Improving Diagnostic Quality and Safety

NATIONAL QUALITY FORUM

CONTENTS

EXECUTIVE SUMMARY

In the United States, at least 5 percent of adults seeking outpatient care experience a diagnostic error.[1] These errors contribute to nearly 10 percent of deaths annually, and up to 17 percent of adverse hospital events.[2] A committee on diagnostic error of the National Academies of Sciences, Engineering, and Medicine (NASEM)—previously known as the Institute of Medicine (IOM)—published a 2015 study that defined diagnostic error as the "failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient."[3] The committee concluded 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 results from many 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 to assist in reducing diagnostic harm, the National Quality Forum (NQF) convened a multistakeholder expert Committee to develop a conceptual framework for measuring diagnostic quality and safety and to identify priorities for future measure development. The conceptual framework is intended to facilitate systematic identification and prioritization of measure gaps and to help guide efforts to fill those gaps through measure development and endorsement.

With guidance from the Committee, NQF staff conducted an environmental scan to identify measures related to diagnostic quality and safety and to inform development of the measurement framework. Following two in-person meetings and five webinars, the Committee agreed on a measurement framework comprised of three domains and 11 subdomains, as described below. The Committee also reviewed measures identified through an environmental scan (see

Appendix F) and established measure concepts through brainstorming sessions. From there, the Committee worked to build consensus around a set of prioritized measurement areas to guide future measure development.

A Framework for Measurement

Table 1 specifies the three domains and 11 subdomains for the measurement of diagnostic quality and safety.

TABLE 1. DIAGNOSTIC QUALITY AND SAFETY MEASUREMENT FRAMEWORK

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

Prioritized Measurement Areas

The Committee reviewed a list of potential measure concepts submitted by Committee members and members of the public during its second in-person meeting. Committee members evaluated the concepts through a series of small group exercises and full Committee discussions. The Committee also conducted a preliminary prioritization exercise to identify an initial set of 62 prioritized measure concepts (see Appendix G). Themes identified as high-priority areas by the Committee include timeliness of diagnosis,

timeliness of test result follow-up, communication and hand-offs, patient-reported diagnostic errors, and patient experience of diagnostic care.

Cross Cutting Themes and Recommendations

The Committee identified seven cross-cutting themes and recommendations intended to apply broadly to those researching or wishing to develop measures related to reducing diagnostic harm. The Committee's cross-cutting themes and recommendations are:
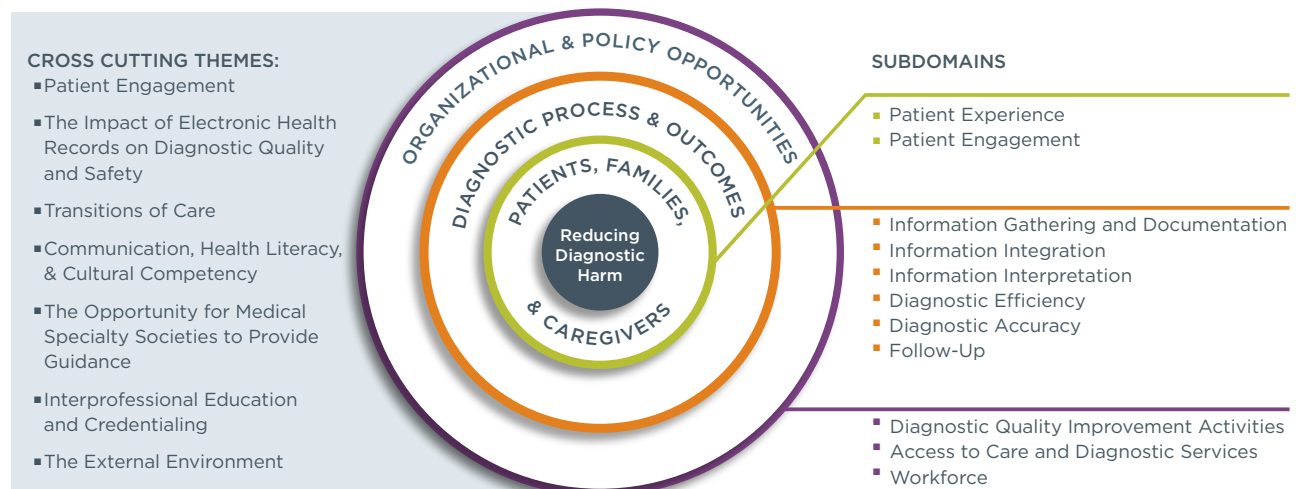
- **Patient Engagement:** Engaging patients and using their knowledge of their own medical histories is a critical aspect of the diagnostic process.

- **Impact of Electronic Health Records (EHR):** Diagnostic quality and safety can be advanced significantly if electronic health records have the capacity to collect key information related to diagnosis and are interoperable within and across organizations.

- **Transitions of Care:** Transitions of care and errors during care transitions (e.g., loss of information critical to patient care) can have a significant impact on diagnostic quality and safety.

- **Communication:** Communication—between

the provider and the patient, and between providers—is a key issue in diagnostic quality and safety. When communicating with patients about their diagnoses, healthcare professionals should be sensitive to the patients' health literacy and cultural needs or preferences.

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

- **Interprofessional Education and Credentialing:** Diagnostic quality and safety should become an important component of professional education, and credentialing organizations should ensure that their reviews emphasize diagnostic quality and safety.

- **External Environment:** Issues related to the external environment, such as the alignment of payment incentives to promote timely and correct diagnosis, are less amenable to quality measurement but will have a significant impact on diagnostic quality and safety.

Figure 1 illustrates the final measurement framework for diagnostic quality and safety.

FIGURE 1. DIAGNOSTIC QUALITY AND SAFETY FRAMEWORK

CROSS CUTTING THEMES:
- Patient Engagement
- The Impact of Electronic Health Records on Diagnostic Quality and Safety
- Transitions of Care
- Communication, Health Literacy, & Cultural Competency
- The Opportunity for Medical Specialty Societies to Provide Guidance
- Interprofessional Education and Credentialing
- The External Environment

ORGANIZATIONAL & POLICY OPPORTUNITIES
DIAGNOSTIC PROCESS & OUTCOMES
PATIENTS, FAMILIES, & CAREGIVERS
Reducing Diagnostic Harm

SUBDOMAINS
- Patient Experience
- Patient Engagement

- Information Gathering and Documentation
- Information Integration
- Information Interpretation
- Diagnostic Efficiency
- Diagnostic Accuracy
- Follow-Up

- Diagnostic Quality Improvement Activities
- Access to Care and Diagnostic Services
- Workforce

BACKGROUND AND PROJECT OBJECTIVES

The delivery of high-quality healthcare is predicated upon an accurate and timely diagnosis. 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.[4] This 2015 study of the National Academies of Sciences, Engineering, and Medicine (NASEM)—previously known as the Institute of Medicine (IOM)—found that at least 5 percent of U.S. adults seeking outpatient care each year experience a diagnostic error.[5] These types of errors contribute to nearly 10 percent of deaths each year, and up to 17 percent of adverse hospital events.[6] The NASEM committee on diagnostic error 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."[7] 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."[8]

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 and reducing diagnostic harm.

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 report describes the Committee's final conceptual framework.

Terminology and Scope

At the onset of this project, the work focused on measurement of **diagnostic accuracy**. However, some 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 project should instead focus 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.[9]

PURPOSE AND LIMITATIONS OF MEASURE CONCEPTS

NQF distinguishes between a measure and a measure concept. A **measure** is defined as a fully developed metric that includes detailed specifications and may have undergone scientific testing. A fully developed measure identifies what should happen (what is being measured), who should be measured (population), where measurement should happen (setting), when it should happen (time), and how it should occur. A **measure concept** is an idea for a measure that includes a description of the measure, ideally including planned target and population. With this report, the Committee intends to provide guidance to the field on the measurement of diagnostic quality and safety. With this in mind, the Committee has proposed measure concepts and measurement areas for further exploration and development (see Appendix G).The Committee is not recommending specific measures for immediate implementation and use. Note that some measure concepts are rooted in current work and others are more forward-thinking ideas with little or no existing research.

As these measure concepts are considered for development, testing, and use, the Committtee notes that some concepts could be developed for use in accountability programs while others may be better suited for quality improvement or benchmarking purposes. This measurement framework is not intended to discern which measure concepts would be appropriate for accountability programs, quality improvement, or both. When measures are used for **accountability applications**, performance results are used to make judgments and decisions as a consequence of performance. For example, performance results can be used for reward or recognition (e.g., certification programs), punishment, payment, or selection (e.g., public reporting). Measures used for **quality improvement** help organizations identify strengths and areas for improvement in healthcare delivery; organizations then use a systematic approach to make improvements in care. **Benchmarking** refers to the process of comparing the performance of accountable entities with that of their peers or with external best practice results.

Characteristics of Good Measures

To receive NQF endorsement, measures must meet four criteria. As measures related to diagnostic quality and safety are developed, these criteria may provide guidance in measure specification and testing. The first criterion, **important to measure and report**, aims to keep measurement focused on high-priority areas with strong evidence that measurement can have a positive impact on healthcare quality. The **scientific acceptability** criterion assesses whether the measure, when implemented, will produce consistent (reliable) and credible (valid) results about the quality of care. Measures are also assessed for whether they are **usable and relevant**—that is whether the intended users of the measure can understand the measure results and use them in a meaningful way. Finally, the **feasibility** criterion assessess whether data needed for the measure are readily available and retrievable without undue burden.

Promoting Advancement of Measurement in Diagnostic Quality and Safety

Because diagnostic quality and safety is still an emerging area of measurement, it will be important to find ways to promote the development and implementation of new measures. NQF continues to examine new pathways for developers to bring measures to NQF. One potential method being explored is a 'graduated measurement approach,' which would provide a way to move innovative measures into implementation for improvement and testing at earlier stages of development. Under this process, innovative measures would receive broad multistakeholder input earlier in measure development and NQF guidance throughout the measure development lifecycle. Development of innovative approaches that are tried out early on at the local and individual organizational levels may help to advance the measurement of diagnostic quality and safety.

FRAMEWORK FOR MEASURING DIAGNOSTIC QUALITY AND SAFETY

The Diagnostic Quality and Safety Committee initially 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 the literature, including Singh and Sittig's SaferDx Framework and Donabedian's organizing concepts of structure, process, and outcome.

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.

The process domain addressed whether actions or processes supporting accurate and timely diagnosis are being performed safely, effectively, and as appropriate. The outcome domain addressed outcomes associated with diagnosis, or the effects of diagnosis-related activities on patients.

During the public and member comment period from January 31 to 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 E**).
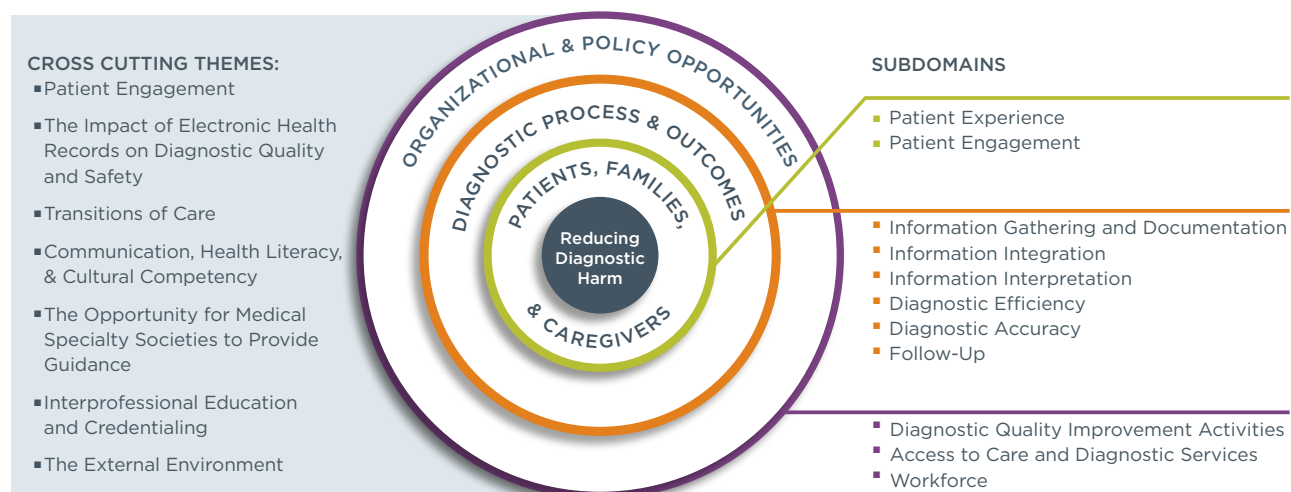
Following the comment period, the initial framework based on Donabedian's model no longer appeared to be optimal, as numerous measurement themes within subdomains crossed over into other domains. Additionally, not every subdomain contained structure, process, and outcome measures. It became evident that structure, process, and outcomes were better suited as measure types than as domains.

After the Committee narrowed down and reviewed several hundred measure concepts (see **Appendix G**) submitted by Committee members and members of the public, the Framework was revised to consist of three broad domains:

1. Patients, Families, and Caregivers;

2. The Diagnostic Process; and

3. Organizational and Policy Opportunities.

The final framework is summarized in the next section and is illustrated in Figure 1 below.

FIGURE 1. DIAGNOSTIC QUALITY AND SAFETY FRAMEWORK

CROSS CUTTING THEMES:
- Patient Engagement
- The Impact of Electronic Health Records on Diagnostic Quality and Safety
- Transitions of Care
- Communication, Health Literacy, & Cultural Competency
- The Opportunity for Medical Specialty Societies to Provide Guidance
- Interprofessional Education and Credentialing
- The External Environment

ORGANIZATIONAL & POLICY OPPORTUNITIES

DIAGNOSTIC PROCESS & OUTCOMES

PATIENTS, FAMILIES, & CAREGIVERS

Reducing Diagnostic Harm

SUBDOMAINS
- Patient Experience
- Patient Engagement

- Information Gathering and Documentation
- Information Integration
- Information Interpretation
- Diagnostic Efficiency
- Diagnostic Accuracy
- Follow-Up

- Diagnostic Quality Improvement Activities
- Access to Care and Diagnostic Services
- Workforce

Patients, Families, and Caregivers Domain

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

Patients, Families, and 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 and/or teams to develop, refine, and 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 diagnostic-related information

- Information Integration: Includes the use of consultants, hand-offs, 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 diagnoses

- Follow-Up: Includes appropriate and timely follow-up of labs, radiology, consultation notes, and other diagnostic findings

Organizational and Policy Opportunities Domain

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

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

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 NASEM model and considers the patient throughout.

PRIORITIZED MEASURE CONCEPTS

After a thorough review of hundreds of measure concepts submitted by the Committee and members of the public, the Committee developed a final list of measure concepts (see Appendix G). The Committee focused on identifying high-priority measure concepts and measurement areas. NQF defines a measure concept as an idea for a measure that includes a description of the measure, including a planned target and population. The Committee acknowledges that not all of the measure concepts are based on existing evidence because of a lack of research in this area. However, the Committee notes that those in the measure development community would be expected to implement a rigorous measure development process to produce fully formed measures that are linked to outcomes.

NQF asked the Committee to identify measures in testing, in development, and in use. Appendix F contains 62 measures related to diagnostic quality and safety identified by NQF staff and the Committee. Twenty-seven are NQF-endorsed measures, 18 were found in the Centers for Medicare & Medicaid Services quality measures inventory, 12 in the National Quality Measures Clearinghouse, and four in the Health Indicators Warehouse. Please see Appendix A for additional information on how measures were identified.

At its second in-person meeting, the Committee reviewed a list of potential measure concepts 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 a final review to hone the list down to an initial set of prioritized concepts.

Based on feedback from the Committee, the concepts were then further refined and grouped together into measurement themes. Themes identified as high-priority areas by the Committee

include timeliness of diagnosis, timeliness of test result follow-up, communication and hand-offs, patient-reported diagnostic errors, and patient experience of diagnostic care.

Patients, Families, and Caregivers

Patient Engagement

Committee members recognized that patients, their families, and their caregivers are key members of the diagnostic team, and stressed the importance of patients understanding their diagnosis, their treatment plans or options, and any important considerations relevant to their diagnosis. Committee members agreed that robust patient engagement is essential to diagnostic quality and safety and should be a focus of measurement efforts.

The Committee identified potential approaches to measuring patient engagement in the context of diagnostic quality and safety.

Communication of Diagnostic Information to Patients, Families, and Caregivers

Measures could address the degree to which diagnostic information, such as lab results, radiology, and consultation notes, and confidence in the diagnosis, is being communicated appropriately to patients and families. 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 issues 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 agreed

that this is a very important issue, but suggested that it may be difficult to achieve meaningful, nuanced measurement in this area.

The Committee noted that structural measures could potentially assess whether processes or procedures are in place to assure that diagnosis and diagnostic information is communicated to patients in an understandable manner, recognizing the impact of health literacy (e.g., jargon-free communication) and cultural competency. Process measures could assess whether communication with patients and their families is documented, or whether patients were given explicit instructions on red flags/symptoms should their condition evolve (e.g., included in after-visit summaries, discharge summaries).

While Committee members pointed out that defining and specifying concepts such as 'understandable' communication could be challenging from a measurement perspective, documentation of communication would not likely have a strong link to outcomes. Moreover, whether patients and/or their families understand what is being communicated is an entirely different issue and more difficult to measure.

Patient Understanding of Diagnosis

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 potentially 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 suggested that patients' understanding of their diagnoses could potentially be measured using patient-reported information. Measures could assess, for example, whether patients are aware of their diagnoses, and whether they understand actions they can take in the event of a change in their condition. Committee members noted that though these are relatively

basic expectations, they could have a meaningful impact on the diagnostic process. Again, the Committee acknowledged that feasibility of measurement in this area is a concern. Defining and measuring patients' understanding or awareness of diagnostic information is likely to be a challenge, especially considering patient variability, and development of this type of patient-reported measures will require significant work. However, Committee members also stressed that advancing measurement in this area would be worth the effort.

Patient Access to Information

Committee members emphasized the importance of patients having full and timely access to their medical records, and suggested that there is a need to increase the transparency and availability of doctors' notes.[10] The Committee largely agreed that patient access to information should be a high priority for measurement efforts, and that measurement in this area is feasible. Structural measures could potentially assess whether patients have timely access to their medical records, including test results. Some Committee members noted that efforts to ensure patient access to information can range from passive (e.g., providing patients with a website and password) to active (e.g., contacting patients with test results and information), and that this may be a consideration when developing measures in this area. Committee members also acknowledged that it may be more difficult to assess whether the access is sufficient from the patient's perspective.

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. The Committee generally considered measurement of patient experience a higher priority than measurement of patient satisfaction. 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 the patient's health problems were explained; whether tests and their results were explained; whether patients understood providers' diagnostic reasoning; how much effort was made to listen to patients and help them understand their health issues; whether patients had opportunities to give input to the process; how well care was coordinated; and similar insights on the diagnostic process that could be gleaned from patient-reported experience. The Committee suggested that research on shared decision making may help inform the development of patient experience measures related to diagnostic care.

Committee members noted that this is another area of measurement that will likely need work and refinement before being ready for implementation. Some Committee members suggested that patient experience has less of a direct connection to safety concerns (i.e., ensuring reduction of diagnostic harm) than some other measurement areas, and that this should be considered when prioritizing measure development efforts. The Committee discussed the possibility of incorporating questions related to diagnostic experience into the CAHPS and HCAHPS surveys.

Diagnostic Process

Information Gathering and Documentation

The Committee identified 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. The Committee agreed that a goal of measurement in this area should be to ensure that complete and accurate documentation about a patient's diagnosis is available in a timely manner to the clinical care team.

Committee members noted that diagnosis is an evolving process and often involves a degree of uncertainty as the care team works to confirm or exclude possible explanations for the patient's health problem. It is important that providers are able to establish and document a differential diagnosis, or identify a set of possible conditions that might explain the patient's health problem, that can be honed through a process of elimination.[11,12] 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. Particular challenges to measurement of EHR-related issues include the wide variety of stakeholders who would need to share accountability, the focus on billing in clinical information systems, and the slow pace of change to these systems. Nevertheless, Committee members wanted to highlight some EHR features that would contribute to improved diagnosis and that could be measureable at some point. These might include ensuring that the EHR can capture a differential diagnosis and, potentially, the certainty or uncertainty of diagnosis; allow patients to be designated as 'not yet diagnosed'; and ensure the ability to distinguish an initial or admitting diagnosis from a final diagnosis.

With regard to process measures supporting appropriate documentation of diagnostic

information, measure concepts considered by the Committee included assessment of the percentage of problem lists that are complete, up to date, and accurate. One approach to ensuring that problem lists are up to date could be measuring the percent of problem lists that contain time stamps. However, assessing the more important issue of whether the problem lists are accurate is likely to prove difficult, leading Committee members to question the feasibility of measuring that concept.

The Committee cautioned that, when considering measurement in this area, stakeholders should seek to avoid adding unnecessary documentation burdens to clinicians who already spend too much time on these tasks.

Information Integration

In discussing the topic of information integration, the Committee focused on the need for effective interactions 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 patient's conditions. 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 interprofessional involvement are important principles to

promote through measurement. However, for measurement purposes, defining "appropriate involvement" is likely to be challenging, and may be complicated by variation in size of the organization, availability of resources, and focus of care across organizations. The Committee also discussed measurement related to second opinions, noting that second opinions can be an effective intervention to prevent diagnostic errors, particularly in situations where there are known diagnostic uncertainties, dilemmas, or pitfalls. Structure measures could focus on organizational policies or procedures to ensure second opinions are available and encouraged, while process measures could focus on how often they are used or how often second opinions are in agreement/ disagreement. Committee members recognized that defining cases with pitfalls or dilemmas may be difficult. The Committee noted that organizations could also foster improvement in this area through institutional activities to review diagnostic decisions, similar to tumor boards or mortality and morbidity conferences.

Hand-offs were identified by the Committee as an important and feasible area of measurement. Committee members stressed the need to ensure that there is a 'closed loop' in interactions between providers, such as referrals to specialists. Process measures could focus on completion of visits and communication of test results and treatment plans or recommendations back to the referring team. Measurement could also assess the use of structured or standardized hand-off programs.

The Committee also recognized that appropriate exchange of information within and across organizations is important to ensure that clinicians have the information they need to make a timely and accurate diagnosis. Measurement in this area could focus on ensuring an information infrastructure is in place to facilitate health information exchange and functional interoperability of electronic health records. However, Committee members acknowledged that achieving easy access to and sharing of

information across organizations is a high hurdle to overcome.

Information Interpretation

The Committee members 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 should 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. Structure measures could focus on whether there are policies or procedures in place to achieve these goals.

Committee members also noted that it might be possible to measure intermediate outcomes associated with these events, such as the percentage of patients with a discordant result.

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 whether information is readily exchanged both within and between organizations.

While many Committee members considered the configuration and use of decision support to be a very important issue that could have significant impacts on diagnostic performance, particularly for complicated diagnoses, the Committee also acknowledged that protocols, algorithms, and pathways for diagnosis are not

as fully developed as those for treatment. There is a need for further research in this area. In addition, with respect to measurement, there is a need to exercise caution in creating the wrong incentives. Committee members did not want to encourage 'mindlessness' in diagnostic decision making, suggesting that measures should capture more than whether or not a decision support tool is used. Members also believe that it will be important to ensure that measurement focuses on proven tools.

Follow-Up

The Committee identified follow-up as being among the most important issues with respect to diagnostic quality and safety. Measure concepts identified by the Committee focus on follow-up in specific situations: tests pending during transitions of care, critical test results, and noncritical but actionable test results. Committee members agreed that follow-up with the patient is essential, regardless of whether follow-up on test results is required.

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 may be the primary care physician or other ordering clinicians.

Communication and Hand-Offs of Test Results

Timely and accurate communication of test results, such as laboratory and radiology findings, has been identified as a significant issue in diagnostic error.[13,14,15] The Committee viewed improvement of communication and hand-offs, particularly those related to diagnostic testing and test results, as relatively 'low-hanging fruit' that would be feasible to measure and could have immediate benefits for diagnostic quality and safety. Committee members noted that existing regulatory and accreditation standards, such as those established by the Clinical Laboratory Improvement Amendments

(CLIA) and the College of American Pathologists' (CAP) Laboratory Accreditation Program, address communication of test results, meaning there is some infrastructure to build on for measurement. The SAFER (Safety Assurance Factors for EHR Resilience) Guides from the Office of the National Coordinator for HIT also address communication and follow-up of test results, offering a range of EHR-based opportunities for improvement and potential measurement in this area.[16]

The Committee suggested that measurement of follow-up on actionable or abnormal test results would be particularly important. While observing that 'actionable' and 'abnormal' are somewhat ambiguous terms, Committee members thought that these concepts were definable for measurement purposes, noting that ongoing efforts by the Veterans Health Administration (VHA) and the CDC-based Clinical Laboratory Improvement Advisory Committee (CLIAC) could provide useful guidance on this issue.[17,18]

Structural approaches to measurement in this area could include assessment of whether processes are in place to monitor communication of abnormal findings and to identify the clinician responsible for test follow-up.

While agreeing that these concepts have face validity, some Committee members suggested that it is not clear that these measure concepts address issues that cause clinically meaningful delays in diagnosis or wrong diagnosis, suggesting that they may be less likely to drive institutional performance improvement strategies that lead to better outcomes for patients.

Diagnostic Efficiency

The Committee discussed potential measurement areas and concepts related to diagnostic efficiency.

Timeliness of Diagnosis
Several of the concepts considered by the Committee address timeliness of diagnosis, particularly for priority diseases. Committee members noted that 'priority diseases' could be defined in different ways—e.g., diseases with high mortality or diseases that are of significant concern for public health. Some Committee members suggested that cancer would be an important focus of diagnostic timeliness measurement. Committee members also noted that this is an area where measurement is likely to be condition-specific, and that engagement from professional and specialty societies will be critical in helping to define what "timely diagnosis" means in the context of different conditions and circumstances. The Committee stressed that timeliness of diagnosis can have a profound effect on patient outcomes.[19] The Committee focused primarily on two aspects of timeliness: timeliness of initial diagnosis—i.e., from the symptoms to the explanation of the health problem—and timeliness of explanation to management.

The Committee discussed measuring timeliness of initial diagnosis by assessing, among patients confirmed to have specified conditions, the percentage of those patients who received an explanation of their health problem within acceptable benchmarked timeframes after presentation of index symptoms, signs, or test results.

With regard to timeliness of 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. The Committee identified the potential measurement approach of assessing the percentage of diagnoses that are refined from explanation to completion of the diagnostic process and appropriate management within an acceptable timeframe (e.g., timeliness of completion of the lung cancer staging process after an initial pathologic diagnosis of "lung adenocarcinoma"). Some Committee members suggested that this type of measurement may be

moving beyond diagnosis to disease management, and they questioned whether it should be a high priority for diagnostic quality and safety.

Measurement of diagnostic timeliness may face challenges, including the difficulty of working back from diagnosis to symptoms (in order to identify where the 'clock' should start), given the heterogeneity in presenting complaints. Committee members suggested that this will be easier for short-cycle diseases (e.g., bacterial meningitis) and harder for long-cycle diseases (e.g., cancer). Data gathering may also be difficult; Committee members noted that data in administrative claims is unlikely to be granular enough to be useful in measuring diagnostic timeliness. Absent structured data in EHRs, measurement in this area will likely require manual chart review. The Committee observed that trigger tools—a method of surveillance for potential errors or adverse events—have shown promise when applied to diagnosis, and may be a useful approach to measuring diagnostic error, including issues related to diagnostic timeliness.[20,21,22,23]

Appropriateness of Testing

Another theme that emerged in the domain of diagnostic efficiency was value in the diagnostic process. Committee members acknowledged that overtesting does occur, and suggested that 'gatekeeper' functions may be needed for tests that are known to be overused. Members noted that overtesting measures could incorporate exclusions to account for potentially high-risk situations. Some Committee members identified appropriate test utilization as a critical concept in diagnostic quality and safety and a useful tool for cost containment, but others suggested that it is only loosely associated with preventable diagnostic harm and should be considered less important than other areas of measurement.

Approaches to measuring appropriateness of testing could include assessing the percentage of patients with specified symptoms, diseases, or conditions who are tested inappropriately based on evidence-based guidelines or best practices. Committee members also suggested that linking test ordering patterns with use of appropriate interventions may help identify and avoid undertreatment or overtreatment and associated complications.

Committee members observed that measurement in this area may be highly feasible in some respects, since tests will already have been done and can be identified using administrative data. However, it was also noted that appropriateness is hard to evaluate in many cases, and that it may be difficult for measures to account for uncertainty at the time of test ordering.

Appropriate Diagnosis

The Committee also considered measurement of appropriate diagnosis, including overdiagnosis as well as underdiagnosis. A potential approach to measurement in this area could be to assess whether certain diseases or conditions are being diagnosed more or less 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 or underdiagnosis. A similar approach could compare disease-specific incidence relative to total disease-specific mortality or morbidity across peers.

Some Committee members suggested that these concepts may be too complicated for routine use, and could require very intense geographical and population-specific integration of data and analysis, which may be unachievable given current data limitations. However, others felt that, while not appropriate for single-institution use, these kinds of approaches could be important aspects of exploratory analyses of national or regional administrative data sets to identify outliers and 'pain points.'

Diagnostic Accuracy

The Committee identified potential measure concepts related to diagnostic accuracy, including measurement of initial diagnostic accuracy as compared to gold-standard testing, 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. The Committee also discussed measuring patient-reported diagnostic error.

Accuracy of Initial Diagnosis

Regarding measurement of the accuracy of initial diagnosis as compared to gold-standard testing, Committee members noted that accuracy is a critically important concept, but that gold standard tests exist only for a relatively small number of conditions, limiting the impact of this approach to measurement. Some Committee members also expressed concern that a focus on initial accuracy may be misguided given the nature of diagnosis as an evolving process that is refined over time.

Harms from Diagnostic Error Based on Unexpected Change in Health Status

The Committee considered measuring diagnostic errors by identifying adverse events or changes in health status that may indicate a missed or inaccurate diagnosis. One way of approaching this kind of measurement is to identify instances of care escalation or de-escalation associated with changes in diagnosis. Unexpected changes in health status accompanied by changes in diagnosis that have a plausible link to index encounter symptoms may be indicators of prior diagnostic errors. Along these lines, the Committee discussed an innovative approach to measurement of diagnostic error currently under exploration. This approach looks at known or suspected symptom-disease pairs (e.g., dizziness and stroke), and identifies clinically meaningful adverse health outcomes that occur within a specified time after discharge and that would not have been expected if the initial diagnosis were

correct. Administrative claims data or large EHR data sets could then be analyzed to calculate observed-to-expected frequencies of similar events in patients with the same symptom-disease pairings, helping to illuminate areas where harm is occurring due to potential diagnostic error. This method is similar to the concept of a trigger tool, but allows for verification of potential errors through statistical analysis of large datasets instead of manual chart review. Examples of similar approaches noted by Committee members include an episode of care followed by unexpected hospitalization, and emergency department (ED) visits for abdominal pain followed by return ED visits within 10 days.[24,25]

Committee members suggested that this is a promising area of measurement, and that further research could provide valuable lessons for improving diagnostic quality and safety. Some members questioned whether this approach to measurement was currently feasible or actionable for providers; however, others suggested that measuring diagnostic error in this way could be highly feasible, as it is based on information that is readily available from administrative claims or large EHR data sets.

A similar measurement approach would be to analyze samples of patients lost to follow-up or who have experienced adverse events, including unexplained deaths, to identify potential misdiagnosis. Committee members suggested that this would require tracking the disposition of patients who do not return, which may be unlikely to happen in practice. Committee members acknowledged that tracking patients who do not follow up could be highly burdensome to organizations and may not be feasible. Additionally, Committee members noted that systematic tracking of deaths and frequent autopsies would be an important way of tracking diagnosis-related harms, but that this may also be difficult to implement in practice.

Organizational and Policy Opportunities

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.

Root Cause Analysis

The Committee discussed several measurement concepts related to diagnostic quality improvement efforts. The subject of root cause analysis (RCA) frequently arose throughout the Committee meetings. The Committee noted that RCAs can play a significant role in improving diagnostic quality and safety, and proposed several measure concepts in this area. The Committee discussed concepts that track the use of RCAs in organizations, measure patient or patient representative involvement in RCAs, and evaluate whether the RCA results have been acknowledged by senior leadership. Committee members acknowledged that these organizational measure concepts may not be as tightly linked to measuring improvements in diagnostic quality and safety; however, the measures are feasible and may represent an important early step in the improvement process.

Organizational Feedback to the Diagnostic Team

The Committee proposed that organizations should establish mechanisms to measure diagnostic performance and provide feedback to the team in the event of a significant change in diagnosis. The Committee also suggested a measure to track whether organizations evaluate performance in key areas (e.g., primary care, lab, radiology, ER).

Similarly to comments on RCAs, Committee members recognized that structure measures at the organizational level may not have a direct correlation to improved outcomes.

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.

Access to Diagnostic Services

The Committee discussed several measurement concepts related to the availability of appropriate testing such as tests for common conditions and the availability of point-of-care testing tools. The Committee noted that measuring access to appropriate testing would be different based on the setting of care delivery (e.g., hospital, clinic, ER) and the most common conditions encountered by providers in that setting. The Committee accepted that measure concepts in this area would likely be structure measures, and may represent a lower priority than other proposed measure concepts.

Access to Care

The Committee discussed access to care as an area to measure with regards to diagnostic quality and safety. The Committee proposed a measure concept to evaluate the average wait time to see a provider, noting that there would be differences by provider type. Additionally, the Committee put forward a concept to measure the availability and effectiveness of telemedicine services.

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 principles that would support the healthcare workforce in improving diagnostic performance.

Committee members observed that diagnosis places a heavy cognitive burden on clinicians, 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 noted as 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.

The Committee discussed several measure concepts to address the aforementioned workforce issues. The Committee rated the concepts around diagnostic workload and workforce competency as the most important. Of note, all of the suggested measure concepts focusing on workforce issues were structure measures.

HIGH-PRIORITY AREAS FOR FUTURE MEASURE DEVELOPMENT

The Committee agreed that all areas of measurement discussed above are important aspects of diagnostic quality and safety, and should continue to be explored to help clinicians and healthcare researchers learn more about improving diagnostic performance. However, Committee members identified measurement areas that they considered as high priorities for measure development. The Committee included both importance and feasibility in their deliberations. Some of these areas are both important and highly feasible—i.e.,

offering opportunities for development and implementation of measures immediately or in the short-term—while others were identified as important but in need of additional research and refinement, and should be considered longer-term goals for measurement efforts.

Table 2 shows measurement areas that the Committee identified as both important and feasible in the near-term. Table 3 shows measurement areas that the Committee considered to be highly important but in need of further development.

TABLE 2. IMPORTANT AND FEASIBLE IN THE NEAR-TERM: MEASUREMENT AREAS

Measurement Areas	Committee Rationale
Timeliness of test result follow-up	The Committee agreed that improvement in this area can have a significant impact on patient safety, and that there are existing efforts and infrastructure in place that could make measurement highly feasible.
Patient access to information	The Committee stressed the engagement of patients in their diagnostic care, and noted that patients having access to information is key in enabling and facilitating that engagement.
Diagnostic quality improvement activities	The Committee noted that some of the most important efforts to improve diagnostic quality and safety are likely to emerge out of internal improvement efforts, where innovative approaches may be developed and validated before being implemented more broadly. Ensuring that organizations are systematically assessing diagnostic performance is also important in driving improvement.
Hand-offs	The Committee agreed that ensuring effective hand-offs related to tests, referrals, and care transitions is essential to diagnostic quality and safety.

TABLE 3. HIGHLY IMPORTANT BUT NEED FURTHER DEVELOPMENT: MEASUREMENT AREAS

Measurement Area	Committee Rationale
Diagnostic outcomes	The Committee generally agreed that efforts to improve diagnostic quality and safety should aspire to measurement of diagnostic outcomes (e.g., timeliness and accuracy of diagnosis). However, Committee members acknowledged that outcome measures related to diagnostic care will need to be studied carefully before being implemented widely, suggesting that organizations should focus internal measurement activities on tracking and benchmarking diagnostic outcomes to help advance the field in this area.
Patient understanding of diagnosis	As with patient access to information, the Committee considered patients' understanding of their diagnoses to be very important to ensuring patient safety and patient engagement. However, Committee members also acknowledged that measuring the degree to which patients understand their diagnosis will be a challenge.
Adequacy of communication with patients	The Committee emphasized that communication with patients is central to the issue of diagnostic quality and safety, as acknowledged by the National Academy of Medicine. The Committee noted that measuring the effectiveness and adequacy of communication—as opposed to simple documentation of communication—will be difficult but important.
Diagnostic workload	The Committee identified the diagnostic workload of clinicians as a critical issue in improving quality and safety. Ensuring that providers have adequate time and opportunity to gather, synthesize, and interpret information would be very impactful, but may be hard to achieve in practice.

CROSS CUTTING THEMES AND RECOMMENDATIONS

In addition to the proposed measure concepts, the Committee defined several cross-cutting themes and recommendations related to 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 the measure development community consider these themes with respect to diagnosis. These recommendations provide guidance to those interested in developing high-impact measures of diagnostic quality and safety. Additionally, these recommendations aim to influence broad policy themes where they intersect with the field of diagnostic quality.

Patient Engagement

Throughout this project, the Committee continually stressed the importance of patient engagement in the diagnostic process. As described above within the Patients, Families, and Caregivers domain, the Committee noted that patients must be considered an integral and essential part of the diagnostic team. Committee members emphasized the importance of patients' knowledge of their own medical history in the diagnostic process.

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

Throughout the Committee discussions, many comments addressed 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. To support the diagnostic process, an EHR must 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 the 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 could record the level of confidence that the provider has with that diagnosis to signal the certainty of the diagnosis to other stakeholders. 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."[26] 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 Committee emphasized the importance of cooperation between economically unrelated entities as they exchange information about a patient's care. 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."[27] 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,[28] medical errors related to the completion of diagnostic work-up,[29] 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 both inside and outside of the organization.

Communication

The Committee frequently referred to the fact that communication of the diagnosis is an integral part of the diagnostic process. Several 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 providers involved in the diagnostic process, and notably 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.

Health Literacy

Regarding patient-system and patient-provider communication, the Committee appealed for the inclusion of health literacy in the diagnostic process. According to the U.S. Department of Education, individuals with low health literacy have worse outcomes[30] 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 integrate the role of health literacy.

Cultural Competency

Cultural competency goes hand in hand with health literacy. In addition to communicating with patients in a way that they are able to understand, cultural competence "involves understanding and appropriately responding to the unique combination of cultural variables... that the professional and client/patient bring to interactions."[31] Healthcare professionals who practice cultural competence may also help improve patient engagement and patient experience in the diagnostic process.

Engagement with Medical Specialty Societies

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 that the Committee identified broadly apply to any condition or specialty. However, the Committee noted the role of condition-specific measure concepts that may require input from specialists. For example, the timeframe in which a provider forms and communicates a diagnosis to the patient may be different in the context of an acute heart attack versus a condition such as a benign

skin lesion. Providers with specialty knowledge are best 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. Specialty societies play a key role in the development of best practices and clinical guidelines, which are often relevant to the diagnostic process. Consequently, healthcare organizations should remain engaged with specialty societies as they develop diagnostic guidelines.

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 duplicate 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 various issues concerning 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. 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.

PUBLIC COMMENTS

Public comment was solicited on a draft version of this report; high-level themes from submitted comments are summarized below. All public comments submitted are also included in Appendix E.

Evidence for Measure Concepts

Commenters noted that there may be little or no evidence base for many of the proposed measure concepts. The Committee concurred that there may be limited evidence for many of the proposed concepts. However, Committee members noted that this project is not intended to produce measures that are ready for accountability, but to provide high-level guidance to the field on high-priority areas for measurement of diagnostic quality and safety. The report was updated to clarify the intent of the project as well as the distinction between a measure and a measure concept.

Use of Diagnostic Quality and Safety Measures

Commenters suggested that many of the measure concepts may not be suitable for performance measurement and accountability, but would be better suited for purposes such as quality improvement, benchmarking, certification, etc. The Committee agreed that many of the suggested concepts may be more suited to certain application than others; the Committee believes that as measures of diagnostic quality and safety are developed, they should be well-vetted and tested for reliability and validity before being used for accountability purposes.

Rationale for Measurement

Commenters raised questions about the need and/or rationale for measurement in certain areas, such as documenting the certainty of diagnosis and assessing patients' understanding of their diagnoses. Commenters were also concerned whether measurement in these areas would improve diagnostic accuracy and whether they would add unnecessary measurement burden. The Committee noted that the scope of this project was expanded beyond 'diagnostic accuracy' to include other issues related to diagnostic quality and safety, and that the topics cited by commenters are an important part of ensuring timely and accurate diagnoses that are appropriately communicated to patients.

Requests for Additional Cross Cutting Themes/ Recommendations

Commenters suggested that the report should place more emphasis on the importance of individual patients and their knowledge of their own medical history in the diagnostic process. Commenters also noted that physician feedback and satisfaction with the diagnostic process should be assessed since system level issues could lead to burnout and overwork, which may affect physicians' ability to make correct diagnoses. The Committee agreed that issues related to patient engagement and physician feedback and satisfaction warrant additional emphasis.

Requests for Additional Measurement Concepts

Commenters submitted several additional measure concepts or revisions to existing concepts for the Committee's consideration. Committee members noted that many of the proposed concepts were already covered or related to current concepts; the Committee agreed to address some issues raised by commenters in the final report in lieu of modifying the identified concepts.

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 its work. The Committee acknowledges that some areas could not be addressed by the framework and require more research and development from other organizations involved in the delivery of healthcare. Though a major

component of the diagnostic process involves working through a differential diagnosis of possible health problems, most electronic health records lack the capacity to capture the evolving nature of the diagnostic process. The Committee also recognized the need for interoperability among electronic health systems throughout the diagnostic process to assist providers 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 the healthcare patients receive. The Committee also recommended that diagnostic performance be included in professional practice evaluations for credentialing and re-credentialing of clinical providers. Finally, the Committee highlighted the importance of communication and health literacy as integral to 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. The Committee hopes that this provides guidance to the field for both short-term improvements and 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 developed 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 solicited input from NQF's multistakeholder audience, including NQF membership and public stakeholders. The project approach is described below. It has four steps:

1. Convene multistakeholder Committee
2. Conduct environmental scan
3. Develop conceptual framework
4. NQF member and public comment

Convene Multistakeholder Committee

NQF staff convened an 18-member Committee with diverse representation and knowledge, representing the NASEM committee, the 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 obtain 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 during the project. Please see **Appendix B** for the full Committee roster and federal liaisons. The first web meeting 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, in 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 Healthcare Research and Quality's National Quality Measures Clearinghouse, and National Guidelines Clearinghouse (see **Appendix F**). Out of the 74 measures, 61 measures were included in the scan. Specific measures were excluded due to duplicates

or 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 assessed the comprehensiveness and adequacy of available measures related to diagnostic quality and safety. This framework used 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 took place on January 10-11, 2017. It included a presentation of the environmental scan, review of the proposed measurement framework, and discussion on potential measure concepts. The Committee were divided into three breakout groups in which 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, 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 criteria are defined in **Appendix D**. Over the course of the project, the Committee provided feedback on the domains and subdomains, based on 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, prioritization of 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, Federal Liaisons, and NQF Staff

Committee Co-Chairs

Missy Danforth
Vice President, Hospital Ratings – The Leapfrog Group
Washington, District of Columbia

Mark Graber, MD, FACP
President of Society to Improve Diagnosis in Medicine
& RTI International
Plymouth, Massachusetts

Committee Members

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

Michael Dunne, PhD
Vice President, Research and Development North
America – bioMerieux, Inc.
Durham, North Carolina

David Grenache, PhD
Professor of Pathology/Laboratory Medical Director –
University of Utah
Salt Lake City, Utah

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
Cleveland, Ohio

Marilyn Hravnak, RN, PhD, ACNP-BC, FCCM, FAAN
Professor of Nursing – University of Pittsburgh
Pittsburgh, Pennsylvania

Mira Irons, MD
Senior Vice President, Academic Affairs –
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Nicholas Kuzma, MD
Attending Physician, Section of Hospital Medicine,
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Prashant Mahajan, MD, MPH, MBA
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Kathryn McDonald, PhD
Senior Scholar and Executive Director – Center
for Health Policy and Center for Primary Care and
Outcomes Research
Stanford, California

Lavinia Middleton, MD
Deputy Chief Medical Officer and Professor,
Department of Pathology – The University of Texas
MD Anderson Cancer Center
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David E. Newman-Toker, MD, PhD
Professor of Neurology; Director, Armstrong Institute
Center for Diagnostic Excellence – Johns Hopkins
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Martha Radford, MD, MA
Chief Quality Office – NYU Langone Medical Center
New York, New York

David Seidenwurm, MD
Quality & Safety Director – Sutter Health
Sacramento, California

Thomas Sequist, MD
Chief Quality and Safety Officer –
Partners Healthcare System
Boston, Massachusetts

Hardeep Singh, MD, MPH
Physician Researcher – Veterans Affairs Center
of Innovation and Baylor College of Medicine
Houston, Texas

FEDERAL LIAISONS

Jeff Brady
Agency for Healthcare Research and Quality

Kerm Henriksen
Agency for Healthcare Research and Quality

David Hunt
Office of the National Coordinator for Health
Information Technology

Marsha Smith
Centers for Medicare & Medicaid Services

Susan (Sue) Sheridan
Centers for Medicare & Medicaid Services

NQF Staff

Helen Burstin, MD, MPH
Chief Scientific Officer

John Bernot, MD
Senior Director

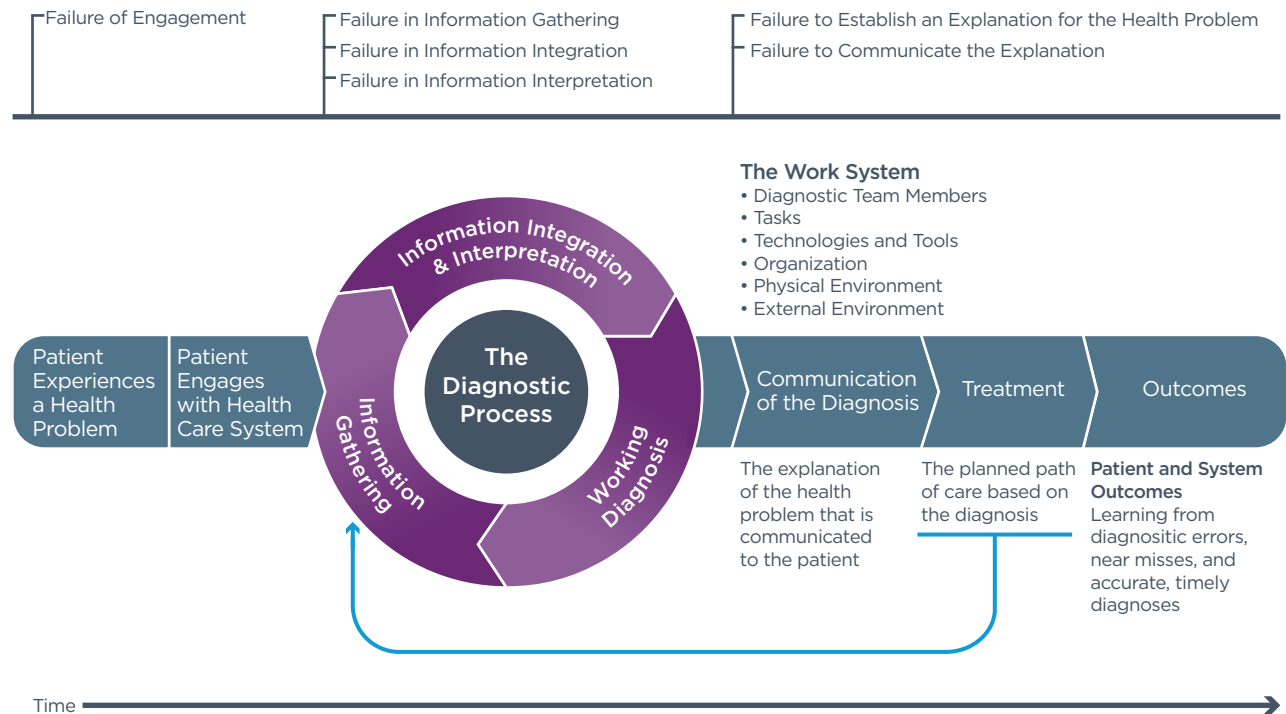**Andrew Lyzenga, MPP**
Senior Director

Tracy Lustig, DPM, MPH
Senior Director

Christy Skipper, MS
Project Manager

Vanessa Moy, MPH
Project Analyst

APPENDIX C:
NASEM Conceptual Model of the Diagnostic Process

Overview of Diagnostic Error in Health Care

Failure of Engagement

Failure in Information Gathering
Failure in Information Integration
Failure in Information Interpretation

Failure to Establish an Explanation for the Health Problem
Failure to Communicate the Explanation

The Work System
- Diagnostic Team Members
- Tasks
- Technologies and Tools
- Organization
- Physical Environment
- External Environment

Information Integration & Interpretation

Information Gathering

Working Diagnosis

The Diagnostic Process

Patient Experiences a Health Problem

Patient Engages with Health Care System

Communication of the Diagnosis

Treatment

Outcomes

The explanation of the health problem that is communicated to the patient

The planned path of care based on the diagnosis

Patient and System Outcomes
Learning from diagnositic errors, near misses, and accurate, timely diagnoses

Time

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

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? – Outcomes – Meaningful to the patient – Supports systemic/integrated view of care • Impact: To what extent does the measurement area address an issue that: – Affects large numbers of patients and/or has a very substantial impact for smaller populations; – is a leading cause of morbidity/mortality; or – 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 Savings	• Likelihood that this measure will directly reduce healthcare costs	Indicate the likelihood of this measure to reduce healthcare cost: • Yes • No

APPENDIX E:
Public Comments Received on Draft Framework and Committee Response

First Comment: January 31 through March 1

General Comments

American College of Radiology on behalf of Anne Brittain

Zach Smith

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 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.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

American College of Radiology on behalf of Anne Brittain

Zach Smith

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.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

American Society for Clinical Laboratory Science on behalf of ASCLS Patient Safety Committee

Stacy Walz

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.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

America's Health Insurance Plans

Carmella Bocchino

We agree with NQF's overall approach to the efforts outlined in the Improving Diagnostic Quality and safety draft report.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Intersocietal Accreditation Commission

Mary Lally

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 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 endeavor.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

RGH Health Consulting on behalf of Wolters Kluwer Health

Bob Hussey

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.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Society to Improve Diagnosis in Medicine

Paul Epner

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 health care 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.

>Committee Response:

Thank you for your comments. The term provider refers to the organization (such as hospitals, ambulatory care facilities, physician offices etc.).

Society to Improve Diagnosis in Medicine

Paul Epner

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.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

The American Society for Clinical Pathology

Liz Waibel

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 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.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

University of Texas MD Anderson Cancer Center on behalf of Karen Bird Alliance of Dedicated Cancer Centers

Tracy Spinks

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).

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Draft Framework – Structure

American Society for Clinical Laboratory Science on behalf of ASCLS Patient Safety Committee

Stacy Walz

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 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 measures diagnostic performance and utilization of laboratory testing".

>Committee Response:

Thank you for your comments. The Committee clarified that the term "advanced imaging" refers to ultrasound, CT, and MRI. Additionally, the Committee does not intend the concept to be interpreted that every health care facility must have these technologies on site.

America's Health Insurance Plans

Carmella Bocchino

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.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

The American Society for Clinical Pathology

Liz Waibel

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 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.

>Committee Response:

Thank you for your comments. The Committee agrees that all members of the laboratory team should support the diagnostic process and recognizes the importance of interoperability between electronic health records and laboratory information systems.

University of Texas MD Anderson Cancer Center on behalf of Karen Bird Alliance of Dedicated Cancer Centers

Tracy Spinks

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):

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

• 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

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

University of Texas MD Anderson Cancer Center on behalf of Karen Bird Alliance of Dedicated Cancer Centers

Tracy Spinks

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

• 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

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Draft Framework – Process

American Society for Clinical Laboratory Science on behalf of ASCLS Patient Safety Committee

Stacy Walz

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).

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Society to Improve Diagnosis in Medicine

Paul Epner

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."

>Committee Response:

Thank you for your comments. The Committee recognizes that it is important to recognized the interactivity of the healthcare process and agreed on the following dyads: patient-health professional, health professional-health professional, health professional-system, patient-system.

The American Society for Clinical Pathology

Liz Waibel

ASCP agrees with the overall approach taken in this domain, particularly the distinction between the diagnostic process and patient engagement. In 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.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Draft Framework – Outcome

American Society for Clinical Laboratory Science on behalf of ASCLS Patient Safety Committee

Stacy Walz

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.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

The American Society for Clinical Pathology

Liz Waibel

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

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

University of Texas MD Anderson Cancer Center on behalf of Karen Bird Alliance of Dedicated Cancer Centers

Tracy Spinks

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)

• 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

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Letter from AdvaMed

March 1, 2017

Shantanu Agrawal, MD
President & CEO
National Quality Forum
1030 15th Street, NW
Suite 800
Washington, DC 20005

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;

1   National Academies of Sciences, Engineering and Medicine. 2015. *Improving diagnosis in health care.* Washington, DC: The National Academies Press.

- 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.

II. 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:

Malnutrition eCQMs Align with Improving Diagnostic Safety, Effectiveness, Patient-centeredness, Timeliness, Efficiency, and Equitability

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 diagnosed (NYD)	• **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**

Domain/Subdomain	Examples of Measure Concepts	Malnutrition eCQM Examples
Outcomes - Diagnostic Outcomes • **Timeliness of diagnosis**	• Timeliness of diagnosing targeted diseases of interest (anemia, asthma, diabetes, COPD, malnutrition)	• **NQF #3088 Completion of Nutrition Assessment for Patients Identified as at-risk for malnutrition within 24 Hours of Malnutrition Screening** • **NQF #3090 Appropriate Documentation of Malnutrition Diagnosis for Patients**
Outcomes - Patient • **Morbidity/mortality related to diagnostic error/failure**	• # of patients targeted through trigger tools designed to avoid harm	• **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**

References

i Deutz et al. Clinical Nutrition 35 (2016) p. 18-26.

Second Comment: June 12 through July 12

General Comments

American College of Radiology

Judy Burleson

The American College of Radiology appreciates the NQF's work on addressing the complexity of measuring improvement of diagnostic accuracy. The framework provides a useful starting point to identify measures focused on this topic. It is, however, a conceptual framework and creating fully flushed out, specified measures that are ready for implementation will require thoughtful development. We support this goal.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

American Medical Association

Koryn Rubin

The American Medical Association (AMA) appreciates the opportunity to comment on this draft report. Understanding and addressing factors to ensure physicians have the systems and processes in place to properly assess a patient's symptoms and needs are critical and we appreciate the work of the panel. However, the AMA is concerned about several issues in the proposed framework including:

The framework lacks information on the underlying evidence to support each of the proposed measure concepts, as well as a discussion on what the barriers are to the development and implementation of these measures including potential solutions. We request that the authors amend the report to address the missing information. Measure concepts must focus on structures, processes, and outcomes that will be useful for performance measurement rather than increase physician's documentation burden.

Many of the proposed measure concepts are better suited to be implemented in quality improvement initiatives and would not need to be captured as a performance measure, which we note in our comments within each of the prioritized measure domains.

It is critical that the concepts included in this report are evidence-based, are clearly linked to improving outcomes and their value outweighs the resources required to collect and report the information.

>Committee Response:

Thank you for your comments. The Committee agrees that that underlying evidence is important for measure development, however the Committee's intention is to (1) provide guidance to the measure development community and to (2) suggest areas for priority measure development. The Committee expects that developers will put forth measures based on sound evidence and that are linked to outcomes. Measure concepts suggested by the Committee may be used where they are most appropriate whether it be for quality improvement purposes, accountability, etc. The Committee would also like to clarify that this measurement framework is based on improving diagnostic quality and safety; that being said, communication with the patient on red flags/symptoms for instance, is a critical part of diagnostic quality and safety. Finally, the Committee acknowledges that there is a need for balancing measures so that providers are not incentivized for overdiagnosis or underdiagnosis.

Curtis Brown, MD, FACEP

Curtis Brown, MD, FACEP

Are you looking into ways to reduce the number of emergent cardiac catheterizations preformed on patients who turn out to have no acute pathology due to a lack of a prior old EKG available on an emergency bases?

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Endocrine Society on behalf of Partnership for the Accurate Testing of Hormones

Stephanie Kutler

In addition to our recommendation that accuracy of diagnostic laboratory tests be incorporated into the

process measures of diagnostic accuracy, we offer specific comments on the draft report below.

Inaccurate, non-standardized tests are important when considering the Diagnostic Process. We recommend that the Information Gathering and Documentation section on page 9 include consideration of actions or metrics that help to ensure data (including lab data) collected and maintained in EHR are accurate.

In the Information Interpretation section on page 11, we recommend that providers also monitor for and manage situations where inappropriate (i.e., free testosterone by analog methods) or inaccurate tests are being used.

In the Diagnostic Efficiency section on page 12, providers should also consider the analytical accuracy of tests when assessing over- and under-diagnosis of patients, especially when comparing findings with peers using different tests.

In the Organizational & Policy Issues section on page 16, the availability of appropriate diagnostic resources is highlighted. However, it appears that only the availability of certain tests is considered important and not their analytical accuracy. We recommend adding analytical testing accuracy and quality as metrics for appropriateness.

>Committee Response:

Thank you for your comments. The Committee has reviewed your comments and appreciates your interest in this project.

Georgia Regents Medical Center

David Andrews

I applaud the general structure and content of the framework and will confine my specific comments to only one issue.

Though there are hints at the role of patient/caregiver participants in the diagnostic process, the overall tone is of something that a provider does to/of the patient. That creates an unfortunate asymmetry in the diagnostic team (of which I believe the patient/caregiver is an essential part). Many diagnostic errors and delays (often with serious consequences) are due to the failure to fully engage the patient/caregiver in the process - find out what the patient/caregiver knows about themselves,

their history and symptoms (not to mention goals and values) that are an essential part of a timely diagnosis. As an example, I have a chronic condition whose diagnosis took an additional 4 months (and many thousands of dollars of tests) because the Drs. involved were totally disinterested in what I knew about me. In my patient advisor work I have encountered countless stories of medical errors (often with devastating consequences) due solely to the diagnosing physician being disinterested in what patients/caregivers knew or were trying to tell them.

I would like to see the draft include a more forcful and direct statement about the importance of the patient and his/her knowledge as a part of the diagnostic process.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

Robert Morris University (on behalf of)

Valerie J H Powell, RT (R) PhD

Dear Quality Forum,

To what extent does the Quality Forum devote attention to quality/safety in oral as well as systemic health? Is oral health neglected? Is dental care regarded as an integral part of healthcare?

Regarding bio-aerosols please see: Zemouri C, de Soet H, Crielaard W, Laheij A (2017) A scoping review on bio-aerosols in healthcare and the dental environment. PLoS ONE 12(5): e0178007. https://doi.org/10.1371/journal.pone.0178007

Regarding integration of oral and systemic health care, please see:

Glick M, ed. (2014), The Oral-Systemic Health Connection: A Guide to Patient Care (Quintessence Books) http://www.quintpub.com/display_detail.php3?psku=B6508#.U9_1B_k7uSo

Genco RJ, Williams RC, editors. Periodontal disease and overall health: A clinician's guide. 2nd ed. Yardley, PA: Professional Audience Communications; 2014. 370 pp. At: http://www.Colgateprofessional.Com/professional-education/articles/periodontal-disease-and-overall-health-a-clinicians-guide-second-edition

Powell V, Din FM, Acharya A, Torres-Urquidy MH, eds. (2012). Integration of Medical and Dental Care and

Patient Data, Springer-UK (Medicine) http://www.springer.com/public+health/book/978-1-4471-2184-8

Lamster IB, ed.(2014). Diabetes Mellitus and Oral Health: An Interprofessional Approach (Wiley) 258 pp.

HRSA (2014). Integration of Oral Health and Primary Care Primary Care Practice: https://www.hrsa.gov/publichealth/clinical/oralhealth/primarycare/integrationoforalhealth.pdf

>Committee Response:

NQF Response: Thank you for your comment. This project is focused on issues related to diagnostic quality and safety, but NQF is interested in advancing quality across the spectrum of healthcare topics; we appreciate your suggestion of oral health as a neglected area of quality, and would welcome further engagement from stakeholders on this topic.

Patients, Families, and Caregivers

American Medical Association

Koryn Rubin

We agree that patients should be active participants in the care delivery process and support the inclusion of this domain in the framework. We are concerned with the implication that providers should document how confident that they are in a patient's diagnosis. While it is not listed as a measure concept in this domain, we are concerned to see it included in the text on page 7 of the report. A patient's status and diagnosis are not static and it is not clear how this 'point in time' estimate would improve patient care and outcomes. We urge NQF to remove any language suggesting that documentation of a physician's confidence in the diagnosis be standard practice.

Many of the proposed measure concepts may be difficult to measure and may not lead to improved outcomes. For example, the Patient Engagement concepts regarding whether explicit instructions were given to the patient on red flags/symptoms and assessing a patient's understanding of what actions can be taken to improve diagnostic performance. Ensuring that patients are informed and are active members in the care process is critical but it is unclear why providing instructions on red flags/symptoms is considered to be a part of diagnostic accuracy and why it is put forward as a process

measure. The intent of the concept around assessing a patient's understanding is also not clear. However, we would support it as a measure of patient safety, not diagnostic accuracy.

We also question the need for a structural measure that assesses whether an organization has a documentation system that captures informal caregiver's roles. Measures that require documentation with little to no demonstrated link to improving patients' outcomes should not be included. We recommend that this measure concept be deleted.

>Committee Response:

Thank you for your comments. The Committee agrees that that underlying evidence is important for measure development, however the Committee's intention is to (1) provide guidance to the measure development community and to (2) suggest areas for priority measure development. The Committee expects that developers will put forth measures based on sound evidence and that are linked to outcomes. Measure concepts suggested by the Committee may be used where they are most appropriate whether it be for quality improvement purposes, accountability, etc. The Committee would also like to clarify that this measurement framework is based on improving diagnostic quality and safety; that being said, communication with the patient on red flags/symptoms for instance, is a critical part of diagnostic quality and safety. Finally, the Committee acknowledges that there is a need for balancing measures so that providers are not incentivized for overdiagnosis or underdiagnosis.

Minnesota Alliance for Patient Safety, Stratis Health and MMIC

Marie Dotseth

We wholeheartedly support this as a distinct category and appreciate separating patient experience from patient engagement.

With respect to the Patient Engagement measure concepts, we support these and would add:

Timely patient access to medical records... this should include notes and should provide some mechanism for patients to add their own feedback including the correction of inaccuracies and errors.

"Patients understand actions they can take to improve diagnostic performance." It might be helpful too for patients to understand that, when it comes to the diagnostic process, they are responsible to "co-produce" their own health. Also, the preceding narrative mentions the recognition of "red flags" or dangerous symptoms – it would be worth adding those as specific actions that need to be addressed in this area.

For the Patient Experience measure concepts our general comment was that it would be very important to convey to patients that there is indeed a "diagnostic process". Patients tend to see this right now as a visit or two to the doctor. Very few understand that diagnosis is a process and one in which they play an important role.

Finally, While the term "patient" in "patient engagement" and "patient experience" is often used in the broadest sense to be inclusive of the person who is the recipient of care in the many settings in which they find themselves, it might be helpful to note directly that this is what is meant when referring to the "patient". This is particularly important since attention is given to transitions of care and the diagnostic process across many settings of care in other sections of the framework.

>Committee Response:

Thank you for your comments. The Committee has considered the revisions to the proposed measure concepts. The Committee also would like to clarify that the term "patient" does indeed refer to the individual receiving care.

Diagnostic Process

American Medical Association

Koryn Rubin

We question the suitability and feasibility of several of the proposed measure concepts in this domain. Many would be better suited toward quality improvement efforts or structural changes to electronic health record systems that are not appropriate for performance measurement, while others require additional research before inclusion within this framework.

We are very concerned to see a measure concept calling for clinicians to document the certainty of a diagnosis. As discussed in the Patient, Family and Caregivers domain, a patient's status and diagnosis are not static and it is not clear what usefulness this 'point in time' estimate would be in improving patient care and outcomes. We urge NQF to remove this concept and any language suggesting that documentation of a physician's confidence in the diagnosis be standard practice.

In addition, the AMA urges NQF to focus on measure concepts which demonstrate a clear link toward improving patient outcomes. Measures that promote additional documentation burden with little to no opportunity to improve diagnostic accuracy are not beneficial. For example, the Information Interpretation subdomain includes a concept on the percentage of encounters in which decision aids were used. While we agree that decision supports can be useful, what evidence exists that measuring the frequency of the use of a decision aid can directly impact outcomes?

We also support ensuring that diagnoses are timely, but the measure concepts outlined in the Diagnostic Efficiency subdomain call for setting acceptable benchmarks, which may have the unintended negative consequences of over diagnosis or misdiagnosis. The AMA agrees that benchmarking is a task in which specialty society involvement is critical. The AMA also recognizes that there may be conditions (perhaps many) for which evidence of the impact on outcomes of a timely diagnosis may be lacking. If such measures are developed, a prerequisite should be that such data exist.

In addition, measure concepts should not be included unless evidence exists that the measure concept will improve care. For example, is there evidence to show that a change in care location is an indication of a diagnostic error or how loss to follow up or a patient adverse event is a marker of potential misdiagnosis? These proxies should not be included unless this evidence exist

The concepts included in the Follow-Up subdomain are appropriate as they clearly contribute to the quality and timeliness of the diagnosis and we support their inclusion under this domain.

>Committee Response:

Thank you for your comments. The Committee agrees that that underlying evidence is important for measure development, however the Committee's intention is to (1) provide guidance to the measure development community and to (2) suggest areas for priority measure development. The Committee expects that developers will put forth measures based on sound evidence and that are linked to outcomes. Measure concepts suggested by the Committee may be used where they are most appropriate whether it be for quality improvement purposes, accountability, etc. The Committee would also like to clarify that this measurement framework is based on improving diagnostic quality and safety; that being said, communication with the patient on red flags/symptoms for instance, is a critical part of diagnostic quality and safety. Finally, the Committee acknowledges that there is a need for balancing measures so that providers are not incentivized for overdiagnosis or underdiagnosis.

COLA, Inc

Brian Reuwer

COLA is the nation's largest private, non-profit accreditor of clinical laboratories and is pleased to submit comments regarding NQF's draft report on Improving Diagnostic Quality & Safety. COLA believes that NQF's work as a follow up to The National Academies' report on Improving Diagnosis in Health Care will be vital to the ongoing efforts to improve diagnoses and to dispose of medical errors which harm patients.

As COLA is looking to align our quality efforts with the recommendations from the National Academies' report and the NQF's efforts, we would like to offer a suggestion for the Committee's consideration keeping in mind the tremendous amount of work that the NQF committee members and staff have already put into this report. COLA has long been dedicated to improving quality in clinical laboratory diagnosis. Since the passage of the Clinical Laboratory Improvement Amendments Act, COLA has advanced the cause of achieving high standards in clinical laboratories through a relevant and effective program of education, consultation, and accreditation.

Presently, we serve almost 8,000 clinical laboratories

nationally, more than any other CMS-approved accrediting organization. We believe this puts us in a position to provide assistance in your efforts to identify quality gaps in diagnostic laboratory services and as those gaps are identified and addressed through quality measurements to assist in your efforts to ensure that those measurements will achieve the laudable goals laid out in your report. Specifically, we agree and support the committee's recommendation as stated in the section on Interprofessional Education and Credentialing:

As you may know, approximately 70 percent of all diagnostic decisions stem from laboratory information as a key input into the diagnosis process. COLA's ultimate mission is to improve patient care by building a lasting and sustainable culture of quality and patient safety in clinical laboratories through a dedicated plan of education that is enshrined in our accreditation program. We believe that this aligns with the Committee's goals and the purposes outlined in the National Academies' report.

We would like to suggest that as NQF moves forward executing this plan that a formal mechanism be created to ensure that accrediting organizations such as COLA are included to make certain that these new measures are disseminated to the organizations. Also, accrediting organizations can serve as a sounding board if certain structural measures or technical questions come up during the development process that accrediting organizations would be in a unique position to answer. A partnership between accrediting organizations and NQF would be mutually beneficial for all organizations involved and ultimately for patient safety by ensuring timely sharing of information.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

NQF Response: NQF appreciates COLA's interest in this issue, and would welcome engagement on measurement of diagnostic quality & safety as well as other topics.

Endocrine Society on behalf of Partnership for the Accurate Testing of Hormones

Stephanie Kutler

PATH proposes that measurements of the accuracy of diagnostic laboratory tests, specifically hormone tests, be incorporated into the process measures of diagnostic accuracy. The process of measuring accuracy for laboratory tests is well-established and involves participation in an accuracy-based quality control program, such as long-standing programs for cholesterol and hemoglobin A1c, from which quality standards can be set. Before the establishment of the latter programs, measurements of cholesterol and hemoglobin A1c were subject to wide assay variability, like those for hormone assays today.

While quality control programs are uniformly used in most accredited local laboratories, they are based on reproducibility using the same assay methodology, i.e. assay-specific precision-based quality control, not accuracy-based programs. The latter are particularly important for hormone assays, because they are the primary means used to confirm the diagnosis of all endocrine disorders.

>Committee Response:

Thank you for your comments. The Committee has reviewed your comments and appreciates your interest in this project.

Minnesota Alliance for Patient Safety, Stratis Health and MMIC

Marie Dotseth

We are generally supportive of the categories and measure concepts in this domain. Through several meetings with stakeholders locally, we also identified follow-up on test results as one of the most important issues with respect to diagnostic quality and safety. We appreciate the addition of a measure concept to include the patient in the process of communication of test results.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

RGH Health Consulting

Bob Hussey

Wolters Kluwer Health notes that a few of the measure concepts within the Diagnostic Process domain have already been the subject of research, and/or deployed within payer-mandated quality reporting programs. For example, there are numerous studies associating the use of decision support tools to improved patient outcomes, so the two "Use of Decision Support" measures within the Information Integration subdomain (one measuring availability of CDS to the clinician, the other tracking the percent of patient encounters in which CDS is used) could be adopted by policymakers in the short term.

Measures tracking "Appropriate Testing" within the Diagnostic Efficiency subdomain could also be part of an early deployment, as these are similar to various "Appropriate Use" measures already incorporated into Medicare's Quality Payment Program. Measures tracking appropriate testing are particularly critical for the Framework as we continue to be concerned that any attempt to measure diagnostic quality could lead to overutilization or overtreatment.

Developing measures to address other concepts within the Diagnostic Efficiency subdomain such as "timeliness of diagnosis" and "appropriate diagnosis" will require more definition and refinement.

Under both the Diagnostic Efficiency and Diagnostic Error subdomains, we see the need for random sampling of patient charts. Within Diagnostic Efficiency, while gauging diagnostic appropriateness might be measured by comparing disease-specific incidence to case-mix-adjusted peer organizations, we're concerned that without a large enough sample size, such a measure will have a wide margin of error. And while sampling is called out within Diagnostic Error, it is focused on unanticipated changes in the level of care, loss to follow-up or adverse events. We agree such focused sampling is likely to have higher yields than random sampling of all patients, but such an approach will also miss diagnostic errors not associated with those three categories.

We commend NQF and members of the Standing Committee for addressing this important topic, and appreciate the opportunity to comment.

>Committee Response:

Thank you for your comments. The Committee has reviewed your comments and appreciates your interest in this project.

Society to Improve Diagnosis in Medicine

Paul Epner

(This comment is provided as an individual, not as a position of SIDM). The proposed framework includes Follow-up as a subdomain, but in reading the draft document, the focus is on follow-up of test results. Follow-up to the degree that it means taking action is important and should not be limited to test results. Asking for insurance review of a non-covered test, or for a patient to return in a certain time frame our examples where follow-up might be important to diagnosis, but which are not specific to test results. Consider a broader perspective on follow-up.

(This comment does not represent an official position of SIDM.) In NASEM's recommendations, they encourage reimbursement for testing professionals to support ordering clinicians on the selection, use and interpretation of diagnostic testing. While this could be expected to dramatically improve the utilization of diagnostic information, often testing professionals do not have access to key patient information. Consider a structural measurement concept that specifies that testing professionals have access to the differential, the problem list and the medication list for a patient to increase the specificity of the supporting information provided.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in this project.

Organizational and Policy Issues

American Medical Association

Koryn Rubin

We question the suitability and feasibility of several of the proposed measure concepts in the Diagnostic Quality Improvement Activities subdomain, and believe they would be better suited to quality improvement efforts. Many of the measure concepts are not appropriate for performance measurement,

including language to encourage organizations to implement processes to consider physician feedback, or satisfaction with systems and functions involved in the diagnostic process, in decisions regarding improving diagnostic error rates. To deal with this issue, an option might be to consider development of a composite measure of diagnostic accuracy and structural capacity, thereby recognizing that a lack of systems and functions will be associated with greater likelihood of not a arriving at the correct diagnosis in a timely manner.

The concepts in the Workforce subdomain, should assess outcomes and feedback from physicians and other team members rather than whether certain structures are in place. It is important that organizations directly collect and assess physician and other clinician's feedback or satisfaction with the systems and functions involved in the diagnostic process. Concepts such as assessing the outliers in the number of encounters may begin to address some of the reasons for physician burnout and other underlying reasons that impact a physician's ability to provide the best quality care to patients but the concepts provided must be based on evidence.

We would like to note and recommend that the report clearly state that any program that measures diagnostic accuracy must include measuring physician satisfaction. Many systems issues[i], such as administrative burdens and lack of organization and system support are leading to physician burn out and overwork and can affect a physician's ability to make a correct diagnosis.

[i] White AA and Gallagher TH. After the Apology—Coping and Recovery After Errors. AMA Journal of Ethics, 13(9): 2011. Available online at http://journalofethics.ama-assn.org/2011/09/ccas1-1109.html.

>Committee Response:

Thank you for your comments. The Committee agrees that that underlying evidence is important for measure development, however the Committee's intention is to (1) provide guidance to the measure development community and to (2) suggest areas for priority measure development. The Committee expects that developers will put forth measures based on sound evidence and that are linked to outcomes. Measure concepts suggested by the

Committee may be used where they are most appropriate whether it be for quality improvement purposes, accountability, etc. The Committee would also like to clarify that this measurement framework is based on improving diagnostic quality and safety; that being said, communication with the patient on red flags/symptoms for instance, is a critical part of diagnostic quality and safety. Finally, the Committee acknowledges that there is a need for balancing measures so that providers are not incentivized for overdiagnosis or underdiagnosis.

Minnesota Alliance for Patient Safety, Stratis Health and MMIC

Marie Dotseth

Under "Diagnostic Quality Improvement Activities", the measure concepts seem to focus on retrospective or reactive learning. Given the emerging importance of prospective risk management and proactive learning in quality improvement and prevention, we recommend adding a structure or process measure concept that would encourage the use of prospective learning and not rely exclusively on reaction to a diagnostic error to improve.

If the patient is a part of the diagnostic team, then perhaps adding "availability of access to the medical record (including notes and test results)" should be added to the measure concepts under "Access to Care and Diagnostic Services".

>Committee Response:

Thank you for your comments. The Committee has considered your comments and appreciates your interest in this project.

Framework

Endocrine Society on behalf of Partnership for the Accurate Testing of Hormones

Stephanie Kutler

Partnership for the Accurate Testing of Hormones (PATH) was established in 2010 to address the need for better hormone tests for use in healthcare and research to enable better patient care. PATH currently comprises 20 clinical, medical and public health organizations. It provides technical and scientific support to the CDC Steroid Hormone Standardization

Program including identifying high priority hormones in need for standardization. It conducts educational activities on hormone measurements for physicians and other health care providers, and advocates for the universal use of standardized hormone tests.

PATH agrees with HHS and NQF that accurate and timely diagnosis is a cornerstone of high quality health care.

The conceptual framework for measurement of diagnostic quality and safety proposed assumes that the diagnostic test used is accurate. The framework proposes categories of process measures for the diagnostic process. Implicit and essential in these processes is that diagnostic tests used, such as hormone tests, are accurate and reliable. Yet, there is no specific mention in the framework of how accuracy of a diagnostic test is measured.

Currently, some hormone tests used to make the diagnosis of endocrine conditions are not sufficiently accurate or reliable, largely due to the lack of standardization and accuracy-based quality control programs (analogous to those for cholesterol and hemoglobin A1c). A consequence of this is that a blood sample measured in two different assays may result in markedly different values. Measurement of serum total testosterone is an example of extreme hormone assay variability. A College of American Pathologist quality control sample containing a testosterone concentration in the range of a man with hypogonadism or a woman with hyperandrogenism analyzed in 1133 different assay instruments measured values that ranged from 43-365 ng/dL, i.e. varying from the severe hypogonadism to normal range for men or normal to severely hyperandrogenism range in women.[1] The potential consequences of this degree of assay variability are misdiagnosis and inappropriate treatment, particularly if clinical presentation is not appreciated. Similar assay variability occurs for measurements of other hormones such as 25 hydroxy-vitamin D, thyroid hormones and parathyroid hormone. The 2011 Institute of Medicine Report stated that a single individual might be deemed deficient or sufficient for vitamin D, depending on the laboratory where the blood is tested.

For some hormones (testosterone, estradiol and 25 hydroxy-vitamin D), the CDC Hormone Standardization (HoST) Program was developed

and provides an accuracy-based standardization certification program that has been used by most major reference laboratories and some hormone assay manufacturers. However, most laboratories still utilize hormone assays that have not been standardized and do not use accuracy-based quality control.

>Committee Response:

Thank you for your comments. The Committee has reviewed your comments and appreciates your interest in this project.

Federation of American Hospitals

Jayne Chambers

The Federation of American Hospitals ("FAH") appreciates the opportunity to comment on the draft framework for improving diagnostic accuracy. The FAH supports the report's focus of driving improvements in diagnostic quality, timeliness and accuracy and the comments that FAH provides are intended to further strengthen the proposed domains, subdomains and measure concepts.

The domains and subdomains identified in this framework are well outlined but many of the proposed measure concepts are not conducive to performance measurement and are better suited to certification or other standards. In addition, the underlying evidence is not apparent for many of these concepts. Given the goal of using this report to assist developers in identifying potential measures for development and to promote those measures that can positively impact the health of patients, the FAH recommends that the final report include only those concepts for which there is demonstrated evidence that the structure or process will improve patient outcomes. Many of the measure concepts appear to be proxies to demonstrate diagnostic quality and accuracy with no supportive evidence identified. Examples include the concept in the Information Interpretation subdomain of the frequency of the use of decision aids; or the change of location as an indicator of potential misdiagnosis in Diagnostic Errors subdomain; and the multiple concepts that call for setting acceptable benchmarks. All of these measure concepts may have unintended negative consequences to patients and prove to be a documentation burden with little to no benefit in terms of quality improvement.

FAH also is concerned to see a measure concept calling for clinicians to document the certainty of a diagnosis. This measure concept is not to our knowledge based on any clinical evidence, and it is unclear how an estimate on diagnostic accuracy serves to improve patients' outcomes and quality of care. FAH does not support the inclusion of this measure concept for these reasons.

The report mentions, but does not address, many of the challenges that are encountered when developing and implementing measures around diagnostic accuracy. Additional information on how to tackle measure development and implementation barriers associated with these concepts would be beneficial.

>Committee Response:

Thank you for your comments. The Committee agrees that underlying evidence is important for measure development; however the Committee's intention is to (1) provide guidance to the measure development community and to (2) suggest areas for priority measure development. The Committee expects that developers will put forth measures based on sound evidence.

Minnesota Alliance for Patient Safety, Stratis Health and MMIC

Marie Dotseth

We are very supportive of the proposed framework. It makes sense and is an effective way to capture the breadth of topics that need to be addressed to ensure diagnostic quality and safety. We especially appreciate identifying and prioritizing a domain for Patients, Families and Caregivers and adding a set of cross cutting topics.

>Committee Response:

Thank you for your comments. The Committee has reviewed this comment and appreciates your interest in the project.

RGH Health Consulting

Bob Hussey

Wolters Kluwer Health appreciates the Standing Committee's efforts to develop a measure framework for diagnostic quality and safety. We continue to believe this is an area that requires substantially more study before any framework can be finalized,

particularly within two measure domains identified by the Committee: Patients, Families and Caregivers; and Organizational and Policy Opportunities. 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.

>Committee Response:

Thank you for your comments. The Committee agrees that additional research and evidence is important for the development of measures for diagnostic quality and safety. The Committee's intention is to (1) provide guidance to the measure development community and to (2) suggest areas for priority measure development. The Committee expects that developers will put forth measures based on sound evidence and that are linked to outcomes.

Themes/Recommendations

Minnesota Alliance for Patient Safety, Stratis Health and MMIC

Marie Dotseth

This is an important addition to the framework and is a helpful section to capture a number of important issues.

We couldn't agree more that care transitions represent a critical potential failure point in the diagnostic process. We ask the committee to consider two important points, first, that we use the most broad definition we can of "settings of care" to include hospitals, long term care settings, community services, primary care and all of the places patients seek help for health care problems. Second, in acknowledgment of the patient as part of the care team, we should appreciate that transitions of care are a health care organization construct – patients experience a continuous process of care; patients are frequently transitioning in and out of settings.

We recommend the addition of "Cultural Competence" in the section on "Communication and Health Literacy". Cultural issues can play a major role on how a diagnosis is understood and acted upon.

>Committee Response:

Thank you for your comments. The Committee agrees that Cultural Competency should be included as a cross cutting theme. Thank you for your interest in this project.

Letter from AAAC

July 10, 2017

National Quality Forum
Diagnostic Quality and Safety Committee

Subj: Improving Diagnostic Quality and Safety: Draft Report

Dear Sir/Madam:

The American Association for Clinical Chemistry (AACC) welcomes the opportunity to comment on the National Quality Forum's (NQF's) Diagnostic Quality and Safety Committee's draft framework for measuring diagnostic quality and safety. AACC commends the panel for its well-designed, thoughtful approach for gathering and evaluating patient and clinical data that can be used to improve the delivery of care.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of progressing laboratory science. Since 1948, AACC has worked to advance the common interests of the field, providing programs that advance scientific collaboration, knowledge, expertise, and innovation.

Patient, Families, and Caregivers
AACC agrees that patients need to understand the diagnostic information pertaining to their condition. Developing measures that assess whether patients comprehend their medical situation is important to engaging them in decisions affecting their health.

Diagnostic Process
AACC agrees that further evaluation of diagnostic management teams is warranted. Studies indicate that many providers are uncertain about what laboratory tests to order[1] or how to interpret test results.[2] Initial reports indicate the inclusion of laboratory professionals within diagnostic management teams can minimize these problems, while improving patient care and reducing healthcare costs.[3] AACC urges the committee to add laboratory professionals to the list of experts comprising these teams. For example, the fourth measure concept in the table on page 11 should read: "Proportion of diagnostic evaluations with appropriate patient and inter-professional team involvement (e.g., nurses, physicians, pharmacists, laboratory professionals)."

Relatedly, AACC agrees that disease specific measures need to be developed to ensure that the appropriate tests are ordered in accordance with evidence-based guidelines. We agree that measures

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1   Marques MB, Hickner J, et al. Primary Care Physicians and the Laboratory. *Am J Clin Pathol* 2014; 142:738-740

2   Hickner J, Thompson PJ, et al. Primary Care Physicians' Challenges in Ordering Clinical Laboratory Tests and Interpreting Results. JABFM 2014; 27:268-274

3   Laposata M. How Can a Diagnostic Management Team Improve Patient Care and Save Money? Long-Standing and Rapidly Worsening Problem of Obtaining An Accurate Diagnosis Quickly. CLN June 4, 2014; Seegmiller A, Kim A (2013) Optimizing Personalized Bone Marrow Testing Using an Evidence-based, Interdisciplinary Team Approach. *Am J Clin Pathol*; 140(5): 643–650. doi:10.1309/AJCP8CK-E9NEINQFL.

should also be developed to assess the underutilization of laboratory tests—this may be as serious a problem as overutilization.[4] We also concur that processes should be in place to 'reconcile' conflicting results/interpretations for a health condition.

AACC strongly supports the development of measures that promote clinicians receiving test results, particularly abnormal findings, in a timely manner. This has been a problem in newborn screening, where results have delayed due to administrative and staffing issues.[5] Putting quality measures in place may spur providers to create a process for ensuring test results are performed and reported without undue delay.

Organizational and Policy Issues

AACC agrees that measures should be developed to evaluate whether individuals have appropriate access to testing for common conditions, including rapid or point-of-care testing to help in critical diagnostic decision making.

We also support assessing whether healthcare providers have sufficient employees available to perform critical diagnostic specialties, such as laboratory testing. A study of the British National Health Service reported that a shortage in laboratory personnel contributed to an "increased error rate, poor team spirit, diminished productivity and suboptimal laboratory service delivery."[6] Adequate numbers of personnel are vital to providing quality, patient care.

We look forward to continuing to work with you on this important issue. If you have any questions, please email Vince Stine, PhD, AACC Director of Government Affairs, at vstine@aacc.org.

Sincerely,

Michael J. Bennett PhD, FRCPath, FACB, DABCC
President, AACC

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4   Zhi M, Ding EL, Theisen-Toupal J, Whelan J, Arnaout R (2013) The Landscape of Inappropriate Laboratory Testing: A 15-Year Meta-Analysis. PLoS ONE 8(11): e78962. doi:10.1371/journal.pone.0078962

5   Government Accountability Office. Newborn Screening Timelines: Most States Had Not Met Screening Goals, but Some are Developed Strategies to Address Barriers. December 2016. https://www.gao.gov/assets/690/681635.pdf.

6   Chima, Erhabor Osaro Njemanze (2014). Challenges of a negative work load and implications on morale, productivity and quality of service delivered in NHS laboratories in England. Asian Pacific journal of tropical biomedicine. (6), p. 421 - 429. (ISSN: 2221-1691) http://ac.els-cdn.com/S2221169115302173/1-s2.0-S2221169115302173-main.pdf?_tid=140c7456-5b4e-11e7-bea5-00000aacb35d&acdnat=1498577836_c69f45aeb63ae003e92f798038a259f5

Letter from AdvaMed

July 12, 2017

Shantanu Agrawal, MD
President & CEO
National Quality Forum
1030 15th Street, NW
Suite 800
Washington, DC 20005

Re: Comments for NQF Improving Diagnostic Quality and Safety: Draft Report

Dear Dr. Agrawal:

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

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.

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 wish to highlight the following recommendations to the current version of the Draft Framework, including several recommendations to direct the Committee's focus to ensure that patients are offered all options in the diagnostic phase of their care.

A. Recommendation to Expand the Concept of Shared Decision-Making to Include Considering Use of New Technologies in Patient Care.
   (Domain: Patient, Families and Caregivers; Sub-domain: Patient Experience)

AdvaMed applauds the Committee's interest in refining the framework around Improving Diagnostic Quality and Safety and we support the Committee's work, but we offer suggestions to more strongly favor the autonomy of the patient and/or caregiver in the diagnostic process by offering patient choice through shared decision-making.

A prime example to illustrate this concept is a randomized trial for colorectal cancer (CRC) screening. The study by Inadomi et al. offered 997 average-risk CRC screening patients fecal occult blood testing (FOBT), colonoscopy, or their choice of FOBT or colonoscopy, with a primary outcome of completion of screening at one year. The study showed that 58% of patients completed CRC screening, but participants for whom

colonoscopy was recommended completed screening at a significantly lower rate (38%) than participants for whom FOBT was recommended (67%) (p <0.001) or who were given a choice between FOBT or colonoscopy (69%).[1] These data support that patient preferences should be considered when making CRC screening recommendations and that choices should be offered to improve compliance. Another example is the recent study by Smith et al. which examined colorectal screening rates for over 33,000 patients and indicates that individuals with insurance policies that cover CT colonography for CRC screening are almost 50% more likely to get screened by any method than those whose policies do not cover the procedure.[2] These examples support the idea that the availability of choice itself may serve to engage the patient and increase participation.

As noted in our previous comments, *the addition of shared decision-making to the Framework general measurement areas and measure concepts should explicitly include the discussion of new technologies in patient care.* This 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.

B. Recommendation to Expand the Patient-Reported Experience of Diagnostic Care to Include the Presentation of All Appropriate Diagnostic Options to the Patient.
(Domain: Patient, Families and Caregivers; Sub-domain: Patient Experience)

As part of the Domain of Prioritized Measures for Patients, Families and Caregivers as it relates to the sub-domain of Patient Experience, the Committee identified several general measurement areas that they expressed an interest in seeing further developed into measure concepts. These are noted on the grid on page 9 of the Draft Framework, under the heading of "patient-reported understanding of diagnosis" and include the following area: "Patient-reported experience of diagnostic care - were problems explained, etc."

Patient-reported understanding of diagnosis	Measure Type
Patient-reported experience of diagnostic care - were problems explained, etc.	Patient-Experience

AdvaMed recommends strengthening these areas to include specific reference to whether all diagnostic options were presented to the patient. Specifically, we suggest that it be modified to state: "were problems explained and were all appropriate diagnostic options presented to the patient."

C. Recommendation to Clarify that "All Appropriate Options" are Presented in the Measure Concept Regarding Clinical Documentation.
(Domain: Diagnostic Process; Sub-domain: Information Gathering and Documentation)

Under Diagnostic Process, Information Gathering and Documentation, the grid on page 10 of the Draft Framework states that "Clinical documentation should support quality in the diagnostic process and be clear, complete, and accurate."

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1   Inadomi JM, Vijan S, Janz NK, et al. Adherence to colorectal cancer screening: a randomized clinical trial of competing strategies. *Arch Intern Med.* 2012 Apr 9;172(7):575-82.

2   Smith, MA, Weiss JM, Potvien A, et al. Insurance Coverage for CT Colonography Screening: Impact on Overall Colorectal Cancer Screening Rates. Radiology. 2017 Jul 11:170924. [Epub ahead of print].

Measure concept	Measure Type
Clinical documentation should support quality in the diagnostic process and be clear, complete, and accurate	Process

AdvaMed suggests stating this as "Clinical documentation should support quality in the diagnostic process and that all appropriate options are presented and are clear, complete, and accurate." This would be aligned with the Committee's general goal of making sure that *complete* and accurate documentation about a patient's diagnosis is available.

D. Recommendation to Include that All Appropriate Diagnostic Options Are Included in the Use of Decision Support.
 (Domain: Diagnostic Process; Sub-domain: Information Interpretation)

Under the Information Interpretation sub-domain in the grid on page 12 of the Draft Framework, the committee provides the following structure measure concept: "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)."

Measure concept	Measure Type
Use of decision support: Availability of EHR-integrated, evidense-based decision support pathways for diagnosis of common symptoms (e.g., chest pain, dyspnea, headache, dizziness, abdominal pain) [structure]	Structure

AdvaMed suggests strengthening the role of decision support to include presenting diagnostic options by stating "Use of decision support: Availability of EHR-integrated, evidence-based decision support pathways that provide all appropriate diagnostic options for diagnosis of common symptoms (e.g., chest pain, dyspnea, headache, dizziness, abdominal pain)." The additional clarifying language would help to facilitate appropriate diagnostic decision making.

E. Recommendation to Include: (a) Providing Timely Access to Medical Diagnostic Technologies as a Measure Concept; and (b) Ensuring that Diagnostic Testing Aligns with the Most Current Guidelines and Standards.
 (Domain: Diagnostic Process; Sub-domain: Diagnostic Efficiency)

Under the sub-domain of Diagnostic Efficiency in the Draft Framework, the Committee discussed several potential measure concepts including timeliness of diagnosis, particularly for priority diseases. Two aspects of timeliness were addressed by the proposed concepts provided on the grid on page 13 of the Draft Framework: 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.

AdvaMed is pleased that the draft framework addresses many of the timeliness issues related to the diagnostic process sub-domain, including timeliness of initial diagnosis and timeliness of explanation to management, **however we also suggest that there should be similar emphasis on providing timely patient access to medical diagnostic technologies. Thus, we recommend including a general measure concept in the Diagnostic Efficiency Sub-domain — universally applicable to priority and non-priority diseases**

— that states "Timeliness of Access to Medical Diagnostic Technologies from time of initial symptoms to time of diagnosis, staging, etc."

AdvaMed also recommends a second measure concept: "Ensuring that Diagnostic Testing Aligns with the Most Current Clinical Guidelines and Standards." This measure concept directly addresses the Committee's intention to provide concepts on the appropriate use of diagnostic resources and tests, as noted in the Draft Framework. AdvaMed believes that timely access to medical technology with alignment to the most current clinical guidelines and standards is a key component to the success of any quality measure concepts to address timely diagnosis and assessment of a patient's health problem.

F. Recommendation to Clarify Access to Appropriate Options for Testing in the Access to Care and Diagnostic Services Sub-Domain.
   (Domain: Organizational & Policy Issues; Sub-Domain: Access to Care and Diagnostic Services)

As part of the Domain of Organizational & Policy Issues under the Sub-domain of Access to Care and Diagnostic Services, the Committee identified several potential measure concepts which are noted in the grid on page 16 of the Draft Framework, including "Access to appropriate testing for the most common conditions encountered by the hospital, clinic, practice, or other care setting."

Measure Concept	Measure Type
Access to appropriate testing for the most common conditions encountered by the hospital, clinic, practice, or other care setting	Structure

In keeping with promoting patient access to all appropriate options available for diagnostic testing, **AdvaMed suggests modifying this language to read "Access to appropriate options for testing for the most common conditions encountered by the hospital, clinic, practice, or other care setting."**

G. Recommendation to Include Availability of Innovative State-of-the-Art testing for Critical Diagnostic Decision Making.
   (Domain: Organizational & Policy Issues; Sub-Domain: Access to Care and Diagnostic Services)

Included as part of the Domain of Organizational & Policy Issues under the Sub-domain of Access to Care and Diagnostic Services, the Committee identified the following measure concept on page 16 of the Draft Framework: "Availability of rapid or point-of-care testing for critical diagnostic decision making."

Measure Concept	Measure Type
Availability of rapid or point-of-care testing for critical diagnostic decision making	Structure

As point-of-care testing is only one of numerous innovative available test types, AdvaMed recommends that this measure concept be modified to state: "Availability of innovative state-of-the-art testing, including rapid or point-of-care testing, for critical diagnostic decision making.

H. Recommendation to Include Nutrition Assessment and Malnutrition Diagnosis Measure in Appendix F: Inventory of Measures in Development, Testing, or In Use

The Academy of Nutrition and Dietetics and Avalere Health developed a set of electronic clinical quality measures (eCQMs) for malnutrition that includes a nutrition assessment and malnutrition diagnosis documentation measure. We recommend that both of these eCQMs be added to Appendix F: Inventory of Measures in Development, Testing, or In Use. These eCQMs have been fully tested and align with the Diagnostic Process Domain and Sub-Domain: Information Integration. The malnutrition measure set is currently under consideration by CMS for a future Hospital IQR program as the prevalence of malnutrition

is estimated to be 20-50% for hospitalized adults yet only 7% of hospital stays have a malnutrition diagnosis.[3] 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: 1) Completion of a Nutrition Assessment for Patients Identified As At-Risk for Malnutrition within 24 Hours of a Malnutrition Screening; and 2) "Appropriate Documentation of a Malnutrition Diagnosis" eCQMs.

Source: CMS List of Measures Under Consideration for December 1, 2016 and full measure specifications can be found at on the measure steward website at www.eatrightpro.org/eMeasures

MUC ID	Measure Title	Description	Measure Type	Measure Steward	CMS Program(s)
MUC16-344	Appropriate Documentation of a Malnutrition Diagnosis	Appropriate documentation of a malnutrition diagnosis for patients age 65 and older admitted to inpatient care who are found to be malnourished based on a nutrition assessment.	Process	The Academy of Nutrition and Dietetics	HIQR
MUC16-296	Completion of a Nutrition Assessment for Patients Identified as At-Risk for Malnutrition within 24 Hours of a	Patients age 65 years and older identified as at-risk for malnutrition based on a malnutrition screening who have a nutrition assessment documented in the medical record within 24 hours of the most recent malnutrition screening.	Process	The Academy of Nutrition and Dietetics	HIQR

I. **Cross Cutting Themes and Recommendations: Recommendation to Include Diagnostic Industry Experts and Patient Advocates to Provide Relevant Input/Expertise**

AdvaMed applauds the Committee of the Draft Framework to seek outside expertise through promoting "The Opportunity for Medical Specialty Societies to Provide Guidance." This is clearly an opportunity to provide insights from the very provider community making the diagnosis. **To strengthen this, AdvaMed encourages the Committee to also seek input from medical technology industry experts who are dedicated to innovative technologies and solutions utilized by providers in the diagnostic process.** Industry is willing and eager to collaborate by providing insights gained in clinical research, utilization and patient experience from around the globe.

Additionally, as NQF and the Committee are fully aware, patient advocates can provide a much-needed end-user experience and can communicate whether the implementation of certain measure concepts would help to deliver better patient experiences, patient engagement, access to care, follow-up of findings and many of the other areas included in the comprehensive conceptual framework. Therefore, AdvaMed also recommends opportunities for additional patient advocates/advocacy groups to directly provide guidance in assisting in further developing measures or measure concepts. Incorporating these insights can lend a breadth of knowledge to improve patient outcomes that may not have otherwise been accomplished.

AdvaMed appreciates this opportunity to share our feedback and comments to NQF regarding the

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3   Weiss AJ, Fingar KR, Barrett ML, Elixhauser A, Steiner CA, Guenter P, Brown MH. Characteristics of Hospital Stays Involving Malnutrition, 2013. HCUP Statistical Brief #210. September 2016. Agency for Healthcare Research and Quality, Rockville, MD.

Improving Diagnostic Quality and Safety: Draft Report. AdvaMed looks forward to working with NQF as it continues 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 F:
Inventory of Measures in Development, in Testing, or in Use

Source: National Quality Forum

#	Measure Title	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 Lower Urinary Tract Injury	Performing cystoscopy at the time of hysterectomy for pelvic organ prolapse to detect 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

#	Measure Title	Description
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

#	Measure Title	Description
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-adjusted)	Percentage of patients who died with documented or 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 disease 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-Up Rates	This measure calculates the percentage of patients with 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 System as Discrete Searchable Data Elements	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 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.

#	Measure Title	Description
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: Percentage of Patients Diagnosed with Strep Pharyngitis Who Had a Rapid Group a Strep Test or Strep Culture	This measure is used to assess the percentage of patients diagnosed with strep pharyngitis who had a rapid group A strep test or strep 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.

#	Measure Title	Description
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: 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	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 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 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 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.
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 nonsmall 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.

APPENDIX G:
List of Measure Concepts

#	Domain	Subdomain	Measure Concept	Measure Type
1	Patients, Families, and Caregivers	Patient Engagement	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
2	Patients, Families, and Caregivers	Patient Engagement	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
3	Patients, Families, and Caregivers	Patient Engagement	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
4	Patients, Families, and Caregivers	Patient Engagement	Explicit instructions given on red flags/ symptoms should their condition evolve (e.g., included in after-visit summaries, discharge summaries)	Process
5	Patients, Families, and Caregivers	Patient Engagement	Patients are aware of their diagnoses	Patient-Reported Diagnostic Outcome
6	Patients, Families, and Caregivers	Patient Engagement	Patients understand actions they can take to improve diagnostic performance	Patient-Reported Diagnostic Outcome
7	Patients, Families, and Caregivers	Patient Experience	Patient-reported experience of diagnostic care – e.g.: • Were problems explained? • Did you have opportunities to give input to the process?	Patient Experience
8	Patients, Families, and Caregivers	Patient Experience	Patient satisfaction with the diagnostic process – e.g.: • Was it worth the effort?	Patient Experience
9	Diagnostic Process	Information Gathering and Documentation	EMR allows for the clinician to document the differential diagnosis and certainty of diagnosis (i.e., provisional, tentative, uncertain, or certain)	Structure
10	Diagnostic Process	Information Gathering and Documentation	EMR does not require documenting a diagnosis before it is appropriate to do so	Structure
11	Diagnostic Process	Information Gathering and Documentation	The EMR allows for the capture of the chief complaint	Structure

#	Domain	Subdomain	Measure Concept	Measure Type
12	Diagnostic Process	Information Gathering and Documentation	Clinical documentation should support quality in the diagnostic process and be clear, complete, and accurate	Process
13	Diagnostic Process	Information Gathering and Documentation	Percentage of problem lists that are accurate and up to date *or* Percentage of problem lists that contain time stamps	Process
14	Diagnostic Process	Information Gathering and Documentation	Communication to patients and their families is documented	Process
15	Diagnostic Process	Information Integration	Organization participates in health information exchange across outside institutions that supports diagnostic quality, e.g., test results, and documentation related to diagnoses	Structure
16	Diagnostic Process	Information Integration	Use of structured hand-off programs in hospital	Structure
17	Diagnostic Process	Information Integration	Closed loop referral to specialists, including completion of visits and communication of test results and treatment plans/ recommendations back to the referring team	Process
18	Diagnostic Process	Information Integration	Diagnosis reconciliation (reviewing and confirming diagnoses across hand-offs; similar to medication reconciliation)	Process
19	Diagnostic Process	Information Integration	Measure concept related to second opinions (e.g., whether a second opinion was sought in cases of known diagnostic pitfalls or dilemmas)	Process
20	Diagnostic Process	Information Integration	Proportion of diagnostic evaluations with appropriate patient and interprofessional team involvement (e.g., nurses, physicians, pharmacists)	Process
21	Diagnostic Process	Information Interpretation	EHR is functionally interoperable both within and outside organization	Structure
22	Diagnostic Process	Information Interpretation	EHR supports high-quality diagnosis: EHR is fully functional for electronic data integration and visualization for diagnosis	Structure
23	Diagnostic Process	Information Interpretation	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 diagnosis of brain tumor vs. pathology diagnosis of demyelinating lesion)	Structure
24	Diagnostic Process	Information Interpretation	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

#	Domain	Subdomain	Measure Concept	Measure Type
25	Diagnostic Process	Information Interpretation	Reconciliation of conflicting results: Percentage of discordant diagnoses resolved through SOPs described above	Process
26	Diagnostic Process	Information Interpretation	Use of decision support: Percentage 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
27	Diagnostic Process	Information Interpretation	Reconciliation of conflicting results: Percentage of patients with finding Q with interpretation discordant with clinical outcomes (e.g., Percentage of patients with colonoscopy said to be "normal" diagnosed colon cancer <3 months)	Diagnostic Outcome
28	Diagnostic Process	Diagnostic Efficiency	Appropriate testing (underuse/overuse): Percentage of adherence to use of appropriate testing by evidence-based guidelines (or perhaps self-imposed policies about testing policies and procedures)	Process
29	Diagnostic Process	Diagnostic Efficiency	Appropriate testing (underuse/overuse): Percentage of patients with symptom A or disease X who are tested inappropriately (e.g., percentage with benign positional vertigo undergoing CT for dizziness; e.g., Lyme disease serology ordered in patient with nonspecific rash in non-Lyme-endemic area)	Process
30	Diagnostic Process	Diagnostic Efficiency	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
31	Diagnostic Process	Diagnostic Efficiency	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

#	Domain	Subdomain	Measure Concept	Measure Type
32	Diagnostic Process	Diagnostic Efficiency	Timeliness of diagnosis for those confirmed to have priority disease X: Timeliness of diagnostic refinement (from explanation to management): Percentage 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
33	Diagnostic Process	Diagnostic Efficiency	Timeliness of diagnosis for those confirmed to have priority disease X : Timeliness of initial diagnosis (from symptoms to explanation): Percentage 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
34	Diagnostic Process	Diagnostic Accuracy	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
35	Diagnostic Process	Diagnostic Accuracy	Sampling based on loss to follow-up, patient adverse events (including unexplained deaths) as a marker of potential misdiagnosis	Diagnostic Outcome
36	Diagnostic Process	Diagnostic Accuracy	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
37	Diagnostic Process	Diagnostic Accuracy	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
38	Diagnostic Process	Diagnostic Accuracy	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 percentage of patients harmed should also be recorded	Patient Outcome

#	Domain	Subdomain	Measure Concept	Measure Type
39	Diagnostic Process	Diagnostic Accuracy	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]	Patient-Reported Diagnostic Outcome
40	Diagnostic Process	Follow-Up	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
41	Diagnostic Process	Follow-Up	Process in place to identify the responsible clinician for tests	Structure
42	Diagnostic Process	Follow-Up	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
43	Diagnostic Process	Follow-Up	Rate of actionable test results that are communicated to the responsible clinician (e.g., primary or other responsible organizing physician)	Process
44	Diagnostic Process	Follow-Up	Percentage of tests that were pending during a transition of care are documented and have adequate and appropriate hand-offs (pending includes awaiting final read or final interpretation)	Process
45	Diagnostic Process	Follow-Up	Rate of closed loop communication of actionable test results to the patient	Process
46	Diagnostic Process	Follow-Up	Rate of critical test results that are acted on in timely manner	Process
47	Organizational & Policy Opportunities	Diagnostic Quality Improvement Activities	Organization measures diagnostic performance for key areas (e.g., primary care, lab, radiology, ER, selected specialties or clinical conditions)	Structure
48	Organizational & Policy Opportunities	Diagnostic Quality Improvement Activities	Organization supports learning around errors in diagnosis, performs peer review, root cause analysis (RCA), identifies opportunities for improvement, and incorporates new knowledge in future practice	Structure

#	Domain	Subdomain	Measure Concept	Measure Type
49	Organizational & Policy Opportunities	Diagnostic Quality Improvement Activities	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
50	Organizational & Policy Opportunities	Diagnostic Quality Improvement Activities	Patient or patient's representative involved in RCA	Process
51	Organizational & Policy Opportunities	Diagnostic Quality Improvement Activities	Percentage of RCAs with actionable results acknowledged by senior leadership	Process
52	Organizational & Policy Opportunities	Access to Care and Diagnostic Services	Access to appropriate testing for the most common conditions encountered by the hospital, clinic, practice, or other care setting	Structure
53	Organizational & Policy Opportunities	Access to Care and Diagnostic Services	Availability and effectiveness of telemedicine services (i.e., teleradiology, telepathology)	Structure
54	Organizational & Policy Opportunities	Access to Care and Diagnostic Services	Availability of rapid or point-of-care testing for critical diagnostic decision making	Structure
55	Organizational & Policy Opportunities	Access to Care and Diagnostic Services	Average wait time to get an appointment by provider (stratify by specialist)	Structure
56	Organizational & Policy Opportunities	Workforce	Diagnostic performance is included in professional practice evaluation for credentialing and re-credentialing (e.g., OPPE) of clinical providers	Structure
57	Organizational & Policy Opportunities	Workforce	Identification of potential outliers related to number of patient encounters per day (e.g., more than 50 patients seen per day by a primary care physician)	Structure
58	Organizational & Policy Opportunities	Workforce	Providers have adequate time for gathering, integrating, synthesizing, and interpreting information to support correct and timely diagnosis	Structure
59	Organizational & Policy Opportunities	Workforce	Providers operate at the top of their license or certification to free up cognitive load of the MD	Structure
60	Organizational & Policy Opportunities	Workforce	Radiologists are available 24/7 to read stat diagnostic imaging studies in real time	Structure
61	Organizational & Policy Opportunities	Workforce	Rate of physician/nurse burnout and institutional turnover	Structure
62	Organizational & Policy Opportunities	Workforce	Vacancy rate for critical diagnostic specialties, such as lab professionals and PCPs	Structure