Proposed Interoperability Standards Measurement Framework Public Comment Form

INSTRUCTIONS: **ALL** comments must be identified as **Critical, Substantive or Administrative**. Comments not marked will be considered Administrative.
Critical - indicates non-concurrence with the document until the comment is satisfactorily resolved; convincing support for critical comments must be provided.
Substantive - indicates that a section in the document appears to be or is potentially unnecessary, incorrect, misleading, confusing or inconsistent with other sections; requires convincing support.
Administrative - corrects what appears to be a typographical, format or grammatical error.
All comments with a Request for Action must have a complete recommended change with a complete rationale provided.

Page #	Comment Entry Date	Critical/ Substantive/ Administrative	Comment (No Action)	Comment (Request for Action)	Commenter Name/Organization
Question 4	6/14/17	Substantive		Document requests answers to questions on page 10. Question 4 - What, if any, gaps exist in the proposed measurement framework? Response: As per the Introduction, if the widespread exchange of health information is not achieved by Dec 2018, ONC is required to issue a report that identifies barriers to achieving widespread interoperability. The Measurement Areas as written appear to be insufficient as none of the measures address the question of barriers to implementation. Recommend a question related to barriers to implementation be added to each Measurement Area.	DHA Dee Leggett, PRMD Dee.C.Leggett.Ctr@mail.mil, 703-861-3335
Question 3	6/14/17	Substantive		Document requests answers to questions on page 10. Question 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? Response: As written it appears the Measurement Area is intended to capture the number of data holders that are planning to implement or have implemented a specific standard. Therefore identification of standards with a unique identifier and identification of the status of planned or implemented with standardized planned/implemented description conditions are recommended so as to decrease the risk of double counting the status of a given standard by a given Data Holder and to facilitate data capture across many organizations.	DHA Dee Leggett, PRMD Dee.C.Leggett.Ctr@mail.mil, 703-861-3336
Question 9	6/14/17	Substantive		Documents requests answers to questions on page 10. Question 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? Question 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? Response: The document itself did not identify that only a subset of standards might be measured. Recommend adding a paragraph addressing the constraint and the potential criteria for selection. Recommend the following addition regarding criteria: Criteria for selecting the standards to be measured will relate directly back to the "calls to action", "commitments", and end state of nationwide interoperability described in the 2015 ONC Interoperability Roadmap referenced in the Introduction. Standards that are selected will be the end-point standard, or the most important standards required to achieve the previously stated interoperability goals.	DHA Dee Leggett, PRMD Dee.C.Leggett.Ctr@mail.mil, 703-861-3337

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Overall Document	6/8/17	Substantive	Because it would measure the wrong thing, using the proposed measurement framework will provide little, if any, useful information about progress towards healthcare interoperability. It will divert/waste a great deal of attention, resources, and time. Healthcare interoperability is the functional requirement/desired end-state. Per HIMSS, "In healthcare, interoperability is the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged." and "Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities." Standards are non-functional requirements that inform, enable, or constrain the execution/fulfillment of functional requirements. HIMSS does not define healthcare interoperability as being the rate or degree of adoption of standards. Progress towards healthcare interoperability is best measured by first defining the healthcare scenarios and associated data exchanges that make up healthcare interoperability and then measuring/tracking the successful (and repeatable) execution of those scenarios and exchanges.		DHA Eric H. Strom (Desk) 571.349.0796 | (Mobile) 703.447.5315 Eric.H.Strom.CTR@mail.mil
3	6/16/17	Substantive	Key measurement areas…use of standards by end users.	This definition of end user (footnote 1) is too broad to describe how this Framework will meet the key measurement objective "… use of standards by end users".	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3652
3	6/16/17	Substantive	Exchange networks will be able to….	It would help to have an example or a definition of an Exchange network to properly appreciate the significance of this outcome.	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3653
6	6/16/17	Substantive	Objective 2. …The focus on use….	I don't quite follow how you intend to build KPI around this objective. There is some implication that end users (again what is an end user for this objective) will know when they are or aren't using the standard unless they know the code. If this is written in the context of an EHR being built with modules and the end user can use only modules they desire, then the only measurement you need is from the vendor -- which modules are being purchased and which are not. There is not enough detail in the current paragraph for this to be a KPI.	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3654
Question 1	6/16/17	Substantive	Question 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?	I don't believe there are a lot of options to consider. As much as I hate to say it, an incentive based framework would probably get you more results.	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3655
Question 2	6/16/17	Substantive	Question 2) What other alternative mechanisms to reporting on the measurement framework should be considered (for example, ONC partnering with industry on an annual survey)?	You could always tie it to meaningful use and make it a condition of certification on a yearly basis.	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3656

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Question 3	6/16/17	Substantive	Question 3) Does the proposed measurement framework include the correct set of objectives, goals, and measurement areas o inform progress on whether the technical requirements are in place to support interoperability?	As a measurement framework I feel that objective 2 does not have a clearly defined set of KPI's with specific enough targeting of outcome. If this is a living document you could break the framework into milestones much like the document "A Shared Nationwide Interoperability Roadmap". With objective 1 deliverable in the first milestone timeframe and objective 2 in the second milestone timeframe. Makes the Framework a little more Agile.	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3657
Question 4	6/16/17	Substantive	Question 4) What, if any gaps, exist in the proposed measurement framework?	Very hard question to answer using it as currently written. Each KPI needs an outcome to measure success. As the outcomes are met you will be able to identify gaps. Making it Agile will allow you to move back to any previous milestone and fill in the gaps.	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3658
Question 5	6/16/17	Substantive	Question 5) Are the appropriate stakeholders identified who can support collection of needed data? If not, who should be added?	The stakeholders are identified adequately, they just aren't tied to the objectives.	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3659
Question 6	6/16/17	Substantive	Question 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?	When I read the document the data holders are the key stakeholders in objective 1. Only they can monitor the implementation of objective 1 measures.	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3660
Question 7	6/16/17	Substantive	Question 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?	This is a great big depends! If developers need to write code to bring their product up to the current standard you have to look at many factors. I don't believe, if you look at the industry as a whole, that we have seen rapid deployment of new standards (e.g. Cerner is still using HL7 V2.x. Also, the way semantic and syntactic standards seem to update more frequently than a transport standard would indicate you might need multiple publications.	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3661
Question 8	6/16/17	Substantive	Question 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?	I would put my money on syntactic and semantic standards. Although they are probably the hardest to monitor, they present the biggest challenge to interoperability and being able to see how they are used in a given Health IT solution they would offer the biggest gain. This is where the FHIM and the ISA would present the most useful tool to developers. What we need is a concise list of what transport, syntax, and semantic standards apply to which domains. The ISA is the cookbook for interoperability and the FHIM is the ingredients.	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3662
Question 9	6/16/17	Substantive	Question 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?	The FHIM and the ISA. The problem here is that the FHIM is still a work in progress, also. It's no wonder that interoperability is so hit and miss. When every target you look at is moving, picking just one is a challenge.	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3663
Question 10	6/16/17	Substantive	Question 10) What measures should be used to track the level of “conformance” with or customization of standards after implementation in the field?	This could be the topic of a whitepaper. If customizations are made to a standard in the field it should tracked by the vendor of the health IT product. The reporting should be targeted to the type of change (e.g. modifying a value in a code set (involves the SDO) as opposed to adding a value in a code set necessarily involve the SDO of the code set until an interoperability situation occurs). Changing a transport standard would be a much greater challenge and likely involve an SDO. Changing a technical standard would be a huge task.	DHA Jan Edwards DHA Enterprise Architecture janice.r.edwards2.civ@mail.mil 210-295-3664

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4	6/12/17	Substantive	Architecture: The concept of "tracking" transactions to be able to measure use of standards is confusing. Granted, different architectures do have different capabilities, and use different standards, but not all standards are used in the same way. Suggest separating transport standards (e.g. network/architecture dependent standards used for routing or carrying payloads between systems and organizations) from content standards (such as terminology or vocabulary standards, used for helping ensure semantic interoperability). Whether the data is "stored" or "cloud based" is not really an indicator of use of standards. They may use different standards for different purposes.	Consider responding to feedback request by recommending that standards be separated into "transport, content, and vocabulary" standards, and not "architecture"	DHA Johnathan Coleman Cyber Security Division Mobile: (843)442-9104 johnathan.p.coleman2.ctr@mail.mil
6	6/12/17	Substantive	Objective 2, second paragraph: Agree that consideration also has to be given to the type of standard being tracked (transport, content, vocabulary), but it is not necessary or feasible to try to track content standards at the time of exchange. Recommend that exchange standards be tracked at the time of exchange, and content standards be tracked at the time of record reconciliation or absorption of healthcare data into the receiving system (when the payload is opened). While structured messages (e.g. HL7 v2 lab messages) can be more readily tracked for content during the information interchange, it is less desirable and possibly more privacy revealing to expose the content of the messages while in transit. The interoperability need for a more flexible and capable exchange transaction is focused on the secure, reliable, non-repudiated information interchange, and should be agnostic of content standards at time of transport. The example of how a HISP is not able to access content standards is exactly why content should be tracked separately from transport. HISPs should not be interested in the content while performing routing, which is by design.	Provide feedback to ONC recommending to separate concepts of transport standards vs content standards.	DHA Johnathan Coleman Cyber Security Division Mobile: (843)442-9104 johnathan.p.coleman2.ctr@mail.mil
8	6/12/17	Substantive		Table column "Data Holders", first row, item (a). Recommend to ONC to add SDOs to the list of data holders. They will know which standards are on a development plan, as they will have project scope statements and will be on a development / balloting timeline. Without involvement from SDOs, standards under development are not standards.	DHA Johnathan Coleman Cyber Security Division Mobile: (843)442-9104 johnathan.p.coleman2.ctr@mail.mil
Question 3	6/12/17	Substantive		Question 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?" Consider separately measuring transport standards, content standards, terminology standards, and security standards.	DHA Johnathan Coleman Cyber Security Division Mobile: (843)442-9104 johnathan.p.coleman2.ctr@mail.mil

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Question 4	6/12/17	Substantive		Question 4: "What, if any gaps, exist in the proposed measurement framework? " Consider measuring use of security and privacy standards which are tied to different interop ability needs (e.g. access control standards such as Oauth), transport (e.g. secure exchange mechanisms), and content (e.g. security and privacy labels in the CCDA).	DHA Johnathan Coleman Cyber Security Division Mobile: (843)442-9104 johnathan.p.coleman2.ctr@mail.mil
Question 1	6/19/17	Substantive	Questions 1 and 2: Do not recommend the use of the word "Survey" in case Federal Agencies have restrictions about participating in surveys. The DoD/MHS (and other Federal Partners) have participated in voluntary requests for information by the Office of National Coordinator for Health IT with proper coordination and approval for providing inputs accordingly. Future requests for information could be released by ONC in this same, voluntary format and advertised on the healthit.gov website as well as through various forums, such as the new Health IT Advisory Committee (under the Cures Act), Federal Health IT Coordinating Council, and Standards Development Organizations.	Recommend ONC use the same (or similar) process for requesting public comments on proposed artifacts, guidance, etc. Maximize distribution and awareness using the healthit.gov website and existing governance forums (such as the new Health IT Advisory Committee, the Federal Health IT Coordinating Council, Standards Development Organizations, and other applicable forums).	DHA Kimberly Heermann-Do, MHA, CBPMP Health Information Exchange (HIE) Lead J6- DHA HIT Directorate Solution Delivery Division - EHR Modernization Kimberly.A.Heermann-Do.civ@mail.mil BB: 703-350-7784 Office: 703-681-3423 Eileen K. Luterzo, MSW, MBA, ITILv3 DHA Federal Health Architecture Liaison DHA HIT Directorate (J6) Solution Delivery Division - EHR Modernization Axiom Resource Management, Inc. Blackberry: 571.263.2312 Email: eileen.k.luterzo.ctr@mail.mil il
7	6/29/17	Substantive	Item c in the measurement areas - from the producer's perspective two data pieces that could be collected would be an accounting of the optional features or extensions used. That information might assist in the standards evolution process. In a related vein, any profiles of the Standard should be highlighted		DHMSM
7	6/29/17	Substantive	Item c in the measurement areas - in the clients perspective a valuable metric would be the amount of time/LOE required to integrate a new connection using a given standard. This metric would seek to capture any ambiguities or challenges associated with the vocabulary or associated semantics of the standard		DHMSM
3	6/1/17	Substantive		"...customizing their use of the standards." **Comment**: If something is customized, it is not standardized. Consider rewording.	IPO CDR Karl Stiller
3	6/1/17	Substantive		"Measuring standards customization/conformance." **Comment**: If there is customization, it is not standardized. A measurement of 'customization/conformance' will be binary; either the 'standard' is used, or not.	IPO CDR Karl Stiller

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4	6/1/17	Substantive		"In the standards measurement framework, the term “standards” is used to refer to both standards and accompanying implementation specifications." **Comment**: The definition of ‘standards’ should be separated into different terms and made explicit earlier in the document. Throughout the document, terminology standards and implementation standards are conflated, often within the same sentence, which leads to confusion as to the actual subject being discussed.	IPO CDR Karl Stiller
4	6/1/17	Substantive		"Stakeholders' current capabilities to measure interoperability standards vary significantly across the health IT ecosystem." **Comment**: So, a standardized method of measuring the extent to which ‘interoperability standards’ [need to define what those are exactly] are in place is desired. However, the ability to perform a standardized measurement is negatively impacted by system variability. To develop this measure (or even determine if this measure is possible), a view of the ecosystem is needed. From this high-level view, a bottom up approach to develop the standardized measure may be possible, but this is not discussed at all.	IPO CDR Karl Stiller
4	6/1/17	Substantive		"The most significant variability in the capabilities of health IT developers and exchange services…" **Comment:** Citation needed. This reads as if the capabilities of both health IT developers and exchange services vary similarly. Further, the ability to track the use of standards (unclear what type of standard is intended) varies, and this variability is related in some unspecified way to the tracking of itself.	IPO CDR Karl Stiller
6	6/1/17	Substantive		Objective 2 **Comment**: Will end users really be aware of any standards (terminology sets or implementation specifications)? End users will use a system that may employ standardized terminologies or implementation specifications, but the standardization will be transparent to them. What standards are implemented in a toaster? Does the user need to know (or even care) what those are if the tool provides the desired function?	IPO CDR Karl Stiller
7	6/1/17	Substantive		"...most pertinent piece of the transaction…" **Comment**: How is this determined, and by whom?	IPO CDR Karl Stiller
Overall Document	6/1/17	Substantive		**Comment:** Overall, it is not clear what they are proposing to measure, or how to determine what to measure. By using the word "standards" to encompass different aspects of standardization (e.g., terminology, implementation), the document is unclear.	IPO CDR Karl Stiller
5	7/14/17	Substantive		The lack of interoperability is also driven by inconsistent information models.	IPO Dr. Steve Kator
6	7/14/17	Substantive		Develop plans should also specify plans for standards configuration management and sustainment.	IPO Dr. Steve Kator
7, bullet a	7/14/17	Substantive	Asking developers to publicly report the percentage of end users that have used a standard is not feasible.	Remove this recommendation.	IPO Dr. Steve Kator
7, bullet c	7/14/17	Substantive	"Stakeholders have limited experience [in measuring conformance to standards]..." Agreed. So why have you put it under "… the following components should be reported nationally on an annual basis"?	Move this to a "For further investigation" section.	IPO Dr. Steve Kator
9, para. 3	7/14/17	Substantive		An alternate approach would be to focus on data governance, with local "data stewards" being responsible for standards implementation and adoption metrics.	IPO Dr. Steve Kator
Question 4	7/14/17	Substantive		Gaps: 1. We need standards or reference models for data governance. Most organizations have inadequate data governance. 2. We need standards for information models and their implementation.	IPO Dr. Steve Kator
4	6/1/17	Substantive		What is the solution to mitigate the "lack of information" and "indirect sales" factors that negatively impact accurate measurement implementation?	IPO LCDR Bui
5	6/1/17	Substantive		Would like more elaboration on the "optionality in standards" and its difference compared to "standard customization by developers in their products". In addition, need to know if there is plan available or in development to counter this practice.	IPO LCDR Bui

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6	6/1/17	Substantive		Regarding "product version with standard implemented deployed to end users", in addition with the number of end users, health IT developers should publicly report the end users' or organizations' **identification** whom are using their products with standards implemented.	IPO LCDR Bui
9	6/1/17	Substantive		What is the process for health IT developers and exchange networks to publicly report standards use and implemented in IT products? Where/when will this information be shared with the public?	IPO LCDR Bui
6 (footnote reference 5)	6/23/17	Substantive		It would be good to start identifying common patterns for capturing point of origin/receipt of a message that may be encrypted. It may have valuable, underlying content/standards that could potentially be categorized for further analysis.	IPO Manisha Khatta
Question 6	6/23/17	Substantive		It is critical for ONC and their partners to explicitly define how data holders track/monitor the measures for the 2 goals. Subjective ideas to monitor the measures can result in many different outcomes in the data which may be hard to group/see trends. Reporting measures should be quantitatively (and qualitatively) defined; a similar concept would be eCQM and how they define how to find/collect data.	IPO Manisha Khatta
Question 7	6/23/17	Substantive		Reporting annually could be feasible, with the exception of providing additional/pertinent findings in small updates in between. It would be valuable and helpful to the industry to stay informed on any urgent data findings/analyses rather than waiting for the annual update/report. The additional findings could help mitigate barriers/gaps the industry may face.	IPO Manisha Khatta
Question 9	6/23/17	Substantive		Measures should be extremely detailed and specified. A good example of a measure specification guideline protocol is the CMS Blueprint for clinical quality measures. ONC should set up explicit guidelines (step-by-step) on how to collect the data needed for the measures. Exceptions and exclusions should be considered to ensure data has some correlation.	IPO Manisha Khatta
Overall Document	6/20/17	Substantive	We did find that it advocated policies and processes that both departments had already implemented. Chris Muir (ONC) explained that the framework targeted organizations whom have yet to really start standardizing. The framework from VA/DoD perspective seems to be low risk; we could fill it out from reporting already available. Both departments would be viewed as highly compliant by this high-level framework.		IPO Mr. Dave Calvin/S&T Division Lead
Question 1	6/20/17	Critical	There will need to be a level of mandate so that vendors comply to the reference implementation of the standards, as well as a testing suite for compliance for certification.		VHA Doug Rosendale/VHA KBS S&I
Question 2	6/20/17	Critical	Surveys are may be of tertiary interest, however they are not effective in fully understanding the true "operational" implementations of the standards. As in question one, there needs to be a target implementation so that developers adhere to the standard and can therefore demonstrate through connectathons, etc. that there are software solution that can generate and consume semantically structured data. The "test suite" for such should be accompanied by a representative simulation "DevOPs" platform of the reference implementation of the standards for the particular clinical domains and ultimately for the FHIR profiles as they emerge.		VHA Doug Rosendale/VHA KBS S&I

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Question 3	6/20/17	Critical	The objectives, goals, and measurement areas are satisfactory. However as above, ONC needs to provide "reference implementations" according to the multiple standards that expected to be complied with. This requires a "Dev Op" platform whereby disparate EHR's, other applications, services, all can test their API's within an innovative ecosystem where the known standards exist and are required for all future development. This is not to constrain development and innovation rigidly, as there will need to be enough flexibility for new standards to emerge and old standards to be modified. But at least the reference implementation of accepted standards exists in an operational test/bed for developers to utilize.		VHA Doug Rosendale/VHA KBS S&I
Question 4	6/20/17	Critical	The "Framework" is a good start and high level. Of course there will need to be more detail in measurements according to "Reference Implementations" that represent clinical use cases where interoperability matters. Syntactic measurements are less structured than Semantic measures with regard to data and meta data. The purpose of which breaks down into usefulness for simple exchange and view, vs.. clinical decisions support, or drug/allergy checks, or complex analytics for pop health. The level of interoperability to be measured need to comply with the "purpose" of the interoperability requirement.		VHA Doug Rosendale/VHA KBS S&I
Question 5	6/20/17	Administrative	Yes		VHA Doug Rosendale/VHA KBS S&I
Question 6	6/20/17	Critical	Reporting measures is a level of interest for "process" purposes. However as noted above a DevOps or Dev/Test environment would provide a representative ecosystem that can be utilized for "connectathons" to prove out applications that can adhere to open standards-based API's. An "Open Platform" model should be provided by ONC as the environment for this.		VHA Doug Rosendale/VHA KBS S&I
Question 7	6/20/17	Critical	It is possible that the process of reporting will be heavier than true testing to the standards and being able to demonstrate compliance. It would be far more efficient to focus on a Dev/Test environment as a public utility with reference implementations, rather than reports that are subject to bias and may not accurately measure S&I capability.		VHA Doug Rosendale/VHA KBS S&I
Question 8	6/20/17	Critical	There are many know and adopted standards that can be evaluated. Prioritization of which ones or which applications, or the level based on purpose can be determined. This determination should be driven by a "governance" process whereby clinical impact is foundational. As reference implementations emerge, there will be an incremental gathering of prioritized artifacts that developers can utilize. As they evolve, are modified, or new standards are required, the Dev/Test environment can evolve and be expanded accordingly.		VHA Doug Rosendale/VHA KBS S&I

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Question 9	6/20/17	Critical	Governance is critical here. The multitude of stakeholders should be evaluated or overseen by the Health IT Advisory Committee such that there is adequate representation by public and private entities. Although vendor communities should weigh in on which standards are applicable or what works and what does not work, there needs to be protections in so that vendor developers do not contribute in a proprietary way, nor opt out of compliance based on individual or group vendor biases. Accountability comes from the multi-stakholder contributions with the primary principles being open-standards-based-interoperable fluidity of data in the best interest of the patient.		VHA Doug Rosendale/VHA KBS S&I
Question 10	6/20/17	Critical	Seems to be a superfluous question, as most is answered above.		VHA Doug Rosendale/VHA KBS S&I
Overall Document	6/20/17	Substantive		First let me answer two questions you didn't ask: a) Can standards even be measured, and b) is the effort worth the cost? A) Interoperability is a yes/no proposition. There's no such thing as being 89% interoperable. No (structural) standard is interoperable out of the box because they leave too much optionality, especially in terminology. Lack of term standardization is the key barrier to interoperability. B) Understanding that if one doesn't measure something, one can't improve it, the costs to measure "interoperability" fall on a different population than those who benefit from such measurement. So when looking at different mechanisms to gather the necessary data, the cost of doing so should be considered. Some inexpensive techniques may yield useful data, while other expensive techniques might not yield much useful at all.	VHA Galen Mulrooney / VHA KBS
Question 1	6/20/17	Substantive		It is hard to imagine that you will get the participation that you desire because the cost to collect the data will be borne by those who gain little from the data. Interoperability is already seen as a cost by most providers - this just increases that cost. The key would be to find the economic incentive to claim improved interoperability over ones competitors.	VHA Galen Mulrooney / VHA KBS
Question 2	6/20/17	Substantive		The best mechanism would be to encourage the SDOs to include measurements and/or measurement capabilities into their standards.	VHA Galen Mulrooney / VHA KBS
Question 3	6/20/17	Substantive		Yes, the objectives and goals are sound, although possibly premature, in that interoperability is not possible without further guidance in the form of "implementation guides (IG)" or regulations like Meaningful Use. Currently one of the most mature "standards" is the CDC Immunization Reporting IG, but there are 50 state variations of it. So ONC needs to first provide the implementation guidance (for example, define the "US Realm" for HL7 standards), before one can measure adherence to that guidance. Again, the biggest variable is the use of terminology standards in conjunction with the structural standard, and this requires specific guidance.	VHA Galen Mulrooney / VHA KBS
Question 4	6/20/17	Substantive		Again, the biggest barrier to interoperability is the optionality with respect to terminology. Any "interoperability measurement" must include a measure of adherence to the appropriate terminology. Before that can be measured, appropriate guidance must first exist. Note that the FHA FHIM and the HL7 CIMI projects are attempting to build the basis for such guidance, but the guidance must come from the "US Realm", presumably ONC.	VHA Galen Mulrooney / VHA KBS
Question 5	6/20/17	Substantive		Yes, the stakeholders seem appropriate	VHA Galen Mulrooney / VHA KBS
Question 6	6/20/17	Substantive		Yes, but only if the ability to measure is built into the standard, and if appropriate guidance with respect to terminology is provided against which to measure.	VHA Galen Mulrooney / VHA KBS

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Question 7	6/20/17	Substantive		It would indeed be good for the ISA to include some notion of interoperability in order to rank the appropriateness of standards. But standards don't exist in a vacuum, but rather are implemented in a legal, regulatory, and business framework. The regulations on how to use a standard, and what data it should contain affect the implementations of the standard. So the measurements might not necessary be meaningful on an annual basis. For example, existing HL7 V2 laboratory reporting standards have been around for decades and are generally working. It wouldn't be cost-effective to frequently update the measurements for that standard. But FHIR is rapidly evolving, so more frequent measurements might be appropriate.	VHA Galen Mulrooney / VHA KBS
Question 8	6/20/17	Substantive		Concentrate on those standards required by legislation/regulation (including those required for public health reporting and quality measures). These will be more ubiquitous and more likely to be uniform.	VHA Galen Mulrooney / VHA KBS
Question 9	6/20/17	Substantive		It would be most efficient for ONC to work directly with the SDOs and SROs (such as Commonwell, eHealthExchange, Direct, and regional HIEs) to encourage them to build measurement capabilities into their standards or frameworks.	VHA Galen Mulrooney / VHA KBS
Question 10	6/20/17	Substantive		The strength and weakness of current standards are that they are both extensible and constrainable. Such extensions and constraints complicate interoperability. If the sending party uses a constrained standard, the receiving party is unaffected, but if the receiving party uses a constrained standard, they may reject a valid instance from the sender. The converse is true with extensions. Again it is incumbent on ONC to define (in coordination with the owning SDO), a core set which must be exchanged, and that and only that can be measured.	VHA Galen Mulrooney / VHA KBS
Question 1	6/20/17	Critical	Voluntary reporting is a non-starter. Organizations don't have enough resources to do what they need to do, much less spend resources on "voluntary" activities. There needs to be a business driver for them to develop something new.		VHA Ken Lord /VHA KBS S&I
Question 1	6/20/17	Substantive	It is critical that there be mechanisms and approaches in place to make it as easy as possible. For example, the Behavioral Health and Substance Abuse population is serviced by local, non-hospital, non-profit healthcare organizations with little or no technical staff. Their operating budgets have little to no margins and generally no reserves. Anything that can make it "easier" and lower cost increases the likelihood of interoperability and reporting for this sector. Easier is important to most small and mid-tier healthcare organization		VHA Ken Lord /VHA KBS S&I
Question 2	6/20/17	Substantive	FHIR should be the target platform, but FHIR is still problematic and non-trivial. FHIR actually increases the "optionality issue" cited in the report.		VHA Ken Lord /VHA KBS S&I
Question 2	6/20/17	Substantive	As mentioned in the first paragraph of the report, a "nationwide interoperability enables a learning health system" is of great value. Because the burden to implement these systems requires different investment by each stakeholder, reporting needs to measure the impact across all stakeholders in order to achieve learning health systems. I think there are multiple industries where partnerships need to be developed, including, but not limited to hospitals, vendors, payers, federal agencies, state agencies and HIEs, patients, etc.. The ONC needs to have sufficient reporting to make the ROI decision that impact multiple stakeholders.		VHA Ken Lord /VHA KBS S&I
Question 3	6/20/17	Critical	My assumption is language refers to defined syntax on how to represent something, examples are JAVA or French. To achieve semantic interoperability we need to have semantic clarity and semantic precision. Having another language does not solve this problem.		VHA Ken Lord /VHA KBS S&I

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Question 5	6/20/17	Administrative	The stakeholders where interoperability impacts them should be better identified, especially those that receive benefits. Patients , payors (both private and public), vendors, administrative functions, federal agencies, state systems (both healthcare and others impacted by healthcare), and others need to be included. Without those who benefit, then it becomes more difficult to justify.		VHA Ken Lord /VHA KBS S&I
Question 9	6/20/17	Administrative	The efforts for the items mentioned are quite useful. However, I believe that the ONC has a very difficult task. The ONC has the responsibility of interoperability without the authority. That situation makes it difficult at best.		VHA Ken Lord /VHA KBS S&I
Question 10	6/20/17	Substantive	Measuring the “number of users” of a standard may is problematic and I don't believe sufficient. There are different “domains” of standards used in the healthcare community; clinical, claims processing, payments that all need interoperability. There are different types of user; a person, an organization, an application, or a service such as a Care Plan Service. The ONC has an opportunity to maximize the ROI of across the these domains. Additionally, CMS, CDC, State Organizations, and others have reporting requirements. However, they have their own interests and objectives. Again, the ONC has the opportunity to leverage and 'normalize" these efforts to minimize the impact. My recommendation is the ONC reporting needs more segmentation by these dimensions, to help measure both returns and costs of interoperability.		VHA Ken Lord /VHA KBS S&I
Question 1	6/20/17	Critical	A voluntary approach will not work – If there is no “intrinsic value” there will little interest in complying regardless of how small the bar is set. Organizations have built into their own budgeting, pricing etc. the cost of implementing such standards so there is little value making them easier.		VHA Sean Muir/VHA KBS S&I
Question 2	6/20/17	Critical	The reporting mechanism needs to be built into the standard itself – For instance FHIR exposes capabilities as services; Extend or create a new API in FHIR that supports clinical quality measure calculations; The open source community may support the implementation of such a service in any open-source development tools (e.g.)with a commercially-viable FHIR server. Establish a FHIR registry where the endpoints are pushed by the various organizations and on a periodic basis a routine pings all the endpoints and collect the data. C-CDA does not lend itself to such extensions easily and the portion of HL7 supporting C-CDA works with a different mindset then FHIR. The definition of a document type containing the measurements would be possible but most like thought out of scope for the base CDA standard.		VHA Sean Muir/VHA KBS S&I

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Question 3	6/20/17	Critical	It's a start but not really, unfortunately the "interoperability" in today's exchanges is very rudimentary and is essentially the exchange of electronic document one step better than Fax. FHIR has pushed the envelope towards a programming framework but has not mechanism to enforce semantic interoperability. If you apply the analogy of "verbal communication" (see http://classroom.synonym.com/components-verbal-communication-7298128.html) to interoperability we are making sound and some speech. Where we need to go next is have language and ultimately conversation		VHA Sean Muir/VHA KBS S&I
Question 4	6/20/17	Critical	Cost of implementing standards is directly proportional with complexity and semantic interoperability relies on the effective use of concept codes and clinical terminology. Addressing both complexity and lack of semantic clarity would improve the standards and as such the information acquired during treatment can be reused effectively for quality, research, and outcomes.		VHA Sean Muir/VHA KBS S&I
Question 5	6/20/17	Administrative	Yes		VHA Sean Muir/VHA KBS S&I
Question 6	6/20/17	Critical	If they are built into the standard framework as implementation guides, then yes, these implementation guides must be focused on the requirements of the information exchange and clarify all aspects of semantics and clinical concepts.		VHA Sean Muir/VHA KBS S&I
Question 7	6/20/17	Critical	The release of standards should follow not only a periodic schedule but coincide with new regulatory requirements because they affect not only interoperability but data collection. For example, information about ethnicity may not have been collected in all states without Meaningful Use. The regulation affected data collection as well the content of CCD document exchanged among EHR systems.		VHA Sean Muir/VHA KBS S&I
Question 8	6/20/17	Critical	The standards that are required by law will be the only ones the industry will adopt. Adding interoperability to a commercially-viable product makes it easier to replace to competitor's so vendors are not naturally-inclined to support such features.		VHA Sean Muir/VHA KBS S&I
Question 9	6/20/17	Critical	In the past ONC had been successful at setting up initiatives and documenting use cases but ended up duplicating some of the standards development activities as "implementation guidance" aimed only pilot implementations without a clear roadmap. It would have been more efficient if ONC simply organized project directly with SDOs and SROs. ONC needs to be actively supporting conformance testing (e.g. S&I Test Environment) and open-source and reference implementations to jump-start the adoption of new health IT capabilities identified by its stakeholders.		VHA Sean Muir/VHA KBS S&I

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Question 10	6/20/17	Critical	First we need to define “customizations” – if we mean further clarifying and constraining a standard IG, then such customizations are useful and they would pass ONC-based conformance test cases. If, on the other hand, providers and vendor decide to “break” conformance by not supporting mandatory elements or using local terminology those implementation will clearly fail ONC-based conformance testing. It’s important that conformance be based on testable criteria to distinguish conformant from non-conformant. If “customization” in this context means point-to-point and while this is a concern any point to point extension to existing standards should not limit the use of the base standard so spending too much time on this is not necessary –what is necessary is the ability to provide a interoperability sand box (crucible etc.) where automated testing of conformance can occur; The issue is the standards themselves are not sufficient for interoperability and there will be the need to provide implemental guidance (similar to CDA implementation guides and companion guides, FHIR implementation guides, and IHE Integration Profiles) The development of such guides may be done % outside of the standards as long as they vetted by industry, provide testable criteria, and they piloted via Connectathon they can be effective.in evaluating conformance to improve interoperability.		VHA Sean Muir/VHA KBS S&I
Question 2	6/13/17	Substantive		Leverage this framework so that it can be incorporated in a certification program into yearly Interoperability Connectathons conducted by Standards Organizations such as HL7 and IHE where diverse vendors demonstrate semantic interoperability based on reference implementations under a structured peer-to-peer test environment. Determine feasibility of adding statistics that detail conformance to the specification(s) as additional output from existing tools used to monitor Connectathon results.	VHA Serafina Versaggi/KBS S&I
Question 3	6/13/17	Substantive		The measurement framework is intended to provide feedback about vendor systems’ level of conformance to interoperability standards but could also provide input to the standards development lifecycle itself based on feedback from real-world implementations exemplifying standards’ fit or shortcomings. While the volume of transactions by standard as a measurement area has been identified, including traceability between clinical system functionality / services and standards designed to support those functions and services in the framework can help better inform the user community of the different types of interoperability standards (i.e., structural (e.g., HL7 V2, CDA, FHIR, etc.); transport (TCP/IP, REST, SOAP, SMTP) and terminology (SNOMED CT, LOINC, ICD, CPT, etc.) and their relationship to the clinical system functionality those standards are intended to support, in particular during information exchange	VHA Serafina Versaggi/KBS S&I
Question 4	6/13/17	Substantive		Table 1 lacks reference to Patients/Health Care Consumers in the Data Holders. Standard implemented in health IT product under Measurement Areas should include reference to the maturity level of the Implementation Guide that is grounded in a given version of a base standard. There are some missing emerging standards that should to be included in this framework so that clinical information systems include Patient Generated information and Patient Reported Outcome Measures to help ensure that clinical information system health care technology supports a more patient-centered, patient-safe health care system.	VHA Serafina Versaggi/KBS S&I

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Question 5	6/13/17	Substantive		• Patients/consumers/anyone on the care team • Healthcare providers of all types • Medical Device manufacturers (technology supporting remote patient care) • Emergency Medical Services (emerging standards to support	VHA Serafina Versaggi/KBS S&I
Question 6	6/13/17	Substantive		To better respond to this question, suggest including definitions for the terms: • health IT developers, • exchange networks, and • data holders.	VHA Serafina Versaggi/KBS S&I
Question 7	6/13/17	Substantive		• Reference implementations based on constrained IGs, defined value sets • Governance process that includes feedback from real world implementers into the standards development lifecycle to improve the base standard, Implementation Guides, values sets, etc., and to communicate known issues, errata, etc., to the industry and user community	VHA Serafina Versaggi/KBS S&I
Question 8	6/13/17	Substantive		The measurement framework and Certification programs should provide feedback on issues related to only the implementation guides or constrained specifications (such as FHIR Profiles) that are fit for purpose for a particular set of use cases (usually those specified by regulatory requirements or to support reimbursement policies, as these are the only 'standards' that will be adopted uniformly across the industry.	VHA Serafina Versaggi/KBS S&I
Question 9	6/13/17	Substantive		ONC should encourage a model-driven approach to the development of standards-based implementation guides and profiles that would help ensure consistency across those derivative artifacts (IGs and profiles). ONC could provide tooling to help 'data holders' to trace their internal software capabilities to the regulatory requirements, terminology standards and implementation guides / profiles intended to support those capabilities. This could benefit the vendors and provider organizations intending to implement vendor solutions by helping them to select and create appropriate functional end-to-end test cases required to pass certification (in the case of vendors) or in the case of provider organizations implementing new systems or functionality, to ensure those features have been appropriately implemented within their environment.	VHA Serafina Versaggi/KBS S&I
Question 10	6/20/17	Substantive		Although the term "standards" is defined on page 4 under the Feedback section ("…the term "standards" is used to refer to both standards and accompanying implementation specifications") the Framework should make better distinction between (1) the categories of interoperability standards (e.g., structural, transport, semantic/terminology) and (2) the difference between base standards (e.g., HL7 Version 2.x, CDA, FHIR Resources) and conformance to the implementation guides and profiles that document the necessary constraints to the base standard(s) inherent optionality in order to address specific (use case) requirements (for example, the Consolidated C-CDA templates referenced by Meaningful Use are sets of constraints of the base Clinical Document Architecture (CDA) Release 2 standard; the which they are designed so the defined in base standards such as HL7 Version 2, C-CDA, FHIR resources are tested to ensure interoperability (and ultimately data portability) between disparate systems). The framework should provide measurable feedback into the standards development lifecycle as well as into technology product lifecycles (such as clinical information systems and medical device applications). A model-driven architectural approach to clinical information systems development that supports consistent requirements gathering, incorporates health care interoperability standards and terminology binding for a defined set of common data elements could help close these important loops and would promote progress towards true data portability.	VHA Serafina Versaggi/KBS S&I

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Question 1	6/13/17	Substantive		Voluntary approaches don't work. The HITECH Act and Meaningful Use (MU) incentives (and penalties) stimulated widespread adoption of certified EHR system technology (. The intent was to support the meaningful use of electronic health records which translated to the ability for EHR systems to support (semantic) interoperability between diverse systems and provider organizations. There were few, if any, incentives for health care organizations to purchase and install clinical information systems, or for vendors to design systems that interoperate with each other prior to MU. Early adopters of health IT technology recognized that clinical systems facilitated health care operations but more importantly recognized that the clinical data generated by those systems were a valuable asset that could be used to improve efficiencies in care delivery and cost, and patient safety. Most investments in clinical system were intended to improve internal operations and competitive edge; not to share valuable patient information with other health care providers. Health IT company business and revenue models were in large part dependent on custom implementations and used proprietary approaches to solving common requirements. As a result, system vendors adopted health care IT standards on an as-needed-basis in response to market demand because health care organizations (HCOs) sought to simplify integration (less time and expense) of best-of-breed clinical systems to 'create' their organization's 'EHR'. The information systems and health IT standards designed to support delivery of care under a fee-for-service reimbursement system do not easily support and promote patient-centered, value-based care, an overarching goal for interoperability.	VHA Serafina Versaggi/VHA KBS S&I
Question 1	6/13/17	Substantive		A primary goal for 'standards-based interoperability' was not to foster interoperability between divergent health care organizations and to share patient information but instead, to create efficiencies to help improve and maintain an organization's competitive edge. Vendors increasingly saw utility in being able to claim 'conformance' to health care interoperability standards and realized the two-pronged benefit for adopting 'standards support' in their products. First, as a marketing tool to increase vendor presence in the marketplace as references to what today, are called base standards (i.e., HL7, X12N) began to appear in large provider organization RFPs for EHR systems. By including requirements to support the standard transactions (X12N 834, X12N 837, etc.) and code systems/terminologies (e.g., ICD, CPT, LOINC, etc.) mandated by payors and for reporting to various regulatory agencies in their system acquisition process for EHR systems, providers hoped to improve operations, revenue capture, public health and quality reporting through the standardizing and simplification of data flow between systems, benefits promised by health care standards adoption. The second important benefit to vendors for adopting health care standards in their products was the fact that while being a selling point, structural standards (e.g., HL7 and X12N) had not yet evolved to a level of conformance that ensured consistent use of a standard due to inherent optionality and the lack of implementation guides based on specified use cases, information models and conformance requirements that had been tested at minimum, under reference implementation conditions to transparently demonstrate plug-and-playable interoperability. As a result, standard-based system integrations continued to essentially be, point-to-point interfaces that contributed to complex system implementations, and was the bread and butter of IT vendors. The best measure by which to judge whether voluntary measures or mandates increase adoption of meaningfully useful standards can be demonstrated by the number of vendor systems that incorporated CMS mandated code systems (ICD and CPT) and X12N transactions (e.g., 837 claims) for reimbursement into their applications to facilitate the flow of clinical documentation captured at the point of care into revenue management modules to automatically generate claims. That most third-party insurers (private payors) follow CMS guidelines offers some additional evidence that regulation rather than voluntary measures encourage wide spread adoption of standards.	VHA Serafina Versaggi/VHA KBS S&I