Health Informatics Standards Review for the M Community

by Arden Forrey and Walter Biggs

November 6, 1995 is an important date for Health Informatics Standards. On that day, the American National Standards Institute (ANSI) Health Informatics Standards Planning Panel (HISPP) began its transition from a temporary committee to that of a permanent Health Informatics Standards Board (HISB). This transition has major implications for M and the M community due to M's pervasive use in healthcare applications. What is important is that the M community be aware of new standards activities, the organizations involved, and, more importantly, that it take a more active role in the planning and direction of standards development.

At the 1995 MTA Annual Meeting, the current status of the Healthcare Informatics Standards was reviewed. Discussions focused on both content standards and implementation standards.

Standards Developers Organizations

The ANSI/HISPP is composed of several ANSI accredited Standards Developers Organizations (SDOs) (see Figure 1). The SDOs, rather than ANSI, develop voluntary (rather than industry) consensus standards that are used by the ISO (International Standards Organization) to develop its international standards.

The major point of contact for all U.S. standards is the American National Standards Institute (ANSI). SDO members of the HISPP are listed in the following table.

Content Standards

Issues of major concern for content standards include: standard terminology, record structure and data models, regulation, and Electronic Data Interchange (EDI).

Standards Developers Organizations
Health Informatics Standards Planning Panel

American College of Radiologists/National Electrical Manufacturers Association (ACR/NEMA) Digital Imaging and Communications Standard (DICOM), current version 3.0

American Dental Association (ADA) - Oral health-specific information

American Society of Testing and Materials (ASTM) - Healthcare Informatics Standards

Health Level Seven (HL7) - Healthcare Messaging

Institute of Electrical and Electronic Engineers (IEEE) -Data Modeling and Draft Data Modeling Methods for Healthcare Standards

National Council for Prescription Drug Programs (NCPDP)

Data Interchange Standards Association (DISA)- X12 EDI messages for commerce, particularly healthcare claims, enrollment, and eligibility

Department of Defense - X3 general data processing issues

Figure 1

Standard Terminology, Record Structure and Data Models

The major concern here is that of diagnosis and procedure coding, primarily related to claims processing but also including the statistical data sets used for research, epidemiology, and official statistics reporting. The ANSI\HISPP Subcommittee on Codes and Vocabulary facilitates and promotes the use of standard terminology among government healthcare organizations.

The World Health Organization (WHO) is publishing a new standard, ICD-10, which is not due in the United States for several years. While ICD-10 is an improvement for health statistics, its lack of specificity compared to ICD-9-CM continues to cause difficulties in claims and clinical management.

The National Center for Health Statistics and the National Committee for Vital and Health Statistics (NCVHS) are major parties included in this terminology review. These agencies are treaty-mandated, which may explain their slow progress. On the other hand, Procedure Coding, which has been largely disavowed by the WHO, has been revived as a result of a project launched by HCFA (Health Care Finance Administration) on March 4, 1995 to create a replacement for ICD-9 Vol. III. Referred to as ICD-10 Procedure Coding System, this project draws on the recommendation of the NCVHS for a Unified Procedure Coding System (UPCS). Currently, its sole use is for hospital procedure coding for Medicare.

Laboratory procedures, which are a large part of hospital data elements, are included in ICD-10 Procedure Codes. They are based on LOINC, Laboratory Observation Identifiers, Names and Codes, a project under way at the University of Indiana and funded partially by the National Library of Medicine (NLM) and the Agency for Health Care Policy and Research (AHCPR). This component, which will eventually apply to all healthcare settings when it is complete and validated in one to two years, will be tested soon in some federal healthcare agencies including the Veterans Administration.

A publicly released version of the LOINC software is available by ftp at: dumccss.mc.duke.edu/standards/HL7/termcode/loinclab/ or http://dumccss.mc.duke.edu/standards/HL7/termcode/loinclab/

Other terminologies will be systematized. The ADA has specialized work groups on oral health terminology consistent with SNOMED-III, and the ANSI/HISPP Subcommittee on Codes and Vocabulary will encourage formation of others.

In mid-October 1994, HISPP hosted a joint meeting with the Committee European Normalization (CEN) Technical Committee (TC) 251 Working Group 2 on terminology which resulted in a declaration of intent to converge laboratory procedure terminology with that of the International Federation for Clinical Chemistry (IFCC), the International Union of Pure and Applied Chemistry (IUPAC), and the American Association for Clinical Chemistry (AACC).

The American Society of Testing and Materials (ASTM) has recently approved standard E-1712. This specifies the rules for naming clinical laboratory procedures such that they are consistent with CEN TC-251, IFCC, and IUPAC. It is the basis for names being developed in the HCFA and NLM\AHCPR projects. CEN TC-251 also has a naming principles document for surgical procedures, thus indicating the convergence now taking place under international as well as domestic pressures.

Terminologies, in addition to data element definitions, have also moved rapidly in recent months. Standard E-1239 on Registration, Admitting, Discharge, and Transfer Functions (RADT), which was first published by ASTM in 1988 (now twice revised), was followed in 1991 by E-1384 on the full Structure and Content of the Computer-based Patient Record. This standard is now in the final stages of revision. It is accompanied by two companion standards: E-1633 on the Coded Values used in the CPR and E-1715 on an Object Model for the RADT Functions in CPR systems. E-1384 covers the conventions for the data to be included in the National Provider File/National Provider Identifier being defined by HCFA along with the ANSI/HISPP to serve the Medicare claims process. It is structured, however, to be a national resource as the healthcare informatics standards identify its best uses.

E-1715 complements another recently approved standard, E-1639 on Requirements for Clinical Laboratory Information Management Systems (CLIMS) which also uses an Object Model. CEN TC-251 is now using object modeling techniques quite widely, and the two efforts reinforce each other. Moreover, an ANSI/HISPP Joint Working Group (JWG) on the Common Data Model has been working since 1993 to create a Common Data Model (CDM) for Healthcare.

One of the first CDMs is the IEEE MEDIX Modeling methods study. These methods create explicit statements that define the structure of data elements (attributes) included in the CPR and the supporting data domains common to both source and destination repositories, such as CLIMS and the CPR. The model will also apply to messages for international communication. The M community needs to be fully aware of these efforts and the responsible agencies.

Regulation and Consensus Groups

The Federal Drug Administration (FDA) is responsible for regulating medical devices and software quality assurance. These issues are best dealt with in the implementation domain using the existing ANSI\IEEE standards. Mandated vocabularies are best examined with regard to the terminology issues identified within the ANSI/HISPP.

Electronic Data Interchange

The Electronic Data Interchange (EDI) issues focus mainly on the compatibility of EDI and CPR data elements and value sets. The HISPP SDOs are jointly working toward this commonality. However, they have not yet resolved these issues sufficiently to be regularly used to compose an electronic claims transaction. The Data Interchange Standards Association (DISA) and Health Level Seven are working on message commonality with the UN\EDIFACT (Electronic Data Interchange for Administration, Commerce, and Transport) variant of commercial messages while ASTM is working toward CPR\clinical message consistency.

Voluntary Consensus \ Content, Groups and Agencies

ACR\NEMA:	PS 3.1-3.10 DICOM 3.0 standard in 10 parts
ADA:	ADA Computer-based Oral Health Record Concept Model Version 0.9
ASTM E-31:	E-792 Standard Guide for Selecting a Clinical Laboratory Information Management System
	E-1029 Standard Guide for Documentation of Clinical Laboratory Systems
	E-1238 Standard Specification for Transferring Clinical Observations Between Independent Systems
	E-1239 Standard Guide for Description of Reservation\Registration, Admission, Discharge and Transfer (R-ADT) Systems for Automated Patient Care Information Systems
	E-1284 Standard Guide for Nosologic Standards and Guides for Construction of New Biomedical Nomenclatures
	E-1340 Standard Guide for Rapid Prototyping
	E-1381 Standard Specification for the Low-Level Protocol in Transferring Messages Between Clinical Laboratory Instruments and Computers
	E-1384 Standard Guide for Description for Content and Structure in a Computer-based Patient Record System
	E-1394 Standard Specification for Transferring Information between Clinical Instruments and Computers
	E-1460 Specification for Defining and Sharing Modular Health Knowledge Bases
	E-1466 Specification for the use of Bar Codes in Clinical Laboratory Specimen Management
	E-1467 Specification for Transferring Digital Neurophysiologic Data Between Independent Computer Systems
	E-1578 Standard Guide for Laboratory Information Management Systems (LIMS)
	E-1633 Specification for the Coded Values Used in the Automated Primary Record of Care
	E-1639 Guide for Functional Requirements of Clinical Laboratory Information Systems
	E-1712 Specification for Representing Clinical Laboratory Test and Analyte Names
	E-1713 Specification for Transferring Digital Waveform Data Between Independent Computer Systems
	E-1714 Guide for Properties of a Unique Healthcare Identifier
	E-1715 Practice for an Object-Oriented Model for Registration, Admitting, Discharge and Transfer (RADT) Functions in Computer-based Patient Record Systems
	E-1744 Guide for View of Emergency Medical Care in the Computerized Patient Record
ASTM F-30:	E-1629 Guide for Data Management in Emergency Medical Systems
HL7:	Application Protocol for Electronic Exchange in Healthcare Environments Version 2.2 1994
IEEE:	1157.1 Standard for Healthcare Data Interchange Information Model Methods
NCPDP:	Standard Billing Unit Format, Manufacturer's Rebate Standard

Figure 2

Implementation Standards

IEEE Society and U.S. TAG JTC1 SC7

The Joint Technical Committee 1 (JTC1) of ISO and the International Electrotechnical Committee (IEC) are the organizations through which M gained its ISO status as 11756. Subcommittee 7 of ISO (Software Engineering) is concerned with creation and maintenance of applications systems. The U.S. ISO Technical Advisory Group (TAG) to JTC1/SC7 presented its work to the MDC at the 1989 meeting in Seattle. Since then the MDC has directed its efforts toward documenting how these standards apply to the engineering of systems in the M environment.

The ANSI/HISPP and the U.S. National Committee (USNC) to JTC1, particularly SC7, are interested in collaborating to make implementation of content for healthcare applications consistent with the ISO 9000 standards applied to software engineering. The Institute for Electrical and Electronic Engineers Computer Society (IEEE-CS) is the TAG (Technical Advisory Group) administrator for these standards and the source of American National Standards in this area.

Standards Publications

ANSI publishes an annual summary of the current standards and projects. The Medical Record Institute (MRI) publishes a book summarizing all of the organizations involved in Computer-based Patient Record standards. Many of these organizations are active in both the ANSI/HISPP and the individual SDO work groups. This volume provides a comprehensive picture of the contributions made by each to the standards mosaic. Although the Computer-based Patient Record Institute (CPRI) has been considered a standards developer, it does not develop voluntary consensus standards; rather, it facilitates involvement in the formal efforts.

CPRI creates forums for understanding the introduction and use of standards, many times in partnership with professional specialty organizations. This function has, until recently, been little recognized for its critical role in the advancement of the technology and the optimal operation of market forces. It is important for the M community to understand the correct roles and contributions of these organizations in order to interact with the most appropriate resources for healthcare applications.

Voluntary Consensus \ Implementation, Groups, and Agencies

X11: ANSI X.11/ISO 11756

Government\Industry Standards:

International Classification of Diseases (ICD) ICD-9 (WHO) and ICD-9CM (Clinical Modification) National Center for Health Statistics

ICD-10 World Health Organization (WHO)

ICD-10 PCS Healthcare Financing Administration

SNOMED-III (Systematized Nomenclature of Medicine International)

Figure 3

Arden Forrey has a doctorate in biochemistry and has been a member of the ASTM E-31 Committee for 18 years. He worked with the VA from 1977–1980 and the Navy Medical R&D from 1980–1982. He is now with the School of Dentistry at the University of Washington.

Walter Biggs has been a software engineer for over 20 years. He is secretary of the ASTM Committee E-31 on Healthcare Informatics and a member of IEEE. He works for the state of Washington implementing the M-based Department of Veterans Affairs DHCP system in a state hospital.

Points of Contact:

Arden W. Forrey - forraw@u.washington.edu

Walter Biggs - biggs.walter_D@forum.va.gov

American National Standards Institute (ANSI)
11 West 42nd Street
New York, NY 10036
(212) 642-4900 Contact: Steve Cornish

Standards Developers Organizations

American Dental Association (ADA)
211 East Chicago Ave.
Chicago, IL 60611
(312) 440-2509 Contact: Sharon Stanford

American Society of Testing and Materials (ASTM)
1916 Race St.
Philadelphia, PA 19103-1107
(215) 299-5485 Contact: Terri Luthy

American College of Radiologists/National Electrical Manufacturer's Association (ACR/NEMA)
2101 L St., NW
Washington, DC 20037
(202) 457-8400 Contact: Dave Snavely

Health Level Seven (HL7)
3300 Washtenaw Ave. Suite 227
Ann Arbor, MI 48104-4250
(313) 677-7777
Contact: Mark McDougall HQ@HL7.WIN.NET

Institute for Electrical and Electronic Engineers (IEEE)
445 Hoes Lane PO Box 1331
Piscataway, NJ 08855-1331
(908) 562-3814 Contact: John Parisi jparisi@stdsmail.ieee.org

IEEE Computer Society (IEEE-CS)
U.S. TAG to ISO JTC1
Leonard Tripp of the Boeing Company
PO Box 3707 MS 6H-TW
Seattle, WA 98102
(206) 237-5240 Contact: Leonard Tripp i.tripp@ieee.org
(Also the chair of the IEEE Computer Society Technical Council on Software Engineering Committee on Standards)

National Council for Prescription Drug Programs (NCPDP)
4201 North 24th Street
Suite 365
Phoenix, AZ 85016
(602) 957-9105 Contact: Lee Ann Stember

The Data Interchange Standards Association (X.12) (DISA)
1800 Diagonal Rd.
Suite 355
Alexandria, VA 22314
(703) 548-7005

Department of Defense (X3)
8457 Rushing Creek Court
Springfield, VA 22153-2532
(703) 487-3305 Contact: William Rinehuls

Others:

Computer-based Patient Record Institute (CPRI)
1000 East Woodfield Rd.
Suite 102
Schaumburg, IL 60173
(708) 706-6746 Contact: Margaret Amatayakul

Medical Record Institute (MRI)
567 Walnut Street
PO Box 289
Newton, MA 02160
(617) 964-3923 Contact: Peter Wagemann
71431.2030@Compuserve.com

Glossary of Acronyms

ACR/NEMA American College of Radiologists/National Electrical Manufacturers Association
ADA American Dental Association
AHCPR Agency for Healthcare Policy and Research
ANSI American National Standards Institute
ASTM American Society for Testing and Materials
CDM Common Data Model
CEN Committee European Normalization
CLIMS Clinical Laboratory Information Management Systems
CPR Computer-based Patient Record
CPRI Computer-based Patient Record Institute
DICOM Digital Imaging and Communications Standard
DISA Data Interchange Standards Association
DOD Department of Defense
EDI Electronic Data Interchange
FDA Federal Drug Administration
HFCA Healthcare Financing Administration
HISPP Health Informatics Standards Planning Panel
HL7 Health Level Seven
ICD International Classification of Diseases
IEC International Electrotechnical Committee
IEEE Institute for Electrical and Electronic Engineers
IFCC International Federation for Clinical Chemistry
ISO International Standards Organization
IUPAC International Union of Pure and Applied Chemistry
JTC1 Joint Technical Committee 1
JWG Joint Working Group
LOINC Laboratory Observation Identifiers, Names and Codes
MDC MUMPS Development Committee
MRI Medical Record Institute
NCHS National Center for Health Statistics
NCPDP National Council for Prescription Drug Programs
NCVHS National Committee for Vital and Health Statistics
NLM National Library of Medicine
RADT Registration, Admitting, Discharge and Transfer
SC7 Subcommittee 7
SDO Standards Developers Organization
TAG Technical Advisory Group
TC Technical Committee
UPCS Unified Procedure Coding System
USNC U.S. National Committee
WHO World Health Organization