

March 18, 2015

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Dear Dr. DeSalvo,

In response to the recommendations from the Standards and Interoperability (S&I) Task Force, the Health Information Technology Standards Committee (HITSC) was asked to provide your office with recommendations around the Standards and Interoperability Framework. This transmittal offers these recommendations, which are informed by the deliberations among the Task Force subject matter experts, and presentations from relevant stakeholders.

Background:

The S&I Framework is one approach adopted by ONC's Office of Standards & Technology to fulfill its charge of enabling harmonized interoperability specifications to support national health outcomes and healthcare priorities, including Meaningful Use and the ongoing efforts to create better care, better population health and cost reduction through delivery improvements. The S&I Framework creates a forum – enabled by integrated functions, processes, and tools – where healthcare stakeholders can focus on solving real-world interoperability challenges.

At the December 10, 2014 HITSC meeting, ONC proposed the time bound interdisciplinary Task Force model as part of the HITSC Efficiency presentation¹. During that meeting, the HITSC recommended that a Standards and Interoperability Task Force (“Task Force”) be formed to address the specific question from ONC below:

In what ways can ONC evolve the S & I Framework to support current industry needs and those anticipated by the 3, 6, and 10-year milestones included in the Interoperability Roadmap?

This was revised based on discussion with the HITSC Steering Committee and at the recommendation of the Task Force Co-Chairs to:

Is there a continued need for the S&I Framework (or an equivalent process) to advance standards and implementation specification development? If yes, in what ways could the current S&I Framework be improved or enhanced to better address identified industry needs? If no, what alternatives should be considered to address the identified industry needs?

¹ http://healthit.gov/facas/sites/faca/files/HITSC_Efficiencies_Final_2014-11-18.pdf

The Task Force², chaired by Stan Huff and Arien Malec, convened six meetings over a two month period to review and discuss the S&I Framework, listen to stakeholder presentations, and produce recommendations to address the Task Force Charge given by ONC. During these meetings, the Task Force heard from different stakeholder perspectives including Implementers, S&I participants, Standards Development Organizations (SDOs), and Industry Associations.³

The Task Force presented its recommendations to the HITSC on March 18, 2015.⁴

The recommendations, presented herein, respond to the Task Force Charge.

The Task Force's highest level recommendation comes from its conclusion that the Standards and Interoperability Framework (or something like it) *does* play an important role in the advancement of standards and interoperability specification development; however, some changes are necessary to better address industry needs. Those changes are summarized in the following recommendations:

Recommendations:

Areas of Focus for a Convening Function

In our deliberation, we separated our analysis of **what** critical functions an ONC Standards and Interoperability Convening Function (e.g., S&I Framework or similar) might accomplish from the question of **how** such a Convening Function should accomplish its task.

Standards Development Organizations and profiling bodies perform a set of essential functions consistent with their respective vision and mission. However, we found that there are key activities SDOs do not consistently fulfill that are critical to support the development, adoption, use and maintenance of standards, implementation guidance, and certification criteria that enable a nationwide health information technology infrastructure.

We found these activities that SDOs do not consistently fulfill fall in two main categories: (1) Aligning efficient development of standards and implementation guidance to identified national priorities; and (2) Ensuring that such standards and implementation guidance are informed by working reference implementations and production use. In addition, we found a need to more effectively engage Federal partners in standards development activities and inform infrastructure and other needs that are outside the purview of any SDO.

Therefore, we make the following recommendations:

1. **Recommendation:** ONC should support a Convening Function that focuses on the following key enabling activities and associated recommendations:

² Task Force Members : http://healthit.gov/facas/sites/faca/files/HITSC_Efficiencies_Final_2014-11-18.pdf

³ Panelists: http://www.healthit.gov/facas/FACAS/sites/faca/files/SITF_Agenda_2015-02-27_v2.docx

⁴ <http://www.healthit.gov/facas/FACAS/calendar/2015/03/18/hit-standards-committee>

2. **Recommendation:** Work with SDOs, coordinate across SDOs and perform additional activities to support identified national priorities:
 - a. Define critical needs, desired outcomes, and evaluation criteria for projects and ensure they have traceability to National Priorities.
 - b. Develop, identify, or refine use cases.
 - c. Include front-end clinical and other requirements into the use case development.
 - d. Support SDOs to identify gaps in existing standards/implementation guidance.
 - e. Support SDOs to reduce optionality for existing standards/implementation guidance.
 - f. Support SDOs to create easy to consume consolidated artifacts (e.g., consolidated implementation guides).
 - g. When new standards/implementation guidance are needed, use a defined process for selecting which SDO(s) to work with.
3. **Recommendation:** Support production use of the above by:
 - a. Facilitating (including by funding) pilots and effective production implementation and adoption.
 - b. Feeding learnings back to SDOs (e.g., to further reduce optionality and clarify ambiguity).
 - c. Evaluating success of standards and implementation guidance in achieving national priorities with respect to individual projects.
 - d. Facilitating (including by funding) and supporting the development of widely available (e.g., open source) reference implementations.
 - e. Facilitating, and seeking input of those with expertise in, development of testing tools in parallel with development of implementation guidance.
4. **Recommendation:** Facilitate effective Federal participation in SDOs by working with ONC to coordinate involvement of relevant Federal agencies in SDO processes
 - a. Identify key representative(s) from each relevant agency.
 - b. Ensure Federal role in SDOs and similar aligned with national priorities.
 - c. Ensure active Federal participation in pilot, technology development, early production and national adoption of standards and implementation guidance.
5. **Recommendation:** Identify needs for infrastructure and artifacts that may be developed outside of or across SDOs. For example:
 - a. Value sets.
 - b. Provider directory data sources (e.g., CMS NPPES modernization).
 - c. Organizational identity assurance.

Prioritization of Identified National Priorities

The Task Force deliberated on the question of what an “identified national priority” should entail as used to drive an effective Convening Function. We found that many S&I Initiatives had been prioritized on the basis of a Federal partner with a strong interest in solving a particular problem; we found that

others had unclear paths to achieve success criteria, because of a lack of participation from healthcare organizations or developer organizations who would be needed to implement the outcome of the project.

While many initiatives may have clear, positive outcomes if successful, we found that having a large number of projects at one time dilutes the availability of talented individuals needed for participation, both in the ONC Convening Function and in SDOs.

It was not in our scope to identify national priorities or even identify the process for national priorities. It **was** in our scope to clarify what must be true of an identified national priority in order to lead to a successful Convening Function.

6. **Recommendation:** A Convening Function should ensure that its prioritized projects actively convened under the function meet all of the following criteria:
 - a. Has high priority among the potential projects as determined by stakeholders including balanced representatives of beneficiaries and developers of interoperability (e.g., Federal, provider, developer, patient stakeholders) and should align with a strategy that has received broad public feedback, such as the Interoperability Roadmap.⁵ Priorities should not be determined by a single Federal Agency who wishes to address a need without respect to rank order prioritization across projects.
 - b. If successful, projects or initiatives conducted through the Convening Function will lead to a measurable and meaningful real-world set of outcomes that will advance a given national priority (e.g., it will create healthcare value and/or equity).
 - c. Has been screened through a consistent gating process to ensure projects have a high likelihood of success to achieve identified outcomes. For example:
 - i. Has a reasonable path to scaled effective production implementation, taking into consideration the end-to-end process, inclusive of standards development, implementation and technology development, adoption, and clinical and operational workflow.
 - ii. There are key enablers (e.g., providers, vendors and developers) who seek to implement the outcomes.
 - iii. Takes into consideration parallel efforts, resources and ability of contributors to participate, including the end-to-end process, inclusive of standards development, implementation and technology development, adoption, and clinical and operational workflow.
 - iv. Considered and aligned with SDO processes and timelines.

⁵ Interoperability Roadmap: <http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf>

Standards and Implementation Guidance Development Lifecycle Recommendations

The Task Force deliberated and heard testimony on the role of the Convening Function with respect to the role of SDOs and implementers.

With respect to informing standards and implementation development by working implementation and production use, we found that effective standards development in other sectors, including Web and Internet standards, often involves a tight interplay between standards development and production implementations (which have often been implemented as open source libraries or projects). As examples:

- The OAuth2 specification went through 31 drafts, many of which were implementation tested by large consumer Internet companies, prior to being adopted as a Provisional Standard by IETF
- The HTTP/2 specification, which was informed by prior work with SPDY and others, was implemented in production within weeks of specification finalization

Although outside our scope, we encourage SDOs in the healthcare domain to consider these lessons for effective standards development and adoption and use in their mission and processes.

This approach to standards development works best in an environment where economic and mission drivers lead key actors to seek interoperability actively, and are willing to dedicate the time, energy and resources sufficient to ensure the tight interplay of standards development and implementation.

In an environment where the coordinated adoption of standards and implementation guidance occurs primarily through a national regulatory timetable aligned with key national programs (e.g., Meaningful Use, Alternative Payment Methodologies, etc.), we consider it essential that standards developed (and adopted) for healthcare be both pilot and production tested before inclusion in certification criteria. We also consider it essential that the lessons from implementation inform further refinement of standards, implementation guidance, and certification criteria.

SDOs perform critical roles with respect to balance of interest, IP rights management, and other activities that are aligned with OMB Circular A-119 on the use of voluntary consensus standards. It is important that the Convening Function carefully align its role with respect to the role of SDOs.

Therefore, in addition to our previous recommendations relating to the role of a Convening Function with respect to effective implementations and adoption, we further recommend:

7. **Recommendation:** Coordinated lifecycle for standard-development
 - a. The ONC should actively encourage, and seek to avoid policies that may inadvertently discourage, market and mission-based work that leads to tight interplay between standards development, production implementation, and adoption. For example, avoid certification approaches that heavily load development roadmaps and implementation and adoption cycles: that would reduce time, energy and effort that could otherwise be used for mission and market-based standards development, implementation and adoption.

- b. When working with SDOs that have processes accommodative both of cycles of implementation and draft standards/implementation guidance feedback and of formal consolidation and balloting, the Convening Function should work within SDO processes
- c. When working with SDOs that do not have processes accommodative of such cycles, the Convening Function should encourage, where appropriate, cycles of feedback and implementation, and align such cycles with the SDO's formal balloting process.
- d. The ONC should not create certification criteria for standards and implementation guidance that lack adequate real-world piloting and production use.
- e. The ONC should ensure that certification criteria point to work aligned with OMB Circular A-119 (e.g., to formally balloted SDO standards and specifications).

Work Practice Recommendations

The Task Force evaluated the work practices of the S&I Framework. We found that, although the general S&I process has been sound and well founded, there were several work practices that are especially necessary for success and were not always followed. For example, establishing a clear charter and clear business requirements was mentioned many times as a key success factor that was followed by the most productive S&I initiatives. On the other hand, unclear roles for facilitators, who sometimes drafted key deliverables, were often mentioned as negative factors, as were initiatives that started with engagement by business and clinical stakeholders, but had that engagement diminished over time by lengthy processes or unclear timelines.

Therefore, we recommend that ONC consider the following in the work practices for a Convening Function:

- 8. **Recommendation:** Clear chartering driving towards real-world outcomes:
 - a. Every project must be accompanied by a charter that lists expected real-world outcomes and interim deliverables/outcomes that lead up to the long-term goals.
 - b. The combination of both process and outcomes measures must be continually evaluated.
 - c. Each project must have a clear plan for how the outcome could be evaluated.
- 9. **Recommendation:** Clear roles for facilitation:
 - a. The recognized stakeholders of the project should be the key, material participants in the initiative itself who should set the timeline for the project consistent with the charter. ONC and other Federal agencies often use contractors to facilitate projects, but such facilitators must not drive outcomes or develop core content for deliverables.
 - b. Appropriate activities for facilitators include effective project management, note taking and editing, content management, and background research.

- c. ONC or other Federal agencies should ensure clear roles for funded subject matter experts, who are expected to be material participants, and the Convening Function should ensure that such experts are peer and equal participants with other stakeholders, and thus do not disproportionately influence project outcomes.

10. **Recommendation:** Clear project management processes

- a. Consider narrowing scope of projects in order to target specific, achievable outcomes.
- b. Set time limits, project plans and processes to expedite the narrowly defined results.
 - i. Process should be appropriate to allow the project to move forward expeditiously.
 - ii. Phases should be time-boxed.
 - iii. Ensure that roles and responsibilities for participation in project phases are well defined in order to allow participants with key needs (e.g., business, clinical, technical, etc.) to participate effectively.
- c. Define an oversight process for the Convening Function that includes:
 - i. Well-defined checkpoints to evaluate the project against the timeline and desired real-world outcomes.
 - ii. If and when it is determined that the outcomes are unlikely to be achieved, there should be a process to end the activity rather than proceed.

We appreciate the opportunity to provide these recommendations and look forward to discussing next steps.

Sincerely yours,

/s/

P. Jon White

Chair, Health IT Standards Committee

/s/

John D. Halamka

Vice Chair, Health IT Standards Committee