Testimony to the Health IT Standards Committee’s S&I Framework Task Force

Virtual Hearing on the Role of the S&I Framework and Initiatives

Walter G. Suarez, MD, MPH, Executive Director, Health IT Strategy and Policy, Kaiser Permanente

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Co-chairs and members of the Task Force, my name is Walter Suarez. I am the Executive Director of Health IT Strategy and Policy at Kaiser Permanente. I am also an active member of standards development organizations, including HL7, and serve as the current co-chair of the Sub-Committee on Standards of the National Committee on Vital and Health Statistics. I have been involved with the S&I Framework in various capacities, including standards development advisor, initiative co-lead, and technical liaison. Thank you for inviting me to provide testimony on the role of the Standards and Interoperability (S&I) Framework and its initiatives. My remarks will reflect the cumulative experience with the S&I Framework process and selected initiatives over the past 5 years.

First, let me say that I believe the S&I Framework has served as a valuable forum for bringing together stakeholders to discuss specific use cases that represent important challenges in the journey towards interoperability. The work done within the various initiatives have helped advance the industry’s understanding of these challenges, identify gaps in standards, and develop tools and products to help address them.

I will focus my remarks on the following three areas, and address the questions posed by the Task Force along the way:

* Refreshing the purpose of the S&I Framework (The Why) and the role and relationship of the Framework to Standards Development Organizations.
* The process components of the framework, including the process for identifying priorities for the Framework (The How)
* The products coming out of the Framework (The What)

**Refreshing the Purpose of S&I Framework (The Why)**

With respect to the purpose of the S&I Framework, there is still some degree of confusion, fragmentation, redundancy, parallel workflows, and overlap between the work done by the various initiatives (whether staff-assigned or community-assigned initiatives) and the work done by the Standards Development Organizations on the same topic.

The S&I Framework Wiki states that the primary objective of the Framework is to “…create explicit, unambiguous documentation of the use cases, functional requirements, and interoperability specifications, guided by real-world implementabiliy…” Other goals include: developing user stories and use cases, harmonizing interoperability specifications and implementation guidance, offer opportunities to pilot and testing of implementations, provide tools and services that facilitate productivity, and identify and document best practices. Lastly, the S&I Framework “…follows a clear development process to enable the community to create harmonized standards, specifications, and implementation guidance…”

All these statements, together with the work products completed thus far by the various S&I Framework Initiatives, raise the question “is the S&I Framework a Standards Development Organization?” Many of the products developed by S&I Initiatives end up having to be introduced, vetted, balloted, and voted within a Standards Development Organization, before they are adopted by the industry (either through regulations or industry consensus).

Given this, I believe the role of the S&I Framework should be reframed to more appropriately align with the actual standards development process, rather than attempting to replicate it outside of this nationally and internationally recognized process. Activities that the S&I Framework should consider focusing on include:

* In the front end, 1) development of user stories and use case documentation; 2) identification of functional requirements; and 3) identification of current standards and possible gaps; and 4) recommend need for SDO products.
* Once these items are completed, the information can be provided to appropriate SDOs for the standards development work to take place. During this time, the S&I Framework can help coordinate the federal participation on the SDO process.
* In the back end, working with the SDO, the S&I Framework can support pilot testings the artifacts developed by the SDO.
* The S&I Framework can also take a leading role in developing and implementing a systematic evaluation process of standards, post implementation.
* The S&I Framework should also continue to offer its resources (wiki, educational tools, etc.) to support the initiatives.

To your question “would you add or change any of the proposed S&I Initiatives?” looking at the current list of staff assigned and community assigned initiatives[[1]](#footnote-1), I believe there are a number of foundational initiatives – such as data provenance, data access framework or structured data capture – that need to reach a point of completion soon, in order to create value to the industry. Other initiatives – such as esMD or a LOINC Order Code – seem to focus on a narrow, specific needs of single stakeholders. And other initiatives, which have been going on for over a year – such as the EU-US eHealth Cooperative initiative – need to be revisited to determine their current status, value, deliverables, and timeframe for completion.

 **Process Components of the Framework (The How)**

One of the S&I Framework process steps that had been difficult to understand is the way in which new initiatives get identified, prioritized, and selected to be part of the Framework. In the future, making the identification and selection of initiatives an open and transparent process will be critical. This process should include defined governance and parameters for evaluation and selection. For example, creating an open process for submission of proposed initiatives (via the Wiki) and having them reviewed and prioritized by a governance group of balanced stakeholders could help establish a representative set of initiatives for the Framework to take on.

Another important concern about the process of implementing Initiatives is the role that staff and consultants play. While it is always valuable to have devoted staffing resources to support and facilitate the implementation of an Initiative, having them lead, staff, and also provide product content plays against the active involvement and participation of key stakeholders. In some cases, the majority of the work, discussion, and ultimate decisions are made with limited participation of a wide cast of stakeholders.

Equally important will be to ensure that initiatives have a defined, time limited span, and not struggle indefinitely.

You asked “How would the proposed criteria below have affected S&I initiatives, had the criteria been in place at the time?” with the proposed criteria for defining federal priorities being 1) Balanced Representation; 2) Measurable, meaningful real-world results; 3) Reasonable implementation path; 4) Interim and long term goals/outcomes; and 5) Rapid Cycle Implementation. I would say that using consistently and systematically these proposed criteria would have meant that some of the initiatives would probably have not made it into the S&I Framework in the first place.

Along with my comments above regarding the need to refresh the purpose of the S&I Framework, I would also suggest considering redefining the Framework process to streamline and simplify the steps, and align them better with the role and responsibilities of the Standard Development Organizations.

 **Products of the S&I Framework (The What)**

There have been many products, tools, services, resources, use cases, functional requirements, pilots, and other documents completed and released by the various S&I Framework Initiatives. Some of them have been moved into the standards development process, and had to be reintroduced, vetted, and balloted (in some cases by the same people that help develop them in the first place). Others currently reside on the S&I Framework repository, or on the wiki pages of each initiative.

Given the number of S&I Framework Initiatives already completed and/or closed, it will be helpful to conduct a more formal evaluation of those products and artifacts, and identify their current status in terms of industry use, as well as learn about possible areas for change and improvement.

This also raises questions about ongoing sustainability models for the entire S&I Framework, as well as ongoing maintenance of Framework artifacts and products as discussed earlier.

 **Concluding Comments**

In conclusion, I believe the S&I Framework has the potential to offer specific opportunities to advance the development of the next generation of standards that support interoperability. To ensure better understanding of its role, avoid duplication and redundancies, and ensure more efficient use of federal and industry resources and expertise, the S&I should refresh its purpose, redefine its process, make the identification and selection of initiatives open and transparent, and ensure full alignment with standards development organizations.

I thank you again for the opportunity to participate in this hearing, and look forward to further discussing some of these points with the group during the Q&A portion of the session.

1. Current Staff Assigned Initiatives: BlueButton Plus, Clinical Quality Framework, Data Access Framework, Data Provenance, Electronic Long Term Services and Support, EU-US eHealth Cooperation Initiative, PDMP & Health IT Integration, and Structured Data Capture. Current Community Assigned Initiatives including esMD, Laboratory Order Interface, Laboratory Result Interface, LOINC Order Code, and Public Health.  *Source: S&I Framework Wiki, February 20, 2015.* [↑](#footnote-ref-1)