Amit V. Trivedi

Program Manager, Healthcare
ICSA Labs, an Independent Division of Verizon

<u>**ONC Certification Hearing May 7, 2014**</u>

What has been your experience with the current certification program?

I helped launch one of the first voluntary national EHR certification programs with CCHIT in 2006, and actively participated in the formation and authorization of two different ONC-Authorized Testing and Certification Bodies. I have a unique perspective on the accreditation process, the development of certification criteria and testing tools, and understanding the needs of certification stakeholders. I hope the feedback I provide will assist the Advisory Committees as they chart the course for future certification criteria to support Meaningful Use.

I am frequently asked whether the program is working, whether all this effort is worth it, and I can confidently say yes. From 2006 to 2011, I helped lead the CCHIT interoperability workgroup and interfaced with the various subgroups that developed certification criteria for CCHIT's proprietary programs. As a voluntary program without the lure of incentive funding, CCHIT made slow, but steady progress with interoperability, which is reflected in the criteria selected for the 2011 Edition (HL7 v2.5.1, NCPDP SCRIPT, CCD/C32 (now CCDA). Every year was a struggle for various reasons: multiple competing standards, incomplete implementation guides, lack of customer demand, a dearth of trading partners to exchange information with, and so on.

The advent of Meaningful Use and the associated incentives led to an unprecedented shift in vendor attitudes and capabilities to include functionality that previously was either not requested by customers, or in some cases not in the best interests of profitability and maintaining a closed system. The incentive funds and Meaningful Use regulations stimulated HIT development in many different areas – terminologies, vocabularies, standards for immunizations, lab orders, quality reporting, patient summaries, and transport. I believe the stimulus funds did what they were supposed to do, in providing a much needed infusion of interest, activity, and development to the industry.

There has been much progress to date, especially with the aggressive push to adopt new standards and implementation guides which is characteristic of the 2014 Edition. As we begin Stage 2, we will hear many critiques, but it is important to recognize that there is finally a focus on the transport of clinical information between disparate systems. At the same time, it is important to also recognize that the industry has faced a major transition progressing through Stage 1; before plunging forward, we may need time to take stock of where we are, given the current inventory of standards and newly implemented functionalities. Although the ONC certification criteria and requirements create a solid standards-based foundation to build upon, we should focus resources not solely on new development, but improvement and enhancement of existing technology. As customers of ICSA Labs, hundreds of hospitals, vendors, and HIT developers consistently remind us of their struggle to balance the design of products based on regulatory requirements and developing to their customer needs.

The differences between the 2011 Edition and 2014 Edition certification programs highlight a number of areas that are positive trends, including:

- A better emphasis on standards and implementation guides;
- More use of conformance testing and tools over self-attestation;
- Focus by the ONC team on continuous improvement and a willingness to listen to stakeholders.

There are also areas that should be improved and adjusted to weigh the tradeoff of increasing costs and growing complexities associated with the program and the benefits realized by users of certified HIT. While the 2014 Edition improved in many areas, there are some areas that should be monitored to prevent requirements from being overly burdensome:

- Lengthy and complex test procedures;
- Test data, procedures, and tools that are constantly changing;
- A lack of robust support for some of the testing tools;
- Unwieldy mechanisms to quickly and efficiently update and correct the Certified HIT Product List;
- Increasing administrative and data collection requirements for ACBs that have questionable value for purchasers and implementers.

What are the challenges you have experienced with the current certification program?

Undue burdens of the testing and certification process. The cost of doing business as an ACB/ATL is something the committees should consider. To date, Orion Registrar (one of the early certification bodies) and then CCHIT (one of the larger ATLs and an ONC-ACB) have bowed out of the program due to financial burdens and the ability to keep up with the requirements to maintain accreditation. There are certain components within the certification process (like surveillance requirements that target customers of certified product vendors, unstable test tools and changing test procedures) that create unnecessary work for ATLs/ACBs and introduce exorbitant costs that either must be absorbed or passed on to customers. As patients and healthcare stakeholders, we all benefit from an efficient, but rigorous and thorough testing and certification processes. Here are some potential suggestions to help keep costs down and support testing labs and certification bodies as they administer the ONC HIT Certification Program:

- **It is critical to pilot test new procedures and test tools prior to publication.** It damages the credibility of the program if vendors are debugging unstable test tools after they are deemed ready for use. Pilot testing should include ample time to recruit participants, validate procedures and test data, and thoroughly test out conformance tools or the effort becomes a meaningless exercise. The 2014 Edition test tools, procedures and data resulted in constant changes that required a great deal of effort from test labs and certification bodies to maintain. Every time procedures, test tools, or test data are revised, it adds to the overall cost on the industry (vendors/developers, ACB/ATLs, *and* ONC). We have better tools for the 2014 Edition than we did for the 2011 Edition, and we need even better testing tools moving forward.

- **Consistency between test labs is vital**. Pilot tests should be a venue for all ATLs and ACBs to observe testing, understand the expected results, learn how test tools operate, and then provide feedback to ONC. To date, this has **never been done prior to publication** of the certification test procedures.
- **Surveillance requirements must be realistic.** The surveillance requirements are well intentioned, however the additional policy guidance for 2014 Edition surveillance issued by ONC requires considerable resources to execute. As currently designed, the surveillance process not only poses an increased burden on ACBs and certified products, but also to *customers* of certified products. As an ACB we question the cost, benefit, and efficacy of some of the surveillance requirements like the continuous monitoring of all marketing collateral related to ONC HIT certified products, tracking every individual certified vendor's complaint process, and surveying customers of certified products without a trigger like a complaint. There needs to be more research on post-market surveillance and how effective the current requirements are. Currently there is an undue burden on the ACBs to require them to investigate how certified products are performing in the field and *proactively search for products that are not conformant*, as opposed to focusing efforts mainly on reported issues.

How would you propose changing the certification program to enhance its value to the stakeholders, while minimizing the burden to the participants?

Focus a higher share of certification criteria on Interoperability and Security testing. ONC HIT Certification should help set a floor for the industry. There has been great work done in the community in developing implementation guides, updating standards and converging on terminologies. *How* EHRs handle various functionality should be left to developers to innovate on. *What* EHRs should be consuming and exporting should continue to be a focus of certification criteria. With the focus on interoperability, security needs to also be considered. The 2014 Edition had a heavy focus on interoperability, but did not take the opportunity to bolster security within HIT products. Cyber security is a concern for all industry sectors, and healthcare is no different. Testing tools need to be more automated, efficiently handle more test cases, and employ more robust types of testing methodologies, including negative testing and testing the security of HIT products.

Keep costs under control. The program will grow cumbersome and expensive to administer if criteria are continually added, but nothing is removed. Each new certification edition should include an evaluation as to what is a reasonable amount of time to spend in the overall certification process (applying, attesting, preparing for test, taking test), in the actual test, and in related activities (reporting, surveillance). Instead of focusing on adding new criteria which will add to the development costs of EHR technology, consider improving current testing methodologies and testing tools to provide more robust testing of existing criteria.

Changes between major MU Stages (like the 2015 Edition criteria) should focus on improvements and corrections, allowing for flexibility and simplification rather than introducing new criteria or standards. Separating content and transport is a perfect example, as is splitting the CPOE criterion into 3 distinct criteria. Although some advance warning, is greatly appreciated, a 12-18 month regulatory cycle may be too aggressive after taking into account the processes around certification and accreditation that are required for ACBs/ATLs to accommodate these frequent changes. Most developers are

midstream in an already-committed release cycle and can't squeeze in brand new 2015 edition requirements on short notice.

Consider the value of certification vs. other techniques to stimulate EHR use. For the certification program to be most effective, it will be important to recognize complementary industry initiatives that may be able to provide value to areas of the industry like external trading partners, and technologies outside of EHR/HIE (such as mobile apps and medical devices). Reciprocity between various established testing and compliance programs and allowing other certifications that build on MU requirements should have value in the ONC program, and will help reduce costs for vendors (as well as ONC) and will introduce additional efficiency in the testing process.

Integrate the Healthcare Ecosystem. The committees have discussed EHR modules and how well they integrate, which is a valid concern. However, external trading partners of EHRs also need to be considered – whether it is a lab, pharmacy, state, or national registry. A common complaint from certification stakeholders is that there are requirements to send information from EHRs but on the other end there is nobody to receive the information. This may be addressed by other programs and initiatives, as alluded to in the paragraph above.

Conclusion

The concept of "glide paths" and gradually "raising the bar" is very important and embraced by all sides. As ONC raises the bar; and as we transition to new and improved standards and requirements we must consider the timing when introducing these changes and what burdens are being imposed on not only the vendors and HIT developers but the certifying bodies and testing labs, as we are charged with executing the certification strategy that is devised. We have a great foundation in place – now may be a time to pause, take stock, and reassess before creating another set of ambitious and aggressive requirements.

As an ACB/ATL, our key needs revolve around finalized test procedures that have been piloted prior to publication. Stable test tools that have robust support are important to preserve the integrity of the program. As we execute the program and are the face of ONC when working with hospitals and health IT vendors, it is important that we have the support going forward to maintain a robust, credible, and efficient program. These potential threats to the success of the program may be solved by pilot testing, more robust automated testing tools, and earlier collaboration and discussion with the ACBs/ATLs and ONC.

Finally, the value of certification lies in providing third party assurance of product capabilities, to aid users and purchasers in their decision making. Certification criteria should be developed with this consideration in mind.

Thank you for considering my comments. Speaking on behalf of my team at ICSA Labs, we consider it an honor to be able to be a partner with ONC and play a role in supporting the transformation and improvement of our healthcare system.