



Virtual Hearing

Panel 4: Health IT Comparison and Informational Tool Vendors

Friday, January 15, 2016 12:00 AM-4:30 PM

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Questions Panel 4 - For ACBs/ATLs:

Q: What information from the testing reports should be made available for vendor comparison?

The following would be helpful information from the ONC HIT 2014 Edition and (as they become available) 2015 Edition Certification Program test results summary reports for comparison purposes:

- Additional software needed to demonstrate the functionality for testing
- Date the product was tested
- Required and optional criteria successfully tested
- Supported standards, when multiple standards are allowed
- Optional transactions
- Information about inherited certification and gap certification (though concepts are not always understood by end-users)
- Quality Management System (latest certification requirements include more helpful QMS information)
- Safety enhanced design – the user center design methodology employed, and summary results of usability testing conducted of modules meeting specific ONC certification criteria (also not always reviewed or fully understood by end-users). Usability testing results for other modules is not collected in certification.

Much more information will be made available per the latest requirements and will be accessible via the ONC's openCHPL.

While the test results summary reports summarize the certification requirements that were met through testing, and therefore accurately compare where vendors meet testing requirements, the test results summary reports were not designed to differentiate products. As a result, if one only looked at the test result summary information, it would be difficult to distinguish how various technologies that have attained the same certification status (such as Complete Ambulatory EHR) might differ.

Certification testing and the information in the test results summary reports should be seen as a floor from which to begin a general comparison. In order for a comparison tool to provide value, the information gathered during the certification process should be augmented with additional information aggregated from other sources and used to then rank, rate, or differentiate technologies. Any comparison should include areas that are not evaluated as part of the certification process.



Q: What information from the disclosures should be made available for vendor comparison?

There is more information that an ACB is now required to collect and report on that could be helpful for purchasers to review when making a decision. Key elements include:

- **Limitations and additional costs:** Health IT developers are now required to disclose factors that may interfere with a user's ability to successfully implement certified health IT, including information about certain "limitations" associated with its certified health IT. Specifically, developers are required to provide (in plain language) a detailed description of any "known material information" about limitations that a purchaser may encounter, and about additional types of costs that a user may be required to pay, in the course of implementing or using the capabilities of health IT to achieve any use within the scope of its certification.
- **Public attestation:** ONC-ACBs are required to obtain a public attestation from every health IT developer certified for any edition of certified health IT in the form of a written "pledge" by the health IT developer to take the *voluntary* step of proactively providing information (which it would already be required to disclose via its website and in marketing and other materials) to all current and prospective customers as well as to any other persons who request such information.

The above requirements are intended to help drive greater transparency and disclosure around the costs and capabilities of certified technology. However, since this is the first year of a new and fairly broad requirement, we expect that the attestation provided from software developers may vary significantly until ONC provides guidance to ACBs in terms of specific templates or discrete requirements for each disclosure requirement. As is, the information is not in a structured format conducive to "side by side" comparison.

ONC-ACBs are also required to collect and submit the following additional information to the openCHPL as part of the post-certification surveillance and maintenance process for certified products starting in 2016:

- Surveillance results that prove the system remains in compliance with the criteria to which it was certified
- Complaints received about certified products
- Software developer supplied corrective action reports based on any noncompliant findings or complaints
- Quarterly submission of product update status (new requirements mandate that the software developer update their ACB at minimum quarterly with any changes or updates to the product)

This additional information should prove helpful when comparing certified products with similar capabilities, especially if the CTC Tool included a "dashboard" that showed key visual indicators (quantitative or short answers such as number of complaints, number of corrective actions, presence of pledge) to help users focus their attention and "drill down" where needed.

Q: Are there limitations in what can be shared?

Certifying Bodies and Testing Labs have contractual obligations to ensure confidentiality around the testing process with the exception of specific required information that must be provided to ONC or shared publicly per regulations. Sharing information that was not specified in the Final Rules or by ONC mandate could prove problematic based on existing contracts. For example, the full set of testing results, test files, and attestation materials are not made public. ACBs are required to ensure to the confidentiality of customer intellectual property and trade secrets.

Additional commentary:

Key decision points include evaluating the following areas:

- **Cost – Total Cost of Ownership, ROI:** The costs of maintenance, upgrades, training, hardware, software, licensing and additional 3rd party software need to be considered, but vary highly from product and implementation. Some information may come from ONC –ACB collected disclosure information, but some of this information may need to be supplied in addition by vendors and then validated or verified by end-user surveys. One possibility could include grouping technologies based on a cost range for a given practice type/size and specialty.
- **Organizational Fit – Usability and Workflow:** The latest safety enhanced design certification requirements in the 2015 Edition criteria include more specificity when it comes to usability testing and reporting requirements compared to previous requirements. However, it is unclear how helpful the information would be for end users as packaged, since it was not originally designed for the purpose of helping prospective buyers compare systems, and is not normalized across products. The certification criteria have a focus on usability in terms of product design, as opposed to usability in terms of actual workflow in an implemented product. Information could be collected from **verified users** to review the quality of support, ease of use, maintenance, training, updates, integration, experience when switching systems, etc. There are a number of models to draw on – for example Amazon.com presents product reviews in a various ways including: average review (based on a 5 star rating), number of reviews, ‘most helpful positive review’ and ‘most helpful critical review.’
- **Integration/Interoperability:** Certification testing evaluates each module separately, not in combination. Interoperability is tested by using tools – so additional information on integration abilities would be desirable to add for comparison purposes such as:
 - Additional vendor/product certifications or accreditations earned such as ConCert by HIMSS, IHE International Conformity Assessment, or DirectTrust;
 - End user experience with data exchange and products that work well together;
 - Participation in other industry initiatives focused on interoperability such as IHE Connectathons, CommonWell, eHealth Exchange/CareQuality.



Additionally, the task force should consider including information from the following sources:

- **CMS/healthit.gov:** information about Meaningful Use attestations submitted and incentive dollars awarded. See the healthit.gov dashboard for information such as “EHR Vendors Reported by Health Care Professionals Participating in the CMS EHR Incentive Programs” (<http://dashboard.healthit.gov/quickstats/pages/FIG-Vendors-of-EHRs-to-Participating-Professionals.php>)
- **US-Cert** (National Cyber Awareness System) for known or reported critical security vulnerabilities in software
- **End user/peer reviews** from verified users of the technology polled on the following:
 - Were costs in line with expectation?
 - Degree of difficulty when integrating with other systems
 - Degree of difficulty when replacing system
 - Quality of vendor support/training
 - Stability/performance of software

Certification testing typically focuses on a product tested in a controlled setting. Many shortcomings identified with products are related to the product once implemented, so gathering post-certification information is important if comparing product performance in the real world. For example, products can perform differently once integrated, or when deployed alongside other applications. Performance can be influenced in so many ways, including but not limited to hardware, network traffic, quality of the data in the information store, or users attempting alternative workflows.

Certification testing evaluates a technology’s capability to meet expected results. Outcomes are either pass or fail. What is not measured or evaluated as part of the certification test methods is the workflow – or *how* results are achieved. More often than not, this translates to usability and how well a product fits in the work environment or gains the acceptance of users. Ultimately there are many various sources of information that could be used to compare technology, but in order to develop a tool that will provide value, it is important to also consider those areas that are not focus areas of certification testing, and to collect information from verified end users who can speak to a product’s performance once implemented.

Given that the HIT market is constantly changing, it may be helpful to also consider publishing a companion guide alongside a simple HIT comparison tool so that first time purchasers and small provider practices can better understand what certification does and does not cover, and so they may also obtain a succinct overview of what key questions and areas they should focus on in order to arrive at a decision when comparing technologies.

A CTC tool should offer value (beyond what users can already do by browsing CHPL) by exposing key factors that users can select to narrow down their choices without having to read many pages of material. CHPL is not good for this purpose, but it is an authoritative repository of detailed information that users can access after the CTC has helped them create a “short list” of products that potentially meet their needs. Ideally, the CTC tool would link directly to the appropriate parts of CHPL, since otherwise users might go to the wrong product or version.



About ICSA Labs

ICSA Labs has been providing testing and certification services as its core competency for over 25 years, with the distinction of being the first commercial lab to attain ISO/IEC 17025 accreditation for information security testing. Additionally, ICSA Labs is accredited as a health IT Certification Body by ANSI (ISO/IEC 17065:2012), as a National Voluntary Laboratory Accreditation Program (NVLAP) accredited Health IT Test Lab, and is an Authorized Certification Body by the Office of the National Coordinator (ONC).

ICSA Labs' experience in healthcare extends to the administration, management and development of a number of certification testing programs as identified below.

ONC Health IT Certification Programs (2011 Edition, 2014 Edition, and 2015 Edition) – ICSA Labs tests and certifies electronic health records and other health IT products for functional, interoperable, security, and exchange requirements per the ONC-approved test methods.

IHE International Conformity Assessment Program – ICSA Labs is an authorized testing laboratory for the IHE International Conformity Assessment Program that tests health IT for conformance to selected IHE profile/actor pairs. IHE USA helped launch this initiative as a founding deployment committee member based on previous work with ICSA Labs, North American Connectathons, and the IHE USA Certification Program. ICSA Labs provides leadership to help author the program scheme, develop the testing framework, and to co-chair the committee governing the program, which was piloted at the European Connectathon in 2015, and is poised to launch in Q3 2016.

ConCert by HIMSS™ Certification Program – ICSA Labs is a partner in the ConCert by HIMSS Certification Program. As part of the program, electronic health records (EHRs), health information exchanges (HIEs), and health information services providers (HISPs) are evaluated using automated testing tools, observed demonstration, and attestation for conformance to Interoperability Work Group (IWG) specifications that have been further constrained for the ConCert program. Products certified in this program have been carefully evaluated to ensure they are interoperable with other certified products.