Improving Diagnostic Quality and Safety: Draft Measurement Framework

DRAFT

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Introduction

The delivery of high-quality health care is predicated upon an accurate and timely diagnosis. The 2015 study of the National Academies of Sciences, Engineering, and Medicine (NASEM) (previously known as the Institute of Medicine [IOM]) Improving Diagnosis in Health Care, found that while most people will experience at least one diagnostic error in their lifetime, stakeholders in quality measurement and patient safety have largely neglected the issue. This is due to a wide range of factors, but the NASEM Committee noted that one major contributing factor is the lack of effective measurement in this area.

In an effort to develop a measurement framework for diagnostic accuracy, the National Quality Forum (NQF) convened a multistakeholder expert Committee to develop a conceptual framework for measuring health care organization structures, processes, and outcomes that address the improvement of diagnostic accuracy; and identify any existing measures consistent with the conceptual framework.

Background and Project Objectives

The delivery of high-quality health care is predicated upon an accurate and timely diagnosis. Diagnostic errors are defined as the failure to establish or communicate an accurate and timely assessment of the patient’s health problem. A 2015 study of the National Academies of Sciences, Engineering, and Medicine (NASEM) (previously known as the Institute of Medicine [IOM]), Improving Diagnosis in Health Care, found that at least 5 percent of U.S. adults seeking outpatient care each year experience a diagnostic error. These types of errors contribute to nearly 10 percent of deaths each year, and up to 17 percent of adverse hospital events. The NASEM Committee suggested that most people will experience at least one diagnostic error in their lifetime.

Diagnostic errors persist through all care settings and can result in physical, psychological, or financial repercussions for the patient. However, despite the importance of accurate and timely diagnosis, stakeholders in quality measurement and patient safety have largely neglected the issue. The NASEM Committee noted that a major contributing factor to this neglect is the lack of effective measurement in the area. The NASEM Committee observed that “for a variety of reasons, diagnostic errors have been more challenging to measure than other quality or safety concepts.” The NASEM report addresses “how measurement can be used to better characterize diagnostic errors by identifying the causes and the risks associated with diagnostic error”

In follow-up to the NASEM report, the National Quality Forum (NQF) convened a multistakeholder expert committee (the Diagnostic Quality and Safety Committee) to develop a conceptual framework for measuring diagnostic quality and safety, to identify gaps in measurement of diagnostic quality and safety, and to identify priorities for future measure development. NQF will engage stakeholders from across the spectrum to explore the complex intersection of issues related to diagnosis.

The conceptual framework is intended to facilitate systematic identification and prioritization of measure gaps, and to help guide efforts to fill those gaps through measure development and endorsement. This document describes the draft conceptual framework being considered by the Committee. The Committee will review comments submitted on this draft as they continue to refine and finalize the framework, and as they work to identify and prioritize measures, measure concepts, or measurement areas.

Terminology and Scope
At the outset of this project, the focus of the work was identified as measurement of diagnostic accuracy. However, a number of Committee members suggested that the term ‘diagnostic accuracy’ was too narrow and did not adequately reflect the range of potential diagnosis-related quality issues that could and should be addressed by measurement. For instance, it is not clear that ‘diagnostic accuracy’ would encompass important issues such as timeliness of diagnosis and communication with patients and families about diagnosis. For this reason, the Committee agreed that the focus of the project should instead be on improving diagnostic quality and safety. Some Committee members argued that the Committee should concentrate its attention on diagnostic safety in particular, suggesting that the term ‘quality’ could create too broad of a scope, and that avoiding or reducing diagnostic errors represents the greatest opportunity to make an impact on patient care. Ultimately, the Committee determined that their work should include all of the dimensions of quality identified by the Institute of Medicine, including safety, effectiveness, patient-centeredness, timeliness, efficiency, and equitability, as these dimensions apply to diagnosis.

Draft Framework for Measuring Diagnostic Quality and Safety
The preliminary draft framework being considered by the Diagnostic Quality and Safety Committee is based largely on the NASEM Committee’s conceptual model of the diagnostic process (see Appendix B), also drawing on concepts from Singh and Sittig’s Safer Dx Framework. For the purposes of identifying, categorizing, and prioritizing measures, elements of the NAM model have been set within Donabedian’s organizing concepts of structure, process and outcome. To illustrate how this framework may be applied in practice, Appendix C presents examples of measure concepts that could reflect the framework domains.

Structure
The Structure domain of the framework comprises aspects or attributes of the work system in which diagnosis occurs; these attributes may include the presence or availability of material or human resources, the characteristics, policies, and procedures of organizations involved in the diagnostic

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process, factors related to tools and technologies used in the diagnostic process, and social or environmental factors that have an impact on diagnosis.

Structure subdomains:

- **People**: Addresses factors related to the diagnostic team, which includes patients and their families as well as all health care professionals involved in their care. This subdomain may include issues

- **Workflow and Tasks**: Addresses the extent to which the work system enables or impedes the various actions and processes involved in diagnosis. This subdomain is not intended to address whether the appropriate actions and processes have themselves occurred—this is covered in the Process domain—but rather the degree to which organizational systems, policies, and procedures have established conditions under which these tasks are likely to be executed successfully.

- **Technologies and Tools**: Addresses the availability and adequacy of tools used in the diagnostic process, including health information technology (HIT), laboratory and imaging resources, data tools, and other resources used by diagnostic team members to reach an accurate and timely diagnosis.

- **Organizational Characteristics**: Addresses organizational attributes that affect diagnostic performance, including culture, leadership, physical environment, policies and procedures related to diagnosis, and quality improvement activities.

- **External Environment**: Addresses the extent to which the external environment (e.g., legal factors, policies, regulations, payment models, etc.) facilitates or constrains diagnostic performance.

**Process**

The process domain of the framework addresses whether actions or processes supporting accurate and timely diagnosis are being performed safely, effectively, and as appropriate. The Committee agreed that, for the purposes of measurement, diagnosis-related processes could generally be categorized into two broad categories: **patient engagement** (e.g., the extent to which patients and families are being involved as members of the diagnostic team; the quality of communication between patients and providers; etc.) and aspects of the **diagnostic process** carried out primarily by healthcare providers (e.g., gathering, integrating, and interpreting information relevant to the diagnosis; clinical reasoning; etc.)

The Committee observed that additional granularity may be needed to facilitate identification and prioritization of measure gaps or measurement areas, and is considering several possible approaches to categorizing measures within the ‘diagnostic process’ subdomain, as described below.

Process subdomains:

- **Patient Engagement**: Addresses actions, processes, and behavior related to engagement of patients and families in the diagnostic process, including ensuring timely access to care, patient behavior, and communication between the patient and provider about diagnosis-related issues.

- **The Diagnostic Process**: Addresses the actions and processes that are carried out by healthcare providers (e.g., clinicians, hospitals, etc.) to develop, refine, and confirm a diagnosis, or
explanation of the patient’s health problem. As noted by the NAM, diagnosis is a complex, collaborative process that occurs over time, iterating and evolving with new information. This creates difficulties in breaking the diagnostic process out into discrete steps or elements, since there is a high degree of overlap and inter-dependence across the various activities involved in diagnosis. Nevertheless, the Committee recognizes that more granular categories may be useful for identifying measurement gaps and prioritizing of measurement areas. To this end, the Committee is considering several approaches to characterizing and distinguishing between different aspects of the diagnostic process. These include:

- **The NASEM model:** The NASEM’s conceptual model identifies three key aspects of the diagnostic process (The NASEM model describes other aspects as well, but these are addressed by other elements of this proposed framework):
  - **Information gathering:** Addresses the actions, processes, and behavior involved in gathering information and carrying out an initial diagnostic evaluation.
  - **Information interpretation:** Addresses the actions, processes, and behavior involved in interpreting information gathered through diagnostic evaluation and generating a hypothesis to explain the patient’s health problem.
  - **Information integration:** Addresses the actions, processes, and behavior involved in integrating information from various sources in order to confirm and revise diagnosis over time; this subdomain includes communication of diagnosis-related information between healthcare providers.

- **The SaferDx model:** Singh and Sittig’s SaferDx Framework identifies five dimensions of the diagnostic process:
  - Patient-provider encounter and initial diagnostic assessment
  - Diagnostic test performance and interpretation
  - Follow-up and tracking of diagnostic information
  - Subspecialty consultation/referral issues
  - Patient-related factors

Committee members suggested other potential approaches to categorizing aspects of the diagnostic process, including distinguishing between things that happen early in the diagnostic process vs. things that play out over time, and distinguishing between things that happen at the bedside vs. things that happen in the interactive process with the rest of the healthcare team.

**Outcome**

The outcome domain of the framework addresses outcomes associated with diagnosis, or the effects of diagnosis-related activities on patients.

Outcome subdomains:

- **Diagnostic outcomes:** Address the extent to which an accurate and timely diagnosis, or explanation of the patient’s health problem, has been achieved.
- **Patient outcomes:** Addresses changes in patients’ health status that can or may be linked to the quality of diagnostic care. The Committee noted that this subdomain would include not just clinical outcomes for patients, but also psychological or financial harm that results from diagnostic error.
• **Patient experience:** Addresses patients’ experiences with their care, as it relates to diagnosis or the diagnostic process

• **System outcomes:** Addresses outcomes for the healthcare system as a whole (or individual health systems), including costs, resource use, patient trust/confidence, and other system outcomes related to diagnosis.

**Other issues and Cross-Cutting Themes**

A number of issues and themes have emerged from the Committee’s initial discussions; these and other issues will be explored further by the Committee as this project moves forward. Themes include:

**Unintended consequences**

Committee members noted that, as with any measurement effort, measuring diagnostic quality and safety carries the risk of creating unintended consequences. The Committee will examine the potential unintended consequences that could be associated with measuring diagnostic quality and safety, including:

• **Measurement burden:** Many stakeholders have raised concerns about the proliferation of measures and measurement programs across the healthcare landscape. Creating a new dimension of measurement in diagnostic quality and safety could add to this burden, and Committee members stressed that this should remain an important consideration as their recommendations are developed.

• **Balancing incentives:** Committee members noted that a focus on measuring diagnostic error and missed diagnosis could potentially incentivize overutilization of testing or lead to unnecessary diagnoses and overtreatment. The Committee suggested that one approach to addressing this concern would be to balance measures of diagnostic error with measures of overuse (e.g., pairing measures of diagnostic error in stroke patients with monitoring of neuroimaging utilization).

**Patient-centeredness**

Committee members stressed that their deliberations and recommendations should be approached with the patient always in mind. It was noted that diagnosis, treatment, and quality improvement efforts can all be improved with robust patient involvement, and that patient engagement is not just a matter of explaining the diagnosis to the patient, but should be a conversation with patients and families, who are often the most knowledgeable parties when it comes to their own symptoms and conditions.
Appendix A. Committee Panel, Federal Liaisons and NQF Staff

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Appendix B. NASEM Conceptual Model of the Diagnostic Process

### Appendix C: Examples of Measure Concepts in Each Framework Category

<table>
<thead>
<tr>
<th>Structure</th>
<th>Subdomain</th>
<th>Examples of measure concepts</th>
</tr>
</thead>
</table>
| **People** | - Patient factors  
- Workforce factors  
- Administrative and clinical support | - Staff involved in diagnosing patients have appropriate competency to do so  
- Provider mix involved in diagnosis are appropriate for the complexity of the case  
- Radiologists are available 24/7 to read stat diagnostic imaging studies in real time  
- Attending staff are on site to supervise trainees 24/7  
- Support staff operate at the top of their license to free up cognitive load of the MD  
- Scribes, administrative staff are available to support diagnosis  
- Patients understand actions they can take to improve diagnostic performance |
| **Workflow and Tasks** | - Workflow  
- Communication  
- Diagnosis | - SOP’s exist for triaging patients and assigning them to appropriate providers  
- Consult agreements exist between primary care and subspecialty consultants  
- SOP’s are in place to ensure test results are communicated reliably  
- Second opinions and specialty consultation are available |
| **Technologies and Tools** | - Hardware and software  
- Clinical content of HIT (e.g., clinical decision support)  
- Human-computer interface  
- Availability of diagnostic resources | - The organization uses an interoperable and certified EHR with CDS functionality  
- Web-based decision support tools and online reference materials are available to all providers to aid differential diagnosis  
- Advanced imaging and laboratory diagnostics are available  
- The organization has an EHR data warehouse and informatics team to enable diagnostics measurement related to diagnostic safety (e.g., trigger tools)  
- Proportion of patients that have electronic portal access  
- EHR allows for the capture of the chief complaint  
- EHR allows for designating patients as 'not yet diagnosed' (NYD) |
| **Organizational Characteristics** | - Culture  
- Policies and procedures (e.g., time allocated for diagnosis, oversight of the process)  
- Layout, noise, lighting  
- Distractions and interruptions | - Leadership understands that diagnostic error is a major safety concern that needs addressing  
- Healthcare organizations develop processes and procedures to identify and learn from cases of diagnostic error  
- The organization has an established mechanism for providing feedback when there is a significant change in diagnosis |
- Monitoring diagnostic performance
- Identifying diagnostic errors
- Learning and improving

- The organization has expertise to conduct a comprehensive RCA in cases involving diagnostic error
- The organization has someone designated to monitor and improve diagnostic performance
- Physicians have adequate time for diagnosis
- Organization monitors adenoma detection rates and provides feedback to endoscopists
- Organization measures diagnostic performance (lab, radiology, ER, selected specialties or clinical conditions)
- Organization sponsors and encourages learning through M&M conferences, etc.
- Policies are in place to encourage apology and disclosure of dx errors, and restitution if appropriate.

### External Environment

- Payment
- Care delivery system
- Legal environment
- Reporting environment

- Payment incentives promote quality over quantity
- Care delivery system promotes primary care approach & care coordination
- Care delivery is patient-centered, not physician-centered
- The legal environment promotes case discussions, error reporting, and learning to improve diagnosis

### Process

<table>
<thead>
<tr>
<th>Subdomain</th>
<th>Examples of measure concepts</th>
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<tbody>
<tr>
<td><strong>Patient engagement</strong></td>
<td>- Proportion of patients with appropriate compliance with cancer screening</td>
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<tr>
<td></td>
<td>- Proportion of patients that actively use electronic portal access</td>
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<td>- Ease of getting an appointment</td>
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<td>- Patient access is expanded geographically and through extra hours nights, weekends</td>
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<td>- Adequacy of assessing patient literacy</td>
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<td>- Communication about the diagnosis is documented</td>
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<td>- Tests pending at discharge are followed-up</td>
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<td>- Revised reports from radiology and pathology are appropriately communicated</td>
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<td></td>
<td>- Critical results are reliably communicated</td>
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<td>- Communication accommodates patient literacy level</td>
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<td>- Access to care</td>
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<td></td>
<td>- Patient behavior</td>
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<td>- Timing of presentation</td>
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<td>- Communication with patient</td>
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<td></td>
<td>- Failure/delay in notification of patient</td>
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<td></td>
<td>- Incomplete explanation</td>
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<td></td>
<td>- Patient does not understand explanation</td>
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<tr>
<td><strong>The Diagnostic Process</strong></td>
<td>- Adequacy of documenting the initial findings; clarity and accuracy of the documentation</td>
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<td></td>
<td>- Adequacy of collecting available data; adequacy of connecting to other providers and the family</td>
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<td></td>
<td>- New problems generate a differential diagnosis</td>
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</tbody>
</table>
• Connecting with family, caregivers, and primary care staff
• Ordering the appropriate diagnostic tests
• Technical errors in handling or processing of diagnostic tests
• Interpretation of history, physical exam findings, test results
• Weighting and prioritization of information
• Integration of team-based information
• Generating diagnostic possibilities that are rational, evidence-based if possible, and not inappropriately biased
• Testing follow-up
• Consultation from specialists
• Time-related aspects of diagnosis: Watchful waiting, re-evaluation after tests and consults;
• Appropriate follow-up

• Clinical decision support is used appropriately to ensure diagnosis is comprehensive
• Proportion of diagnostic evaluations with appropriate team involvement
• Proportion of patients with timely follow up
  • After an initial diagnosis
  • After identification of a red flag condition
  • After identification of incidental but possibly important findings
• Proportion of patients diagnosed with a specified target disease of interest (e.g., known diagnostic dilemmas) who received a second opinion
• Problem list is accurate and up-to-date
• Diagnosis is timely:
  • Proportion of laboratory test results or diagnostic imaging not performed within the expected turnaround time
  • Proportion of abnormal diagnostic test results returned but not acted upon within an appropriate time window
  • Proportion of clinical providers who identify a surrogate to review diagnostic test results while on vacation or when leaving employment
  • Timeliness of cancer evaluation; e.g., time from positive blood in stool to colonoscopy

<table>
<thead>
<tr>
<th>Subdomain</th>
<th>Examples of measure concepts</th>
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<tbody>
<tr>
<td>Diagnostic outcomes</td>
<td>• Proportion of patients with newly-diagnosed colorectal cancer diagnosed within 60 days of first presentation of known red flags</td>
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<td></td>
<td>• Discrepancy rate of pathological interpretations</td>
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<td></td>
<td>• Timeliness of diagnosing targeted diseases of interest (anemia, asthma, diabetes, COPD, etc)</td>
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<tr>
<td>Patient outcomes</td>
<td>• Failure to rescue episodes</td>
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<td></td>
<td>• % of cancers diagnosed at late stage, or that should have been found through screening</td>
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<td></td>
<td>• # of diagnostic errors reported by MD’s or patients</td>
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<td></td>
<td>• # of patients targeted through trigger tools designed to avoid harm</td>
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<tr>
<td>Patient experience</td>
<td>• Patient satisfaction with the diagnostic process</td>
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</tbody>
</table>
- Patient surveys or other patient-focused assessments of diagnosis-related experience

<table>
<thead>
<tr>
<th><strong>System outcomes</strong></th>
<th><strong># of malpractice suits</strong></th>
<th><strong># of re-visits and re-admissions related to diagnostic error</strong></th>
<th><strong># of patients who leave the system to get diagnosed elsewhere</strong></th>
</tr>
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<tbody>
<tr>
<td>- Cost &amp; resource use</td>
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<td></td>
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<tr>
<td>- Efficiency</td>
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