

Standards

STANDARDS WORK

Seven organizations working to improve communication across the industry summarize their latest efforts and initiatives.

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ASTM E31 Committee

Recent activities address CCR, transcription and documentation, and security and privacy.

by Claudia Tessier

West Conshohocken, Pa.-based ASTM International works on standardization issues across the globe. The E31 Committee addresses standardization in healthcare informatics. Following are some of its subcommittees' activities.

Electronic Health Records (E31.28)

The E31.28 subcommittee focuses on the continuity of care record (CCR) initiative, which is led by sponsors representing more than 400,000 clinicians, 13,000 IT professionals and 12,000 long-term care institutions. Approved in April of this year, the CCR standard is a core data set of relevant patient information that can be communicated from one provider to another, such as when a patient is referred or transferred to a new physician or hospital or moves to a new community. It may also be incorporated into a personal health record.

The CCR's XML codes enhance interoperability and allow its preparation, transmission and viewing in multiple ways. An implementation guide will be balloted this month.

The CCR is considered to be relevant, doable and potentially valuable toward improving patient care, reducing medical errors, lowering costs and inefficiencies, and expanding patients' involvement in their healthcare.

Contact Claudia Tessier at ctessi@attglobal.net for information.

Health Information Transcription and Documentation (E31.22)

The E31.22 subcommittee recently approved two new standards. The Standard Guide for Data Capture

through the Dictation Process (E2344) enhances the quality of documentation by improving the dictation process, thereby improving the dictated message.

The Standard Guide for Speech Recognition Products in Health Care (E2364) assists users in making informed decisions about the design and utilization of speech-recognition systems.

Contact Brenda Hurley at bhurley@medware-inc.com for information.

Security and Privacy (E31.20)

The E31.20 subcommittee is revising several ASTM standard guides referenced in drafting the Health Insurance Portability and Accountability Act (HIPAA) to establish technical specifications that will help ensure compliance with HIPAA security and privacy rules.

Also under revision are the Standard Guide for Electronic Authentication of Health Care Information (E1762-95) and the Standard Specification for Authentication of Healthcare Information Using Digital Signatures (E2084-00), which will provide reference materials and specifications to support the CCR, e-prescribing and other e-health initiatives.

A Privilege Management Infrastructure standard is under development to address complexities of role-based access control and management of user privileges. The standard will establish consistent means for protecting personal health information within and across enterprises. Sponsors are being sought to optimize consensus-building among the numerous stakeholders.

Contact Lori Reed-Fourquet at lori.fourquet@sbcglobal.net or Dale Miller at dwmiller@irongateinc.com for information.

Claudia Tessier, CAE, RHIA, is co-chair of ASTM's E31.28 subcommittee and executive director of the Mobile Healthcare Alliance, Washington, D.C.

DICOM Additions and Advances

The standards committee works to keep up with technology.

by Robert J. Horn

During the course of the past year, the Standards Committee for Digital Imaging and Communications in Medicine (DICOM), headquartered in Rosslyn, Va., has made progress in important ways.

- Upgrading two of its original communications objects
- Adding new objects to extend DICOM's scope, especially in describing computer-generated and -assisted medical analysis
- Incorporating and integrating with standards from the larger IT community

Additions and upgrades

The new objects for describing computed tomography (CT) and magnetic resonance (MR) images reflect the experience of 10 years of operational use of the original DICOM objects for these images. Information provided by new CT and MR hardware capabilities introduced over the past decade has been incorporated as new optional attributes for these objects. A gradual transition to these new objects is

anticipated. Some object organizational changes were made to reduce processing overhead and simplify routine presentation of complex studies.

New objects have been designed to support the increasing numbers of computer-assisted reporting and analysis tools. Among the output of such tools are breast imaging and computer-aided diagnosis reports; catheterization laboratory procedure logs, hemodynamics, and final reports; and ob-gyn, vascular and cardiac ultrasound reports. Additional imaging specialties, such as ophthalmic photography, are also supported.

Diversified support

Other IT standards have been incorporated and supported in several ways.

- Unicode and GB18030 (Chinese) support has been incorporated.
- JPEG2000 compression is available as an option.
- DVD and USB devices for removable media were defined.
- Web access to DICOM objects (via HTTP) was defined.
- Configuration management for DICOM applications (DHCP, DNS, NTP, LDAP) was defined.

Ongoing efforts The committee continues to work on defining upgrades needed for other old objects (e.g., X-ray fluoroscopy), new imaging objects, and image reporting objects; workflow support; and privacy and security support. Visit <http://medical.nema.org> for more information.

Robert J. Horn is chair, Working Group 6 (Base Standard), Digital Imaging and Communications in Medicine, Rosslyn, Va.

HL7 Makes Headway on Version 3

Framers of the EHR draft standards invite the industry to try them out.

by Mark Shafarman and Karen Van Hentenryck

In April 2004, the Ann Arbor, Mich.-based Health Level Seven (HL7) Electronic Health Record-System (EHR-S) Functional Model and Standards passed as American National Standards Institute (ANSI) Draft Standards for Trial Use (DSTU). Their purpose is to enable consistent expression--providing a foundation for common understanding of possible functions of the EHR-S. They do not address implementation or technologies, nor do they include the data content of the EHR.

Industry members are encouraged to use the draft standards during the two-year period of DSTU status and contribute comments based on their experiences. These comments will be incorporated into the version that will be balloted as ANSI-approved standards.

First edition of Version 3

HL7's Sept. 26 to Oct. 1 plenary and annual group meeting is themed "Version 3 is Here, Now!" David Brailer, National Health Information Technology Coordinator, is the invited keynote speaker. International affiliate members from the United Kingdom, Mexico and Canada will discuss their implementations and contributions to the success of Version 3 through their participation in the Early Adopters Program.

The first official core Version 3 specifications are slated for December publication. The following are ANSI-approved items:

- Reference information model
- Scheduling
- Claims and reimbursement
- Refinement, constraint and localization to Version 3 messages
- Shared messages
- XML implementation technology specification--data types
- UML implementation technology specification
- Regulated studies--ECG

In process for ANSI approval are data types abstract specification, common message element types, XML implementation technology specification--structures, and period reporting of clinical trial laboratory data.

Medical records, patient administration, transport specification-Web services, and transport specification-ebXML have been submitted to ANSI as DSTUs.

Additional developments

HL7 continues to collaborate with other standards development organizations. We are updating our memorandums of understanding with the Clinical Data Interchange Standards Consortium, Austin, Texas, and with ASTM International, West Conshohocken, Pa. (including harmonization between the Continuity of Care Record and the Clinical Documentation Architecture).

We also are working with the Geneva-based International Organization for Standardization (ISO) technical committee 215 (progressing the reference information model to an ISO standard) and the European Committee for Standardization (CEN) technical committee 251 (including datatypes and electronic health record standards).

HL7's first advisory committee, currently composed of six high-ranking industry professionals, held its inaugural meeting in July.

Mark Shafarman is chair and Karen Van Hentenryck is associate executive director, Health Level Seven, Ann Arbor, Mich.

ISO Reference Terminology Model

Nursing diagnosis and action models look to testing for practical application.

by Suzanne Bakken, Amy Coenen and Virginia Saba

HHealth Informatics-Integration of a Reference Terminology Model for Nursing (18104) was approved as an international standard in 2003 by the International Organization for Standardization (ISO), Geneva, and is now in a five-year testing period. Experts within ISO Technical Committee 215 (Health Informatics) Working Group 3 (Health Concept Representation) developed the standard under the leadership of the Nursing Special Interest Group of the International Medical Informatics Association and the International

Council of Nurses, Geneva. Models were based on seminal work in the European Committee for Standardization, Brussels, Belgium.

Intended uses

Primary intended users of the ISO models are terminology, system and software developers. The models are not intended for direct use in clinical care. Potential uses are to:

- Support intensional definition of nursing-diagnosis and nursing-action concepts in a manner that renders them suitable for computer processing
- Provide a framework for generation of compositional expressions (e.g., severe, acute pain) from atomic concepts (severe, acute, and pain) within a reference terminology
- Facilitate mapping among concepts from various nursing terminologies, including those developed for direct use in practice, and for statistical classification purposes
- Enable integration with other terminology and information models

Diagnosis/action model descriptors

The nursing diagnosis model includes mandatory descriptors for focus (e.g., cognition) and judgment (e.g., im- paired). The subject of information descriptor is used as necessary to establish a single interpretation of nursing diagnosis concepts (e.g., ineffective individual coping versus ineffective family coping). Site and dimension are optional.

The nursing action model requires two descriptors for definition of concepts: target (e.g., smoking cessation) and action (e.g., counsel, teach). The recipient of care is identified (e.g., instruction on diabetic foot care to an individual versus to a family caregiver). Optional aspects include route, means, site and timing.

Little research has been done on ISO models related to their practical application in terminology or system development. Additional testing is critical to ensure that the models serve their intended purposes. For further information, visit www.icn.ch/icnp_iso.htm.

Suzanne Bakken, R.N., D.N.Sc., is former chair, technical work item group, ISO Standard 18104; Amy Coenen, R.N., Ph.D., is a member of the U.S. TAG and ISO Technical Committee 215; and Virginia Saba, R.N., Ed.D., is former chair, Steering Committee, ISO Standard 18104.

LOINC Links Grow

More and more groups are finding content in the database that they can use.

by Stanley M. Huff

Logical Observations, Identifiers Names and Codes (LOINC), a free-for-use database maintained by the Regenstrief Institute, located on the Indiana University School of Medicine campus, Indianapolis, continues to grow in content and adoption. LOINC contains precoordinated concepts for identifying observations--including laboratory and clinical measurements, survey questions, clinical documents and diagnostic reports--and names for panels (collections) of clinical and laboratory results.

LOINC was designed to provide universal identifiers for the observation identifier (OBX-3) and order (OBR-4) fields in Health Level Seven Version 2 messages. However, it is also used in other message

standards, including those of Digital Imaging and Communications in Medicine, Rosslyn, Va. To date, the database includes names, codes and synonyms for 36,000 concepts. It is particularly rich in content from laboratory, radiology, cardiology, general clinical measurements, survey instruments, ventilator management, ophthalmology and obstetrical measurements.

Organizational adoption

Significant milestones in the last 18 months include:

- March 2003: U.S. Department of Health & Human Services Secretary Tommy Thompson announced adoption of Laboratory LOINC as the standard for ordering and reporting laboratory tests and identifying clinical reports.
- November 2003: The National Committee on Vital and Health Statistics recommended LOINC as the terminology for representing the laboratory observations as part of Patient Medical Record Information terminologies.
- July 2004: The National Committee for Quality Assurance announced that HEDIS (the Health Plan Employer Data and Information Set) would support use of LOINC codes for some measures.

The U.S. Department of Defense has adopted LOINC as a standard for radiology and laboratory ordering and reporting. Many large healthcare and insurance organizations and referral laboratories use LOINC in clinical messages. It is included in the Unified Medical Language System metathesaurus.

Overseas, the German national standards organization (DIN) adopted LOINC as a national standard. New Zealand, Canada, Australia and China also have adopted it, and the Swiss have translated the most common 3,800 terms into German, French, Spanish and Italian.

Freely available

A free download of LOINC is available at www.loinc.org and includes the Regenstrief LOINC Mapping Assistant (RELMA), a user-friendly browser for the LOINC database. RELMA is also a tool for matching local names and codes to the universal names and codes in the LOINC database.

Stanley M. Huff, M.D., is co-chair, Clinical LOINC, Regenstrief Institute, Indiana University School of Medicine, Indianapolis.

SNOMED CT Milestones

Endorsements are added to already-impressive standards credentials.

by Kent A. Spackman

Although technical progress toward fully electronic health information systems has been impressive, a critical component is often missing--standard clinical terminology. This element would enable more accurate and timely comparisons and more effective communication.

SNOMED Clinical Terms (SNOMED CT) offers controlled clinical terminology with comprehensive coverage of diseases, clinical findings, etiologies, therapies, procedures and outcomes. SNOMED CT was developed, in collaboration with the U.K.'s National Health Service, by SNOMED International, a division of Northfield, Ill.-based College of American Pathologists (CAP), which is accredited as a standards development organization by the American National Standards Institute (ANSI), Washington, D.C. Currently, SNOMED CT contains:

- More than 357,000 concepts with unique meanings and formal logic-based definitions organized into hierarchies
- More than 957,000 English-language synonyms, for flexibility in expressing clinical concepts
- About 1.37 million semantic relationships to enable robust reliability and consistency of data retrieval

An approved code source in ASC X12, SNOMED CT also cross-maps to ICD-9-CM (via an epidemiological/statistical mapping); ICD-03; logical observation identifiers, names and codes (LOINC); Nursing Interventions Classification (NIC); Nursing Outcomes Classification (NOC); North American Nursing Diagnosis Association (NANDA); and Perioperative Nursing Data Set (PNDS).

Steps toward the standard

In recent months, SNOMED CT has seen significant milestones in advancement toward the clinical terminology standard:

- The U.S. Department of Health & Human Services (HHS) and CAP signed a \$34 million agreement to license SNOMED for U.S. distribution through the National Library of Medicine's Unified Medical Language System.
- ANSI approved the Healthcare Terminology Structure Standard, which specifies a file structure for use in distributing healthcare terminology.
- The National Committee on Vital and Health Statistics recommended use of SNOMED CT for the core set of U.S. Patient Medical Record Information terminologies.
- The federal government's Consolidated Health Informatics Initiative recommended SNOMED CT for anatomy, nursing, diagnosis and problems, and nonlaboratory interventions and procedures.

SNOMED CT includes terms required for basic interoperability and is recognized by interoperability initiatives, such as the eHealth Initiative, Washington, D.C., and the National Alliance for Health Information Technology, Chicago.

The CAP helps advance industrywide interoperability efforts through participation with the Technical Advisory Working Group on Health Concept Representation of the International Organization for Standardization (ISO), Geneva; Working Group 8 of Digital Imaging and Communications in Medicine (DICOM), Rosslyn, Va.; and Health Level Seven Inc., Ann Arbor, Mich.

Kent A. Spackman, M.D., Ph.D., is chair, SNOMED International Editorial Board, Northfield, Ill.

WEDI Workings

Tasked with advising HHS, the group develops consensus and recommendations on standards implementation.

by Steven S. Lazarus

The Health Insurance Portability and Accountability Act (HIPAA) requires that the U.S. Department of Health & Human Services (HHS) consult with the Workgroup for Electronic Data Interchange (WEDI), Reston, Va., on implementation of the HIPAA Standards for Administrative Simplification. This includes standards developed by the Washington D.C.-based American National Standards Institute (ASC X12N); the National Council for Prescription Drug Programs, Scottsdale, Ariz.; and Health Level Seven, Ann Arbor, Mich.

The WEDI Strategic National Implementation Process (SNIP) is designed to develop a consensus among industry constituents on how to approach each of the HIPAA standard implementations. Business process and technical views are addressed in SNIP's many listservs and white papers. Following are some significant WEDI and SNIP standards activities in 2004.

Standard transactions and code sets

In January, WEDI received testimony from 51 healthcare entities at a public hearing in Tampa, Fla., to assess implementation progress of transactions and code sets since the compliance date of Oct. 16, 2003. A summary letter, submitted to HHS Secretary Tommy Thompson in March by the WEDI board of directors, made recommendations that HHS continue to allow contingency plans, enhance the implementation process, revise and enhance the standards development process, and validate costs and benefits of transactions and code sets implementation.

Findings and recommendations were discussed in more detail in March and May testimony by WEDI officers at National Committee on Vital and Health Statistics hearings.

Security

At its annual national conference in May in La Jolla, Calif., WEDI--along with the National Institute of Standards and Technology (NIST), Gaithersburg, Md., and URAC, Washington, D.C.--presented findings to date of cross-walking of the HIPAA security requirements to ISO 17799, the NIST 800 series, Federal Information Processing standard 199, CMS-CAS and other security standards. Sponsoring organizations expect to complete the project and make it publicly available before the end of 2004.

At present, 30 security and privacy white papers are available or under development (visit <http://wedi.org/snip>).

National Provider Identifier

In June, WEDI held a National Provider Identifier (NPI) Policy Advisory Group (PAG) forum in Washington, D.C., to review the NPI final rule published in January. Industry concerns regarding implementation as well as CMS' plans to issue and maintain the NPIs are being addressed by WEDI SNIP transactions and code sets sub-workgroup initiatives, listservs and white paper activities. The WEDI board will review and approve NPI PAG recommendations in 2004.

Interoperability

In collaboration with the eHealth Initiative, WEDI is studying key interoperability issues between the electronic health record and other business systems, focusing on data flow and workflow efficiency. Resulting task group preliminary recommendations were submitted to David Brailer, National Health Information Technology Coordinator, in July. An update on this study will be presented at the WEDI/SNIP national conference in Atlanta in November (visit www.wedi.org).

Steven S. Lazarus, Ph.D., FHIMSS, is past chairman of the WEDI Board of Directors and is the WEDI board's liaison for WEDI SNIP.

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