoses, and assess the presence, use, and adherence of protocols that exist with the diagnostic process
 - Identify which clinical syndromes have protocols, clinical decision support tools, or other electronic tools in place and use chart review to measure the rate of protocol use



Measure Clinicians' Level of Competency in Diagnosis and Adherence to Protocols, and Measure Clinician Feedback to Support Further Reduction of Diagnostic Error (2 of 2)

Implementation

- Organizations should (continued):
 - Promote transparency by including a dashboard that assesses clinician-level adherence to protocols within the EHR or actual rates of diagnostic errors through the EHR, e-trigger tools, or chart review
 - 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)
 - Existing measures:
 - <u>NQF #0090</u>: Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain
 - <u>NQF #0577</u>: Use of Spirometry Testing in the Assessment and Diagnosis of Chronic Obstructive Pulmonary Disease (COPD) to assist in the diagnosis of COPD

• Opportunities for measure developers include:

- Prioritizing measure development of measures that assess clinician feedback (e.g., clinician-reported measures on receiving feedback on diagnostic performance and adherence to protocols)
- Exploring measure concepts that evaluate the proportion of existing protocols that use an e-trigger tool to monitor protocol compliance



Evaluate the Impact of Technology on Diagnostic Error, and Leverage Technology to Improve an Organization's Ability to Detect and Reduce Diagnostic Errors

Rationale

• Recognizing the impacts of the technology on the diagnostic process, stakeholders must assess how technology itself both reduces and contributes to diagnostic errors

- **Organizations** should:
 - Assess the usability of the EHR by measuring clinician-reported assessments of usability and addressing specific issues that arise
 - 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
 - Existing measure: <u>NQF #490</u>: The Ability to use Health Information Technology to Perform Care Management at the Point of Care
- **Stakeholders** should also monitor for unintended consequences (e.g., over adherence to protocols leading to an increase in a different diagnostic error)
- **Opportunities for measure developers** include measuring how technology can detect errors across settings, such as evaluation the proportion of diagnoses where an e-trigger tool is used



Measure the Use of and Communication Between Specialists, Second Opinions, and Teamwork Throughout the Diagnostic Process (1 of 2)

Rationale

- 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
- Measuring and understanding communication and teamwork processes will help reduce systems errors due to communication failures, as well as cognitive errors due to missed subtle clinical findings and clinician biases

- 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
 - Share measurement results transparently with staff to create a learning and feedback system
 - Measure care coordination and teamwork across settings
 - Existing measure: <u>NQF #0291</u>: Emergency Transfer Communication Measure
 - Use disease-specific quality measures that incorporate specialized exams being performed with documented communication to the physician who manages the ongoing care of the patient



Measure the Use of and Communication Between Specialists, Second Opinions, and Teamwork Throughout the Diagnostic Process (2 of 2)

- Organizations should (continued):
 - Use disease-specific quality measures that incorporate specialized exams being performed with documented communication to the physician who manages the ongoing care of the patient
 - Existing measures:
 - <u>NQF #0089</u>: Diabetic Retinopathy: Communication with Physician Managing Ongoing Diabetes Care
 - <u>NQF #0045</u>: 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
- Opportunities for measure developers include:
 - Measuring the percentage of systems that have protocols for closed-loop communication for test results and relational coordination
 - Prioritizing measure concepts that assess when team-based approaches are initiated (e.g., 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)



Assess the Appropriate Use and Follow-up of Laboratory Testing and Radiology During the Diagnostic Process (1 of 2)

Rationale

- Advancements in testing and imaging over the past several decades have enabled clinicians to obtain increasing amounts of data to inform the diagnostic process, and communication on laboratory and radiology test results and follow-up is essential
- Using laboratory test and radiology appropriately during the diagnostic process helps reduce errors due to missed subtle clinical findings, and the timely and thorough follow-up on results helps limit communication failures

- Clinicians should:
 - Communicate and coordinate with individuals to facilitate testing and follow-up on results, often across care settings and health systems
 - Recognize the impacts of overusing diagnostic tests and thoughtfully order the appropriate test in the context of a patient's entire care process
 - 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



Assess the Appropriate Use and Follow-up of Laboratory Testing and Radiology During the Diagnostic Process (2 of 2)

- Organizations should:
 - Measure the appropriate use of imaging and radiology for specific conditions that are relevant for their patient population
 - Existing measures:
 - CMIT ID 2553: Overuse of Imaging for the Evaluation of Primary Headache
 - <u>CMIT ID 2539</u>: Appropriate Follow Up Imaging for Incidental Abdominal Lesions
 - NQF #0508: Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms
 - Measure how information is shared across clinicians when ordering, performing, and following-up on radiology and laboratory results to evaluate closed-loop communication processes
 - Existing Measures:
 - NQF #0645: Biopsy Follow-Up
 - NQF #0491: Tracking of Clinical Results Between Visits
 - Use balancing measures to evaluate over testing, overuse, and incidental findings
- **Opportunities for measure developers** include focusing efforts on assessing the appropriate use of testing, communication of test results, and sharing of laboratory testing and radiology information across settings 26



Measure the Total Cost, Time, and/or Other Impacts of Diagnostic Odysseys

Rationale

• Patients may experience diagnostic delays through long, diagnostic odysseys, with wide-reaching impacts and potential for harm, that ultimately lead to a rare or complex diagnosis

- Healthcare organizations and clinicians should:
 - Engage patients who have undergone diagnostic odysseys to evaluate their experiences with the diagnostic process
 - Conduct root cause analyses of delays to identify solutions to remediate identified problem
- Opportunities for measure developers include:
 - Focusing measure development efforts on assessing the total cost, time, and/or other impacts of diagnostic odysseys (e.g., amount of days from original chief complaint until a final, accurate diagnosis)
 - Developing 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
 - Assessing the frequency of late-stage or emergency presentations in patients who have sought care before (e.g., late stage cancer presentations for a patient who has been to the ED multiple times)



Measure Participation in Health Information Exchanges and Other Data Sharing Programs (1 of 2)

Rationale

- Measuring the current use and limitations of interoperability of health information and information sharing across settings will help reduce communication issues and support future interoperability to reduce diagnostic error
- If organizations do not have strong data infrastructures in place, patients may be more likely to experience diagnostic errors related to communication failures, missed subtle clinical findings, and dismissed patient concerns

- Organizations should assess EHR interoperability
 - Existing measure: <u>NQF #0489</u>: The Ability of Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data Elements



Measure Participation in Health Information Exchanges and Other Data Sharing Programs (2 of 2)

- Opportunities for measure developers include:
 - Focusing efforts on measuring the interoperability of health information technology.
 - Assessing the presence of interoperability and data sharing across EHRs and communities
 - Identifying the rates and percentages of health system participation in health information exchanges and other data sharing programs
 - Building on the measure concepts proposed in NQF's *Identification and Prioritization of Health IT Patient Safety Measures* report (e.g., 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)

Review and Discuss Public Comments



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

Name Comment Comment Response	
Nicholas Kuzma St. Christopher's Hospital for ChildrenProvide education to support clinicians in engaging patients and families as part of the diagnostic team:Thank you for you feedback. We have included informa about creating 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 you feedback. We have included informa about creating contingency plan solution to addred the challenges outlined in the US Case 1.	ve tion s as a ss



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

Bob Hussey RGH Health ConsultingWolters 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).Thank you for your comments. We appreciate your thoughtful feedback on the recommendations in the Report.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). Degular use of Wolters Kluwer's UnTendetoThank you for your comments. We appreciate your thoughtful feedback on the recommendations in the Report.	Commenter Name	Comment	Response
software, for example, may qualify clinicians for continuing medical education credits.	RGH Health	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	comments. We appreciate your thoughtful feedback on the recommendations in



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
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. 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 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).	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.



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.



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	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).	Thank you for your comments. We appreciate your feedback on the measure concepts.
	Measures that utilize patient-reported data also merit development, including patient-reported understanding of diagnosis and/or diagnostic uncertainty after discharge (page 37).	


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 re-evaluated after initial implementation.



Commenter Name	Comment	Response
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 alert software performance, several of which may help reduce diagnostic error. Though it is more common for medication 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.	Thank you for your feedback. We appreciate the information you have provided.



Commenter Name	Comment	Response
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.



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.



Commenter Name	Comment	Response
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.



Commenter Name	Com	nent Respo	onse
Nicholas Kuzma St. Christopher's Hospital for Children	Yes	Thank you fo feedback.	or your



Commenter Name	Comment	Response
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.	Thank you for your comments. We appreciate your thoughtful feedback on the Report.
	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.	



Commenter Name	Comment	Response
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 practices is essential to improving patient safety, diagnostic quality and clinical outcomes.	Thank you for your comments. We appreciate your thoughtful feedback on the recommendations outlined in the Report.
	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 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.



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	Continued: 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.



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

Commenter Name	Comment	Response
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 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_reasoning13.aspx). I would consider deemphasizing the importance of these biases as explanations for errors.	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/teac h-back as a solution in Use Case 2.



Please also share any general comments or feedback on the Draft Report. (1 of 2)

Commenter Name	Comment	Response
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 the distinction between these types of findings and perhaps specify which solutions are more effective at addressing the different types of subtle findings.	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.



Please also share any general comments or feedback on the Draft Report. (2 of 2)

Commenter Name	Comment	Response
Gerard Castro Society to Improve Diagnosis in Medicine	Continued: 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.



Please also share any general comments or feedback on the Draft Report. (1 of 3)

Commenter Name	Comment	Response
Brenna Rabel Battelle Memorial Institute	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.



Please also share any general comments or feedback on the Draft Report. (2 of 3)

Commenter Name	Comment	Response
Brenna Rabel Battelle Memorial Institute	Continued: 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 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.	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.



Please also share any general comments or feedback on the Draft Report. (3 of 3)

Commenter Name	Comment	Response
Brenna Rabel Battelle Memorial Institute	<i>Continued:</i> 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.



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

Commenter Name	Comment	Response
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 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.	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 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.



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

Commenter Name	Comment	Response
Carlos Higuera- Rueda	It is a well written and clear document. I do not have any changes.	Thank you for your feedback.

Opportunity for Public Comment

Next Steps



Next Steps for Reducing Diagnostic Error

Event/Item	Date
Final Report	October 7, 2020



Project Contact Information

- Email: <u>diagnosticerror@qualityforum.org</u>
- NQF phone: 202-783-1300
- Project page: <u>http://www.qualityforum.org/Reducing Diagnostic Error.aspx</u>
- SharePoint: <u>http://share.qualityforum.org/Projects</u>

Questions?

Closing Comments

THANK YOU.

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