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**Networking and Health
Information Exchange**

Unit 3c
National and International Standards
Developing Organizations

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Unit 3 Objectives

- To learn about standards developing organizations and the standards they create – a continuation of the focusing on U.S. standards bodies.

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International Health Terminology Standards Development Organization (IHTSDO)

- Purpose is to develop and promote use of SNOMED CT to support the safe, accurate, and effective exchange of health information.

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Formed in 2007 as a charter organization with initially nine country members. That number has now increased to 15.

Membership in IHTSDO enables country-wide use of SNOMED CT.

WHO and IHTSDO recently announced a collaborative arrangement to harmonize WHO classifications and SNOMED CT

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Digital Imaging and Communications in Medicine

- Formed by American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) in 1983
- Purpose: create a standard for the transmission of medical images and their associated information.

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With the release of version 3.0 in 1993, the committee changed its name to DICOM, and became international in scope. DICOM is perhaps one of the most stable and widely used standards. It is ubiquitous in all imagine devices. However, there is less stability in the accompanying standards, such as the demographics of the patient and other data relating to the reasons for the image.

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DICOM

- DICOM addresses images in cardiology, dentistry, endoscopy, mammography, ophthalmology, orthopedics, pathology, pediatrics, radiation therapy, surgery, and others.

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The DICOM Committee has 27 work groups, addressing different kinds of images, different domain focus, reporting, and security.

DICOM addresses multiple levels of the ISO OSI network model and provides support for the exchange of data.

DICOM also has adopted JPEG and MPEg in its suite of standards for images.

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DICOM functionality

- Transmission and persistence of objects (images, waveforms, and documents)
- Query and retrieval of such objects
- Performance of specific functions (such as printing images on film)
- Workflow management (support of worklists and status information)
- Quality and consistency of image appearance for display and print

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Almost, if not all Pictures and Archiving Systems (PACS) uses DICOM. The standard includes storage of images and persistence of images – a structure of indexing, labeling, storing and retrieving images. DICOM also supports other related functions such as printing images on film. With the digitalization of images and the effectiveness of DICOM standards, very few analogue images are put on film today. In fact, many places convert old images to digital images, and recover the silver from the old films.

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ASTM E31 Healthcare Informatics

- Develops standards related to the architecture, content, storage, security, confidentiality, functionality, and communication of information used within healthcare.

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Established in 1970
Has over 300 members, has 3 technical subcommittees, and over 30 current, approved standards. ASTM is a large, international standards body that creates standards in many areas. The health care focus, E31, is relatively small. With the exception of the Continuity of Care Standards, ASTM standards are not widely used.

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ASTM E31 key standards

- Continuity of Care Record (CCR) is a core dataset sent to the next provider whenever a patient is referred, transferred, or uses a different clinic, hospital or other provider.
- Standards for medical transcription
- Content and structure of the EHR

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There is a strong competition between HL7's CDA and ASTM's CCR. In an attempt to diffuse this competition, HL7 working with ASTM created the CCD which is essentially taking CCR and inserting it into a CDA. Unfortunately, that did not solve the competition, and both standards continue to be developed independently. The American Academy of Family Practice is a strong supporter of the CCR as are many small vendors. The CCR is simpler to implement than the CDA.

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ASTM E31 key standards

- Confidentiality, privacy and security; authentication and authorization
- Guideline Elements Model (GEM)
- Quality Indicators
- Voluntary Universal Healthcare Identification System

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Other ASTM standards are recognized and used in the field. Perhaps of this group, the Guideline Elements Model is most widely used. GEM defines elements and composition for clinical guidelines. The Voluntary Universal Healthcare Identification System is frequently referenced as the only standard of its kind. However, it has not come into widespread use.

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ASC X12N

- Chartered by ANSI in 1979 to develop electronic data interchange (EDI) standards.
- Responsible for insurance/ claims/ reimbursement standards.
- HIPAA requires the use of a number of X12N standards.

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Accredited Standards Committee (ASC) X12 was chartered by NIST in 1979 to develop electronic data interchange (EDI) standards. ANSI has the authority to create a standards body for any area in which it believes a standard should exist and for which no SDO exists. This gap in reimbursement standards resulted in the creation of ASC X12N. The N suffix stands for insurance, and is the largest subcommittee of X12. X12N has created a suite of standards (notes as EDI standards or business standards) for the purpose of claims reporting and processing. These standards are specifically identified in the HIPAA legislation and are required for use with Medicare and Medicaid reimbursement. The standards support eligibility and claims tracking as well as claims and reporting.

X12N and HL7 have worked together to create the Claims Attachment Standard. The current status of that activity is using CDA for claims attachment.

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X12N key standards

- 835 – Health Care Claim Payment/Advice
- 837 – Health Care Claim
- 274 – Health Care Provider Information
- 275 – Additional Payer Health Care Information
- 277 – Health Care Claim Acknowledgement
- 276 – Health Care Claim Status Report
- Claims attachment standards – co-developed with HL7

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These are some of the standards defined by X12N.

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National Council for Prescription Drug Programs (NCPDP)

- Create and promote data interchange standards for the pharmacy services industry.
- NCPDP standards have been named in HIPAA legislation in in Medicare Prescription Drug, Improvement, and Modernization Act (Medicare, Part D).

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Founded in 1977
Membership exceeds 1500 persons and represents most sectors of the pharmacy services industry.
Members are pharmacists, payers, and drug companies.

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NCPDP key standards

- Script (v10.10) – allows communication between physician and pharmacist
- Telecommunication (vD.3) – addresses data format and content, transmission protocol
- Data dictionary – names and definitions of data elements used in all NCPDP standards

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These are important standards that are also named and required for use by HIPAA and also by new legislation to support e-Prescribing. Script supports communication between the physician and the pharmacists. These standards are being expanded to include the management of refills, and for the actual dispensing of drugs by the pharmacy.

NCPDP takes a strong step towards interoperability by creating a data dictionary that includes the data elements with

attributes used in all NCPDP transactions.

NCPDP and HL7 work closely together,

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NCPDP key standards

- Batch Standard Implementation Guide (IG) (v1.2)
- Billing Unit Standard IG (v3.0)
- Formulary and Benefit IG (v2.1)
- Prescription File Transfer IG (v2.0)
- Universal Claim Form (v1.1)

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NCPDP standards are also used by Pharmacy Benefit Managers (PBMS) for pharmacy claims and reimbursement. These standards relate to the billing and claims process.

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SDO Charter Organizations objectives

- Create common information model
- Define common method for expressing stakeholder commitments
- Leveraging current terminology and data types work
- Use common approach to achieve interoperability across healthcare community
- Recognizing roles and responsibilities of stakeholders and creating an effective outreach to subject matter experts

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Formed in 2009
Provides an environment that facilitates effective coordination and collaboration of U.S. national healthcare standards development
Thus far, little progress has been made in bringing SDOS together, altho some of the goals identified above are being discussed.
For example, a common reference model would provide easier interoperability among the different standards as well as addressing the terminology problems.

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Category	Examples	SDOs
Generic, broad use	XML, TCP/IP, Web services, OCL, OWL, CCOW, GIS	W3C, IETF, OMG, HL7
Data definition	RIM, data elements, data types, terminology, templates, archetypes, clinical statements	HL7, CEN, ISO, NCPDP, X12N, IEEE, SNOMED, LOINC, RxNorm, SPL, openEHR
Data exchange	Structured and free form documents, images, CDA, CCR	HL7, DICOM, ASTM, NCPDP, IEEE, X12N, ISO
Knowledge representation	Guidelines and protocols, Arden Syntax, GLIF, GEM, PRODIGY, PROTIGE, vMR, GELLO, disease management	HL7, ASTM, CEN, openEHR, ISO

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This slide and the next summarize the category of standards, gives examples, and names some of the SDOs creating those standards. You will see some examples that you have not seen before. In the generic use category, OCL is Object Constraint Language which is a language to constrain standards perhaps related to data characteristics, linkages, or use. OWL is Web Ontology Language, and GIS is Geographic Information System or geocoding standards. These groupings will be discussed throughout this component.

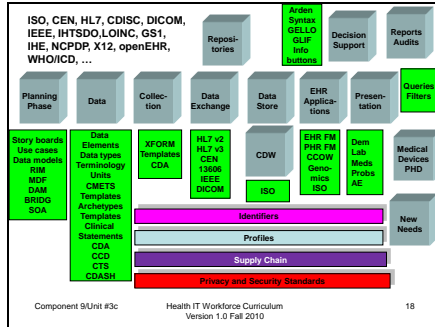
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Category	Examples	SDOs
Electronic Health Record	Functional requirements, content data sets, minimum data sets, EHR models, architecture	HL7, ASTM, CEN, openEHR, ISO
Security and Privacy	Encoding, encryption, authentication, authorization, integrity, digital signature	IETF, OMG, ASTM, HL7, ISO
Application	Identifiers, resource registries, tool sets, conformance requirements, certification, SOA, simulation, implementation manuals	HL7, ASTM, ISO, CEN

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This slide continues to define the categories of standards. In the applications, clinical standards that need technology syntax are beginning to appear in the SDOs we have discussed.

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This very busy graphic also presents a summary of what we have learned in this unit. The cubes represent the categories of standards required for interoperability. The green boxes represent the standards that exist to support the category of standards. The standards contributing to what is required are identified in the upper left of the slide. Story boards and use cases are part of the planning process. MDF is Methodology Development Framework, and DAM is Domain Analysis Model, an important standard/process for planning. Although you may not use these standards formally, you should plan before embarking on any system. We have not mentioned identifiers – person, provider, facility, employer, or health plan, but these identifiers are critical for interoperability. And obviously privacy and confidentiality must be addressed across all of the components and standards.

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Getting access to standards

- Standards Knowledge Management Tool
 - JIC/ISO project sponsored by Universite de Sherbrooke
 - www.skmtglossary.org
 - Most major standards listed
- Duke Center for Best Practices
 - www.ctnbestpractices.org/standards-inventory/

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The two URLs above will provide access to many of the standards we discussed. Navigation might be challenging, but it is worth a look.

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Getting involved

- HIT data standards will continue to evolve, and new standards will be introduced.
- Most standards are created by a consensus process by individuals interested in influencing, developing and using the resulting standards. To participate, join the SDO and participate in the work groups.
- Most SDO provide tutorials and educational opportunities to learn about the standards.

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Standards change continuously. Most standards are in constant evolution as requirements change. We hope you have developed an appreciation for standards and their importance to HIT and the current models for health care.