Use Case: The Fulcrum of Standards Development

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Information for general health information managers about the standards development framework and process—with a focus on mobile health For Patient and Self Care

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It is not always clear whether a developing standard drives a use case, or if development of a use case drives the establishment of a standard. Our Western culture often prescribes to the thought that a difficult or impossible problem (a use case) will prompt inventions (standards) aimed at reducing the difficulty. So, naturally, the need to solve a problem should drive the process.

Introducing a valuable use case that fits business needs starts with knowing how and where to intervene. Knowing how and when to suggest revisions and introduce specificity to existing use cases can help in the triangulation process so the best and most widely applicable or best conceived standards can emerge. Health information management (HIM) professionals work within existing data and health information systems to ensure the data generated by those systems are accurate and purposeful as they are adapted to emerging standards. The purpose of this article is to influence the development of those standards so they are the best attainable for the needs of providers and patients, as well as the needs of the HIM and IT staff who must implement and integrate standards into enterprise systems.

Success or failure of a standard can be traced back to having a committed patient population involved as well as informaticists committed to solving an issue. Patients and their caregivers who identified unmet needs and have interest or abilities in clinically relevant technology are those most likely to join standards development groups.

How a use case develops, what it accomplishes, and how it influences national and international cooperation through standards development in the healthcare IT market and its affiliated markets is also addressed in this article.

Standards Start with a Story

A standards development organization (SDO) typically starts its focus on a health problem with a user story.

Although the notion of standards development implies a standardized process to that end, in most situations multiple attempts are needed. This may involve many stakeholders that might have competing interests, necessitating a core group of "organizers" to distill the needs and solutions down to the essence of a technical solution capable of addressing the industry challenge (i.e., information exchange). This solution is called a standard when it has been endorsed by a standards organization —such as the International Organization for Standardization (ISO) or Health Level Seven (HL7)—and when a unique solution to a bedeviling issue is recognized using a consensus process. Only when a consensus is reached with a solution that meets the needs of most of the stakeholders most of the time does a standard emerge. This article describes how that process unrolls in healthcare terminology standards development. In clinical standards development, a "user story" (known as a storyboard) represents the cumulative experience of most healthcare entities and precedes the use case. The storyboard scopes and drives subsequent standard development.

In 2009, the HITECH Act identified problems that had been impeding interoperability of health records and provided the economic and regulatory stimulus to solve them. To help resolve interoperability issues, the Office of the National Coordinator for Health IT (ONC) and the Centers for Medicare and Medicaid Services (CMS) have influenced which use cases and standards are worked on and in what sequence. The Standards and Interoperability (S&I) Framework of ONC hosts multiple workgroups that develop use cases in a variety of clinical domains. ONC's Interoperability Roadmap also lays out a strategy for standards development in the US.[1]

ONC's S&I Framework brings together a collaborative community of participants from the public and private sectors who use a set of integrated functions, processes, and tools that enable execution of specific value-creating initiatives. Each S&I initiative tackles a critical interoperability challenge through a rigorous process that typically includes the development of clinically-oriented user stories and robust use cases.

Through white papers, storyboards, and use cases, the S&I Framework community seeks to bond policy, user, and producer interests into technology standards development to support healthcare transformation. The main value of a use case is that it helps distill solutions that have broad applicability both domestically and internationally within a construct and allows different views to be expressed and then harmonized. The use case functions as a bridge between the world of the clinical informaticist and the clinically oriented standards informaticist. One person rarely represents both roles.

The clinically oriented standards informaticist works comfortably in a Robert's Rules of Order Framework for adjudication of abstract terminology questions using a model-driven approach. The model that serves as the goal is a derivative of the Reference Implementation Model of HL7—a fully abstract representation of the future computational framework of the electronic health record (EHR)—one that to date exists only as a concept, not in reality. Thus, not all its adherents agree on all its details—they just agree temporarily on certain key components of the abstract model sufficient to launch a logical model use case.

The logical model, as its name implies, begins to translate the abstract model into actionable components. Notice that this article has discussed the bottom-up clinical-to-architectural approach and the top-down conceptual-to-logical approach. Both are required and both must proceed for resolution of all contradictory aspects so harmonization can emerge. A use case has value when it helps create an object-oriented model between the system model and reality. How the use case forms the basis of the construction and testing process controls a large part of the system development.

How a Use Case is Developed

The author of this article worked for over five years with three teams that generated two use cases and several storyboards:

- The closed loop PCP & Specialist Provider referral use case, which led to the stage 2 "meaningful use" EHR Incentive Program's requirement of demonstrating the ability to provide a clinical summary to the recipient clinician electronically and bidirectionally.
- The Home Care use case, which helped elucidate how physician and nursing service providers could communicate electronically to develop a care plan and certify Medicare payment for it.
- The Case Management/Disease Management storyboard, which helped expand the HL7 Care Plan Abstract Model. It broadly describes how health plans and providers can collaborate to improve communications in situations involving complex care teams and interstate care situations. Whether this storyboard will lead to a formal use case remains to be seen.

During development of a use case, some aspects are worked out by individuals working alone or in small groups, punctuated with larger gatherings via a webinar of like-minded or interested volunteers. This work of individuals and groups feeds the standards process, itself a multi-stakeholder endeavor also driven by the consensus process used at each level of input.

Some of the use case development work is done by individuals working alone, punctuated with gatherings usually by webinars of like-minded or interested volunteers. When working with HL7, guidance is provided by HL7 committee leads and input is sought from organizations like ONC and similar organizations elsewhere in the world that provide technical experts and sometimes consultants to help shape and refine the resulting standards.

Governmental oversight helps ensure maximum applicability and, ideally, that there are no competing or contradictory standards for a given market segment or technological approach. Committee leads and chairs are themselves selected by a consensus process. Over time they exert more influence because of this endorsement of their peers and they help to guide development. The committee leads' and chairs' role is one that straddles policy and technical goals and as well as clinical ones.

In committee, one of the ways the leads exert influence is by determining what is "in scope" or "out of scope." Whoever has the responsibility of leading such a work group must continually scan and determine if the ongoing discussion remains in scope.

In the case of mobile technology use cases, user stories need to address the applicability of the standard and the technologies that rely on it, beginning with the development of a storyboard.

Some workgroups and use cases are very grassroots, while others are chartered by recommendation of an organization like ONC. A variety of stakeholder groups may send representatives to participate in standards workgroups. They include advocacy groups, state agencies, CMS, and a very broad representation of vendor organizations both for profit and not-for-profit, like AHIMA. HL7 and Integrating the Healthcare Enterprise (IHE), both international SDO-based entities located in the US, host closely related standards work involving use case development. ONC contractors and staff often participate in use case development. SDOs typically also participate.

These entities operate as not-for-profit businesses or all volunteer groups with a constellation of sponsoring organizations that have an interest in determining how a standard is defined. They provide meeting calendars, listservs or Skype communities, and a wiki where open source documents are viewable. It is increasingly common to have website-based interest groups working by consensus, informed by internationally vetted policy objectives, and funded through arms length transactions of sponsoring professional entities who stand to profit from the work in the future as a market, rather than as individual businesses.

Usually, indirect support is provided and influence exerted by interest groups, such as large healthcare institutions, electronic systems vendors and their employees, and US government agencies like ONC and the National Institute of Standards and Technology (NIST). A consortium of US government agencies participates in the Federal Health Information Model (FHIM). The FHIM meets monthly to review topics of common interest in healthcare interoperability standards development that spans US government agency needs.

There was an early initiative to connect the government agencies in a network that would allow industry representatives, including clinical informaticists, to access their use case and standards content. This was to be attained by use of open architecture. Other industry groups, like the Object Management Group (OMG), influence the marketplace through standards development and stipulated implementation by standards contributors, in addition to fostering broad educational pieces (i.e., www.tutorialspoint.com/uml/index.htm).

Some ways the HL7 Care Plan standard is distinguished from the FHIM standard of the same name is that the HL7 Care Plan is written to the Fast Healthcare Interoperability Resources (FHIR) standard, whereas the FHIM standard was developed in Unified Modeling Language (UML), the leading type of object-oriented programming. The FHIM also takes a more pragmatic look at care plans from the perspective of care planning, taking into account the existing actors and payment systems in use today. The HL7 Care Plan Model is more abstract, and has endeavored to remain as free from governance influences as possible to be applicable worldwide. It is being modeled as a FHIR implementation.

Why Standards are Needed in Health IT

In the healthcare domain, guidelines drive best practice. For the software industry, it is standards. A new HL7 standard reaches a state of development known as Draft Standards for Trial Use (DSTU), a “pre-standard” that is broadly available to gain implementation experience before members vote on it. Negative votes are reviewed and discussed in a reconciliation process until consensus is reached. Vendors pilot and develop projects at the DSTU stage. Having the proper expertise and sponsorship will affect the delivery of quality standards. Ultimately, the healthcare industry needs to produce timely work products that meet industry needs. Based upon experience with the DSTU, the work product is improved and re-vetted as a “normative” standard, elevating the stature of the work and marketplace assurances that it is fit for a purpose, representing the norms to which vendors may elect to build products.

Successful standards development depends upon clear use cases that rely on identified commonalities, principles, and examples contributed by participants who have a broad and overlapping base of knowledge and who are available and willing to participate in an interdisciplinary standards development discussion. Use case development needs to be done agilely and iteratively, just like software development. Bringing a national focus to health informatics standards development has helped accelerate the process. In the US, the creation of ONC was the catalyst. This speed is new for healthcare, which usually builds conceptual awareness slowly and over years with much supporting documentation and logical deductive arguments applied. The inductive thinking that is key to successful standards development is much more akin to the consultant world than to clinical thinking.

A story is formalized as a storyboard. It defines the setting, the intended target of the technology, the way it will be used, and its clinical aim. The storyboard sets out when and where messaging will occur to facilitate communication, and then a use case is developed. The use case breaks the storyboard down into segments involving actors, actions, and outputs. As the use case develops, terminology questions arise. Pre- and post-messaging features are identified when interoperability is in focus. Certain types of software and specific approaches to terminology, known as "ontology," help create a shared technical and historical terminology development framework within which a given term or set of vocabulary can be selected and evaluated. A term's place in the hierarchy of concepts needs to be identified within SNOMED CT, the most widely used clinical vocabulary in medicine.

Determining ontological relationships and term choices can be very simple or incredibly complex. Ontology specialists are often in short supply as even specialists have difficulty agreeing on what ontology is, how to apply it, and even how much meaning it has for a given use case development. Ontology provides the right contextual framework for the terms needed to define and support a comprehensive use case even though it is the least well defined part of the process.

Work on models and terminology, actors, and formal modeling processes are followed by "connect-a-thons," such as those hosted at the annual Healthcare Information and Management Systems Society conference, which help stimulate interest in pilots that may lead to product development and implementation.

Characteristics of a Good Standards Developer

It is the rare individual who knows standards approaches, is conversant with the software development world that relies on them, and appreciates and masters comprehensively the clinical and healthcare process knowledge necessary to derive and complete a use case applicable to all. Such a person needs to be as much or more of an inductive thinker to help shape the common approach to concept and terminology as he or she can deductively apply the right standard to the right purpose in system development. The use case represents a distillation of structure and function of each contributing discipline, harmonized using descriptive language that a practitioner in each contributing field who lacks comprehensive knowledge can understand. In short, it must distill complex thought to simple activities and actions.

The type of individual drawn to such work is one with an interest in design and architecture, as well as in clinical systems and computer systems engineering. The thinking that influences discussion includes what is needed, why it is needed, what are possible solutions, and which are elegant solutions that will solve problems affordably. Participation is driven by a collaborative mindset and interest in the greater good.

Available expertise limits topics that can be addressed in a use case. Standards experts, application software engineers, telecomm technology experts, privacy and security experts, clinical experts, patients with self awareness and an appreciation of technology, the people who care for these patients, and communications experts and writers all play an important part in the use case development process. The need to involve this wide group of individuals is essential and a potential gap, as the inability to attract subject matter experts to contribute expert opinions illustrating the current problems and how things should work is a limiting step with the potential to adversely affect the efficacy of health IT standards.

Participation in standards development is a pro-bono activity of highly committed people. Participating companies may sponsor some of the participants as part of their job. What unites everyone is the realization that having industry norms makes it easier to meet minimum expectations and predict the cost of software development. It also makes it clearer where there is opportunity for innovation and where all must sacrifice some creativity to reach consensus.

How Standards Influence the Mobile Health Industry

Mobile health standards groups are currently hosted by HL7.[2] Mobile health standards are of interest because this affordable technology is the most widespread technology available to patients and allows all to capitalize on their improving affordability and ease of use. Healthcare providers use mobile devices in some facilities to manage personal time and workflow. Many would like to gain access at work or use their own devices at work and outside of it. Patients use mobile devices to communicate and to obtain information. If patients are to have the benefit of health data then it must be on a platform convenient to them that they know how to use and that they want and can afford to use.

Most patients now own a mobile phone, but not all have a smartphone. For this reason, Short Message Servicing (SMS), the formal name for text messaging, is the technology of choice in the developing world. It may also be the best way to help those in the US who cannot afford a smartphone or who are less likely to want to use them, such as the elderly and the economically disadvantaged. SMS is used for low or no cost messaging. In the healthcare environment, security and privacy concerns have constrained development even though consumers seem to be pressing ahead in arenas such as use of fitness-monitoring applications.

For mobile health, the use cases under consideration include public emergency systems, disease-focused technology, cultural and socio-economic interest groups, patients at risk of adverse events, and those who can benefit from frequent or continuous monitoring. For example, an HL7 Mobile Health Workgroup co-hosted by Matthew D. Graham of the Mayo Clinic and Gora Datta of Cal2Cal has been considering these options along with the Mobile Health FHIR-frame Group organized by Associate Professor Christopher Doss of North Carolina A&T State University and his colleague Nathan Botts. They decided to focus their work on communicable disease outbreak communications.

To date, most of the technical efforts are directed to provider needs and uses on behalf of patients. Yet, patients themselves have electronic information needs that could help them perform better self-care as well as improve their capacity to make value-driven choices about their providers. ONC has taken the lead in identification of the types of use cases that will be beneficial for data that patients themselves will generate in the future as an integral part of their health record. A summary of what patient-generated health data (PGHD) or patient-generated health information (PGHI) can be found is available at www.healthit.gov/sites/default/files/patient_generated_data_factsheet.pdf. PGHD and PGHI include, but are not limited to, health history, treatment history, and symptoms. An AHIMA Practice Brief on patient-generated health data in EHRs is also available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050841.hcsp?dDocName=bok1_050841.

The National eHealth Collaborative/ONC Patient Generated Health Information Technical Expert Panel developed a taxonomy in 2013 to provide a common language to discuss, compare, and contrast PGHI examples and to permit categorization of planned PGHI implementations to help organizations prepare people, processes, and technology in their institution. The full report can be accessed at www.healthit.gov/sites/default/files/pghi_tep_finalreport121713.pdf.

HL7 is working to create a standards framework for consumer health smartphone applications. This project intends to define standards for app security, privacy, and data storage/use. The task is complicated by the range of issues addressed by mobile health apps, and their connectivity with devices, data repositories, and EHR/personal health record (PHR) systems. To develop the framework, the workgroup refers to three model use cases that attempt to capture app commonalities and differences, including:

1. A walking app with no attached devices in which user data is stored on a smartphone.
2. A weight management app that receives exercise data from a wireless wellness device, which is not FDA-regulated, and allows data to be exported to a PHR.
3. A diabetes management app that collects data from a FDA-regulated glucometer, and sends data to an EHR to be reviewed by a clinician as well as allows the user to see their own data through a graphical display on the app.

How to get service and value to the patient means different things to different groups. The Datuit company's patient- and population-focused Care Plan Manager Application can be accessed via a smartphone browser as well as by computer. A patient can message any member of his or her care team, including family caregivers, from the application, providing an early example of how PGHI can be used. Patients and family caregivers can access their shared care plan to understand what medications and other interventions are included on their plan.

It can collect and display biometric data (weight, blood pressure, glucose) as well as symptom monitoring (pain, food intake, strength, depression) for chronic care management so that patients, family caregivers, and clinicians can all look at the same data in real time. This includes a medication reconciliation function that allows the various clinicians to access the same medication list and correct it when necessary. Patients can directly subscribe to Datuit's Blue Button app, and provider organizations can also utilize it for shared communication. How and whether PGHI formulated in writing can be formally included in a provider health record is controversial. A variety of patient advocacy organizations have sprung up to help focus interest in standards development for and about patients' self-care, such as Connected Health Resources (www.connectedhealthresources.com).

Populations whose health can fail suddenly, whose care changes frequently, or whose care benefits from knowing one's biometric data status are good candidates for mobile health solutions. Joe Kvedar, MD, president of the Partners Center for Connected Health, has been working with vendor organizations like McKesson to develop and pilot applications to improve fitness and health status and to validate not only the results but also the acceptability of the technology to patients.

People everywhere see the benefit to improving health using technology. The Institute for eHealth Equity advocates for and supports the collection, sharing, and reporting of data stratified by race, ethnicity, and gender to improve health outcomes and reduce health disparities. The institute's Text4Health project was designed to assist targeted communities through thoughtful health messages about general wellness, prevention, active living, diet, and medication adherence. It is also designed to support specific initiatives focused on managing specific chronic illnesses such hypertension or diabetes.

The project used SMS texting to reach out to and engage its mainly African American constituency. Implemented with assistance from five faith-based organizations, the Text4wellness.com program, funded by the Aetna Foundation and Drexel University, was successfully piloted in Columbus, OH, Atlanta, GA, and Dallas, TX. Pastors in each of the faith-based organizations agreed to chat about health improvement and parishioners were asked to respond to surveys about attitudes to healthy living from the pew. Patients have much better ability to self-monitor and self-regulate than ever before when technology provides ways to help track schedules, events, and results. The "activated patient" is a central objective of patient-centered care and care management, especially in chronic disease management.

Triangulating Use Case Objectives for Standards Development

The existence of available technology as well as the purpose, intent, and technologies' perceived value can influence whether a given technology and a given storyboard is selected for a use case. Mobile technologies that manage health outcomes via motivation, education, passive biometric data collection and transmission, converting data to knowledge, performing aspects of clinical information management, or communicating needs and findings are the focus of mobile health solution development.

Deciding which use cases, devices, and communications systems must be selected for the few use cases that are being developed by standards organizations is driven by a myriad of economic, cultural, and socio-technical factors. The cost/benefit structure and priority of the intended audience, as well as the likelihood of adoption by developers, relies on market analysis or policy imperatives and funding. In the future, interest groups, individual government agencies, and vendor organizations may want or need to develop additional use cases and share them widely.

The devising of a use case is the first step in a long series of events that hopes to result in health IT-enabled and transformed care. It is the step where the need and the path to a solution meet in a modeling format that is human-readable as well as symbolic. It is the place where human systems and machine specifications meet and influence each other.

Notes

1. Office of the National Coordinator for Health IT. "Connecting Health and Care for the Nation: A 10-Year Vision to Achieve an Interoperable Health IT Infrastructure." June 5, 2014. www.healthit.gov/sites/default/files/ONC10yearInteroperabilityConceptPaper.pdf.
2. Health Level Seven. "Events." www.hl7.org/events/index.cfm?ref=nav.

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