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| **Implementation, Certification, and Testing (ICT) Workgroup**Interoperability Roadmap Comments Package |
| **Questions for Workgroup Discussion** | * **Are the actions the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?**
* **What, if any, gaps need to be addressed?**
* **Is the timing of specific actions appropriate?**
* **Are the right actors/stakeholders associated with critical actions?**
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| **Charge Question: In what ways can semantic interoperability be tested? (e.g., CCDA content semantics)** |
| **John Travis (JRT)**: Conceptually, does this mean testing for semantics based on use of standard code sets? Does this require everything intended to be understood as structured data to be codified data? It would seem to. Isn’t that what semantic interoperability is? Sender and receiver know the same structured data to be semantically of the same meaning? Narrative text, non-codified structured data and/or use of non-standard codified data would all seem to go against semantic interoperability. So the testing of it would seem to be predicated on testing for specific code sets and code set values adopted as vocabulary standards. What more is there to the question?**Andrey Ostrovsky (AO):** Not sure**Kyle Meadors (KAM):** Semantics deal with language and meaning. We should start with what are providers/patients want or need to “say” to each other and then work backwards to define the language and requirements (i.e. coding requirements) and then define methods for testing or enforcing this. Coming up with test requirements is not necessary difficult. The key is determining exactly what we want to see/not see within EHR systems exchanging and using data. If we are clear on the outcome, then coming up with requirements is a natural outcome.The current clinical information reconciliation (b.4 and b.9) criteria is a good example. It does give some direction of reconciling medications, problems and allergies from a received CCDA, but it does not address things such as history (does this include historical and inactive entries), extra details to include (or not to include) such as what parts of medication SIG or allergic reaction, etc. Without these specifics, interoperability can significant diminish.Once you define what is to be shared and used by users, then we can make test requirements. The methods for testing this can include:* Clearly define what patient information should be consumed/displayed with a checklist. Checklist should be very detail with things which are required vs optional vs conditional.
* Several examples of specific CCDA files with various combinations of code elements (included and excluded) to give vendors a wide scope of features to test on.
* Ensure the CCDA files produced (exported) are conservative (or at least detailed) in what is sent. For testing, you align with the Internet adage to verify systems are conservative in what they send and liberal in what they accept. Again, you require specific scenarios of patient data and then upon export it is verified to be code per spec with very limited flexibility.

**Zabrina Gonzaga (ZG) :*** Recommend starting with a small, prioritized set of content to ensure interoperable exchange.
* Cleary define the settings where interoperability is expected to create a successful implementation. For example, is the expectation to have interoperability among acute care, ambulatory care, long term care, mental/behavioral health, and long term services and support settings?
* Continue to define and refine HIT vocabulary standards and their versions to support semantic interoperability.

**Steven Waldren (SW):*** Semantic interop means (at least to me) the ambiguous exchange of concepts and context from one work environment to another.
* First step is to identify the concepts and contexts that need to be shared. This prioritization work is needed due to the scope of concepts/contexts in health care
* Form those specific test messages and responses can be constructed for testing.
* Full end-to-end testing is needed to insure semantic interop. The testing should start at the encoding of the concepts and context into the source system then the message would be created and transported to the receiving system. Then a user would extract the clinical concepts and context and compare with the concepts and contexts used for encoding. The receiving user would then modify the concepts and context and the process would be repeated in reverse. This would provide an end-to-end test and simulate the process of collaboration between two work environments.
* A process could be created to capture errors and issues in semantic interoperability in the real-world. These reports could then be used to continue to improve the testing process
* Semantic interop is about concepts and context not about documents. The certification criteria must focus on the standardized representation of those concepts and context and not just on a document template. Those concepts will transcend specific document templates.
* There needs to be clear and systematic decoupling of the certification criteria for transport and for payload content. The content standards will continue to be in a state of flux for many, many more years

**David Kates (DK**)Learning from what did and didn’t work in testing compliance of CCDAs for MU2, it would seem that the best approach would be to have a single, comprehensive set of test tools to ensure consistent implementation and interoperability. This should be done both as part of certification and as an inspection process for evaluating compliance in actual usage.The only other comment here is that the scope of interoperability testing needs to expand beyond just individual patient data exchanged between providers at transitions of care or for consumer access. Interoperability as described in the JASON report and recommendations from the JASON Task Force would create APIs that allow secure, bi-directional sharing of information among authorized applications/users. This would facilitate access to data about individuals and populations of patients to authorized users and application developers and drive development of innovative applications that will advance the use of HIT to support value-based population health, improved decision-making, consumer engagement, and realize the broader vision of a learning health system. Certification of interoperability needs to address this more expansive view of interoperability.**Sarah T. Corley (SC)*** First one must make sure that everyone is working upon the same definition of semantic interoperability. Semantic interoperability is the ability of computer systems to exchange data with unambiguous, shared meaning. There has been a backlash over HIT generated documentation. Complaints include the loss of the rich texture of meaning by always using the same terminology and phrasing. It will be important before we start discussing testing to make sure that there is broad agreement on what parts of the information being exchanged need semantic interoperability and what does not. Making the entire medical record semantically interoperable would result in something that no physician would want to use. So all stakeholders must engage in the discussion of what the core data is that must use the same code set and phrasing. When there is a complaint about a lack of interoperability, what is the intended goal? Should every piece of data entered in one EHR be able to populate the same structured fields of a different EHR? Or is it just a subset that need to be consumed at the granular data element level and the remaining data can come across as text? A good starting process would be evaluating the current cCDA. What important data elements are missing, which data elements require additional codified and structured elements to assure they can be consumed by the receiving system? What challenges have existed in the real world implementation? As we have found with the MU mandated exchange of cCDAs, problems have occurred because no time limits were placed on the data to be sent with a cCDA. Real world generation of these voluminous documents made them unusable in practice. So issues such as what data elements need time limits would have to be specified and tested for.
* Once that minimal set is defined and refined and standards identified where necessary one can begin to construct testing tools. Testing needs to also reflect that this set of data is likely to change over time as new needs are identified and unforeseen unintended consequences are identified with implementation. A key aspect of having testing that will reflect performance in the real world is removal of optionality. That will assure that the data is always going to be represented, packaged, and transported in the exact same way. If that is done, one would need only a single testing methodology to assure compliance. One could then test at the creation, transport, receipt, modification, transport to another system, etc.

**Udayan Mandavia (UM)**Achieving semantic interoperability among EHRs with different data architectures is a challenge. The certification program has been able to reduce the gaps to a great extent, however, there is still a long way to go. Being a CMS designated Test EHR, we have been able to collect manys such examples of issues hindering interoperability and share with the Interoperability Work Group. We need to address three important questions:1. What further might be done to simplify and disambiguate the specifications?
2. What are the means available other than having great specs to ensure the maximum compatibility among interoperating EHRs?
3. What needs to be done as part of certification and testing for ensuring interoperability.

Simplify and disambiguate 🡪 The common clinical data sets in CCDA further needs to be constrained in a manner to make the clinical data exchange simplified and more reliable.Other Means 🡪 Provide richer and more standardized samples and tools to validate the conformance. In additions to the syntactic conformance, the tools should focus on the best practices and help find the gaps to ensure semantically robust document exchange in real-world and mechanism to monitor the same. Smart CCDA scorecard is one such tool.Certification and testing 🡪 EHR certification testing to include validation of codes and vocabulary. At the same time, ONC must give careful attention to the cost, which is borne by vendors and end users. Extensive interoperability testing as a part of certification could dramatically raise the time required by system developers and inspectors for the certification bodies. This would dramatically raise the cost. This may also result into longer cycle times in preparing, submitting for public review and freezing the certification rules, scripts and auxiliary data. Moreover, maintaining the requirement by incorporating clarifications and adjustments into Interop specifications based on the issues discovered in testing and real-world use would be a further challenge.**Rick Moore (RM)**On a very basic level, semantic interoperability can be “tested” with a very simple question: “did data sent from System A make it to System B with the same contextual meaning so that System B could use that data as expected by user of said system.” What complicates this very basic and simple question is the seemingly infinite number of contextual meanings that each health care interaction creates to include the infinite number of unexpected uses of that data upon request. The real challenge in gaining traction on the semantic interoperability issue is to have ONC focus on a parsimonious set of necessary data exchanges with clearly defined contextual meanings that are necessary across the continuum of care to achieve the Meaningful Use objectives. Tackling interoperability any more broadly than that defined narrow scope is an ocean to wide to cross at this point. Assuming ONC can reach consensus on a clearly defined set of specific data elements that can be codified and structured to result in a universally understood contextual meaning of the data exchanged, testing that exchange is fairly straightforward in terms of the technical, syntactic, and semantic correctness. It is my experience that a best practice method used to test a system for accuracy in its ability to collect, store, transmit, consume, and report data is to feed it a series of “cases” that result in the system demonstrating its ability to perform each operation with complete accuracy. These “cases” must be accurate depictions of actual (real world) data to simulate the real world functioning of the target system. Depending on the use case being tested, a series of cases (test decks) could be created (automatically) and sent to target system for ingestion and then the target system would demonstrate consumption and then reporting of some output. For example, let’s assume referral management is a test case. In this scenario, a test deck of hundreds of thousands of referral cases would be fed to target system and a series of functions could be expected from the target system in the form of output readings from that test deck. All these outputs would demonstrate the target system’s ability to exchange data at a technical, syntactic, and semantic level. |

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| **I1. Testing Tools** | **2015-2017****Send, receive, find and use a****common clinical data set** | 1. **ONC, NIST and other health IT stakeholders will provide testing tools necessary to support the criteria in ONC's certification program.**
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| **(JFT)** The main issues we experienced with testing tools were with issues of either data set validity where specific testing outcomes were tied to expectations built into the test data validated by the testing tools in a rather hard wired sort of way or expectations built into the validation business rules that were not correct. The key need that vendors have at least is to have reliable testing tools with which to do their own validation testing in their own development efforts prior to going through certification, and then to have stability in the testing tool instances used to actually conduct conformance testing when a vendor goes through certification and testing. Issues of validity caused by testing tool instability create questions of the veracity of the testing process. Testing tools need to be considered part of what is necessary to have a complete set of certification requirements with adequate lead time to allow for vendors to validate their own development efforts. This does not replace the need to pilot the tools for purpose of vetting their readiness to be used in certification but is an additional need to be serviced.**(AO)** As long as testing tools/approaches are clear and as simplified as possible, this activity seems timely.Re stakeholders – we should anticipate that interoperability will be moving beyond EMRs and into other digital health spaces and other healthcare venues (post- acute care, community based care), so the processes for testing should keep in mind those future use cases.**(KAM)** Following our interoperability principles, we should build on what we currently have. We should look to use the SMART C-CDA scorecard or something like that within certification to address coding (which also means making some best practices actual certification requirements). Similarly, expanding the TTT-type tools to enable them to send a variety of CCDA files (like a batch job) so that we can test EHR’s ability to properly consume a variety of files with different types of coding so as to ensure systems are liberal in what they receive and consume. But while tools are part of the answers, efforts to reduce the ambiguity in the requirements and acceptable methods of communication will go further than just making new tools. Strong documentation and what is allowed/not allowed will be critical.**(ZG)** * When providing testing support, provide guidance on how to use multiple tools could be used to validate the different aspects of the interoperability certification requirements. For example, the NIST tool for MU will check a clinical summary for compliance with MU standards and a schematron validation tool will test against the structure of the file and not necessarily the requirements for MU standards.
* Recommend incorporating a plan to test and pilot all certification interoperability tools prior to putting into production.

**(SW)** Project to identify the key data that needs to be push to providers in high need contexts. This work was started with the ASTM CCR. More work is needed to understand the high priority concepts and contexts for semantic interoperability.A reporting tool to report errors or critical issues in certified technology around semantic interoperability**(DK)** Test tools should be more exhaustive than those used for 2014 certification. Our experience was that the tools the ATCBs used provided by NIST did some basic validity checking but were not sufficiently robust to ensure the level of “plug and play” interoperability we’re striving for. Visual inspections were required in 2014 and even there the scope of that testing varied in terms of the level of consistency they were attempting to evaluate – ensuring that different test cases explicitly represented clinical events in a consistent manner, e.g., PRN meds, etc.**(SC)** Testing tools need to be complete and adequately pilot tested and released well in advance of deadlines for clinical use of the products to be tested with them. Numerous problems were seen because test tools were immature and changed over time such that vendors were not tested to identical requirements. Test data was not clinically relevant, inaccurate codes were used, obsolete codes or medications were included. Often testing tools required back dated data to be entered which may not be allowed by a vendor product to protect data integrity. All of these issues must be addressed before we can expect that testing tools will validate performance in practice. We hear that test tool developers have not been able to get volunteers for pilots. This is because the requirements are made in advance of market readiness. If requirements were road mapped accurately, vendors would have time to begin development well in advance of the need and there would be products available for pilot testing. When every vendor is just starting development because requirements are premature, no one will have product ready to pilot in time to release accurate testing tools. As mentioned on the first question, if there is variability or optionality allowed in practice that is not required, testing tools can never predict real world performance. If the goal is to support backwards compatibility or alternatives already in widespread use, that needs to be explicitly made a requirement of certification and testing tools will need to accommodate all allowed methods. Ambiguity will result in failure of testing to reflect actual performance in production.**(UM)** Providing the testing tools is a step in the right direction.These tools need to geared towards semantically robust document exchange, in addition to the syntactic conformance. One of the major issues that needs to be addressed is the stability and continuous availability of the tools. In addition, the versioning of the tool is one of the major concern. The vendor community needs to have a greater insights on the upcoming changes in the tool well ahead of time in order to align their development process.It would be nice to have high-level break-up of what will be covered under each of the three-year milestones. Stability and continuous availability are the actions that is needed immediately.**(RM)**1. Are the actions the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term? INPUT: Agreed, ONC should seek to provide test tools where currently none exist. Where test tools, processes, methodologies already exist, ONC should deem or otherwise license those test tools. 2. What, if any, gaps need to be addressed? INPUT: Currently, there are too many gaps in the specificity of what data must be exchanged to achieve contextual/semantic meaning. Addressing these gaps first must be job 1.3. Is the timing of specific actions appropriate? INPUT: Solving the gaps must come before any test tool selection.4. Are the right actors/stakeholders associated with critical actions? INPUT: There are several industries that healthcare could benefit. Suggest that ONC team with the telecommunications and banking industry experts as key stakeholders in achieving interoperability. Those industries have many lessons learned that we (health care) are overlooking. |
| **I1. Testing Tools** | **2015-2017****Send, receive, find and use a common clinical data set** | 1. **Health IT developers, SDOs and government will explore and accelerate a suite of testing tools that can be used by implementers post-implementation to ensure continued interoperability while health IT is in use.**
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| **(JFT)** This is an intriguing point as it suggests that implementers (and vendors for that matter) may have access to testing tools on demand to verify their continued conformance with a certification criterion where there are interoperability conformance requirements at hand or to provide support for trading partners to validate what they put into production. It would be a good level of assurance as long as the implementation specifications used as the basis for conformance reflect market based real world use and does not repeat the eRX experience. It would allow a vendor or an implementer to provide evidence if necessary of that continued conformance. For vendors, we also suggest that could be a means of supporting attestation based evidence of conformance at any time dependent on validation through a tool at times vendors do updates. If that can ever be decoupled from live testing, it may be interesting to pursue, but the reluctance from ONC’s perspective may be the trust that a vendor could easily game that. On the other hand, the market would reject quickly any solution that is a paper tiger. I think ONC could put more faith into that than may be expected. **(AO)** See above**(KAM)** We should definitely be open to leveraging test tools developed outside the certification program (e.g., SMART C-CDA scorecard) that focus on niche or specific elements of the interoperability exchange. In these cases, these new tools will hopefully be used BEFORE formal adopting the tools in the certification program and thus have been piloted by other groups and proven to be viable for industry at large.**(ZG)** How will these tools differ from the testing tools provided during the certification program? How will they be built to ensure continued interoperability while in use?**(SW)** Work to create a robust set of simulated scenarios for semantic interoperability based on real-world cases of care coordinationA set of unit tests that looks for errors reported from the provider community using the ONC semantic interop error reporting tool (see above).Providers need to be part of this work as well.**(DK)** I would think we’d want the same group as above (ONC, NIST) to develop these inspection tools. OK to solicit input from others but in order to attain consistency, would want to rely on centralized authority (even if they aren’t the originator of the tools, that they identify and consistently implement them).**(SC)** It is unrealistic to expect that vendors and SDOs will be using their limited resources to create test tools for requirements mandated by certification that do not reflect work already underway to solve a business need identified by the customers of HIT. If changes occur in the MU and certification program to prevent the mandating of premature requirements , then it is much more likely that testing tools would have already been developed and could be leveraged by NIST and others. It would save a tremendous amount of time and resources if we could “deem” rather than certify for services already in place and widely used. Example include e-prescribing. We saw that despite widespread use of this important functionality, complete conformance with NCPDP scripts were required by vendors but not by Surescripts so all vendors had to waste time creating throw away code to pass certification because use in a production environment would cause all e-prescribing to grind to a halt. In that case, if complete compliance with 10.6 was the goal, the hubs needed to be on board first. Lab interfaces are widespread and again deeming would be in order here. If the goal is to drive compliance with a single set of lab interface requirements, labs must be approached first or we have the same wasted effort in writing code that will not be used. And let’s not even get started with immunizations and syndromic surveillance. **(UM)** Rather than having separate sets of organizations getting involved to accelerate the suite of testing tools for post-implementation, can we think of utilizing the tools provided for certification testing to be used for post-implementation testing as well? Such tools, coupled with robust test cases and test data to replicate real-world scenario can perform context-based validations, in addition to context free-testing.An example of post-implementation testing is CMS designated Test EHR for testing Transition of Care. This testing ONLY tests conformance to the direct transport specification, but validating the C-CDA by performing Clinical Information Reconciliation is not included in the scope. The scope of future post-implementation tools has to be in line with the complete certification requirements to ensure the end-to-end interoperability. **(RM)** This is an important aspect of the “real-world” interoperability issue. It is entirely plausible (and occurring today) that a system can pass “lab tests” but fail in deployed mode because of environmental issues. The following suggestions could assist with improving upon and avoiding this phenomenon:1. Vendors must define the correct implementation (configuration) of certified system to achieve same results as in the lab. And each vendor must attest that each implementation site achieved that configuration upon “install”
2. ONC should require random audits of implementation sites to determine effectiveness of site implementation. Could be in the form of survey and onsite evaluations.
3. Test tools at site implementation may be too costly to develop and/or administer. Suggest combination of suggestions 1 and/or 2 above may be more cost and time effective.
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| **I1. Testing Tools** | **2015-2017****Send, receive, find and use a common clinical data set** | 1. **SDOs begin to develop and maintain additional testing tools in support of more stringent testing of standards**
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| **(JFT)** At the kaizen, I asked if SDOs were in the habit of developing testing tools in the context of a discussion about potential deeming of the conformance testing done by other entities than by the ATLs using NIST developed tools. The answer was no – SDOs are not in the habit of doing that as they are organizations of volunteers with no funding or budgeting for tooling of that kind or purpose. This would require a change in operation and a source of funding that does not now exist and so seems very unlikely for this current time period.**(AO**) Not sure stringent testing standards are the answer. More simple rather than more stringent may lead to ultimate aim of reproducibly high quality interoperability function.**(KAM**) The biggest challenge for test tool development is always the funding and resource allocation. But we do need to think of test tools originating from organizations beyond just NIST and be open to them coming for other sources, which is something NIST said they support at our recent certification kaizen. **(ZG**) Consider leveraging existing standard tools, like the VSAC, when validating files for common clinical data sets. Also, consider expanding tools to validate against HL7 value sets.**(SW)** No comment**(DK)** Same as above comment**(SC)** Development of testing tools requires money and skilled resources. SDOs in general rely upon the use of volunteers and lack the resources necessary to create rigorous testing tools. We should certainly be open to the use of tools provided elsewhere but government agencies should not expect SDOs to relieve the government agencies from financial responsibility to provide the tools required for certification testing.**(UM)** As stated previously, wouldn’t it be nice to have only ONE set of tools for the testing at a time, be it certification testing or post-implementation? These tools may focus on more stringent testing as we move along each milestones. Having only one set of tool will ensure that all the EHRs conform to the SAME standards and remain interoperable. It would be nice to have a clear insight on the upcoming version of tools and the constraints for more stringent testing. Also the tools may be made available for beta and pilot testing for getting the feedback and necessary corrections, before releasing it for certification and post-implementation testing. **(RM)** ONC should determine “more stringent” – if that definition is meant to imply more stringent than two test cases per function, then yes, ONC should require more stringent tests. There are mathematical/statistical models that can assist ONC with determining the appropriate amount of test cases needed to run through a system to ensure adequate testing of each “node” in the decision-tree. For example, if a particular function being tested has 10 nodes and thus permutations resultant from each combination of those nodes, there is no way that two test cases can adequately measure the accuracy of the target system. |
| **I1. Testing Tools** | **2018-2020****Expand interoperable health IT and users** | 1. **ONC, NIST and other health IT stakeholders will provide updated testing tools in support of ONC's certification program.**
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| **(JFT)** See question 3 if it goes beyond what NIST and ONC may directly provide…..but other considerations can play in to deem testing done by other entities like EHNAC or SureScripts where industry has accepted their testing role for certain purposes. **(AO**) This is really far into the future – not sure where interoperability will be at this point. Good approach would be to leave room for innovation and keep up with the market rather than limiting it. **(KAM)** Nothing else to add beyond previous comments. **(ZG)** See #3**(SW)** The suggested ONC semantic interop public reporting tool could be a great resource to provide evidence to direct update activities.Could ONC and others work to create community based collaboratives to further drive semantic interoperability. This could be another source of input to update tooling and certification criteria. It might also work to address the non-technical issues hindering semantic interoperability.**(DK)** It seems like the participants and authority for certification testing and inspection shouldn’t change over time… just the scope of their activities. I believe that’s what these recommendations indicate though unclear. Bottom line, there should be a single authority for defining the scope and tooling for testing with contributions from the broader community that should expand over time both in scope and in constraining the expression of data towards “plug and play” interoperability for a growing set of use case.**(SC)** I don’t really have any answer that is different than what I provided for #1. Tools need to be updated as standards change and need solid pilot testing before release. Deeming should be used for testing of functionality already widespread. Additional stakeholders would be those on the non vendor side of exchanges to assure all parties are on board with the required standards.**(UM)** Yes, the tools need to be continuously updated to accommodate the lessons learnt from certification testing as well as real-world scenarios. At stated previously, it would be nice to have a broad roadmap for the testing tools, which will get realigned as we move along.**(RM)** Agreed – if ONC is going to provide the tools, it’s implicit that “up to date” tools are required |
| **I1. Testing Tools** | **2018-2020****Expand interoperable health IT and users** | 1. **Health IT Developers, SDOs and government will maintain a suite a testing tools.**
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| **(JFT)** See prior responses.**(AO**) How can we make this suite of testing tools accessible to broader stakeholders so 1) they can understand what they mean for better care 2) so these stakeholders can weigh in on clearer use care of interoperability and then “we” experts can incorporate that feedback into how we approve/evaluate EMRs for adherence to standards. Let the user experience drive the testing of EMRs which will drive the design of EMRs to be more useful for care and not just billing.**(KAM)** Nothing else to add beyond previous comments.**(ZG)** Where will the various stakeholders maintain the testing tools – one site or multiple sites? Recommend providing the tools (and or links to tools) on one site so it is easy to maintain and access. **(SW)** No comment**(DK)** No comment**(SC)** Health IT vendors and SDOs are not in the business in general of creating and maintaining testing tools and lack the resources necessary to do so. Vendors will use existing testing tools throughout the development and certification lifecycle if they are stable and reflect results that translate to real world performance.**(UM)** Same comments as #3.**(RM)** ONC should not develop testing tools where tools already exist. ONC should adop, deem, or otherwise license tools that currently exist. |
| **I1. Testing Tools** | **2018-2020****Expand interoperable health IT and users** | 1. **Health IT developers will regularly use testing tools to maintain interoperability while health IT is in use.**
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| **(JFT)** This is a great idea for vendors to be able to come back and make use of testing tools ongoing within their own development lifecycles for their own testing and validation purposes to assure continued compliance. Whether or not that satisfies any given retesting needs or could be a source for surveillance evidence for ONC-ACBs to draw on may also be something to be considered. There may also need to be an ability to provide for public reporting of any such testing results on a voluntary basis or even in the future on a mandated basis. The value of this would need to be connected to satisfying a legitimate market need and to reflect production use of the types of interoperability specifications at hand. **(AO)** **See previous****(KAM)** Picking up on what John Travis said, I think there is something do here in the area of surveillance or certification maintenance. Just like have now a Designated Test EHR, what if there was a means to have a test tool (or list of actual EHR systems) used by providers/hospitals and vendors alike to verify ongoing compliance to both support vendor quality efforts, streamline certification and ensure production-level interoperability. 1. Vendor makes changes to EHR; prepares to roll out of new version
2. Vendor self-tests with designated test tools and submits results to ONC-ACB
3. ONC-ACB approves results with occasional sample retesting for spot-checking; new version is tentatively approved for certification pending next steps
4. Vendor rolls out new version to a few customers who deploy and then run same tests with designated test tools; if problems found, vendor rolls back changes and makes fixes
5. ONC-ACB confirms production-deployed surveillance results and finalizes certification
6. Vendor rolls out new version to all customers

The idea is we make internal quality testing, certification testing and production-deployed testing more aligned. One complaint now, whether valid or not, is that what is tested in certification efforts in the vendor-controlled environment is not consistent with what providers/hospitals encounter. **(ZG)** Please define “regularly use” testing tools ... Is this intended to mean that IT developers should iteratively use of a testing tool while developing functionality to meet interoperability requirements? While “health IT is in use” seems more on the client/user side. Is the intention to develop testing tools that clients/users would use to test interoperability?**(SW)** No comment**(DK)** No comment**(SC)** I am not sure what you mean by regularly use the testing tools to maintain interoperability. A functioning interface would not require re-testing unless one of the parties to the exchange made a change to their software that affected the performance of the interface. If there is a testing tool that is stable and test results reflect performance in production, HIT vendors would use it when developing new software or making changes to existing software. Broader stakeholder participation to include all partners to the exchange of data and open lines of communication about development changes would prevent issues we have seen, particularly with device interfaces where a client upgrades their device and the interface breaks.**(UM)** We agree.**(RM)** Same input from question 2 – I don’t see how this question is any different? |
| **I1. Testing Tools** | **2021-2024****Achieve nationwide LHS** | 1. **ONC, NIST and other health IT stakeholders will provide updated testing tools in support of ONC's certification program.**
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| **(JFT)** See previous comments. In none of the questions though has there been a goal to provide for appropriate levels of piloting and testing of new testing tools. That is a must. Also as criteria change, and testing requirements change – what is the update cycle for that and how do those changes get introduced? How transparent is the process thought to be for their development? Given the importance of their role to the trustworthiness and utility of the certifications they support, that is very significant.**(AO)** See previous**(KAM)** Nothing else to add beyond previous comments.**(ZG)** See comment for question #5. Questions to consider - Who is responsible for updating the testing tools and when? Will the tools be updated annually or with each updated to the certification program? **(SW)** No comment**(DK)** No comment**(SC)** The only difference I see here is that the goal of a learning health system implies that we will need to be sharing and acting on quality information between systems and also suggests increased focus on clinical decision support. It is outside of our purview to address these requirements here but broad stakeholder participation will be needed to assure that any new requirements be mature with mature testing tools. Decision support has so much potential to interrupt workflows and create cognitive dissonance that expanded testing tools will need to be able to support testing a broad spectrum of workflows if they are to be meaningful predictors of performance in practice.**(UM)** Same comments as #1 & #4.**(RM)** No additional input – similar to previous question on same subject |
| **I1. Testing Tools** | **2021-2024****Achieve nationwide LHS** | 1. **Health IT developers, SDOs and government will explore and accelerate a suite of testing tools that can be used by implementers post-implementation to ensure continued interoperability while health IT is in use.**
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| **(JFT)** This also is a good idea if it helps support the interoperability of production systems, and could serve to help drive out what may be attributable to localization of implementation versus standard capability. It would require settling what to do about segments that may be optional or conditional depending on the implementation use case, and invites the question of just what would be subject to this testing and its value? One need reflect on the experiences of testing new HIPAA transactions or for ICD 10 and how that was facilitated through testing tools versus with actual trading partners. This only adds value to the extend it actually models production transacting and may be premature without the development of what if we were speaking of HIPAA EDI would be “operating rules” and standardized companion guide templates.**(AO)** **See previous****(KAM)** Nothing else to add beyond previous comments. **(ZG)** See comment for question #2. I am not clear on how the post-implementation tools would differ from tools used for certification. Could the strategy provide more guidance on the difference if any?**(SW)** No comment**(DK)** No comment**(SC)** Again, once interfaces are in production and functioning the only use for testing would be if changes were being made in one of more of the participants of exchange. As we see more device interoperability, it will be important to have tools available to health systems and practices to test upgrades in a test environment to assess impact. Many of the important stakeholders in exchange are not part of the MU regulatory oversight process and so I am not sure what resources their would be to create those types of testing tools.**(UM)** Same comments as #2**.****(RM)** No additional input – similar to previous question on same subject |

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| **Questions for Workgroup Discussion** | * **Are the actions the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?**
* **What, if any, gaps need to be addressed?**
* **Is the timing of specific actions appropriate?**
* **Are the right actors/stakeholders associated with critical actions?**
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| **I2. Certification Programs** | **2015-2017****Send, receive, find and use a****common clinical data set** | 1. **Health IT Developers, ACBs, ATLs and other stakeholders will analyze, identify gaps and provide feedback to ONC regarding certification criteria that should be added to the ONC HIT Certification Program. Specifically, criteria that would support ONC’s desire to expand the scope of the certification program to support health IT used in a broader set of health care settings, such as criteria for long-term and post-acute care, home and community based services in non-institutional settings and behavioral health settings. Additionally, criteria related to accessibility and usability of health IT.**
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| **(JFT**) Certification requirements need to always have a clear program purpose and linkage if there is to be federal sponsorship and oversight of it. The federal government should not be in the business if there is not a regulatory underpinning mandating that linkage. Certification should focus on what is of high value for the public good and less so on the internal workings of the provider setting and programs that require certification should not entail many prescriptive low level “functional measures” that are questionable as to their merit and their ability to be derived as a byproduct of clinical care. Instead, certification should focus on what is of merit to support interoperability requirements needed for high value clinical information exchange, security and privacy, quality measure reporting in support of value based programs, patient safety, consumer engagement and public health reporting. Certification of interoperability related requirements need to provide for much more support to modularity of clinical information exchange suited to and supportive to the clinical need at hand and not be based on prescriptive document based exchange that has no good basis for value or that over-presumes what is of common interest to all care venues. A significant complaint as to meaningful use has been of the useless nature of the current Transition of Care document and many providers continue to rely on other manners of exchanging what they believe really is of value. What is of value is not going to be uniform between acute care, long term care, home health, etc. With any given new criterion, part of the completeness of requirements also needs to include transparent guidance from ONC on the intent of how the criteria are to be tested such as the interpretive guidance ONC would give to the ATLs currently. This should be considered a companion guide to the test method. **(AO**) Yes – this is a great focus and totally hits the mark. The challenge of standardizing evaluation of HIT in other care settings (ie community) is having community members that understand the overcomplex process of interoperability standards and testing. We need to bring our conversation down to their level.**(KAM)** I addressed this somewhat in the charge question, but I see a strong need for more detailed specificity of how patient records are communicated. Beyond that, a gap in criteria is that we places where expect certain data elements to be exchanged, like procedures or care plans, but we don’t require them to be captured per se in the system. It is not necessarily a huge deal since system are finding ways to capture, but if providers don’t have a good way to capture this information, then it will certainly not be exchanged in a way that is interoperable.As you are looking at support for post-acute and long-term care, one area to consider is the ability for EHRs to limit the data it shares. The longer we go in this world of electronic health records the more data our health records contain. Just as Google provided a service to allow users to quickly find data most relevant to them given the incredible amount of data available in the Internet, EHRs will need to provide value is sifting through large volumes of patient data to show the most recent items.For example, some provides may want to see blood pressure readings over the last 2 years, but other provider will not need anything but the most recent vitals. This telescopic aspect of seeing patient data will be important and some requirements will need to be in place.We already see this now in certification testing. The clinical summary test is designed to support actions of the recent office visit, but too many vendors simply give you all patient data, like a full patient historical summary. While we do require EHRs to support a customization of clinical summary data, it is often clunky and really it should be intuitive to the providers needs.**(ZG)** Expanding the scope of interoperability to support exchange of information to a broader set of health care settings would be enhanced by conducting an assessment of potential setting-specific challenges and barriers to create a usable, accessible interoperability plan. This assessment may include identifying and prioritizing the key information that is needed for interoperability for each setting. These findings may impact the “common clinical data set”. **(SW)** Public health and immunization registries are not specifically included, yet they are part of MU currently but are not required to use the MU standards.An analysis of the information flows outside of EPs and EHs could help to identify the other entities that need to support the same common clinical data set that currently are not incented or penalized for non-compliance.**(DK)** Same comments as previous section**(SC)** I think that all stakeholders can and will provide feedback on areas of the current certification where requirements should be modified or removed. Stakeholders should guide the direction of future certification requirements based on existing market needs and demands and assuring that additional requirements will have an ROI to the participant incurring the expenditure. This includes EHR developers not being forced to develop functionality they cannot sell to their market, as well as healthcare providers not being required to purchase interfaces where the ROI accrues outside of the practice.In terms off adding certification requirement to include additional domains, I recommend caution. The push for long term care certification is unlikely to move the needle in terms of adoption without an incentive for use. As these facilities were not part of the MU incentives, they will adopt HIT as makes sense for them from a business perspective. Unfortunately we have not seen that certification requirements have matched our clients business needs so without such an alignment, additional certification suggestions are not likely to have an ROI. In years past, under CCHIT, there was demand to create requirements for specific specialties and domains. In part this was because core certification was limited to a general set of requirements common across all specialties. For example growth charts were not required for baseline certification so a vendor who only served an adult specialty would not be required to develop functionality no one wanted. So there was a child health domain to certify those additional requirements. There was a domain certification for LTC but we did not see a lot of uptake by HIT vendors in that space or demand on the part of LTC facilities for certified products. **(UM)** Yes, it would be a great step to expand the scope of certification program to include the other care settings. Still this would be limited to the interoperability among various EHRs under different care settings. However, the external entities such as Labs, Immunization registries, HIEs are not covered under certification program. For example, many HIEs have their own home-grown specifications for interoperability. So EHR vendors are burdened with developing multiple interfaces for different entities although they have been certified for the industry-standards. It would be nice to have these entities also included under certification program to ensure smoother end-to-end interoperability and reduce the burden on EHR vendors.**(RM)** To the extent that there are MU criteria (care coordination) that extend to these external entities, yes, it is a must that ONC ID the precise data exchange required of these entities to ensure MU objectives attained.  |
| **I2. Certification Programs** | **2015-2017****Send, receive, find and use a common clinical data set** | 1. **Other existing industry certification programs will continue to complement ONC's certification program to ensure that different aspects of health IT conform to the technical standards necessary for interoperability.**
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| **(JFT)** ONC needs to provide for a deeming recognition of certifications and accreditations that are widely recognized and of proven value to the industry where certification requirements overlap with those other recognized credentials. Electronic prescribing and SureScripts certification is a perfect example. Certifying eRX within MU adds no value to what the industry already practically requires. Certifying any capabilities related to controlled substance prescribing also would be useless to incorporate into anything other than what the DEA already recognizes. Doing anything in the future that would supplant CAQH CORE recognition similarly would be poor.**(AO)** No Comment**(KAM)** I think there is value in having a certification framework where ONC-ACBs can potentially accept results from other certification and accreditation organizations. Going off what John Travis said, the Surescripts certification program is a good example since it more completely covers testing of e-Prescribing than the ONC criteria. However, it is also an example of how other certification programs need to be vetted before results can be approved as the Surescripts requirements did not necessarily align with the ONC requirements, specifically in the area of their lack of support (or requirement of support) for RxNorm codes in medication identification. Still, we want to reduce redundant testing efforts to maximize resources and maintain overall consistency within the HIT industry. **(SW)** Could there be voluntary certification as a way for those vendors/developers to demonstrate their support of the standards around a common clinical data set.**(DK)** No comment**(SC)** As I previously stated, we should accept deeming from other bodies who are testing the same functionality but stakeholders should be aligned in advance to make sure that certification requirements match what is being used in production or have a plan for all parties in the exchange to migrate in a timely fashion to the agreed upon standard. It would be useful to have a certification testing that matched that used by any public health agencies or Immunization registries that adhere to the CDC IG. That would allow for real world testing of an interface that actually could be sold once developed and perhaps provide an incentive to state and local entities to adhere to a single implementation guide as it would speed the availability of interfaces to feed data to them.**(UM)** Agree. The other certification programs may complement the ONC’s certification and should have a common recognition. Currently, EHRs which are certified with SureScripts, still have to go through e-Prescribing test under ONC’s program. Such duplications of testing should be avoided by giving recognition to industry standard certification programs within ONC’s certification program. This will reduce the chances of conflicting requirements as well as burden on EHR developers.**(RM)** Concur – to the extent possible, ONC should adapt, adopt, deem, or otherwise license technical standards or testing tools/suites vs trying to develop their own. And the push to make everything “open source” is not an option, given the time constraints and expense to develop/maintain. ONC should guide policy and let market forces drive development. |
| **I2. Certification Programs** | **2015-2017****Send, receive, find and use a common clinical data set** | 1. **FACAs will make recommendations for standards and certification criteria for inclusion in ONC’s certification program.**
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| **(JFT)** See comments on question 1**(AO)** Great**(KAM**) I agree – we are doing that now ;)**(SW)** No comment**(DK)** No comment**(SC)** FACAs need to have broad participation by all stakeholders willing to serve and not just those from larger organizations. A broader group of participants would result in feedback that more accurately reflects the populations impacted by regulation.**(UM)** Agree. Let us continue to contribute**(RM)** Agreed |
| **I2. Certification Programs** | **2018-2020****Expand interoperable health IT and users** | 1. **Health IT developers, ACBs, ATLs and other stakeholders will continue to provide feedback to ONC regarding certification criteria that could be added to the ONC HIT Certification Program in order to increase its impact on interoperability**
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| **(JFT)** See other responses**(AO)** Important to 1) identify the right stakeholders and 2) to make those stakeholders have a really good change to learn about the opportunity to provide feedback. Happy to elaborate on what channels to use**(KAM)** This is obviously something good to do and something we are doing now. One improvement opportunity is that once a rule is released and certification testing for it begins, it seems ONC/CMS start moving on to the next set of requirements which will ultimately be released in 2-3 years. Not that they should not do this, but it would be good to reconvene a kaizen-type meeting 6 months or so after launch to evaluate current progress and see areas can be improved now for the current requirements. Again, it would not be new requirements nor invalidate anything previously tested, but an early effort to correct/improve our certification program.**(SW)** No comment**(DK)** No comment**(SC)** I expect again that stakeholders will continue to provide feedback on how certification can support the needs of the market and that there not be certification just for certification sake. There should be a demonstrated need that will be met by ongoing certification and it will need to be much better aligned to the needs of the users of certified software.**(UM)** Yes. We have participated in recent Health IT Certification Program mini-Kaizen program and it was a great gathering where different stakeholders shared their feedback on the ONC’s certification program. It would be nice to have similar programs on ongoing basis with more focus on improvements and also mechanism to track the progress.**(RM)** Agreed |
| **I2. Certification Programs** | **2018-2020****Expand interoperable health IT and users** | 1. **ONC and other industry certification programs will focus on including more stringent testing such as scenario-based testing and post-implementation testing to ensure interoperability while health IT is in use.**
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| **(JFT)** This may not be the best place for making other manners of comments but I will do so as I am not sure there was a good place to make these in response to other questions – these work to be general comments for any given certification program as to the overall cycle time defined for introduction of new criteria.1. The cycle time of the introduction of new criteria editions and their impacts on vendor and client timeframes for development and deployment need to adequately account for all of the following activities beyond the obvious activities of gap assessment, design, software coding, testing and rollout for upgrade/update – *Training, testing, workflow redesign, policy/procedure development, queuing of resource demand on vendor capacity, potential new licensing/contracting needs, engaging with external entities (state agency onboarding or registry onboarding), identifying trading partners locally*2. Vendors need the opportunity to evaluate clinical workflow impact of not only requirements but of making both functional and clinical quality measures by products of care that fit seamlessly not only within the one exemplar workflow that may be used for testing but also for all workflows that similarly support the same activity as alternative workflows3. Vendors need to evaluate for usability – a steady criticism has been of certified systems being technically able to meet testing requirements but not being very usable. Part of that stems from a compression of time to get the requirement met which makes it difficult to do a full job of human factors review, and accounting for usability design - measurement requirements can be challenging to fold in without an adequate cycle of that kind of review4. Client adoption includes time needed for reasonable upgrade/update rollout and adoption timely to first year need of anything new – inclusive of 5. An overall strategic view of how a given certification program fits within the framework of balancing with many other regulatory demands contemporary to the timeframes of new criteria adoption and use (e.g. ICD 10, value based initiatives, etc) needs to always be considered**(AO**) Great – important to have the right people determine what the right scenarios should be. Ie: if you look at the use cases we’re developing in the eLTSS workgroup, there are scenarios for interoperability which are VERY different from the “doctor” or “hospital” centered view of MU that we have today**(KAM**) I do like the concept of this idea, but we need to approach it with fresh eyes. The previous efforts for scenario-based testing have not been successfully, and I feel it is largely because we tried to take our existing unit-based testing and just combine them together like Legos. It really did not add anything to our current work. To do true scenario-based testing, we need providers/hospitals to clearly document their scenario workflows and then think of how EHR systems should be responding to them. Then, we can determine key requirements which can flow into a test case. But it should really look different than our current models of testing just a problem list for examples, which is primarily focused on basic functionality. We need to start with the end in mind and work backwards rather than trying to force our existing test procedures and criteria into that model.**(SW)** No comment**(DK)** No comment**(SC)** Stringent testing is only helpful where the requirements are clear and tightly constrained and match what is available in the marketplace. If all parties to exchange are not constrained by the same requirements, stringent testing will still not reflect performance in an operational environment.**(UM)** It would be nice to have scenario based testing in line with real world scenarios. Here are some suggestions:* Before we go for scenario based testing, the ambiguities in the present individual test procedures and test data would need to be addressed first.
* The scenarios need to be crafted keeping in mind the interdependencies between different steps/procedures.
* It needs to consider how the test outcomes will be measured against the different test procedure and in case of non-conformity on a particular step, how will the retesting be performed.

**(RM)** If scenario-based testing = case-based that can be auto-created, then agree. If scenario-based testing is a group of experts sitting around a table developing scenarios, disagree. There are much more automated and stringent case-based software systems that can auto-generate hundreds of thousands of cases (scenarios) that more stringently test a system’s capabilities to accurately capture, store, manipulate, analyze, exchange, and report data/information than a team of experts sitting at a table developing use cases. |
| **I2. Certification Programs** | **2021-2024****Achieve nationwide LHS** | 1. **ONC and other industry certification programs will continue to update criteria as needed in support of a learning health system's evolving needs, new standards and expanded program's scope to include health IT used in a broader set of health care settings.**
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| **(JFT)** No comment**(AO)** A really good approach would be to develop simple to understand technical assistance site accessible to end users or service/tech providers that service end users. Happy to provide good and bad examples. **(KAM)** I think a major lesson from 2014 Edition testing and certification is that releasing a significant number of new criteria/modified criteria at one time does almost more harm than good. It was too much at one time to take in for the industry. I know rule making is not a quick process, but it would help the industry to make small changes spread out over time rather than releasing many new changes all at once.I know that is where ONC is going based on their discussions related to R2 final rule and other discussion, but I definitely affirm it. As important as it is to pilot test requirements, we will always learn more once a product is deployed for real-world use and we can fully prepare for that. It is a reality products will be released with bugs or deficiencies and vendors will need to make changes to work at customer sites. If we can spread out our requirements so vendors have fewer new features going into each release that should ensure less disruption for users.To lend itself to this learning health system, smaller changes are more easily absorbed but also allow you to more easily identify the areas most needing attention. Like the analogy of throwing one rock in a pond vs several at one time, the small changes are more quickly identified and then lessons learned from their deployment are fed back into the certification program to catch for future iterations of products and versions. We definitely should see certification as part of product lifecycle. When certification becomes an incredible undertaking, vendors start developing solely around certification rather than integrating certification requirements into their development lifecyle. **(ZG)** In continuation of comments for question #1, as the certification programs develop iteratively, the common core data set may need to expand to incorporate the needs from the other settings or we may find there is a common core data set for all settings and perhaps an extended data set unique to groups of settings that would further promote interoperability in specific settings like long term care, behavioral health, specialty care. **(SW)** No comment**(DK)** No comment**(SC)** ONC will need to do a thorough environmental scan to assure that requirements do not outpace the ability of vendors to develop to those requirements in a safe orderly fashion accounting for the specialized workflows of the different specialties, settings, or domains in which there clients function. This environmental scan to not only assess market readiness for requirements that meet ONCs goals but will also need to assure that ONCs goals are aligned with those of the purchasers of HIT.**(UM)** Yes, it is a process of continuous improvement. At the same time, enough consideration needs to be given for time required for development and testing of the newer requirements. Also adequate time needs to be considered for implementation of the certified technologies. In addition, gathering the feedback, providing clarifications and making adjustments to the criteria would remain to be a challenge. As stated previously, broadening the scope of program to cover the other entities would be necessary to ensure end-to-end interoperability. **(RM)** Agreed |
| **I1. Testing Tools** | **General Comments** | **Please provide general feedback that may not necessarily relate specifically to Section I** |
| **KAM:** Nothing further.**Mario G Hyland:** 1) **Certification Programs**should leverage proven test cases.  Far too often we have observed organizations (including ONC) publish Certification Test Cases which the industry as a whole has not benefited from having an opportunity to "Test the Test".  We believe any mature Certification program will publish in draft form a series of Test Cases which Industry has an opportunity to vet "test out" within their systems.  This allows industry an opportunity to report back on the "maturity" (status) of support and identify any potential challenges which may exist, which later on could/may prove to be politically difficult for a Certifying Body to execute and report on or enforce.    We remain concerned that during these efforts, Certification based Test Cases could be released which limited (or very few) EHR vendors may be able to pass, this would provide those few with a significant market advantage.  Later, facing increased public pressure the Certification Body may try to relax some of the published Testing requirements (potentially deemed too difficult).  With our proposed proactive approach to introduce test cases early to industry and to provide an opportunity for feedback - we believe ONC could avoid potentially politically difficult situations in the coming years.    2) **Negative and Exception Error Handling type Testing**.  Organizations such as Gartner, AMA and others (including AEGIS) have spoken to the lack of negative testing within Health IT implementations as an industry wide issue.  We remain concerned that ONC in an effort to address "Negative" or "Exception" calls for Test Cases, will introduce a sprinkling of Negative Test Cases across the Certification Testing Program.  Our concern centers on the readiness of Vendors EHR systems supporting Patient Safety concerns in the real world.  Our desire is that ONC share with organizations such as ours, the objective and approach to support "Negative" and "Exception" type testing.  Nearly 70% of what we test involve either negative or exception conditions.  Meaning, publishing a Certification Program which claims 5% or even 10% Negative or Exception test cases does not ensure the rigors appropriate for a "Production Ready" system.  Please note, we are not proposing that the ONC Certification Program undertake a burden of forcing EHR Vendors into an undertaking of 300% or 400%  more testing, rather we propose developing comprehensive suites of "Negative" or "Exception" test cases, and fielding those in trial mode.  The Certification Program could randomly select from those suites up to 5% or 10% of the negative test cases, thereby exposing a Vendor EHR to typical real world situations.   We are working to establish a mechanism to gradually raise the bar so that EHR Vendors learn over time that more rigorous testing will be required.   3) Understand that **Health IT Interoperability**will encounter a variety of versions of standards and specifications within the Health IT Community.  AEGIS is currently focused on educating and supporting the Health IT community ensure not only Interoperability, but rather to recognize and support"Continuous Interoperability" going forward.  This requires that ONC and others SDO (Standards Development Organizations) and Standards Bodies recognize that standards are continuously evolving.  Our approach to ***Test*** an EHR which claims support for Interoperability will require they demonstrate an understanding of and support for multiple versions of a standard which may exist in Production and ensure they remain both backwards compatible along with future proofing.     If ONC reviews Healtheway eHealth Exchange they will see a combination of 2010 and 2011 versions of specifications being supported simultaneously, with multiple versions in Production at this time.  Many organizations support either 2010 or 2011, while some support both 2010 and 2011 at the same time.     AEGIS has quickly learned that the Health IT Community can not move in locked step.  We need to ensure our approaches to Testing and Certifying Health IT EHR solutions address these concerns.   4)  **Avoid One-and-Done**.  The Certification Program should not seek to claim an EHR Vendor product is certified today and remains certified indefinitely.  Experience has demonstrated that many organizations which obtained their ONC Meaningful Use Stage 1 Certification, remained under product development with patch releases and product updates - while rarely returning to their ONC Certification ATB for retesting (note: some vendors did operate at higher levels of adherence than others).  But, by far a majority of EHR vendors did not return for retesting.  We really should consider doing a deeper dive of analysis into this effect if we are to recognize the risk to patient safety and ensure Certification Programs in the future have higher degrees of assurance of Patient Safety.    Rather than a point-in-time Certification being the sole measurement for an "EHR" Production readiness, we would like to propose to ONC that "Quality Assurance" be considered as a future measure for EHR Vendors to strive towards.  We are in the process of publishing a "Case Study" based on our recent engagement with HHS/OPA in which we were able to demonstrate a number of these best-practices.     A) **Test-early Test-often**, by supporting the EHR Vendor incorporate into their standard development lifecycle better testing approaches.  Where appropriate link EHR Testing which are standards based to a Shared Services Testing Platform which is leveraged by the community at large.  Similar to implementing an Industry Standard (which many agree is a best-practices towards eventual Interoperability), why then are we (each organization) developing unique individual approaches to testing.  AEGIS believes that there is a better way, a cloud based testing service which has been called The AEGIS Developers Integration Lab (DIL).     B)  **Providing Feedback Loops to SDO's.** Far too often AEGIS (along with many other organizations) has borne witness to a general lack of feedback to the many SDO's who publish standards.  Numerous implementations fail to include the SDO's in difficult implementation discussions.  We believe there is a significant opportunity for improvement, by supporting a Shared Services based Testing Platform - the SDO would be kept apprised of which standards were being tested, how the testing was progressing, and when applicable, what areas of the standards or specifications are proving more difficult to implement - with a potential solution being to issue a CP and improve the standard for future implementations.     AEGIS believes there is a significant opportunity to ensure future standards and specifications would decrease adoption time, and improve Interoperability if a Shared Services based Testing Platform were utilized.      C) **Test Driven Development (TDD).**  Integrate testing systems end-to-end earlier in the process.  Provide the tools to the Developers and any organization tasked with ensuring EHR or Health IT systems are operating correctly - this approach improves Patient Safety.   5)  **Leverage Industry Experience**.  The ONC continues to offer as a core mission their desire to engage with Industry. AEGIS is an active member of the Health IT Community who has advanced Standards based Testing to a new level.  Our Cloud based testing approach delivers to a Global Community a suite of Standards based testing capabilities which could be leveraged by anyone or any organization.  Currently we are the Testing Platform used by Healtheway for the eHealth Exchange and HL7, one of the largest standards organization.  The Developers Integration Lab (DIL) is a sponsor based approach, which offers that to any organization once the test cases have been developed and published they are FREE to the entire community.      AEGIS continues to offer as evidence the National ROI for a Shared Services based Testing Platform the following, Healtheway on average paid $576/per test case commissioned to be implemented into the AEGIS DIL.  Over the course of the first year, the cost per test execution was $0.06/cents.  After the second year, the cost per test execution was $0.01/cent.     Why would the government seek to compete with Industry rather than collaborate with Industry best practices and Industry leaders who are demonstrating a better way forward.    6)  **Gamification of Testing EHR and Standards**, During the past few months AEGIS has embarked on the next generation of our testing approach.  Our recent engagement supporting HHS/OPA allowed us an opportunity to challenge the Health IT Vendor community to improve the Quality of their implementation and be rewarded for doing it.  The ingredients to arranging this situation include: a new standard, a group of vendors, and a finish line (to aim for).       A) HHS/OPA was the sponsor for a new IHE Profile called Family Planning (FP) published August 2014.       B) HHS/OPA contracted with AEGIS to aid in advancing the implementation of this new FP standard.       C) HHS/OPA and AEGIS canvased the vendor community and located a number of (3) vendor organizations interested in participating in implementing this new standard.       D) Objective: Attend the IHE Connectathon with the three (3) vendors and prove to IHE that the standard was Interoperable. A final step in any standards maturity process.  A feat rarely accomplished in the first year a standard has been published.         E) By implementing the standard via Test Cases within the AEGIS DIL the Vendors were able to in a "self-service environment" advance their implementations in near record time.       F) AEGIS developed a rubric (with a points system) and notified the vendors they were in competition for an all-expenses paid trip to the HIMSS National Conference and Interoperability Showcase - and their company and product would be showcased as successfully implementing the IHE FP Profile.       G) The resulting effect was that the vendors recognizing they were in competition with each other, and Quality was the measure by which organizations were being judged - resulted in something unique (dare we say "magical") the vendors found it fun and challenged each other.  Not to get to market first, but rather to out do the other organizations on **Quality** of the systems and versions of the software they published.      H) In summary, the net effect of our efforts were that three (3) new organizations who had never been to an IHE Connectathon, attended and all passed the 2015 IHE Connectathon Testing associated with IHE FP Profile.  Additionally, (3) other organizations were engaged who had never read about or implemented the IHE FP Profile, yet were able to, with the aid of the AEGIS DIL and the IHE standard, implement (develop), test and pass the IHE Connectathon within the event's single week period.  A total of six (6) Organizations passed a brand new profile at the National IHE Connectathon Event.  This was something which we believe has never been accomplished before.  7)  **Education thru the use of Testing Standards.** AEGIS continues our outreach to the communities at large AMIA, AHIMA, CHIME and others in an effort to push forward with approaches to improve the Education of Health IT adoption based on Standards development thru improved Testing Approaches.  We believe Testing will play a critical and essential step in the future education of Interoperability and Standards development.**(SC)** It is critical to adjust timelines to allow for all participants in the process to comment, develop, and implement in a safe fashion recognizing the complexity of the healthcare delivery system and the need to avoid disruption that can adversely affect the care that is provided. I will reiterate what John has said and was covered in detail in our recent Kaizen. I will reiterate some of those points. Many vendors have developed products over decades that take into consideration specific workflows of different medical specialties. What an Ophthalmologist requires in an EHR is nothing like what a cardiologist needs. These compressed timelines and one size fits all requirements have led vendors to constrain workflows for MU elements to a single workflow. There is simply inadequate time to tailor requirements to each specialty, especially considering the ancillary requirements to calculate numerators and denominators. Stage 2 introduced too many new requirements that were not already being developed based on client requirements so workflow efficiency has suffered. Development is not the only factor in the timeline. Once a vendor analyzes the requirement, does a gap analysis, identifies impact to existing workflows, identifies dependencies, identifies if copyright releases must be obtained or third parties contracted with, writes requirements, develops, unit tests, QAs, creates training materials, alpha tests, beta tests, adjusts all of the preceding based on that feedback, trains internal staff and support, and makes their products available to clients, the clients have a complex set of activities before they can start to use these products. They also have to do an assessment of there existing products and where the upgrade might affect their functioning, plan for any changes that must occur first, purchase and install any additional hardware to support the upgrade, train, test, redesign workflows, acquire and train additional resources if needed for the workflow changes (someone to take vital signs, scribes, etc.), write up their own training materials, changes policies and procedures as necessary, purchase any new interfaces, acquire any new resources needed to support the new interfaces/functionality (portals, syndromic immunization, onboarding, testing, etc.) So requirements need to be limited to support use cases that have broad stakeholder approval and support, will have a measurable impact on the triple aim, are limited enough to be feasible within the identified timelines, and that leverage mature standards and code sets. |

Comments Received:

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