



Meeting Notes

Health Information Technology Advisory Committee Conditions and Maintenance of Certification Requirements Task Force April 12, 2019, 3:00 p.m. – 4:00 p.m. ET Virtual

The April 12, 2019, meeting of the Conditions and Maintenance of Certification Requirements Task Force (CMCTF) of the Health IT Advisory Committee (HITAC) was called to order at 3:00 p.m. ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

Lauren Richie conducted roll call.

Roll Call

MEMBERS IN ATTENDANCE

Raj Ratwani, Co-Chair, MedStar Health
Denise Webb, Co-Chair, Individual
Kensaku Kawamoto, Member, University of Utah Health
Carolyn Petersen, Member, Individual
Sasha TerMaat, Member, Epic

MEMBERS NOT IN ATTENDANCE

Leslie Lenert, Member, Medical University of South Carolina
John Travis, Member, Cerner

ONC STAFF

Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC)
Kate Tipping, ONC Conditions of Maintenance of Certification Requirements Task Force Lead
Lauren Wu, ONC SME

Lauren Richie turned the meeting over to Raj Ratwani, co-chair.

Raj Ratwani suggested editing the recommendations real-time based on the feedback received from the HITAC.

Sasha TerMaat made changes in the shared document throughout the meeting which the task force discussed and clarified. The edits made during the meeting are reflected below.

Recommendation 2

ONC should reconsider the due date for real world testing plans. The Committee recommends ONC provide more flexibility for the deadline that will avoid holidays and avoid overloading the ONC-ACBs/federal government. The Committee recommends an alternative for 170.405(b)(1): instead of



requiring submission of an annual real world testing plan to the ONC-ACB via a publicly accessible hyperlink no later December 15 of each year, require submission no later than the latest certification anniversary date each year for the health IT developers' applicable certified 2015 Edition Health IT modules.

This will be moved to considerations: The CMC TF supports the idea of a pilot year and recommends having ONC-ACBs assess plans from the pilot year then come up with a template for vendors to use.

Recommendation 3

The Committee recommends ONC provide more clarity in the preamble of the final rule around the care settings/venues the test plan must cover with the goal of making minimum expectations clear and establishing which settings and the number of settings for the applicable certified health IT modules.

Recommendation 4

The Committee recommends ONC provide guidelines in the preamble of the final rule for a test plan and also suggest, after the pilot year, the creation of a standardized template incorporating the elements of an acceptable test plan. The Committee supports the proposed pilot year.

Recommendation 5

The Committee recommends ONC provide clarity in the final rule preamble on how successful real world testing is met for the following: (1) continued compliance with certification criteria (including standards and code sets), (2) exchange in intended use settings, and (3) receipt and use of electronic health information in the certified EHR. The CMC TF reviewed and determined not all three elements are possible for *all* certification criteria proposed for real world testing.

Recommendation 6

ONC should clarify and define the terms, “scenario” and “use case.” (170.405(b)(1)(iii)(A) If these terms mean the same thing, choose and use just one of these terms in the regulatory text and in the preamble. ONC should also clarify the term “workflow” as it is used in the preamble regarding real world testing.

The TF recommends ONC clarify in the final rule preamble where existing interoperability testing (such as that performed by The Sequoia Project or other existing networks) can satisfy expectations for real world testing.

Recommendation 7

We recommend modifying (170.405(b)(1)(iii)(A) to also include as permissible testing approaches automated testing and regression testing:

- (A) The testing method(s)/methodology(ies) that will be used to demonstrate real world interoperability and conformance to the certification criteria's requirements, including scenario, use case-focused, automated, or regression testing;



Recommendation 8

The task force decided to break this recommendation out and add additional context included in the discussion, resulting in the following changes. There was a lot of discussion about how to best approach this during the call, these details were included in the discussion section of the recommendation.

Recommendation

The TF recommends ONC provide clarification in the final rule preamble around testing the exchange of information, or about the use of the information. When there are no end users of the product being tested, use-based testing would not be pertinent.

The TF recommends ONC expect that if health IT developers are testing the use of data received through exchange, the health IT vendors should have intended users involved in usability testing.

Users (providers) were not considered in the cost estimates for real world testing in the proposed rule preamble. The TF recommends ONC revise cost estimates to incorporate this.

To reduce cost, the TF recommends ONC prioritize real world testing criteria based on risk.

Discussion

The task force thinks testing of the use of information is important to the usability of interoperability. Testing the use of that information requires consideration of human factors and usability to understand whether the intended users efficiently and effectively use the presented information.

Use of data testing would be pertinent to the receipt of data in the EHR. If health IT developers are testing the use of data received through exchange, the health IT vendors should have users involved in the testing to validate that users can process and use that information. When certified health IT products receive “foreign” data, we have heard user feedback desiring it be presented in the same view as the “native” data to be useful and reduce the burden on providers using the technology. The intent of this task force is not to prescribe certain design approaches but to encourage user-centered design. The CMC TF recommends the use of data testing to validate the data a user receives in the certified health IT is viewable, actionable, and reportable alongside the user’s native data.

The task force recognizes that the expense of this testing is significant, for both health IT developers and users of HIT. The task force significantly discussed the costs of this proposal, for multiple players: vendors, the other interoperability partners who would be involved, provider organizations and users. The concern was how to prioritize where testing is helpful without unnecessarily increasing cost or burden.

Recommendation 9

The TF recommends ONC clarify in the final rule preamble the expected involvement of providers and third parties to support the “real world” nature of the testing.

The TF recommends ONC provide guidance in the final rule preamble on testing options that address the use of simulated data and address requirements for unidirectional versus bidirectional test cases. For example, the final rule should clarify whether the health IT developer is required to provide testing for both endpoints/sides in a bi-directional testing scenario.



Recommendation 10

The TF recommends ONC allow in the final rule preamble for flexibility for vendors with regard to real world testing where there is no difference in the testing approach, result or capability. The CMC TF suggests the preamble address the following:

- Common capability – test once across all settings and test cases if truly the same capability for the same requirement
- Unchanged capability – allow the vendor to attest to capabilities that remain unchanged from prior year
- Common requirement – test once if the requirement does not vary across all settings and test cases for requirements such as secure communication
- Production experience – clarify whether real world testing is required for what already has long-standing evidence and history of operating in real world production environments
- Clarify applicability of requirement for various practice and care settings. For example, clarify whether all of the named CDA/document types apply to every venue
- Attestation – allow for attestation instead of retesting

Sasha TerMaat suggested that the task force continue to edit the remaining recommendations offline and review the changes on the next call.

Lauren Richie opened the lines for public comment.

Public Comment

There was no public comment, but Sasha TerMaat read Didi Davis' comments below to the group.

Comments in The Public Chat

Didi Davis (The Sequoia Project): Don't forget that The Sequoia Project does perform "real world" testing today for the eHealth Exchange network that exchanges data with 75% of the US hospitals with the federal agencies.. It may be good to include comments that industry programs should be assessed.

Didi Davis (The Sequoia Project): The testing that is performed today covers transport, security and content for data quality.

Didi Davis (The Sequoia Project): I am not dialed in, thank you for reading this.

Didi Davis (The Sequoia Project): Agree, it should be called out better.

Didi Davis (The Sequoia Project): Our federal partners and all consumers use the information.

Didi Davis (The Sequoia Project): Thank you. for your consideration.



Didi Davis (The Sequoia Project): VHIE is doing early use testing with vendors as our partner. They are one of the most advanced users of the data and we are working together to improve the data quality.

Didi Davis (The Sequoia Project): VHIE = Veterans Health Information Exchange.

Next Steps and Adjourn

The next meeting of the task force is Wednesday, April 17 at 10:30 a.m. **Lauren Richie** adjourned the meeting at 4:00 p.m. ET.