

# Ehealth standards

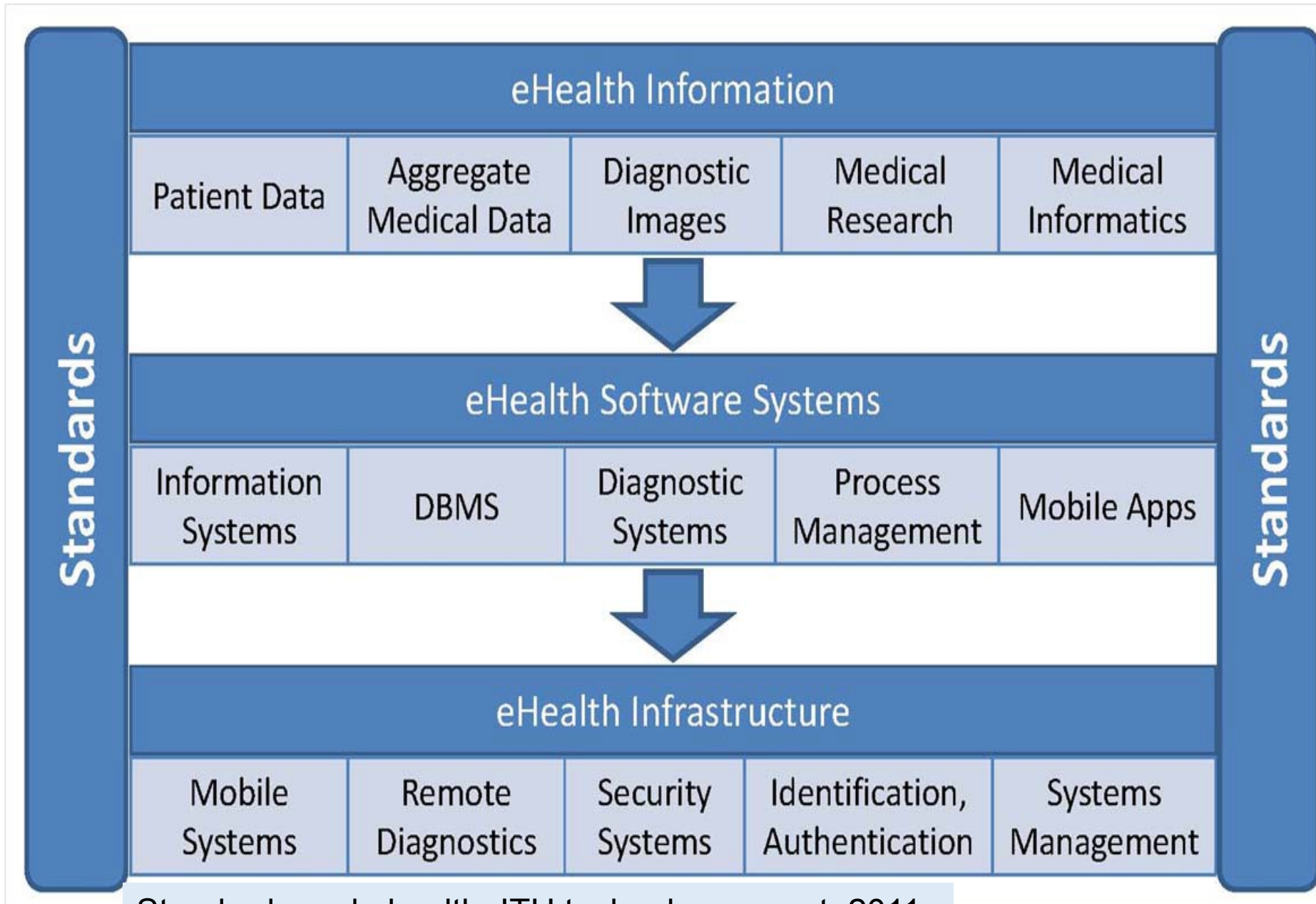
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**Standards are important – they facilitate interoperability among systems and devices, provide unqualified privacy and security, address the unique needs of the developing world, and leverage existing ubiquitous technologies such as social media applications and mobile devices**

- **eHealth standardization** is concerned with the principles of information processing, management and governance of information with the provision of solutions for associated problems in the field of health and care
  - eHealth field has many actors, e.g. a number of very large software producers, with a great many small and medium enterprises operating primarily either in domain niches or in geographic areas

# What is a standard?

- A standard comprises **a set of rules and definitions that specify how to carry out a process or produce a product.**
  - Standard is useful because it provides a way to solve a problem that other people can use without having to start from scratch
  - Generally, standard is useful because it permits two or more actors or systems to apply a generic approach or solution
- **Standard is a thing/ quality / specification by which something may be tested or measured**



# Standards development process

- **1. Ad hoc method**: A group of interested people and organizations agree on a standard specification. These specifications are informal and are accepted as standards through mutual agreement of the participating groups. An example DICOM standard for medical imaging
- **2. De facto method**: A single vendor controls a large enough portion of the market to make its product the market standard. An example is Microsoft's Windows
- **3. Government-mandate method**: A government agency, such as the National Institute for Standards and Technology (NIST) creates a standard and legislates its use
- **4. Consensus method**: A group of volunteers representing interested parties work in an open process to create a standard. Most health-care standards are produced by this method. An example is the Health Level 7 (HL7) standard for clinical-data interchange

# ISO- International standards organisation

- ISO/TR 14639-1:2012 aims to identify the business requirements of an eHealth architecture as well as providing a generic and comprehensive context description to inform architectural structuring of Health Information Systems (HIS).
- ISO/TR 14639-1:2012 reviews international experiences in the construction of national eHealth architectures and introduces a methodology for strategic development of HIS
- **ISO 13606-1:2019: Health informatics — Electronic health record communication — Part 1: Reference model**
- **ISO 13606-2:2019: Health informatics — Electronic health record communication — Part 2: Archetype interchange specification**
- more [www.iso.org](http://www.iso.org)

# CEN TC251- Committee European Normalisation

- TC251 – technical committee for health informatics
- CEN supports standardization activities in relation to a wide range of fields and sectors including: air and space, chemicals, construction, consumer products, defence and security, energy, the environment, food and feed, **health and safety, healthcare, ICT,** machinery, materials, pressure equipment, services, smart living, transport and packaging.
- <https://www.ehealth-standards.eu/centc251/>

# IHE – Integrating the health care enterprise

- IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information
- IHE promotes the coordinated use of established standards such as **DICOM** and **HL7** to address specific clinical needs in support of optimal patient care
- [www.ihe.net](http://www.ihe.net)



# Important standards

- **HL7 – Health level 7**
- The HL7 Version 3 Clinical Document Architecture (CDA®) is a **document markup standard** that specifies **the structure and semantics of clinical documents** for the purpose of exchange between healthcare providers and patients
  - It defines a clinical document as having the following six characteristics:
    - 1) Persistence, 2) Stewardship, 3) Potential for authentication, 4) Context, 5) Wholeness and 6) Human readability.
- CDA can contain any type of clinical content -- typical CDA document is a Discharge Summary, Imaging Report, Admission & Physical, Pathology Report and more
- <https://www.hl7.org/>

# HL7 Reference Information Model (RIM)

- The Reference Information Model (RIM) is the cornerstone of the HL7 Version 3 development process
- RIM is a large, pictorial representation of the HL7 clinical data (domains) and identifies the life cycle that a message or groups of related messages will carry
- It is a shared model between all domains and the model from which all domains create their messages
- <http://www.hl7.org/implement/standards/rim.cfm>

# HL7 FHIR

- FHIR® – Fast Healthcare Interoperability Resources (hl7.org/fhir) – is a **next generation standards framework**
- Fast Healthcare Interoperability Resources (FHIR) is a **standard describing data formats and elements, resources, and an application programming interface (API) for exchanging electronic health records (EHR)**
- FHIR combines the features of HL7's V2 and V3 and CDA® product lines and leverages the latest web standards with a tight focus on implementability
- <https://www.hl7.org/fhir/>

# HIPAA

- The HIPAA - **Health Insurance Portability and Accountability Act**
- **USA** legislation that provides data privacy and security provisions for safeguarding medical information
- Privacy Rule establishes **national standards to protect individuals' medical records and other personal health information** and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically
- <https://www.hhs.gov/hipaa/index.html>

# SNOMED CT - Systematized Nomenclature of Medicine - Clinical Terminology

- **SNOMED CT** - a systematically organized computer processable collection of **medical terms: codes, terms, synonyms and definitions used in clinical documentation and reporting**
- The primary purpose of SNOMED CT is to encode the meanings that are used in health information and to support the effective clinical recording of data with the aim of improving patient care
- SNOMED CT provides the core general terminology for electronic health records
- SNOMED CT comprehensive coverage includes: clinical findings, symptoms, diagnoses, procedures, body structures, organisms and other etiologies, substances, pharmaceuticals, devices and specimens
- <https://www.snomed.org/>

# ICD-10, 11

- The International Classification of Diseases (ICD) is designed to **promote international comparability in the collection, processing, classification, and presentation of mortality statistics**
  - format for reporting causes of death on the death certificate, the reported conditions are then translated into medical codes through use of the classification structure and the selection and modification rules contained in the applicable revision of the ICD, published by World Health Organization (WHO)
  - ICD-11 for Mortality and Morbidity Statistics (ICD-11 MMS <https://icd.who.int/browse11/l-m/en>) published May 2021
- <https://www.cdc.gov/nchs/icd/icd10.htm>

# LOINC

- **LOINC – Logical Observation Identifiers Names and Codes**
- **LOINC** is the world's most widely used terminology standard for health measurements, observations, and documents, a set of identifiers, names and codes
- Reference labs, healthcare providers, government agencies, insurance companies, software and device manufacturers, researchers, and consumers from around the globe use LOINC to identify data and move it seamlessly between information systems
- <https://loinc.org/>

# Use of standards in Finland

- Finland utilizes international standards, mainly these standards belong to the **HL7-standard-family (HL7Finland)**:
  - HL7/ISO CDA R2; HL7 FHIR; HL7 v3 Medical Records;
  - DICOM, IHE XDS, CT etc for national imaging information sharing
- **Several ISO/CEN** originated standards for various eHealth related aspect including general topics and security;
  - XUA / SAML2; JSON / XHTML; NEMESIS as base for national emergency data structures;
  - SNOMED CT and some recommended reference standards by ISO
- **Several international standards** or their localized versions for terminology, e.g. WHO ICD-10 & ICF, LOINC, ATC, ICPC-2, NCSP, MeSH etc as base for nursing classification, various ISO classifications etc

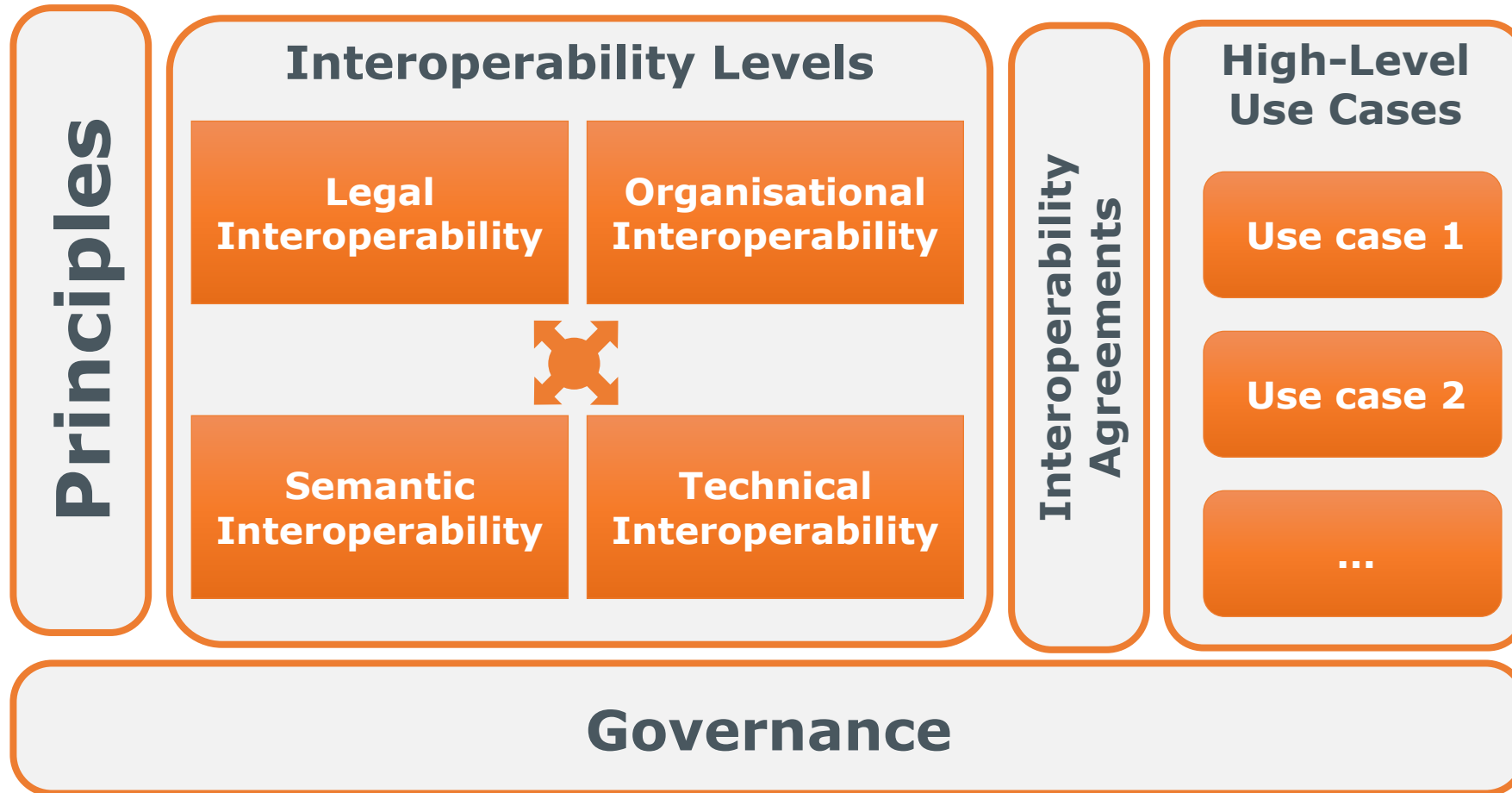


# Summary of standards

- Standards are very helpful, they help in providing **generic solutions and enable interoperability and exchange of data between ISs**
  - HL7 FHIR – EHR information to be exchanged;
  - OpenEHR- storing of information when the systems already are based on openEHR data structure;
  - Unified Modeling Language (UML) – consolidation of information models based on different standards/specifications
- Application is not always easy - Standards may be very abstract level representations, or they may be very detailed and complicated specifications
- **Standards do not all comply with each other !!!.**



## Vision on eHealth EIF structure



# FAIR principles

- **FAIR Guiding Principles for scientific data management and stewardship, 2016**
- The purpose is to provide guidelines to improve the **Findability, Accessibility, Interoperability, Reuse** of digital assets
- The principles emphasise machine-actionability

# Standards used in Tanzania?

- What is the situation?
- National decisions /guidance for the selection /use of standards?

Thank you for your attention!

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