



July 31, 2017

National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
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Washington, D.C. 20201

Submitted electronically at: https://www.healthit.gov/policy-researchers-implementers/interoperability/Proposed_Interoperability_Standards_Measurement_Framework_Public_Comments

Re: Proposed Interoperability Standards Measurement Framework

Dear Dr. Rucker,

Thank you for this opportunity to comment on the Proposed Interoperability Standards Measurement Framework.

As an electronic health records (EHR) developer based in Verona, Wisconsin, Epic actively encourages interoperability and has significant experience in measuring it for Epic users. Our first sites went live with Epic's interoperability application, Care Everywhere, in 2008. As of 2014, all U.S.-based Epic organizations—which includes over 1,800 hospitals and 34,000 clinics—use Care Everywhere to exchange patient data with each other and with healthcare institutions that use other EHR systems. Over 2 million patient records are exchanged daily using Care Everywhere.

Epic software continually measures user interoperability and provides dashboards and reports that help organizations improve interoperability. Many Epic community members have publically shared their interoperability exchange statistics, and the Care Everywhere Governing Council shares network-level statistics with the industry (see [Appendix 1: Network-Level Statistics Shared at HIMSS 2017](#) for an example). The suggestions we make in this letter are informed by our years of experience measuring interoperability and supporting the healthcare organizations that rely on it to provide quality care.

We think it's important to both measure interoperability and find ways to improve it. We are glad to see ONC taking this step to quantify existing interoperability, which we believe is underestimated. We also value the effort to drive change based on statistics rather than speculation. However, we believe that the goal of measuring the use of standards should be to improve quality-based outcomes for patients, and the volume of standards use does not necessarily correspond to improved outcomes. We acknowledge that this goal of measuring outcomes is out of scope for this project and the current reporting capabilities. We envision this initiative as a first step toward a long-term focus on the measurement of outcome and impact.



To be successful with this first initiative, we believe ONC should:

- **Select a small number of metrics to avoid overburdening data collectors.** Around five measures collected annually is reasonable. A larger measure set is likely to prove burdensome and reduce overall participation. We suggest measures below in our comments for objective 2b.
- **Engage with healthcare organizations.** Data regarding what happens in an EHR belongs to healthcare organizations and sharing that data, whether directly or through a health IT developer, requires the participant's agreement. ONC needs to involve healthcare organizations so those organizations understand the value of this initiative and contribute their data.
- **Define measures in detail to avoid ambiguity about what is measured.** Measure definition is the most critical part of this project because poorly specified measures can lead to inconsistencies in reporting and, in turn, less meaningful data that limits the value of this initiative.
- **Avoid creating burdensome data capture or over-prescriptive workflows.** While defining measures, keep in mind the amount of stakeholder effort required for reporting and whether the measure's definition places limits on workflows. To provide meaningful data, the initiative must not burden stakeholders or restrict workflows.
- **Determine how to present and interpret data to avoid drawing false conclusions about what current interoperability trends mean.** There are countless variations in interoperability patterns based on factors such as shared EHRs (where data is available without using specific interoperability standards), patterns of clinical practice, clinician preference, innovations in types of HIT tools and approach, and more. Overlooking these factors can lead to false conclusions about the data. For example, a lower rate of sending e-prescriptions to a pharmacy network might not indicate that prescriptions are being printed, but rather that the clinician and the pharmacy share access to an integrated system. Users of the data should exercise caution in presenting the data and drawing conclusions to account for nuances not captured by this initiative.

We've attached specific comments on the objectives proposed and responses to your questions. We are happy to discuss further or contribute our expertise in interoperability measurement to this project.

Sincerely,

Peter DeVault
Vice President of Interoperability
Epic

Objective 1a: Standards in Development Plans

In objective 1a, ONC proposes that health IT developers report which standards are part of their development plans. In general, we agree that publicizing planned standards development helps ensure that different parties across the industry invest in the same standards. Today, health IT developers often do this by communicating with other systems they work with and by participating in standards development organizations and interoperability projects such as the IHE Connectathon and HL7 CDA Implementathon.

However, reporting of future standards use would need to be voluntary to account for scenarios where publicly sharing standards that are under consideration would be premature or would place the developer at a competitive disadvantage. For example, it might be too soon to report a planned standard if the development is in an early stage and standard use hasn't been firmly decided. Alternately, the standards being considered might reveal competitively sensitive factors such as a developer's launch of a new product line. Collecting this data voluntarily supports sharing when aggregate information on standards usage is valuable, while allowing for reasonable exclusions when sharing the information could have negative consequences.

Objective 2a: Standard Used by End User

To identify deployed standards that aren't used by end users, ONC proposes that health IT developers and exchange networks "publicly report what percentage of end users [...] have actually used a particular standard." ONC also explains that "clearly establishing what counts as 'use' will be a vital step" in the process. We agree that establishing clear definitions is essential before reporting can begin. Without specificity, developers are unlikely to report uniformly and the data won't be meaningful. Currently, it isn't clear how to interpret the denominator, attribute the use of a standard to particular users, or address the fact that some standards are applicable to only certain users.

- **Denominator.** Without a clear definition of the denominator, there won't be standardized, meaningful data. For example, past ONC-contracted surveys use a denominator of "ambulatory practices." This term isn't defined or standardized. One developer might consider a two-doctor clinic to be an ambulatory practice, while another developer might think a multi-specialty network is an ambulatory practice. Some developers might not count users by practices at all but might have different metrics, such as the number of clinicians with a particular license. Even the more-standardized concept of a hospital has some ambiguity. For example, Medicare does not consider children's hospitals as hospitals in their definition, but it makes sense to consider children's hospitals as hospitals for the purpose of measuring interoperability. Clarification is key for the success of this objective.
- **Use and attribution.** Defining what counts as a use and how the use is attributed is also essential to ensure meaningful data. For example, suppose a developer is reporting the percentage of its users who submitted immunization data to a registry using a particular standard. Consider the challenges of counting uses in the following relatively simple scenario:

At a family practice, a physician places an order for an immunization, and the nurse administers the immunization to the patient. Every few minutes, the EHR system sends a batched message to the immunization registry of all immunizations documented since the last batched message.



First, the denominator must be clear. It isn't obvious whether the denominator should be 2 (the physician and nurse) or 1 (the physician or the team). Second, it isn't technically accurate to say the physician or nurse used the standard because the data was sent automatically by the EHR and neither user interacted with the standard directly. However, both play important roles in a workflow that sends the expected data to a registry. Counting by user, you get a numerator and denominator of 2/2 even though there was only one message.

- **Applicability.** ONC must also recognize that not all standards are applicable to all users. For example:

A pediatric practice and an ophthalmology practice share the same EHR, which is configured to automatically send any immunizations administered to a registry using the standard. Pediatricians order immunizations frequently; ophthalmologists don't order any this year because immunizations aren't relevant to their practice.

Has the ophthalmology practice used the immunization registry sending standard? It might be technically correct to say that the ophthalmology practice didn't use the standard, but that conclusion doesn't accurately reflect the goals of this initiative, considering that any immunization the ophthalmologists did administer would have been sent using the standard.

As shown in the above examples, there is not necessarily a direct relationship between a user (such as the nurse in the family practice clinic) and a standards-based transaction (which might be automated or batched). Complex attempts to associate users and transactions might add more burden to measurement efforts than is valuable and should be avoided. In the example of immunizations and similar scenarios, it is better to avoid measuring the percentage of users who used the standard and instead measure the percentage of actions expected to use the standard that actually did. For example, for immunizations we would suggest the best measurement is:

Denominator: Number of immunization administrations

Numerator: Number of immunizations sent to a registry using the standard

This measurement is simpler to calculate and easier to report than attempting to assign messages to specific users or to make determinations about whether certain actions in the system constitute use of a standard.

Objective 2b: Volume of Transactions by Standard

ONC proposes that health IT developers and exchange networks "publicly report the volume of transactions by standard" in an effort to track trends of standard use. As with objective 2a, we see the lack of specificity as a challenge to ONC obtaining uniform, meaningful data.

ONC does not clearly define whether the objective is meant to capture transactions that occur outside of the health system only or transactions that occur both outside of the health system and within it. Without a clear definition, it is up to the organizations and developers to determine the scope of the objective, which might result in inconsistencies across data contributors. ONC should define the



objective to include only transactions that occur outside of the health system in order to capture the data most relevant for interoperability.

Additionally, ONC proposes that, “for transactions that include multiple steps, measurement should focus only on the most pertinent piece of the transaction.” It isn’t obvious how the “most pertinent piece” would be determined. If this objective is left open-ended, different data contributors will likely identify different pieces of a transaction that are most pertinent based on their own use case.

For example, in some cases of a document query workflow, seeing the document list with its included metadata is enough for the provider to complete a task like computing an updated risk score, such as risk of readmission. (Refer to the “LACE+ index: extension of a validated index to predict early death or urgent readmission after hospital discharge using administrative data” article for more information on how readmission risk scores are calculated: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3659212/>.) In other cases, the provider needs to retrieve several documents from previous visits to review the content. In the past year, Epic users retrieved over 438 million document lists and over 2 billion documents. Without clear definition, data contributors might define either the response to a document list query or a document retrieval as the most pertinent piece and report inconsistent metrics. ONC should explicitly define the pertinent piece of the transaction to ensure uniform reporting.

To better measure existing interoperability and determine trends, ONC should orient the data around use cases that focus on the most important areas for interoperability. That focus makes it easier to use the data to identify opportunities for improvement. For example, if the data shows the volume of transactions only by standard, you might see that a healthcare organization doesn’t use the SMTP standard but not understand why. If the volume of transactions is broken up by use case, you’d see that the healthcare organization doesn’t use SMTP to send summaries of care because they use XDR and XDS.b instead. Use cases allow you to measure interoperability across health IT developers that use different but comparable standards to accomplish the same workflow.

We propose the following five use cases, with examples of what standards they might include:

- Sending discretely structured patient charts (XDR, SMTP, XDS.b, XCA, FHIR)
- Receiving discretely structured patient charts (XDR, SMTP, XDS.b, XCA, FHIR)
- Sending data to immunization registries (HL7 v2, HTTP (WSDL), TCP/IP, PHIN MS)
- Provider-facing API use (FHIR)
- Patient-facing API use (FHIR)

These suggested use cases focus on what we identify as important areas in interoperability and keep the scope limited so data can be reasonably collected.

Objective 2c: Level of Conformance/Customization of Interoperability Standards

We anticipate that tracking conformance and customization of standards will be challenging and worry that the challenge of collection will reduce the usefulness of the data gathered. To collect conformance and customization data, ONC should use free-text responses from health IT developers. For example, ONC could supply a question like: “Are there areas that required significant standards customizations?”



We are uncertain how more structured data could be gathered, and we think narrative survey responses would provide useful input to share with standards development organizations.

Questions

1. Is a voluntary, industry-based measure reporting system the best means to implement this framework? What barriers might exist to a voluntary, industry-based measure reporting system, and what mechanisms or approaches could be considered to maximize this system's value to stakeholders?

We agree that a voluntary, industry-based measure reporting system works best for this framework. Mandated reporting would be burdensome in the early stage of the initiative while ONC continues to refine their approach.

Epic intends to voluntarily participate in gathering and submitting data and believes that market pressures will drive widespread participation. We encourage ONC to implement the initiative as a voluntary system and revisit the mandatory reporting option only after it is more established and stable.

2. What other alternative mechanisms to reporting on the measurement framework should be considered (for example, ONC partnering with industry on an annual survey)?

We agree that an annual survey is the best option for reporting and suggest involving Standards Developing Organizations (SDOs) to better ensure that data informs standards creation.

3. Does the proposed measurement framework include the correct set of objectives, goals, and measurement areas to inform progress on whether the technical requirements are in place to support interoperability?

See our comments on the proposed standards measurement framework above.

4. What, if any gaps, exist in the proposed measurement framework?

We identified the measurement approach for objective 2b as a gap. See our comments on Objective 2b: Volume of Transactions by Standard above.

5. Are the appropriate stakeholders identified who can support collection of needed data? If not, who should be added?

Healthcare organizations are important stakeholders to include in the discussion because healthcare organizations own much of the data that ONC proposes collecting. A health IT developer can obtain and report on the data only with permission of the healthcare organization. Without the support of healthcare organizations, the data returned won't be comprehensive and it will be difficult to accurately gauge standards use across the industry. ONC should also include public health agencies as stakeholders to support the collection of data sent to these agencies.

6. Would health IT developers, exchange networks, or other organizations who are data holders be able to monitor the implementation and use of measures outlined in the report? If not, what challenges might they face in developing and reporting on these measures?

We identified the following potential challenges to developing and reporting on these measures:

- **Number of measures.** Developing methods for tracking and reporting many measures would require significant effort. With too many measures, it is likely health IT developers couldn't report on all of them in the reporting period and would instead choose only certain measures. Different prioritization of measure implementation between developers could result in less useful data. As we recommended above for objective 2b, ONC should limit the scope of measures to roughly five priority areas so developers are not overburdened.
- **Lack of specificity.** We identified in our comments on objective 2a and objective 2b above that not clearly defining measures might jeopardize the data's uniformity and make it difficult to draw accurate conclusions. Additionally, how ONC defines the measures determines the amount of time that health IT developers and healthcare organizations need to spend to report on the data. ONC should carefully define the measures to make expectations for reporting clear and, to the best of their ability while prioritizing the initiative's goals, minimize the effort required to gather data on the measures.
- **Data ownership.** As described in question five, the healthcare organization itself owns much or all of the data, even in cases where the developer hosts the system. This provides a challenge for health IT developers and exchange networks in cases where they don't have permission to report on the data. ONC should engage healthcare organizations to encourage data contribution.

7. Ideally, the implementation and use of interoperability standards could be reported on an annual basis in order to inform the Interoperability Standards Advisory (ISA), which publishes a reference edition annually. Is reporting on the implementation and/or use of interoperability standards on an annual basis feasible? If not, what potential challenges exist to reporting annually? What would be a more viable frequency of measurement given these considerations?

We agree that reporting annually is feasible and appropriate. Additionally, ONC should specify the amount of time stakeholders have to gather the data. We suggest providing a submission date one quarter after the end of the reporting period. A quarter gives stakeholders the time needed to gather data.

8. Given that it will likely not be possible to apply the measurement framework to all available standards, what processes should be put in place to determine the standards that should be monitored?

ONC should create a public prioritization process to allow for stakeholder input, which will keep the standards monitored more relevant. Using our proposal for use case measures, it should be easier to determine which standards to monitor because narrowing the focus naturally narrows the list of relevant standards.



9. How should ONC work with data holders to collaborate on the measures and address such questions as: How will standards be selected for measurement? How will measures be specified so that there is a common definition used by all data holders for consistent reporting?

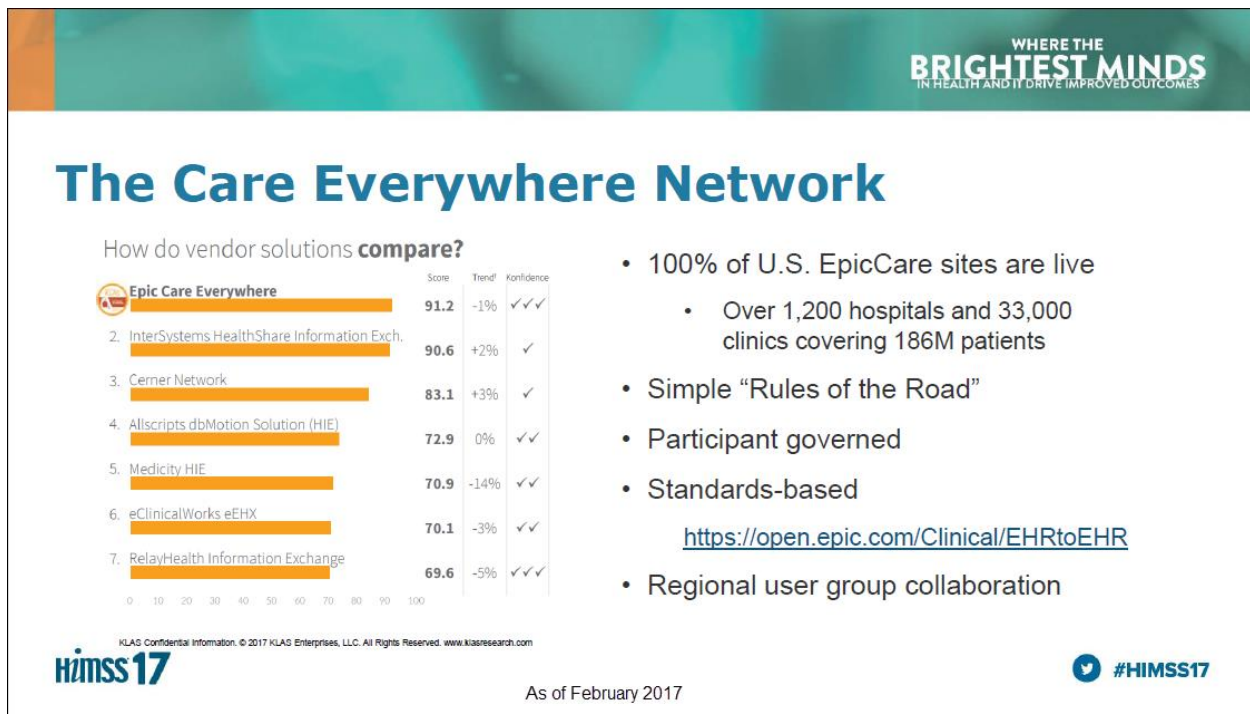
As described in question 8, ONC should create a public process to get stakeholder input on the prioritization of standards, measures, and other relevant topics.

10. What measures should be used to track the level of “conformance” with or customization of standards after implementation in the field?

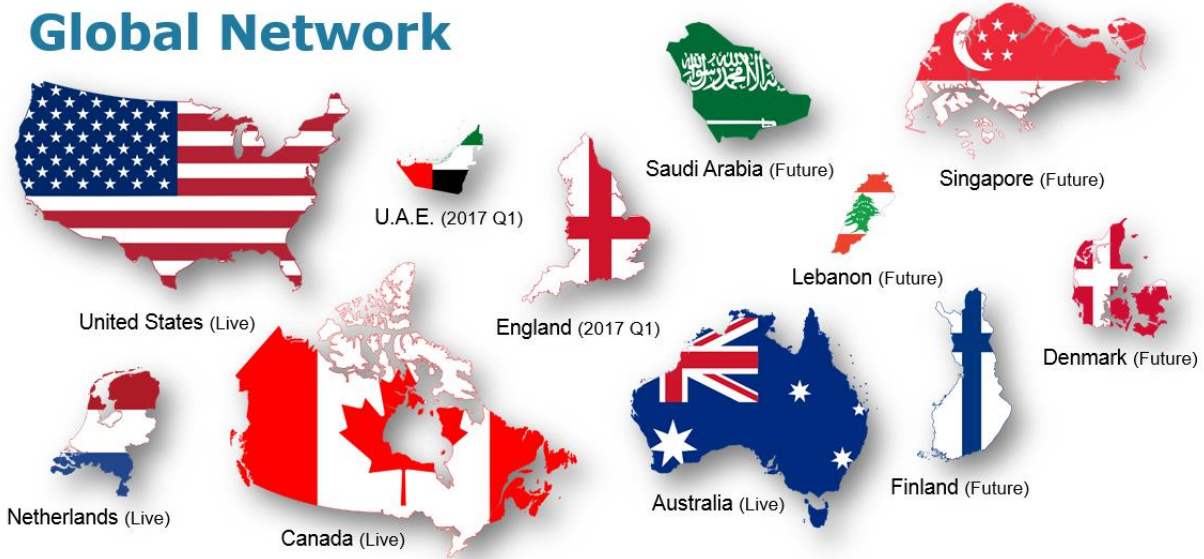
See our comments on Objective 2c: Level of Conformance/Customization of Interoperability Standards above.

Appendix 1: Network-Level Statistics Shared at HIMSS 2017

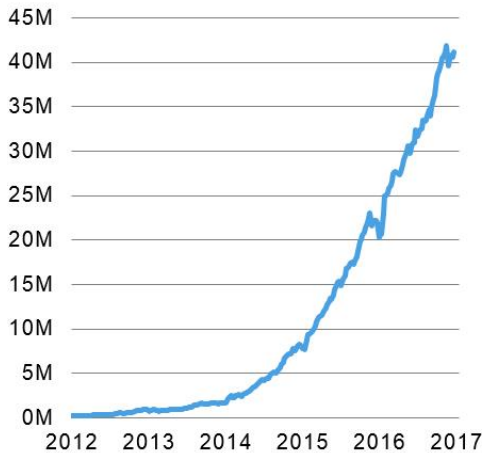
We've included a selection of slides from the Care Everywhere Governing Council's 2017 HIMSS presentation, Promoting Expansion and Innovation in a Mature HIE Network, to demonstrate our continued effort to share interoperability statistics. The full presentation is publically available online (http://www.himssconference.org/sites/himssconference/files/pdf/20_1030%20HIMSS%202017%20EPI%20Presentation.pdf).



Global Network



Patient Record Exchanges per Month



Interoperability Exchange Statistics Sutter Health

Care Everywhere 2016 Year in Review



We've exchanged patient records with organizations spanning



23,095,907
patient records exchanged in 2016

12,371,337
patient records exchanged in 2015

40,613,037
since Care Everywhere Go-Live in 2010

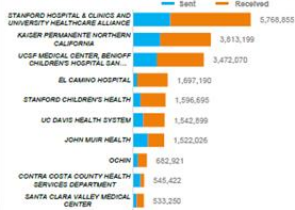
We've exchanged patient records with more than

910
hospitals

1,360
emergency departments and

25,080
clinics

Top Patient Record Exchange Partners in 2016



Incorporated Outside Data

In the past year, clinicians added:

Problems	Allergies	Medications	Dispenses	Immunizations
186,983	71,789	209,053	444,230	409,924

Implemented Features

- Carequality**
We are Carequality connected!
Connection Live Since: 03/09/2016
- Government Connections**
We are live with all available connections
VA Live Since: 08/05/2015
SSA Live Since: 12/16/2015
DoD Live Since: 07/11/2016

Discrete Data Reconciliation

64,604,928

Medications

5,184,025

Allergies

12,576,195

Problems

14,615,546

Immunizations

Outside information added to the local chart in 2016

HIMSS17

#HIMSS17

Hospitals Using Epic Connected to Government Agencies

