NATIONAL QUALITY FORUM

Memo

June 12, 2017

TO: NQF Members and Public

FR: NQF Staff

RE: Commenting Draft Report: *Improving Diagnostic Quality & Safety*

Background

The delivery of high-quality healthcare 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 quality and safety, the National Quality Forum (NQF) convened a multistakeholder expert Committee to provide guidance and input on the development of a conceptual framework for measuring the quality and safety of diagnostic care, and to identify any existing measures consistent with the conceptual framework.

Ahead of this comment period, the Committee provided feedback to provide more emphasis on:

- The importance of outcome and patient reported outcome (PRO) measures as it relates to diagnostic quality and safety
- Diagnostic error and harm, highlighting for example the most common causes of harm in diagnostic error
- The importance of interoperability, intraoperability and cooperation among non-economically linked entities
- The possible link between pay for performance and diagnostic quality and safety measures

Note that some of the Committee's feedback has already been incorporated into the report; further revisions will be made during the comment period.

NQF Member and Public Commenting

NQF Members and the public are encouraged to provide comments via the online commenting tool on the draft report as a whole, or on specific measure concepts or measurement areas identified by the Improving Diagnostic Quality & Safety Committee.

Please note that commenting concludes on July 12, 2017 by 6:00 pm ET – no exceptions.

Improving Diagnostic Quality and Safety: Draft Report

DRAFT REPORT FOR COMMENT

June 12, 2017

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Contents

Introduction

The delivery of high-quality healthcare 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.[1] 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 related to the diagnostic process and diagnostic outcomes.

In an effort to develop a measurement framework for diagnostic quality and safety, the National Quality Forum (NQF) convened a multistakeholder expert Committee to provide guidance and input on the development of a conceptual framework for measuring the quality and safety of diagnostic care, and to identify any existing measures consistent with the conceptual framework.

Background and Project Objectives

The report 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.[2] 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.[3] These types of errors contribute to nearly 10 percent of deaths each year, and up to 17 percent of adverse hospital events.[4] 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 responsible for quality care 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."[5] 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."[6]

In follow-up to the NASEM report, the National Quality Forum (NQF), with funding from the Department of Health and Human Services (HHS) convened a multistakeholder expert Committee (see Appendix B) 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 engaged stakeholders from across the healthcare spectrum to explore the complex intersection of issues related to diagnosis.

The conceptual framework intends 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 under consideration 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 onset of this project, the work focused on 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 through 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 submitted that the Committee should concentrate its attention on diagnostic safety in particular, suggesting that the term 'quality' could create too broad of a scope. They noted that avoiding or reducing diagnostic errors represents the greatest opportunity to make a near-term 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.[7]

Draft Framework for Measuring Diagnostic Quality and Safety

Preliminary Framework

The Diagnostic Quality & Safety Committee developed a preliminary draft framework based largely on the NASEM Committee's conceptual model of the diagnostic process (see Appendix C), while also drawing on concepts from Singh and Sittig's SaferDx Framework and Donabedian's organizing concepts of structure, process, and outcome.

Structure Domain (Preliminary)

In the preliminary framework, the **Structure** domain comprised aspects or attributes of the work system in which diagnosis occurs. These attributes may include the presence or availability of diagnostic material or human resources; the characteristics, policies, and procedures of organizations involved in the diagnostic process; factors related to tools and technologies used in the diagnostic process; and social or environmental factors that have an impact on diagnosis.

Process Domain (Preliminary)

In the preliminary framework, the **Process** domain addressed 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: 1) **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 2) 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 considered several possible approaches to categorizing measures within the 'diagnostic process' subdomain.

Outcome Domain (Preliminary)

In the preliminary framework, the **Outcome** domain addressed outcomes associated with diagnosis, or the effects of diagnosis-related activities on patients.

During the public and member comment period on January 31 – March 1, 2017, the Committee and members of the public submitted comments on this preliminary draft framework and submitted measure concepts related to diagnostic quality and safety. Over 20 comments were submitted on the framework and 200 measure concepts for the Committee's consideration (see Appendix F for comments).

Current Draft Framework for the Measurement of Diagnostic Quality & Safety

Following the comment period, the initial framework based on Donabedian's model no longer appeared to be optimal, as numerous measurement themes within subdomain crossed over into other domains. Additionally, not every subdomain contained structure, process, and outcome measures. It became evident that structure, process, and outcomes were better suited as measure types than as domains. After a thorough review of several hundred measure concepts submitted by Committee members, the Framework was revised to consist of three broad domains: 1) Patients, Families, and Caregivers, 2) The Diagnostic Process, and 3) Organizational & Policy Opportunities. Measure concepts were then organized into these three new domains, while still preserving the key elements of the initial proposed framework. Only slight changes were made to the subdomains: the Patient Clinical Outcomes subdomain is now represented within the Patient, Families, and Caregivers domain; the Intermediate Diagnostic Outcomes subdomain is represented within the Diagnostic Process domain; System Outcomes are included in the Organization Domain; and issues related to workflow, technology, and tools are included across multiple domains. Committee members also concluded that, while the external environment is a critically important factor influencing the quality and safety of diagnosis, it is not particularly well-suited to measurement. For this reason, the external environment was removed from the measurement framework and added as a cross-cutting theme. The redesigned draft framework is presented below.

Patients, Families, & Caregivers Domain

The Patients, Families, & Caregivers domain includes the patient's perception of the diagnostic process, inclusion and communications among providers, patients, caregivers, and the system.

Patient, Families & Caregivers subdomains:

- Patient Experience: Addresses the patient perception of diagnostic activities and outcomes

- Patient Engagement: Includes actions to facilitate patient involvement with the diagnostic process such as communication with the patient, patient's family, and/or patient's caregiver (e.g., provider-patient/caregiver, system-patient/caregiver communication)

Diagnostic Process Domain

The Diagnostic Process domain addresses the actions and processes that are carried out by the healthcare providers to develop, refine, confirm a diagnosis, or to explain the patient's health problem. This domain remained largely unchanged from the previous version of the framework with the exception of two additional subdomains: diagnostic efficiency and diagnostic accuracy.

Diagnostic Process subdomains:

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

Organizational & Policy Opportunities Domain

The Organizational & Policy Opportunities domain addresses organizational attributes that affect diagnostic performance. This includes organizational learning from diagnostic errors and quality improvement activities, availability of diagnostic resources (e.g., organizational access to on call radiology services), workforce sentiment, and policy and cost issues around diagnostic quality.

Organization subdomains:

- Diagnostic Quality Improvement Activities: Includes organizational activities that facilitate diagnostic quality and continued learning such as outcome analyses, root cause analyses, peer review, and tumor boards
- Access to Care and Diagnostic Services: Includes timely availability of appropriate provider and human and diagnostic resources
- Workforce: Includes staffing and workforce sentiment
- External Environment: Includes policy, cost, and legal issues that influence diagnostic quality and safety

The Committee observed that, while the domains and subdomains were renamed, the proposed changes to the framework preserved the intent of the original domains and remain appropriate for characterizing and categorizing issues related to diagnostic quality and safety. The Committee agreed that the new proposed framework still reflects the NAM model and considers the patient throughout.

Prioritized Measures

At its second in-person meeting, the Committee reviewed a list of potential measure concepts that were submitted by Committee members and through public comment. Committee members evaluated the concepts through a series of small group and full Committee discussions, conducting a preliminary prioritization exercise and honing the list down to an initial set of prioritized concepts identified below.

The Committee will conduct a second prioritization of the concepts for the final report, with input from comments submitted on this draft report.

Patients, Families, and Caregivers

Patient Engagement

The Committee identified a number of measure concepts intended to ensure that patients can and do participate as key members of the diagnostic team, and that they understand their diagnosis, their treatment plans or options, and any important considerations relevant to their diagnosis. Committee members agreed that effective communication between patients and providers or health systems is essential to diagnostic quality and safety. The Committee discussed the need for providers to communicate with patients in a way that accommodates individual patients' health literacy levels, noting that there is a substantial body of research highlighting the importance and impact of patient health literacy. However, Committee members also cautioned that an overemphasis on health literacy can lead to an excessive focus on things like the reading level of printed materials. What is most important is that patients actually understand what is being communicated to them, and this may require tailored approaches based on individual patient needs.

The Committee also emphasized the importance of patients having full and timely access to their medical records; some Committee members suggested that there is a need to increase the transparency and availability of doctors' notes.

In addition, Committee members stressed that patients need to know what to expect with regard to their diagnosis, including an understanding of how to recognize any 'red flags' or dangerous symptoms that might be associated with their condition. The Committee also noted that providers should express their confidence in the patient's diagnosis (e.g., whether tentative or known with 100 percent confidence).

The Committee identified several areas of interest with respect to measurement, acknowledging that these areas are in need of further elaboration and specification to become true measure concepts:

Measure Concept	Measure Type
Timely patient access to medical record, including test results in and out of hospital; records should be available to the patient electronically or otherwise	Structure
Process to assure that diagnosis and diagnostic information is communicated in a understandable manner to the patient while recognizing the impact of health literacy (e.g., jargon-free communication)	Structure
Explicit instructions given on red flags/symptoms should their condition evolve (e.g. included in after-visit summaries, discharge summaries)	Process
Patients understand actions they can take to improve diagnostic performance	Patient-Reported Diagnostic Outcome
Whether the organization has a documentation system that captures informal caregivers' roles for each patient and do they reconcile it with the patient and their caregivers at some interval, or every encounter, etc.	Structure

Patient Experience

The Committee felt that capturing patients' experience of the diagnostic process is critical to assessing and understanding diagnostic performance. Committee members stressed that patient experience should be distinguished from patient satisfaction, noting that 'satisfaction' ratings may be particularly difficult to interpret in the context of diagnosis, and hard to separate from satisfaction with treatment or other aspects of care. Committee members also distinguished between patient experience measures and patient-reported outcomes, such as patient-reported diagnostic error, which is addressed in a separate section of this report.

The Committee suggested that patient experience measures should address issues such as whether tests were adequately explained to patients, whether patients understood providers' diagnostic reasoning, how much effort was made to listen to patients and help them understand their health issues, how well care was coordinated, and similar insights on the diagnostic process that could be gleaned from patient-reported experience. It was noted that research on shared decision making may be helpful in informing the development of patient experience measures.

As with patient engagement, the Committee identified general measurement areas that they expressed an interest in seeing further developed into measure concepts:

Patient-reported understanding of diagnosis	Measure Type
Patient-reported experience of diagnostic care - were problems explained, etc.	Patient-Experience
Patient satisfaction with the diagnostic process (e.g., patient had opportunity to give input to the process)	Patient Experience
Patient experience with the diagnostic process (e.g., was it worth the effort)	Patient Experience

Diagnostic Process

Information Gathering and Documentation

The Committee identified a number of measurement areas that could help improve the process of gathering and documenting diagnostic information. Issues highlighted by the Committee included the importance of maintaining accurate and up-to-date problem lists, and ensuring that clinical documentation, including electronic health record (EHR) infrastructure and capability, supports quality in the diagnostic process.

Committee members noted that diagnosis is an evolving process that plays out over time and often involves a degree of uncertainty as the care team works to confirm or rule out possible explanations for the patient's health problem. It is important that providers are able to establish and document a differential diagnosis, or set of possible conditions that might explain the patient's health problem and that can be honed down through a process of elimination. Many EHRs do not allow differential diagnoses to be recorded in structured fields, and as a result, such information is never documented, diminishing providers' ability to carry out a high-quality diagnostic process.

The Committee acknowledged that measurement is not always the answer to every problem, and that some EHR-related issues may be better addressed through certification requirements or other approaches. Nevertheless, Committee members wanted to highlight some EHR features that would contribute to improved diagnosis and that could potentially be measureable at some point. In addition to the concepts listed below, these might include allowing patients to be designated as 'not yet diagnosed,' allowing providers to assign the probability of a diagnosis being correct, and the ability to distinguish an initial or admitting diagnosis from a final diagnosis.

The Committee's general goal was to make sure that complete and accurate documentation about a patient's diagnosis is available in a timely manner to the clinical care team.

Measure concept	Measure Type
Percent of problem lists that are accurate and up to date *or* Percentage of problem lists that contain time stamps	Process

Clinical documentation should support quality in the diagnostic process and be clear, complete, and accurate	Process
The EMR allows for the capture of the chief complaint	Structure
EMR should not require documenting a diagnosis before it is appropriate to do so	Structure
Communication to patients and their families is documented and patients are aware of their diagnoses	Process/ Patient-reported outcome
Allow for the clinician to document the differential diagnosis and certainty of diagnosis (i.e., provisional, tentative, uncertain, or certain)	Structure

Information Integration

In discussing the topic of information integration, the Committee focused on the need for effective communication between providers, including consultations and referrals, and across care transitions. Committee members noted, for example, the importance of managing referrals from placement of referral, through occurrence of visit, to communication of treatment plans and results back to referring providers.

Committee members suggested that measurement could potentially address the reconciliation of diagnosis across visits or care providers, similar to the process of medication reconciliation, to help ensure that existing diagnoses are confirmed and that the problem list or medical record is accurately listing the conditions the patient actually has. However, Committee members acknowledged that measurement of diagnosis reconciliation could be subject to the same limitations and challenges as medication reconciliation – e.g., reliance on documentation of the process occurring and potential for 'check-the-box' measures that do not actually drive improvement or lead to better care.

Committee members agreed that encouraging team-based care and inter-professional involvement were important principles to promote through measurement. The Committee discussed measurement related to second opinions, noting that getting a second opinion can be very important in some cases, particularly in situations where there are known diagnostic uncertainties, dilemmas, or pitfalls. Some Committee members suggested the same goals could be achieved through institutional activities to review diagnostic decisions, similar to tumor boards or mortality and morbidity conferences.

Measure Concept	**Measure Type**
Closed loop referral to specialists, including completion of visits and communication of test results and treatment plans/recommendations back to the referring team	Process

Organization participates in health information exchange across outside institutions that supports diagnostic quality ex: test results, and documentation related to diagnoses	Structure
Use of structured handoff programs in hospital	Structure
Proportion of diagnostic evaluations with appropriate patient and inter-professional team involvement (e.g., nurses, physicians, pharmacists)	Process
Diagnosis reconciliation (reviewing and confirming diagnoses across handoffs; similar to medication reconciliation)	Process
Measure concept related to second opinions (e.g., whether a second opinion was sought in cases of known diagnostic pitfalls or dilemmas)	Process

Information Interpretation

The Committee identified and discussed measure concepts related to information interpretation, focusing much of their attention on the availability and use of clinical decision support, as well as reconciliation of conflicting test results or interpretation of results.

The Committee agreed that there ought to be processes or procedures in place to identify and reconcile discordant interpretations or findings. Committee members suggested that providers should monitor for and manage situations where, for example, radiology finds a diagnosis of brain tumor, while pathology finds a diagnosis of demyelinating lesion. Such situations should be tracked and the information fed back into the system so that the results can be reconciled and the organization can learn from the event.

Committee members also noted that it might be possible to measure intermediate outcomes associated with these events – e.g., the percentage of patients where there was a discordant result of some kind.

With regard to decision support, the Committee identified potential concepts addressing whether the EHR supports and facilitates diagnostic decision making, whether decision support systems include pathways for diagnosis of common symptoms (and whether providers are following those pathways), and the ability of information to be exchanged both within and between organizations.

Measure Concept	**Measure Type**
EHR supports high-quality diagnosis: EHR is fully functional for electronic data integration and visualization for diagnosis [structure]	Structure
Reconciliation of conflicting results: Policy/procedures in place for systematically identifying and reconciling discordant/incompatible interpretations related to a specific health problem (e.g., radiology	Structure

diagnosis of brain tumor vs. pathology diagnosis of demyelinating lesion) [process]	
Reconciliation of conflicting results: % of patients with finding Q with interpretation discordant with clinical outcomes (e.g., % of patients with colonoscopy said to be "normal" diagnosed colon cancer <3 months) [intermediate outcome]	Diagnostic Outcome
Use of decision support: Availability of EHR-integrated, evidence-based decision support pathways for diagnosis of common symptoms (e.g., chest pain, dyspnea, headache, dizziness, abdominal pain) [structure]	Structure
EHR supports high-quality diagnosis: EHR is functionally interoperable both within and outside organization	Structure
Reconciliation of conflicting results: % of discordant diagnoses resolved through SOPs described above	Process
Use of decision support: % of encounters in which decision aids (web-based, decision support, etc.) are used (either measured by click tracking, administrative data [e.g., use of tests], or survey)	Process

Diagnostic Efficiency

The Committee discussed a number of potential measure concepts related to diagnostic efficiency. Several of the concepts address timeliness of diagnosis, particularly for priority diseases. Committee members noted that 'priority diseases' could be defined in a number of different ways – e.g., diseases with high mortality, that are of significant concern for public health, etc. Two aspects of timeliness are addressed by the proposed concepts: timeliness of initial diagnosis—i.e., from the symptoms to the explanation of the health problem—and timeliness of explanation to management. With regard to timeliness from explanation to management, the Committee noted that diagnosis is often a continuum, and there may be a need to assess the efficiency with which providers move, for example, from an initial diagnosis of cancer to completion of the testing, staging, etc., necessary to understand, which course of chemotherapy to administer.

Another theme that emerged in this area was value in the diagnostic process. Committee members acknowledged that overtesting does occur, and suggested that there may be a need for 'gatekeeper' functions to be in place for tests that are known to be overused. Members noted overtesting measures could incorporate exclusions to account for potentially high-risk situations.

The Committee also wanted to ensure that measurement does not only address issues of under-diagnosis or missed diagnosis. To assess overdiagnosis, Committee members suggested measuring whether certain diseases or conditions are being diagnosed more frequently by a provider or provider

organization than peers with a similar patient base. The Committee suggested case-mix adjusted comparisons could help identify outliers (e.g., those in the 90th or 99th percentile) to illuminate patterns of overdiagnosis.

Measure Concept	Measure Type
Timeliness of diagnosis for those confirmed to have priority disease X : Timeliness of initial diagnosis (from symptoms to explanation): % diagnoses rendered within acceptable "timely" benchmark timeframe from index symptoms/signs/test results to explanation of patient's health problem (e.g., timeliness of meningitis diagnosis from initial headache/fever to diagnosis of meningitis)	Diagnostic Outcome
Timeliness of diagnosis for those confirmed to have priority disease X: Timeliness of diagnostic refinement (from explanation to management): % of diagnoses refined within acceptable "timely" benchmark timeframe from explanation to completion of the diagnostic process and appropriate management (e.g., timeliness of lung cancer staging process post initial pathologic diagnosis of "lung adenocarcinoma")	Diagnostic Outcome
Appropriate testing (underuse/overuse): % of patients with symptom A or disease X who are tested inappropriately (e.g., % with benign positional vertigo undergoing CT for dizziness; e.g., Lyme disease serology ordered in patient with non-specific rash in non-Lyme-endemic area)	Process
Appropriate testing (underuse/overuse): % of adherence to use of appropriate testing by evidence-based guidelines (or perhaps self-imposed policies about testing policies and procedures)	Process
Appropriate diagnosis (underdiagnosis/overdiagnosis): disease-specific incidence relative to case mix-adjusted peer organization sample (measure: percentile rank relative to peers) [this may include stratification by disease severity, such as the relative proportion or absolute prevalence of early-stage vs. late-stage diagnoses]	Diagnostic Outcome
Appropriate diagnosis (underdiagnosis/overdiagnosis): disease-specific incidence relative to total disease-specific morbidity/mortality (i.e., excess diagnosis with or without benefit) relative to peer organizations (measure: percentile rank relative to peers)	Diagnostic Outcome

Diagnostic Error

The Committee identified measures of diagnostic error, grouping those measures into two major themes: measurement around unanticipated changes in level of care, and measurement of loss to follow-up, adverse events or unexplained deaths. These events may serve as potential markers of misdiagnosis or other diagnostic error.

Measure Concept	**Measure Type**
Escalation: Early care escalation (e.g., PC to ED, ED to ward, ward to ICU) associated with a diagnosis change linked to the index encounter symptoms/signs/test results	Patient Outcome
Rate of patient-reported diagnostic error at (time interval T [e.g., 30d]) after index encounter (assessment could be done via text, robocall for all patients; then human call for verification of cases where patient reports diagnosis incorrect and random subsample of cases in which patient says diagnosis correct) (such a measure would be more likely to be used for purposes of internal rate tracking within an organization, rather than comparison across organizations, though one could use case mix adjustment based on demographic variables that reflect health literacy [e.g., socioeconomic status, education]) [intermediate outcome]	Diagnostic Outcome
Initial diagnostic accuracy for disease X referenced to gold standard testing (for diseases with accepted diagnostic 'gold standards' [e.g., pathology for cancer; MRI-DWI for stroke; culture for bacterial infection; autopsy / radiographic autopsy])	Diagnostic Outcome
De-escalation: Early care de-escalation (e.g., ICU to ward) associated with a diagnosis change linked to the index encounter symptoms/signs/test results	Patient Outcome
Sampling based on unanticipated change in level of care (escalation or de-escalation) associated with an unexpected diagnosis change as marker of misdiagnosis with or without adverse consequence [time windows for new diagnosis are context-specific and must be defined relative to base rates]; for all such events, the % of patients harmed should also be recorded)	Patient Outcome
Sampling based on loss to follow-up, patient adverse events (including unexplained deaths) as a marker of potential misdiagnosis	Diagnostic Outcome

Follow Up

The Committee agreed that follow-up on test results is among the most important issues with respect to diagnostic quality and safety. Measure concepts identified by the Committee focus on follow-up in a number of specific situations: tests pending during transitions of care, critical test results, and non-critical but actionable test results.

Committee members noted that pending tests would include tests awaiting final read or final interpretation. The Committee suggested that processes for hand-offs and communication are critical to ensuring appropriate follow-up, noting that it is very important to identify the clinician responsible for coordinating the patient's care. This is often the primary care physician, but may also include other ordering clinicians.

Measure Concept	Measure Type
Rate of actionable tests and findings that are communicated and acted on in a timely manner (e.g., Malignant pathology, blood culture pathogen identification/sensitivities)	Process
Rate of actionable test results that are communicated to the responsible clinician (e.g., primary or other responsible organizing physician)	Process
Process in place to ensure monitoring of communication of abnormal findings (e.g., incidental radiology finding, physical exam findings such as suspicious mole, incidental lab finding)	Structure
Rate of critical test results that are acted on in timely manner	Process
Rate of closed loop communication of actionable test results to the patient	Process
Percentage of tests that were pending during a transition of care are documented and have adequate and appropriate handoffs (pending includes awaiting final read or final interpretation)	Process
Process in place to identify the responsible clinician for tests	Structure

Organizational & Policy Issues

Diagnostic Quality Improvement Activities

The Committee agreed that it is extremely important for organizations to engage in quality improvement activities focused on diagnostic quality and safety. The Committee suggested that learning from diagnostic errors through peer review, root cause analyses and other programs is critical, and that

care teams should receive feedback on their diagnostic performance, particularly when there is a significant change in diagnosis. Moreover, Committee members noted that measuring diagnostic performance in itself helps to drive improvement, and the extent to which organizations do so should be evaluated as an indicator of diagnostic quality and safety.

Measure Concept	Measure Type
Organization supports learning around errors in diagnosis, performs peer review, root cause analysis (RCAs), identifies opportunities for improvement, and incorporates new knowledge in future practice.	Structure
Percent of RCAs with actionable results acknowledged by senior leadership	Process
Patient or patient's representative involvement in RCA	Process
The organization has an established mechanism for capturing, measuring, and providing feedback to the diagnostic team when there is a significant change in diagnosis	Structure
Organization measures diagnostic performance for key areas (e.g., primary care, lab, radiology, ER, selected specialties or clinical conditions)	Structure

Access to Care and Diagnostic Services

Measure concepts identified by the Committee in this subdomain focus on access to testing for common conditions and for critical diagnostic decision-making, as well as access to care as indicated by patient wait time. Committee members intended these concepts to assess whether healthcare organizations are ensuring the availability of appropriate diagnostic resources for their patient populations, and whether patients have reasonable access to care when in need of diagnosis.

Measure Concept	Measure Type
Access to appropriate testing for the most common conditions encountered by the hospital, clinic, practice, or other care setting	Structure
Availability of rapid or point-of-care testing for critical diagnostic decision making	Structure
Average wait time to get an appointment by provider (stratify by specialist)	Structure
Availability and effectiveness of telemedicine services (i.e., teleradiology, telepathology)	Structure

Workforce

The Committee identified measure concepts intended to ensure that the healthcare workforce is staffed, trained, resourced, and deployed in such a way that optimizes diagnostic quality and safety. Committee members acknowledged that many of these concepts need additional specificity to be made actionable, but wanted to outline a number of principles that would support the healthcare workforce in improving diagnostic performance.

Committee members observed that diagnosis places a heavy cognitive burden on healthcare providers, in addition to time pressures and other potential barriers to high-quality diagnostic care. The Committee wanted to encourage team-based practice and to ensure that care teams have adequate time and resources to gather, integrate, and interpret all of the data needed for timely and accurate diagnosis. The Committee also emphasized that it is the organization's responsibility to provide the resources needed to ensure a timely, accurate diagnosis. Among the issues discussed by the Committee was whether providers should be measured on the number of patient encounters per day. Committee members noted that it can be a problem when clinicians are seeing too many patients, making it impossible to conduct an appropriate diagnostic evaluation. However, the Committee also recognized that the number of patients that is reasonable to see per day is likely to be specialty-specific, and that it would be difficult to identify a hard-and-fast rule about the maximum number across all providers. Committee members suggested taking the approach of comparing providers to their peers and looking for outliers.

Other issues the Committee felt it would be important to address through measurement included burnout, vacancy rates in critical areas, such as laboratories, and the need to include diagnostic performance in professional practice evaluations for clinical providers.

Measure Concept	**Measure Type**
Providers have adequate time for gathering, integrating, synthesizing, and interpreting information to support correct and timely diagnosis	Structure
Diagnostic performance is included in professional practice evaluation for credentialing and re-credentialing (e.g., OPPE) of clinical providers	Structure
Radiologists are available 24/7 to read stat diagnostic imaging studies in real time	Structure
Identification of potential outliers related to # of patient encounters per day (e.g., more than 50 pts seen per day by a primary care physician)	Structure
Vacancy rate for critical diagnostic specialties, such as lab	structure

professionals and PCPs	
Providers operate at the top of their license or certification to free up cognitive load of the MD	Structure
Rate of physician/nurse burnout and institutional turnover	Structure

Cross Cutting Themes and Recommendations

In addition to the proposed measure concepts, the Committee defined several cross cutting themes and recommendations that comment on both the development of performance measures and the overall advancement of the field of diagnostic quality and safety. Some recommendations may not be suitable for measurement; however, the Committee asked that these themes be considered by the measure development community with respect to diagnosis. These recommendations provide guidance and direction to those interested in developing high-impact measures of diagnostic quality and safety conducted a preliminary prioritization exercise. Additionally, these recommendations aim to influence broad policy themes where they intersect with the field of diagnostic quality.

The Impact of Electronic Health Records (EHRs) on Diagnostic Quality and Safety

Throughout the Committee discussions, many comments surrounded the impact of the EHR on diagnostic quality and safety. The ability to track diagnostic-specific data throughout the diagnostic process is paramount to improving quality. For an EHR to support the diagnostic process, it needs to be capable of both recording and presenting the current state of the diagnosis as well as the steps that occurred to reach the current state. Many EHRs collect a principal diagnosis, which may be symptom-specific or disease-specific, depending on what information is available to the provider at that point in time. Most EHRs lack the ability to track changes in a diagnosis from one level of granularity to another. In an ideal setting, the EHR would permit the diagnosing provider to qualify the diagnosis as a working diagnosis or a final diagnosis. It would record the level of confidence that the provider has with that diagnosis to signal to other stakeholders the certainty of that diagnosis. Additionally, the EHR should support and record any changes in the diagnosis. A clearly recorded history of the diagnosis would contain invaluable information for collaborating clinicians, patients, and caregivers.

In addition to the EHR's ability to track the diagnostic process, the Committee frequently realized the need for interoperability among electronic health systems. The Office of the National Coordinator for Health Information Technology defines interoperability as "the ability of a system to exchange electronic health information with and use electronic health information from other systems without special effort on the part of the user".[8] Throughout the diagnostic process, interoperability influences the provider's ability to diagnose a health concern in an accurate and timely manner. The availability of electronic health data is paramount for the provider to create, confirm, or refine a patient's diagnosis. Additionally, interoperability plays a large role in provider-to-provider communication as well as provider-to-patient communication. The lack of timely, relevant diagnostic information has the potential to lead to diagnostic errors and patient harm.

The Committee has interwoven EHR-related issues into the measure concepts when appropriate. However, broad policy changes should accompany the development of quality measures.

Transitions of Care

Transitions of care refers to "the movement of patients between health care practitioners, settings, and home as their condition and care needs change".[9] Closely related to the Committee's theme that interoperability among EHRs is essential to the diagnostic process, Committee members observed that care transitions also have a significant impact on diagnostic safety and quality. Ineffective care transitions can lead to adverse events such as medication errors,[10] medical errors related to the completion of diagnostic work-up,[11] and loss of information critical to the patient's care.

Committee members noted that there are opportunities for diagnostic failure as patients cross organizational boundaries, but also recognized that there are opportunities to improve diagnostic performance through better communication among providers.

Communication and Health Literacy

The Committee frequently referenced that communication of the diagnosis is an integral part of the diagnostic process. A number of the measure concepts designed by the Committee address the role of communication in the diagnostic process. Despite this, the Committee sought to emphasize the importance of communication at all levels. The Committee recommended that future measures and measure concepts consider communication with the patient, amongst and between all physicians and staff involved in the diagnostic process, and during care transitions. Specifically, they noted that the diagnostic process is susceptible to errors or failure at all of the following levels: provider-provider, provider-system, patient-system, and patient-provider. The Committee appreciated that poor communication at any of these levels could disrupt the diagnostic process.

Regarding patient-system and patient-provider communication, the Committee appealed for the inclusion of health literacy in the diagnostic process. According to the US Department of Education, individuals with low health literacy have worse outcomes[12] and are less likely to follow treatment plans. Effective communication of the diagnosis is paramount to diagnostic quality and safety. The Committee recommended consideration of health literacy as a method to engage patients fully in the diagnostic process. Future measure development in this area as well as broad approaches to improve diagnostic quality and safety should overtly integrate the role of health literacy.

The Opportunity for Medical Specialty Societies to Provide Guidance

The Committee designed a comprehensive measurement framework and measure concepts to address gaps in the measurement of diagnostic quality and safety. Many of the measure concepts the Committee constructed are broadly applicable to any condition or specialty. However, the Committee noted the role of condition-specific measure concepts that may require input from medical specialists. For example, the timeframe in which a provider forms and communicates a diagnosis to the patient may be different in the setting of an acute heart attack versus a condition such as a benign skin cancer. Providers with specialty knowledge are well suited to offer guidance on the definition of a timely

diagnosis for a given condition that is both patient-centered and realistic for the providers. Specialty societies are in an ideal position to identify conditions within their expertise that are frequently misdiagnosed or can lead to serious harm in the event of a diagnostic error. Lastly, specialty societies develop or influence many best practices and clinical guidelines, which are often relevant to the diagnostic process.

Interprofessional Education and Credentialing

The education and training level of the diagnosing provider emerged as a recurring theme in many of the Committee's discussions. The Committee appreciated the complex nature of the diagnostic process and recognized that multiple individuals take part in this process. Several conversations focused on how to measure the training, aptitude, and performance of the diagnosing clinician. In the end, the Committee members stated that measure concepts in this area could be duplicative of the functions of credentialing bodies. Instead, they advocated for a broad recommendation that credentialing organizations ensure that their reviews emphasize diagnostic quality and safety and include a component of diagnostic performance measurement. Furthermore, the Committee recommended that diagnostic quality and safety become a formal component of professional education for those who participate in the diagnostic process.

The External Environment

The Committee discussed a number of issues in the external environment that have an impact on diagnostic quality and safety. Committee members noted that some of these concerns may not be easily measurable, or even appropriate to address through measurement, but like some other areas, wanted to identify issues that affect diagnostic practice. Among the topics discussed by the Committee was the need to align payment incentives to promote timely and correct diagnosis. Committee members noted that important aspects of the diagnostic process—for example, the time pathologists and ordering physicians spend talking to each other—are not measured or reimbursed under typical payment models. The Committee stressed that payment should be aligned to promote collaborative, team-based care. Committee members also suggested that diagnostic quality and safety would benefit from a legal environment that promotes case discussions, error reporting, and organizational learning to improve diagnosis.

Conclusion

An effective diagnostic process leads to an accurate, timely, and well-communicated explanation of a patient's health problem and informs subsequent decisions about a patient's care. Missed, incorrect, or poorly communicated diagnoses can lead to significant quality and patient safety issues, such as delayed care, failure to receive needed care, or the provision of inadequate or inappropriate care. Any of these may lead to major adverse consequences for the patient and the patient's family.

With this in mind, the Committee designed a measurement framework that can be used to improve quality and safety in the diagnostic process. The final measurement framework takes into account the patient, the patient's family, caregivers and their experiences with the diagnostic process. The

framework considers the diagnostic process itself, including the initial steps in identifying the patient's health problem, the timeliness of the diagnosis, communication of diagnosis, and whether appropriate follow up services were provided. Finally, the framework addresses organizational issues, including efforts to learn from diagnostic errors, patients access to diagnostic services in a timely manner, availability of appropriate staff and material resources as well as the organization's culture as it pertains to diagnostic quality and safety.

From the start of the project, the Committee wanted to ensure that the patient was at the center of their work. Still, there were other areas, which could not be addressed by the framework, that require more research and development from other organizations involved in the delivery of healthcare. A major portion of the diagnostic process relates to assessing the patient's health problem before coming to a final diagnosis. However, most electronic health records lack the capacity to track changes and, make refinements or additions to a diagnosis. The Committee also recognized the need for interoperability among electronic health systems throughout the diagnostic process as it assists the provider in arriving at an accurate and timely diagnosis.

In their review of measure concepts, the Committee expressed a desire for input from medical specialty societies to assist in development of measures or measure concepts for specific disease conditions that are the most prone to diagnostic error. The Committee believed that measure development around diagnostic error that addresses these critical conditions would be a major step forward in improving the quality and safety of patients. In efforts to make recommendations to credentialing organizations, the Committee noted that evaluations of healthcare professional should contain some component of diagnostic quality and safety and that it become a formal part of their education. Finally, the Committee highlighted the importance of communication and health literacy as an integral part of engaging the patients in the diagnostic process.

As the field of healthcare continues to realize the need for diagnostic quality and safety, a measurement framework is a key component in assessing improvements. The Committee developed a comprehensive, conceptual framework that provides structure and organization to this vast topic. It is the hope of the Committee that this provides guidance to the field for both short-term improvements as well as aspirational initiatives.

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Appendix A: Project Approach and Timeline

General Approach and Timeline

Over a 12-month period of performance, NQF staff will develop a conceptual framework for measuring healthcare organization structures, processes, and outcomes that address the improvement of diagnostic quality and safety. NQF staff compiled an inventory of measures in development, in testing, and in use consistent with the framework. Throughout this project, NQF staff will solicit input from NQF's multistakeholder audience, including NQF membership and public stakeholders. The project approach is described below and illustrated in Figure 1.

Figure 1

Convene Multistakeholder Committee

NQF staff convened an 18-member Committee with diverse representation and knowledge representing the NASEM Committee, Society to Improve Diagnosis in Medicine, other relevant professional societies, experts from healthcare organizations, healthcare disparities research and underserved communities, Patient Safety Organizations, health services delivery administration, federal and state governments, and patient advocates. NQF staff also consulted with HHS and federal liaisons to provide guidance to NQF throughout the project. NQF staff met and convened with the multistakeholder Committee via a series of five web meetings and two in-person meetings throughout the project. Please see Appendix B for the full Committee roster and federal liaisons. The first web meeting on December 5, 2016 oriented the Committee to the project background, scope, and objectives. The Committee reviewed and discussed the NASEM framework and any other existing frameworks related to diagnostic accuracy/diagnostic error. During this web meeting, the Committee provided early input on key search terms and parameters for the environmental scan.

Conduct an Environmental Scan and Analysis of Gaps

With parameters established in consultation with the Government Task Lead (GTL), Contracting Office Representative (COR), and the Committee, NQF staff completed an environmental scan of measures and measure concepts to improve diagnostic quality and safety, including those that are in development, testing, and in use. Upon completion of the environmental scan, NQF staff gathered the information and used it as a foundation for a gap analysis to develop measure concepts. The Committee used the analysis during its in-person and web meetings to: (1) provide input and direction on the development of a conceptual framework for analyzing measures to improve diagnostic quality and safety; (2) identify the highest priority measure gaps; (3) make recommendations for addressing the measure gaps that

draw on promising practices; and (4) identify priority measurement areas with the greatest potential for reducing diagnostic error.

In the environmental scan, NQF staff identified 74 measures from the NQF Quality Positioning System, the Centers for Medicare & Medicaid Services Measures Inventory, the Health Indicators Warehouse, and the Agency for Health Care Research and Quality's National Quality Measures Clearinghouse, and National Guidelines Clearinghouse (See Appendix G). Out of the 74 measures, 61 measures were included in the scan. Specific measures were excluded due to duplicates or its irrelevance to diagnostic quality and safety. With input from the Committee, NQF members, and the public, 232 measure concepts were identified. For the purposes of the environmental scan, NQF staff defined a measure as a fully developed metric that has a specific numerator and denominator that has undergone scientific testing. A measure concept is defined as an idea for a measure that has a specific numerator or denominator, but has not undergone testing.

Develop a Conceptual Measurement Framework

The Committee employed a conceptual framework to analyze, prioritize, and make recommendations for filling measure gaps through measure development and endorsement. With guidance from the Committee, and informed by the results of the environmental scan, NQF staff modified an existing conceptual measurement framework against, which the Committee will assess the comprehensiveness and adequacy of available measures related to diagnostic quality and safety. This framework utilized the evidence, concepts, models, and recommendations contained in the NASEM report *Improving Diagnosis in Health Care*.

NQF staff drafted a conceptual measurement framework containing domains and subdomains related to diagnostic quality and safety. The Committee engaged in a process of identifying and then prioritizing measure concepts over two in-person meetings, in Washington DC, conference calls, and through a prioritization exercise to identify the highest priority measurement areas. The first in-person meeting met on January 10-11, 2017 that included a presentation of the environmental scan, reviewed of the proposed measurement framework, and discussion on potential measure concepts. The Committee were divided into three breakout groups where the group engaged in a brainstorming exercise to identify measure concepts or gaps in measures. NQF staff followed-up with the Committee and solicited additional feedback on measure concepts within the domains. This process yielded a list of 232 measure concepts. These concepts served as a guide for discussion and further prioritization at the second in-person meeting convened on April 12-13, 2017.

During the second meeting, each Committee members individually ranked their top measure concepts across each subdomain. The Committee was then divided into four breakout groups, with each group reviewing at least two subdomains with a subset of measures and measure concepts. Each group discussed and reached consensus on the prioritized measures for each subdomain and further discussed any gaps in the measurement framework.

Measures and measure concepts were mapped to the domains and subdomains, and were prioritized by three evaluation criteria: importance, feasibility, and cost savings. These ratings are defined in Appendix

E. Over the course of the project, the Committee provided feedback on the domains and subdomains, informed by the public and NQF member comment.

Obtain Public Comment and Finalize Recommendations

Throughout the project, the public, NQF members, and federal liaisons submitted comments on the draft measurement framework and Committee discussion during web and in-person meetings. The Committee members considered the comments in refining the domains, subdomains, prioritizing measures and/or measure concepts, and recommendations for the development of priority measures to address gaps in structures, processes, and outcomes to drive improvement of diagnostic quality and safety.

Appendix B: Committee Panel, Federal Liaisons, and NQF Staff

Panel Co-Chairs

Missy Danforth (Co-Chair)
Vice President, Hospital Ratings- The Leapfrog Group
Washington, District of Columbia

Mark Graber, MD, FACP (Co-Chair)
President of Society to Improve Diagnosis in Medicine & RTI International
Plymouth, Massachusetts

Panel Members

Jennifer Campisano, JD
Attorney and Patient Advocate- Booby and the Beast Blog
Phoenix, Arizona

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Vice President, Research and Development North America- bioMerieux, Inc.
Durham, North Carolina

David Grenache, PhD
Professor of Pathology/Laboratory Medical Director- University of Utah
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Helen Haskell, MA
President- Mothers Against Medical Error
Columbia, South Carolina

Carlos Higuera-Rueda, MD
Vice Chair Quality and Patient Safety- Orthopaedic and Rheumatologic Institute; Assistant Professor of Surgery- Cleveland Clinic
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Thomas Sequist, MD
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Hardeep Singh, MD, MPH
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Susan (Sue) Sheridan
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Christy Skipper, MS
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Vanessa Moy, MPH
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Appendix C. NASEM Conceptual Model of the Diagnostic Process

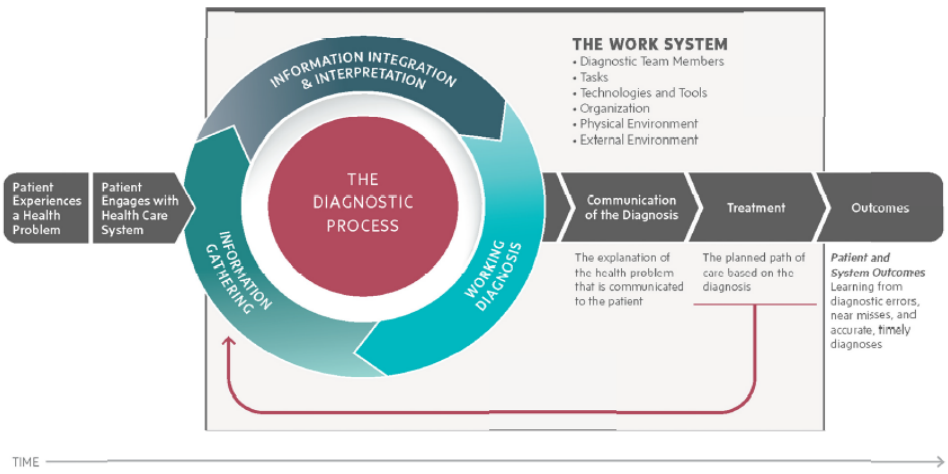

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FIGURE 3-2 Places in the diagnostic process where failures can occur that contribute to diagnostic errors.

Source: Institute of Medicine. *Improving Diagnosis in Health Care.* Washington, DC: National Academies Press; 2015.

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Appendix D: Measure Prioritization Criteria

Criteria	Questions/Considerations	Rating Scale
Importance	• Relevance: How relevant is this measurement area to diagnostic quality and/or safety? • High-Priority: To what extent does the measurement area reflect the following goals for measurement? o Outcomes o Meaningful to the patient o Supports systemic/integrated view of care • Impact: To what extent does the measurement area address an issue that: o Affects large numbers of patients and/or has a very substantial impact for smaller populations; o is a leading cause of morbidity/mortality; or o contributes to inappropriate resource use (current and/or future) • Actionability: likelihood that measuring the issue will drive changes in organizational behavior	Indicate the importance of this measurement area: • 1-Low Importance • 2-Moderate Importance • 3-High Importance
Feasibility	• Availability and ease of capturing data for measurement in this area • Resource requirement (education and training of the workforce, whether high resources are needed to implement the measure, etc.) • Readiness of organizations to tackle the problem	Indicate the feasibility of measurement in this area: • 1- Long-term/aspirational goal • 2- Feasible in the medium-term • 3- Feasible immediately or in the short-term
Cost Saving	• Likelihood that this measure will directly reduce healthcare costs	Indicate the likelihood of this measure on healthcare cost:

		• Yes • No

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Appendix E: Public Comments Received on draft framework and Committee Response

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
1	Stacy Walz, American Society for Clinical Laboratory Science on behalf of ASCLS Patient Safety Committee	General Overall Comment	"Thank you for the opportunity to submit comments for the "Improving Diagnostic Quality and Safety: Draft Measurement Framework". First and foremost, we want to respond to the following statement by Co-Chair Mark Graber, MD, FACP, from page 11 of the transcript for Day 2 of NQF Improving Diagnostic Quality and Safety In-Person Meeting. "The clinical laboratory staff would be so valuable in helping us understand the best testing algorithm to use or how to interpret a test or to know the next best test to order, and yet we rarely talk to them." Clinical laboratory professionals—Medical Laboratory Scientists (MLS) and Doctors of Clinical Laboratory Science (DCLS)—welcome the opportunity to assist clinicians on test selection and test interpretation as members of the interprofessional healthcare team. Laboratory test information is a significant component of the diagnostic process, and clinical laboratory professionals are integral to two components of the Safer Dx model: "diagnostic test performance and interpretation" and "follow-up and tracking of diagnostic information". In addition to submitting these comments, we would like to offer our expertise on future iterations of this document and the development of specific measures and measurement tools to improve the quality of diagnoses related to the use of clinical laboratory test information."	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.
2	Stacy Walz, American Society for	Draft Framework -	"Structure: Technologies and Tools—Advanced imaging and laboratory diagnostics are available. Of course, we believe that laboratory diagnostics need to be available to clinicians in order to provide information necessary	The Committee clarified that advanced imaging includes ultrasound, computed

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
	Clinical Laboratory Science on behalf of ASCLS Patient Safety Committee	Structure	for diagnoses. Our question revolves around the word 'advanced'. Does this adjective refer to imaging and laboratory, or just to imaging? If it refers to laboratory diagnostics, what does "advanced" mean with respect to laboratory testing? Does it mean genetic or genomic testing is available? If it does mean this, it is important to note that not all laboratories are capable of these methodologies. Equipment to perform these types of analyses are expensive and require specific expertise for interpretation. However, most laboratories have access to these testing methodologies via reference laboratories, and can collect the specimens and transport these specimens to those laboratories. Structure: Technologies and Tools—The organization has an EHR data warehouse and informatics team to enable diagnostics measurement related to diagnostic safety (e.g. trigger tools). We concur; this is a critical tool to improve the diagnostic process and to develop protocols and practice guidelines for test selection, to monitor compliance with practice guidelines and to implement quality improvement protocols. We believe that this standard will facilitate its use of these data by laboratories. Structure: Organizational Characteristics—Organization measures diagnostic performance (lab, etc.) ASCLS has a long history of supporting and promoting improving the quality of laboratory services. What does "diagnostic performance" mean? Does it refer to utilization of the laboratory? Or does it refer to compliance with clinical practice guidelines? The ability to successfully meet this criterion will require tools such as an EHR data warehouse, clinical and practice guidelines and significant information technology support. We recommend that this measurement concept be written as "Organization	tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET) scan. The wording of the measure concept was changed to "Access to imaging and laboratory diagnostics".

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
			measures diagnostic performance and utilization of laboratory testing"."	
3	Stacy Walz, American Society for Clinical Laboratory Science on behalf of ASCLS Patient Safety Committee	Draft Framework - Process	Process: Patient Engagement—"Tests pending at discharge are followed-up ASCLS believes that this is an important measurement to improve the quality of patient care. We recommend that this measurement concept include sending the results of tests that were pending at discharge directly to patients along with their provider [SW1] to improve continuity of care. Process: Patient Engagement—"Communication accommodates patient literacy level ASCLS concurs with this measurement concept and recommends that laboratory test reports are available through multiple modalities, e.g. paper via USPS mail, email, secure text, telephone and secure patient portal. Process: The Diagnostic Process—"Diagnosis is timely" ASCLS concurs with measuring the turn-around-time for laboratory test results; however, we believe that measuring the actions taken after receipt of all laboratory tests should be measured, not just the abnormal laboratory test results. ASCLS proposes that there should be a mechanism, or measurement tool, to provide feedback to clinicians on the process of accepting and acting upon laboratory test information (normal, abnormal and critical)."	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.
4	Draft Framework - Outcome	Stacy Walz, American Society for Clinical Laboratory Science on behalf of ASCLS	"Outcome: Diagnostic Outcomes—"Timeliness of diagnosing targeted diseases of interest" ASCLS concurs with the concept of measuring timeliness of diagnosing diseases. As with other measures noted above, this criterion will require tools such as EHR data warehouses and other technology support to be completed and to be accurate."	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
		Patient Safety Committee		
5	General Overall Comments	Bob Hussey, RGH Health Consulting on behalf of Wolters Kluwer Health	"Wolters Kluwer Health appreciates the Standing Committee's efforts to develop a measure framework for diagnostic quality and safety. We believe this is an area that requires substantially more research and study before any framework can be finalized. It is true that certain subdomains of the proposed structural framework such as the availability and use of clinical decision support have been the subject of significant research that demonstrate a positive impact on clinical decision-making, quality of care, and patient safety. But much more research needs to be conducted on the impact of staff, workflow and organizational characteristics on diagnostic accuracy. Similarly, the connection between diagnostic process, patient engagement and diagnostic quality needs much more exploration before attempting to craft measures. Of the three categories proposed for the measure framework, outcomes would appear to be the most promising, but so many factors contribute to a positive patient outcome that it may be difficult to create measures that establish a direct link between timely diagnosis and the eventual outcome. We also share the Standing Committee's concern that any attempt to measure diagnostic quality could lead to overutilization of testing or overtreatment. We commend NQF and members of the Standing Committee for addressing this important topic, but counsel caution in your deliberations. Finalizing a measure framework on diagnostic quality and safety may be premature until further research is conducted that can shed more light on the best way to proceed. Thanks for letting us comment."	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.
6	Draft Framework -	Liz Waibel, The	ASCP agrees with the overall approach taken in this domain, particularly the distinction between the diagnostic process and patient engagement. In	Thank you for your comments. The Committee

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
	Process	American Society for Clinical Pathology	developing our quality data registry, we have focused on the former, while we see great potential for the field of pathology in the latter. We have included a patient representative in the discussion of diagnostic measures for the NPQR to ensure the patient perspective is taken into account as we believe it is critically important.	has reviewed this comment and appreciates your interest in the project.
7	Draft Framework - Outcome	Liz Waibel, The American Society for Clinical Pathology	"We would reiterate the comments above regarding the process domain; again, ASCP agrees with the distinction of diagnostic versus patient outcomes as this is an important difference. Further, ASCP appreciates the inclusion of system outcomes as a subdomain in this category (particularly costs/resource use) because pathologists are uniquely positioned to collaborate with fellow practitioners and patient to reduce costs through curbing unnecessary test ordering, but have not historically received credit in this area (e.g., in Centers for Medicare and Medicaid quality payment programs). Conversely, we acknowledge that diagnostic errors can be extremely costly to the system and can also have significant impact on patient safety, so we appreciate the NQF Committee's efforts to measure system-wide impacts. Comments on Other Issues and Cross-Cutting Themes ASCP agrees wholeheartedly with the concepts outlined in this section, specifically acknowledgement of the following: Potential Unintended Consequences: Increased measurement and reporting burden Balancing incentives to avoid overutilization and/or unnecessary diagnoses or overtreatment Patient-centeredness	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
8	General Overall Comments	Tracy Spinks, University of Texas MD Anderson Cancer Center on behalf of Karen Bird Alliance of Dedicated Cancer Centers	The Alliance of Dedicated Cancer Centers ("ADCC") is pleased to submit comments on the Improving Diagnostic Quality & Safety Draft Framework for Comment. These comments focus on diagnostic quality and safety for patients with a suspected or confirmed cancer diagnosis (including the diagnosis of related conditions that present during cancer treatment). We support a conceptual model that promotes timely, accurate, and complete diagnosis and appropriate resource utilization. Such a model must facilitate continuous improvement through a culture of transparency and safety to report and learn from diagnostic errors. As reflected in the Standing Committee's recommendations, the patient (and his/her caregivers) must be at the center of that model and part of the integrated care team. The first step to implementing this model in cancer is ensuring that the minimum necessary structural elements are in place to support diagnostic accuracy (see specific comments under Draft Framework – Structure). Measuring the presence of these structural elements through a self-reported composite measure can promote adoption and facilitate a transition to monitoring compliance with diagnostic best practices. Ultimately, providers must have experience with such an infrastructure and ready access to robust systems capable of capturing diagnostic changes and errors within structured datasets. This will support timely outcomes measurement, both for provider assessments and population-level monitoring. Measuring patient and referring provider experience with the diagnostic process will complement outcomes data collection (see specific comments under Draft Framework – Outcome).	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.
9	Draft Framework - Structure	Tracy Spinks, University of Texas MD Anderson Cancer Center on	We recommend beginning with a structural measure that assesses the following components (over time, transition to monitoring adherence and outcomes as structured data systems are in place to capture diagnostic changes and errors along with timeliness of communicating diagnosis to patients and referring providers):	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
		behalf of Karen Bird Alliance of Dedicated Cancer Centers	People – Staff involved in diagnosing patients have appropriate competency (training, accreditation, specialization) – Provider mix involved in diagnosis (or available for timely consultation) are appropriate for the complexity of the case (e.g., access to subspecialized/radiologists pathologists) – Tumor boards – Designated expert providers to monitor for completeness of diagnostic testing/reports and diagnostic errors Workflows and Tasks – Practices that support multidisciplinary diagnosis and shared decision-making with patient/caregivers – Practices that support completeness of pathologic and radiologic diagnosis and reporting and adherence to industry best practices (e.g., synoptic pathology reporting) – Practices that support timely communication of diagnoses to referring physician and to patient/caregivers – Practices that support secondary review of all outside diagnoses before treatment start – Practices that support communicating all significant diagnostic changes (leading to a change in oncologic treatment, workup, or surveillance) to referring physician/pathologist/radiologist and to patient/caregivers	

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
			– Practices that support identifying and learning from diagnostic errors through RCAs in support of a culture of excellence/transparency – Practices that support appropriate surveillance post-treatment completion	
10	Draft Framework - Structure	Tracy Spinks, University of Texas MD Anderson Cancer Center on behalf of Karen Bird Alliance of Dedicated Cancer Centers	Technologies and Tools – Advanced imaging and laboratory diagnostics are available and maintained – Pathology/radiology reports generated from structured data systems – EHR/systems that support health information exchange (e.g., sending/receiving electronic diagnostic reports and plans of care) – Patient portal where patients have access to diagnostic reports and plans of care – Structured data system to track changes in outside diagnoses – Structured data system to track diagnostic errors Organizational Characteristics – Policies that support multidisciplinary diagnosis and shared decision-making with patient/caregivers – Policies that support completeness of pathologic and radiologic diagnosis and reporting and adherence to industry best practices (e.g., synoptic pathology reporting) – Policies that support timely communication of diagnoses to referring physician and to patient/caregivers	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
			– Policies that support secondary review of all outside diagnoses before treatment start – Policies that support communicating all significant diagnostic changes (leading to a change in oncologic treatment, workup, or surveillance) to referring physician/pathologist/radiologist and to patient/caregivers – Policies that support identifying and learning from diagnostic errors through RCAs in support of a culture of excellence/transparency – Policies that support appropriate surveillance post-treatment completion	
11	Draft Framework – Outcome	Tracy Spinks, University of Texas MD Anderson Cancer Center on behalf of Karen Bird Alliance of Dedicated Cancer Centers	As structured data systems (see Draft Framework - Structure) are in place to capture diagnostic changes and errors along with timeliness of communicating diagnosis to patients and referring providers, institute outcomes measurement as described below): Diagnostic Outcomes – Rates of false positive/negative cancer diagnoses (primary diagnosis) – Rates of delayed cancer diagnoses – Timeliness of results communicated to referring provider and patient/caregivers – Timeliness of additional diagnostic testing – Overuse of advanced imaging/other diagnostic tests at end of life – Underuse of advanced diagnostics at presentation (e.g., imaging and genetic markers)	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
			– For cancer patients in active treatment, timeliness of diagnosis of treatment-related complications (e.g., CMS Hospital-Acquired Conditions), sepsis, pneumonia, renal failure Patient Experience – Within existing patient experience measures, incorporate patient awareness of prognosis, explanation of treatment options (including different treatment options with curative or palliative intent for advanced cancer diagnoses or disease progression), shared decision-making re: intensity of oncologic treatment, adequacy/timeliness of communication regarding cancer diagnosis, prognosis, and costs Provider Experience – Establish referring provider experience measure to assess referring provider's experience with adequacy/timeliness of communication regarding cancer diagnoses, patient prognosis, and quality/clarity of results Systems Outcomes – Population-level false positives/negatives (primary diagnosis) – Population-level rates of major/minor diagnosis change (leading to a change in oncologic treatment, workup, or surveillance) through secondary pathology review/diagnostic imaging over-reads – Population-level early- and late-stage diagnoses by cancer site"	
12	General Overall Comments	Zach Smith, American College of Radiology on	I do not see any discussion of errors of omission, meaning circumstances where diagnostic testing was delayed or not performed, resulting in harms to the patient. This falls under the broad category of underutilization. While concerns of overutilization and over treatment are discussed, the counters	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
		behalf of Geoffrey Rubin	and their impact are not explored. Another area that is unexplored is picking the right diagnostic process amongst competing choices. A classic example would be the assessment of coronary artery disease using CT, stress echo, or radionuclide scintigraphy. In these settings the possibility that redundant testing is performed or that multiple tests are required when the wrong test is selected first. Finally mention is made of psychological harms. I would encourage the Committee to also include psychological benefits, such as the comfort of having an answer or well-being from a negative result."	in the project.
13	General Overall Comments	Zach Smith, American College of Radiology on behalf of Anne Brittain	I agree that the document does a pretty good job representing Radiology, especially considering it is really talking about ALL diagnostic testing not just imaging. I really don't have any comments other than some of this would be very difficult to measure in imaging.	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.
14	General Overall Comments	Mary Lally, Intersocietal Accreditation Commission	Diagnostic accuracy is critical to appropriate patient management and treatment and is difficult to measure. In order to begin to measure the issue, physicians and health professionals must be able to identify areas for improvement and put processes in place to reduce poor quality imaging and inaccuracies in the interpretation. IAC Accreditation program educates and helps facilities implement processes to improve their diagnostic and procedural imaging and interpretive accuracy for the better patient care. The IAC accreditation program captures and reviews many aspects of quality and safety, with the rigor of the program focusing on patient safety, the diagnostic quality of the images and the accuracy of the interpretation through an independent third party clinical peer review. The clinical peer review includes physicians with specific expertise in the clinical area being examined; technologists and medical physicists. The IAC is the only CMS	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
			recognized accrediting body requiring the submission of case studies to include pathology for real world case study evaluation. Our data demonstrates there is room for improvement in overall interpretive accuracy and image quality. The IAC program encompasses the quality domains of structure, process and outcomes. In order to improve accuracy of testing, physicians must be able to self-identify their own errors in a culture that embraces transparency for process improvement. The IAC accreditation program provides a mechanism for internal clinical peer review of the image quality and report accuracy using the Quality Improvement (QI) tool. By reviewing images and reports, physicians can identify deficiencies and implement activities for process improvement. The tool provides analytics for benchmarking within their own group as well as with other facilities in the various quality measures categories. The tool measures: 1) Appropriate use or test appropriateness; 2) technical quality and safety; 3) interpretive accuracy and 4) report timeliness and completeness. The IAC has recognized the importance of this measure on patient care and management for over 25 years. With 44 medical societies that are represented on our Board of Directors, IAC provides the best program to identify and improve the diagnostic quality of images and the accuracy of interpretation leading to improved patient care. In order for behavior to change it must start at the operator level. Providing a mechanism of a non-punitive independent clinical peer review with constructive feedback as well as a tool for physicians to self-identify inaccuracies in their report is a critical component to improving the diagnostic quality for better patient care. The IAC is committed to this mission. Visit the IAC website for more information: http://www.intersocietal.org/ I applaud the group for moving forward to identify a way to measure diagnostic accuracy. I am happy to assist the Committee to explore this	

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
			endeavor.	
15	General Overall Comments	Paul Epner, Society to Improve Diagnosis in Medicine	Congratulations on the very important progress the Committee has made. I believe that the proposed framework represents a major first step towards the development of measures that can be used as guideposts for the improvement of diagnostic safety and quality. I hope you will consider the following comment for its potential impact on multiple elements of the framework. The NAM report identified the importance of effective teamwork in the diagnostic process among healthcare professionals, patients and their families. However, the framework uses language that is unclear. References to "provider" might be misinterpreted by many to refer to clinicians and clarifying a broader intention could be helpful, i.e. that all references to providers could include any member of the care delivery team.	The Committee agreed that the term provider referenced to various individuals involved in the diagnostic team. The Committee considered the following alternatives: healthcare professional and allied professional.
16	Draft Framework - Process	Paul Epner, Society to Improve Diagnosis in Medicine	Establishing a separate sub-domain for patient engagement on one hand brings extra focus to this dimension, but simultaneously, establishes a separation between the patient and healthcare professionals. Furthermore, references to "provider" might be interpreted by many to refer to clinicians. If creating sub-domains is seen as important, consider creating three domains that recognize both the interactivity of the healthcare process as well as the major dyads that exist: "clinician-patient," "non-clinician healthcare professionals – patient," and "clinician-non-clinician healthcare professionals. The examples in Appendix C certainly help in clarifying the direction of the Committee. It is hoped that the Committee will consider examples that reflect appropriate usage of language in describing the examples. For example, a sample measure concept shown is "Proportion of abnormal diagnostic test results returned but not acted upon within an appropriate time window." More appropriate wording would reference "actionable diagnostic test results" instead of "abnormal diagnostic test results.	The Committee considered re-naming process domains as follows: patient-health professional; health professional-health professional; health professional-system; and patient-system.

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
17	General Overall Comments	Paul Epner, Society to Improve Diagnosis in Medicine	First, let me preface this final comment and hope that it is understood to be equally true for the other two comments I have already inputted and cannot edit. All of my comments reflect my personal opinion and do not necessarily reflect the official position of the Society to Improve Diagnosis in Medicine. Unintended Consequences: Concern is raised about increasing the burden of measurement. While a valid concern, there are few, if any, measures focused on improving diagnostic quality and safety. Yet getting the diagnosis right is fundamental to the efficient and effective delivery of treatments. It is hoped that NQF will clarify for concerned parties that this newest field of measurement has generated almost no burden today and should not carry the burden of measurement-fatigue generated by unrelated and non-overlapping areas of medicine. I share the Committee's concern about the potential overuse of diagnostic testing modalities. However, it could be detrimental to consider any accurate diagnosis as unnecessary. Inappropriate treatment is indeed a problem and increased research into the appropriateness of treatment is necessary. If a situation exists where a particular diagnosis should never be treated, then our labeling and coding system should be altered. However, to suggest that some accurate diagnoses should be handled differently from others with the same diagnosis has the potential to ration knowledge. Patient Centeredness: I congratulate the Committee on its deliberate focus on patient centeredness. I hope it will stress through explicit language or examples, that to be truly patient centered, care must be provided in a way that is actionable for the patient, not just healthcare professionals. For example, use as proof of patient centeredness that they provide test results to their patients through a portal. However, nearly always, those results are written for healthcare professionals using acronyms of test results, vague symbols like H, M, L or asterisks. The framework should that patient centeredness should be measured from the perspective of patients.	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
18	Draft Framework - Structure	Carmella Bocchino, American's Health Insurance Plans	The Framework the Committee is using is well thought out and includes different and critical variables that play a significant role in the accuracy of Diagnostic information regarding processes and outcomes. We would recommend that as the Committee begins its work to evaluate the different elements under each Domain in this Framework, that they look at the elements for measurement that could be most impactful in the overall outcome and results of the Diagnostic Accuracy Framework.	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.
19	General Overall Comments	Carmella Bocchino, American's Health Insurance Plans	We agree with NQF's overall approach to the efforts outlined in the Improving Diagnostic Quality and safety draft report.	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.
20	General Overall Comments	Liz Waibel, The American Society for Clinical Pathology	On behalf of the American Society for Clinical Pathology (ASCP), we appreciate the opportunity to provide comments in response to the National Quality Forum (NQF)'s Improving Diagnostic Quality and Safety: Draft Measurement Framework. ASCP is grateful for the work that is being done to protect patients and improve quality in this area; as an organization dedicated to promoting quality, patient safety, and optimum patient outcomes, we greatly appreciate the NQFs efforts and commitment to an issue that is vitally important to our membership. The ASCP is a 501(c)(3) nonprofit medical specialty society representing over 100,000 members. Our members are board certified pathologists, other physicians, clinical scientists (PhDs), certified medical laboratory scientists/technologists and technicians, and educators. ASCP is one of the nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
			comprehensive educational programs, publications, and self-assessment materials. As a patient-centric organization, ASCP agrees that diagnostic errors persist through all settings of care and harm an unacceptable number of patients. ASCP applauds the National Academies of Sciences, Engineering, and Medicine (NASEM) for producing a report that defines "…diagnostic error from the patient's perspective;" we also agree that increased effective measurement in this area may lead to improvements in patient safety and quality of care. As a sponsoring organization of the study, Improving Diagnosis in Health Care, we wholeheartedly agree with the report's findings that "…diagnostic errors have been more challenging to measure than other quality or safety concepts." This observation is precisely why the ASCP has created a National Pathology Quality Registry (NPQR) to set standards for patient-centric diagnostic care. Through this work, we have identified similar gaps in measurement and generally agree with the draft conceptual framework put forth by the NQF. ASCP appreciates the opportunity to comment on the Improving Diagnostic Quality and Safety Draft Measurement Framework and look forward to collaborating with the NQF in the future on this issue. Please refer any questions to Elizabeth Waibel, Senior Manager, Health Policy at 202-347-4450, Ext. 2902 or Elizabeth.Waibel@ascp.org.	
21	Draft Framework - Structure	Liz Waibel, The American Society for Clinical	Overall, ASCP agrees with the Structure domain and associated subdomains and measure concepts examples. However, further granularity as described below, is necessary to adequately capture all aspects of the diagnostic process in this area. People Subdomain: We would like to emphasize the fact that all members of	The Committee considered whether to revise the concept to ready Support staff operate at the top of their license, training, and/or certification. The Committee agreed that

Number	Commenter Name and Organization	Comment Type	Comment	Committee Response
		Pathology	the laboratory team (PhDs, laboratory professionals, etc.) should be able to support the diagnostic process. While we agree that support staff should "operate to the top of their licenses to free up cognitive load of the MD," ASCP suggests extending this measure concept to recognize certification in cases where non-physician staff are not licensed. Further, ASCP strongly supports inclusion of clinical laboratory professionals – such as those mentioned above – in assisting clinicians in test selection and interpretation of results. Technologies and Tools Subdomain: While ASCP agrees that the measure concept examples included in the draft framework are a step toward ensuring that health information technologies support patients and healthcare professionals in the diagnostic process, the subdomain should also include mention of laboratory information systems (LIS). Interoperability between electronic health records and LISs is critical to achieving accurate and timely results communication.	the technologies and tools subdomain should mention interoperability between electronic health records and laboratory information systems
22	Overall General Comments	Donald May, AdvaMed	Please see the full comment on the next page.	Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

NATIONAL QUALITY FORUM

Full Comment submitted by AdvaMed on the Draft Framework

Re: Comments for NQF Improving Diagnostic Quality and Safety: Draft Measurement Framework

Dear Dr. Agrawal:

On behalf of the Advanced Medical Technology Association (AdvaMed) and AdvaMedDx, we appreciate the opportunity to comment on the National Quality Forum's *Draft Measurement Framework for Improving Diagnostic Quality and Safety.*

AdvaMedDx member companies produce advanced *in vitro* diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease and often reduce overall health care costs. Functioning as an association within the Advanced Medical Technology Association (AdvaMed), AdvaMedDx deals exclusively with issues facing *in vitro* diagnostic manufacturers both in the United States and abroad. Throughout this letter, AdvaMed refers to both AdvaMed and AdvaMedDx.

I. General Comments:

AdvaMed commends the National Quality Forum for taking up the challenging and important issue of quality measurement for improving diagnostic quality and safety. NQF's focus on diagnostic quality highlights the value of diagnostic testing, and particularly the importance of diagnostics. Diagnostic tests account for only a small fraction of health expenditures, yet they provide important information that can significantly influence health care decision-making.
Diagnostic tests are an essential component in the health care continuum and are sometimes undervalued. Importantly, diagnostic testing serves to address important unmet medical needs.

We agree with the NQF Committee assessment that the scope should be expanded to encompass improving diagnostic safety, effectiveness, patient-centeredness, timeliness, efficiency, and equitability, as these dimensions apply to diagnosis. We also support the recommendation to align the preliminary draft framework to the National Academies of Sciences, Engineering and Medicine (NASEM) conceptual model of the diagnostic process.

AdvaMed has long supported the use of appropriate quality measures in all settings to improve the quality of patient care and patient safety. Many quality measures are aimed at providing early diagnosis, timely treatment decisions and treatment delivery, which can lead to reduced patient morbidity and mortality, improved patient quality of life and contribute to lowering the over-all cost of care.

It is important to note that when it comes to diagnostics, there are many different paths and players along the diagnostic journey. A laboratory may perform a test, which may then be interpreted by a pathologist who relays the result to a clinician who makes a medical decision, or a referral for care, perhaps with or without the input of the patient. Various medical providers may communicate different information to patients and their caregivers over the course of the journey, and clinically-

related decisions are made or not made based on that information. In addition, it is important to note that there is unnecessary waste in the healthcare system when patients go through a medical odyssey with inaccurate diagnoses.

Measure development related to diagnostic testing needs to be clear regarding who is being evaluated and at what point in time. As noted on the NASEM website, there are numerous stories provided to illustrate the significant issues surrounding communication/miscommunication between treating clinicians and patients, as well as between treating clinicians concerning the reasoning for the ordering of the test, the test results and future implications. The draft NQF Measure Concept Framework provides a starting point for addressing these communication errors and avoiding unnecessary and unintentional patient harms and waste in the healthcare system.

In developing measure concept and subsequent clinical measures, measure stewards need to be keenly aware of the innovations that are taking place at a rapid pace in diagnostic testing. For example, molecular diagnostics is becoming an increasingly important determinant of diagnosis, treatment selection and patient monitoring. These testing methods are becoming increasingly complex. Molecular tests that initially identified single mutations now often are complex multi-marker panels generated by advanced next generation sequencing technologies and interpreted by proprietary algorithms. These are the transformative advances enabling precision medicine, but they also are creating an increasingly difficult landscape for laboratorians, clinicians and patients to understand and navigate effectively.

Innovations in diagnostic technologies also are shifting some testing outside the laboratory, which raises additional considerations regarding the interpretation, communication, and use of test results. Point-of-care tests can be performed and deliver time-sensitive results in a wide variety of care settings, including the emergency room, the hospital bedside, the doctor's office, and the clinic. Emerging in-vivo diagnostic technologies, of which continuous glucose monitors are an early example, will enable the collection, transmission, and interpretation of patient- generated data and empower earlier and more effective health interventions by patients and clinicians alike.

Therefore, the context of when and how different tests should be incorporated into standard practice is constantly evolving to keep pace with the technological/clinical innovations which are occurring. As personalized medicine becomes more and more available, the need for these concepts and correct and timely communication becomes increasingly necessary. Thus, measure concepts related to education of providers and their communication to other providers and patients regarding diagnostic testing along the patient journey will be an essential component in future measures.

As noted in the draft framework report, a significant portion of the concepts were based on the National Academies of Sciences, Engineering and Medicine's (NASEM's) study titled Improving Diagnosis in Health Care.1 We believe that many of the goals contained in the report aimed at reducing diagnostic error and improving diagnosis address many significant considerations when developing quality measures in this landscape including:

- Facilitating more effective teamwork in the diagnostic process among health care professionals, patients, and their families including coordination of care;
- Enhancing health care professional education and training in the diagnostic process;
- Ensuring that health information technologies (IT) support patients and health care professionals in the diagnostic process;
- Developing and deploying approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice; and
- Establishing a work system and culture that supports the diagnostic process and

improvements in diagnostic performance.

I. Recommendations for Future Measures and Measure Concepts to Improve Diagnostic Safety, Effectiveness, Patient-centeredness, Timeliness, Efficiency, and Equitability

As the Committee considers measure concepts that align with the structure, process and outcomes domains and sub-domains outlined in "Appendix C", we urge NQF to also consider potential, as well as existing measures that could be adopted immediately to fill these diagnostic quality measure gaps.

a. Potential Measure Concepts:

i. Recommendation to Include Shared Decision Making in Considering Use of New Technologies in Patient Care.

AdvaMed applauds NQF for considering numerous measure concepts related to patient engagement and workflow as noted in Appendix C. In this regard, AdvaMed recommends that NQF incorporate the concept of shared decision making for discussion of new technologies in patient care. The activity would encourage practitioners and groups to take time and provide thoughtful engagement with their patients when potential new diagnostic technologies may be used as an option in their care. For some practitioners, this would allow them a new way to practically incorporate new technology and new procedures in their practice for the benefit of their patients. Additionally, this concept would aid in achieving improved beneficiary health outcomes and reducing health care disparities.

ii. Recommendation to Include Providing Timely Access to Medical Diagnostic Technologies

AdvaMed is pleased that the draft framework addresses many of the timeliness issues related to the diagnostic process subdomain; however we also recommend that there should be similar emphasis on providing timely patient access to diagnostic technologies. For example, the ability to complement existing colorectal cancer diagnostic testing with innovative technologies such as colon capsule endoscopy may be a viable solution for improving access of this important diagnostic test for patients in rural areas, patients at high risk for a colonoscopy or patient populations with low engagement. Ensuring that diagnostic testing aligns with the most current clinical guidelines and standards is another important measure concept. As innovations in diagnostic testing are rapidly evolving it is important that the right test is conducted in the right population at the right time. In addition, it is important to provide timely access to medical diagnostics for patients in need of social services including disabled patients and underserved populations to ease the healthcare burden. AdvaMed believes that timely access to diagnostic technology is a key component to the success of any quality measure concepts to address timely diagnosis and assessment of a patient's health problem.

b. Existing Quality Measures for Adoption:

i. Malnutrition Electronic Clinical Quality Measures (eCQMs):

NQF is currently considering a malnutrition measure set for endorsement that includes a diagnosis-related measure that could be adopted to fill diagnostic quality measure gaps. In addition, CMS is considering these measures for the inpatient quality reporting program.

The measure steward, the Academy of Nutrition and Dietetics and Avalere Health, developed a set of electronic clinical quality measures (eCQMs) for malnutrition that includes a diagnosis- related measure, described in more detail in Appendix A. The Appendix outlines how the malnutrition eCQM

measure set aligns with the proposed domains and sub-domains for improving Diagnostic Safety, Effectiveness, Patient-centeredness, Timeliness, Efficiency, and Equitability.

Timely screening, diagnosis and treatment of malnourished or patients at risk for malnutrition is critical to improving outcomes and patient safety by reducing complications that can lead to readmissions including infections, falls, and pressure ulcers. Documentation of Diagnosis is key component in the diagnostic and care process, as it triggers interventions linked to improved outcomes. In the case of malnutrition, the dietitian conducts an assessment, documents malnutrition findings and makes a recommendation of nutritional status in the medical record; but until the physician documents the diagnosis, the care plan implementation and care coordination is not consistently triggered. This example supports the existence of a measure gap and the opportunity to improve diagnostic safety, effectiveness, patient-centeredness, timeliness, efficiency, and equitability with adoption of the malnutrition eCQMs. Again, Appendix A provides additional information regarding this measure set, which is being considered by CMS for adoption in the Hospital Inpatient Quality Reporting program.

AdvaMed appreciates this opportunity to share our feedback and comments to NQF regarding the Draft Measurement Framework for Improving Diagnostic Quality and Safety. AdvaMed looks forward to working with NQF as it continues on this important activity. We understand that there will be multiple opportunities available to participate in public meetings or to comment on the proposed framework, quality measure concepts, or other related proposals, and we look forward to participating and contributing.

Please contact me or Steven J. Brotman, MD, JD at sbrotman@advamed.org if you have any additional questions or need any additional information.

Sincerely,

Donald May
Executive Vice President, Payment and Health Care Delivery

Appendix A:

Domain/Subdomain	Examples of Measure Concepts	Malnutrition eCQM Examples
Structure/Technologies & Tools • Clinical Content of HIT • Availability of diagnostic resources	• The organization uses an interoperable and certified eHR that integrates nutrition data standards, CCDA 2.0 and CDS functionality • eHR allows for designating patients as "not yet	• **NQF #3090 Appropriate Documentation of Malnutrition Diagnosis for Patients**
Structure/External Environment • Care Delivery System • Reporting environment	• Care delivery system promotes care coordination • Care delivery is patient- centered, not physician centered	• **NQF #3089 Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment**
Process- Patient Engagement • Access to Care • Communication with Patient	• Communication about the diagnosis is documented	• **NQF #3089 Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment**

Process- The Diagnostic Process Eliciting patient history & performing the nutrition-focused physical assessment Integration of team- based information Consultation from specialists Appropriate follow-up	Adequacy of documenting the initial findings; clarity and accuracy of the documentation Proportion of patients with timely follow up after initial diagnosis Diagnosis is timely	NQF #3087 Malnutrition Screening within 24 Hours of Admission NQF #3088 Completion of Nutrition Assessment for Patients Identified as at-risk for malnutrition within 24 Hours of Malnutrition Screening NQF #3089 Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment NQF #3090 Appropriate Documentation of Malnutrition Diagnosis for Patients

Appendix F: Inventory of Measures in development, testing, or in use

Source: National Quality Forum

#	Measure Title (Developer)	Description
1	0417 Diabetic Foot & Ankle Care, Peripheral Neuropathy – Neurological Evaluation	Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months
2	3055/0089 Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months
3	0090 Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain	Percentage of patients aged 40 years and older with an emergency department discharge diagnosis of non-traumatic chest pain who had a 12-lead electrocardiogram (ECG) performed
4	0088/3054 Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months
5	0091 COPD: Spirometry Evaluation	Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry results documented
6	0166 HCAHPS	HCAHPS (NQF #0166) is a 32-item survey instrument that produces 11 publicly reported measures: 7 multi-item measures (communication with doctors, communication with nurses, responsiveness of hospital staff, pain control, communication about medicines, discharge information and care transition); and 4 single-item measures (cleanliness of the hospital environment, quietness of the hospital environment, overall rating of the hospital, and recommendation of hospital)
7	2063 Performing cystoscopy at the time of hysterectomy for pelvic organ prolapse to detect	Performing cystoscopy at the time of hysterectomy for pelvic organ prolapse to detect lower urinary tract injury

	lower urinary tract injury	
8	2522 Rheumatoid Arthritis: Tuberculosis Screening Recommended for eMeasure Trial Approval	Percentage of patients 18 years and older with a diagnosis of rheumatoid arthritis who have documentation of a tuberculosis (TB) screening performed within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).
9	0577 Use of Spirometry Testing in the Assessment and Diagnosis of COPD	The percentage of patients 40 years of age and older with a new diagnosis of COPD or newly active COPD, who received appropriate spirometry testing to confirm the diagnosis.
10	0297 Procedures and Tests	Percentage of patients transferred to another healthcare facility whose medical record documentation indicated that procedure and test information was communicated to the receiving FACILITY within 60 minutes of departure
11	0508 Diagnostic Imaging: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms	Percentage of final reports for screening mammograms that are classified as "probably benign"
12	1364 Child and Adolescent Major Depressive Disorder: Diagnostic Evaluation	Percentage of patients aged 6 through 17 years with a diagnosis of major depressive disorder with documented evidence that they met the DSM-IV criteria [at least 5 elements with symptom duration of two weeks or longer, including 1) depressed mood (can be irritable mood in children and adolescents) or 2) loss of interest or pleasure] during the visit in which the new diagnosis or recurrent episode was identified
13	0567 Appropriate work up prior to endometrial ablation procedure	To ensure that all women have endometrial sampling performed before undergoing an endometrial ablation.
14	1854 Barrett's Esophagus	Percentage of patients with esophageal biopsy reports for Barrett's esophagus that contain a statement about dysplasia and if present the grade of dysplasia.
15	0661 Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT or MRI Scan Interpretation within 45 minutes of ED Arrival	This measure calculates the percentage of acute ischemic stroke or hemorrhagic stroke patients who arrive at the emergency department (ED) within two hours of the onset of symptoms and have a head computed tomography (CT) or magnetic resonance imaging (MRI) scan interpreted within 45 minutes of ED arrival. The measure is calculated using chart-abstracted data, on a rolling, quarterly basis and is publicly reported, in aggregate, for one

		calendar year.
16	0386 Oncology: Cancer Stage Documented	Percentage of patients, regardless of age, with a diagnosis of cancer who are seen in the ambulatory setting who have a baseline AJCC cancer stage or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period
17	2091 Persistent Indicators of Dementia without a Diagnosis – Long Stay	Percentage of nursing home residents age 65+ with persistent indicators of dementia and no diagnosis of dementia.
18	2092 Persistent Indicators of Dementia without a Diagnosis – Short Stay	Number of adult patients 65 and older who are included in the denominator (i.e., have persistent signs and symptoms of dementia) and who do not have a diagnosis of dementia on any MDS assessment.
19	1853 Radical Prostatectomy Pathology Reporting	Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.
20	0455 Recording of Clinical Stage Prior to Surgery for Lung Cancer or Esophageal Cancer Resection	Percentage of surgical patients aged 18 years and older undergoing resection for lung or esophageal cancer who had clinical staging provided prior to surgery
21	0392 Colorectal Cancer Resection Pathology Reporting –pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade	Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade
22	2930 Febrile Neutropenia Risk Assessment Prior to Chemotherapy	Percentage of patients with a solid malignant tumor or lymphoma who had a febrile neutropenia (FN) risk assessment completed and documented in the medical record prior to the first cycle of intravenous chemotherapy
23	0379 Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry	Percentage of patients aged 18 years and older, seen within a 12 month reporting period, with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart
24	0352 Failure to Rescue In-Hospital Mortality (risk-	Percentage of patients who died with documented or

	adjusted)	undocumented complications in the hospital
25	0353 Failure to Rescue 30-Day Mortality (risk adjusted)	Percentage of patients who died with documented or undocumented complications within 30 days from admission
26	0649 Transition Record with Specified Elements Received by Discharged Patients (Emergency Department Discharges to Ambulatory Care [Home/Self Care] or Home Health Care)	Percentage of patients, regardless of age, discharged from an emergency department (ED) to ambulatory care or home health care, or their caregiver(s), who received a transition record at the time of ED discharge including, at a minimum, all of the specified elements
27	0651 Ultrasound determination of pregnancy location for pregnant patients with abdominal pain	Percentage of pregnant patients who present to the ED with a chief complaint of abdominal pain and or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound.

Source: Health Indicators Warehouse

#	Measure Title	Description
1	Diagnosed diabetes: adults with diabetes	Percent of adults aged 20 years and older with diabetes whose condition has been diagnosed
2	Diagnosis awareness: adults aged 65 years and older with dementias	Persons aged 65 years and over diagnosed with Alzheimer's disease or other type of dementia (as specified in the Denominator), or their caregiver, who are aware of the diagnosis
3	Late HIV diagnosis: persons 13+ years	Percent of new HIV infections diagnosed before progression to AIDS among persons aged 13 years and over
4	von Willebrand Disease diagnosis: women	Percent of women with von Willebrand Diseasae diagnosis, enrolled in UDC, who were diagnosed within one year after experiencing their first bleed

Source: CMS Quality Measures Inventory

#	Measure Title	Description
1	142 Mammography Follow-	This measure calculates the percentage of patients with

	Up Rates	mammography screening studies that are followed by a diagnostic mammography , ultrasound or Magnetic Resonance Imaging (MRI) of the breast in an outpatient or office setting within 45 days.
2	243 Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months
3	246 Age-Related Macular Degeneration (AMD): Dilated Macular Examination	Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or hemorrhage AND the level of macular degeneration severity during one or more office visits within 12 months
4	254 Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months
5	267 Osteoporosis: Communication with the Physician Managing On-going Care Post-Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older	Percentage of patients aged 50 years and older treated for a hip, spine or distal radial fracture with documentation of communication with the physician managing the patient's on-going care that a fracture occurred and that the patient was or should be tested or treated for osteoporosis
6	356 Appropriate Testing for Children with Pharyngitis	Percentage of children 2-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.
7	420 Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade	Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade
8	928 The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR	Documents the extent to which a provider uses an Office of the National Coordinator for Health Information Technology (ONC) certified electronic health record (EHR) system that incorporates an electronic data interchange with one or more laboratories allowing for direct electronic transmission of laboratory data in the EHR as

	System as Discrete Searchable Data Elements	discrete searchable data elements. This measure applies to all outpatient departments associated with the facility that bill under the Outpatient Prospective Payment System (OPPS). This may include the emergency department (ED), the outpatient imaging department, the outpatient surgery department, and the facility's clinics.
9	1107 Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients	This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer
10	1147 Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness	Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness
11	1174 Preoperative Diagnosis of Breast Cancer	The percent of patients undergoing breast cancer operations who obtained the diagnosis of breast cancer preoperatively by a minimally invasive biopsy method
12	1180 Biopsy Follow-Up	Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician
13	2283 Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description	Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems
14	2344 Oncology: Cancer Stage Documented	Percentage of patients, regardless of age, with a diagnosis of cancer who are seen in the ambulatory setting who have a baseline American Joint Committee on Cancer (AJCC) cancer stage or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period
15	2395 Lung Cancer Reporting (Biopsy/Cytology Specimens)	Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary nonsmall cell lung cancer classified into specific histologic type or classified as NSCLC-NOS with an explanation included in the pathology report.

16	2396 Lung Cancer Reporting (Resection Specimens)	Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer, histologic type.
17	2397 Melanoma Reporting	Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate.
18	2875 Non-melanoma Skin Cancer (NMSC): Biopsy Reporting Time - Pathologist	Length of time taken from when a biopsy is performed to when a patient is notified by the biopsying physician that he or she has cutaneous basal or squamous cell carcinoma (including in situ disease). This measure evaluates the reporting time between the biopsying clinician and patient.

Source: National Quality Measures Clearinghouse

#	Measure Title	Description
1	Epilepsy: percentage of children diagnosed with epilepsy, who still had that diagnosis at 1 year.	This measure is used to assess the percentage of children diagnosed with epilepsy, who still had that diagnosis at 1 year.
2	Chronic graft versus host disease (cGVHD): percentage of patients diagnosed with cGVHD with diagnosis confirmed with at least one diagnostic manifestation or one distinctive manifestation with confirmation by pertinent biopsy, lab tests or radiology in the same or different organ.	This measure is used to assess the percentage of patients diagnosed with chronic graft versus host disease (cGVHD) with diagnosis confirmed with at least 1 diagnostic manifestation OR 1 distinctive manifestation with confirmation by pertinent biopsy, lab tests or radiology in the same or different organ.
3	Diagnosis and treatment of headache: percentage of patients diagnosed with primary headache using the appropriate diagnostic criteria	Percentage of patients age 12 years and older diagnosed with primary headache using the appropriate diagnostic criteria
4	Diagnosis and treatment of respiratory illness in children and adults:	This measure is used to assess the percentage of patients diagnosed with strep pharyngitis who had a rapid group A strep test or strep

	percentage of patients diagnosed with strep pharyngitis who had a rapid group A strep test or strep culture.	culture.
5	Non-Hodgkin lymphoma: percent of patients with lymphoma whose initial lymphoma diagnosis was established by one of the following: incisional or excisional biopsy AND immunohistochemical characterization, OR core needle biopsy AND appropriate ancillary techniques employed.	This measure is used to assess the percent of patients with lymphoma whose initial lymphoma diagnosis was established (or confirmed) by one of the following: Incisional or excisional biopsy of the lymph node AND Immunohistochemical characterization OR Core needle biopsy AND Appropriate ancillary techniques employed (at least one of the following must have been done) Cell phenotype for immunoglobulin heavy chain variable (IgHV) and/or T-cell receptor (TCR) gene rearrangements Fluorescence in situ hybridization (FISH) for major translocations (at least one positive result [rearrangement] consistent with a lymphoid neoplasm) Immunophenotypic analysis
6	Diagnosis and management of chronic obstructive pulmonary disease (COPD): percentage of patients with a diagnosis of COPD who had spirometry testing to establish COPD diagnosis	This measure is used to assess the percentage of patients age 18 years and older with a diagnosis of chronic obstructive pulmonary disease (COPD) who had spirometry testing to establish COPD diagnosis.
7	Communication of changes in patient care: percentage of healthcare professionals who affirm that in their unit or area information affecting a patient diagnosis is always communicated clearly and rapidly to all professionals involved in the care of that patient.	This measure is used to determine the percentage of healthcare professionals who affirm that in their unit or area information affecting a patient's diagnosis is always communicated clearly and rapidly to all professionals involved in the care of that patient.
8	Use of spirometry testing in the assessment and diagnosis of COPD:	This measure is used to assess the percentage of members 40 years of age and older with a new diagnosis of chronic obstructive pulmonary disease (COPD) or newly active COPD, who received

	percentage of members 40 years of age and older with a new diagnosis of COPD or newly active COPD, who received appropriate spirometry testing to confirm the diagnosis	appropriate spirometry testing to confirm the diagnosis.
9	Distal symmetric polyneuropathy (DSP): percentage of patients age 18 years and older with a diagnosis of DSP who had their neuropathic symptoms and signs reviewed and documented at the initial evaluation for DSP.	This measure is used to assess the percentage of patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy (DSP) who had their neuropathic symptoms and signs reviewed and documented at the initial evaluation for DSP.
10	Parkinson's disease: percentage of patients with a diagnosis of Parkinson's disease who had their Parkinson's disease diagnosis reviewed, including a review of current medication and a review for the presence of atypical features (e.g., falls at presentation and early in the disease course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor, or dysautonomia) at least annually.	This measure is used to assess the percentage of patients with a diagnosis of Parkinson's disease who had their Parkinson's disease diagnosis reviewed, including a review of current medication and a review for the presence of atypical features (e.g., falls at presentation and early in the disease course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor, or dysautonomia) at least annually.
11	Distal symmetric polyneuropathy (DSP): percentage of patients age 18 years and older with a diagnosis of DSP who had screening tests for diabetes reviewed, requested or ordered when seen for an	This measure is used to assess the percentage of patients age 18 years and older with a diagnosis of distal symmetric polyneuropathy (DSP) who had screening tests for diabetes (e.g., fasting blood sugar test, a hemoglobin A1C, or a 2 hour glucose tolerance test) reviewed, requested or ordered when seen for an initial evaluation for DSP

	initial evaluation for DSP.	
12	Pathology: percentage of biopsy and cytology specimen reports with a diagnosis of non small cell lung cancer that are classified into specific histologic type or classified as NSCLC-NOS with an explanation included in the pathology report	This measure is used to assess the percentage of biopsy and cytology specimen reports with a diagnosis of non small cell lung cancer (NSCLC) that are classified into specific histologic type or classified as NSCLC-not otherwise specified (NOS) with an explanation included in the pathology report