

HIT Standards Committee

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Summary of the August 15, 2012 Web Meeting

KEY TOPICS

1. Call to Order and Opening of the Meeting

Mary Jo Deering, Office of the National Coordinator (ONC), welcomed participants to the 39th meeting of the HIT Standards Committee (HITSC). She reminded participants that it was a Federal Advisory Committee (FACA) meeting, with an opportunity for the public to make comments, and that a transcript of the meeting would be available on the ONC Website.

2. Review of the Agenda

Jonathan Perlin, Chair, observed that the items on the agenda indicated that Health IT is moving into considerations of how information will be used. The mobility of information and its capacity to support patients are under consideration. Information will bring about an expansion of the learning environment. He shared his excitement about this stage of HIT. The timeline must support infrastructure development. The agenda items reflect awareness that the right systems must be in place in order to proceed. Perlin referred to the summary of the meeting on July 19, 2012, which had been circulated with the meeting material, and asked for amendments or comments. Dixie Baker pointed out a typo on p. 4, in which she was incorrectly referred to as Dixie Banker. Hearing no other request for corrections, Perlin declared that the summary was approved with the correction of Dixie Banker to Dixie Baker.

Action item #1: The summary of the July 2012 meeting was declared approved with the correction of the name of Dixie Baker.

3. Comments

John Halamka, Vice Chairperson, talked about being on the cusp of Stage 2 and the importance of moving forward in a timely manner. The testing and certification process must be robust. The Stage 2 timeline is extremely compressed. The HITSC must focus on timing. He reported that he had received numerous requests from the HITPC workgroups for information on the maturity of standards to support draft meaningful use recommendations. To answer the questions, the committee must have guidelines for assessing maturity of standards.

4. NwHIN Power Team: Final Report on Criteria to Assess Maturity of Standards and Specifications

Dixie Baker, Chair, showed slides and presented evaluation criteria, attributes and the accompanying metrics for evaluating the readiness of standards for adoption and implementation. Baker reviewed slides on criteria:

Maturity Criteria:

- Maturity of Specification
- Maturity of Underlying Technology Components
- Market Adoption
- Adoptability Criteria:
 - Ease of Implementation and Deployment
 - Ease of Operations
 - Intellectual Property

She described changes made by the team in response to the discussion at the July 2012 HITSC meeting:

- Incorporated “voluntary consensus standards body” as the metric for the breadth of support attribute for the Maturity of Specification criterion
- Changed “Degree of Optionality” to “Appropriate Optionality” as the attribute of the Ease of Implementation and Deployment criterion (no changes to metrics)
- Under Ease of Operations criterion, clarified meaning of “peer coordination” by changing attribute to “Degree of Peer-Coordination by Technical Experts Needed”
- Re availability of alternatives (HITSC discussion), we believe this should be considered prior to, and perhaps as part of, a request for a specification evaluation – not as an evaluation criterion or attribute
- Removed Interoperability among a Number of Independent Implementations as an attribute for both Maturity of Specification and Maturity of Underlying Technology Components criteria, and added to Market Adoption criterion as “Interoperable Implementations” attribute
- Changed attribute names to achieve semantic consistency with a “low” level of a given attribute being the least desirable and a “high” level the most desirable
- Integrated Complexity of Specification metrics into Specification Modularity attribute of Ease of Implementation and Deployment criterion
- Revised Maturity of Underlying Technology Components metrics to reflect change in approach from separate evaluation of each individual technology component, to single evaluation of the maturity of the complete set of technologies used in the specification, with evaluator identifying those technologies that contributed to assigned ratings

After describing the rationale for and the results of the team’s application of the evaluation criteria to the Infobutton standard, Baker explained the process. The team members were provided the specification and draft Individual Evaluation Worksheet, with a pointer to the Infobutton implementation guide for functional assessment. Only three members submitted their ratings. To encourage participation in the consensus discussion, the chair distributed the Consensus Evaluation Worksheet with the evaluators’ ratings to the non-participating members and asked them to conduct ratings. Only one additional evaluator submitted the Individual Evaluation Worksheet, noting the benefit of seeing others’ ratings in areas he was unsure about. The team discussion resulted in consensus ratings and classification. Baker then presented the team’s recommendations:

- The proposed evaluation process and metrics are intended to provide structure and discipline to a qualitative evaluation and classification of technical specifications
- Metrics should not be used to generate a “score” as input to a numeric “average” or to determine whether a “minimum score” has been attained; metrics are best used to inform and justify a classification decision
- ONC should select specification(s) for evaluation based on industry needs for specific use cases and provide a description of use case(s) and:
 - If specification is non-functional, include implementation guidance in the evaluation
 - If alternative specifications exist, consider asking for comparative evaluation
- Incorporate process for identifying national standards that may need to be re-evaluated

Q&A

Halamka announced that he had received a request from Paul Tang for the evaluation of standards to support possible meaningful use measures by September 12. He noted the significance of the team’s work for responding to Tang’s request.

Wes Rishel pointed out the huge value of the evaluation criteria for generating discussion among the various actors. He noted that the grid shown in Baker’s presentation was given to the team; it is not a result of the team’s work. He wondered whether any standard implemented in the health care environment would have been evaluated “high” prior to its implementation. Halamka responded that the envelope must be pushed. Emergent standards have to be used, but with transparency. Baker replied that the security standards would rate high. Rishel said that he was referring to standards on functionality.

Jim Walker suggested that the next step should be to establish a process for coming back after six months to reassess any previously evaluated standard. Leslie Kelly Hall talked about standards informing policy. During its deliberations, the Meaningful Use Workgroup frequently asks about the availability of standards before going forward with policy recommendations. Standards can support innovation. Halamka talked about transition of care plans for which the S&I framework is developing a standard but the extent of its readiness has yet to be determined. The team's criteria can be used to assess the standard and thus inform policy.

Walter Suarez suggested that the assessment criteria be communicated to all SDOs for reference, in addition to posting on the website. The S&I framework initiatives' staffs should likewise be informed. These criteria should be the basis of the HITSC's work. Baker agreed, saying that publication should be considered.

Rishel stressed the bidirectional relationship between standards and policy. The time required for deployment of new standards in order to support meaningful use criteria is such that policy can easily get ahead of standards. Agreement between policy and standards makes a strong lever for success.

Halamka asked about taking a formal vote. Deering advised him to submit a formal recommendation via letter to the national coordinator. She said that the committee members have communication networks that they may use to distribute the recommendations. Halamka asked about any changes prior to sending the transmittal letter. Perlin said that there seemed to be consensus on the recommendations as a predictive model. Baker said that she wished to include Walker's point as an additional recommendation—establish a process to validate the classification of a standard as a predictive rule. Halamka said that, recognizing the preliminary nature of these recommendations, the workgroups would use the criteria to respond to Tang's request. Deering concurred, informing them that the Office of the General Council had recently ruled that workgroups can communicate directly across committees. If any changes occur, the transmittal letter can be revised.

Action item #2: It appeared that the recommendations of the NwHIN Power Team, including the additional recommendation to establish a process to validate over time the classification of a standard, were approved.

5. Remarks

Farzad Mostashari, National Coordinator and Chairperson, HITPC, observed that the conversation is moving from standards per se to their real-life implementation. There is an emphasis away from acceptance of standards to their practice, including testing beyond compliance to interoperability and exchange. Close communications among implementers and developers is required. Everyone must be brutally honest about what is working. All of this must occur below the regulatory stage. He asked them to consider how to bring implementers closer together in this process.

6. Implementation Workgroup: Draft Letter Regarding Timelines for Meaningful Use

Liz Johnson, Chair, referred to a draft letter that had been distributed with the meeting materials. She explained that the workgroup was requesting that the committee send the letter to ONC, CMS and OMB. She described the increasing concern about the delayed announcement of the Stage 2 and certification final rules. The committee has repeatedly informed ONC that a minimum of 18 months is required for software development and implementation of HIT. In order to enable eligible hospitals (EHs) and critical access hospitals (CAHs), which are currently expected to start qualifying for Stage 2 on October 1, 2013, with Certified EHR Technology, to meet their meaningful use obligations, all of the following must be achieved:

- Development of EHR and associated HIE technology to support meaningful use
- Quality assurance based on the final meaningful use measures, associated certification criteria, and the test scripts to be used by testing and certification bodies
- Testing and certification of the EHR Technology with ONC-accredited testing labs and certification bodies against the finalized test scripts

- Upgrading and testing of the Edition 2014 Certified EHR Technology (CEHRT) in the hospitals seeking to achieve Meaningful Use Stage 2
- Training of physicians and staff on the upgraded technology and associated clinical workflow changes to support meaningful use
- Implementation of interoperability connectivity supporting meaningful use
- Production upgrade and use of the upgraded EHR and interoperability by physicians and staff

The NPRMs were published in mid-March and insofar as the final rules have not yet been published, with mid-August being the minimum date for publication to stay within the 18-month period, the letter recommended an expedited process to ensure publication and release of test scripts by mid-August. Since mid-August had arrived, Johnson put forward the following recommendations:

Should publication of the rules and test scripts by mid-August not be possible, we further recommend that additional flexibility be given to EHs, CAHs and EPs in order to reduce the risk that hospitals are not able to meet the timeline despite reasonable effort on the part of HIT vendors and hospitals. We suggest the following approaches to provide the needed flexibility:

- For EHs, CAHs and EPs for which 2014 is the first reporting year, no additional flexibility is required as they already have a 90-day window to achieve Stage 1 measures during 2014
- For EHs, CAHs and EPs that would currently require a full year window for Stage 1 in 2014 (those whose first Stage 1 year was 2013), we recommend allowing use of either Edition 2011 or 2014 CEHRT for the beginning of the reporting period.
- For EHs, CAHs and EPs that would currently start Stage 2 in 2014 (those who started Stage 1 in 2011 or 2012), we recommend allowing use of either Edition 2011 or 2014 CEHRT and Stage 1 Meaningful Use measures at the beginning of the reporting period between updated Stage 1 criteria and Edition 2014 certified CEHRT. In these cases, we recommend either allowing attestation under current Stage 1 criteria for the full year or requiring attestation for the updated Stage 1 criteria for a 90-day reporting period. For the latter group, to enable the widest set of EHs, CAHs, and EPs to achieve Stage 2 Meaningful Use in 2014, we would recommend the use of a 90 day attainment period for Stage 2 measures during 2014. We recognize this would create some additional complexity in attestation, and could imagine supporting dual attestation for the Stage 1 and Stage 2 period, simply requiring detailed attestation only for the Stage 2 requirements for the 90-day period and summary attestation for the Stage 1 requirements, or supporting a simple 90-day period for Stage 2 requirements (under the assumption that EHs, CAHs and EPs who meet criteria for Stage 1 will continue to do so in preparation for the 90-day attestation period).

Mostashari reminded the HITSC of its role, which is advisory to ONC. Consequently, it is inappropriate to communicate directly with agencies other than ONC. He told them that ONC had received comments on the NPRM from the HITPC and the HITSC during the comment period. By law, ONC cannot entertain comments received outside of the comment period. He asked that they respect the integrity of the established process. Johnson reminded him that the letter was based on previous recommendations, which have not been implemented. She wished to state for the record the committee's concern and to get a response. Mostashari suggested that they focus on achieving compliance and meaningful use, whatever the timeline. Action by the HITSC would not have that effect. The Implementation Workgroup should focus on its role. Johnson assured him that the workgroup takes its charge very seriously. Members are working on testing scripts and will reconsider them after publication of the final rule. She asked Perlin and Halamka how to proceed. Halamka said that the letter was intended to help move things along. He asked what would help ONC. Mostashari assured him that there is a broad and deep commitment throughout the administration to get this done. Halamka observed that the letter brought the group's concerns to light; the expression of the sentiments is the most important objective. Perlin declared that everyone, including vendors and providers, is committed. He thanked Johnson for outlining the concerns in the letter, which he hoped would help accelerate the process. He requested advice from Deering.

Arien Malec announced that he wanted one piece of the letter to get a full airing. When the script testing period is delayed, the risk of failure downstream increases. The relationship of timing and risk is not linear. He

said that he wanted ONC officials to fully understand the seriousness of their timeline.

Rishel recognized the fundamental issues; the deadlines are fixed in the legislation and are not amenable to change because of process delays. He acknowledged that the overlap in planning cycles may have been missed in Stage 2. In order to minimize harm in anticipation of Stage 3, they must examine the regulatory process for more flexibility to deal with process delays.

Johnson noted that the concerns expressed by the Implementation Workgroup are universal. The workgroup is committed to assertively prepare for Stage 3. She withdrew the request for a transmittal letter at this time.

Suarez talked about the need to monitor the steps delineated in the letter over the next 18 months. He suggested that the Implementation Workgroup convene a hearing on readiness for 2014. ONC must be alert to industry problems. He went on to suggest the creation of a template for the worst case scenario over the coming 18 months. The template would outline a timeline for reaching milestone steps, which implementers could then use for planning and avoiding problems. Johnson said that she will take up the suggestion at the next meeting of the workgroup.

Someone agreed that a timeline template would be useful for executive level managers and boards of directors.

7. Clinical Quality Workgroup: Update on Recommendations on Value Set Repository

Jim Walker, Chair, began with a slide listing the HITSC recommendations that formed the basis for the workgroup's efforts:

- Establish NLM as the single validation authority for value sets to be used in MU 2 quality measures.
- Expedite recommendations of the Implementation WG (1/2012) and the Vocabulary TF (4/2010) for a public value-set repository.
- Build on the IHE Sharing Value Sets (SVS) profile for storing and serving value sets and incorporate Common Terminology Service 2 (CTS-2) methods for managing the vocabularies referenced by value sets.
- Establish a Web service for human and machine consumption of MU 2 value sets.

He went on to describe accomplishments. A Value Set Authority for Stage 2 value sets has been established by NLM. The value sets have been validated, and value set authors are making needed edits. NLM and ONC are tracking outstanding issues to completion. The Sharing Value Sets (SVS) standard will be used for Stage 2 and Common Terminology Services 2 (CTS-2) is being considered as an additional standard for future use. NLM, ONC, AHRQ and CMS are collaborating on development of delivery mechanisms for Stage 2 value sets.

He described efforts beyond Stage 2, including:

- Formalize governance for the Value-Set Authority.
- Provide curation, versioning, value set harmonization and re-use
- Extend NLM tools for end-to-end support, including value set validation at the point of authorship and value-set discovery and re-use.

Discussion

Halamka declared the work foundational for meaningful use. Johnson agreed to involve the Implementation Workgroup. Chris Chute reported that the CS-2 community has been working with NLM for simultaneous releases. SVS is not a standard. It has a robust capacity to handle not just value sets but full restful services and terminology and integration. Rishel announced that he wants the HITSC to maintain a strict division of labor between distributing, updating and creating value sets and implying standards on their implementation inside the EHR. Without a good knowledge of CTS-2, the focus will likely be on the operation versus the value set. David McCallie agreed with Rishel, saying that many value sets will not have one-to-one matchings. Baker asked about human consumption of value sets. Walker said that the workgroup would consider the three comments.

Doug Fridsma, ONC, talked about the need for standards-based ways for these to fit together. He wondered what the committee planned. Perlin asked Fridsma for his suggestions. Fridsma responded that in the short

term, it is important to get value sets out there. The CTS-2 standard is rich. He wondered whether portions can be simplified into a suite. Formalizing the governance is a key concern along with other policy issues. He suggested formation of a group to look at governance.

Rebecca Kush pointed out the need for standards to support research objectives. Chute reported that CTS-2 is partitioned and identifiable. McCallie suggested this as a topic for the NwHIN Power Team's evaluation process. Perlin noted that Fridsma's suggestion about a new group and McCallie's suggestion for the NwHIN Power Team seemed to be well received.

8. Updates from ONC

Doug Fridsma, ONC, announced that he had no presentation slides; instead he expected a follow-on discussion from the July meeting. He told the members that he had several updates and also wanted to talk about dental vocabularies. In July, ONC published a bulk purchasing agreement (BPA), which is a mechanism for task orders, to support the S&I framework and to accelerate standards. The period of performance for ARRA funding ends in September 2013. Testing is an important part of ONC's portfolio. He indicated that he wants to give vendors the opportunity to examine implementation guides in a timely way. He plans to develop a support platform to share and incorporate learnings into implementation guides. There may be a need to change the paradigm to use gaps in the guides to develop standards. In New York organizations developed the constrained CDA at the same time as the consolidated CDA was being developed. Ways to share and build on solutions are needed. The S&I framework can set a goal and define policy that results in a building block. People will use these building blocks for a solution.

Q&A

Malec referred to the BPA and asked how many CDA-like S&I initiatives can be funded. Fridsma responded that it will depend on the budget and priorities. BPA is a flexible mechanism, dependent on resources. He went on to talk about focusing on what is necessary for meaningful use and to build infrastructure. Direction from the HITSC and HITPC may be sought.

Mostashari informed them that the FY13 budget is not yet set. ONC must consider the possible levels of support needed and the number of initiatives. Contributions from the private sector may be sought. Halamka noted the gaps in the standards required for meaningful use. The standards development process must be accelerated in order to have mature standards for stage 3. He mentioned resources for the committee versus allocations for the framework. Fridsma referred to a mix of public and private funds.

McCallie observed that the CCDA is a moving target with remaining ambiguities. Since work is also being done outside of the S&I framework, he wondered how to avoid a multitude of standards and solutions. Mostashari opined that when standards are important and in use, they will continue to be refined, a process that is applicable to CCDA.

Rishel expressed agreement with Mostashari's statement that vendors were "clamoring" for standards. The HL7 community is increasingly focused on making standards work during implementation. He described various forums that may be used for development and testing. Curated forums and mechanisms to enable ad hoc testing data and repositories of testing data are possibilities.

Fridsma talked about the importance of using a robust testing approach, something like a Skype test call, to test connectivity and interoperability. Judy Murphy, ONC, reported that ONC officials are thinking about Stage 2 interoperability standards and implementation. More than understanding the standards is required; the policy in which the standards operate must be understood as well. ONC staff is developing tools for the website. The experience with grantees is being used to design a tool kit for interoperability. Mostashari emphasized that not all of this can be done by ONC. ONC must move from a creation role to one of validation.

Rishel suggested that ONC consider creating an implementation timeline, a consensus-based project plan that identifies the tasks in conjunction with the consensus of users. The implementation timeline would incorporate planning steps for workflow changes, and the subsequent need for training and agreements. CMS is using an implementation timeline in planning for ICD 10. He went on to share his ideas on funding. To date, much

of standards funding has come from vendors and the for-profit sector. Now that many large institutions are concerned with standards implementation, they may be willing to contribute resources to achieve a more balanced approach.

More Q&A

More information about the testing schedule will be tied to the final rule.

Regarding ONC's authorization of the certification bodies, staff reported that the applications are under review. An announcement is forthcoming. ONC does not need to authorize the testing bodies. ONC is reviewing the surveillance plans of the certification bodies for the permanent program. After authorization, their staffs may need training.

9. Next Steps

The requests from Tang on behalf of the Meaningful Use Workgroup will be assigned to the HITSC workgroups with a September 13 deadline (See appendix for final responses from Workgroups). ONC is working on the 2013 meeting schedule. The November 2012 meeting may be rescheduled.

10. Public Comment

Michael Arrigo, No World Borders, said that his company provides cost containment solutions. He expressed interest in the pharmaceutical impact of the quality measures: What about drug codes being tied in to payment? Jamie Ferguson and Halamka indicated that the committee is focusing on RxNorm in coordination with NLM.

John Travis, Cerner and a member of the Implementation Workgroup, commented that the letter submitted by the workgroup did a wonderful job of describing the impact of the timeline on users.

The meeting adjourned at 11:56 a.m.

SUMMARY OF ACTION ITEMS:

Action item #1: The summary of the July 2012 meeting was declared approved with the correction of the name of Dixie Baker.

Action item #2: It appeared that the recommendations of the NwHIN Power Team, including the additional recommendation to establish a process to validate over time the classification of a standard, were approved.

Meeting Materials:

- Agenda
- Summary of July 2012 meeting
- Presentation slides
- Draft timelines letter
- NwHIN Power Team standard evaluation worksheets

APPENDIX

SUBGROUP 1: IMPROVE QUALITY SAFETY, EFFICIENCY AND REDUCING HEALTH DISPARITIES

SGRP 102

Stage 3 Certification Criteria Only:

EHRs need to be able to consume external lists of DDIs (e.g., “never” combinations).

Questions 102

- EHRs need to be able to consume external lists of DDIs (e.g., “never” combinations).

HITSC Comments

Preliminary response:

Would need to harmonize SNOMED-CT, Structured Product Labeling, and RxNorm. There are no current standards to represent DDIs.

Clinical Quality WG response (primary):

Need a description for drug-drug interaction that could be derived from structured product labeling and would utilize Rx Norm (for clinical drug entities), NDFRT (for drug classes) and probably would require additional value sets to define possible drug interactions. The data element structure would need further definition and structured back labeling to “couple” drugs and their classes with the reaction. There is not a vocabulary term that codes for “never” interaction so that would also need to be developed. Background information would likely be required and coded as data elements to determine the intent of the measure.

Clinical Operations WG /Vocabulary Task Force response (secondary):

There is a vocabulary standards gap for the use of drug related terminologies including RxNORM, SPL and SNOMED CT for DDIs. We suggest ONC could partner with NLM to coordinate solving the vocabulary standards gap, which we think could be filled within 2 years. There also is a standards gap for representation of rules for DDIs. We suggest ONC could partner with both OMG and HL7 to fill this gap for representation of rules, but it is less likely to be able to be filled within 2 years.

SGRP 104

Objective:

Record the following in structured data:

Demographics:

- Preferred language
- Sex
- Race
- Ethnicity
- Date of birth
- Occupation and industry codes

Clinical:

- Sexual orientation, gender identity
- Disability status

Measure:

More than 80 percent of all unique patients seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data

- (Hospital Only) date and preliminary cause of death in the event of mortality in the eligible hospital or CAH

Questions 104

- Are there mature standards ready for adoption for functional status and gender identity? Is there a standard list for disability status? Are there emerging standards for other scales, such as depression?
- Need standards for the more granular race/ethnicity and language preferences

HITSC Comments

Preliminary response:

N/A

Clinical Operations WG/ Vocabulary Task Force response:

There are existing standards in meaningful use except for 3 areas: (1) occupation and industry codes, (2) sexual orientation, and (3) disability and functional status. Standards exist for most of these three areas but their maturity and suitability for this purpose must be assessed. We suggest ONC could coordinate with other government agencies through NLM to analyze the suitability for purpose of existing standards and to develop new ones as necessary. This is likely to be able to be accomplished within two years if the work starts now.

SGRP 107

Stage 3 Certification Criteria Only:

EHR systems should provide functionality to code medication allergies and link to related drug family, and code related reaction.

Questions 107

- Are there mature standards for drug intolerance or allergic reaction value sets?
- Also standard value sets for overriding an allergy alert?

HITSC Comments

Preliminary response:

N/A

Clinical Operations WG/ Vocabulary Task Force response:

There are mature standards that could be used to identify drug intolerance and allergic reactions and which could be adopted quickly for MU3. However there are no standards for overriding allergy alerts and this is very unlikely to be solved within 2 years.

SGRP 109

EP/EH Objective:

Record smoking status for patients 13 years old or older

Measure:

More than 80 percent of all unique patients 13 years old or older seen by the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have smoking status recorded as structured data

May consider retiring the objective because captured within CQMs.

Questions 109

- Is there a mature standard for coding smoking status?

HITSC Comments

Preliminary response:

Yes, already part of MU code sets.

Clinical Operations WG/ Vocabulary Task Force response:

There is already a standard for coding smoking status in meaningful use.

SGRP 112

EH Objective:

Record whether a patient 65 years old or older has an advance directive

Add for EPs if not included in Stage 2 and make core for EH.

Ensure standards support in CDA by 2016

Questions 112

- Where does Advanced Directives fit with CDA?

HITSC Comments

Preliminary response:

N/A

Clinical Operations WG/ Vocabulary Task Force response:

Advanced directives can be represented in CDA today, but are not well standardized in CDA templates for MU. We feel this work could be done within 2 years.

SGRP 113

Objective:

Use clinical decision support to improve performance on high priority health conditions

Measure:

1. Implement 15 clinical decision support interventions related to five or more clinical quality measures that are presented at a relevant point in patient care for the entire EHR reporting period. The 15 CDS interventions should include one or more interventions in each of the following areas, as applicable to the EP's specialty:
 - Preventative care (including immunizations)
 - Chronic disease management (e.g., diabetes, hypertension, coronary artery disease)
 - Advanced medication-related decision support [definition, Kuperman, JAMIA 2007 footnote] (e.g., renal drug dosing)
 - Appropriateness of lab and radiology orders
2. The EP, eligible hospital, or CAH has enabled the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

Certification criteria only:

1. Ability to track CDS triggers and how the provider responded [footnote: this is used to improve the effectiveness of CDS interventions]
2. Ability to flag preference-sensitive conditions, and provide decision support materials for patients.
3. 3. Capability to check for a maximum dose in addition to a weight based calculation.

Questions 113

- For both renal and age-related dosing suggestions how well developed are the "structured sig" standards?
- Ability to track CDS triggers and how the provider responded?
- Ability to flag preference-sensitive conditions, and provide decision support materials for patients?
- Capability to check for a maximum dose in addition to a weight based calculation?

HITSC Comments

Preliminary response:

N/A

Clinical Operations WG/ Vocabulary Task Force response:

Structured SIG standards are not well developed and are unlikely to be developed within 2 years. Also the ability to track CDS triggers is not well developed and is unlikely to be developed within 2 years.

The ability to flag preference-sensitive conditions and to provide decision support materials is not well developed and these standards are unlikely to be developed within 2 years.

Regarding the capability to check for maximum dose in addition to a weight based calculation, no such standards exist and these are highly unlikely to be developed within 2 years.

SGRP 119

Objective:

Record high priority family history data (including colon cancer, breast, glaucoma, MI, diabetes)

Measure:

Record high priority family history in 40% of patients seen during reporting period

Certification criteria:

Make sure that every CDS intervention can take into account family history for outreach (need to move that functionality along as part of preventative outreach).

Questions 119

- Is there a mature standard for family history?
What about, HL7 Pedigree or SNOMED-CT?

HITSC Comments

Preliminary response:

N/A

Clinical Operations WG/ Vocabulary Task Force response:

Mature standards do not exist for family history, despite the fact that important individual elements may be well standardized. Standards for family history for this objective are unlikely to be sufficiently well developed for this purpose by MU3.

SUBGROUP 2: ENGAGE PATIENTS AND FAMILIES

SGRP 204A

Stage 3 Certification Criteria Only:

Retain View/Download/Transmit

Explore further in RFC:

Provide 50% of patients the ability to designate to whom and when (i.e. pre-set automated & on-demand) a summary of care document is sent to patient-identified care team members and create ability of providers to review/accept updates.

Questions 204A

- Ability to identify other meaningful users, even those on other EHR systems?

HITSC Comments

Clinical Operations WG /Vocabulary Task Force response (secondary):

Standards are not sufficiently mature to achieve this objective and are not likely to be mature within 2 years.

Option 1:

1. Provide 10% of patients with ability to submit information (provider chooses one or more of these information types according to what is most appropriate to their practice) such as:
Family Health History [as per Surgeon General]
2. ODLs [as per How's Your Health]
3. Caregiver status and role [as per DECAF]
4. Functional status [as per PROMIS 10]
5. Patient-created health goals (needs a standard, also in care summary and plan)
6. Medical device: Glucose level*
7. Medical device: Blood Pressure*
8. Medical device: Weight*

*[SNOMED/LOINC]

Option 2:

Provide 10% of patients with ability to submit information using:

1. A generic semi-structured questionnaire platform and
2. Capability to receive uploads from home devices (e.g., glucometer, BP device, scale) that accommodate the data above.

Questions 204B

- **If Option 2** (which sounds easier) **how does it work?** We seek to be as efficient as possible for vendors to comply, and yet make it easy for physicians to select a topic that already has a standardized value set associated with it. (e.g., the value set is the tool mentioned in parenthesis to the right of the first 5 topics)
- We've heard the **surgeon general's FHH standards** aren't quite ready. Can they be ready in time for stage 3?
- There are standardized value sets/tools associated with the first five topics. For example, with functional status there is a PROMIS 10 survey that is validated and in use. **How do we translate this into standards for an EHR** and can they **be ready by MU3**, given that there is a standard tool for collecting the data?
- **Can we be ready** by MU3 to accept glucose, BP and weight from home medical devices?
- **What other factors do we need to consider here?**

HITSC Comments**Preliminary response:**

N/A

Clinical Operations WG/ Vocabulary Task Force response:

For patient information forms and questionnaires to address items listed in Option1, LOINC can be used to identify the survey instruments. For Option2 the question is ambiguous and we believe either a structured or unstructured format must be chosen; however, standards are unlikely to be sufficiently mature for Option2 #2 in time for MU3. In answer to the specific listed items in Option1:

1. 1. Family History: The Surgeon General's XML format is not widely adopted and is not expected to be sufficiently well developed within two years.
2. 2. Mature standards for ODL do not exist and are unlikely to be sufficiently well standardized by MU3.
3. 3. Mature standards for caregiver role and status do not exist and are unlikely to be sufficiently well standardized by MU3.
4. 4. The WHO International Classification of Functioning (ICF) and SNOMED CT together are HHS adopted standards for disability and functional status, however, we do not believe they are appropriate to be used for patient provided information at this time nor are they likely to be able to be adapted for use by patients in time for MU3. Nonetheless, it is possible that patient-friendly survey instruments could be mapped to these standard vocabularies.
5. 5-8: These all are unlikely to be sufficiently well standardized by MU3.

SGRP 209

Explore For Certification Rule Only:

Capability for EHR to query research enrollment systems to identify available clinical trials.

Questions 209

- The idea is that the **EHR could use the infobutton standard to identify patient-specific clinical trials** at a general level. Similar to how it can use the infobutton standard to identify patient-specific education materials. This query would be based on patients' location and disease for example, but not so detailed as to qualify or screen patients' specific eligibility for that trial. It **will still require human interaction** examine the clinical trials identified as a potential match. As we understand it, the research community doesn't use the infobutton standard yet, but if EHRs were to have the capacity in MU3 to use the infobutton standard to query, the research community would align and adapt. The idea is to build EHR capability in MU3 so that moves research community and this function can be in active use by stage 4.
- Is this a **feasible** approach?
- Are there organized enrollment system(s) to query in an efficient way, if that/those system(s) could accommodate the infobutton standard? Such as Clinicaltrials.gov? Is this feasible from research enrollment system point of view?

SUBGROUP 3: IMPROVE CARE COORDINATION

SGRP 302

EP / EH / CAH Objective:

The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform reconciliation for:

- medications
- problems

EP / EH / CAH Measure:

The EP, EH, or CAH performs reconciliation for medications for more than 50% of transitions of care, and it performs reconciliation for problems for more than 10% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).

Stage 4:

Reconciliation of contraindications and medication allergies

Questions 302

- Are there value sets that exist related to the nature of reaction for allergies (i.e. severity)? We are considering including medication allergies for Stage 4.

HITSC Comments

Clinical Quality WG response (primary):

Infobutton could be used as first step but will require human interaction. Although info could be coded to include and exclude possible participants, say by condition, it would not be able to actually code all the potential criteria needed to enroll patients.

It is feasible but not currently a feature in any known system
Research community will be very likely to adapt and participate

Clinical Operations WG/ Vocabulary Task Force response (secondary):

Standards are not yet mature, but the ability to perform standards based queries based on a first pass of clinical trials eligibility criteria could exist within 2 years if the work were to start now. We suggest that ONC could work with NLM for the vocabularies, and with CDISC and HL7 to mature existing standards for this work further.

HITSC Comments

Preliminary response:

N/A

Clinical Operations WG/ Vocabulary Task Force response:

Substantial work would have to be done to adapt and further develop existing standards for this purpose but we feel the development of standard value sets could be done within 2 years.

SGRP 304

EP/ EH / CAH Objective:

EP/ EH/CAH who transitions their patient to another site of care or refers their patient to another provider of care

For each transition of site of care, provide the care plan information, including the following elements as applicable:

- Medical diagnoses and stages
- Functional status, including ADLs
- Relevant social and financial information (free text)
- Relevant environmental factors impacting patient's health (free text)
- Most likely course of illness or condition, in broad terms (free text)
- Cross-setting care team member list, including the primary contact from each active provider setting, including primary care, relevant specialists, and caregiver
- The patient's long-term goal(s) for care, including time frame (not specific to setting) and initial steps toward meeting these goals
- Specific advance care plan (POLST) and the care setting in which it was executed
- For each referral, provide a care plan if one exists

Measure:

The EP, eligible hospital, or CAH that transitions or refers their patient to another site of care or provider of care provides the electronic care plan information for 10% of transitions of care to receiving provider and patient/caregiver.

Questions 304

- What counts as a transition?
Definition of a transition?
- We need a definitional statement about what the care plan refers to.
- What standards exist for structured data elements to include in summary of care?

HITSC Comments

Preliminary response from Standards:

N/A

Clinical Quality response (primary):

Typically care plan is free text-- there are places in a consolidated CDA that accommodate text but little is encoded data.

There is no standard around defining goals and related interventions for the care plan, but many other elements can be pulled from the EHR.

The care plan should be present regardless of transition but should certainly be transmitted at transfers of care.

Transitions of greatest concern are separate encounters— hospital to other facility would probably be first step and therefore moving from one encounter to another is a possible definition, although this does not capture the full intent and might still be difficult to define for the denominator.

Clinical Operations WG/ Vocabulary Task Force response (secondary):

Consolidated CDA currently enables templates for problems, medications, allergies, notes, labs, and care plans. There are no standards to support the structured recording of a number of items listed in the suggested criterion. Much more specific policy requirements for the criterion must be documented quickly to have any hope of using sufficiently mature standards in time for MU3.

SGRP 305

EP / EH / CAH Objective (new):

EP/EH/CAH to whom a patient is referred acknowledges receipt of external information and provides referral results to the requesting provider, thereby closing the loop on information exchange.

Measure: For 10% of patients referred during an EHR reporting period, referral results generated from the EHR are returned to the requestor (e.g. via scan, printout, fax, electronic CDA Care Summary and Consult Report).

Questions 305

- Are there mature standards available to “close the loop” for this process?
- What format/infrastructure would you recommend?

HITSC Comments

Preliminary response from Standards:

If the intention is simply to send free text electronic summaries, the capability is there. If you are interest in closing the loop and having both sender and receiver held accountable, then no there are not standards out there.

Clinical Operations WG/ Vocabulary Task Force response:

There are no mature standards available to close the loop for this process. Standards for provenance on CDA could be developed but work would have to be done.

SUBGROUP 4: IMPROVE POPULATION AND PUBLIC HEALTH

SGRP 401B

EP/EH Objective (New):

Capability to receive, generate or access appropriate age-, gender- and immunization history-based recommendations (including immunization events from immunization registries or immunization information systems) as applicable by local or state policy.

Measure:

Implement an immunization recommendation system that: 1) establishes baseline recommendations (e.g., Advisory Committee on Immunization Practices), and 2) allows for local/state variations. For 20% of patients receiving an immunization, the EP/EH practice receives the recommendation before giving an immunization.

Exclusion:

EPs and EHs that administer no immunizations.

Certification criteria:

EHR uses a standard (e.g., national, state and/or local) rule set, plus patient age, gender, and prior immunization history to recommend administration of immunizations; capture the act and date/time of recommendation review.

Questions 401B

- Are the standards for transmission of immunization history and recommendations sufficiently mature?

HITSC Comments

Preliminary response:

No standards to represent immunization rules exist.

Clinical Quality response (primary):

A concern is that the standards transmit what immunizations were given at the visit, and human readable text could depict recommendations, but there is no standard for electronic transmission of both elements or importing the immunization rules into the system.

There will be a decision support artifact but immunization rules are highly complex, it is unclear that that amount of complexity will be encodable by MU3, particularly in depicting local variation.

It is reasonable to suggest this be considered a high priority use case moving forward.

Clinical Operations WG/Vocabulary Task Force response (secondary):

Standards to represent and query Immunization history exist and are mature.

Standards for representing the rules for immunization are unlikely to be sufficiently well-developed within 2 years.

SGRP 402B

EP/EH Objective (New):

Capability to receive, generate or access appropriate age-, gender- and immunization history-based recommendations (including immunization events from immunization registries or immunization information systems) as applicable by local or state policy.

Measure:

Implement an immunization recommendation system that: 1) establishes baseline recommendations (e.g., Advisory Committee on Immunization Practices), and 2) allows for local/state variations. For 20% of patients receiving an immunization, the EP/EH practice receives the recommendation before giving an immunization.

Exclusion:

EPs and EHs that administer no immunizations.

Certification criteria:

EHR uses a standard (e.g., national, state and/or local) rule set, plus patient age, gender, and prior immunization history to recommend administration of immunizations; capture the act and date/time of recommendation review.

Questions 402B

- Is the infrastructure in place for a consolidated CDA as a feasible method by which case report data can be structured for sending to public health agencies from the EHR?
- Is there a standardized method and infrastructure for exchange of knowledge (e.g., CDS, immunization schedules, reportable conditions criteria) for use across meaningful use objectives?

HITSC Comments

Preliminary response:

No standards which parse external data generated requests exist, although Query Health may help.

Clinical Quality response:

There are some structured data elements that can be supported in CDA but more data that is needed right now will be unstructured—public health agencies would need to translate if they want structured data. A standard “envelope” for packaging data could facilitate the transition of data for public health use.

SGRP 404

EH/EP Objective (New, pending Stage 2 Rule):

Capability to electronically participate and send standardized, commonly formatted reports to a mandated jurisdictional registry (e.g., cancer, children with special needs, and/or early hearing detection and intervention) from Certified EHR to either local/state health departments, except where prohibited, and in accordance with applicable law and practice. This objective is in addition to prior requirements for submission to an immunization registry.

Measure:

Documentation of ongoing successful electronic transmission of standardized reports from the Certified EHR Technology to the jurisdictional registry. Attestation of submission for at least 20% of all patients who meet registry inclusion criteria during the entire EHR reporting period as authorized, and in accordance with applicable State law and practice.

Certification criteria:

EHR is able to build and then send a standardized report (e.g., standard message format) to an external mandated registry, maintain an audit of those reports, and track total number of reports sent.

Exclusion:

Where local or state health departments have no mandated registries or are incapable of receiving these standardized reports

Questions 404

- Is there a standardized message format that may be used across a variety of registries? Cancer registries have developed a standardized CDA format for meaningful use submissions. A flexible registry reporting infrastructure should support meaningful participation by the EH/EP in several registries. Might a standardized format (e.g., consolidated CDA) be promoted for registry implementation guides?

HITSC Comments

Preliminary response:

No such standards exist. To my knowledge the cancer registry standards you cite have not been implemented in any commercial product.

Clinical Quality response:

These cancer protocols exist but are not necessarily generalizable—the public health IT side should create a core data element subset but now there is nothing that exists across registries.

An additional consideration is that the cancer registry project was created but it is unclear that it is being used.

SGRP 405

RFC ONLY

EP Objective (New, pending Stage 2 Rule):

Capability to electronically submit standardized reports to an additional registry beyond any prior meaningful use requirements (e.g., immunizations, cancer, early hearing detection and intervention, and/or children with special needs). Registry examples include hypertension, diabetes, body mass index, devices, and/or other diagnoses/conditions) from the Certified EHR to a jurisdictional, professional or other aggregating resources (e.g., HIE, ACO), except where prohibited, and in accordance with applicable law and practice.

Measure:

Documentation of successful ongoing electronic transmission of standardized (e.g., consolidated CDA) reports from the Certified EHR Technology to a jurisdictional, professional or other aggregating resource. Attestation of submission for at least 20% of all patients who meet registry inclusion criteria during the entire EHR reporting period as authorized, and in accordance with applicable state/local law and practice.

Certification criteria:

EHR is able to build and send a standardized message report format to an external registry, maintain an audit of those reports, and track total number of reports sent.

Note: This objective is the same as the previous, but adds a second registry and does not need to be jurisdictional.

Questions 405

- Is there a standardized message format that may be used across a variety of registries for public health reporting?

HITSC Comments

Preliminary response:

No such standards exist

Clinical Quality response:

There are specific formats for reporting to specific registries but in the absence of unity there is no standardized format.

A method has been created to get some of this data from EHRs for registries—need to collect data to determine what has been working for those systems that collect reporting data from the system.

HEDIS has a messaging format but there is no agreed upon format and it is unclear that there is consensus or enough agreement to reach that at this time.

SGRP 407

EH Objective (new):

Capability to electronically send standardized Healthcare Associated Infection (HAI) reports to the National Healthcare Safety Network (NHSN) using a common format from the Certified EHR, except where prohibited, and in accordance with applicable law and practice.

Measure:

Documentation of successful electronic transmission of standardized healthcare acquired infection reports to the NHSN from the Certified EHR Technology. Total numeric count of HAI in the hospital and attestation of Certified EHR electronic submission of at least 20% of all reports during the entire EHR reporting period as authorized, and in accordance with applicable State law and practice.

Certification criteria:

EHR is able to sending a standard HAI message to NHSN, maintain an audit and track total number of reports sent.

Questions 407

- Is the current standardized message for HAI sufficiently mature and as in previous recommendations, is there a standardized message format that may be used across a variety of registries for public health reporting?
- Is there an opportunity for automation of this reporting based on ICD-10 HAI triggers rather than intensive abstraction by hospital staff? How would facilities generate denominators (e.g., hospital admissions or hospital admissions by service) to calculate of rates of HAI?

HITSC Comments

Preliminary response:

The CDC has created an HAI specific CDA document implementation guide. No HAI standard has been incorporated into any commercial product to my knowledge.

Clinical Quality response (primary):

The CDC has HAI reporting that has been created but with unclear implications for implementation.

CDC and NHSN would need to define the use of ICD 10 data and it is not clear that it would be possible to incorporate into the record and reporting. The statement also assumes that utilization of codes would be robust enough and that HAI triggers would be in widespread use.

Clinical Operations WG/ Vocabulary Task Force response (secondary):

For HAI an implementation guide exists and is likely to be developed into a mature standard within 2 years.