HIMSS Electronic Health Record Association

Summary

The HIMSS Electronic Health Record (EHR) Association is pleased to respond to the NIST request for information on behalf of the National Science and Technology Council's Sub-Committee on Standards. We hope that this response will help the Sub-Committee on Standards to improve the methods by which federal agencies collaborate on future engagements in standards development and conformity assessment.

The focus of this response is on standards for health information technology (HIT). In it, we address the following four points requested in the RFI.

(1) The effectiveness of the methods federal agencies have used to engage in standards-setting activities by identifying which methods have enhanced or limited the public/private standards-setting processes;

(2) The effectiveness of federal agencies' coordination with the private sector;

(3) The adequacy and availability of federal resources; and

(4) Other issues that arise and are considered during the standards-setting process which impact the process, and the timeliness, adoption, and use of the resulting standards.

In summary, this response from the EHR Association discusses and makes recommendations on three major issues:

- Our general satisfaction with Federal agencies' participation, but stress the need for more communication from these agencies on their standards strategy for HIT.
- We want to highlight the critical need for transparency of standards strategies across government agencies, including goals and supporting initiatives. We have been concerned that recent standards-related initiatives are not utilizing the normal, transparent, consensus-based process of standards developed by standards-development organizations (SDOs), a process that provides for a balanced level of participation and influence among all stakeholders, whether providers, software developers, or policymakers.
- Our concern with the lack of an inter-agency coordination process that includes the HIT industry in a true partnership to ensure solid consensus and cost-effectiveness of implementation. We recommend increasing the engagement of agencies with existing public/private partnerships in coordinating the selection and adoption of standards.

Standards-Setting Processes, Reasons for Participation, and the Benefits of Standardization

Who participates in standards-setting activities?

Based on publicly available information on the web, the following federal agencies participate in standards organizations and activities at the membership level in bodies developing standards or conformance testing materials. Health Level 7 (HL7), International:

- Agency for Healthcare Research and Quality
- Centers for Disease Control and Prevention
- Centers for Medicare and Medicaid Services
- Food and Drug Administration
- National Cancer Institute Center for Bioinformatics
- National Center for Health Statistics
- National Institute of Standards and Technology (NIST)
- Office of the National Coordinator for Health IT
- U.S. Army Institute of Surgical Research
- U.S. Department of Agriculture Animal and Plant Health Inspection Service
- U.S. Department of Defense, Military Health System
- U.S. Department of Health and Human Services
- U.S. Social Security Administration
- Veterans Health Administration

IHE:

- Centers for Disease Control and Prevention
- National Institute of Standards and Technology (NIST)
- U.S. Social Security Administration
- Veterans Health Administration

DICOM:

- National Cancer Institute

US Technical Advisory Committee to ISO TC-215:

- Agency for Healthcare Research and Quality
- National Institutes of Health
- National Library of Medicine
- U.S. Department of Defense
- Veterans Health Administration

ANSI Health Information Technology Standards Panel (as of end of contract, January 2010)

- Agency for Healthcare Research and Quality
- Center for Mental Health Services
- Centers for Disease Control and Prevention
- Centers for Medicare and Medicaid Services
- Department of Defense
- Department of Health and Human Services
- Department of Veterans Affairs
- Food and Drug Administration (FDA)
- General Services Administration
- Indian Health Services
- National Cancer Institute
- National Center for Health Statistics
- National Center for Research Resources
- National Library of Medicine
- National Institute of Standards and Technology

- Office of the National Coordinator for Health IT (Contract Holder)
- Office of Management and Budget
- Office of Recoveries and Fraud Investigation
- Office of the Surgeon General
- SAMHSA Center for Substance Abuse Treatment
- Social Security Administration DCS/ODS
- Tricare Management Activity Privacy Office
- United States Access Board

Certification Commission on Healthcare IT (CCHIT)

- TRICARE Management Activity (TMA)
- Indian Health Service
- U.S. Army
- Department of Veterans Affairs
- Centers for Medicare and Medicaid Services
- Uniformed Services University of the Health Sciences

What are the most important reasons for participation?

This information is not publically available from the relevant agencies or the organizations in which they are members. It seems readily apparent that all participate in order to foster the development of standards forwarding the specific agency's mission.

What are the benefits of developing standards for this sector?

Quoting OMB Circular A-119: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities:

"Many voluntary consensus standards are appropriate or adaptable for the Government's purposes. The use of such standards, whenever practicable and appropriate, is intended to achieve the following goals:

a. Eliminate the cost to the Government of developing its own standards and decrease the cost of goods procured and the burden of complying with agency regulation.

b. Provide incentives and opportunities to establish standards that serve national needs.

c. Encourage long-term growth for U.S. enterprises and promote efficiency and economic competition through harmonization of standards.

d. Further the policy of reliance upon the private sector to supply Government needs for goods and services."

How do the standards impact organizations and their competitiveness?

Standards can impact organizations and their competitiveness both positively and negatively. Positive impacts include eliminating variations among information systems to allow organizations to meet existing needs, focus on expanding markets, and improve products with new innovations. Many of the positive impacts are addressed by OMB Circular A-119 as quoted above, applying the principles to organizations instead of the federal government.

Negative impacts include requirements for changes to existing products which can halt or even reverse progress depending upon how the standard changes existing implementations. Standards can also have negative effects on global business opportunities when they are specific to a single nation (e.g., the U.S.) in a larger market, which is clearly the case for HIT.

How has standardization spurred innovation in the technology sector(s) that is the subject of your comment?

Standards alone do not create a market for innovation. It is only when there is an existing or emerging market that standards support, that use of standards is successful in creating innovation. For example, in 2004 when a standards adoption initiative, Integrating the Healthcare Enterprise (IHE), first developed the Cross-enterprise Document Sharing (XDS) standards-based profile, there was no health information exchange (HIE) market to speak of. There was at least an interested audience, if the response at the 2005 HIMSS demonstration was to be believed. As the HIE market emerged, XDS gained adoption to the point where there are hundreds of HIEs around the world which use this standards-based profile specification. Similarly, CDA Release 2.0 was completed by HL7 in 2005, but it was not until there was a market for healthcare information exchange between providers starting in 2007 that it began to take hold in the U.S. (see http://tinyurl.com/wwxds).

Without NIST participation in developing what has become the reference implementation for testing XDS, and its engagement in the testing of XDS and CDA profiles, the industry would not be at the stage it is today. According to Gartner research[1], CDA is entering the "Plateau of Productivity" and IHE (XDS) is "Climbing the Slope" into it.

What is the current phase of the standards development process for this technology?

There is no current phase because there are a variety of different HIT technologies in which standards can be applied, and they are in different phases. For the purpose of segmentation, we will use the

[1] Hype Cycle for Healthcare Provider Technologies and Standards, 2010, Gartner Research. Accessible on the web at http://www.gartner.com/DisplayDocument?doc_cd=205271

terms found in "Crossing the Chasm" by Geoffrey Moore, adapted from the model created by Bohlen, Beal and Rogers in "Diffusions of Innovations", in which they describe Innovators, Early Adopters, Early Majority, Late Majority, and Laggards.

Genomics: Innovators Electronic Health Records (EHR): entering Early Majority
Health Information Exchange (HIE): Early Adopters into Early Majority
Clinical Decision Support: Innovators into Early Adopters
Imaging: Late Majority
Laboratory Reporting: Late Majority
Laboratory Ordering: Early Adopters

How has the process worked so far?

The process is highly variable with respect to how well it has worked. Different agencies have different strengths and degrees of maturity with respect to the standardization process.

Current processes for execution of the Standards and Interoperability (S&I) Framework being created by HHS-ONC are being executed outside of the usual standards development process, but with SDO participation. Governance of these projects is not well integrated with existing SDO processes, and dilutes existing SDO participation. There are several challenges here, including communications, disparate styles of project governance in the framework, and lack of stakeholder participation in the development of projects and their scope, a fundamental component of existing SDO governance that is being avoided by running these outside of existing processes. Maintenance of project outputs (e.g., specifications) generated outside existing SDO processes is also a major challenge. A good example of this challenge is what happened to the Health Information Technology Standards Panel (HITSP) specification maintenance that was discontinued after the expiration of the ONC contract.

When developing standards, how are the standards-setting processes managed and coordinated?

Some federal agencies manage their own efforts fairly well. However, there is a lack of transparency.

Within the CDC, activities around Immunization, Electronic Laboratory Reporting for Disease Surveillance and Healthcare-Associated Infections would benefit from increased coordination. Finally, looking at activities over the past years, one can find a single office in the CDC responsible for two different programs on Public Health Alerting.

There is little to no publically available information on the management and coordination of standards by federal agencies. There are also no federally available information sources that identify agency participation, sponsored initiatives, et cetera, with respect to standards and certification activities in which they participate.

It is clear that while a single federal agency might manage their own efforts, there is little to no coordination across agencies. At the top-most level, DOD, VA, HHS, and FDA seem to have no publically available strategy for coordination. Drilling a little deeper, AHRQ, CDC, CMS, HRSA, IHS, NIH, and

SAMHSA each have their own activities, which are not coordinated. We believe that cross-agency coordination is needed, but should not be conducted as an internal federal activity, but rather require the agencies to engage along with industry in collaboratively coordinate the standards strategies to address shared needs. Standards profiling organizations such as IHE or Continua are effective forums where there is engagement of some of the agencies, which should be expanded.

There are three main avenues agencies use for participation in standards setting:

1. Direct participation by agency staff in the leadership of SDOs, and leadership and development of standards.
2. Staffing of standards engagement activities through contractors.
3. Direct contracting of standards development.

Direct Participation by Agency Staff

Few agency staff directly participate in standards efforts due to the highly technical skills needed and the availability of staff with the prerequisite skills. When agency statements or positions need to be made directly, they are most often generated by agency staff. Several federal agency staff directly participates not only in the leadership and development of standards, but also in the governance of SDOs. For example, VA, DOD, and CDC staff, currently or in the past, has participated as board members or officers of HL7.

Staffing of Standards Engagement through Contracts

Many federal agencies contract with organizations for staff support on IT, where part of that contractors' responsibility is to participate in the leadership or development of standards. Notable[2] contractors include TIAG, SAIC, Northrop Grumman, Deloitte, and Apelon. The latter organization is well known for its work in healthcare vocabulary and terminology standards.

Direct Contracting of Standards Development

Several agencies, including AHRQ, the Military Health System, and the CDC engage in direct contracts that lead to the development of standards and implementation guides. Some of these may then be sub-contracted further. There are a number of smaller consulting organizations that are well known to contract for development of standards, but again, a list of these is also hard to come by because it is hard to find the specific contracts for development of standards.

[2] This is by no means a complete list. Such information is hard to come by because they are often contracted for "IT support" or similar positions.

Is there a strategic plan that identifies the standards needs and defines the standards development life cycle?

Strategic plans for federal agencies with respect to standards are typically not available. The most notable exception is ONC, who has made substantial efforts to publicize what their plans are with respect to the S&I Framework. While proposed programs have been announced, the overall plan for implementation of these through the S&I Framework has not been communicated to the public. Planning and communication to the public still lags behind stakeholders' desire for information.

Are there barriers to developing high level strategies for standard-setting activities?

Most assuredly, there are barriers. The lack of publically available information about agency participation is almost as complete inside federal circles as it is outside. It is only upon meeting one's counterparts from other agencies that federal agencies may become aware of overlaps. Because of sometimes tenuous relationships between agency contractors and agencies themselves, it is often difficult to determine what the agency position is on a particular standards activity. Many federal agencies prohibit contractors from speaking on behalf of the agency directly, and so can only provide "indirect" information about agency goals. Some contractors, while they represent a given agency, may not have been given specific directions about participation in efforts being led by other agencies.

Perspectives on Government's Approach to Standards Activities

What methods of engagement are used by Federal agencies to participate in private sector-led standards development?

Federal agencies engage in several ways:

1. Contracting for the Development of Standards and Implementation Guides. The most recognized contractor is the CDC, but VA and DOD are also known to contract services to develop standards.

2. Many agencies have direct staff or contractor participation in standardization activities. These individuals are often well-recognized experts in healthcare standardization who devote substantial time to standardization activities.

3. The VA, DOD, and NIST have engaged at a leadership level in standards development, leading not only committees that develop standards, but also in the governance of the standards organizations.

4. Some agencies sponsor development of infrastructures that foster standards development efforts through grants and contracts (e.g., HL7 NLM Contract)

How transparent is each method?

Contracting

The least transparent method is contracting. Standards development is often limited in its capacity because it relies upon volunteer resources to complete the work. Many federal agencies have discovered that engaging contractors who are familiar with the standards development process to participate in the development of standards and implementation guides can greatly speed up the process of development. We would note that contractor-led development is often less participatory than other efforts, often because the SDO is used to validate rather than develop the work.

Any development effort relies on a triangle of resources, scope, and quality. Once any two sides are fixed, the third side is also determined. Federal contracting processes often fix resources and scope. As a result, some outcomes have not had the desired quality that would otherwise be expected if organizational processes were followed without outside pressure to "finish" the work. This is especially true in cases where the work is in new areas where standards and implementation guides have not been developed previously (e.g., healthcare quality measures).

Direct Participation

Direct participation in standardization activities is typically the most transparent. Even so, agency goals are sometimes not clearly stated, or are in conflict across agencies. The most memorable case we can recall is when two federal agencies (CDC and FDA) disagreed with the priorities of third (ONC) as set by a federal advisory committee (AHIC), only to later find out that the CDC had already engaged and was developing an alternate standards-based solution that was announced in HL7 after HITSP had announced completion of its work on Public Health Case Reporting in that cycle.

Indirect Participation

Sometimes agencies will contract with others who subcontract yet again. Two notable cases in recent memory include CDC contracting with ISDS who sub-contracted to HLN Consulting for Public Health Surveillance efforts on meaningful use, and AHRQ contracting through NQF, which eventually subcontracted to an outside firm for the development of standards around healthcare quality measures.

The first case resulted from the CDC which provided what proved to be problematic guidance to ONC on standards to use for Syndromic Surveillance, and after the CDC suggested standard was withdrawn by ONC, CDC engaged ISDS to develop a new standard/guide using a process that was inconsistent with the "voluntary consensus standards" as defined in OMB Circular A-119. The most notable objections with this latter activity involved the balance of interests and openness of that process. The eventual outcome of this process appears to be on the right path and moving towards the voluntary processes recommended by Circular A-119.

The second case provides an example where the development timeline was very short due to contractual requirements set by AHRQ, resulting in a work product (HL7 HQMF) that could have benefited from more development time.

How effective is each method?

Effectiveness depends upon how you measure success. If effectiveness is measured based upon successful completion of a standard on a schedule, contracting for their development appears to be the most effective. On the other hand, when measured by voluntary implementation by industry, direct and indirect participation appear to be much more effective because it leads to the development of a true industry consensus in both design and implementation, rather than just "validation" of a contracted result.

As currently stated, ONC is driving towards implementation of specifications as a better measure of effectiveness than just completion of the standard. However, the Direct Project, while quite effective in implementing a specification, is now in search of a home to maintain the specifications as standards. The split effort across development and maintenance means that the project will take additional time to complete the "creation of a standard". There is no assurance that once entering the maintenance process of an SDO the specification will not change in ways that are backwards compatible with what has already been implemented.

How could the methods be improved?

1. Make agency participation in standards development transparent to agencies and the public.
    a. Identify agency contracts for the development of standards.
    b. Identify agency staff participating in standards development and governance.
    c. Identify agency contractors participating on behalf of an agency in standards development and governance.
2. Make agency goals with respect to participation in standards transparent to other agencies and the public.
    a. Identify specific agency objectives that are to be met.
    b. Identify specific projects that the agency intends to participate in.
3. Coordinate federal agency activities with industry and with the public.
    a. Foster the engagement of agencies in relevant standards profiling and adoption organizations.
    b. Publically identify specific agencies that are taking the lead in different areas.
    c. Publically identify agency support for specific projects.

Federal agencies should coordinate with industry and the public through public/private profiling initiatives to transparently develop an effective consensus strategy with all stakeholders. This will facilitate rapid adoption across engaged stakeholders.

What other methods should the Federal agencies explore?

Given its focus on standards, we take note that the Office of Standards and Interoperability should coordinate with federal agencies with regard to participation in standards activities, including contracting, direct, and indirect involvement. This comes under the charter of ONC as specified in section 3001 of Federal Law 111-5, specifically:

> ‘‘(C) review Federal health information technology investments to ensure that Federal health information technology programs are meeting the objectives of the strategic plan published under paragraph (3).”

And:

> ‘‘(A) IN GENERAL.—The National Coordinator shall coordinate health information technology policy and programs of the Department with those of other relevant executive branch agencies with a goal of avoiding duplication of efforts and of helping to ensure that each agency undertakes health information technology activities primarily within the areas of its greatest expertise and technical capability and in a manner towards a coordinated national goal.”

As previously discussed, we recommend that this scope should be extended to require federal agencies to explicitly coordinate with industry and the public through public/private profiling initiatives to transparently develop an effective consensus strategy with all stakeholders. This will facilitate rapid adoption across engaged stakeholders.

What impact have Federal agencies had on standards activities?

Regulatory agencies (e.g., CMS, ONC, and FDA) have the largest impact on standards by their ability to effect adoption through regulation on compliance (e.g., FDA and CMS on HIPAA) or through regulation on incentives (e.g., CMS and ONC on meaningful use). Agencies also have an impact through development of implementation guides supporting the use of standards (e.g., NLM on SNOMED CT, CDC on immunizations and Electronic Laboratory Reporting). Other agencies have had some impact by supporting research on standards (e.g., AHRQ on Clinical Decision Support).

Standards activities often have long lead times from development through adoption (see “The Standards Value Chain[3]”) which makes it difficult to evaluate impact and effectiveness. Current initiatives seek to shorten this timeframe and scale it up. These efforts need to be coordinated with existing SDO

[3] Marshall, Glen F. "The Standards Value Chain: Where Health IT Standards Come From." *Journal of AHIMA* 80, no.10 (October 2009): 54-55, 60-62. Available on the web at

governance on the development of standards. The Direct Project for example, while completing work and reference implementations in a one-year time frame, have done little to speed up development of standards because the project worked outside existing SDO governance and now needs to seek an SDO to maintain and validate the work. Other efforts such as the CDA Consolidation project will not suffer from this same problem because they are working inside existing SDO governance.

To act as an impatient convener of standards, ONC should be careful in trying to replace the existing SDOs and profiling organizations such as IHE and Continua. Their objectives can be better met by convening activities inside or across existing bodies. Creating competing initiatives is not conducive in promoting the strategic changes it would like to see in those SDOs. There is already limited volunteer bandwidth in SDO activity. Creating new places to volunteer may succeed once or twice, but will not achieve the long-term goals because bandwidth is already limited. Such changes are best made by participating in the governance processes of existing SDOs.

How well do Federal agencies coordinate their roles in standards activities in the sector of interest?

Across different agencies, coordination is generally very poor with a few exceptions (e.g., CMS and ONC on meaningful use). Within some agencies, such as the VA, there are excellent programs within the agency itself. Others, such as the CDC, have standards-related programs that appear to be able to benefit from greater internal coordination.

When Federal agencies have been involved in standards setting efforts in a technology sector, how has the progress of standards setting efforts in this technology sector changed after Federal agencies became involved?

In the Care Management and Health Records workgroup in HITSP, the efforts of that committee were greatly improved by the contribution of VA contractors with specific expertise. AHRQ efforts have greatly contributed to the knowledge about Clinical Decision Support (CDS), but have not yet addressed specific needs in this area to the point that CDS can be widely implemented. Both have contributed positively, but net effects are different because of the different stages of standards development. The ONC S&I Framework project supporting the CDA Consolidation effort has vastly increased the volunteer pool, but not without some negative impacts. Adding more people does not necessarily accelerate standards development, but can improve adoption.

Are Federal agencies generally receptive to input from other participants in standards-setting activities?

Agencies are “generally receptive” to input, but that their receptivity varies depending up circumstances. Recommendations on any topic are rarely accepted once “decisions have been made” and cannot be changed by the agency personnel involved in the activity. This is fairly typical in any activity involving technology where decision-makers are separated from technologists. As a case in point, the AHIC Use Case for Public Health Case Reporting was broadly rejected by technology (and

standards) savvy individuals in federal agencies because the necessary standards were not yet available. In fact, HL7 and ISO joint ballots were passed just last year, and are still awaiting publication as a standard. Yet, because such an initiative was an ONC and AHIC priority, it went on in HITSP even though it was likely to fail. And because HITSP was an ONC contractor, with specific deliverables, it performed work that many involved were quite aware would be insufficient to the task. In this case, a short-term tactical effort (Public Health Case Reporting) failed, but the long-term strategic goal (ICSR) may yet succeed.

A similar case occurred when the CDC contracted for development of an Immunization Guide using HL7 2.5.1. In this case, some industry input was that such a guide was not needed, and would interfere with existing efforts to standardize around the CDC 2.3.1 guide, which had already been successful. Given that the guide was going to be developed whether or not others felt it was needed, AIRA participated in its development. There seems to be very little adoption of the new guide even though it is included in the meaningful use regulation. It appears that the deployed standards are sufficient to the task.

Does receptiveness tend to depend on whether the Federal agency is a regulator or a customer?

Receptiveness almost certainly depends upon the regulatory status of the agency and whether the scope of the input affects the regulation. It is also affected much more directly by agency timelines for pending regulation. Current ONC initiatives for meaningful use have legislative mandates on timelines that make it difficult for them to complete their mission. FDA initiatives on completing standards necessary for medical device identification are less restrictive, making that agency more receptive to outside input.

In those sectors where Federal agencies play a significant role in standards activities, how valuable and timely is the work product associated with this effort?

Federal participation varies, as does quality, effectiveness, and timeliness. Standards should be part of an agency's overall strategy, not a tactical effort to meet a short-term objective. Tactical efforts may be timely, but typically lack in quality or effectiveness. Strategic efforts are more successful.

Issues Considered During the Standards Setting Process

With respect to intellectual property, the Sub-Committee would like to understand the approaches you have experienced or found most appropriate for handling patents and/or other types of intellectual property rights that are necessary to implement a standard.

In general, healthcare standards setting organizations (e.g., HL7, ISO, DICOM and IHE) have policies around the use of patents and other intellectual property that are the most appropriate and effective for handling these issues.

How does the need for access to intellectual property rights by Federal agencies factor into the use or development of standards?

Existing policies of SDOs means that patented material is rarely used, and only when necessary, and only when the patent holder makes it readily available. See the question below for other challenges.

To what extent, if any, has the development, adoption or use of a standard, by Federal agencies in this technology sector been affected by holders of intellectual property?

Our response to this question may take the conversation in a direction that was not anticipated when the question was posed in the original RFI.

The key challenge to adoption has been the need to use several different kinds of intellectual property (IP) to ensure standards and implementation guides meet the needs of the U.S because many standards are developed at the international level, and require localization. In addition, some standards are applicable to a wide array of use cases and need to be further "profiled" or constrained for use in a specific case. In these cases, the IP of several SDOs and related bodies may be needed to form a complete specification that will support U.S. requirements. However, the creation of profiles or implementation guides is development of a derivative work, and so is governed by IP policies of the individual organizations holding copyright on the published works. This creates a complex "onion" made up of many layers of standards. Implementers who must "peel the onion" to create an implementation have complained that this delays adoption.

An issue related to this problem is the need for a "standard" form for the IP contained within standards to be used in off-the-shelf tools. Many standards are available in print only formats (most commonly HTML or PDF) and do not include the necessary data for use in off-the-shelf applications used to create software.

How have such circumstances been addressed?

ONC is currently sponsoring work through one of its Standards and Interoperability Initiatives that is being jointly developed by HL7, IHE, and the Health Story Project under HL7 governance. This work will address this particular problem for the Templated-CDA implementation guides, but will not address other standards. The end result should generate a UML-based artifact that can be delivered in a standard form (XMI) as well as be transformed to other formats for use in the development of software implementing the guide.

We would encourage the federal government to sponsor similar initiatives to address similar problems in other standards using various EDIFACT variants found in Healthcare (NCPDP, X12 and ER7 [HL7 V2]), Web Services, Restful Services, and terminology. The lack of use of common formats for delivering these standards is problematic. If it is only available in print, the transfer of information from print to implementation will be just as problematic.

Are there particular obstacles that either prevent intellectual property owners from obtaining reasonable returns or cause intellectual property owners to make IP available on terms resulting in unreasonable returns when their IP is included in the standard?

This discussion is a continuation on the previous topic, and so, perhaps slightly off the expected track.

The SDOs' chief value is in the intellectual property they produce and in the opportunity they provide to members to participate in its development. The availability of an SDO's IP depends upon its business

model, and whether they receive enough revenue from membership or other sources to support making the IP freely available in multiple formats for reuse by others.

What then is the business value of a standard if the producer creates something that is then derived from twice before being implemented? How is that value retained by the producer? Some of these challenges are business problems that SDOs may be able to resolve for themselves, but federal aid or other incentives could result in quicker resolution.

For example: The federal government already licenses SNOMED CT from IHTSDO for use in this country. It could similarly license other content to the benefit of the industry. Another alternative would be for the government to mandate certain requirements that a standard must meet before it could be adopted for certain kinds of use (e.g., availability of standards-based machine readable formats containing relevant vocabularies and models). These are posed as examples of possible solutions; other models are certainly possible, and a great deal more discussion on this topic is needed.

What strategies have been effective in mitigating risks, if any, associated with hold-up or buyers' cartels?

Our discussions on this topic do not address hold-up or buyers' cartels. In many years of industry participation in healthcare standards, we have encountered only a few cases where patents or other IP issues prevented or held up standards development or deployment in the traditional way these problems are thought of.

Adequacy of Resources

What resources are needed to successfully complete the efforts?

The key resources needed for federal success in the development of HIT Standards are those that would foster the development of an overall coordinated U.S. strategy across the federal government and the private sector. That includes keeping track of what agencies are engaged and how, what their goals are, and communication of those goals to industry and the public.

Taking into account budget constraints and competing initiatives, have Federal agencies committed adequate resources?

Federal agencies have committed adequate resources to the development of standards, but few other than ONC, NIST and to some degree, CMS, have committed adequate resources to support education, adoption and use of standards, and very few have successfully committed resources to communications about their activities.

What resource constraints impact the successful completion of the standards efforts?

The most common resource constraint impacting the quality of a standards effort is an arbitrary deadline on their completion. This presents unnecessary pressure to complete the development of a standard or implementation guide before it has attained the necessary consensus for adoption. For

example, the HL7 HQMF Draft Standard for Trial Use project rejected several negatives and suggestions for re-balloting because of contract imposed deadlines on completion.

Another major issue is the limited ability of federal agencies to participate in international standards activities and standards profiling initiatives. As these activities are increasingly conducted at the international level, federal agencies should be encouraged, rather than often restricted, in their standards adoption activities to engage at the international level. This brings important benefits to the U.S. HIT industry in more easily partaking in markets outside the U.S., and provides broader and more stable standards adoption for the federal agencies.

Process Review and Improvement Metrics

What lessons about standards development in complex technologies have been learned so far?

More is less, and less is more. Creating more standards does not add value unless those standards build upon and extend existing work. Having fewer standards to conform to is more valuable to the industry than having several competing or overlapping standards (e.g., CDA and CCR).

The job is not done when the standard is complete. A specification is just that until it is implemented. The phrase "there are no standards for ___" which so often annoys those of us who can point to them, more often means "there are no standards that have been commonly implemented for ___". Federal strategies on standards development should include the entire life cycle, from development, through testing, and aiding implementation.

How have these lessons learned been implemented?

The ONC S&I initiatives are starting to implement some of these lessons learned. They seem to be less likely to be implemented elsewhere due to lack of an overall strategy.

Have there been any impediments to implementing these lessons?

In HIT, the time to market needed to implement requirements of federal laws and regulations is mostly ignored by the existing legislation (ARRA/HITECH). The biggest complaint is "too much, too soon". Changing the way standards are developed will improve the situation, but not in time to have its full effect on meaningful use by 2015.

How has this information been documented or disseminated, and implemented?

As best we know, this RFI is the first attempt to document and disseminate this sort of information.

What kinds of performance metrics are appropriate to measure the effectiveness of the standards-setting process?

1. Size of specification (pages).
2. Elapsed time from project inception to publication.
3. Number of products implementing/testing in initial stage.

4. Number of products implementing/testing after one year.
5. Number of balloters.
6. Number of participants in development.
7. Some objective measure of “ease of implementation”

If any such performance metrics have been used, what are the results?

No such comprehensive study has been performed to our knowledge. Partial data is available from HL7, IHE, and HITSP activities. HITSP did publish member effort in hours across its working groups.