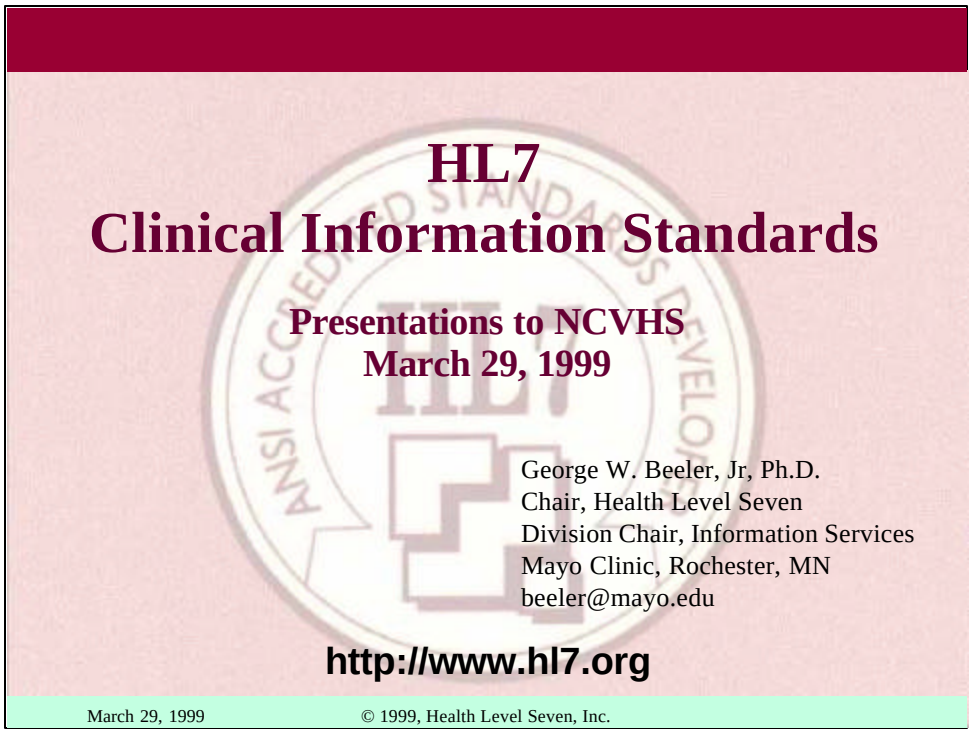

On behalf of my colleagues on this panel, and on behalf of Health Level Seven, thank you for providing us the opportunity to share our views on patient medical record information and on the critical role that standards must play with regard to this information in the future.

I am “Woody” Beeler, the current Chair of the HL7 Board of Directors, and an active participant in the Methodology and Modeling Technical Committee. I am a Division Chair in Information Services at the Mayo Clinic, Rochester, Minnesota. I am one of several Mayo individuals who are active in standards.

The panel this morning is a partial cross-section of HL7 participants. Two of us come from health care provider organizations, and two are active consultants in health care computing. This afternoon’s vendor panel will broaden that cross section as individuals on that panel are also active HL7 participants.

HL7 presentations

- Overview of HL7 presentations
  - Requirements for patient medical record information
  - The power of model-based interoperability standards
  - HL7 Reference Information Model
  - Model and Vocabulary interdependence
  - Clinical templates
  - HL7 Patient Record Architecture
  - XML document communication & management
  - Messages, documents and medical logic
  - Component messaging
  - Conformance

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This slide lists the topics we seek to address this morning. In order to allow a full dialog, we cannot cover any of them in detail.

Simultaneously, we will each attempt to provide answers to the core questions posed by NCVHS. These will be both individual responses, and our assessment of the organization's belief. Although we did not seek a "formal" HL7 position on these matters, we believe the actions and activities of HL7 give a clearer answer than would a formal position..

Patient medical record information

- What is it?
  - Data about the events and findings that characterize an individuals health status and health care
  - Depending upon the use, it may be fully specific, summarized or aggregated with data from other individuals
- Where is PMRI used?
  - Within an institution - clinic, hospital, home health, office
  - Across institutions in a health care system
    - Particularly critical as health care systems adapt to new organizations and relations
  - Between systems for patient referral
  - In federal, state, local and private agencies that oversee or manage patient care and public health

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Footnote: This set of questions is intriguing. I suspect that there are as many answers to this question as there are respondents to it. In large measure, one's answer depends upon "where you are coming from."

With my Mayo background, clearly I have a strong interest in sharing data within our institution and across our regional system in order to provide more efficient and effective care to our patients.

The HL7 perspective, however, is as broad as our constituency which includes providers and vendors of all shapes and sizes, public health and home health interests, and active government and international participation.

Patient medical information (continued)

- What functions does it serve?
  - Clinical decision making in support of the care of patients - CPR or clinical repository applications
  - Facilitate the efficient provision of health care to individuals
  - Decision support for the assessment and management of health care and health maintenance services
- How comparable does it need to be?
  - Any degradation in the comparability of this information threatens correct decision making
  - Incorrect decisions are at best **wasteful**, and at worst **life threatening**
  - Comparability is less about precision and accuracy than about interpretation -- the semantic understanding of the information

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Note: It is hard to imagine any information that is actively managed by an enterprise managed where that information exists for other than decision making purposes. In the case of patient medical record information those decisions affect the management of a particular patient's health status, the management of health care processes at both micro- and macro-levels, and the assessment of health and health care on a populations basis.

The most critical issue surrounding the ability to "compare" or "share" data is its meaning. Do the data represent equivalent concepts? If not, no amount of precision or accuracy will provide a useful comparison.

Why worry about data interchange standards?

- It is impossible to carry out any of the functions above in any of the anticipated settings without communicating data between disparate computer systems.
- The core issue is known as interoperability, defined as:

> "The ability of two or more systems or components to exchange information and to use the information that has been exchanged."[IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries, IEEE, 1990]

- The ability to exchange information is functional interoperability
- The ability to us the exchanged information is semantic interoperability

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Footnote: The dynamic nature of health care informatics - whether it is due to the rapid growth of health care knowledge and capability, or due to the continuing changes in health care services structures, or due to the rapidly evolving technologic capability - means that we must not assume that a common computing environment will support all, or even most of the components of interest.

Rather, we must assume a heterogeneous environment and then seek those standards that provide **both** functional and semantic interoperability for patient medical record information.

Basic requirements for interoperability

- Most of the applications of this data, and virtually all of its sources will rely on commercial software purchased and used by the health care provider.
- Thus the computing environment is
  - Data and software designs from the private sector
  - Independent clinical care repositories serving institutions and health care systems
- For these systems to interoperate, they must have a common understanding of their shared environment:
  - Data model
  - Data representation - vocabulary
  - When to communicate - events
  - Security

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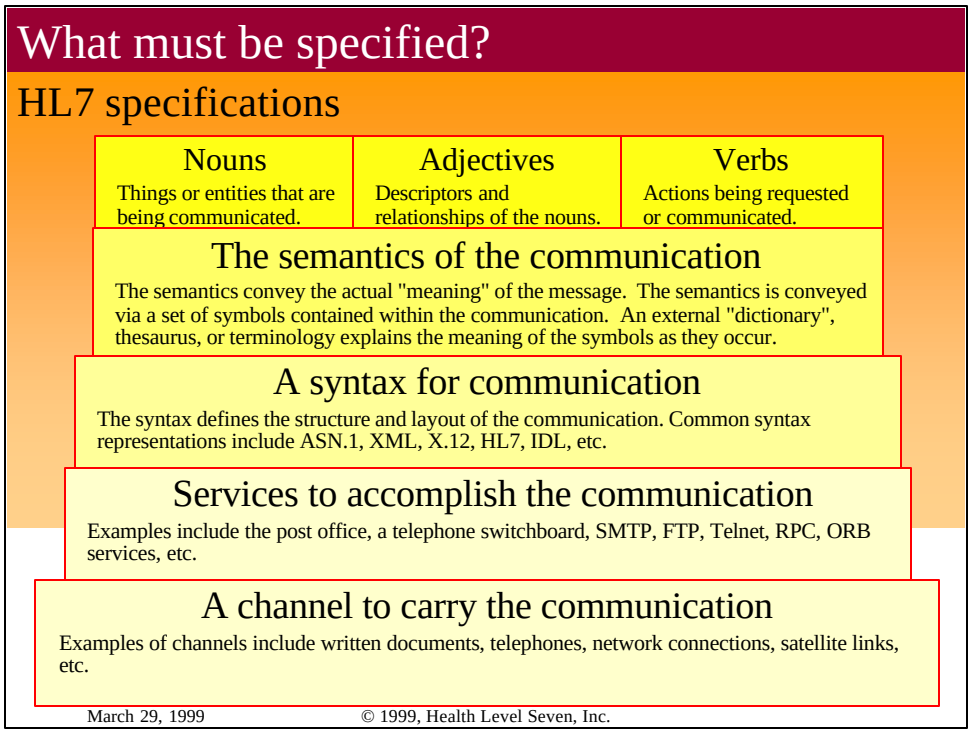
Footnote: The core observation here is that the "marketplace" determines the systems that the clinicians, care managers, and monitoring agencies will be using. Interoperability will be an essential requirement if we wish to marshal the capability of these systems as we seek to collect and analyze data across them.

Basis for Communication

Any meaningful exchange of utterances depends upon the prior existence of an agreed upon set of semantic and syntactic rules

ISO TR9007:1987 *Information Processing Systems – Concepts and Technology for the Conceptual Schema and the Information Base*



HL7's approach to standards has always focused on the upper levels of this "stack." The first challenge is to get the communications correct semantically. Only then, is it worthwhile harnessing the capabilities of various syntaxes and services.

As you will see, HL7 Version 3 is, in point of fact, attacking both the top and middle of this stack. By developing sound semantic models, we believe we can then help the users of our standards take advantage of the more flexible and robust syntactic and service level functions provided by today's technologies.

HL7 - How did we get here? What did we learn?

- Founded by healthcare providers early in 1987

  "to develop and publish protocol specifications for application level communications among diverse health data acquisition, processing, and handling systems."

- Produced Version 1.0 late in 1987 - prototype
- Produced Version 2.0 late in 1988
- Versions 2.1 - 2.3.1 published from 1990 - 1999 -- the "production" standards
- Accredited as a Standards Developing Organization by the American National Standards Institute (ANSI) in 1994
- Version 2.2 and later are "American national standards"

Who is HL7? Where are HL7 standards used?

- Who is HL7 - a not-for-profit, ANSI accredited SDO
  - About 450 organizational members -
    - Providers, vendors, consultants
  - About 1700 total members
  - Up to 400 attend the Working Group Meetings
  - International affiliate organizations in seven countries
- Where are HL7 standards used?
  - CHIME survey of 153 CIOs
    - 80% use HL7 and another 13.5% plan to implement in future
    - In hospitals over 400 beds, more than 95% use HL7
  - Formal adoption in Australia, Canada

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In large measure, the key to HL7's ability to succeed has been the diversity and energy of the participants. Earlier I noted that you will hear from providers, consultants and vendors alike. HL7 could not achieve breadth, depth and usefulness of its standards without the active and collaborative participation of all three groups.

HL7 Version 3 -

- HL7 “grew up” on the Version 2 series, culminating in 2.3.1
- But now, HL7 is into Version 3
  - What is it?
  - How is it different?
  - Why is it important?

> **It is change, continuing change, inevitable change, that is the dominant factor in society today. No sensible decision can be made any longer without taking into account not only the world as it is, but the world as it will be. . . .**
>
> Isaac Asimov (1920–92)

Versions 2.x

- Widely used:
  - secondary and tertiary facilities
  - large practices
- Broad functional coverage:
  - **clinical:** laboratory, pharmacy, radiology, dietary, most other diagnostic services, patient care, public health
  - **"clinical administrative:"** patient registration, admission; patient accounts; medical document life cycle; master file maintenance, HIPAA attachments
- Designed in 1987
  - Based on older messaging formats such as X12

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The Strengths of HL7 Version 2 are also its limitation:

It has broad functional coverage, but provides little if any guidance to the user as to how to solve any particular problem. Implementations that follow different strategies find it difficult to interoperate.

The standard is highly adaptable, with the adaptability coming from numerous optional parameters, but with no guidance as to which to select. Thus implementers must perform an independent analysis to select among these these options.

HL7 specifies none of the lower level technology. As a result, each implementation environment is different and therefore difficult to link.

Most of Version 2.3 is vocabulary independent, leaving the users to select their own codes and vocabularies.

By selecting a least common denominator technological base, Version 2 provides little guidance as to how to adapt the capabilities of newer technologies to the data interchange problem.

Version 3 Differences

- Design based on ***consensus*** Reference Information Model
- Adaptable to current and future technology bases
- Vocabulary-level interoperability
- Explicit conformance model
- Built on strongly accepted industry base technologies

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A major element of the Version 3 strategy is to separate the definition of the semantic components of the standard from the definition of the technical implementation. This allows the technical committees to select the "best" of the model and vocabulary worlds, and to apply these selections to a variety of technical implementations.

This separation strategy reduces the risk of working with "leading edge" technologies, and ensures the durability of the standards. One can change out the underlying technology without losing continuity in the semantic interoperability.

What is Version 3?

- A new form of standards
  - **Messaging standards** that are logically consistent with Versions 2.x, but with crucial semantic improvements
  - **Document standards** based on SGML/XML document architecture
  - **Component standards**
  - **Knowledge representation**

AND

- A new process for developing those standards
  - A wholly new approach to the way HL7 develops its standards

Amounts to “re-engineering” the HL7 organization and process

Version 3 as a Standard

- A new communication framework that
  - Separates message content definition from transmission formats
  - Includes a Patient record architecture (PRA) - to support sharing and reuse of documents
  - Facilitates use of external codes and terminologies
- Clinical templates
  - Ability to define specific clinical content that can be exchanged with standard messages from Versions 2 and 3
- Components for
  - Clinical communications
  - Workstation integration
- Medical logic representation - Arden syntax

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HL7 is more than messaging. Although this has been HL7's foundation, and will remain a critical element of the HL7 standards for the future. HL7 is "Messaging and **more**."

Over the last several years, the HL7 working environment has attracted standards developers whose primary interests are other than messaging:

•The SIG on Object Broker Technologies formed to tackle the challenge of performing HL7 messaging over ORB-mediated communication channels

•The SGML.XML SIG formed to provide a basis for document based communications stemming from a Patient Record Architecture

•The Vocabulary Technical Committee formed to meet the challenge of using externally defined vocabularies and terminologies in HL7 communications.

•The Security SIG formed to address techniques for providing the necessary security implementations for HL7 messaging.

•The Arden Syntax committee felt that its requirements for data definitions could be better met by the HL7 RIM.

•The CCOW consortium brought its component interface specification activities to HL7

Each of these groups will work with and enhance the Version 3 process.

Version 3 as Process

- A wholly new approach to developing HL7 standards
  - Model and repository-based for increased control and standards that are internally consistent
  - Specific coupling of events, data elements, messages. documents, and more
  - Increased detail, clarity and precision of specification
  - Finer granularity in the ultimate messages
  - Explicit inclusion of standard vocabularies, terminologies and code sets.

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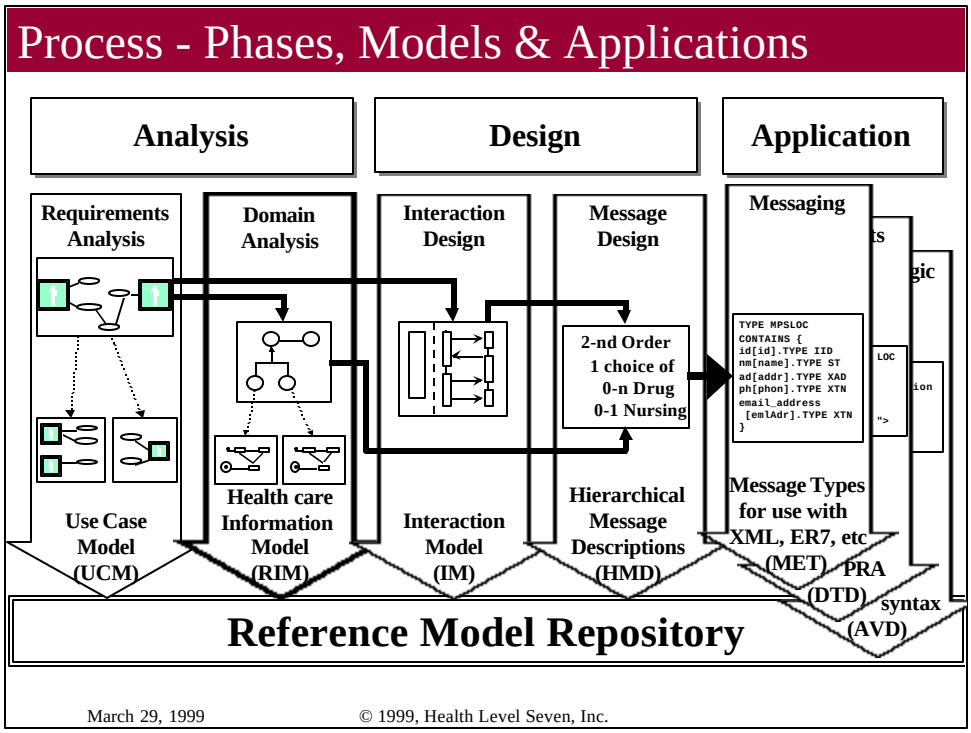
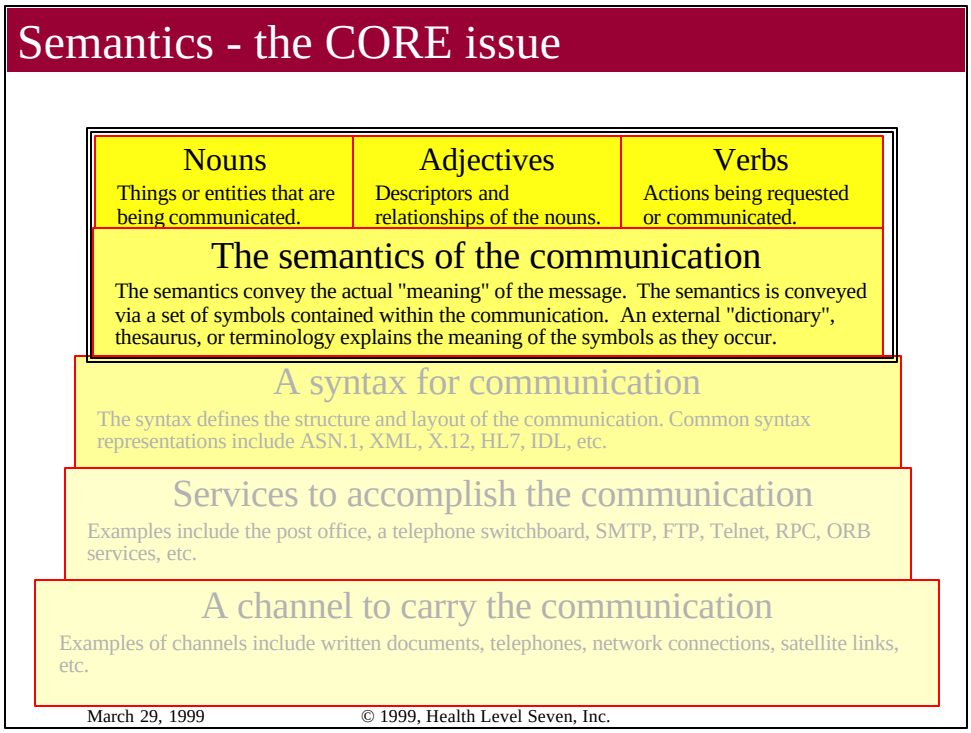
Footnote: HL7 will maintain its models and specifications in a repository - a database. This repository will be central to the ability of HL7 to manage the process, to assure an historic thread of its development, and to assure that each specification is, indeed, consistent with the models upon which it is based.



This diagram shows the four essential development steps for Version 3 standards, and the application of the resulting models to specific standards.

Although this diagram implies a sequential series of tasks - a waterfall methodology - the process is actually iterative. Knowledge gained in the later steps always leads to improvement in the models of the earlier steps.

The fourth step “Message design” is probably misnamed. Working with the context provided by the interaction requirements, this step considers the information entities defined in the Reference Information Model, and uses these to build an abstract information structure to meet the requirements. Certainly this abstract structure forms the basis for messages. Equally, however, it will serve to structure XML Document Type Definitions, and provide specific definitions for the variables contained in Arden syntax “curly braces.”



The following slides consider examples of the problems one runs into if there are not precise semantic definitions for a given communication.

What does it mean when ...

- I identify the "**patient's attending physician**?"
  - a single individual? Or
  - all of the physicians' involved in the case?
- I send a "**patient identifier**?"
  - their Social Security Number? Or
  - the medical record number in my institution? Or
  - a shared MPI number?
- I key my action to the end of the current "**episode**?"
  - the period of time the patient undergoes care on a given day? Or
  - the period of time the patient spends being an inpatient? Or
  - the period of time during which the patient is diagnosed with the same health condition (diabetes, hypertension, etc.)

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These examples reflect common misunderstandings about the nouns, adjectives and verbs in communications. Recently, these questions were posed on a list-server. Several individuals responded with exact answers to each question. Not unexpectedly, their assuredness notwithstanding, their responses varied depending the context they presumed.

The role of an information model is to establish a common understanding of such contextually dependent questions. Implementers need not adopt this model in their systems, but they must understand how the model maps to their environment and vice-versa. Consistent mapping to a common representation permits interoperation between systems built on different models.

What do coded values mean?

- Site 1:
  OBX|1|CE|ABO^**ABO GROUP**||O^**Type O**|
- Site 2:
  OBX|1|CE|BLDTYP^**ABO GROUP**||TYPEO^**Type O**|
- Site 3:
  OBX|1|CE|ABOTYPE^**ABO GROUP**||OPOS^**Type O**|

You and I might be able to interpret these, but could our computers do so?

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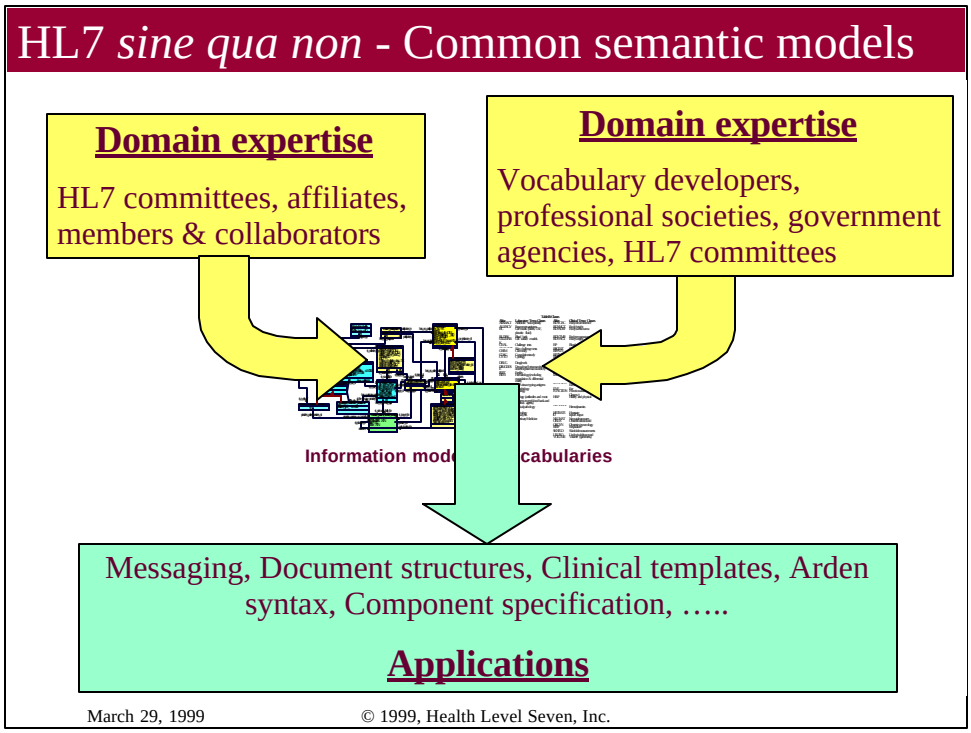
Here are three examples in which a pair of coded phrases “ABO GROUP” and “TYPE O” have different semantics.



The key to arriving at common semantic models is the ability of the standards process to incorporate the domain expertise of all user communities, and meld this expertise into a single set of unified information models and vocabularies.

Only then, can one apply these models to messages, documents and the like.

The standards challenge

- Expertise
  - Good standards require expertise and time to extract that expertise.
  - The experts must come from a base of “reality” - practitioners, software developers, vendors, health care consultants
  - The experts are there, and willing to help
- HL7, for one has demonstrated ability to attract expertise
- Logistics - the not-so-hidden cost of standards
  - Facilitating meetings
  - Documenting vocabularies and models
  - Publishing standards and models
  - Coordinating meetings
  - Support for travel and electronic collaboration

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The standards challenge is multi-faceted. First, one must excite the experts to the challenge and provide an environment in which they can collaborate.

Second, one must provide logistic support to the process -- facilitators to capture the expertise; staff to document and publish the models; meeting planning and coordination; and support for electronic collaboration and/or travel.

Over the last three years, HL7 has expended over $100,000 per year to support the interim activities need to be sure the models are captured, harmonized and published for the HL7 Working Group as a whole. HL7 has dipped into its reserves to fund this, but the reserves are finite.

What might the government do?

- Be supportive, not directive
  - The “marketplace” is the most effective director
- Provide support through the standards developers for
  - Development and collaboration on models
  - Development and maintenance of vocabulary mapping
  - Collection and publication of models and terminology mappings
- Avoid the temptation to focus on the current “hot” technology
  - Technologies will change far faster than you or we can
  - Establish a foundation for health care semantic interoperability, and let the surrounding technical environment change as it will.

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Attempting to “drive” the standards process is rarely effective. Standards have their own marketplace, and additionally are responsive to the broader health care computing market.

Logistic support can be extremely beneficial. HL7 can and does expect its volunteers and member organizations to “foot the bill” for the Working Group Meetings it holds three times a year. However, the organization feels it cannot expect a subset of these volunteers to fund the travel and meetings for an additional three interim meetings in which the work product of the large meeting is harmonized. Thus HL7 has underwritten the travel (but not time) for the experts who attend these meetings. Staff time and travel to provide secretariat services for these meetings is an additional burden,

In the vocabulary field, the government has played an important role by providing the UMLS as a place for mapping disparate terminologies. This service must continue. In addition, however, the legal relationships between the contributors to the UMLS and the users of the UMLS must be addressed so that they have an unequivocal understanding of what the users may and may not do, and what the contributors may and may not demand.

Finally, mandating technology is almost always a bad strategy. Consider GOSIPS, ISO OSI, ADA and others. Rather, pursue a strategy that assures the technology independence of patient medical record information, and let the technology marketplace work its wiles.

The Change Paradox

It is change, continuing change, inevitable change, that is the dominant factor in society today. No sensible decision can be made any longer without taking into account not only the world as it is, but the world as it will be. . . .

Isaac Asimov (1920–92)

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Above all, the world we are planning for will be different. Plan for change rather than setting a strategy which the inevitable change will negate.