

Coming to Terms: **Scoping Interoperability for Health Care**

FINAL

Health Level Seven EHR Interoperability Work Group

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Foreword

As an Emergency Physician, I often treat patients without the benefit of any historical clinical information. I do my best by working the patient to develop a list of active medications, calling next of kin to assemble medical history and trying to locate previous treating physicians for insight into previous admissions. It's a bit like flying without radar in the fog.

All of this ambiguity could be solved by implementing interoperable electronic health records. Care quality would improve, costs would be reduced and patient satisfaction would increase. From Hillary Clinton to Newt Gingrich, policymakers in Washington are enthusiastic about interoperability. However, no one has crisply defined what it means to be interoperable.

If I'm faxed a discharge summary which I can read, is that interoperable, since it's human interpretable? If I'm sent an electronic note via email that notes "Allergy to MS", is that interoperable? Of course MS could mean Morphine Sulfate, Magnesium Sulfate, or even Minestrone Soup. If I'm sent an electronic message which has an agreed upon format, a standard vocabulary, and a set of business rules which enable me to take action, is that interoperable? i.e. Your patient is allergic to medication NDC Code 123456789. Administration will cause a SEVERE reaction with HIGH CONFIDENCE. My e-Prescribing software could use this information to display a warning alerting me to the issue and could suggest an effective alternative medication.

In August of 2006, President Bush signed an Executive Order mandating the Federal Government use of interoperable standards. At a high level, this Executive Order defined Interoperability

"Interoperability" means the ability to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks in various settings, and exchange data such that clinical or operational purpose and meaning of the data are preserved and unaltered.

"Recognized interoperability standards" means interoperability standards recognized by the Secretary of Health and Human Services (the "Secretary"), in accordance with guidance developed by the Secretary, as existing on the date of the implementation, acquisition, or upgrade of health information technology systems under subsections (1) or (2) of section 3(a) of this order.

Defining interoperability and its requirements are the first step in creating a connected healthcare system. As Chair of the Health Information Technology Standards Panel (HITSP), I facilitate the work of 170 stakeholders selecting the most appropriate interoperable data standards for specific use cases. In 2006, we will issue our first work

products and will create committees to formally codify foundational definitions such as interoperability.

This paper introduces a framework for the definition of interoperability based on a review of the literature and a survey of existing uses of the term across all industries. As we improve healthcare through the use of electronic health records, it is our hope that all stakeholders will use this definition to gain a better understanding of the future we are seeking.

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Executive Summary

The characterization of “interoperability” offered in this white paper is based on an analysis of how the term interoperability is being defined and used in actual practice. Over 100 definitions were collected and the 65 definitions from organizations were closely analyzed. Most definitions were from standards development organizations, health care organizations, professional societies, and government agencies. Of these, approximately two thirds were from organizations relating to health care and about two thirds were from organizations which affect the United States. Substantial differences in how interoperability is defined were identified based on organization type (health care vs. non-healthcare) and, for health care organizations in the United States, based on longevity (years since founding). Three principal types of interoperability were identified: technical interoperability, semantic interoperability, and process interoperability.

On “Coming to Terms”

In June 2005, Secretary Michael Leavitt noted that the field of Health Information Technology (HIT) involves bringing together the two communities of practice most known for their use of complex and difficult language: medicine and computer science. Adding to this challenge, not only are these two fields in the process of merging, but they are also evolving very quickly. A symptom of this is an increase in the amount of time that even high-level groups must spend on “coming to terms” about the terms to use and what they mean. Common agreement on interoperability is not easy because individual and even group understandings of its meaning are presumed as self-evident and nurtured, by clinicians, institutions, vendors, payers, and others, to the exclusion of other definitions. Rather than seek to understand one another, we assume we already do; so full collaboration is difficult and progress is impeded.

As Raymond D. Aller, MD, Chair of the 2005 HIMSS Standards Committee, wrote in the Foreword to the 2006 HIMSS Dictionary¹:

One troublesome aspect of [compiling this dictionary] is that words are misused, or come through usage to assume two or three mutually exclusive meanings.... Be aware that when you use [a] term, the listener may be thinking of a different definition than you are.

The achievement of interoperability in health care is challenged by intersecting dynamics at many levels. These include not only converging “languages,” emerging sciences, and pressure for results, but also conflicting demands, entrenched interests, disparate incentives, challenges to professional identities, and dissimilar communication styles. The need for clarity and consistency in communication about complex emerging knowledge is among our greatest challenges.

We must move to new, more objective and scientific ways of understanding and communicating, especially with regard to pivotal, foundational concepts like “interoperability.” While not sacrificing broad participation, openness or transparency, we must find ways of usefully naming concepts with x, based on methodological tools which anchor our use of terms in an

¹ HIMSS Dictionary of Health care Information Technology Terms, Acronyms and Organizations (2006).

understanding of established practice and professional consensus -- even while not retarding the emergence of new knowledge and new insights -- if we are to keep pace with the explosion of new biomedical and clinical knowledge in an increasingly volatile world. What better place to start than with the term “interoperability”? -- for this is the foundational concept which itself refers most directly to the ability to communicate clearly and to collaborate effectively.

Introduction

The task of improving healthcare information technology is being addressed by many practitioners, vendors, organizations and governments around the world. For example, in his January 2004 State of the Union Address, United States President George W. Bush announced his intention to provide Americans with electronic health records within a decade. Subsequently, in May 2004, Dr. David Brailer was appointed National Coordinator for Health Information Technology. That moment was heralded as a “tipping point” in the progress of health information technology. New organizations had been forming, driven by alarm over the rising cost of care, regional differences in practice patterns, and concerns about patient safety. Non-health industry leaders, such as PepsiCo and General Motors, attributed the high cost of American health care to the inadequate use of information technology (IT) and pressed for more IT investment in the health system. However, dissatisfaction with earlier government-mandated initiatives along with reluctance to fund improvements using public monies prompted an interest in identifying more market-based, consumer-driven incentives to spur HIT investment. This led to the call by the Office of the National Coordinator (ONC) for a National Health Information Infrastructure (NHII) that would be market-driven, self-propelling, and “interoperable.”

→ But what was this thing, “interoperability”?

There are many health care-related loci that fall within the potential scope of an interoperability definition. Some have to do with interoperability within a hospital or clinic – from one department, such as the emergency department, to another. Perhaps the most familiar has to do with the need for interoperability between ancillary systems, such as from the laboratory information system (LIS), to an electronic health record system (EHR system). The need to convert information from one form to another, such as from natural language text to encoded terms or classified categories presents another dimension of interoperability. Other interoperability issues have to do with the need for interoperability between clinical sources such as EHRs and research databases, recently coined ‘clinical and translational research.’ Sharing EHR information about a patient with other health care institutions (via point-to-point data exchanges or through regional health information exchanges or RHIOs); the extraction of EHR information for personal health records (PHRs); and providing longitudinal data for patients as they utilize the health care system over time, are additional arenas where interoperability has been declared to be the keystone.

Interoperability is of profound importance to biomedical and clinical research, where a continuous cycle of clinical quality improvement begins with patient data gathered at the point of care, maintained and supplemented in clinical databases, and provided as phenotype data for life enhancing research. Through the use of differential outcomes analysis, the effectiveness of clinical interventions can be understood. Subsequently the information from research will be made available to the practitioner at the point-of-care as ‘knowledge of best practice’ by means of on-line clinical protocols or reference information, interactive clinical advice, and as safety and

quality reminders or guidelines. This can be thought of in terms of “arcs of interoperability” which potentially will allow information to flow easily between researchers, point-of-care practitioners, and computer software developers.

Recognizing the need streamline and expedite the transfer of knowledge between research and practice, the United States National Institutes of Health (NIH) is currently in the process of restructuring its grant processes to eliminate unnecessary barriers between clinical practice and basic and clinical research by bundling its grants awarded to specific provider organizations as “Clinical and Translational Science Awards” (CTSAs). This streamlining is intended to remove barriers between practitioners and researchers and decrease the amount of time it takes to introduce new knowledge to the practitioner at the point of care. The long term goal is to improve the ability to collaborate – not only by bringing research results rapidly to the point of care, but also through quick dissemination of phenotype findings to researchers. This is especially important given the new discoveries in genomics and proteomics that are dramatically increasing and improving our understanding of the causes of many diseases. (See figure 1)

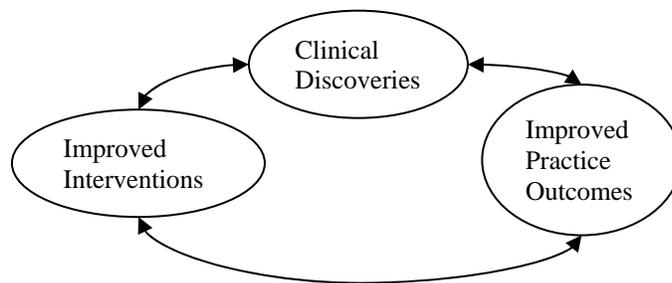


Figure 1 ‘Interoperability Arcs’ enable the flow of mutually-agreed HIT conversational contexts (i.e., interoperable information), benefiting all participants.

Interoperability Definitions: Previous Work

The vision above shows interoperability existing at many points, but just what is it?

It has been suggested that the term interoperability is too technical for discussions with policy-makers or the general public and some have recommended using a simpler term. *The danger is that by using a simpler definition we assume a simpler reality.* A conversation on the meaning of the term “interoperability” was introduced by the federal government in 2003, as funding for a future National Health Information Infrastructure were begun. A few organizations volunteered their legacy definitions or quickly developed one. The fact that there were different definitions prompted Dr. David Brailer to observe that we are ‘not even interoperable in our ability to define interoperability.’ Of special concern were the huge discrepancies in scope attributed to the term, ranging from straightforward physical connectivity, to the communication of meaning (known as “semantics”), to including even “social, political and organizational factors.” [Wikipedia]

Two particular organizations, the Center for information Technology Leadership (CiTL), and Health Level Seven (HL7), began efforts to develop a more scientifically based definition of HIT interoperability. CiTL based its approach on an economic analysis of technologies. It identified four layers of progressively complex interoperability, from a simple and inexpensive fax document to an expensive, fully transparent and ‘computable’ semantically interoperable document. Each layer entailed a mixture of technologies (hardware) and semantic transparency

(software). The study was used to project a period of financial investment (and loss) in the early years of adoption of interoperable systems, with benefits accruing only in the later years, when the achievement of greater degrees of semantic interoperability was realized.

This computational and financially oriented stratification was then appended to a definition developed by The National Alliance for Health Information Technology, which used it as an addition to the widely used definition developed by the Institute of Electrical and Electronics Engineers (IEEE) in 1990. This resulted in an admixture of technology along with *implicit* degrees of semantics within both parts of the definition, but did not break out major types of interoperability and did not differentiate semantic deliverables from technical ones.

The HL7 EHR Technical Committee's (EHR TC) Interoperability Work Group gathered and analyzed existing definitions to determine how the term was currently being used in the field. The results of this initiative are defined in this paper.

HL7 Work Group Approach

A Quality, a Benefit, a Thing?

Defining broad concepts such as interoperability is difficult. It is particularly difficult because not only are such concepts intangible, but they can change over time; in fact dynamism may be a sign of a concept's vigor and relevance. Case in point: what was a "decision support system" in 1983 is now referred to as a "business intelligence system"; and today a "decision support system" is usually used to refer to a system or function which offers real-time advice or guidelines interactively during a work process.

In situations when the meaning of a term is static, it is sensible to simply look it up in a dictionary, even a paper-based dictionary. But with complex, emerging concepts -- such as interoperability -- this may be inadequate. Questions arise.

- * Who will use the definition and for what purpose?
- * How will the definition be used -- to define a general policy goal? To allocate funds to specific companies or organizations for research or development? To design a standard for exchanging data between two electronic health record systems?
- * What level of communication is required? Is it enough that the bits or bytes sent from one location arrive intact at another location? That the message transmitted securely? Those computers at the two locations place a data element into the same data field? Or is some kind of transformation of the information required to preserve the meaning in its new context? Are there situations when each of these is appropriate? What factors would determine the approach taken?
- * To what use will the data be put? Does interoperability assure that the meaning of the data element is understood in the same way at both locations? -- That it is *used* the same way? -- That the same *result* is produced at both locations when it is combined with other information?
- * For that matter, does it matter that the data is understood at all -- if so by who or what? A human being? A specialist? A computer program? Must information be specified with multiple such users in mind?

- * We might as well throw in the last of the “Journalism 1.01” questions: “when?” When is the exchanged data to be provided: -- at a specifiable point in time? At a specific point in a sequence? When certain pre-specified conditions are met? A combination of these?

In short, to paraphrase one sharp-witted HIT commentator: defining complex, foundational concepts like interoperability is “Not for Wimps.” However, neither is it -- we might counter -- beyond the understanding by a typical high school student who puts his/her mind to it. This biggest problem is that typically we all *believe we already know the answer*, as if we could ace the history text without attending class or reading the book. What we need to do is “do our homework.”

To use the well-known metaphor of the Blind Men and the Elephant: with interoperability, there exists “an elephant”. And it is important to understand that there is a whole elephant, even if one is personally interested only in the elephant’s trunk; -- not knowing that the elephant also has legs could, as it is said, result in “severe injury or even death.” In 2006, it is no longer enough to indicate “toxemia of pregnancy” in a patient history. To practice obstetrics, continuing use of an antiquated term reflects an overly simple or rejected understanding, could result in a lawsuit, not to mention patient harm. We too are specialists -- computer scientists though we may be. We must continue to learn and adopt our terms to take into account new knowledge.

A More Scientific Approach?

Science depends at upon the notion that there is an underlying reality that we seek to understand and express, even though we may expect this reality to be re-understood with each generation, perhaps each decade or even every few years. In our industry, we may also be hampered by the need for individual stakeholders to develop customized products to maximize their market share. Hence, competitiveness can be implicitly tied up with exclusivity and it is a major challenge to our industry to find the best balance between interoperable systems and “value-add” features provided by particular business entities.

Notice that we have not yet mentioned “stakeholder preferences.” This is a legitimate subject of discussion, but it does not apply to what interoperability *is* but rather to things like the benefits stakeholders may expect or the technical component (software or hardware) that a particular technology vendor focuses on. This is not to say that there cannot be differences in what benefits people expect from “interoperability,” which systems they want to be interoperable with one another, or what their goals for interoperable systems are. This particular paper is not intended to address these differences -- they are being addressed elsewhere, and indeed, there are many reasons for desiring interoperable systems. The purpose of this paper is to derive a comprehensive, correct definition of interoperability and, if necessary, to identify and describe what the different levels and/or types of interoperability are each capable delivering in terms of the set of marvelous benefits people predict will result if only we all “become interoperable.”

Interoperability is not a quality or qualification, but rather a noun describing a relationship between systems. It may sound ephemeral, but it can and must be translated into real things. Think of the Titanic. “Unsinkable.” This may sound like an insubstantial concept, but we all know that “unsinkability” in this particular infamous case boiled down to some very concrete things, such as: bolts, hulls, lifeboats, icebergs; as well as some all-too-human characteristics: pride (*hubris*), belief in progress, denial of danger. Interoperability is similar, with broad range of basic, conceptual as well as human factors to consider. One needs only examine the excruciating detail required to specify the requirements for “trusted end-to-end transmission” of data, being

specified by HL7 as one part of one software layer of technical interoperability, to see in just how specific and detailed our specifications must eventually be. At the same time, policy makers expect of interoperability huge social and financial rewards. This requires us to identify those aspects of interoperability which can actually produce such advantages.

Yes, we must define interoperability rigorously, we must define interoperability comprehensively, and we must define interoperability *now* – or risk being left with a useless collection of politically correct or incorrect opinions and no clear idea of what to work on. Worse, we will be left without the basic shared conceptual base which can allow for the emergence of a vital new community of practice in which practitioners, researchers, computer scientists, government, and payers can all collaborate, using new tools and methods and improved forms of communication. Without such a common understanding, we will not be in a position to bring forth what Secretary Mike Leavitt challenged us to achieve -- to make that leap into “the next level in human productivity based on the improvement in collaborative decision making.” Nor will we be able to achieve interoperability among health care systems.

Why Define Interoperability?

Different assumptions about what interoperability can result in profound differences in what we do, when we do it, how resources are distributed, and which goals are met (if, in fact, they are met at all). Our definitions of interoperability dramatically affect how data is stored and used and how software is designed. If we don't understand the context for the information, how can we use it in the translational or clinical research process? In the May 2005 HIMSS Insider, Ed Larson expressed it this way:

“**Why** is defining interoperability **so important**? Certainly, lack of interoperability is commonly cited as the biggest barrier to attaining the promised benefits of HIT investment. One's definition of interoperability shapes the size and scope of the problem and thus the response in terms of policy, resources and priorities.” [Emphasis added.]

Methodology of the Study

Data Collection

The Interoperability Work Group of HL7's Electronic Health Record (EHR) Technical Committee was formed in April 2005 to attempt to define the concept of interoperability.

The HL7 EHR working group began with the dictionary definition of the term interoperability (Merriam-Webster) and asked its members to begin gathering definitions or suggesting their own. This request resulted in an interesting short list of definitions, opinions, not to mention the ever-present, “Don't waste time defining it; just do it!”

The group plowed on, soliciting additional definitions via the Internet, including Google searches. Since raw Google hit counts can be misleading, the group went to web sites suggested by work

group members.² Some sites included more than one definition; some provided their own catalogue of definitions. Informal definitions were considered, but the group focused primarily on those that had been adopted by organizations, such as those formally listed in glossaries or prominently displayed on web sites.

Most definitions were submitted by e-mail, either as a single definition, a list of definitions, or as one or more links to web sites or documents. All definitions were reviewed. Approximately 100 definitions directly relating to HIT interoperability were retained; the rest were deemed tangential (e.g. definitions developed for use by one state in the United States).

After four months, the group was satisfied that the 100 definitions thoroughly covered HIT interoperability’s universe of discourse and began their analysis. The results of the initial analysis were shared with individuals from major standards and professional groups including HL7, the Health Information Management Systems Society (HIMSS), the American Medical Informatics Association AMIA), and several others. The preliminary findings were first presented at the HL7 meeting in September 2005 by Harold Solbrig of the Mayo Clinic. Additional contributions have trickled in, but this paper is based on definitions received as of July 31, 2005.

Sources of Definitions

The full set of definitional participants was categorized as follows:

| Number of Participants | Type of Participant |
|------------------------|-----------------------------|
| 65* | Organizations |
| 19 | Individuals |
| 9 | References |
| 3 | (Too generic ³) |
| 4 | Articles |
| 100 | Total |

Table 1. Categorization of Definitional Participants

*Most of the group’s analysis focused on definitions received from organizations. Those 65 organizations⁴ were categorized by realm as follows:

- 48 (74 percent) were organizations that impact the United States (including nine organizations that were global and which had the U.S. as a member (e.g., the World Health Organization))
- 13 (20 percent) were U.S. federal agencies (e.g., the Centers for Disease Control and Prevention)

² After the study was concluded, an analysis of raw Google counts, was done. The results are shown in Appendix A.

³ Two sources, HL7 and ISO EHR used a self-referential definition, defining “interoperability” as their reason for existence (*raison d’etre*). For IEEE there were two definitions, quite similar. WEDI/SNIP though health related defined business functions so was excluded in the following analysis.

⁴ Two definitions were available from different IEEE sources and are similar. The older IEEE definition is retained because it was widely adopted by other organizations. In addition, IEEE-USA developed a more expanded version of the definition for the health care field.

- 4 (6 percent) organizations were neither U.S.-related nor U.S.-based

Those 65 organizations were also categorized by industry as follows:

- 40 (62 percent) were health-related and also involved in HIT
- 25 (38 percent) were not health-related (including those related to defense, communications, engineering, and library science)

Again, this sample of 65 organizations is from the full set of all definitions that were contributed in the four month period (April through July 2005).

Analysis

An Excel spreadsheet was used to capture the information about the definitions. The attributes of the data initially included:

A simplified excerpt showing values for some of the attribute follows. The entire table appears in spreadsheet format in the appendix.

| Geographic Realm | Domain | Source Type | Description |
|------------------|----------|-------------|--|
| US | Engineer | IEEE | (a) exchange, use; (b) exchange data, work properly together |
| Global | General | ISO | exchange info between two or more IT system and make mutual use of exchanged information |
| US | Health | NAHIT | exchange, use; in accurate, effective and consistent manner |
| NonUS | Health | ConnUK | semantic: entry to standard; standard to standard |
| US | Health | MRI | snapshot of commonly defined key data providers (mixed approach); summarization process |
| Global | Health | WHO | Semantic pre-requisite for efficient e-health systems; |
| Global | WWW | W3C | Semantic Web: explicitly [fully] define meaning so can be understood by software |
| US | Health | AMIA | <i>syntactic</i> , semantic; semantic requires ontology |
| NonUS | Health | CEN/251 | syntactical interoperability + semantic interoperability = eHealth |
| US | Health | ConnMK | physical connectivity, network authentication, application: simple through complex semantics |
| NonUS | General | DCITA | interoperability= <i>functional</i> interoperability; vs semantic interoperability |

Table 2. HL7 Interoperability Definitions (excerpt)

Note: color-coding reflects classification.

Findings

Initial Categorization of Findings

The group initially categorized the definitions of interoperability as:

- those that referred only to technical interoperability, which equated to the concept of connectivity,
- those that included both technical interoperability and semantic interoperability, and
- those that included other dimensions – most commonly (and these dimensions were

interrelated) process and social interoperability.

The group made these initial categorizations by noticing contextual patterns within various stakeholder types. For example:

- engineering SDOs and financial stakeholders mentioned sending technically-interoperable messages;
- health oriented SDOs and biomedical researchers mentioned receiving semantically-interoperable clinical documents; and
- hospital system workflow and quality improvement stakeholders mentioned process-interoperable workflow triggers that altered workflows.*

*Note: Stakeholders who mentioned social or process interoperability in their definitions tended to be clinical process oriented, including management engineering; others were “next generation” sources and academics (the Federal CIO Council’s Semantic Interoperability Community of Practice SICoP, the Institute of Medicine) and several were non-U.S.

Further Categorization of the Findings

The working group noticed that the authors of the existing definitions had been attempting to describe the notion of interoperability in terms that were important (meaningful, relevant) to the authors’ world view and problem set. The group also noticed that the authors had a tendency to express those world views and problem sets using similar terms in their definitions. As contextual differences emerged (e.g. differences such as between a “run” in baseball and a “run” in a stocking; or between a “table” in a medical text and a “table” in a furniture store), the group further categorized the new findings under additional spreadsheet attributes (columns). These new attributes included:

- Source Type (e.g. dictionary, organization, etc)
- Realm (US, Global, Non-US)
- Domain (health, engineering, banking)
- Year organization was founded (later categorized as ‘2000 or earlier’ and ‘2001 or later’)
- Link to internet source (for realms in which US participates)
- Organization or other source
- Type(s) of interoperability (technical, semantic, process)
- Description (a summary of salient aspects of definition, underlining indicates what the “type” was based on)
- Notes

NOTE: Classification type is the focus of this paper. This is for several reasons. For one, it was the only attribute that was present in all definitions, as it has to do with the nature of interoperability itself. The other attributes are of interest, but are peripheral to understanding the “is-ness” of interoperability.

Results: Three Types of Interoperability Identified

Example

It became apparent early on that some stakeholders based their definitions on standard technical

definitions such as the IEEE-90 and tended to view interoperability as a matter of simple connectivity – the ability to ensure that a message was exchanged completely and in correct format. The IEEE-90 definition does not include the notion of the semantics – the preservation of the meaning – of the message. Simply expressed, if technical interoperability is the presumptive definition, as long as a verifiable message payload arrives at the receiving application, it does not matter whether the recipient understands the content or the intent of the message or whether the original message retains its structure and meaning. For example, if the transmitted message clearly shows that the patient needs an evaluation for appendicitis, but the receiving application loses the structure of the historical sequence and shows instead a broader picture of just “abdominal pain,” the technical interoperability criterion could still be satisfied, but the semantic aspect of the message would not be understood by the receiving application or human recipient.

Classifying Interoperability Types: Example 1 (Rossi-Mori)

The types of interoperability are well-described in a paper by Angelo Rossi-Mori, et al. which offers the following hierarchy for the “*Computer-based handling of clinical information*”:

| # | Goal | Computer-based handling of clinical information |
|---|---------------------------------|--|
| 1 | layout-based presentation | display, print information (without health care -specific constructs) |
| 2 | Health care -aware presentation | present information using health care -specific kinds of constructs |
| 3 | reorganization of information | browse with variable criteria, prepare multiple views, select, index; aggregate data from diverse patients (epidemiology, audit, QA) |
| 4 | trigger to reference knowledge | use pointers in look-up tables and knowledge bases (e.g., on drugs, on guidelines, on statistical tables for QA) |
| 5 | update content | write and amalgamate information into a different record system |

Table 3. Computer-based Handling of Clinical Information

Technical interoperability relates to Rossi-Mori's first goal. Semantic interoperability relates to goals 2-5. Process interoperability goes beyond Rossi-Mori's goals and provides the capability to recognize the content of the transmitted data, place it into a process model and trigger actions that should be taken by the software system to support a clinical process (such as generating a message stating that a patient will need to be prepared for a specific procedure at a specific time).

Classifying Interoperability Types: Example 2 (IEEE-USA)

According to a compilation of IEEE Standard Computer Glossaries, IEEE 1990 (or “IEEE-90”), interoperability generally refers to “the ability of two or more systems or components to exchange information and to use the information that has been exchanged”. On November 11, 2005, IEEE-USA issued a policy statement clarifying how the term interoperability should be used when applied to health care:

**IEEE-USA Clarification of Definition of interoperability:
Importance of SEMANTIC interoperability**

From Policy Position: **interoperability FOR THE
NATIONAL HEALTH INFORMATION NETWORK**

Approved by the IEEE-USA
Board of Directors (11 Nov. 2005)

IEEE-USA believes that interoperability [1] is one of the most critical concepts confronting the adoption and implementation of enhanced electronic information technologies into our national health care infrastructure....

In health care, the ability to use the information that has been exchanged means not only that health care systems must be able to communicate with one another, but also that they must employ shared terminology and definitions. This latter emphasis places a much greater burden upon system designers and electronic engineers to make the information truly usable in the distributed clinical setting of our health care environment....

....3) In health care, Semantic interoperability, or shared terminology, is as important as System interoperability, or shared functions, and must occur to achieve maximum benefit for the use of information that has been exchanged. [emphasis added]

<http://www.ieeeusa.org/policy/positions/NHINinteroperability.html>

Hierarchy of Interoperability

As a general rule, the analysis of definitions indicated that when the three types of interoperability – technical, semantic and process – were mentioned, they were hierarchically related as follows:

- if **technical interoperability** was mentioned (in the sense of exchange or use), it was mentioned either alone or in combination with the other types of interoperability;
- if **semantic interoperability** was mentioned, technical interoperability was usually also specified;
- if **process/social interoperability** was mentioned, it was typically mentioned along with both technical AND semantic interoperability.

Successful process interoperability relies on successful technical and semantic interoperability because the desired data must be successfully transmitted (technical interoperability) and properly understood (semantic interoperability).

Note: There were several fascinating exceptions to the above hierarchy “rule”. **Technical** and **process** interoperability appeared twice without **semantic** interoperability when this combination was used to describe interoperability for *service architectures* (SOA) and by the Architecture Subcommittee of CEN’s TC 251 (12265) where the scope was limited to architecture. Another exception was the use of **semantic** interoperability alone in reference to the W3C’s Semantic Web initiative, where the scope was limited to the semantics of the web. Both of these exceptions are reasonable given the scope addressed by each of the organizations.

The Work Group’s Consensus

As a result of the working group’s research, evaluations, and findings (described above), three

interoperability classification types emerged, namely:

- Technical⁵ interoperability
- Semantic interoperability
- Process⁶ interoperability

Type 1: Technical Interoperability

We determined to use the expression “technical interoperability” over “functional interoperability” (and several other expressions) to define the most basic, hardware-based form of interoperability. IEEE-90 defines interoperability as, “The ability of two different systems to exchange data so that it is useful”. When applied to health care, some health care organizations have adopted the term “functional” as in “Functional interoperability is the ability of two or more systems to exchange information so that it is human readable by the receiver.” The problem with the word “functional” is that it has so many possible meanings in health care domain. There are bodily functions, organizational functions, transmission of bits and bytes over a wire, computer software functions. Indeed, each definition reviewed had to be carefully examined in its context to be sure which of the above possible senses of the word “functional” was meant. Therefore, for the rest of this paper, (and as our recommendation) we have adopted the term “technical interoperability.” It is quite crisp and narrow in scope: we are referring to hardware, transmission, and closely related functions like access and security management.

The focus of technical interoperability is on the conveyance of data, not on its meaning. Were it not for the fact that computers tend to use written language, this would be similar to the level of interoperability provided by voice communications, e.g., via a telephone. Technical interoperability encompasses the transmission and reception of information that can be used by a person but which cannot be further processed into semantic equivalents by software. Note that mathematical operations can be -- and frequently are -- performed at the level of technical interoperability. A good example is the use of a “check digit” to determine the integrity of a specific unit of transmitted or keyed-in data. The same mathematical formula is performed at each end of a transaction and the results compared to assure that the data was successfully transmitted.

Type 2: Semantic Interoperability

To maximize the usefulness of shared information and to apply applications like intelligent decision support, a higher level of interoperability is required. This is called semantic interoperability which has been defined as the ability of information shared by systems to be understood... so that non-numeric data can be processed by the receiving system. Semantic interoperability is a multi-level concept with the degree of semantic interoperability dependent on the level of agreement on data content terminology and the content of archetypes and templates

⁵ This group included interoperability described as “technical,” “functional,” “exchange,” and “exchange and use” and “syntactic.” “Syntactic” was often coupled with “semantic,” by those who chose to mention semantic. It can be argued that there are differences among these terms. For the purposes of this paper, “technical interoperability” is used when the definition appears to be relating to Levels 1-6 of the ISO OSI Model. Rossi Mori et al break Level 7 into 5 layers; of these, the upper 4 (layer 2-5) would roughly correspond to “semantic interoperability,” although as they note, the boundaries are not rigid. http://www.prorec.it/documenti/EPR_EHR/EuroRec01-30z.doc

⁶ The number of definitions including “process” as a distinct type was small. Other words used were “procedural,” “operational,” “organizational” and “social.”

used by the sending and receiving systems.”⁷ HL7 also defined a quality that is necessary for optimal semantic interoperability to exist. The quality-based rationale of the HL7 semantic interoperability messaging standard asserts that *health information systems will communicate information in a form that will be understood in exactly the same way by both sender and recipient.*

Note that the greater the level of software-level semantic interoperability the less “human” processing is required. For some functions, this can provide relief from redundant, error-prone human data entry or analysis. However, it also creates opportunities for the intrusion of misleading information, even misguided policies, into patient care processes, if not thoughtfully and responsibly developed, tested and deployed. Full semantic transparency is indeed the Holy Grail of HIT informatics, but it is also the greatest scientific and ethical challenge. The maturation of the technologies of personalized genomic profiling are expected to allow us to predict the susceptibility of an individual and their offspring to potential difficulty, expense, disability, disease, and premature of painful death. What is to be done with this information? These are huge issues. Semantic interoperability is at the heart of them.

Type 3: Process Interoperability

Process interoperability is an emerging concept that has been identified as a requirement for successful system implementation into actual work settings. It was identified during the project by its inclusion in academic papers, mainly from Europe, and by its being highlighted by an Institute of Medicine (IOM) report issued in July 2005 which identified this social or workflow engineering as key to improving safety and quality in health care settings, and for improving benefits realization.⁸ It deals primarily with methods for the optimal integration of computer systems into actual work settings and includes the following:

- Explicit user role specification
- Useful, friendly, and efficient human-machine interface
- Data presentation/flow supports work setting
- Engineered work design
- Explicit user role specification
- Proven effectiveness in actual use

A Puzzle Metaphor of Interoperability

At the first meeting of the American Health Information Community, Secretary Leavitt Michael introduced the metaphor of a cardboard to describe the processes that he encouraged the group to adopt. The same puzzle metaphor can be used to help distinguish the various types of interoperability. For illustration, we will assume that the assembled puzzle displays a map of a subway system.

- **Technical interoperability** describes the actual, physical puzzle pieces and their ability to be linked.
- **Semantic interoperability** describes the image printed on the puzzle and the picture’s ability to convey information to people.

⁷ There are, of course, instances in which diseases “break apart” as it were, as with “anemia.” Low iron anemia rolls up into a different class of diseases than does sickle cell anemia.

⁸ *Building a Better Delivery System: A New Engineering/Health Care Partnership*, The National Academies Press, 2005. <http://newton.nap.edu/books/030909643X/html>

- **Process interoperability** describes the methods and strategies used by those assembling the puzzle, perhaps grouping pieces with straight sides, grouping pieces by color, etc.

Now consider that each stakeholder views the puzzle differently with respect to interoperability:

- **Technical interoperability.** The puzzle manufacturers do not care about the meaning of the map – it might as well be a picture of a bird since they do not intend to use the map to navigate the subway. Nor do they do not need to concern themselves with which approach is used to assemble the map or how long it takes to do so. Rather, they are concerned with ensuring that the pieces are cut properly, that all the pieces are placed in the box, and that the box is sealed and shipped correctly.
- **Semantic interoperability.** The people assembling the puzzle do not care how it was manufactured, packaged, shipped, or assembled. They are concerned with viewing the map to understand how the subway may be used to travel from “here” to “there.”
- **Process interoperability.** The process of putting the puzzle together requires working with characteristics of *both* the physical pieces of the puzzle and the picture printed on it. The assemblers may change their workflow process depending on their goals. For example, the assemblers may concentrate on the red puzzle pieces if they are in a hurry to discover the red-colored subway route.

A Clinical Example of Interoperability

Let us consider the types of interoperability involved when a patient with chest pain is being transported to a hospital’s Emergency Department (ED) via ambulance. The patient offers a few words about a previous heart attack to the paramedic and then loses consciousness. Before the patient’s arrival, the ED system queries a Regional Health Information Organization’s (RHIO) system to acquire a more comprehensive history:

- **Technical interoperability:** A query that achieves technical interoperability would ensure that data flowed reliably from the RHIO to the ED. However, the data received may be structured or unstructured and may or may not be similar to previous queries or queries to other systems. Because of this uncertainty, the data must be carefully examined, interpreted and sequenced in terms of its relevance to the patient’s current condition – ideally, before the ambulance arrives at the hospital. A query based solely on *technical interoperability* might not be useful to the care practitioner if the time and staff required to perform all these tasks is inadequate.

→ *Technical interoperability neutralizes the effects of distance.*

- **Semantic interoperability:** Regardless of how the data is transmitted technically, a response that achieves semantic interoperability provides structured, sequenced, unambiguous, and even summarized information that can immediately be put to use in patient care. Assuming both the RHIO and the ED use the same semantic standards, such information can be reliably integrated directly into the provider’s ED system. *Semantic interoperability* can contribute to improved care and outcomes by enabling the

communication of meaning (what is known about the patient's health status and morbidity) between the RHIO and the ED for patient care and for allowing for continuity of care for subsequent visits. It is also at the core of translating scientific discovery into care delivery.

→ *Semantic interoperability communicates meaning.*

- **Process interoperability:** Process interoperability optimizes not only the communication of information, but does this in a time-, event-, or sequence-oriented manner to coordinate the work processes of the care team. Key documentation (e.g., previous cath lab reports, stent placements, or bypass surgery reports) and well as safety and quality reminders can automatically enhance human interventions to assure that the care team can access information to treat the patient in the most effective, efficient and safe way possible.

→ *Process interoperability coordinates work processes.*

Together, these three types of interoperability are all required to the consistent and timely achievement of what has come to be called "Best Practice."

A Closer Look at the Three Interoperability Types

More about Technical Interoperability

Technical interoperability has to do with connectivity across the network and across applications. There were various types of connectivity discussed. They are listed below in approximate order of complexity, from the simplest to the most advanced.

- Simple exchange, where the sending application sends a message over the network to another application, which receives it in complete and correct form.
- Simple exchange with a defined message format, where the sending application structures the message in an expected form (that is, the data elements appear in a defined way within the message but the meaning of the data is not specified). HL7 version 2.x is an example of this type of technical interoperability standard.
- More complex exchange, in which there is a mapping of the data in an agreed-upon form. In other words, there may be a data model that defines how the data in the message relates to other data. HL7's Reference Information Model (RIM) is an example of this type of interoperable exchange. One system can say that it is sending an HL7 RIM patient identification message and the receiving system can understand how the data received fits into a predefined patient identification model without having to understand the underlying data model in the sending system.

A data model, or RIM, is based on an ontology. This is a structure (often hierarchical) which attempts to model an underlying reality. Ontology is defined by Merriam-Webster as "a particular theory about the nature of being or the kinds of things that have existence." Unfortunately -- or fortunately! -- an ontology will change as our understanding of reality changes. The Ptolemaic model of the universe assumes a different ontology than the Newtonian model of the universe, and Einstein changed it yet again. At this level, however, we are already

talking about semantic interoperability.

More about Semantic Interoperability

Semantic interoperability has to do with the *meaningful* exchange of information along with the context of the information (referred to as a “domain”), derived from an ontology (see above). It goes beyond structuring the data and gets into communicating the intent or understanding of the meaning of the data to the sender to the information user. This is essential for clinical care due to the complexity of the domains involved and the nuanced implications of information for the overall care of a patient.

The levels of semantic interoperability can be defined (in order of information processing accessibility) as:

- “Blobs” of data which is meaningful to the user at either end of the transmitted message but is not meaningful to the underlying computer applications involved in transmissions. An example of this would be a handwritten clinical note that was faxed to another clinician’s system. Assuming that the handwriting was legible, the receiving physician could understand what was intended. The information would have to be re-entered into the system in order to be used in a structured application, such as a chronic disease tracking system.
- Free text, which can be read by the receiving application but which does not have a defined structure. Natural language processing software may be used to identify structure within the free text so that it can be further used within the applications. However, there remain many challenges to this approach (including quality control and ensuring accuracy), and it is not yet clear to what extent the ambiguity of free text (especially in English) may turn out to be intractable. Lacking more structured data, however, methods for eliciting meaning from free text will continue to be of use.
- Classification systems, such as the International Classification of Diseases (ICD-9), Common Procedural Terminology (CPT) or the various nursing terminologies, which set up hierarchical models for specific descriptions of diagnoses, procedures, activities, etc.
- Standardized clinical nomenclature within structured messages. These are often called reference terminologies and use compositional expressions that can be post-coordinated to produce standard names, and also be mapped to multiple ontologies. An example is SNOMED (Standardized Nomenclature of Medicine).

Semantics lurk everywhere in clinical interoperability. Some elements of the HL7 RIM, described above, have semantically-oriented ways to characterize data elements. Each data element has a number of structured fields that are defined in a specific way, which allows different terminologies to be used in establishing the semantic meaning of the message. Each field in the RIM may allow for a pointer to a clinical coding vocabulary like LOINC. Each LOINC concept in turn, contains “semantic” axes, such as the body system, test timing and sometimes a method. The semantic environment necessary to communicate the full range of clinical information is very rich and complex.

More about Process Interoperability

The third type of interoperability which emerged from the analysis is “process/social” interoperability. Although it was cited infrequently, it was remarkable that it was cited by a number of cutting-edge organizations, including caBIG and the Federal CIO Council, Canada’s CanCore and the CEN (Committee European Normalization) community. In the United States, this type of interoperability has emerged from the management engineering field where it been

referred to as “workflow management” or “systems engineering,” both established terms having to do with the design of and implementation of human work processes, which increasingly include interaction with computer systems. There is certainly no question that process interoperability places requirements and constraints on how information is provided for use in real-life settings, as a commonly cited example will show. The continuous improvement movement, popular in health care in the early 1990s, based on the work of W. Edwards Deming, Joseph M. Juran, and others is primarily concerned with process interoperability as the term is used in this paper.

Let us consider the situation of an emergency department physician who must adapt to the current needs of the patient in the most stressed situation imaginable. Everything must fall into place: a team of individuals, each with his/her own special tasks, must work together seamlessly; decision-making processes must be understood explicitly by all players, information must be arranged to convey essential facts accurately and instantaneously. To save a person’s life, an invasive procedure, such as a tracheotomy, may be needed and once this is decided by the lead physician, the team must go to work. There is no time to have “all the patient’s information” pour out of a computer any more than there is time to be confronted by a six-inch thick paper record. There is no time to page through screens of detail or enter billing codes.

In “the heat of battle,” critical summary information is needed: a clinically correct and up-to-date list of the patient’s chief problems (diagnoses), a list of current medications, allergies and sensitivities, relevant lab results. Advice about what to do must be triggered in time for it to be acted on. Collecting information about whether or not a needed intervention occurred after the fact from chart review may meet an external requirement, but it will not help the patient. Nor will it, in the long run, lead to improvement in safety or effectiveness. For this to happen, processes must be optimized.

Simply put, medical information organized for the “heat of battle” (actual practice) has significant process-driven characteristics, such as filtering, summarization and alert triggers that may not be needed in routine situations; time is critical and workflows must be smooth and quick. These characteristics may trump more structural ones, and comprehensiveness and detail can fall prey to time constraints and explicit external mandates. Direct patient care, especially in emergency or disaster situations, is different from the needs of research, where it’s almost impossible to talk about too much detail or clutter.

Interdependencies

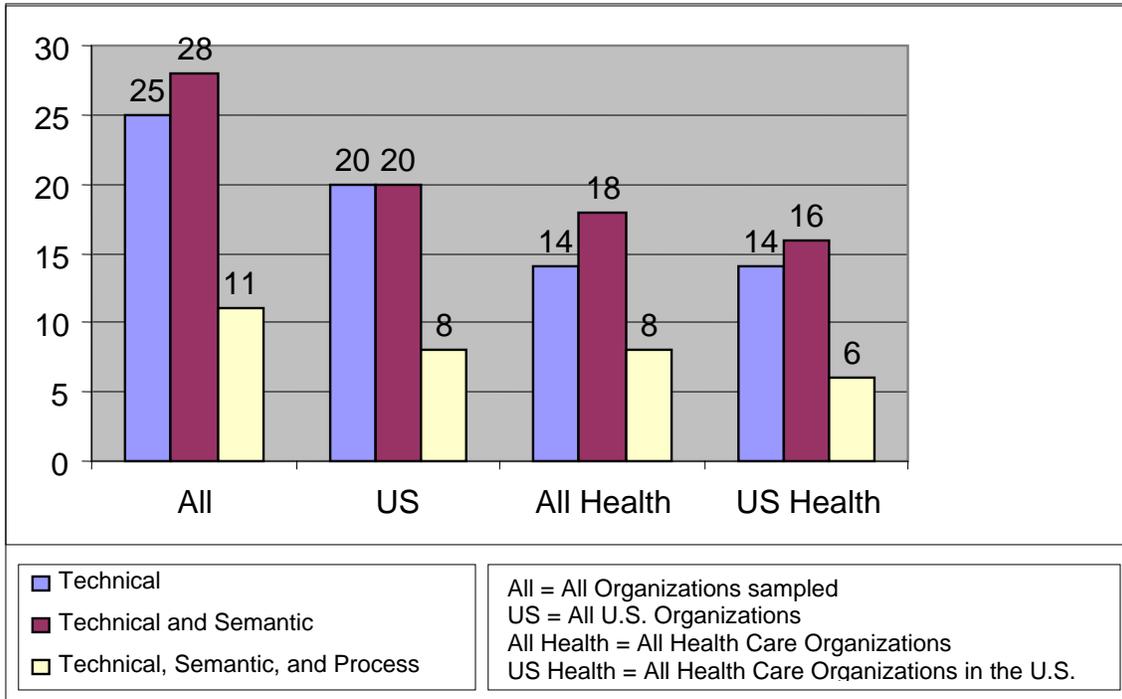
The three types of interoperability are closely related to one another and this can lead to confusion. Obviously, when a communications infrastructure goes down, not only technical but semantic interoperability ceases (or, more correctly, is transferred to other media, such as a telephone network). Indeed, during Hurricane Katrina, telephone communications were also interrupted and officials were reduced to using runners and flag signals. Many processes also would break down in a catastrophic situation like this, requiring new processes, hopefully prepared for ahead of time. In the interim, -- firefighters, police, government, Public Health agencies, the Red Cross, the National Guard, not to mention the many everyday people, who rise to meet the crisis. These people we gratefully call heroes.

Interoperability in Health Care

Interoperability Definitions by Organization Type

The chart below shows that “technical” and “technical *plus* semantic” interoperability were mentioned about the same number times. It was not possible in this analysis to absolutely differentiate instances in which technical (often using the IEEE-90 expression “exchange and use”) was intended to be a global term (encompassing the other type(s) of interoperability) -- or that it is considered as a stand-alone definition invoking only the idea of connectivity and successful exchange of bits and bytes. There was one instance in which a definition of interoperability for HIT went into great length to point out that “use” needed to include semantics; and IEEE-USA also took great pains to make this distinction in its statement of November 2005. In these two cases, we classified these organizations’ definitions as “technical *plus* semantic.”

However, there are two reasons to assume that others defining interoperability as “exchange and use” should be considered to assume “technical only” was what was meant. First, the word “use” does not automatically imply semantic interoperability -- “use” is an extremely broad term; if greater precision were meant it would have made sense to make this explicit. Second, the evolution of subcategories (e.g. technical, semantic, and process) from a generic term is one of the most common ways that terms evolve. This is both a common way we adjust our thinking as we know more; it is also a constant challenge to informatics in general. “Pneumonia” was recognized as a disease before either bacteria or viruses were identified as causes. Now we are able to discern the specific organisms (bacteria or virus) causing the pneumonia. Yet, practitioners will use the more general term in, perhaps a text note, assuming that the reader (other provider or coder) will know what domain the term falls into. “Cervical” means something different to a spine surgeon than to a gynecologist.



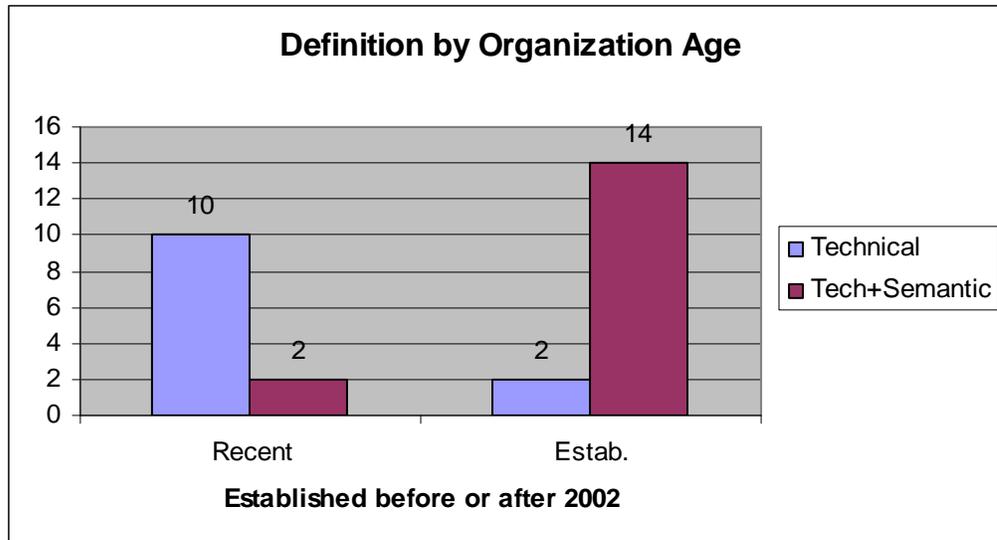
Interoperability Definitions of US Health Care Organizations

The table below shows the breakdown for the twenty-eight health care organizations in which the US is an active participant. Only the technical and the technical +semantic interoperability types were counted.

Health Only

| SUMMARY | New | Older |
|---------------|-----------|-----------|
| Exchange/Use | 10 | 2 |
| Tech+Semantic | 2 | 14 |
| Total | 12 | 16 |

This is a breakdown which differentiates organizations founded in 2002 or later and those established before 2002. The differences are dramatic, as the graph below shows:



The simple conclusion that can be reached from this analysis is that established organizations which were in existence prior to 2001 usually specify *both* “technical” (or “exchange/use”) interoperability *and* “semantic” interoperability (having to do with the persistence of meaning) in their definitions. On the other hand, new organizations (that have started up since 2001) tend to include *only* “technical” interoperability and omit mention of “semantic” interoperability from their definitions.

What is startling is the absence of any mention of, or focus on, semantic interoperability among newer health care oriented organizations in the United States, compared to the other groups of organizations. This is an unexpected anomaly, given the rest of the data. Yet it goes far toward explaining why the major failing of HIT interoperability, as perceived by newer organizations, has to do with a basic lack of connectivity or the simple exchange of data. Several of these newer organizations have been championed by leaders from non-health industries such as business, computer vendors, and purchasers of health care services who tend to assume that all that is needed is straightforward technical interoperability.

Interoperability Definitions of Non Health Care Organizations

A look at the definitions collected from non health care related fields helps explain which kinds of organizations cite technical interoperability alone, and which kinds of organizations cite both technical and semantic interoperability. Of the 64 responding organizations, 24 were classified as non-health care-related (although several of these were classified as “General” meaning they included some health care; e.g. ISO). Below is the complete breakdown of those non health care organizations:

| Organization Type (Non-Health) | Technical | Technical + Semantic |
|--------------------------------|-----------|----------------------|
| Banking | 1 | |
| Copyright Office | 1 | |

| | | |
|--|-----------|-----------|
| Engineering | 3 | |
| Telecommunications | 3 | |
| Computer Science | 1 | 3 |
| DOD | | 1 |
| Engineering in health care (special case) | | 1 |
| Library Science | | 1 |
| Research (InteliGRID) | | 1 |
| Semantic Web (W3C) | | 1 |
| Tourism | | 1 |
| General (incl some health) | 3 | 3 |
| Total | 12 | 12 |

Setting aside General (which is a wash) and Computer Science,⁹ which appears in both groups, there is a significant difference between these two groups. The set of organizations defining interoperability as technical only deals primarily with hardware or “hard data” (e.g., banking) including: such as numbers, mathematical formulas, inventories and currency. The group of organizations using technical *and* semantic deals more with words, images, qualitative values, codes and classifications and language content.

The above analysis raises the obvious question: is health care “more like” the non health care related group of organizations in the technical interoperability group, -- or -- is it more like those organizations in the technical *plus* semantic group? This sheds light on the difference between how the older health care organizations tend to define interoperability versus how the newer organizations tend to view it. The established HIT organizations say health care is concerned with both technical and semantic interoperability. The newer organizations are more in alignment with non-health care -related organizations such as banking, engineering, and telecommunications and view health care as being concerned with “technical interoperability.”

Technical Interoperability in Health Care

Technical interoperability is of course important to HIT systems. It is the very foundation of the “trusted point-to-point flow of information” that makes the other types of interoperability possible. Security of patient information systems resides at this level, and without secure transfer of health care data, neither patients nor providers will ever agree to trust their medical information to computers. However, the analysis shows that though necessary, technical interoperability is not sufficient for describing the interoperability needs of the health care industry.

⁹ Also excluded were those classified as “General,” such as ISO which develops standards for many domains, both health care and non-health care -related.

When Interoperability Fails

To illustrate failure with respect to the three types of interoperability, we will use examples taken from an imaginary school bus accident:

Technical interoperability failure: An Emergency Department physician receives an electronic message from the primary care physician of a critically injured student stating that the student has no allergies to drugs. However, an electronic bit was inadvertently flipped during transmission; the patient dies from an allergic reaction to the drug.

Semantic Interoperability in Health Care

Even while acknowledging the foundational importance of technical interoperability for health care, it alone is not sufficient for the health care field. Health and medicine deal with language in ways that finance, manufacturing, and retail simply do not. One might argue that interventional medicine, is a set of human-designed activities and so can be treated as a set of discrete artifacts. It is indeed the case that classifications and systems for coding procedures, surgeries and other interventions are more logical, more discrete and more straightforward than the nomenclatures and classifications for describing health status and disease (even when they are part of the same classification “family,” such as ICD.

Diseases on the other hand belong to the world of *natural* phenomena, of which our knowledge is constantly evolving. This dynamism, which can be addressed down to the molecular -- indeed even to the atomic -- level make the semantics of medicine particularly challenging; more so even that the proverbial “rocket science.” No field is more difficult to master; indeed no one individual can fully understand it all, which is why the delivery of medical care is organized into specialties and subspecialties and also stratified into various layers of acuity managed in distinct care settings (inpatient, outpatient, ED, nursing home, hospital) at different levels of service: i.e. primary, secondary, tertiary). Teamwork, professionalism, and continuous learning are absolutely mandatory in the medical field and are characteristic of many of the best delivery systems, most of which are organized around academic medical centers and integrated group practices. The socio-geo-economic stratification of the health care system is unmatched by any industry, and is driven primarily by the sheer complexity of human life and well-being and the value we attribute to these.

The Complexity of the Semantics of Health

In just the last ten years, the new fields of genomics, proteomics, remote monitoring and remote intervention have blossomed. As our understanding grows, practice of medicine will be transformed, perhaps in ways we still cannot even imagine. Not only are the current “coding systems” (e.g. ICD, CPT) becoming outdated; the entire notion of a relying on a single inflexible hierarchical structure of diseases and interventions itself is becoming outmoded. With genomics and proteomics (as well as yet unforeseen ‘-omics’ of the future), nanotechnologies and remote interventions, we must be able to search, classify and summarize on the basis of freestyle “aggregation logics,” for a specific purpose, for a specific phenotype, for a specific patient.

The Importance of Knowledgeable Listening

The work of trailblazers like Vimla Patel of Columbia University has focused on the complexities of translating the language the patient uses into the language of the care provider, how human-computer interaction contributes to safety problems, and Horsky, J., Zhang, J., & Patel, V.L. (in press, 2005) "To Err is Not Entirely Human: Complex Technology and User Cognition." *Journal of Biomedical Informatics*. It is increasingly being evidenced that poor communication, -- *not* lack of competition -- is what is most often to blame when safety and quality are compromised.

Indeed, a number of other recent articles have identified a wide range of communication failures between patients, families, nurses, physicians and others (including between treatment units at transfer points) as being at the heart of problems with clinical quality and safety. Yet we assume that electronic records and other investments in HIT alone will result in improved outcomes. Can it be that semantic interoperability (the communication of meaning) is a major challenge to health care informatics, rather than what was once called "the electrification" of medical records, or what we have been referring to as "technical interoperability"?

Recent Developments (since July 2005)

We have found that the awareness of the issues surrounding the importance of semantic interoperability is occurring. Within the last six months, two organizations that had been classified by the study as "technical only" developed new documents which added semantic interoperability: EHRVA, which revised its scope of work, and IEEE-(USA), which sent an HIT report to the Senate on November of 2005 noting the need for both "syntactic" and "semantic" interoperability. In addition, Canada's Health Infoway project has announced a major new project dealing with terminology and semantic interoperability. United States' leadership in this area may be at risk if the HIT industry loses track of this important dimension of interoperability, considered by many experts to be the most critical "piece of the puzzle."

Most importantly, however, is the fact that to realize many -- if not most" of the benefits expected from "interoperable HIT" simply cannot result from addressing technical interoperability alone. To use an earlier metaphor, you can build an airplane without wings, but you can't make it fly. Without continued progress on semantic interoperability, much of the progress expected from the investment in technology will be seriously hampered, or never even begun, including:

- Exchange of computable diagnostic information
- Use of diagnosis-driven clinical advice and guidelines (including real-time quality/error monitoring)
- On-line access to medical literature, keyed to current patient diagnosis
- Access to "best practice" information derived from research, decreasing the time needed to deploy new knowledge to the bedside (now called clinical translational research)
- Ability of clinical records to be retrieved for research, including genomics
- Biosurveillance (when diagnosis-based)
- Ability to "roll up" diagnostic data for public health assessment, alerting and monitoring
- Ability to derive meaning from text notes ("natural language processing").

When Interoperability Fails

An example of the failure of semantic interoperability from the school bus accident:

An Emergency Department physician sends an electronic message to an overseas physician asking whether there were any warnings about a visiting student's health. The foreign doctor sends the message code "N/A" that asserts that the information regarding allergies was never gathered. The ED physician interprets the response as "Negative for Allergies" and gives an antibiotic drug; the patient dies from an allergic reaction to the drug.

Process Interoperability in Health Care

During the course of our study, it became apparent that an additional type or dimension of interoperability was being identified, called variously, "process," "workflow" or "social" interoperability. "Systems engineering" – in the sense of the management of systems implementations in actual work settings – appears to refer to the same concept. Process interoperability has to do with process/workflow management, the successful integration of advice/alerts into data presentation and workflows, and/or the deployment of resources in keeping with a plan or protocol (often computer-based). Assuring that automated systems are interoperable with work processes is critical to successful implementation and use of HIT, and lack of process interoperability may be why 50%+ of implementations fail to meet expectations. Although the number of organizations mentioning this type of interoperability was fewer than those mentioning technical and semantic interoperability, these organizations were notable for being leading-edge, and – interestingly – originating outside the United States. In the summer of 2005, the Institute of Medicine published a report titled: Building a Better Delivery System: A New Engineering/Health Care Partnership¹¹ which emphasizes the importance of process interoperability and the need for further development.

Process interoperability is another way of talking about workflow management or workflow engineering. It has to do with two distinct types of processes: 1) *prescribed process* (either routine or emergent, or other variations in between) and 2) *disaster management*, which has to do with a) surviving the disaster, and b) recovering from it. Typically (1) is considered to be a field in which engineering techniques are applied to clinical processes. Disaster management, which can include both natural and manmade disaster management, involves public health and may related fields.

¹¹ <http://www.iom.edu/CMS/3809/28393.aspx>

When Interoperability Fails

An example of the failure of process interoperability from the school bus accident:

The busload of injured schoolchildren overwhelms the capacity of a remotely located Emergency Department. The hospital information system and the overwhelmed staff each fail to notice that the hospital's antibiotic supply is depleted. A student dies from failure to receive antibiotic drugs.

Discussion

A Recent History of Interoperability in Health Care

In 2003 and even before, health care was said to be far behind banking and retail with a relatively low level of computer adoption due to a lack of “interoperability” resulting from its principal focus on administrative systems, with clinical systems development stifled by missing, overlapping or multiple standards. This, it was claimed, has resulted in unacceptable error rates and safety problems, and to high costs from duplicate tests and excessive levels of administrative overhead (20 to 30% were often cited) from keeping records in paper form. The health care marketplace was characterized as a gaggle of ‘mom and pop’ organizations without adequate leadership. Several new organizations boldly emerged to fill the leadership “vacuum.” Large vendors joined with major payers, big business, quality assessment organizations, and the federal government to suggest ways to cut costs and improve health care quality by an insertion of competitive forces and pay-for-performance reimbursement (basing payment in part on quality and safety measures) and to make HIT “interoperable.”

As this study has shown, for most business, electronics, and telecommunications organizations, interoperability has primarily been characterized as involving the successful exchange of information from one system to another. In fact, several of these new organizations simply picked the “exchange and use” definition adopted by the IEEE in 1990. In this paper we have called this basic type of interoperability “technical interoperability.” Health care financial systems, including sophisticated planning, cost accounting, payment and product line systems -- were humming along just fine; these after all were similar to the kinds of applications used by the business offices of retail, manufacturing, and financial companies. So what was wrong with health care?

For the health care field, the concern had focused more on the dizzying set of issues having to do with semantic interoperability, or the successful communication of meaning. Just to recall a few of these challenges:

- * the characterization of diseases and interventions, which constantly evolve
- * summarization and alerting for public health
- * the derivation of computable knowledge from free text
- * the cross-mapping of terms from one formal terminology or classification to another
- * human factors issues, including user interfaces for data gathering that is both explicit

- * characterization of genomic and proteomic, as well as other detailed findings and observations, many of which involve attribution of evaluative criteria to numeric values
- * perhaps the newest area of concentration -- patient → practitioner communication; team → team communication -- especially in the multi-lingual modern world

One observer (a world class orthopedic surgeon) noted that *technical* interoperability is like the production of a book -- the cover, the pages, the binding, the printing -- without concern with what the book says, its meaning: “That,” he said, “is *semantic* interoperability, what the book is *about*, the information in it.” This is what the health care industry was struggling with, and making -- it can be claimed -- significant progress.

Conclusions

The concept of interoperability allows us to communicate in broad terms about how systems interact with one another. It can refer to inter-institutional interactions as well as intra-institutional interactions and even intra-system interactions – such as a system’s ability to convert clinically descriptive codes (e.g., SNOMED) to billing codes (e.g., ICD-9-CM).

Interoperability exists as one or more systems are considered in relation to one another. It is not a “thing” in and of itself, and it is not a general adjective (like “robust” or “transparent”). Interoperability can range from non-existent (between two or more systems) or comprehensive and complete, allowing for total transparency and near-complete simultaneity between the two systems.

Interoperability may, then, be most useful as a scoping concept, particularly with regard to the three main “types” – technical, semantic, and process:

- technical (physical conveyance of a ‘payload’),
- semantic (communication of meaning), and
- process (integration into a work setting)

Hopefully, this description of the “troika” of technical-semantic-process interoperability will help with the planning and scoping of electronic health systems, related standards, software and hardware, and will inform policy discussions and decision-making regarding health care information system.

The more we know about the three types of interoperability, the more we are unlikely to underestimate what is required to make health systems increasingly interoperable or to specify functionality without consideration for the types of degree of sophistication required to deliver. For instance, we will be less likely to promise or assume we can purchase a system which can “give advice to providers at the point-of-care” without knowing that this will require semantically interoperable source systems with linkages to indexed external databases. Advice capabilities rely on semantics -- at a highly developed level, and much work remains before this particular set of capabilities is available on a widespread basis. To promise an advice capability without adequate semantic interoperability would be like designing an airplane without wings.

Similarly, to believe that installing a new automated pharmacy system will automatically result in fewer medication errors is naïve unless it is realized that processes -- and attitudes -- will likely

need to be transformed for the system to be installed, accepted, tested thoroughly and carefully integrated into the workflows of the specific areas affected and the organization as a whole. To promise a new automated pharmacy system without consideration for process interoperability would be like trying to land a plane in a jungle with no runway.

We must realize that, at least for health care, semantic interoperability is very much at its core, and that all electronic systems are, *de facto*, ‘surrounded’ by processes that will be affected by any new system implementation. The question is whether the processes enable the system to work effectively and efficiently. Perfectly “good systems” *will fail* if not enough attention has been paid to these process changes during implementation. Indeed, David Schulke, Executive Vice President of the American Health Quality Association testified to the Health Subcommittee of the House Ways and Means Committee April 2006 that “Providers and practitioners...need support from systems change experts who can help ensure that care processes are redesigned to reflect best practices. This hands-on support is needed because literature and experience tell us that as many as half of all EHR implementations fail for one reason or another, often because practices did not go through the rigorous preparation and development necessary for success.”¹² [*Emphasis added.*]

Fruit Basket or Claim Shanty?

Rather than seeing these three types of interoperability as “apples and oranges and bananas” -- as though nothing but a label connects them to one another consider the following analogy. When the pioneers settled the Midwestern prairie in the 1880s, the first thing they did was to build a claim shanty, to hold their claim and to allow them to survive the brutal Dakota winters. For the shanty they needed: a foundation, materials (wood, tar paper, a stove for a fire), and the tools and skills to make a sturdy and safe structure. Once they survived that first winter and brought in their first harvest, they could transform the shanty into the entry of a small house, or into a stable, or into a hay manger. They left their options open, and they were able to adjust their dreams as new technologies, infrastructures and resources were developed and made their way West or were devised on the spot by entrepreneurial pioneers.

What is important about the claim shanty was that though it was small and basic, it was functional, safe, and complete in its own right -- and it did not have to be thrown away. Even as we take step by reasonable step, we must keep our eye not only on that shifting horizon but also, by devising deliverables that, because they are flexible, standardized, reusable and interoperable, can rapidly adjust to new materials, methods, knowledge and policies which compose the reality we live in.

There can be no question that interoperability in health care requires work. But what *kinds* of interoperability need the *most* work? Might it be that at the “Tipping Point” declared in 2004, we risked tipping the *wrong way*, backwards into a simplistic perception of a multifaceted reality?

¹² Statement by David Schulke Executive Vice President American Health Quality Association (AHQA)— in testimony submitted for the record at a hearing of the Health Subcommittee of the House Ways and Means Committee, April 2006. http://www.ahqa.org/pub/media/159_678_5413.cfm

Recommendations

“Facts,” said President Ronald Reagan, “are stubborn things.” Thankfully, truth though never entirely apparent tends to function like a kind of gravity, pulling us back to issues that cannot be “spun” away, announcing themselves over and over again, first by heroes, martyrs or scientists, then by those who choose to lead, until at last they gain broad understanding and credibility, becoming the foundation upon which further knowledge can be based.

This study of the term “interoperability” in health care has identified three major types of interoperability -- technical, semantic, and process. The ubiquitous use of this term without awareness of these complexities can lead to confusion, poor communication and potentially organizational dysfunction. More importantly, not being aware of the importance of semantic and process interoperability can lead to systems prone to medical errors and to implementation failures. We encourage all those working on health care interoperability to be aware of how they are using the term and make sure when you converse with colleagues that you are sure you are “all on the same page.” If the use of the term interoperability is to persist and retain its coherence and usefulness, -- avoiding both oversimplification and overgeneralization, -- it will need to be kept new by further discussion and development, which this paper will hopefully stimulate.

“We shall not cease from exploration
And the end of all our exploring
Will be to arrive where we started
And know the place for the first time.

From “*Four Quartets*”
T.S. Eliot

Appendix A. Google Analysis

| Google Search Terms | | | | |
|---------------------|---------|----------------|---------|--|
| Health | 47,900 | 47,900 | 34.94% | definition+'interoperability'+health' [type unspecified]] |
| | 47,900 | 47,900 | 34.94% | Total health interoperability, unspecified |
| Technical | 15,000 | 15,784 | 11.51% | definition+'interoperability'+health+'technical' |
| Syntactic | 295 | | | definition+'interoperability'+health+'syntactic' |
| Functional | 489 | | | definition+'interoperability'+health+'functional' |
| Semantic | 55,400 | 55,400 | 40.41% | definition+'interoperability'+health+'semantic' |
| Process | 418 | | | definition+'interoperability'+health+'process' |
| Proc Eng | 17,600 | 18,018 | 13.14% | definition+'interoperability'+health+'process engineering' |
| | 137,102 | 89202 | 65.06% | Total health interoperability, specified |
| | 185,002 | 137,102 | 100.00% | TOTAL |

63,684 46.45% Unspecified + technical group

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