

Written Testimony for Panel 3: Vendors: Developing Systems to Meet MU3

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1. What is the experience of vendors in implementing meaningful use in their systems, and how can that inform meaningful use Stage 3

Despite all the struggles, most vendors have now seemed to have made their way through stage 1, and there are several customers that have achieved meaningful use. So, it is at least doable, and with such an undertaking, some inefficiency is unavoidable. We therefore applaud the alignment that has resulted as a direct effect of the strong efforts of ONC and the MU workgroup in particular.

In our experience, however, MU was and continues to be a very large undertaking, and in general less efficient than normal software development. This has been primarily due to a combination of very short runways and ambiguity in the regulations.

In general, we tried to treat most of the certification criteria as an opportunity to prioritize product areas that customers had requested and make them work better. On most criteria and objectives we worked with customers to create workflows that would be what the customer desired independent of certification or MU requirements, while at the same time satisfying the certification and MU requirements. This was not always possible, however. Often it was unclear how the certification requirements might be interpreted, and in some situations unclear that filling the certification requirement could create any benefit to the customer.

Internally, we had a large team of experts monitoring regulations as they were being formulated, and rather than traditional requirements analysis where scope and clear use cases are established prior to coding, requirements were marked as “potential risks” where it was unclear if the existing functionality was sufficient or if entirely new structures would be required.

We created a “core team” to manage communication both internally and with our customers around ARRA related issues. We also created a variety of tools to track customer plans and questions (including if and when they planned to attest, readiness state, what software they would be using).

There are several lessons learned.

First, better clarity of the objectives/measures and certification requirements is paramount if the process is to be efficient. Because certification was “100% pass/fail”, countless hours were spent discussing if requirements were or were not being met. Some took loose interpretation, others extremely strict. For example, many fruitless discussions occurred about questions like “does encryption of data at rest and transit really require changing SANs in the datacenter”, or “what ‘data’ needs to be hashed, and why isn’t use of SSL sufficient here?” Likewise, it was very hard to understand what use case is being filled with the surveillance transactions. Use cases that described how and where these functions were anticipated to be used would have helped significantly.

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Next, the short lead time was problematic because in order to ensure that customers had software in time to implement, we had to start development before the real requirements were known. Where we guessed incorrectly, this led to wasted effort implementing functionality that was not needed then changing direction mid course. Thus, clarity of requirements isn't something that can wait – it needs to be delivered with the NPRM. We therefore applaud the extension of Stage I for customers so that they are given adequate time to implement, and are not penalized for implementing aggressively in 2011. The sooner real test scripts can be made available, the sooner resources can be used more effectively toward customer goals rather than chasing unknown desires. Pilots such as those for ONC's S&I Framework, will also help with this because they form solid examples from which to work from.

Next, just reading and digesting the regulations, commenting on them, tracking comments and communication with customers was a onerous and expensive venture. This team utilized highly experienced people. Customers, benefited from this, and began relying on this as a translation layer from the complexity of the regulations. But, this is an opportunity cost -- time spent on this was drawn from working on customer requested activities.

Additionally, we ran into challenges where many customers were happy with functionality using multiple, connected systems and were able to meet MU goals. Yet, because of the certification rules, these customers could not adequately claim certification on either system. The MU certification modules sometimes required functionality created by the intersection of separately licensed products (for example, a criteria that requires the "creation and storage" where the creation occurs in one system and the storage occurs in another). To meet these criteria the specific **combination** of systems had to be certified (which crossed vendor boundaries). This then forced customers into a situation of having to self certify, but the prospect of having to self certify (in particular understanding and showing all the security criteria) was so discouraging that they elected to simply switch to a single vendor for both products, thus purchasing and installing systems that they did not really need. We therefore strongly recommend simplification of this process to allow customers who have a mix of systems to more easily claim certification status and not be "forced" to change vendors just to meet certification requirements while they could have easily met the MU goals with their existing systems.

2. Which core and menu objectives have posed the greatest challenges in attempting to implement them (and why)?

Not all requirements were equal in scope or maturity. For some of the harder features (notably CPOE), development and implementation started long before meaningful use, and therefore were not a challenge for us during this period. Without that runway, there would not have been time to achieve the utilization targets set. Ironically, Medication Reconciliation, another functionality that would have otherwise been considered very hard to do, and certainly one which hospitals have struggled with for years, in the end turned out to be extremely easy because it only required showing "2 medication lists side by side!" This level of detail was very hard to predict early on. So, the greatest challenge was in determining what was truly required and what was not, and waiting to get clarity on particular points.

It is also worth noting that some requirements for MU were more difficult because of the volume of references created by a single sentence in the regulation. For example, HITSP C32 referenced over a thousand of pages of requirements (CCD and IHE specifications in turn referencing HL7 CDA, CCR and terminology references, CDA in turn referencing HL7

RIM, etc.). It is hard to compare this to the criteria for Smoking Status which required simple alignment with a single value set.

a. What have been the challenges in implementing the clinical quality measures?

The problems centered primarily around the misalignment between the standards required for certification, and the standards used in e-measures. Also, vocabularies in the e-specifications were very precise, but differed from vocabularies required for MU, and no assistance was provided in “mapping” the specifications from HITSP TN906 into the vocabularies permitted for MU (ICD9, many drug vocabularies, etc.) Siemens applauds the more recent statements to try to align these efforts more closely.

b. Looking at the “measure concepts” proposed for Stage 2 and 3, please comment on the ease/difficulty of implementing them in your platform. Please comment on how policymakers and vendors can maximize flexibility and adaptability to allow for the introduction of new and more complex measures in the future.

In general, we strongly endorse EHR computable measures. However, as currently proposed, we do have several concerns about the measure concepts.

First, while the approach is flexible, it is also complex and expensive. Although each provider only needs to implement a more limited set of measures (core + menu), it is difficult to explain (5 menu items, 5 domains, 5 core items), and vendors must generally have to support the superset of customer choices which creates a significant development burden. Each measure requires careful review to determine its feasibility, and surrounding workflows. And, while some flexibility is clearly needed, when there is wide disparity between implementations, costs cannot be appropriately shared, and it therefore raises costs overall.

Additionally, we have concerns with the ambiguity in these measurements and with the unintended consequences of implementing these measures on large scale, while at the same time potentially associating them with payment. The latter may create incentives to use them incorrectly.

For example, NQF 0139 records the number of central line catheter associated infections. Its numerator is based on a laboratory confirmed infection or clinical sepsis. It is not clear if ‘confirmed infection’ is any bloodstream infection, or more specifically tip culture, but both ways may have problems. If simply based on positive blood culture or clinical marking of Sepsis, it would inappropriately count many cases of sepsis which are not at all related to the catheter, and may have even been the reason for inserting the catheter. On the other hand if the numerator is based on catheter tip culture, this may encourage clinicians to simply pull the catheter and treat empirically without checking the tip culture to confirm the etiology.

This sort of example shows the need for oversight to ensure that the measurement system is in fact measuring what it intended to. This is what we referred to in previous feedback as “protection against unanticipated consequences”

3. How long will it take to develop and implement the proposed Stage 2 objectives?

Given that this is a general market requirement with a fixed deadline, there is little option on the timeframe: vendors will have to release their new releases well before Stage 2 MU begins to enable their customers to implement and operationalize new versions. Instead it is a matter of what percentage of resources will be pulled from other customer requests to implement and verify stage 2 functionality. This level of detail cannot be known until we have more detail about what the objectives mean. As mentioned above, minor wording changes may cause significant shifts in implementation.

4. How are customers implementing their systems: ASP, local install, etc?

We have a mix of both ASP and local installs.

5. What are the biggest challenges customers are facing in deploying their systems?

There is a separate panel of providers which could answer this question more accurately. For the inpatient setting in particular, we hear CPOE, maintaining an up to date problem list, and supporting quality metrics repeatedly cited as pain points. For those that choose the menu items, data exchange with external providers has also been challenging. Customers often indicate that these are largely driven by the need for process and culture change more so than system implementations issues. It is just very difficult to change practice patterns that have been in place for decades. The most successful customers started a long time ago, and have rooted good practice patterns whereby they can extend an existing pattern rather than uprooting it.

Another repeatedly cited challenge is the “perfect storm” and having to manage too many projects all at once. In particular, MU stage 2 and 5010/ICD10 changes occur during the same time period.

6. Comment specifically on support of health information exchange.

Siemens has been a strong advocate for the exchange of health information for many years, with leadership and contribution roles in HL7, IHE, X12, HITSP, and more recently with pilots in the NHIN Direct project and active participation in the ONC S&I Framework initiatives.

With experience, we also recognize that standards alignment work is difficult however, and we therefore advocate that standards that are thoroughly tested to ensure they work before **requiring** their implementation in the form of certification (as distinct from guiding or advising their use).

In particular, we applaud the recent S&I Framework for establishing pilot projects to test with real world systems prior to specifying their use in the MU objectives.

7. Comment specifically on capturing data from and sharing data with patients; What have been the issues related to sharing data with patients?

This question is probably better directed at providers and hospitals. In general, it seems that the most successful efforts revolve around patient education and data availability more than having the data in electronic forms per se. As an example, several of our customers print out a patient summary for all its patients each day. In one example, it lists for each patient their providers, the events scheduled for that day, the patient’s problems, and their medications

(and what they are for using the patient's language). This is just a paper report, but has been extremely well received, and facilitates communication. For example, patients often notice that medications are not ordered correctly. While it substantially contributes to the goal of patient engagement and has led to preventing incorrect medications, it would not count towards electronic exchange of data with patients.

In another example, one customer finds that text messaging is a better medium than a portal for their patient population. In their study of this, they feel it would be a step back to require that a portal become the primary method of communications. Thus, we believe the emphasis should be on facilitating communication, not necessarily that everything has to be "web enabled" or uploaded to/from the patient's PC to do this.

We see the role of providers to actively seek communication with patients and ensure follow-up (as opposed to patients seeking medical care) as increasingly important as accountable care comes into effect. With this, capturing some forms of data (e.g., blood glucose, blood pressure, family history, etc) and tagging its provenance will become an important function particularly for the ambulatory setting. However, these functions are less relevant in the inpatient setting where physical location and patient condition are significantly different and therefore change the character of workflows.

When receiving data **from** patients, it is important to tag provenance as well, and we hope that consistent metadata will be available from IT systems (PHRs, etc.) that may become sources of data for EHRs, so that data liquidity to/from EHRs and PHRs can be increased.

8. What image capture, storage, and review capabilities does your system have?

Siemens has a large portfolio of products in this space from the devices to RIS/PACS to document imaging systems. Various customers have asked if these products need to be certified, and specifically if Radiologists are "meaningful users". In this we feel strongly that imaging is critical to the overall care of the patient, but that as meaningful use is defined, it does not fit the flow of a typical radiologist. For example, while certification would require functionality to maintain an active problem list or record smoking status, radiologists would rarely enter this sort of data, but rather need to have access to the data entered by someone else – probably transacted from a different system. Additionally, we believe that access to images and imaging reports, not just structured data such as CCD, is worth consideration for future MU stages.

9. What will be needed in MU Stage 3 to help your customers achieve the broad goals of accountable care?

Accountable Care will bring many more needs for business intelligence, population management, predictive analytics, and point of care decision support (for 'evidence based' care, but also more specifically around understanding relative treatment costs). The current meaningful use proposals do much to prepare for these needs, and we applaud the meaningful use workgroup for their leadership in this area.

One area that we feel is under appreciated is the need to understand the context and quality of certain data, prior to its use in other BI or decision support.

For example, misunderstanding which problems the patient has will lead to misunderstanding what interventions can or should (should not) have been applied. Yet, the current metrics for problem lists are encouraging problem lists that are inaccurately representing the patient's problems.

For the inpatient setting, the current MU metrics set the threshold for percent of patients with problems on the problem list high (80%). However, because this is hard to achieve, it sets the requirements for the quality of problems on the list are very low. Specifically it requires only one problem to be recorded, does not require that other problems are reviewed, and allows problems to be entered by ancillary personnel, even after the visit. This encourages everybody but the physician to be working with the problem list. For example we are aware of problems being generated through protocols (e.g. if BMI>30, add problem of obesity). While obesity is clearly an epidemic, problems entered this way are irrelevant because no clinician is managing this problem. In essence, the current MU definitions and metrics are unintentionally promoting problem lists of poor quality just to “check the box.”

We again advocate for a more realistic, initially very low threshold of use for stage 2 to be increased in stage 3. Along with this there should be a much higher threshold for **quality** of data. The intent is to change behavior and incentivizing capture of quality data (i.e. **meaningful using**), not just payment for having turned on the functionality.

A variety of measures might be used to improve this. One example is to measure % of active problems on the problem lists which have some evaluation or status (stable/improving/worsening, etc), or have an order associated with them during that visit. This metric should encourage review of the problem list to both add new problems, and to mark problems as inactive (i.e. clean up the list, too). For inpatients, measuring discharge/transfer summaries generated from the EHR's structured problem list would also encourage peer pressure to make sure the information captured in the EHR is clinically rich, and up to date.

10. What specific major initiatives have you had to postpone due to work on Meaningful Use?

Yes, we did delay various initiatives due to work for MU, involving customer prioritized features. As noted in question 1, we did try to align and leverage work that we already planned to do, but the overhead involved for tracking the MU project has definitely slowed implementation speed of other features that customers requested.