Standards and Protocols

Foundational Curriculum:
Cluster 6: System Connectivity
Module 10: Interoperability, Interfaces and Integration of eHealth
Unit 4: Standards and Protocols
FC-C6M10U4

Curriculum Developers: Angelique Blake, Rachelle Blake, Pauliina Hulkkonen, Sonja Huotari, Milla Jauhiainen, Johanna Tolonen, and Alpo Värrri
Unit Objectives

• Describe the importance of data standards in the process of data sharing (DDB04)
• Explain the role of technical standards and how those standards support syntactic and semantic interoperability (DDB06)
• Describe the range of technical and clinical standards for information needed to support the creation of interoperable systems (DDB02)
• Describe the relationship of core data elements to health IT/eHealth/health informatics standards and organizational requirements in electronic environments (DDB05)
• Describe how to apply data and IT standards in a healthcare setting (DDB01)
• Describe processes and standards for classification, metadata, and filing structures (DDB07)
• Explain how general acceptance of technical specifications can create de-facto standards without formal recognition (DDB03)
• Describe how standards can improve clinical system usability and reduce risk (DDB08)
• Provide examples of some International standards organisations that influence eHealth, such as: WHO (World Health Organisation) ISO (International Organisation for Standardisation) HL7 (Health Level 7 ) DICOM (Digital Imaging and Communications in Medicine) (DDL01)
Data Standards

• Data standards are the rules by which data are described and recorded

• In order to effectively share, exchange, and understand data, the format as well as the meaning of the data should be standardized. Standards make it easier to create, share, and integrate data by making sure that there is a clear understanding of how the data are represented and that the data that is received are in a form that is expected

• Data standards are the principal component of health informatics that allow the flow of information flow through the healthcare infrastructure
Data Standards in Healthcare

In terms of healthcare, data standards encompass the methods, protocols, terminologies, and specifications for the collection, exchange, storage, and retrieval of information associated with health care applications.

Specifically, healthcare data standards include:

Data elements and content
- the determination of the data content to be collected and exchanged

Data interchange formats
- standard formats for electronically encoding the data elements (includes document architectures for structuring data elements)

Terminologies
- the medical terms and concepts used to describe, classify, and code the data elements, data expression languages and syntax

Knowledge representation
- standard methods for electronically representing medical literature, clinical guidelines, etc., for decision support

This work is produced by the EU*US eHealth Work Project. This project has received funding from the European Union’s Horizon 2020 research and innovation programme under Grant Agreement No. 727552 EUUSEHEALTHWORK
Data Standards in Healthcare (cont’d)

- **Data elements** determine the data content that is collected and exchanged. This defines *what* to collect, *how* to represent the collected data and *how* to encode the data for transmission.
- **Data interchange formats** define the standards for electrical encoding, and include the relationships of data elements in a message.
- **Terminologies** determine all the terms and concepts in medicine and how they are coded in the electrical format, such as SNOMED and LOINC.
- **Knowledge representation** is the standard for representing medical material, such as literature, best practice recommendations, or clinical guidelines, that can be accessed via clinical decision support.
- **HIT standards** are an entity of several different groups of standards, since they are related to both the technical aspect of HIT but also the human-readable consensus.
Data Elements

- Data elements are objects that can be collected, used, and/or stored in clinical information systems and application programs.
  - A data element is considered the basic unit of information in standardization.
  - Each data element has a unique meaning and subcategories of distinct units or values.
  - They include objects such as patient name, gender, and ethnicity; diagnosis; primary care provider; laboratory results; date of each encounter; and each medication.
  - Data elements of specific clinical information, such as blood glucose level or cholesterol level, can be grouped together to form datasets for measuring outcomes, evaluating quality of care, and reporting on patient safety events.

This work is produced by the EU*US eHealth Work Project. This project has received funding from the European Union’s Horizon 2020 research and innovation programme under Grant Agreement No. 727552.

EUUSEHEALTHWORK
Data Elements (cont’d)

Data elements are classified according to standards defined by an international standards organization, which we will discuss in depth later. The organization, ISO/IEC, in registry 11179 states that each data element must have five qualities, including that it:

• should be *registered*
• will be uniquely *identified* within the register
• should be *named* according to Naming and Identification Principles
• should be *defined* by the Formulation of Data Definitions rules
• may be *classified* in a Classification
Data Elements Standardization Process

• At the most basic level, data standards are about the standardization of data elements

• This process includes:
  1. **Data element collection**: defining what to collect
  2. **Data element representation**: deciding how to represent what is collected (by designating data types or terminologies), and
  3. **Data element encoding**: determining how to encode the data for transmission
Data Standards Adoption

• Standards in healthcare are created by several methods. New standards are created by one of four ways:

1. A group of parties in the field agree upon a new standard and it is adopted in the system
2. The government regulates that a new standard needs to be created, and then a group of experts starts building the new standard
3. Market competition introduces a new de facto standard
4. A formal consensus is used by a standard development organization (e.g. ISO)
Importance of Data Standards in the Process of Data Sharing

• Data standards are needed to ensure patient safety and security. Both physical safety as well as privacy are equally important when saving and using medical data.

• Cybersecurity is considered in ensuring system functionality. Outsiders need to be kept out of the system, but intended users need to be able to access and use systems effectively.

• Standardized healthcare makes information systems optimally beneficial for the patient and the user, facilitates clear communication and enables data exchange across organizations.
Technical Standards in Interoperability

- New network complexity brings new challenges to healthcare system interoperability
- **Fast Healthcare Interoperability Resources (FHIR, pronounced "fire")** is a draft standard describing data formats and elements (known as "resources") and an application programming interface (API) for exchanging electronic health records
- The standard was created by the **Health Level Seven International (HL7)** health-care standards organisation in 2014. Level seven refers to the seventh level of the ISO Seven-Layer of Communications Model for Open Systems Interconnection (OSI).
- This standard is based on developer friendly application programming interfaces, and it provides more interoperability between different applications
  - For example unified data formats, XML and JSON are human and machine readable and allow data exchange across systems

This work is produced by the EU*US eHealth Work Project. This project has received funding from the European Union’s Horizon 2020 research and innovation programme under Grant Agreement No. 727552 EUUSEHEALTHWORK
Relationship of data elements and standards and organizational requirements

• Standards and regulations are national and international communications on how the data interoperability should be acquired

• In addition to this, the organizations may have their own requirements of data and its use, so they need to fulfill their expectations but still maintain interoperability to other organizations and applications

• Standards keep interoperability in national and international coordination, thus making interoperability possible
Standards in Data Sharing: Why is it important?

- De-identified healthcare data is important in making global health statistics and studying larger populations for new diagnoses and treatments.
- Patients own their own data, but research is being undertaken to understand how data sharing could have a positive effect on future healthcare.
- Challenges from systems lie in ensuring the privacy and security of patients sharing their information. All information should be de-identified and not trackable to the original individual.
- To ensure these issues are handled, standards exist and are being developed and updated for data sharing between organizations and internationally as well. This is also affected by the current legislation on national and international levels (e.g. the new GDPR privacy legislation in the EU, 2018).
Classification Standards and Processes

- A data classification standard is a framework for sensitivity of data for an organization.
- The classification scheme should apply throughout the enterprise, based on the criticality and sensitivity of enterprise data, from:
  - Top Secret
  - Secret
  - Confidential
  - Restricted
  - Protected
  - Unclassified
- The scheme should include details about:
  - data ownership
  - definition of appropriate security levels and protection controls
  - a brief description of data retention and destruction requirements
  - criticality and sensitivity
- It should be used as the basis for applying controls such as access controls, archiving or encryption.
Classification Standards and Processes (cont’d)

• Data classes have different levels of sensitivity; thus they need to be stored and used in individual and separate ways
• The correct data classification is important to protect patients’ privacy and the operations of the organization
• Loss of confidentiality in data protection could result in:
  – Loss of critical operations
  – Endangerment of patient safety
  – Negative impact and publicity, or damage to the reputation of the organization
  – Regulatory or legal actions
• However, if all data are classified at the highest level of security, organizations would be very slow and rigid, and this would provide no extra benefit

This work is produced by the EU*US eHealth Work Project. This project has received funding from the European Union’s Horizon 2020 research and innovation programme under Grant Agreement No. 727552

EUUSEHEALTHWORK
Use of Metadata

• The simplest definition of metadata is “the data about the data.” AHIMA defines metadata as descriptive data that characterize other data to create a clearer understanding of their meaning and to achieve greater reliability and quality of information.

• Metadata provides the context of healthcare (or other) data. It is important to effectively utilize health information.

Metadata Context of Data
Use of Metadata (cont’d)

• Metadata is divided to four categories:
  – Application metadata: created specific to the application used in the electronic storage. This may be altered if the file is copied
  – Document metadata: includes the properties of the file itself, e.g. document author, creation and revision dates
  – File system metadata: created by the system but stored separately from application metadata, e.g. name, size, usage
  – Embedded metadata: generally hidden but still an integrated part of application metadata. E.g. the tracked changes –option in word

• In a healthcare organization, metadata is important to log, store and trace file attributes, for example, to audit who has had access or made edits to patient files
• Metadata can help monitor that only the appropriate personnel accesses patient files and that patient privacy is maintained
How Standards Support Syntactic and Semantic Interoperability

• Syntactic:
  – Syntactic interoperability enables the exchange of the structure of the data. However, the meaning may not be interpreted identically by all parties.
  – Web pages built with standardized HTML or XML are good examples of machine-to-machine syntactic interoperability because a properly structured page can be read by any machine with a Web browser.

• Semantic:
  – Computable semantic interoperability requires that the meaning of data is unambiguously exchanged from machine to machine.
  – Semantic interoperability ensures the meaning of a structure is unambiguously exchanged between humans.
  – Documents such as progress notes, referrals, consults, and others rely on the specifics of standardized medical vocabularies such as SNOMED and LOINC, and common practice to guarantee semantic interoperability at a clinician-to-clinician level.
Filing Structures of Records

• It is important that healthcare records are filed in a correct location in order to ensure that all information can be found for later use if needed

• This is especially true for scanned, hybrid and legacy paper records (old files or collections of physical papers) that are transformed into electronic health records

• **Physical storage structure** references the correct physical location
  - for example, patient names are listed in alphabetical order and vital signs are recorded in chronological order

• **Electronic storage structure** refers to the use of right forms and formats and possibly key words to structure data. Chronological order can be achieved by entering the correct date to all documents
De-facto Standards in Healthcare

- **De-facto standards** are standards that are not formally regulated, but are adopted from common and functional policies.

- For example, if one organization starts to use a certain type of computers (e.g., Windows-based personal computer), then other organizations adopt this same product for their use and it becomes a de-facto standard.

- Also, other products or policies based on usability and good experiences may become de-facto standards amongst the healthcare centre staff.
International Organizations Influencing eHealth by producing International Standards

- These four international organizations and their relation to standards are introduced on the following slides:
  - World Health Organization (WHO)
  - International Standards Organization (ISO)
  - Digital Imaging and Communications in Medicine (DICOM)
  - Health Level 7 (HL7)
WHO (World Health Organization)

- **WHO** is an international and worldwide organization (more than 150 countries) for improving health and healthcare.
- WHO addresses health problems from chronic illnesses to accidents and improvement of poor living conditions and even financial crises affecting public and global health.
- WHO provides standards for several fields, including electromagnetic fields, child growth assessment, HIT systems, etc. They also participate and facilitate communication of standardization committees and development work (e.g. [http://www.who.int/ehealth/WHO_Forum_on_HDSI_Report.pdf](http://www.who.int/ehealth/WHO_Forum_on_HDSI_Report.pdf)).
ISO (International Organization for Standardization)

- **ISO** is a non-governmental international organization with 162 national standards bodies.
- ISO develops consensus-based and market relevant standards to ensure safety and security of products and innovations globally.
- ISO works in all areas of business and research, also in healthcare including:
  - Innovations, research
  - Healthcare devices and methods
  - Physical safety and security, privacy
- For example: ISO 9000 guidelines for health care sector, ISO 45001 Occupational health and safety.
- ISO web site: [https://www.iso.org/home.html](https://www.iso.org/home.html)
**DICOM (Digital Imaging and Communications in Medicine)**

- **DICOM** is the international standard for medical images and other related information.
- DICOM defines the data formats used for certain images to ensure interoperability of images at different organizations and between imaging device companies.
- Standardized image formats ensure the quality of the images and the appropriate functioning.
- [http://dicom.nema.org/](http://dicom.nema.org/)
• **HL7** is a not-for-profit organization dedicated to provide a comprehensive framework and related standards for electronic health information and its related functions

• For example: Clinical Document Architecture (CDA®)

• HL7 standards are grouped to seven subcategories:
  – Section 1: Primary Standards
  – Section 2: Foundational Standards
  – Section 3: Clinical and Administrative Domains
  – Section 4: EHR Profiles
  – Section 5: Implementation Guides
  – Section 6: Rules and References
  – Section 7: Education & Awareness

Unit Review Checklist

- Described the importance of data standards in the process of data sharing (DDB04)
- Explained the role of technical standards and how those standards support syntactic and semantic interoperability (DDB06)
- Described the range of technical and clinical standards for information needed to support the creation of interoperable systems (DDB02)
- Described the relationship of core data elements to health IT/eHealth/health informatics standards and organizational requirements in electronic environments (DDB05)
- Described how to apply data and IT standards in a healthcare setting (DDB01)
- Described processes and standards for classification, metadata, and filing structures (DDB07)
- Explained how general acceptance of technical specifications can create de-facto standards without formal recognition (DDB03)
- Described how standards can improve clinical system usability and reduce risk (DDB08)
- Provided examples of some International standards organisations that influence eHealth, such as: WHO (World Health Organisation) ISO (International Organisation for Standardisation) HL7 (Health Level 7) DICOM (Digital Imaging and Communications in Medicine) (DDL01)
Unit Review Exercises

1. What four classifications do data standards in healthcare include?

2. What are the three steps of the data elements standardization process?

3. List some of the international standardization organizations in healthcare.

4. Explain de-facto standards and their meaning in healthcare.
1. “Standard formats for electronically encoding the data elements” defines which of the following data classifications?
   a) Data elements
   b) Data interchange formats
   c) Terminologies
   d) Knowledge representation

2. Which is not a quality of a data element?
   a) it should be interpreted
   b) it should be defined
   c) it should be registered
   d) it should be identified

3. What is metadata in healthcare?
   a) Data gathered from patients e.g., heart rate
   b) Institutional data
   c) Contextual data
   d) Organizational data
4. Which of the following lists protected data from most to least protected (some levels may be excluded)?
   a) Top Secret – Confidential – Protected – Unclassified
   b) Restricted – Secret – Protected – Confidential
   c) Protected – Secret – Confidential – Unclassified
   d) Classified – Top Secret – Restricted - Protected

5. Which of the following statements about Fast Healthcare Interoperability Resources is false?
   a) It was developed by HL7 in 2016
   b) The acronym (FHIR) is pronounced like “fire”
   c) It uses APIs, and integrates JSON and XML
   d) based on developer friendly application programming interfaces, and it provides more interoperability between different applications

6. Which of the following statements are true?
   a) Identified, confidential shared patient healthcare data is important in making global health statistics and studying larger populations for new diagnoses and treatments
   b) Physicians and hospitals own patient data; however, research is being undertaken to understand how data sharing could have a positive effect on future healthcare
   c) Challenges from systems include ensuring the privacy and security of patients sharing their information. All information should be de-identified and not trackable to the original individual.
   d) The new GDPR privacy legislation in the EU from 2018 does not address data sharing, privacy or classification