American Hospital Association

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Dr. Janet Corrigan
Chief Executive Officer
National Quality Forum
601 13th Street, NW
Suite 500 North
Washington, DC 20005

Dear Dr. Corrigan:

RE: *Draft Requirements for eMeasure Review and Testing*

On behalf of the American Hospital Association's more than 5,000 member hospitals and health systems and our nearly 40,000 individual members, we greatly appreciate the opportunity to comment on the National Quality Forum (NQF) Draft Requirements for eMeasure Review and Testing. America's hospitals are strongly committed to quality improvement, as well as adoption of electronic health records (EHRs). Realizing the promise of EHRs as a tool for quality reporting will rest on the ability of providers, payers, and other users of the information to know that e-measures provide valid and reliable data.

Automated quality reporting has clear potential benefits, including greater efficiency in producing data, real-time results and the potential to include whole populations in measure calculations, as well as the ability to easily look at sub-groups. AHA strongly supports the move toward automated quality reporting to ease burden and provide real-time information. To be useable, however, automated quality measurement must be feasible, generate valid and reliable results and have benefits that outweigh the costs. Early experience from the hospital field in implementing Stage 1 of meaningful use calls into question whether e-measures will deliver on that promise. NQF has a key role to play in ensuring that they do. This letter briefly summarizes early hospital field experience with the meaningful use Stage 1 eMeasures. It then addresses the specific questions posed by the NQF.

Experience with the Stage 1 "Re-tooled" Hospital Measures

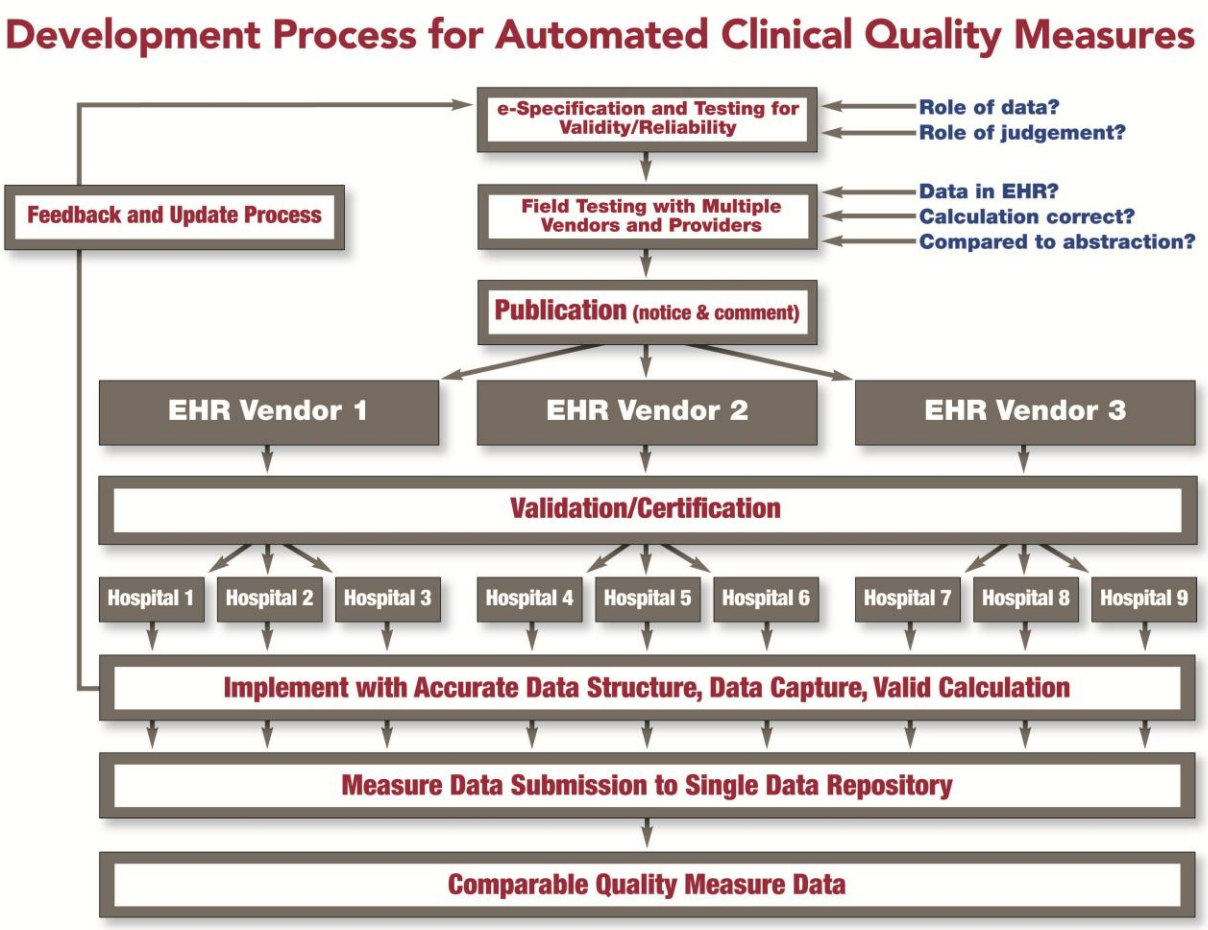
Providers and vendors have encountered significant issues with the re-tooled e-specifications for quality measures used in meaningful use. These measures contain known errors and were never field tested.

In particular, the clinical quality measures (CQMs) for stroke and venous thromboembolism (VTE) were e-specified under contract to CMS, and not by the original measure developer. Although CMS announced its intention to test the feasibility of using the e-specifications in fiscal year 2010, the pilot was never conducted (https://www.cms.gov/hospitalqualityinits/15_HospitalInpatientEHRTesting.asp). The underlying measures were developed for use by specially trained clinicians performing manual abstraction. The original versions of the measures were endorsed through the NQF process, but the e-specifications were not. Despite reservations expressed by the AHA and others, these specifications were finalized by CMS and vendors embedded them into their products using the e-specifications provided. This functionality was completely new for most vendors, who had limited ability to map the needed data elements to where they actually reside in the EHR, or test their products given short timeframes. Vendor products have, however, been certified for the CQMs, due to the very light testing requirements. The certification process for EHRs specifically does **not** include testing the accuracy of the embedded measure calculations, nor does it look to see if the needed data are, in fact, available in the EHR. It only requires that vendors, using their own data, show that their product can electronically produce numerators, denominators, and exclusions in the required standardized format. There is no verification of the accuracy of these numbers.

In practice, the existing CQMs require a level of clinical documentation and the use of coded data fields that are far more extensive than the Stage 1 requirements and not in common use. Much of the data for the inpatient measures come from physician documentation that is currently contained in written or dictated notes. The measures also include concepts not easily captured in structured format, such as "time patient last known well." Thus, the needed data are often not gathered electronically during the course of care. As a result, AHA members report that the certified EHR products they have purchased do not generate accurate quality data without significant effort, including use of custom fields and screens, significant training and increased work for clinicians to capture the necessary data during the care process, and even the use of abstractors to fill in missing data elements. Even those investing considerable resources to validate and correct the CQMs have little reason to trust the data integrity of the CQMs reported out of certified EHRs that they have not developed in house.

In addition, no structured process is in place to ensure that corrections or updates are communicated and adopted by vendors, such as the addition of new medications to treat patients with stroke or to support smoking cessation. Many AHA members report working with individual vendors to fix errors they have found during validation processes. However, to have comparable data across vendors and hospitals, we need a systematic process in place to ensure these changes are broadly communicated and systematically incorporated.

Given the struggle to operationalize the current quality measures, the AHA has urged CMS to conduct a pilot program to field test the measures used in the EHR incentive program and determine the ability of vendors and hospitals to accurately capture the necessary data in the required formats to generate valid, reliable and comparable quality measures directly from the EHR. We also have asked CMS to establish a clear process to manage updates to specifications for quality measures, and a mechanism through which vendors and providers can provide feedback on problematic or unclear measures.



The above chart illustrates the process that the AHA believes CMS and the quality measurement field should follow to develop automated clinical quality measures that will result in comparable data across hospitals. While NQF will not be involved in each of these steps, it has a critical role to play to give providers reassurance that an NQF-endorsed eMeasure will provide valid and reliable results once implemented and in use.

The AHA believes that measure developers and the NQF should consider up front whether a measure can be automated or requires a level of clinical judgment that makes automation difficult. The endorsement process should include testing to determine whether e-specifications are valid and reliable. It should also include field testing to ensure that the needed data are in the EHR and vendor products can capture it. The certification process should validate that vendor products can, in fact, accurately calculate the measures based on test data sets. CMS, NQF, and measure developers should work together to establish a structured feedback and update process.

Review of NQF Draft Requirements for eMeasure Review and Testing

It is clear from the experience in Stage 1 that many steps in addition to the existence of e-specifications are needed for automated quality measurement to occur. However, the rigorous review and testing of eMeasures before NQF endorsement are of bedrock importance. As we transition toward greater use of automated measurement, we must know that the resulting data are sufficiently valid to support public reporting, and possible links to payment.

The AHA believes that all eMeasures need independent testing and separate endorsement by the NQF. No measure should "inherit" NQF endorsement from a measure specified for manual abstraction. All "retooled" eMeasures need more rigorous testing before earning NQF endorsement. We do not believe that the suggested eMeasure Format Review described in the draft requirements will be sufficient. Based on the description provided, the eMeasure Format Review would not test the validity or reliability of the eMeasures, but only include a desk review by NQF staff to check "consistency with endorsed measure specifications and measures logic," as well as appropriate use of data types and taxonomies. Nor is it equivalent in rigor to the full endorsement process, which we believe is needed for each eMeasure. While the eMeasure Format Review is helpful, it does not ensure that the retooled measure will provide valid data. Retooled measures should also undergo "head to head" testing to ensure that the results of measurement are equivalent between manual abstracting and e-measurement. If the measure specified for each method of data collection does not yield the same result, it is not, in fact, measuring the same thing.

Responses to Specific Questions

This section responds to the specific questions posed by NQF in the request for comment.

Question 1. The document offers two accepted methods for testing eMeasures: 1) Measure testing in a simulated EHR data environment; and 2) Testing the output of EHRs v. visual inspection of an electronic record. The CSAC questioned whether a single method would be acceptable or whether both testing methods should be required.

The testing of eMeasures should include both approaches, to ensure both that the measure can be processed in a simulated EHR data environment, and to ensure that someone conducting manual review of an electronic record would get a similar result. Where an eMeasure is a "retooled" version of an existing measure, it should also be tested against the original data collection method to ensure that similar results are obtained.

Question 2. The document allows endorsed measures that have been retooled for EHRs to undergo eMeasure Format Review at initial maintenance review with testing using one of the two accepted methods required by the time of the second maintenance review. The CSAC questioned wither testing using one of the two accepted methods should be required at the time of initial maintenance endorsement rather than only eMeasure Format Review.

NQF endorsement implies that a measure has been tested and shown to have adequate rates of validity and reliability. The AHA does not believe any retooled measure should have NQF endorsement without first undergoing the required testing. While we understand that this has happened in the past, it should not happen again. Further, all retooled measures currently shown as being NQF-endorsed should go under expedited maintenance review, including specific testing for validity of the e-measure itself. The eMeasure Format Review does not require any testing, and is not, therefore, sufficient for either initial endorsement or maintenance endorsement.

Question 3. Are the proposed methods of eMeasure testing sufficient or should eMeasure testing incorporate implementation and workflow issues?

The use of EHRs is growing, and implementation experience suggests that attention to implementation and workflow issues is key to clinician acceptance and use of the systems. It is important, therefore, to ensure that the eMeasure data can reasonably be expected to be incorporated into the record as part of the care process without significant disruption to workflow. Otherwise, eMeasures that have been tested and endorsed will not, in fact, be usable in practice, as many hospitals have found with the Stage 1 meaningful use measures.

Question 4. What are the respective roles of eMeasure developers and EHR vendors to ensure that the measures are implemented appropriately across EHRs?

Implementation will take cooperation across measure developers, EHR vendors, and providers that implement systems. To ensure the best possible outcomes, measure developers must be able to test their measures in multiple vendor products, and have a systematic process in place to share updates and answer questions.

Question 5. Should eMeasure testing require testing on multiple installations and vendor systems?

Yes, eMeasure testing should be done on the major vendor systems in use to ensure that reliability and validity will translate broadly when eMeasures are implemented in the field.

Question 6. Should eMeasure testing incorporate the feasibility of data capture for the data elements utilized in the eMeasures?

The use of EHRs to document care is an evolutionary process, with the level of structured documentation growing slowly from a very low base. It is imperative that the data elements needed for eMeasures be something that is available in the EHR, and can reasonably be expected to be entered in structured format during the care process. Otherwise, as experienced with the Stage 1 meaningful use measures, providers will be forced to abstract data into the EHR, undoing any efficiency benefits of moving to automated quality measurement.

In closing, the AHA appreciates the opportunity to provide comment on eMeasures.
The NQF is doing very important work to set the stage for automated quality measurement that increases the availability of quality data to support quality improvement efforts and inform the public and payers alike. We recognize the promise of eMeasures, but encourage the NQF to do everything possible to ensure that endorsed measures are valid and reliable. As with any innovation, it will be important to proceed carefully and lay a solid foundation. If automated quality measurement is to become widely used, it is more important to get it right than to move quickly.

Sincerely,

Nancy Foster
Vice President, Quality & Patient Safety