American Hospital Association

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Submitted Electronically

Carolyn Clancy, M.D.
Director
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

Re: Request for Information on Quality Measurement Enabled by Health IT

Dear Dr. Clancy:

On behalf of our more than 5,000 member hospitals, health systems other organizations, and our nearly 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Agency for Healthcare Research and Quality's (AHRQ) request for information (RFI) on quality measurement enabled by health information technology (IT). The AHA is strongly committed to the adoption of electronic health records (EHRs) as a means to achieve its vision of a society of healthy communities, where all individuals reach their highest potential for health. Realizing the promise of EHRs as a tool for quality reporting, and ultimately quality improvement, will depend on the ability of providers, payers, and other users of the information to know that health IT-enabled quality measures (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 patient subgroups. Perhaps more importantly, automated quality reporting can, and should, play a role in identifying and supporting quality improvement activities by hospitals and clinicians. The AHA strongly supports the move toward automated quality reporting to ease burden and provide real-time information.

To be effective, 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, as currently configured, will deliver on that promise. We greatly appreciate, therefore, AHRQ's efforts to identify opportunities to rethink how e-measures

are developed and used. We strongly encourage the agency to invest in and incorporate findings from field-based research that will move us toward successful attainment of the goal of efficient and meaningful e-measurement to support quality improvement.

Our comments briefly summarize the hospital field's early experience with the meaningful use Stage 1 e-measures. We also address several of the specific questions included in the RFI.

EXPERIENCE WITH THE STAGE 1 "RE-TOOLED" HOSPITAL MEASURES

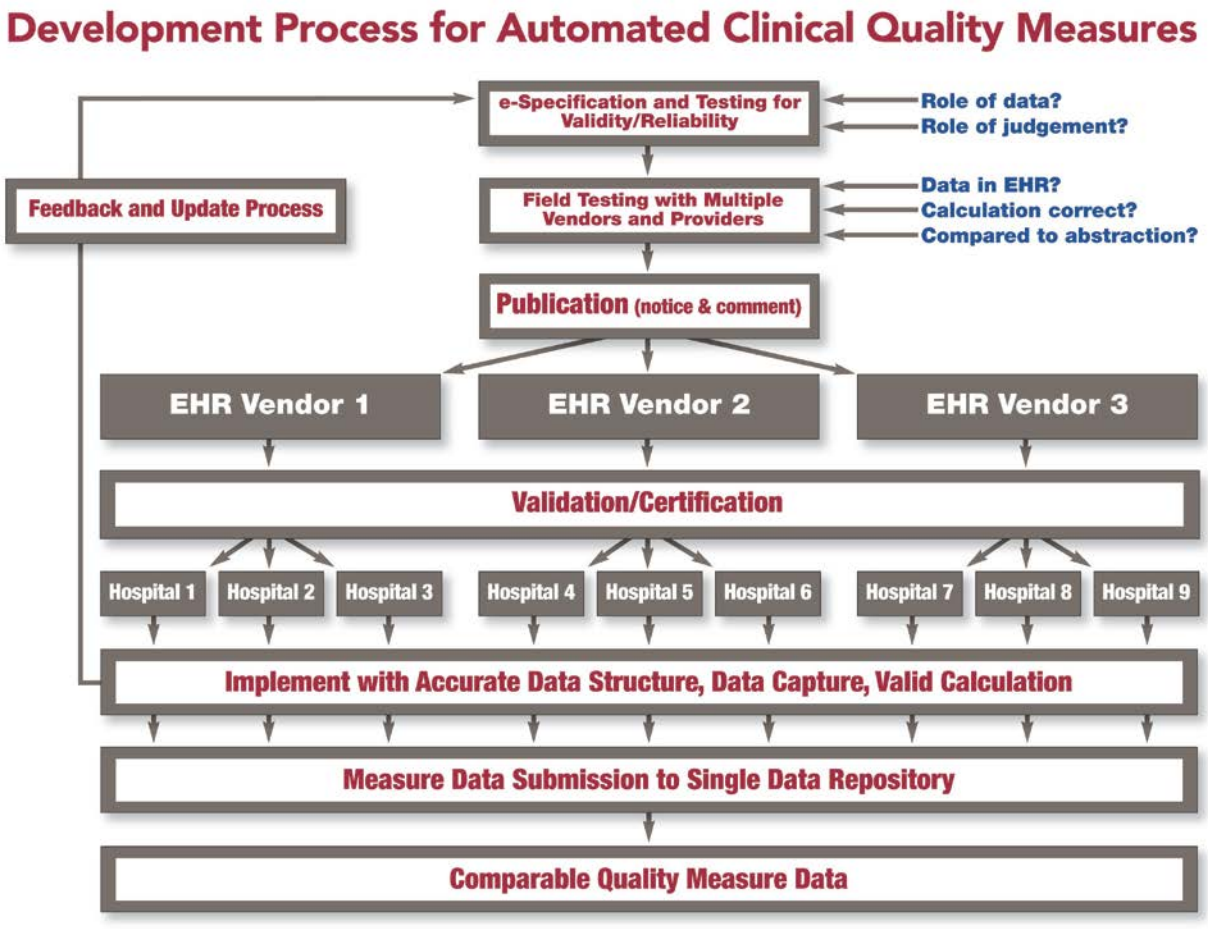
Providers and vendors have encountered significant issues with the re-tooled electronic specifications for quality measures used in meaningful use. These measures contain known errors and were never field tested. In particular, the clinical quality measures (CQMs) for stroke and venous thromboembolism (VTE) were e-specified under contract to the Centers for Medicare & Medicaid Services (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. The underlying measures were developed for use by specially-trained clinicians performing manual abstraction. The original versions of the measures were endorsed through the National Quality Forum (NQF) process, but the e-specifications were not. Despite reservations expressed by the AHA and others, these e-specifications were finalized by CMS and embedded by vendors into their products. 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 does not include testing the accuracy of the embedded measure calculations, nor does it look to see if the needed data are available in the EHR. It requires only 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 meaningful use requirements and not in common use. Much of the data for the inpatient measures comes 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. This includes 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.

In addition, there is not a structured process 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 discovered during validation processes. However, to have comparable data across vendors and hospitals, there needs to be a process that ensures these changes are broadly communicated and systematically incorporated.

Given the struggle to operationalize the current quality measures, the AHA has urged CMS not to add hospital measures in Stage 2 of meaningful use. We have recommended that NQF separately endorse all e-measures, and require field testing of e-measures to 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 identify measure stewards, manage updates to e-specifications for quality measures, and facilitate feedback on problematic or unclear e-measures to the measure stewards.

The following chart illustrates the type of process for federal reporting 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.



ANSWERS TO SELECT QUESTIONS IN THE REQUEST FOR INFORMATION

1. Briefly describe what motivates your interest in clinically-informed quality measures through health information technology. To what extent is your interest informed by a particular role (e.g., provider, payer, government, vendor, quality measure developer, quality improvement organization, standards organization, consumer advocate) in this area?

America's hospitals have a strong interest in harnessing the power of health IT for quality improvement and quality measurement. Tremendous investments are under way in the development, adoption and use of EHRs. Coordinated activities across providers, vendors, and those who want to receive quality measurement data are crucial to improving the ability of EHRs to support care improvement.

2. Whose voices are not being heard or effectively engaged at the crucial intersection of health IT and quality measurement? What non-regulatory approaches could facilitate enhanced engagement of these parties?

Providers consistently demonstrate a willingness to harness innovations that enable the delivery of the best possible care for their patients. Therefore, the inclusion of the provider voice in the design and field testing of EHRs is crucial to achieving health IT that supports quality measurement and quality improvement. Moreover, ongoing, coordinated and transparent discussions among providers, informaticians, vendors and the consumers of quality reports will increase the prospect that quality measurement enabled by health IT will support care delivery transformation. The current panoply of initiatives is challenging to navigate and creates considerable confusion. Therefore, continued outreach to and inclusion of providers and other stakeholders increases the opportunities for engagement by those participating in concurrent initiatives working toward a common goal.

3. Some quality measures of interest have been more difficult to generate, such as measures of greater interest to consumers, measures to assess value, specialty-specific measures, measures across care settings (i.e., measures enabled by health information exchange), and measures that take into account variations in risk. Describe the infrastructure that would be needed to ensure development of such measures.

While we understand the importance of these kinds of measures, they must be developed and deployed in a way that results in valid and reliable data that are feasible to collect. In the area of measurement across care settings, field experience will need to build to identify the types of data that are available, as well as best practices in collecting data across settings. For example, hospitals and health systems are currently forming accountable care organizations (ACOs) and developing tools to integrate data across ACO participants. Learning from these market leaders could inform measure development and deployment strategies. Given the importance of these measures to the

federal government, funding for "learning laboratories" in the field that build on the experience of providers using a variety of EHR vendor platforms would be beneficial. The AHA would be pleased to assist AHRQ in the development of this vehicle for gathering and disseminating best practices.

4. How do we motivate measure developers to create new health IT-enabled quality measures (which are distinct from existing measures which were retooled into electronically produced quality measures) that leverage the unique data available through health IT? Please provide examples of where this has been done successfully. What new measures are in the pipeline to leverage data available through health IT?

The AHA is encouraged that AHRQ is considering development of measures that build from the data in the EHR, rather than re-tooling measures that were developed for manual abstraction by clinicians. Our members report that measures and decision support tools that build on structured data such as medications and specific laboratory values could represent opportunities for short-term action. For example, some hospitals are using their EHRs to monitor the laboratory markers for patients who are taking blood-thinners like Coumadin to ensure that they are within therapeutic ranges.

5. Describe how quality measurement and ''real-time'' reporting could inform clinical activity, and the extent to which it could be considered synonymous with clinical decision support.

Hospitals are experimenting with how best to harness EHRs as a part of their clinical care improvement processes that also address workflow and other care processes. For example, Peninsula Regional Medical Center in Salisbury, MD, harnessed its EHR as an important component in identifying patients with sepsis and alerting the care team to diagnosis, thereby triggering early and aggressive treatment. In this case, the medical center was applying best practices identified in the research and using the EHR as one tool in a far-reaching quality improvement activity.

Similarly, Intermountain Healthcare has used data in its EHR to identify opportunities for quality improvement and support care improvement activities. Analyzing data from Intermountain Healthcare's vast enterprise data warehouse helped researchers at the Salt Lake City-based organization find the optimal gestational age for babies born in its hospitals, and develop programs to drive down the share of pregnancies induced before 39 weeks of gestation from 28 percent in 1999 to 2 percent today. Guidelines based on this research benefit new babies and their moms, and save about $1 million each year. In recognition of Intermountain's leadership in this area, the health care system's IT team won the CHIME-AHA Transformational Leadership Award in 2011.

The AHA believes AHRQ could serve as a valuable resource by identifying and sharing these kinds of best practices, and perhaps identifying systematic approaches to deploying EHRs in this way so that individual clinical programs within a hospital could adopt the best practice to advance their particular priorities.

6. Among health IT-enabled quality measures you are seeking to generate in a reliable fashion, including the currently proposed Meaningful Use Stage 2 measure set, what types of advances and/or strategies for e-measure generation if pursued, would support more efficient generation of quality measures?

Please see our initial comments in this letter for a full discussion of experience with Stage 1 meaningful use measures.

A key component of success in widespread use of EHRs for quality measurement is a step in the development process that maps the data elements required for the measure to the data available in certified EHRs. For example, if a quality measure requires information on whether a particular order has been placed, the measure developer will need to ensure that certified EHRs actually support the automated inclusion of the scope of orders that are included in the measure. In addition, the measure developers should consider the balance between the data needed for the measure and the documentation burden on the provider to collect that data. Ideally, e-measures will leverage the data collected in the course of care without requiring additional data fields. In addition, rigorous field-testing of e-measures at sites that have implemented a variety of vendor products is crucial to ensure that e-measures can be reported.

7. How do you see the establishment and adoption of data standards impacting the future of health IT-enabled quality measurement? For what types of quality measures should a combination of natural language processing and structured data be considered?

The AHA and its member hospitals have participated in the development of health IT standards for many years. The movement toward standards adoption and greater interoperability will facilitate the ease of sharing health information so that clinicians and patients have the information they need to provide treatment and promote health. The adoption of standards also could facilitate quality reporting. The success of a standard, however, is demonstrated through its actual use and usefulness to those providing care. We must ensure that the transition to greater standardization of health information appropriately balances the burden and benefit of the changes in practice and investments in technology that are required to support standards. The federal government must ensure there has been sufficient testing and independent evaluation of testing results before requiring widespread use of any standard. In addition, federal requirements for the adoption of data standards must be accompanied by planning and phasing that take into consideration the full spectrum of demands placed on providers. Transitions to standards required for different federal programs must be aligned – particularly across the standards to support meaningful use of EHRs and the transition to ICD-10.

Use of new or updated standards is difficult, requiring providers to change or upgrade information technology systems, review and potentially redesign how care is provided, and conduct extensive – and ongoing – training of staff. All of this happens in a fast-paced, rapidly changing health care system where there is a strong emphasis on reducing costs. Based on experience to date in Stage 1 of meaningful use, it seems clear that we still have work to do. An effective transition to standards adoption needs to be supported

by educational resources that are easy to find and understand. The HIT Standards Committee recommended on April 28, 2010 that the Department of Health and Human Services (HHS) provide a single location for tools to support standards adoption, including code sets and educational materials. The AHA has previously urged the Office of the National Coordinator for Health IT (ONC) to take the lead on expanding the availability of tools to support adoption of the standards that CMS and ONC put forward in their respective meaningful use regulations. These resources should be available to providers sufficiently ahead of designated compliance dates.

Given the need to balance burden and benefit from standards adoption, the possibility of capturing data through natural language processing is intriguing. We encourage AHRQ to investigate this possibility, with an emphasis on real-world testing of the approach. Our members report that the accuracy and usability of commercially available products on the market varies tremendously, and generally are not sufficient to generate accurate quality data.

8. Much support has been voiced for the need of longitudinal data in quality measurement. What are the strengths and weaknesses of different information architectures and technologies to support health IT-enabled quality measurement across time and care settings? How can data reuse (capture once, use many times) be supported in different models? What examples might you provide of successful longitudinal health IT-enabled quality measurement (across time and/or across multiples care settings)?

The ability to easily collect and use data across settings hinges on the nation's success in enabling health information exchange, which is a work in progress. In the meantime, large health care organizations and those that provide care across settings have invested in clinical data repositories that collect data from disparate, internal systems for analysis. This approach is useful for developing analytics, but is likely beyond the scope of smaller organizations due to costs.

11. What are the most effective means by which to educate providers on the importance of health IT-enabled quality measurement and how clinical information is used to support health IT-enabled quality measurement and reporting? How can providers be better engaged in the health IT-enabled quality measurement process?

The AHA's members report that real-time information has the greatest likelihood of engaging clinicians in quality measurement because it offers an immediate opportunity for care improvement. Quality reporting that is shared after the fact has far less impact. In addition, the AHA has long heard from its members that the proliferation of measures and the lack of measure alignment across reporting programs diminish provider interest in quality measurement. Providers want to know how data will be used, and how they can be used to improve care. Rigorous field-testing to ensure feasibility of collection will likely increase interest in using EHR-enabled quality measures. If the data are burdensome to collect, do not appear to be valid, or will not support timely quality improvement, clinicians will be less inclined to use them.

In closing, the AHA appreciates the opportunity to comment on quality measurement (and improvement) enabled by health IT. AHRQ is doing very important work to improve automated quality measurement that increases the availability of quality data to support quality improvement efforts and inform the public and payers alike. The AHA recognizes the promise of EHRs to help create of a society of healthy communities, where all individuals reach their highest potential for health, and we encourage AHRQ to work with all stakeholders to ensure that automated measures are valid, reliable and feasible to collect. As with any innovation, it will be important that automated quality measurement establish a solid foundation for development and test proposed e-measures in real-world settings before proceeding. Such an approach will enhance confidence among all stakeholders in this important initiative. If automated quality measurement is to become widely used, it is more important to get a small number of measures right before moving on to more measures or moving too quickly.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Diane Jones, AHA senior associate director for policy, at (202) 626-2305 or djones@aha.org.

Sincerely,

Linda E. Fishman
Senior Vice President, Public Policy Analysis & Development