



Standards Insight

An Analysis of Health Information Standards Development Initiatives

November 2002

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Background

As regular readers of the *Standards Insight* know, we have provided an ongoing commentary on the progress of HL7 since our first issue in December 1999. At that time we termed HL7 to be “the best single prism for observing healthcare interoperability standards.” We are in good company. Just last March, the National Committee on Vital and Health Statistics (NCVHS) recommended to the Secretary of Health and Human Services that HL7 be recognized as the core message format standard for exchanging patient medical record information (PMRI). It should be clearly noted that these analyses are based on HL7’s past history, specifically Version 2¹ – a messaging standard that is widely used both in the US and internationally. However, since 1996, HL7 has been focusing most of its resources on developing a replacement standard – Version 3.0.

We have followed the challenges created by the scope and methods of Version 3.0 as well as HL7’s expanding portfolio of opportunities. Usually we could report progress, but time is passing and Version 3.0 remains two years away just as it appeared back in 1996. The needs for and benefits of integrated clinical systems, which animated HL7’s vision, are now being acted upon. The healthcare information systems industry is implementing enterprise clinical information systems to reduce errors, improve care processes, and control costs. Interoperability has become a highly visible management and policy issue in the United States and internationally. And HL7 is not ready with its new standard.

In previous issues we have discussed the need for establishing clear business priorities to drive technical standards. On the surface, the fact that Version 3 is eight years in development and is not yet available to support the surging growth in clinical information systems is reason for examination. So we will use this issue to look at HL7 at some depth to see how it is meeting the business needs of its “customers” and other stakeholders.

HL7 History

Health Level 7 (referencing the top or application layer of the ISO/OSI seven-layered networking standard) was initially formed in 1987 to address the challenge and opportunity presented in using local area networking to link best-of-breed departmental systems. Using the ISO model, this founding consortium² of vendors, consultants, and providers developed a basic set of standard messages to exchange clinical and administrative data between the primary hospital information systems.

Version 2.0 was introduced in 1988 and it and its successive point releases have become widely accepted as the standard for clinical messaging interfaces and HL7 has become the brand name for interoperability. No vendor could afford not to claim HL7 compliance. But Version 2, in all of its releases, is highly flexible (to accommodate a wide range of existing applications and local implementations), leaving wide ranges of options for each implementation. This ambiguity is summed up in the common phrase “when you see one HL7 implementation, you have seen one HL7 implementation.” Although one still needed an interface engine and had to craft and maintain these many-to-one interfaces, Version 2 supported basic interoperability for most hospitals in the

¹ Version 2.3 is the most widely used version of the 2.x standard and was the baseline cited by the NCVHS in its PMRI recommendations. Version 2.4 is the most current release. Version 2.5 is currently in ballot. Although each successive release adds some new messages and fixes and extends existing messages, all Version 2.x messages share common characteristics in terms of syntax, optionality, and use. For simplicity we will use Version 2 to reference the current set of standards unless there is need to reference a specific version.

² Many of the key, early HL7 members have remained active and guided the organization over its 15-year life. This leadership, made up of recognized clinical and technical experts, has served the organization well in infusing purpose and mission. Many of the key leaders are physician informaticists. They are joined by a cadre of information technology consultants, HCIS vendor-based developers and informaticists from major provider organizations. In recent years this group has been expanded by similar HCIS elites from the international community. In sum, they represent some of the best and brightest in healthcare informatics.

United States and in other countries. But this basic interoperability, such as ADT updates, order and results communications, and billing support, was not seen as sufficient to meet changing business requirements or to leverage changing IT paradigms, e.g., Web technologies.

Vision for Version 3.0

Recognizing these emerging trends and with significant foresight, the HL7 leadership in 1995 decided that fixing Version 2 weaknesses³ did not offer the potential value compared to starting with a new approach. Thus, in 1996, HL7 began to develop Version 3.0 based on a vision of where new information technology could take the HCIS industry as well as the lessons learned from Version 2 messaging.

Version 3.0 objectives were to:

- Build unambiguous messages,
- Derived from a reference information model (RIM),
- Using object-oriented methods,
- To eliminate optionality by specifying message structure, content, and trigger events,
- Subject to conformance testing,
- Leading to better, faster, and cheaper interfaces for both vendors and end users.

Much has happened since to enhance, change, and expand the vision as well as alter the development plan and methodologies.

Web Technologies Changed Messaging

Web technologies in all their manifestations⁴ have changed the information systems landscape. In 1996, IT was struggling with client/server systems, which were evolving around object broker technologies. (Remember the CORBA-COM wars?) By 1998, the Web had not only become a widely used interactive network changing consumer and business relationships,⁵ but also had introduced new IT architectures and paradigms. We went from tightly coupled systems to loosely coupled distributed servers linked by messaging over Internet Protocol (IP) using Simple Object Access Protocols (SOAP).

Of the entire set of Web technologies, XML (extensible mark-up language) became the most pervasive. It is the preferred language of Web technology-based messaging and human-machine interoperability. HL7 leadership once again foresaw this pervasive importance of XML early and steered HL7 Version 3.0 to target XML as the “preferred” implementation.

The HCIS Market Changed Dramatically

³ The obvious fix to Version 2 is developing and registering message profiles and ultimately defining a conformance standard. This was an approach pursued by the Andover Working Group in the mid-90s. AWG eventually failed to achieve critical mass and “joined” the HL7 Conformance SIG, which continues the effort to create message profiles.

“Conformance templates” are presently being used by Integrating the Healthcare Enterprise (IHE) for its standards acceleration effort.

⁴ Web technologies are loosely used to mean system approaches stemming from W3C standards, e.g., HTTP, URL, IP, and others.

⁵ One of the primary business impacts of Web technologies was to transfer focus from intra-enterprise systems to inter-enterprise systems. In healthcare, this technology-driven shift has tended to move focus from improving the efficiency and effectiveness of internal processes and systems in favor of external efficiencies, such as e-health, electronic billing, supply chain management, and EDI.

Business Requirements

It is important to understand that HL7 was, and in many respects still is, a hospital-centric messaging standard. Fueled by the changing business requirements arising from hospital mergers and integrated healthcare enterprises, from managed care pressures and now from process improvement and quality initiatives, the HCIS market expanded beyond its traditional hospital data messaging focus to one supporting integrated health systems and inter-enterprise transactions and now to workflow management. The rapid change of scope greatly complicated HL7's model-based project. It also has caused some consternation in the membership, as we will note later. Finally, it is not clear that HL7 itself has formally re-examined the changing business requirements of its end-user stakeholder community of vendors, healthcare organizations, and governments.

HIPAA

HIPAA has had a profound impact on both business requirements and on standards development. We and many others have addressed HIPAA-mandated standard transactions and its privacy and security regulations. Besides the actual redirection of IT resources that it mandated, HIPAA also introduced an observable politicization of standards as Standard Development Organizations (SDOs) pursued the use of regulations to mandate their standards. For some SDOs, this appeared to be a path to ensured adoption, organizational importance, and personal success. This induced or forced HL7 to play the game – gaining entry into HIPAA through claims attachment and then promoting its role in the NCVHS PMRI “standards.” This eye to Washington caused some level of defocusing and “scope creep.”

Clinical Document Architecture

In the mid 1990s, XML and its standardized general markup language (SGML) superset inspired other medical informaticists to envision standards for medical documents. One of these, the Kona Group, decided to join the HL7 umbrella to gain broader participation and support. The quid pro quo was that any XML-based documents would be harmonized with the Version 3.0 RIM. This required the SGML/XML special interest group (SIG) to work both with rapidly changing XML technologies as well as with an unstable RIM. This work, now known as the Clinical Document Architecture, is under the evolved Structured Documents Technical Committee (XML messaging was split off as a separate SIG). The inherent difficulties of applying the same model and its methods and artifacts to both messages and documents has presented an ongoing challenge, probably well worth the effort in the end,⁶ but nevertheless adding to the complexity of version 3.0 and possibly delaying XML-based document standards.

Process and Workflow

While XML generated new enthusiasm for document standards, the business requirements had moved beyond documentation as a necessary but not sufficient justification for clinical information systems. The focus has shifted to clinical transformation that includes a focus on workflow, process management, and decision support functions. Again the prescience of the HL7 leadership in moving from Version 2 messages to a service act-based model implemented through constrained application roles is remarkable. However, it moved HL7 from areas of comfort and expertise into new methods and skills.

International Affiliates

⁶ Mark-up language has great potential to bridge the gap between human-readable and machine-processable information. The rigor of the CDA and RIM approach can yield a high degree of interoperability. However, others have suggested that more distributed approaches, e.g., the Semantic Web, or greater use of ontologies can provide the same human-machine interoperability without the central model.

Despite or perhaps because of greater government regulation of HCIS standards in the EU and other countries, HL7 Version 2 messaging has been widely accepted as a simple, proven clinical interoperability solution for hospitals, other providers, and health systems. As we noted in a special issue of the *Standards Insight* (March 2002), clinical systems have much greater potential for internationalization than administrative and financial systems, which reflect the specific needs of each national health system. Order communication and results-reporting messages are part of most IT-supported clinical care process everywhere. Today, HL7 has 18 international affiliates. Some countries, such as Germany, have officially adopted HL7 standards for use in their health systems. Like the HIPAA effect described above, HL7 can be part of a strategy to mandate national HCIS standards. Thus HL7 is responding to many agendas and interests beyond US market needs. One cannot underestimate the impact of expanding the scope of end-user stakeholders, particularly without a formal process of re-examining business requirements and priorities. While such diversity will cause a better standard to emerge, it will take longer and require more effort to harmonize Version 3.0 to support the multiplicity of interests and localization requirements.

The Special Case of the EHR

The electronic health record (EHR) is a specific instance of the impact of international interests intersecting with Version 3 RIM, messages, and the Clinical Document Architecture. A year ago HL7 approved the EHR SIG, primarily to provide a place for international developers working on specific medical records projects. As with the CDA, the EHR was considered too important by HL7 leadership not to embrace. However, it is not clear a year later how the EHR relates to clinical documents, to medical records, to Version 3.0 messaging, or the RIM and its artifacts. Moreover, the EHR SIG has in fact remained primarily a forum for standards developers from the EU, UK, and Australia and has attracted limited participation from US-based developers. This may reflect alternative approaches, such as the CDA or the US lack of consensus business requirements for an EHR. Fortunately there is a growing sense that “templates” might become the unifying artifact between different EHR models and the CDA but not because it was planned that way. One of the impacts of the EHR, but not solely applicable to the EHR SIG,⁷ is the diffusion of efforts across more groups resulting in reduced critical mass of experts in any given group and in the need for more overhead to coordinate across the multiple initiatives.

HL7 Cannot Just Say No

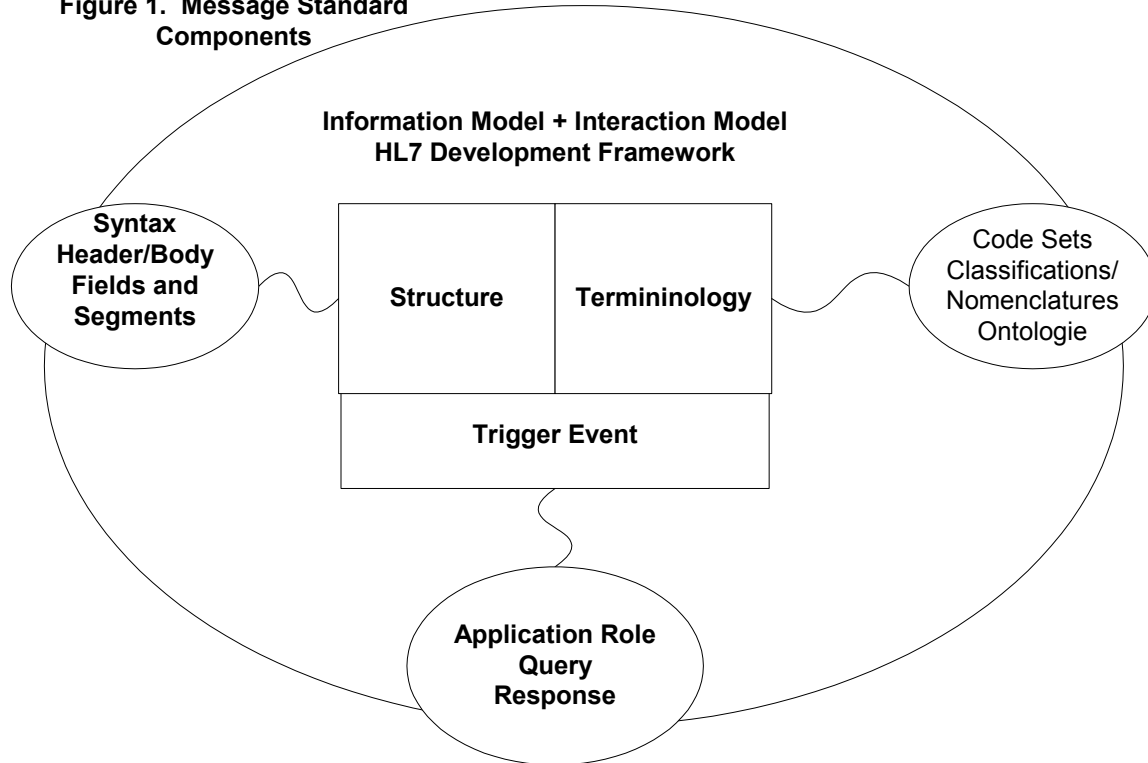
HL7 has been better at its marketing than any other healthcare SDO. HL7 means interoperability among healthcare information systems. It achieved this position through both the value of Version 2 and its own aggressive promotion and marketing programs. Even in its earliest days it was not reluctant to stage interoperability demos at HIMSS, to sell itself to end-users to pressure vendors, and to co-opt new initiatives and technologies. Last year, lest other SDOs should seize the PMRI prize, it expanded its mission to include the electronic medical record. We have just noted how it expanded its scope to take in the CDA and the EHR. But it has a longer list of diverse technical committees and SIGs including CCOW, clinical trials, clinical guidelines, Arden syntax, and with its October meeting, clinical genomics. Just as many immature standards initiatives came to HL7 for its brand name, HL7 finds it hard to resist taking on the next big thing for fear that it will become a competitor.

⁷ Even without the EHR SIG, HL7 committee structures and overlapping domains, compounded by a unified model that must be kept in harmony, are creating organizational gridlock.

Is HL7 Designing the Next Generation of Healthcare Information Systems?

The use of message conformance profiles and potentially document templates insures all of the key elements of interoperability exist, i.e., structure, content, and triggers. See Figure 1.

Figure 1. Message Standard Components



In fact, such profiles and templates define how an application must work externally. In an OO world, the application has become a component with standard public interfaces and private internal functions. The more granular the message package, the less value is enclosed within the "application bundle." This defines how vendors (or users) can develop and package their applications whenever the application needs to obtain or provide data to any other external application. For example, in clinical decision support (which is first a receiver application), the data granularity and trigger (timeliness) rules of external message profiles dictate with what data and at what frequency a CDSS engine can run its rules. In the example, would a nurse charting application be required to broadcast each charting entry as it occurs in real time in order to support CDSS? If so, does that make the nursing application simply a front-end user interface for some other medical record application? If not, what could a real-time CDSS depend on for patient data? Does that imply that a CDSS should be a Q8 hour application? It is not clear how, within the models, methodologies, and committee structure and processes, HL7 will actually develop clinical domain-based profiles and templates. Moreover, it is not clear how software vendors will interact with the standard to protect "proprietary" software from becoming interchangeable commodity-like components. To actually move to standards-based implementable messages, Version 3.0 methods and processes must address these issues by message and by application role for each clinical domain. While we might expect that HL7 will start with retooling existing Version 2 messages, none of this work has been done.

HL7 Organization and Management

HL7 is an open, voluntary, consensus-driven standards development organization accredited by the American National Standards Institute. HL7 is managed by an elected chairman, officers, and board of directors. Only members can hold any of these or other leadership positions. HL7 is supported by an executive director and staff. It has contracted a few members as full-time consultants but volunteer members do most work. HL7 is organized into technical committees (TC) and special interest groups (SIG). Each SIG is assigned to a TC and both are chartered with stewardship of some part of the HL7 standards. Figure 2 represents an unofficial organization chart. Chairs of the TCs and SIGs make up the Technical Steering Committee, which coordinates and directs their overall activities subject to Board oversight.

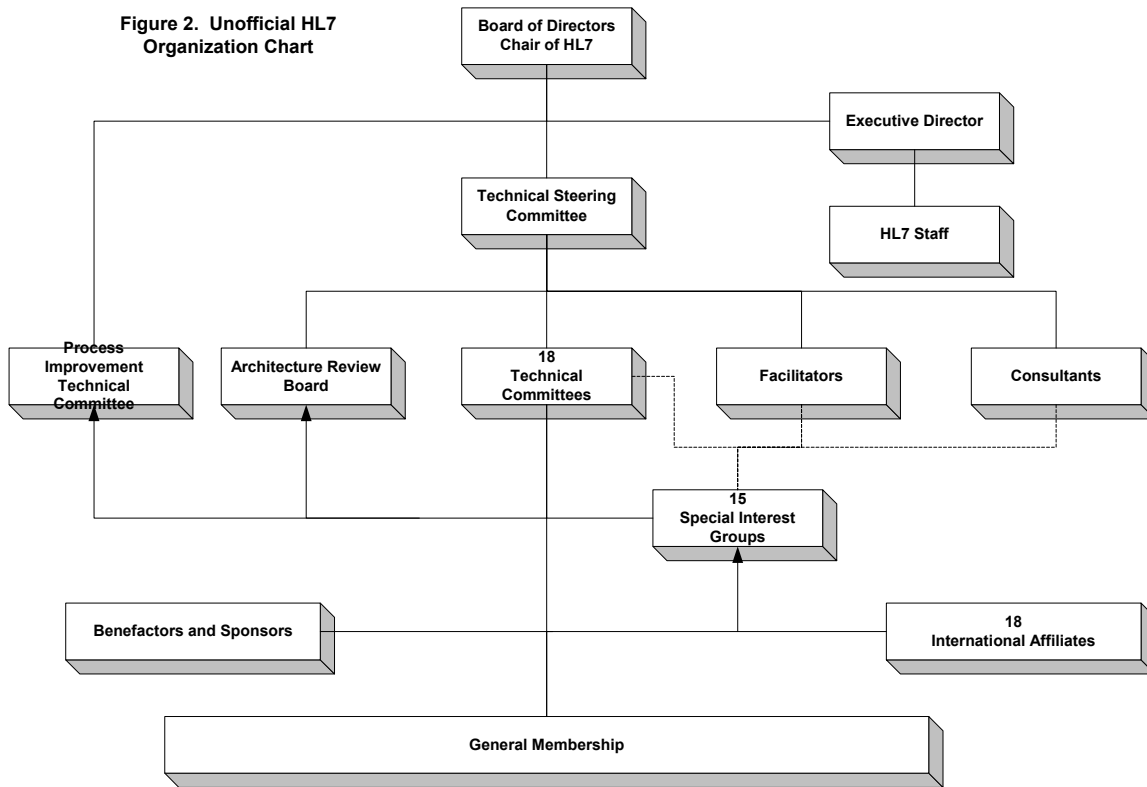
There are two further points to make in understanding HL7. The leadership is elected by the membership. But given the nature of voluntary organizations, leadership and influence flow to those with the most interest and time to devote to the activity. The Board and the chairs are elected from this cadre and, because they spend more time and work together, tend to perpetuate themselves in leadership roles.⁸ This can have good and bad effects. The leadership brings extensive experience and expertise and continuity of purpose, which probably could not be duplicated by any other organization. On the other hand, the leadership can be closed to new ideas or criticism and begin to take short cuts based on long experience working together. This leads to a lack of transparency in some decision processes. Because there are no “outside” board members or executive management team, there is no forum independent of the member leadership to provide feedback, counsel, and performance measurement.

The second point is that the organization chart does not reflect the workflow, which really flows through the “informal” TC hierarchy. The Control Query and Modeling and Methodology (MnM) TCs have primary roles in managing HL7 overall. It is beyond our scope here to trace the management and harmonization of the standard and its artifacts through these TCs and SIGs. The fact that there is this real flow of decision-making processes is a point to consider in evaluating HL7’s performance.

HL7 operates on a budget approaching \$2 million a year. The volunteer effort certainly contributes 10 times that amount. But by any measure, HL7 is not a large organization in relationship to its importance to a worldwide HCIS industry approaching \$50 billion, which supports a much larger healthcare industry. HL7 is an exceptionally well-run membership organization, fortunate in the quality of its staff. Moreover, it has gone to great lengths to recruit new members and to be an open and sharing organization. We have already remarked on the high level of leadership expertise and indisputable market prowess. So why is such a good organization so “late” with Version 3.0 and having all of these problems?

⁸ This observation in no way implies that the existing leadership is not very open to (in fact anxious for) more extensive volunteer participation. Certainly any individual that can and does put in the time and effort is able to rise to some level of leadership. Unfortunately, as workload increases and skill sets shift, members must devote more time to just keeping up with weekly conference calls. Not all member sponsors see the benefit of this level of involvement. Thus the circle of insiders tends to collapse on those whose outside interests are dependent on HL7 standards themselves, not on how the standards will be used by vendors and end users.

Figure 2. Unofficial HL7 Organization Chart



Current Status

The foregoing background brings us to the present and informs us about the future. This perspective is important in trying to assess how the industry might assist HL7 or what HL7 might do itself to release Version 3.0 interoperability standards in a timely manner.

Anyone in the HCIS industry will recognize a “pattern” common to big software projects: creeping requirements fed by delays and the promise of new technologies. Unlike software projects that result in code that can be tested, HL7 is developing the standards for implementing interoperability but not the code itself. This deprives HL7 some of the immediate feedback that results from actual implementations. Moreover, in the unified modeling language (UML)⁹ method, feedback is from end-users based on business requirements, not just from the technical developers. HL7’s procedure is in contrast to Object Management Group (OMG) that insists that sponsors implement its standards within six months of passage. That said, HL7 does encourage prototype implementations, particularly through its HIMSS demos.

Tyranny of the RIM

The RIM is the central reality of Version 3.0, both its greatest strength and weakness. It has gone from an informative artifact to a planned normative ballot item. In fact, some members and their sponsors may value the RIM more than any of its derived standards. After all, few if any industries of anywhere near the complexity of healthcare have created a comprehensive

⁹ HL7 decided to use UML, which has become the most widely used OO methodology, for developing Version 3.0. UML is a top-down modeling process based on a set of technology-neutral interlocking models and diagrams for system software development projects. It is relatively scaleable although it is not clear that anyone has modeled so rich and complex a domain as healthcare using UML.

reference information model, a fact that is in itself telling. For example, HL7 is invited to participate as the healthcare vertical industry standard for many interoperability consortiums, most specifically ebXML.¹⁰

The RIM is no longer seen as a reference where one might look up how to develop or interpret a downstream message as much as a method. It is the primary source for all messages, documents, and other Version 3.0 artifacts. Everything is derived from the RIM by adding constraints. Thus the corollary is that the RIM must contain all concepts that will be needed or the RIM must be revised. While no one expects that the RIM is finished or will ever be finished, one can see how changes in core classes, data types, and attributes could have far-reaching implications for all other artifacts, software implementations, and existing instances of messages, documents, and records.

One of the touchstones of Version 2.0 was forward and backward compatibility. It is not clear how or if version compatibility will be maintained. The RIM also creates localization issues – what must be in the RIM and what can be “added” in local profiles?

Vocabulary - What is in the model and what is in the terminology?

HL7 appears to have a love-hate relationship with vocabularies and code sets. On the one hand, it is clear that interoperability depends on using standard code sets wherever controlled vocabulary is appropriate. On the other, HL7 is in the business of message structure standards. The more structure one can add to a message, the less important a rich code set is. One might envision a continuous spectrum of methods for defining concepts – from very highly structured formats that reduce the possible values to yes/no, to very granular, multi-axis vocabularies that express every nuance of a context within its terms.

How HL7 will specify or allow different code sets to be used within its standards is becoming an acute issue. If, for example, one were to say that SNOMED CT was the only coded vocabulary used for clinical observations, then one could build message, document, and record structures that depended on the granularity of SNOMED. Trivial examples of the issue are how to differentiate “fracture” as part of the current problem list from part of the patient’s history or “congestive heart failure” from a patient’s diagnosis or from the family history. The terms “fracture” and “congestive heart failure” would each have respective codes but their meaning for this patient would depend on where in the message, document, or record structure they were placed. Or one could use a compounding code structure so that one created a term “family history congestive heart disease.” Alternatively, one could set up a value pair hierarchical structure – a Tower of Babel, but a possible use of the Observation sub-class of Act. Again, these are simplistic and trivial examples. However, the problem is very real. HL7 must resolve how to trade off the semantics and syntax to specify unambiguous content in all aspects of V3 standards from the RIM downward.

What Are the Business Requirements?

Certainly one of the major weaknesses of the UML method, particularly as used by HL7, is the lack of overall business requirements to control and measure subsequent activities. UML is primarily a software development process despite the fact that it nominally begins with a business vision that is refined by use cases. UML is not a business-planning methodology. Use cases and

¹⁰ An additional Version 3.0 business requirement is “technology-neutral.” Of course, messages, documents, and records will eventually be implemented in a specific environment on specific platforms. It is this level of application software, services, and platform that generates revenue. As most IT observers understand, there are significant middleware or Web services wars going on. While the ebXML consortium is open and is based on technology-neutral standards, it is most strongly supported by one set of vendors. The Web Services Interoperability Organization (WS-I) is a fundamentally competing consortium using IBM- and Microsoft-sponsored standards. This level of competition is present throughout HL7. For example, if there is a Java SIG, can a .NET SIG be far behind?

storyboards do not establish priorities among use cases nor reflect comparative values and ROIs. They do not mediate political and business interests or establish schedules.

In the case of HL7, the overall business vision, as described in 1996 as shown above, is relatively unchanged and, perhaps, even unexamined. There is little evidence that any high-level, i.e., above the RIM, use cases exist and most certainly are not invoked to drive downstream decisions. In the HDF currently envisioned, each message profile would be based on a use case, and one would surmise that a collection of profiles into a clinical application might be derived from an application use case, e.g., a clinical laboratory or respiratory therapy application. But this level of use case no longer addresses the real business requirements of vendors and users that exist at an integrated system level.

We have noted the apparent lateness of Version 3.0. However, that is more a function of measuring elapsed time than it is of evoking business requirements unmet. It is always possible that Version 3.0 is not important or relevant to end-user stakeholders.

The lack of high-level business requirements to control the technical development is the single weakest link in HL7. There is no external yardstick or reporting requirement upon which the Version 3 activities are measured and to which HL7 is accountable. Self-governance may be the necessary form for a consensus-driven voluntary organization, but it is not a good form of executive management.

The Process Improvement Technical Committee

We have described how the HL7 leadership has evolved and changed Version 3.0 as it discovered new issues and found new methods. In some cases, the active general membership has not been brought along and has experienced increasing frustration. HL7 is the most dynamic and successful of healthcare SDOs, but it is no longer growing dramatically financially or in membership and participation. Of course much has changed since 9/11 in terms of travel budgets and voluntary participation. Still, attendance at HL7 meetings continues to be relatively flat and for all the first-time attendees that continue to show up, it implies others are not returning. In the recent plenary session in Baltimore, attendance was under 500, more or less the level of meeting participation over the last few years. In fact it took local members from federal agencies to fill what would have otherwise been empty seats. There are specific reasons for budget shortfalls – such as unexpected meeting expenses – and for lower international participation – such as timing conflicts with other Australian and European meetings – but in the big picture, HL7 active membership and funding is not keeping pace with the growth in scope and vision and is not sufficient to accelerate Version 3. In fact, it is only a core group of mostly long-term insiders, roughly congruent with the Technical Steering Committee made up of the TC/SIG co-chairs, that is moving the ball forward.

The HL7 Chair and Board have chartered a new Process Improvement TC to address general discontent among the membership. We will highlight some of the issues raised. The TC, of course, was in a listening mode at the initial meeting and so has not proposed solutions.

Skills Mismatch and Frustration

HL7 is most closely associated with messaging. Many active members and their corporate sponsors, whether vendors or providers, are much less interested in models and methods as in integrating disparate systems. Some, if not many, active participants have been forced to go from being message-domain experts to learning modeling and methodologies. Moreover, since neither models nor methods have been stable, this has led to wasted efforts. The leadership has directed

that the efforts on Version 2 be reduced in favor of Version 3.¹¹ Thus, for some for whom messaging is the justification for their participation and for whom improving Version 2 is sufficient for their needs, Version 3 represents a mismatch with their interests and skills.

Time Pressures

Version 3.0 and its artifacts are seen as a whole; each ballot cycle brings the whole Version 3.0 forward. One of results of inadequate high-level business requirements and priorities is the inability to prioritize or phase ballots to best meet industry needs and accommodate development workloads and resources. In fairness, this version of the whole is also driven by the unified process methodology for UML development, which dictates that there are multiple incremental iterations to constantly provide the sponsor feedback and identify problems. When used within the HL7 context, an iteration is a ballot cycle. Ballot cycles carry tremendous overhead in terms of reconciliation and harmonization. This discipline is probably necessary given how interrelated the Version 3 models and artifacts are. The ballots do identify technical problems but there is no real feedback based on business requirements and industry needs – a distinct departure from the unified process. Moreover, not all projects and components are equal in terms of importance, complexity, or level of resources and support. Thus some work groups are always behind while others are waiting for things to do.

Finally, the leadership is trying to reduce development time and cycles, putting pressure on volunteers to produce and not ask questions. This has led to more conference calls and list servers and paradoxically to less transparency in decision-making. Small groups can make key and far-reaching decisions based on informal meetings or poorly scheduled and attended calls with loose agendas – if necessary to move forward. As one would suspect, this creates the need to go back and rehash issues and creates frustrations on all sides.

Loose Ends

There are two important HL7 issues that we will not develop in this issue of *Standards Insight*: the security framework and transitioning from Version 2 to Version 3. We have pointed out that despite a Security SIG, security modeling and standards have not been a focus of HL7. Basically, security was seen as an external function and defined out-of-scope. We have demurred on this point. It is obvious that message content and certainly documents and records must include security in terms of authorship, authenticity, and trust. That MnM is adding it as one of the new artifacts within its meta-model shows a shift here.

There is no intent that Version 2 and Version 3 be compatible. Moreover, we anticipate that Version 3 message and document standards will emerge over time based on profiles and template creation. Thus, there will be some indefinite period in which both Version 2 messages and Version 3 messages and documents overlap. While HL7 maintains that the use of super interface engines will bridge the gap,¹² this begs the question of why and when either a vendor or end-user will make the transition. We see this as a critical business requirement issue that we will address as part of the next issue.

¹¹ Nonetheless HL7 expects to continue to develop and support Version 2 albeit on a diminishing scale. Version 2.5 is in ballot and it appears that there will be a Version 2.6. The Conformance SIG is completing work on Version 2.x message profiles – if anyone is interested in submitting and using them.

¹² A strange form of plug and play.

The Bottom Line

HL7 is central in any map of interoperability standards in the clinical domain. Its success in bringing forward new messaging and document interoperability standards in a timely manner is important to the entire healthcare industry both in the United States and internationally. There is no current viable alternative *except extending the status quo*.

HL7 is faced with some slippage in support and some lack of consensus on how to move forward, at least among some important membership groups. The technical and organizational challenges could probably be best solved within the context of overall purpose and priorities as determined by the end-user stakeholders of vendors, healthcare organizations, and governments.

In the next issue we will offer some suggestions on how HL7 might better align itself with external stakeholders and thus focus its strategy, technologies, resources, and members on deliverables and schedules that meet end-user needs and requirements.

Next Issue

Besides suggestions on how HL7 might get Version 3 back on track by re-examining its business purpose and eliciting input and support from its external stakeholders, we will wrap up the year's standards activities with a report on the IHE and other new standards initiatives. One might expect that there could be some synergy between the IHE's template-driven implementation demonstrations and HL7's need for external partners. If warranted, we will also touch on HIPAA-driven security standards.

Please direct any questions, suggestions or comments regarding *Standards Insight* to Joyce Sensmeier (jsensmeier@himss.org) or its author, Ed Larsen (erlarsen@erlinc.com).