



**Testimony of Rich Elmore,
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Clinical Quality Hearing

Health IT Policy Committee and Health IT Standards Committee

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Distinguished Members of the Committee, my name is Rich Elmore, and I am the Vice President of Business Development at Allscripts Healthcare Solutions. Allscripts is the largest provider of Electronic Health Record (EHR) and revenue cycle management software, and more than 180,000 physicians, 1,500 hospitals and many thousands of other healthcare providers in clinics, post-acute care facilities, and homecare agencies utilize Allscripts solutions to automate their daily activities and connect their clinical and business operations.

While I've been an Allscripts employee for several years, I recently returned following a one-year sabbatical from the company during which I served as ONC's coordinator for Query Health, working to establish standards to "send questions to the data" while keeping patient level information safe at the data source. Virtual distributed query networks are using these standards in pilots for insights on diabetes and hypertension, national and regional situation awareness, post-market surveillance and dynamic querying for quality measures. My testimony today is largely based on my work on the Query Health initiative, and I look forward to commenting on the importance of agile, responsive, clinically relevant measures to the success of the multitude of other initiatives underway in the industry.

How can the measure development process be improved?

The clinical quality measure development process today is slow and unresponsive to the rapidly evolving state of medicine in this country. Measures may take one to two years to define, and once defined, measures then take several more years to move through the regulatory cycle, be incorporated into EHR systems, be deployed to providers and then finally implemented for reporting.

Quality measures, even in their latest most formal expression using the Health Quality Measure Format (HQMF), are impossible for a system to digest "automagically", as HQMF is verbose and not fully computable, with aspects of the measure even described in text. Ambiguity in measure specification leads to multiple interpretations by providers and thus variability, which then requires rework during implementation of the measure in the field.

Some measures are so complex that they would require thousands of test patients to exhaustively test all logical paths through them (actually millions of test patients in a few cases). Extensive testing of measures should be required as part of the measure development process.

One of the key challenges inherent in maximizing the potential benefit of clinical quality measures is collecting the right data in an effective manner so that it fits naturally into a provider's workflow. In some cases there may not be a natural fit – for example, the natural location for stages of cancer may be in a radiology report or a dictated note and not in a structured field. To accomplish this, EHR developers who work with quality measures have described the need for greater clarity and specificity on the supporting data requirements up front, and validation that required data elements can be effectively collected in the provider workflow. .



Measure development can also be improved by focusing on a common set of building blocks which could be used to create simple computable queries, which could in turn serve as the foundation for more complex queries. Currently such queries are highly complex and require a vast amount of interpretation to get any sense of what the measure requires to be computed. Creating simple, re-usable queries will go a long way towards the future goal of a measures development system that is efficient and easily replicable. This will also help us to mature the queries without having to re-implement and redefine every concept as part of each individual complex query.

For example, if we are studying diabetes with a need to evaluate the effect of a drug in one measure and the effect of a procedure in a different measure, creating the basic simple query to identify the subset of the population with diabetes would be the first step. That could then be re-used across the two different efforts described and would not require redesign or re-implementation as part of each query. In fact, creating the simple query as a basic building block of this process will standardize many procedures, including how we identify diabetic patients using existing data elements, which value sets need to be used, how the value sets map to EHR data that currently exist and how we check the EHR data that is recorded to drill down to the relevant population.

As measures focus more on actual clinical outcomes, the idea of “case mix adjustment” – ensuring that outcomes measures are comparable across providers – becomes more important. Ambulatory quality measures do not provide a means for adjustment based on population risk.

Patients with complex and chronic conditions see many physicians, each with different focuses on aspects of the patients’ conditions. If these patients are managed by different providers, and if the data is not routinely shared between these providers, some aspects of the patients’ data is selectively available at different settings of care. Methods to address this in measures should be considered.

How can measures better leverage electronic health record capabilities?

In collaboration with HL7, NQF and CMS, Query Health standards will enable Health IT vendors to dynamically respond to queries, including queries that align with quality measures. So assuming the data is being captured, the quality measure cycle time could go from years to truly a matter of days. The ability to generate measures nationally in a short cycle time has powerful benefits for patients and patient populations while enabling researchers and healthcare organizations to substantially reduce costs and increase speed.

Query Health standards provide a road map to better leverage EHR capabilities for dynamic querying of the EHR for quality measures, including the questions (a “new” HQMF), the target data (ONC’s Clinical Element Data Dictionary or CEDD), the results (QRDA Categories 2 & 3) and the Query Envelope.

Further, reference implementations provide data source translation capabilities from new HQMF to a simplified intermediate model that is easily worked by the source system to extract and return the appropriate aggregate results. Reference implementations of these standards also provide RESTful service integration with a policy layer that is aligned with much of the Health IT Policy Committee’s guidance on distributed queries. Note that Query Health’s CEDD is aligned with NQF’s Quality Data Model (QDM), which is referenced in the ONC NPRM on Standards & Certification Criteria for the 2014 Edition.



I'm also happy to say that a Query Health pilot being conducted by Allscripts will evaluate Query Health standards and target data to deliver sample quality measures.

How can the measurement infrastructure and data be leveraged for other types of improvement?

Quality measures are an important class of aggregate measures that can be immensely valuable. If you map out the trajectory of clinical quality measurement in the meaningful use program, you can see the foundation associated with basic EHR infrastructure (the 2011 Edition), the uptick to improved health information exchange in the 2014 Edition, and finally the delivery of improved outcomes through mechanisms for learning that should be fundamental to the 2016 Edition. The kinds of envisioned improvements can be applied to this larger effort to establish a learning health system through rapid feedback mechanisms that can be applied not only to quality measures, but also to any aggregate measure related to safety, disease outbreaks, management of scarce resources, research, performance measures, and many other categories of population health.

Today, when health researchers develop questions about a population, in many cases they manually pose these questions to care delivery organizations, which employ technical teams to again go through a manual process to generate queries and produce reports. Even where distributed queries are automated, the costs and time to link each data source are unacceptably high. The Query Health Initiative will make this much more efficient, however: the question can be delivered in a format that will be interpreted automatically by an EHR system with the corresponding report generated to "answer" the query.

Pooled "big data" in healthcare has its benefits but also has several drawbacks. "Big data" is typically managed in large pooled data sets, combining data from many settings of care. While there are terrific applications for pooled data, including registries and other successful use of large research and commercial databases, there are also critical issues of policy and strategy that must be resolved.

From a policy perspective, pooled data approaches are highly problematic for several reasons. Large pools of Protected Health Information (PHI) are targets for attack from bad actors, and many PHI-holders have their own consent agreements with their patients. It is very difficult to manage these different consent agreements when pooling PHI in one place, and HIPAA also requires covered entities to control the flow of PHI, either directly or through agreements. When data is pooled, in fact, the party pooling the data must have a business associate agreement or data use agreement (in the case of research databases) with every covered entity that contributes data to the pool, and the terms must be virtually the same. This can be impracticable for the third party and undesirable for covered entities, as they often have to agree to non-negotiable terms in the agreement.

Additionally, from a strategic standpoint, pooled data in healthcare is typically less flexible, grows stale and can even be inaccurate due to many of the limitations described above. Pooled data approaches are likewise less sustainable – the benefits are too indirect to support the operational costs and complexity. Furthermore, healthcare organizations are frequently unwilling to relinquish control of their information not just for reasons related to privacy, but also due to competitive considerations. And yet, the absence of a standards-based alternative has given rise to pooled data approaches even with all of these substantial drawbacks.



Ultimately, we're at a defining moment for new standards that will enable big data analytics in a distributed environment. Researchers will be able to leverage these standards to “send questions to the data.” Questions can be sent to numerous data sources including EHRs, HIEs, PHRs, payers’ clinical record or any other clinical record, and aggregate responses leave patient level information secure behind the data source’s firewall. Those responses can support questions related to disease outbreak, quality, research, post-market surveillance, performance, utilization, public health, prevention, resource optimization and many others. The opportunities are truly endless.