



AdvaMedDx
Vital Insights | Transforming Care

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

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].

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.”

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, evidence-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

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.

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 *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,

A handwritten signature in black ink, appearing to read "Donald May". The signature is fluid and cursive, with a long horizontal stroke extending from the end.

Donald May
Executive Vice President,
Payment and Health Care Delivery