C.J. McDonald, P.R. Dexter, B. Takesue, J.M Overhage

Regenstrief Institute for Health Care, Indiana University Medical Center, Indianapolis, Indiana, USA

Review Paper

Health Informatics Standards: A View From Mid-America

1. Perspective

Those who develop standards face a number of problems and confusions. For voluntary health informatics standards efforts, the real problem might be described as a reverse tragedy of the commons[1]. In contrast to farmers on English commons, having more information systems (cows) browsing on the same informational commons provides the most economic gain for all. The tragedy is that for early adopters of standards the cost of putting their systems into the standard commons can exceed their gain, and this inhibits the adoption of standards. The challenge is to get enough information providers onto the standardized commons to create the critical mass to draw in all of the other potential browsers.

We also face a confusion between standards that enable and those that control. An enabling standard says: "Here is a vehicle. This is how it operates. You are free to use it as you will." The most successful technical standards have been enabling. They typically provide an interface or envelope to carry, or process, some kind of information. They do not prescribe what information must be included in the envelope. The CD-ROM music format and MIDI music format are good examples of enabling standards.

Regulatory organizations are more interested in standards that control behavior. Highway speed limits are a familiar example. Most health informatics message standards are enabling. They provide a way to transmit whatever information has been collected (e.g., a chest X-ray report or a set of vital signs) to another medical facility. By themselves they will not induce a particular behavior, such as the mandatory collection of a particular set of clinical variables wanted by a regulatory agency. As a consequence, regulatory agencies may dismiss a voluntary informatics standard and write their own very specialized flat file standard instead. It would be better for all of us if regulators wrote their requirements (assuming they are reasonable) as another "layer" to the enabling standard, for example, as a table listing the variables required for a particular transmission.

Misconceptions also exist about the difficulty of health-care standardization efforts. Banking is fully standardized and health-care should be no more difficult, or so the argument goes. Note that banking transactions all deal with one completely fungible quantity: money. Health-care deals with tens of thousands of different quantities -- test values, drug doses, clinical measurements, etc. Health-care deals with literally hundreds of thousands of descriptors. Count the code/vocabulary entries in SNOMED or the Read Codes to confirm these numbers. Until recently, everyone used their own idiosyncratic codes to identify laboratory tests and clinical measurements. Further, health-care also deals with free text, containing information which we cannot yet resolve into discrete items.

A further challenge for medical data standards is the strict need to maintain privacy while simultaneously allowing access by many health-care professionals, and the accompanying necessity of carrying patient identifying information along with the medical data. Banks only need to know account numbers, not individual persons.

Finally, Nathan Myhrvold's assertion that there will "always be a software crisis because ambition absorbs all advances" applies equally to standards. As soon as we sniff success in one domain of standards we extend our expectations. We master standards for patient registration and structured test results, and then we want to standardize the entire work flow of the health-care system.

Despite our laments, standards developers have made substantial progress toward more automated sharing of information among health-care organizations and providers. In the following we will document those areas about which we are most familiar and which we hope will be of interest to the reader. Table 1 provides a summary of these standards, including the responsible organization and contact information.

Table 1: Summary of standards/contact information

AMIA	American Medical Informatics Association	http://www.amia.org/ or amia-office@camis.standford.edu
ASTM	American Society for Testing and Materials	http://www.mcis.duke.edu/standards/ASTM/astm.htm
ATCC	American Type Culture Collection	sales@atcc.org or help@atcc.org
CAS	Chemical Abstract Society	help@CAS.ORG
CORBA	Common Object Request Broker Architecture	info@omg.org
CPRI	Computerized Patient Record Institute	http://www.cpri.org/
CPT	Current Procedural Terminology	http://www.mcis.duke.edu/standards/termcode/cpt4.htm
DICOM	Digital Imaging and Communications in Medicine	http://www.mcis.duke.edu/standards/DICOM/dicom.htm
HIMSS	Healthcare Information and Management Systems Society	http://www.himss.org/
HL7	Health Level Seven	http://www.mcis.duke.edu/standards/HL7d/hl7.htm or HQ@HL7.org
ICD10-PCS	International Classification of Diseases	www.who.org/programmes/mnh.ems/icd10/icd10.htm
IEEE	The Institute of Electrical and Electronics Engineers	http://www.mcis.duke.edu/standards/IEEE/ieee.htm
IETF	Internet Engineering Task Force	ftp://ietf.org/ or ietf-ediint@imc.org
IUPAC	International Union or Pure and Applied Chemistry	http://www.mcis.duke.edu/standards/termcode/iupac.htm
LOINC	Laboratory Observation Identifier Names and Codes	standards@regenstrief.iupui.edu or http://www.mcis.duke.edu/standards/termcode/loinc.htm
SNOMED	Systematized Nomenclature of Human and Veterinary Medicine	http://www.mcis.duke.edu/standards/termcode/snomed.htm
SSL	Secure Sockets Layer	http://ds.internic.net/internet-drafts/draft-ietf-tls-ssl-version3-00.txt
UMDNS	Universal Medical Device Nomenclature System	http://www.mcis.duke.edu/standards/termcode/ecri.htm
UMLS	Unified Medical Language System	http://www.mcis.duke.edu/standards/termcode/umls.htm or wth@nlm.nih.gov

2. Message Standards

HL7 has progressed since we last reported on its status. It has completed balloting of version 2.3 [2]. This version includes enhancements to existing areas: order entry, observation reporting, admission discharge and transfers, financial transactions and master file exchange. It also includes specifications for entirely new areas, including appointment scheduling, problem list maintenance, nursing goal maintenance, referral notices, the US UB92, the capture of clinical data from automated bed-side instruments, clinical trial management, immunization reporting, and adverse product experience reportng. In printed form, including cross refernces, it is now 863 pages. The electronic version of the penulti-

mate draft of the vs. 2.3 document is available at no cost from the Duke HL7 server. (http://www.mcis.duke.edu/standards/HL7/hl7.htm)

The HL7 SIGOBT group has been working on using CORBA [3] and Microsoft OLE (ActiveX) as alternative mechanisms for delivering HL7 message content [4]. This approach has the advantage that the information content of a message is identical whether delivered via ASCII characters, OLE, or CORBA. Two successive OLE prototypes have been built. Fourteen different parties demonstrated OLE interconnections at the HIMSS '96 meeting in San Diego. It took three days to prepare this demonstration, one day of which was consumed by the physical network installation. This relatively fast setup contrasts with the six-week marathon required to prepare for the first HL7 demo at the 1990 New Orleans HIMSS Conference.

Hewlett-Packard and the Andover Working Group are focusing on the CORBA side of the SIGOBT and the Microsoft Health User Group (MSHUG) on the ActiveX side, but both use the same compatible models based on the combined CORBA and OLE experience. The SIGOBT is about to release a recommendation for implementing HL7 over CORBA and OLE (ActiveX).

An early strawman version of the version 3 HL7 reference object model has been completed. What is now on the Web is an amalgam of the models produced by the HL7 chapter subcommittees and eleven other submitted models. At present (1997) it does not include all of the functionality present in version 2.3. It does represent a heroic effort by one modeling expert, but substantial chapter committee work remains, so very large improvements should be expected. CEN has developed elegant models for a number of health-care domains. These are worth a close review [5].

The version 3 model is a large model even now. As we increase the scope and the detailed workings of the health-care world, how will health systems developers be able to cope with such large and detailed models and how will they accommodate the variations and evolution of real health systems? One possibility would be to create more abstract models with fewer parts, that is, fewer objects with more expressivity. Huff presents a good example of model abstraction by reducing a medical record model down to about six heavy-duty objects [6]. In his proposal, all patient attributes are modeled as time-varying observations. This is also the modeling approach of one large U.S. pharmaceutical manufacturer, and is reminiscent of the PEN & PAD model which is, in many ways, an even more compact and exquisite model [7].

The advantage of greater abstraction is ease of implementation, flexibility, and internal consistency. The disadvantage is the greater difficulty that application users have in matching their world with the model because the specifics that are represented as field names in a traditional model are represented as master file data in the abstract model. Of course, the storage of the details as data rather than as distinct objects has the advantage that new entities can be added without changing the standard and without recompiling and linking the software that implements such a model.

HL7 members have created a number of new special interest groups (SIGs) since 1995, including: SGML, vocabulary, master patient index (MPI), and reminder/alert. The SGML group is exploring many uses of SGML [8] including its use as an alternative syntax for transmitting the content of HL7 messages, DTDs that could be included as content of HL7 message fields, and other options. Interestingly, a Japanese effort called MERIT-9 uses SGML to encapsulate both HL7 and DICOM [9].

The goal of the vocabulary SIG is to specify the codes and vocabulary systems that should be used for each coded field in HL7, not to create new vocabularies per se. The vocabulary SIG is collaborating with the National Library of Medicine (NLM) to incorporate HL7 vocabulary lists in the NLM's Unified Medical Language System(UMLS) [10]. If this effort is successful, and other U.S. standards groups follow a similar strategy, the UMLS could provide a mechanism for unifying the contents of various messages standards. The goal of the clinical alert SIG is to define a way to convey alert messages from decision support system using the Arden Syntax [11,12] to represent medical record and clinical care systems.

HL7 now has affiliates in New Zealand, Australia (where HL7 is being adopted as a national standard), Canada, Germany, and the Netherlands. HL7 provides an Internet discussion group (HL7@virginia.edu), as well as a web site (http://www.mcis.duke.edu/standards/guide.htm) which contains the minutes of all work groups, draft proposals, proceedings, and the draft standard. Minutes and work products for all of the chapters and SIGs can be found on this site.

We have been lobbying the medical informatics standards groups to increase the Internet availability of standards. The Internet Engineering Task Force provides a good example by providing all Internet standards on the Internet for free use. We have argued that all STOs should follow that example. The fewer the barriers to obtaining health informatics standards, the faster they will be adopted. HL7, CEN, and DICOM have been providing their draft standards via Internet servers for quite a while. This is a good beginning.

ASTM has also been busy. It has published standards for many health informatics subjects, including those for connecting laboratory instruments

to computers (E1381, E1394), and standards for ADT transactions (E1239), bar codes (E1467), and medical records.

ASTM's subcommittee E31.15 for medical logic modules (Arden Syntax) is close to balloting a revision of E1460-92 [13]. The revision clarifies ambiguities and extends the original standard. It includes operators for sorting data, defines Arden Syntax "events" more explicitly, and provides the ability to format strings. A draft version of their revision is available from cucis.cis.columbia.edu in directory pub/mlm. Proposed Arden revisions are in file El460_2.rtf, and a compiler for the new Arden Syntax (including the as yet unapproved revisions) is in ardenc.tar.Z.

ASTM subcommittee E31.16 has also completed a revision of their standard E1467 for transmitting electrophysiologic signals [14]. While this standard has focused primarily on electroencephalograms and electromyograms, it follows the syntax and borrows most of its segments and fields from ASTM E1238 and HL7. ASTM produces a series of standards related to the electronic medical record. E1384 describes medical record content and some structures, a companion standard E1633 organizes the data elements and assigns them codes, and a third, E1769, describes the desired qualities of an electronic medical record. ASTM has also developed guides regarding the data related to emergency medical care — E1744 and F1629. ASTM E31.12 has also balloted a number of documents, including a proposed approach to patient identifiers, a general approach to medical records, and a Standard Description for Content and Structure of an Automated Longitudinal Health Record.

IEEE has balloted and published the first three documents related to the management of bedside devices that are connected to the patient [15]. Two of these define the specification for Ethernet and Internet protocols (IP) over a network. The third one provides the overview and philosophy of these standards. Work continues on twelve more documents describing the objects and the specific codes to be used. Most of these are either currently being balloted or are quite close.

DICOM provides standards for diagnostic images[16,17]. It is in use by radiology device and PACs system vendors. It has specific capabilities for recording and retrieving MRI, CT, plain film, angiography, and other kinds of radiologic images. The storage and retrieval is done in the context of a four level storage structure: patient, study, series and image. Study corresponds roughly to the ordered procedure, and series corresponds to multiple images within a procedure. DICOM tool kits are available for public use from the Mallinckrodt Institute of Radiology at Washington University in St. Louis, and Indiana University/Regenstrief Institute for Health Care in Indianapolis.

DICOM is compatible with the CEN WG4 MEDICOM standard and the Japanese JIRA standard. It is being widely adopted, and its utility was demonstrated in a very complex demonstration at the Radiological Society of North America (RSNA) in Chicago last December. DICOM has distributed new specifications for images (photos of pathology specimens, pathology slides, endoscopy, etc.) for public comment. Other extensions are either being developed or are in trial release: work list management, ultrasound, digital radiography, positron emission tomography, image data compression, and reporting. (For more information visit http://www.nema.org).

DICOM is also developing strong links to the coding systems SNOMED and LOINC to assure that codes of sufficient granularity will be available for accurately recording the facts. A draft version of the DICOM standard is available from xray.hmc.psu.edu, and by anonymous FTP from rsna.org (192.203.125.2) or wuerlim.wustl.edu (128.252.118.15).

DICOM supports the JPEG compression standard [18] and that is good. Every browser has built in JPEG compression and the Internet has defined a standard file format for JPEG called JFIF (the JPEG standard describes how to do the compression but not how to store the results of the compression). JPEG compression does result in a few lost bits, so it is labeled "lossy" compression. Vendors do not want this pejorative adjective associated with their storage systems, so they support JPEG timidly or not at all, and that is bad [19].

All reports to date suggest there is no difference in diagnostic quality between an uncompressed and a 10 to 20:1 JPEG compressed film [20,21]. Indeed, at 20:1 most observers cannot distinguish the compressed from the non-compressed image. Vendors counter that disc is cheap, but it is not so cheap that they can avoid pushing the images from hard disc storage to optical disc farms with their associated 15 seconds or longer latency penalties. And movement of data has a time cost — especially across phone lines to office practices where practitioners would like to see electronic radiographs. The solution is to keep the lossless image on hard disc storage for a limited time after it is read. Then move the lossless image to slower storage (optical disc forms or tape) and store a JPEG compressed image on the hard disc. With this approach, no information is lost, and clinicians will be able to obtain an image quickly from wherever they work.

3. Code Standards

The American Medical Informatics Association (AMIA) identified lack of code vocabulary standards as the most important barrier to the development

of Electronic Medical Records system, outcome management, and quality assurance [22]. Today, organizations that receive standardized electronic messages cannot easily aggregate information from many sources because each source uses its own local codes for identifying the clinical variables reported. Further, universal code systems for many clinical subject domains have not been available at all. Happily, there has been progress on code standards, on many fronts, since 1994.

In most countries a universal code for drug products has been available for some time. In the United States it is the National Drug Code (NDC). The structure of the NDC is something like that of the Universal Product Code. However, the NDC uses a very granular code. It is specific to the manufacturer (brand name), dose type, dose size, and packaging. Even a change in the printing on the package requires a new NDC code. As a result, the NDC is not directly useful for many clinical purposes. However, an entire industry has sprung up to provide mapping from the NDC code to more handy drug codes and other pieces of information. The great success of NCPDP [23] (the community pharmacy standard which is used by 90% of community pharmacies in the United States) is due in part to the existence of the NDC code standard.

Now, however, we have increasing choices in medically "handy" drug codes. In addition to the WHO Drug Dictionary [24] which we have described in the past, there are now other codes available for free use. MediSource DAT [25] offers a code system that identifies individual drugs in a data base that carries links to information about drug class and route. MediSpan's 14 digit GPI code is a hierarchical code that carries information down to dosage forms, dose, and route, and may also be provided as a public use code system.

The Universal Medical Device Nomenclature System (UMDNS) from ECRI is a device and equipment classification scheme [26]. UMDNS has codes for everything from tongue blades to pacemakers. If UMDNS codes were always stored along with the local (idiosyncratic) billing codes, managers and researchers could easily mine billing databases for clinical and management gold. The UMDNS codes are available for free use by care organizations. ECRI is now collaborating strongly with the European Community and European informaticians, and UMDNS will be the European standard for device classification as well as an ISO standard. For many purposes, UMDNS is presently too coarse. For example, it includes only two codes for pacemakers: internal and external. However, the European Community is exploring the development of a more granular version.

The world of "big" coding systems has also expanded. The two well known coding systems in this class are SNOMED [27] and the Read Codes [28]. SNOMED, under the College of American Pathologists, is reorganizing to be a faster and more responsive provider of concept codes. It is likely that they will provide a more federated structure where some of the content is produced by SNOMED and some by allied but independent producers. They are collaborating with DICOM in this effort. SNOMED is now completing the multiple hierarchies that had always been implicit within it, and collaborating with other content sources. We are not as up-to-date on the Read Codes, but an effort has been underway to create a multiaxial system from the originally single axial Read Code system, and we understand that progress continues apace.

The Medical Dictionary for Drug Regulatory Affairs (MEDDRA) [29] and MEDCIN [30] are two new "big" code systems. MEDDRA is an international effort supported by the major pharmaceutical manufacturers and the drug regulatory agencies of industrialized countries, via the International Conference on Harmonization. MEDDRA is not literally a code system, but a vocabulary — it does not assign formal codes to its vocabulary items. MEDDRA's purpose is to provide a common vocabulary for reporting drug adverse effects, both pre- and postmarketing. The vocabulary is hierarchical, and covers diagnoses, tests (loosely), symptoms, and adverse effects. MEDDRA had originally been described as a no cost public vocabulary list, but we have heard reports recently that it will have a license fee. We were unable to obtain any proposed release dates for MEDDRA for this report.

MEDCIN is a new large and precoordinated coding system, but not as large or comprehensive as either SNOMED or the Read Codes. MEDCIN was developed by a electronic medical record system vendor. It is described as a "pro bono" effort made available electronically for a modest fee, and is published by Springer Verlag in book form [24].

The Logical Observation Identifier Names and Codes (LOINC) data base is of special interest to us because we have been directly involved in its development [31]. At present, the LOINC database contains more than 10,000 records incorporating universal identifiers for reporting laboratory tests, vital signs, 12-lead EKGs, intakes and outputs, the standard parts of discharge summary, history, physical exam, critical care measurements, obstetrical ultrasound and the DEEDS emergency room data base [32]. Codes for cardiac ultrasound, cardiac bypass surgery, and endoscopy reports are under development.

LOINC provides coded identifiers for variables (e.g., glucose, EKG impression), not for discrete findings (e.g., diagnostic codes). Its special purpose

is to provide universal codes for the observation identifier (OBX-3) field of ASTM/HL7 messages and the corresponding fields in CEN PT008 and PT022. It has since been adopted for use in DICOM messages as well. The LOINC committee constructed the LOINC codes and names empirically from the content of existing master files. For example, the lab codes were shaped by the laboratory master files from Mayo Medical Laboratories, the Veterans' Administration, Quest Diagnostics (formerly Corning Clinical Laboratories), Associated Regional and University Pathologists (ARUP), and Indiana University. The obstetrical ultrasound terms were developed from the master files from four obstetrical ultrasound vendors.

LOINC is (mostly) a pre-coordinated code system based on a multiaxial structure. The decision to pre-coordinate was driven by the reality of current laboratory systems, which use, and report, pre-coordinated concepts such as serum sodium (analyte plus the specimen) and chlamydia IGM antibody in serum by EIA (analyte plus specimen plus method). It was developed with substantial input from the EUCLIDES project which is a multiaxial system [33] The LOINC data base, a users guide, and a mapping tool are available for free use (commercial and noncommercial) on the Web, at http://www.mcis.duke.edu/standards/guide.htm

The National Library of Medicine has mapped LOINC into the Unified Medical Language System (UMLS), and HCFA's ICD10-PCS has used it as the basis of their laboratory code system. A number of large laboratories, including the two largest U.S. commercial laboratories, which account for 30% of the commercial market have committed to its use [34]. In addition, the Veterans' Administration, the Council of State and Territorial Epidemiologists, the U.S. Center for Disease Control and Prevention, and the Province of Ontario, Canada have adopted it for laboratory messaging.

The International Union of Pure and Applied Chemistry (IUPAC) and their clear vision of the structure of scientific information [35] strongly influenced the LOINC committee. Indeed, most of the name structure, e.g, the component (analyte), the system (specimen), and the precision, comes directly from IUPAC. The IUPAC strategies have provided guidance and stability to the clinical as well as the laboratory naming rules in LOINC. IUPAC has elucidated many principles that have been adopted by the scientific community. A new one worthy of adoption is the goal of finding a source for atomic concept codes that anchors the code to an unambiguous definition. They propose, for example, to use the Chemical Abstract Society (CAS) codes to define chemical entities [36] What could be better? — the CAS codes provide all of the identifying characteristics of the chemical, down to the molecular formula. Similarly, they use the American Type Culture Collection (ATCC) class codes to identify bacteria. These codes link to a physical sample of the bacteria that can be ordered from the ATCC [37]. Using existing codes with iron clad definitions, rather than inventing new atomic codes, is an idea that all code developers should consider.

4. UMLS

The National Library of Medicine has been investing in the Unified Medical Language System (UMLS) for many years [38]. The UMLS is not a coding system per se, but a highly structured thesaurus or cross reference to the content of many coding systems. It cross references more than thirty coding systems, including most of SNOMED and the Read Codes, all of LOINC, ICD9, CPT, and many others. It includes a number of attributes for each concept, including a cross reference to synonyms, and links to the various code systems. It is an extraordinary resource for anyone interested in working with code systems or medical vocabularies, and the 4 CD-ROM set can be obtained from the National Library of Medicine, 8600 Rockville Pike, Bethesda, MD (800) 272 4787. http://www.nlm.nih.gov.

5. Security and Communication Standards

Privacy, security and confidentiality are a most important subject. The Internet engineering task force has had a long-term interest in this subject and has produced a number of solutions. Secure Sockets Layer provides public key encryption across the network (public or private) [39]. RFC 1767 describes mechanisms for encrypting e-mail. A recent task force, EDI over Internet (ftp://ietf.org/internet-drafts/draft-ietf-ediimt-reg 02.txt), provides encryption, content integrity, signature authentication (RSA based signature), and non-repudiation of receipt. It uses S/MIME or Pretty Good Privacy (PGP) to encode the content. Testing by major commercial partners and e-mail systems vendors is almost finished. More comprehensive but competing security authenticated standards are being offered by Intel, Common Security Services Manager (CSSM) and Microsoft, Common Data Security Architecture (CDSA).

Special problems are associated with health-care information and its protection. These have been thoroughly reviewed by Barrows and Clayton [40] and the National Research Council [41]. So most of the message standards developers are actively pursuing

this issue. CEN, in Europe, has made the most progress [42]. ASTM has two committees working on privacy and security issues: E31.17 is dealing with privacy, confidentiality and access, and E31.20 is addressing data and system security for health information. These two subcommittees are drafting many potentially ballottable documents.

6. Provider and Patient Identifiers

Before we will be able to easily build medical record or outcomes management systems, the medical informatics industry will also require universal identifiers for patients, providers, and sites of care. We cannot easily link patient data from many sources in a unified medical record or outcomes management database if each source defines its own independent patient identifier. We can't assess provider quality in population based data sets if providers are not identified uniquely in the database.

Many industrialized countries already have assigned master healthcare identifiers to all patients. The Kennedy Kassebaum health bill, passed last year, mandates national provider numbers (NPI), payor numbers, and universal patient numbers for the USA. It also mandates the standardization of a number of insurance related transactions and the institution of privacy regulation. In the longer term (four years) it asks for recommendations on standards that would facilitate the development of electronic medical record systems. The Health Care Financing Administration (HCFA) is well on the way to producing the provider and payor numbers. These are to be available within the next year. The question of a national patient identifier is quite controversial; so we cannot be as certain about its time table.

7. Conclusion

The field of health informatics has reached a new high water mark as countries struggle with new technology and health-care inflation. Hopes for better health-care at less cost hinge on health-care data which can only come with better health informatics standards. Satomura, describing the importance of standards, said it well: "We will be responsible for the health-care system of the next generation" [43].

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Address of the authors:
C.J. McDonald, M.D.,
Regenstrief Institute for Health Care,
Indiana University Medical Center,
1001 West Tenth Street,
Indianapolis, Indiana 46202-2859
phone: +1 317 630 7070
fax: +1 317 630 6962
E-mail: info@regen.rg.iupui.edu