

Key Talking Points and Issues For Standards Development Organizations (SDOs) and The SDO Charter Organization (SCO)

Background:

- During 2008 and 2009, as part of the push to improve healthcare, there have been efforts to improve the use of information technology in the healthcare industry.
- As part of the effort, HITSP was created as one of the ways to deal with the challenge of the standards – gaps in the standards, overlapping standards, missing standards, etc.
- Sometimes, the standards development organizations are seen as part of the problem – the approval processes are too slow, standards may compete, there are different vested interests, and they are drawing from similar pools of resources.
- It is important that the valid, valuable and important role of the SDOs be clarified, that our collective commitment be clear, and the complexity of the challenges and issues be explained.

Goals of these talking points and FAQs:

- Provide a basis for SDO leaders and their respective Boards to be consistent on the issues and our value proposition.
- Provide a joint, agreed upon common list of positions on SDOs, our value, contributions and current initiatives.
- Provide the basis for formal communication that can be consistent from both the SCO members and their supporting SDO press release activities.
- Provide a common basis for both formal and informal communication on key standards issues.
- Provide a document upon which the SCO can make a decision on next steps and whether this talking-points document can or should be basis for a written commentary and/or a formal outreach/education effort by each voting member's organization.

Key Issues:

- Perception that SDO are not timely
- Perception that SDO cannot work together effectively
- Perception that there is problematic conflict by SDO stakeholders, in terms of vested interests of the vendors, or volunteers
- Concern that we are not working well or efficiently with HITSP
- Concern about resources to respond to the needs of the industry
- Concern that certification is expensive and not a guarantee of connectivity
- Concern that standards overlap
- Concern about gaps in the standards

Key Points:

- Healthcare technology and workflow issues are difficult to solve.
- Subject matter expertise from the industry in creation of standards is critical.
- Timing and responsiveness of the process of reaching industry consensus.
- There is a need to identify and bridge the gaps in overlapping work efforts in healthcare.
- There is a need to identify and bridge the gaps of/between standards.
- There is a need and willingness for the SDOs to collaborate for the implementers.

Frequently Asked Questions

Introduction

There is clearly a need to connect the healthcare environment (doctors, hospitals, pharmacies, other providers, insurance companies, employers and patients) in better ways than we have today. This poses an opportunity to some, a challenge in many spheres and a threat to some

others. The challenges arise from: the various different perspectives of the different stakeholders; educational/operational/training needs; workflow issues; modifications to the existing install base; determining a return on investment; citing the benefits; and, lack of desire to change.

The following attempts to answer some of the frequently asked questions (FAQ's) about how to do this:

What is a standard?

A standard is a commonly used and/or agreed to definition. There are standards for electricity outlets, weights and measures, time, temperature and data formats.

The earliest data format standard for transmission of the English alphabet characters was Morse Code (dots and dashes in various combinations). Today, the predominant data format for a character set is in the United States is called ASCII. This character set is used in keyboards, in exchanges of data via computers, etc.

What kind of data standards exist today?

There are many kinds of standards. There are standards created by governments, vendors, industry groups and consensus bodies. Examples of government standards are an IRS tax form, an electronic tax filing format, interstate highway systems, and requirements for healthcare privacy. Examples of vendor standards are formats such as Adobe PDF or Microsoft Word Doc files. An industry group example is the financial automated clearing house (ACH) funds transfer formats. Examples of consensus body standards include standards created by standards development organizations (SDOs) such as ASC X12, Health Level Seven, NCPDP, ASTM, and CDISC.

Do all standard development organizations use the same process?

No. However, all American National Standards Institute (ANSI)-accredited standards development organizations must follow the ANSI requirements in their processes.

At an international level is the International Standards Organization (ISO). Both ANSI and ISO accredit and audit the processes of these organizations. The ANSI-accredited SDOs take very seriously the requirements of openness, balance, consideration of views, gaining industry consensus, and following procedures.

Other organizations have processes which may be more or less rigorous; they may restrict membership or avoid subjecting their standards to public review.

Is there one standard which solves all the connectivity issues in Healthcare?

There are many connectivity standards in healthcare. Some include: X12, HL7, NCPDP, ASTM, DICOM, CDISC, IHE and others. These organizations may provide expertise for a given area of healthcare, or a given level of exchange of information. There are gaps which are not covered by any of the existing standards and some overlap between the standards. In addition, there are multiple interpretations of each message/document/transaction/service of each standards organization. The organizations are working together to reduce the differences in how these are implemented. The organizations are working together to reduce the differences between the base standards, condense the options for given messages and increase the number of messages available.

Doesn't the internet and XML solve everything for us?

Truly establishing point to point connectivity requires agreement on many fronts. First, there must be agreement on a communication protocol and infrastructure. At one point this was all dial-up and leased lines, now it is the internet. Second, there needs to be agreement on character representation or encoding (this is now ASCII). Third, we need to have a common syntax structure, this is now XML. Lastly, we need to agree on common messages or services. This is also known as arriving at a common semantic base and information model. While the internet

provides transportation and XML provides syntax, structure, entities still must agree on the intent of the exchange, of the data elements exchanged, of the code lists used.

Why are common semantics important?

The end goal is seamless operations of exchange of information. For this to occur, the systems must understand the meaning of the data. For example, when a consumer purchases an item with their debit card, the merchant's sales system notes the exchange; a message is conveyed moving money from the consumer's bank to the merchant's bank seamlessly. Similarly, when your primary care physician wishes for a patient to be seen by a specialist, the referral should appear seamless in the specialist's work flow and the resulting observations should also appear in the primary care physician's work flow.

Why can't we do this with just exchanging secure emails?

Secure emails are part of the picture. Secure emails do not necessarily contain structure in the text body or attachments. To reduce the amount of data entry at each end computer systems in healthcare should be able to accurately understand the intent of the exchange, and the data. This means that patient name, doctor name and other fields should be easily found by other applications – potentially with coded, structured data, which cannot be accomplished with just secure email.

Can't one big software company solve all of this?

Unfortunately, no one software company produces all the components necessary for any given enterprise, whether it is in healthcare or not. Healthcare enterprises have additional complexities which are generally satisfied by multiple unique software systems. There are varying complexities, different needs (specialty practices, large/small enterprises, clinics versus hospitals), and broad technology needs that would be difficult to be satisfied by one company.

Add to the functional requirements the differences between operating systems (Windows, MacOS, Unix) and platforms (servers, handhelds, personal computers) – it would be difficult for one software company to create one integrated solution.

Is certification important?

Interoperability is important. If one can assure interoperability without certification, then certification is not needed i.e., one is not worried that their email software will not connect to other email systems. However, without certification, how can compliance to acceptable standards be measured and assured? Certification attestations help assure connectivity before the purchase of a system.

Why can the standards development process take so long?

Sometimes the process does take long, other times it is a perception. Some standards organizations ballot changes multiple times per year; others have yearly or bi-yearly schedules. The creation of standards changes relies on industry business needs coming forward. These business needs may address current problems, or reflect future ideas. The analysis and development of the change requirements involves volunteers from the industry. These volunteers sometimes have other priorities. Sometimes meeting the business need is difficult – the problem is complicated or there are competing perspectives. Sometimes the technical standards solution is waiting for industry to determine how to build their business needs. Sometimes the standards require a new terminology, or a modification to an existing terminology.

The process of changes to the standards is governed by the *ANSI Essential Requirements: Due process requirements for American National Standard*¹s. The ANSI-accredited SDOs take very seriously the requirements of openness, balance, consideration of views, gaining industry consensus, and following procedures.

¹ http://www.ansi.org/standards_activities/overview/overview.aspx?menuid=3

Why does the HIPAA regulatory process for standards take so long?

Since the passage of the HIPAA regulation, three standards development organizations (SDOs) - ASC X12, Health Level Seven (HL7), and the National Council for Prescription Drug Programs (NCPDP) have worked with the Office of E-Health Standards and Services (OESS) to propose a process of naming new versions of standards under HIPAA that is more timely and efficient for the industry. The SDOs testified to the National Committee on Vital and Health Statistics (NCVHS) in December 2005 and October 2006 and presented this [paper](#) with discussion of the current problems in the process and a proposal for the future. NCVHS discussed with HHS who noted they are constrained by their interpretation of the Administrative Procedures Act. Modifications to this process would require regulatory changes. The document is available at http://www.ncdp.org/news_hipaa_trans_current.asp#SSH

Who are the stakeholders in the SDO process?

The standards development process includes a broad array of stakeholders, those who use the standards, those affected by the standards, those that develop the standards and those that support the development of the standards. In the healthcare industry the stakeholders include (but are not limited to) the following:

- Providers, clinicians and their related organizations and associations (e.g. AAFP, ACP, NACDS, NCPA, AMA, ADA, etc)
- State, federal and local governments
- Payers, insurers, third-party organization and their related associations (e.g. PCMA, AMCP, BCBSA, etc)
- Volunteer members of the SDOs & paid staffs of the SDOs
- Consumers and consumer advocacy organizations
- Organizations that directly or indirectly support the SDO efforts (e.g. ANSI, CDISC, WEDI, HITSP, NCVHS, NUBC, NUCC, etc)
- Organizations that represent specific areas of healthcare (e.g. American Heart Association, American Health Information Management Association, Health Information Management Systems Society)

Are you involved?

Have you wondered “why can’t this be added to the standard?” or “why doesn’t someone fix this”? The questions and the answers come from the industry; it’s the implementers, the users of the systems, who bring the questions forward and help find the solutions. If you aren’t involved with a standards organization or have a voice at the table, how are the problems corrected?

What is the purpose of the SCO?

The mission of SDO Charter Organization (SCO) is to provide an environment that facilitates effective coordination and collaboration on U.S. national healthcare informatics standards development, with recognition of the international and multi-industry stakeholder implications and challenges. Its purposes include:

1. To facilitate the coordination of conventions for enhanced interoperability among diverse standards development organizations in the areas of health data acquisition, processing, and handling systems.
2. To communicate and coordinate when appropriate with the U.S. Technical Advisory Group (US TAG) in order to facilitate a unified representation of US standards (this is not intended to supersede any member’s existing coordination with the US TAG).

How does the SCO work with HITSP?

HITSP is a member of the SCO. In addition to working on use cases from the Office of the National Coordinator, HITSP’s Foundations Committee is comprised of SDOs and interested parties, working on collaborative items. HITSP does not create standards; the standards development organizations create standards. When HITSP recognizes a need or a gap, it is

brought to the SDOs. It was recognized by SDO participants on the Foundations Committee that there needed to be executive-level support by the SDOs. While the Foundations Committee contains industry expertise, there are working items which must be brought into the SDO's processes for delivery. There may be tough decisions that may need to be made in collaboration, which would require executive-level support.