After three years of dedicated effort, the IT department of General Hospital announces that it completed integration of all 45 of the lab, medication management, orders management, scheduling, and financial systems in its five buildings. The interfaces are either HL7 V2.x or specific-system-to-specific-system file transfer protocols.

Three weeks after the announcement, the management team of General Hospital announces it signed a merger...
agreement with Regional Medical System. Regional Medical, which is located on the opposite side of the river from General Hospital, operates seven affiliate hospitals, 10 home care organizations, two wound care clinics, an outpatient surgery facility, and a high-tech imaging center. Each of these facilities has at least one information system connected to other systems as needed by interfaces built by Regional’s IT department. The management teams of the merged organizations express their confidence that “citizens who work on one side of the river and live on the other can now enjoy high-quality integrated healthcare.”

Three months later, a patient who normally receives care at General Hospital is brought unconscious to the emergency department of Regional Medical after a car accident and mistakenly given a drug to which he is allergic because “his records were in a different system.” When asked how long full integration of the merged organizations’ IT environments will take, the newly appointed CIO states that integrated admission-discharge-transfer and lab should be up and running within the year, but that the time frames for additional system integration have not yet been determined because of the magnitude of the task.

The problem is not the systems per se, but rather the difficulty of data exchange between systems, or data incompatibility. The numbers are simple, but daunting: if each system-to-system connection requires a separate, non-standard interface, the number of interfaces required to connect n systems is roughly (n**2)/2. Thus, full connectivity of 20 information systems requires approximately 200 interfaces; for 40 information systems, the number jumps to around 800.

Admittedly, assuming that every system needs to be connected to every other system is an overly pessimistic assumption. However, balancing that assumption is the small number of systems cited in the example. Large healthcare organizations often have five to 10 times that number of systems, and, as a result, interface management can consume significant amounts of healthcare IT resources.

The absence of a robust set of standards to resolve data incompatibility issues is becoming increasingly costly to the U.S. healthcare delivery system. A recent study estimated savings of approximately $78 billion could be achieved annually if data exchange standards were utilized across the healthcare sector.

**Introduction and Overview**

The task does not seem all that hard. It is not unusual to hear comments like the following ones.

“Why is the problem of data exchange in healthcare so difficult? After all, other industries—banking, for example—have solved the problem. Healthcare transactions cannot be that much more complicated than those managed by a geographically distributed, multiple line-of-business banking system with multiple lines of businesses.”

“Doesn’t HL7 V2 solve this problem? It has been around for a long time and seems to be implemented everywhere, at least in the United States?”

“If HL7 V2 doesn’t work well enough to satisfy our current needs—admittedly, healthcare is a bit more complex now then when HL7 V2 was first developed—can’t we just fix it?”

“Do we really need a new version of HL7? From everything I’ve seen or heard, HL7 V3 is much harder to understand and implement, and things are hard enough now as it is.”

“What about migration issues from V2 to V3? That’s always a terrible nightmare.”

“Won’t the National Healthcare Information Infrastructure solve these problems?”

This article is intended to address these critical questions. It provides an overview of the key structures and concepts behind HL7 V3, collectively referred to as the “V3 Toolkit” or the “Four Pillars of Semantic Interoperability” (See Figure 1). It focuses on how V3 differs from V2, and why healthcare IT organizations need to begin adopting V3 rather than expecting that an “improved V2” will enable the healthcare IT sector to realize data interchange.

In particular, the V3 Toolkit is presented as an instance of a class of information modeling, data definition techniques and tools required to solve the increasingly complex challenges presented by today’s clinical information system environment. The V3 Toolkit is designed to enable unambiguous data exchange and to thereby facilitate meaningful solutions to the data incompatibility problem.

**Definition and Terms**

Unambiguous data exchange is described most succinctly as computable semantic interoperability, or CSI. Critical to the discussion of CSI is the definition of this and several other related terms.

**Syntax vs. semantics.** Syntax is structure; semantics is meaning. To illustrate the difference of the two concepts,
consider the following sentences as examples: “The dog eats red meat.” “The dog sings blue trees.” The two sentences have identical syntaxes or structures; they start with an article, then have a noun subject, verb, modifying adjective and direct object noun. Their semantics or meanings are different; the first one makes sense, while the second one is nonsense.

The sentences for the second example are, “The patient was given pain medication” and “The patient was given medication for pain.” The two sentences obviously do not have the same syntax. Depending on your level of clinical experience, they may or may not have the same meaning. The example illustrates that syntax alone is often not a reliable determinant of semantics.

The sentences for the next example are, “Time flies like an arrow” and “Fruit flies like a banana.” Do these two sentences have the same syntax?

**The semiotic triangle.** The word semiotic means, “pertaining to signs or symbols.” Originally formalized as a framework for understanding human communication, the Semiotic Triangle (See Figure 2) forms the crux of any meaningful understanding of the challenges of CSI by delineating the difference between the thing, the symbol that is used to refer to the thing, and the meaning or semantics of the thing.

The upper portion of Figure 1 shows how humans believe they communicate, by using symbols to point to things, while the lower portion shows that communication is enabled via the existence of an intermediary concept that is referenced by a particular symbol. It is the concept and not the symbol that holds the meaning of the thing.

Although human beings are relatively adept at what Douglas Hofstadter calls “concept slippage,” the ability to find the right concept for an ambiguous symbol in a particular context, software is notoriously limited in its ability to disambiguate a symbol that can point to more than one concept. One of the cornerstones of CSI is the use of unambiguous, coded concepts rather than arbitrary symbols such as character strings as the *lingua franca* between machines.

**Datatype.** Datatypes are the fundamental building blocks around which the semantics of a given piece of data are built. Formally, a datatype is fully specified when both its semantics (in other words, its formal meaning) and the set of legal computational operations that can be performed on an instance of the datatype are rigorously specified. Historically, system developers talked about atomic datatypes, such as integer, floating point, character, and string, and more recently about complex datatypes, such as date and time, address, and others.

Healthcare requires several complex datatypes to support concepts, such as physical quantity and time (including both events and intervals), as well as datatypes describing coded terms within a terminology, such as coding system name, version, primary code, alternate codes, and others.

**Interoperability.** Interoperability is the ability of two parties, either human or machine, to exchange data or information. Unfortunately, the term is significantly overloaded with nuances.

First, syntactic interoperability guarantees the exchange of the structure of the data, but carries no assurance that the meaning will be interpreted identically by all parties. Web pages built with HTML or XML are good examples of machine-to-machine syntactic interoperability because a properly structured page can be read by any machine with a Web browser. The meaning of the page to a particular machine may vary substantially—however, this is not usually considered a problem because the semantics of a page are meant to be interpreted by human viewers.

Next, human or semantic interoperability guarantees that the meaning of a structure is unambiguously exchanged between humans. Documents such as progress notes, referrals, consults, and others rely on the specificity of medical vocabularies and common practice to guarantee semantic interoperability at a clinician-to-clinician level.

Finally, computable semantic interoperability requires that the meaning of data be unambiguously exchanged from machine to machine. This does not necessarily mean that all machines need to process the received data the same way, but rather that each machine will make its processing decisions based on the same meaning.

**Messages vs. documents.** In general, messages differ from documents because they are trigger-based and
Transient, although the data within them may be persistent. In contrast, documents are assumed to be persistent, and therefore subject to long-term management, as well as to carry strong notions of global vs. local authorship, authentication, and human readability.

Healthcare data collection is often document-centric—data are collected in the context of a document, such as history and physical, progress note, appointment registration, and so on. By contrast, healthcare data usage often is data-centric, for example, “I need to see the last three weeks of sodium values on this patient.” Healthcare data often must be extracted from documents and integrated with data from other documents or from non-document sources.

The absence of a robust set of standards to resolve data incompatibility issues is becoming increasingly costly to the U.S. healthcare delivery system.

How is this overlap between message data and document data handled from the perspective of CSI? The traditional answer has been, “Not well.” The failure of healthcare data processing standards to recognize and effectively deal with the dichotomy of data structure and origin, as well as the unity of usage, has been a source of frustration in many healthcare IT settings.

Part of the HL7 V3 Toolkit is a specification for documents called the Clinical Document Architecture, or CDA. The strength of CDA lies in the fact that all CDA document instances are derived from the V3 Reference Information Model, or RIM, the same model from which all non-document message structures also are derived. This means that the data collected within a CDA document are computationally semantically interoperable with data obtained via non-document V3 messaging sources.

Information model vs. terminology model. It is beyond the scope of this paper to discuss in detail the differences between information messages and terminology except to note that both types of models can be arbitrarily complex and that, at some point, semantics not represented in one must be represented in the other if one is to achieve CSI. In particular, the seeming simplicity of their inter-relationship is shown in the top half of Figure 3, while the actual complexity of the relationship is alluded to, but not fully explained, in the lower half of Figure 3.

Just as an example, consider the data structures required to support a CSI-compliant representation of the statement “The patient had a Grade IV anaphylactic episode to the administered penicillin, with diffuse hives, erythema, hypotension (85/70) and audible wheezing.” Neither a terminology model nor an information model alone can represent this as a CSI-compliant statement and still be able, possibly utilizing a different or additional TMs, to also represent the statement “The patient is scheduled to be operated on at 2 p.m. tomorrow to rule out Stage III Hodgkin’s Disease.” The HL7 RIM can, with help from terminologies such as SNOMED-CT, LOINC, CPT and others.

Semantic scalability. A process is scalable when what works for 100 instances also will also work, with possible linear increases in applied resources, for 1 million instances. In this discussion, it is semantic scalability because the reference involves the ability of a given message to be unambiguously understood by an increasing number of systems on a plug-and-play basis. One of the core issues with HL7 V2 is that although specific HL7 V2 messages may be semantically scalable, HL7 V2 in general is not.

A lack of semantic scalability also is demonstrated when XML is used as a simple solution to achieve CSI. In particular, any set of locally defined XML tags, such as metadata, can easily be transmitted between machines and rendered in virtually any operating environment through use of Web browsers, thus providing an apparent demonstration of semantic interoperability. However, this interoperability is often limited to humans who can read the data and understand it within a browser. The data are not semantically interoperable from a computational perspective unless all systems are informed of the semantics of the specific tag set before receiving the data. However, if the tag set was initially locally defined, its semantics most likely will be either unknown or in conflict with other locally defined tags on a receiving machine. Thus, XML solutions are not guaranteed to be semantically scalable from a CSI perspective.

This is not meant to be a condemnation of XML. On the contrary, XML is a powerful enabling technology and is the core of the first Implementation Technology Specification of
The Four Pillars of CSI

The motivation behind the creation of V3 was the growing awareness that V2 could not meet the robust requirements for CSI in a semantically scalable, cost-effective manner. In particular, HL7 V2.x message implementations were becoming increasingly costly to support and evolve as both the number and scope of messages—as well as the number of systems—increased.

The limitations of HL7 V2.x become most obvious when data exchange requirements cross inter-enterprise boundaries, thereby exposing conflicts or ambiguities in locally defined data semantics. A list of the weaknesses of V2 is a mirror image of the strengths of V3, a collected set of characteristics referred to as the Four Pillars of Semantic Interoperability:

V2: Lacks a common information model that spans all domains of interest.
V3: Offers a common model, the HL7 V3 Reference Information Model, that can span all domains of interest, such as clinical, administrative, and financial, and provide unambiguous definitions of the semantics of the “common structures” present in all healthcare data interchanges. These common structures ultimately form the core XML tag set for a given V3 message. The RIM is now an ANSI standard.
V2: Lacks a computationally robust datatype specification.
V3: Provides machines with unambiguous semantics for each data element transferred, through the V3 Datatype Specification, now an ANSI standard. Each concept-attribute in the RIM is bound to only one datatype.
V2: Lacks a sufficiently robust infrastructure for specifying and binding concept-based terminology values to specific message elements.
V3: The HL7 Vocabulary Technical Committee and Modeling and Methodology Committee manage a formal process for interleaving the RIM with various terminology models, as well as enabling the binding of domain-specific terminologies such as SNOMED, LOINC, DICOM, MeDRA, MIAME/MAGE and others to message specifications.
V2: Lacks a formal top-down message development process.
V3: Does not allow use of a top-down methodology for defining each data interchange structure using only RIM elements bound to domain-specific values, i.e. a methodology in which optionality (e.g. HL7 V2 Z-segments) is not allowed. HL7 V3 provides a number of tools to assist developers in building RIM-compliant, V3-conformant interchange structures for ANSI balloting.

CSI is a difficult goal to achieve, and the Four Pillars are necessary but not sufficient to reach that goal. For example, the Four Pillars say little or nothing about critical issues, such as enterprise-wide person identity management; security, auditing or consent services; or terminology management services, including intra-terminology version management and inter-terminology cross-mapped semantic relationships. Support for these critical tasks is left to vendor organizations or other IT resources. However, without the Four Pillars in place, CSI is virtually impossible to achieve in a consistent and computationally stable manner.

Even with the rigors of the Four Pillars in place, it is still possible to “say the same thing several different ways.” To achieve full CSI, additional data structures must be defined using the V3 Toolkit and related technologies to specify fully the structures used to express a specific set of semantics. That type of work is now going on in the UK’s National Program or the HL7 Term Info project.

The Reference Information Model

Although each of the Four Pillars is critically important in achieving the overall goal of CSI, the first—a common information model spanning all domains of interest—is the most visible. The HL7 V3 RIM defines the semantics of a set of common clinical, administrative, and financial data structures. More specifically, the HL7 V3 RIM defines a high-level backbone containing five abstract structural concepts:

- **Entity**: Things in the world, including place, organization, material and living subject, either person and non-person.
- **Role**: Capability, capacity or competency, usually time-based.
- **Participation**: Role in the context of an act.
- **Act**: Clinical, administrative or financial definitions, plans, occurrences, and so forth.
- **Act relationship**: The semantics of links between acts.

The semantics of each of these backbone classes is specified through a number of attributes. In turn, the semantics of each attribute is specified through its binding to an HL7 V3 datatype. The semantics of a specific data interchange structure are the combination of these pre-defined semantics expanded or modified by virtue of bindings to codes or data values specified either by HL7 (structural codes that affect XML representations) or external organizations, such as domain-specific terminologies. Backbone classes may have any number of subclasses, each
of which is defined by additional attributes. Figure 4 shows a high-level view of the RIM backbone, without attributes and subclasses. Figure 5 shows the use of the act relationship class to capture the notion of a diagnosis as an observation about observations.

The RIM also introduces the concepts of state and mood as attributes of acts to enable CSI-compliant descriptions of complex healthcare processes. Mood describes the critical phases of a business process through which instances of a concept may pass; for example, a drug or lab test that may be defined in a master service catalogue, ordered for multiple patients, and administered or performed any number of times based on the order. Mood is orthogonal to the more familiar notion of state, the denotation of the phase in the lifecycle of an instance of a concept. A single act instance may pass through many states in the course of its life. However, it may have only one mood, such as define, order or request, event, goal, or others.

**An Example Using the RIM**

Although it is not possible to demonstrate many of the powerful representational aspects of the RIM within a paper of this scope, here is a basic example of the process of representing healthcare delivery semantics through common structures bound to domain-specific terms.

**I—General premise.** The documentation of the healthcare delivery process—clinical, administrative, or financial—can be broken down into a series of statements. Careful analysis of these statements reveals that the semantics of each is contained in the combination of a small set of common structures bound to a large number of domain-specific terms.

**II—The common structures.** The model for a general statement spanning all aspects of healthcare delivery can be simply stated as follows. An instance of an entity may play zero or more roles. In turn, each instance of a role may play zero or more instances of a participation in the context of an instance of an act. Each instance of a participation may participate in one and only one instance of an act for the duration of that act. Acts may be related to other acts through instances of act relationship.

**III—An exemplar set of statements.** This is a simple example that neither includes all of the data to fully document the situation as it would be in an electronic health record nor represents all the data. Marcia Smith, seen by Dr. Tom Jones, complained of abdominal pain. After a physical exam and lab tests, Dr. Jones booked Marcia for an appendectomy at St. Mary's Hospital. Following a successful recovery, Marcia was sent home and received a statement from her insurance company saying that they had paid for her surgery.

**IV—The binding of RIM structures and domain-specific terms.** When bound to specific values, this general statement can be expressed in a CSI-enabled format.

**Persons:** Marcia Smith; Tom Jones

**Organizations:** St. Mary’s Hospital; insurance company

**Roles (standard code set):** Patient; healthcare practitioner; healthcare delivery facility; guarantor.

**Participations (HL7 code set):** Primary performer; target subject; target location.

**Acts (LOINC, CPT, ICD, SNOMED, other code):** Observation (HL7 code); diagnosis (HL7 code); surgical procedure (HL7 code); schedule (HL7 code); bill (HL7 code).

**Relationships (HL7 code set):** Diagnosis act, supported by observations (physical, lab and others); surgical procedure act “has reason” diagnosis act.

**Frequently Asked Questions**

Here are some answers to the questions posed at the beginning of this article.

**Why can’t HL7 V2.x solve these problems?**

HL7 V2.x is not built on a foundation of sufficient rigor to address, in a semantically scalable manner, the challenges of CSI. Although it is certainly possible to restrict
specific message sets, particularly those involving quantitative data and well-known attribution like lab data, to achieve bounded (particularly intra-enterprise) CSI, the absence of the Four Pillars as a basis for V2 leaves it unable to address the breadth and depth of the challenges and complexity of CSI as it might be used in an EHR, particularly at the inter-enterprise level.

Assuming that HL7 V3 is needed to solve important healthcare IT problems, when can these solutions be applied? Is HL7 V3 “ready for prime time?”

Yes. Many organizations both within and outside of the U.S. are actively involved in various V3 implementations. These include the National Cancer Institute Center for Bioinformatics, the Veterans Administration, the Centers for Disease Control, the National Health Service of the United Kingdom, government-level projects in The Netherlands and the Canadian Infoway Project. Also, several vendors are using the V3 Toolkit, including Oracle, which has built a Version 3 Service-Oriented Architecture toolkit around a RIM-based persistence layer. Adoption of V3 in the U.S. has lagged behind adoption elsewhere, for a variety of reasons. Recently, HL7 inaugurated an early adopter program to support organizations building V3 implementations. Early adopters are able to utilize V3 technologies and data structures in parallel with the formal ANSI balloting processes. A list of HL7 V3 early adopters is available on HL7’s Web site.

Many people who have looked at HL7 V3 say that it’s too hard; is that true?

A: CSI is hard, and there are no easy answers to it. V3 is only as hard as it needs to be to solve the problem. With the Four Pillars in place, the problem is now solvable. The RIM and the datatype specification have been stable for more than three years. While there will be ongoing changes and modifications to HL7 V3, the robustness of the framework will support this evolution in the same manner that well-architected software evolves through versions over time. Several organizations are building V3-based applications. Any healthcare IT professional given the task of achieving CSI, particularly in the context of an EHR project, will be working with HL7 V3.

What about other standards? How do they interact with HL7 Version 3?

Several other standards, including some ISO standards, have been or are being mapped to Version 3 structures. In some cases, the mapping effort has required that HL7 add new structural codes to the RIM through a process called harmonization. HL7 is eager, willing and able to enter harmonization efforts with any standards organization. The goal is to facilitate CSI; no one wins when standards try to compete, and everyone wins when they are harmonized.

How is the migration from V2 to V3 achieved?

Those wishing to make the migration must rigorously define the semantics of the data and then represent that data in V3 RIM-based structures. It is hard work, and fuzziness or holes in some data models will be discovered. The effort often involves changing both the input data collection forms and the schema of persistence frameworks. Another strategy is to use the RIM-compliant CDA specification to support computable document exchange. Regardless of the strategy selected, the problem is substantial, and because of the magnitude of the problem, meaningful solutions must be carefully selected for clear business and clinical value. In addition, they are likely to be specified and implemented incrementally, such as for a single domain and a small number of systems. It is definitely a matter of “crawl before you walk, and walk before you run.”
written into regulations and entered into the Federal Register:

- Interface definitions for health information service providers and NHIN-provided services.
- Service-level requirements.
- Data exchange standards, including syntactic standards defining data interchange structures and methods; semantic standards, defining data meaning with sufficient robustness so data can be understood by all processing machines. Toward that end, HL7 Version 3, the associated Reference Information Model (RIM) and other pertinent industry standards should provide the basis for semantic standards.

The consortium’s recommendation for HL7 Version 3, as opposed to earlier embodiments of HL7 Version 2.x, is a clear statement of its collective understanding that the problems facing healthcare IT require a data interchange strategy that enables CSI. Anything short of that capability, although arguably faster, easier, and less expensive to implement in the short term, will not achieve the long-term goals that the Office of the National Coordinator for Health Information Technology has articulated as necessary for the evolution of the nation’s healthcare delivery system.

Conclusions

Rather than present a verbose synopsis, I will use a somewhat tongue-in-cheek sequence of pseudo-code statements.

1. The need for CSI and semantic scalability, i.e. broad-based exchange of machine-processable healthcare data, is increasing —> there is a mouse that needs to be caught.
2. Enabling and achieving CSI and semantic scalability is hard —> this is not your average easy-to-catch breed.
3. CSI-enabled, semantically scalable solutions can only be achieved around the Four Pillars of CSI —> we need a new mousetrap.
4. The connectivity tools (networks, the Internet, XML and others) now exist —> we have some of the parts required for a new mousetrap.
5. The data specification tools—common structures and domain-specific terminologies—did not exist until recently. However, we now have a definition of the common structures through HL7 RIM and datatype specification, and many of the required domain-specific terminologies have been developed, such as LOINC and SNOMED —> we have some of the other parts required for a new mousetrap.
6. CSI-enabled, semantically scalable solutions can be built using the HL7 V3 Toolkit —> it is now possible to build the new trap and catch this elusive mouse.
7. Q.E.D.

About the Author

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