EHR Standards Landscape

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A trans-national eHealth Infostructure

Wellness
Fitness
Complementary health

Citizen in the community

Social care
Occupational health
School health

Teaching
Research
Clinical trials

Education
Research
Epidemiology
Data mining

Point of care delivery

Continuing care
(within the institution)

Long-term shared care
(regional national, global)

Public health
Health care management
Clinical audit

rapid bench to bed translation
real-time knowledge directed care

explicit consent

de-identified
+/- consent

implied consent
Electronic Health Record - EHR 2.0

Clinical trials, functional genomics, public health databases

EHR repositories

Decision support, knowledge management and analysis components

Clinical trials, functional genomics, public health databases

Personnel registers, security services

Clinical devices, instruments

Integrating information

Centring services on citizens

Creating and using knowledge

Social computing: forums, wikis and blogs

Mobile devices

Clinical applications
## 13606 Publication

<table>
<thead>
<tr>
<th>13606 Part Standard</th>
<th>Status in CEN</th>
<th>Status in ISO</th>
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<tbody>
<tr>
<td>1: EHR Reference Model</td>
<td>EN published in February 2007</td>
<td>Published in February 2008</td>
</tr>
<tr>
<td>2: Archetype Interchange Specification</td>
<td>EN published in July 2007</td>
<td>Published in November 2008</td>
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<tr>
<td>3: Reference Archetypes and Term Lists</td>
<td>EN published in February 2008</td>
<td>Published in January 2009</td>
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<td>4: Security</td>
<td>EN published in March 2007</td>
<td>Published as TS in September 2009</td>
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<tr>
<td>5: Interface Specification</td>
<td>ISO and EN published jointly in February 2010 (developed under the Vienna Agreement)</td>
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</table>
ISO/IEC 10746:1998 Information Processing Systems - Open Systems Interconnection -
Basic Reference Model of Open Distributed Processing

- **Enterprise Viewpoint**
  - Business requirements
  - Use Cases
  - System requirements
  - Constraints

- **Information Viewpoint**
  - Interaction diagrams
  - Information models
  - Knowledge models

- **Computational Viewpoint**
  - Interaction diagrams
  - Service models
  - Interface specifications

- **Engineering Viewpoint**
  - Examples:
    - XML Schema
    - Java class package

- **Technology Viewpoint**
  - Examples:
    - Oracle 10i
    - Apache web server
Scope of interoperability standards

Enterprise Viewpoint
- Business requirements
- Use Cases
- System requirements
- Constraints

Information Viewpoint
- Interaction diagrams
- Information models
- Knowledge models

Computational Viewpoint
- Interaction diagrams
- Service models
- Interface specifications

Engineering Viewpoint
- Examples:
  - XML Schema
  - Java class package

Technology Viewpoint
- Examples:
  - Oracle 10i
  - Apache web server
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<tr>
<th>Interoperability standards relevant to the EHR</th>
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<tr>
<td><strong>Enterprise Viewpoint</strong></td>
</tr>
<tr>
<td>ISO 18308 EHR Architecture Requirements</td>
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<tr>
<td>HL7 EHR Functional Model DSTU</td>
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<tr>
<td>ISO 14292 PHRs: Definition, Scope and Context</td>
</tr>
<tr>
<td>EN 13940-1 Systems for Continuity of Care</td>
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<tr>
<td>EN 12967-1 HISA Enterprise Viewpoint</td>
</tr>
<tr>
<td><strong>Information Viewpoint</strong></td>
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<tr>
<td>EHR system reference model openEHR</td>
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<tr>
<td>EHR interoperability Reference Model ISO/EN 13606-1</td>
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<tr>
<td>Clinical content model representation openEHR ISO/EN 13606-2 archetypes</td>
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<tr>
<td>ISO draft 13972 Detailed Clinical Models</td>
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<tr>
<td>ISO 21090 Healthcare Datatypes</td>
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<td>EN 12967-2 HISA Information Viewpoint</td>
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<td><strong>Computational Viewpoint</strong></td>
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<tr>
<td>EHR Communication Interface Specification ISO/EN 13606-5</td>
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<td>EN 12967-3 HISA Computational Viewpoint</td>
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<td>HL7 SOA Retrieve, Locate, and Update Service DSTU</td>
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<td><strong>Security</strong></td>
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<tr>
<td>EHR Communication Security ISO/EN 13606-54</td>
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<td>ISO 22600 Privilege Management and Access Control</td>
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<td><strong>Knowledge</strong></td>
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<td>SNOMED CT</td>
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<td>Archetypes</td>
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Other relevant standards

- ISO 27799 Information security management in health using ISO/IEC 27002
- ISO CD 27789 Audit trails for electronic health records
- ISO 22221 Good principles and practices for a clinical data warehouse
- ISO TS 29585 Deployment of a clinical data warehouse
- ISO DTS 14265 EHR purpose of use
- ISO draft 13119 Knowledge Resources - Metadata
- CEN Concurrent use of EN 13606, EN 12967, and EN 13940
Standards alignment Part 1

- Subset + simplification of openEHR Reference Model
- Preliminary alignment (partial) with CDA R2
- Mapping to relevant portions of EN12967 (HISA)
- Mapping to relevant sections of EN13940 (ContSys)
- Mapping to registry metadata of IHE XDS
- Mapping to HL7 classes for demographics package
- Use of CEN Data types (subset of HL7) as a stepping stone towards use of the ISO data types
- HL7 R-MIM (specialisation of HL7 Clinical Statement) in draft form (needs fine tuning)
Standards alignment Part 2

- Identical to the openEHR Archetype specification
- Requirements have been adopted with minor revision by HL7 Templates
- Archetype model has been explored and a candidate for mapping to HL7 Templates (since 2004)
- Aligns with CEN Metaknow standard
- Partly aligned with ISO 11179
Standards alignment Part 3

- Links term list contains mapping to HL7 Act Relationship codes
- Act status term list mapped to EN12967 HISA
- Includes Reference Archetypes (mappings) to openEHR ENTRY sub-classes
- Includes Reference Archetypes (mappings) to HL7 Clinical Statement Act classes
- Includes a worked example mapping Barthel Index R-MIM to 13606
Standards alignment Part 4

- Aligns with ISO 22600 (PMAC) on a logical level (stated in the standard)
- Fit with several in process security standards has been agreed informally with those leads
- Has been contributed to IHE in defining its privacy management services
- An approach to feeding it into HL7 needs to be determined
Standards alignment Part 5

- A specialisation of HISA services relating to clinical data and to clinical knowledge
- Deliberately limited to payload specification to enable use of messaging paradigm wrappers such as HL7 v3
- Most parts map to IHE XDS query parameters - to be elaborated
- Agreement to incorporate within HL7 via the Services Oriented Architecture TC
  - as a profile of its Resource Location and Update Service (RLUS)
Comparing 13606 with CDA

- CDA is an individual-document exchange message
  - fine for narratives with a few codes, or a fixed structure like CCD
  - advantage includes consistency with rest of HL7 v3
  - some technical artefacts are ready (XML schemata)
  - (although real interoperability yet to be demonstrated)
- CDA documents can be fully represented in 13606
- Parts of 13606 Composition can be mapped to CDA
- The scope of 13606 is broader than CDA
  - 13606 is more appropriate to support a regional or national healthcare network: an EHR federation or data warehouse
- 13606 is archetype-ready
- 13606 includes access control & is PMAC-ready
Relating openEHR and 13606

- openEHR offers a comprehensive and rich EHR architecture, for use within an EHR system or for a regional/national shared EHR
  - using open source software, in active development
  - or as a specification for commercial products
- CEN/ISO 13606-1 offers a simpler, more generic model supporting interoperability between heterogeneous clinical systems and components
  - including HL7 version 3 mappings
- Both support archetypes as the means to represent and share EHR domain knowledge
  - Both separate domain knowledge from generic models
Conclusion: the 13606 EHR Communications standard

- defines a logical model for the core EHR
  - supporting interoperability between heterogeneous systems
  - providing a common view across message paradigms
- meets published EHR requirements
- draws on 15 years of significant R&D
  - including multi-national implementation experience
- draws on two generations of CEN EHR standard
- mapped to HL7 v3
- incorporates archetypes for sharing semantic structures
- offers a framework for sharing disclosure consent and access control information
The content of standards

Scope and requirements

Use cases and interaction scenarios

Information models and semantics

Services, interfaces, messages

R & D results

Health information stakeholders

Implementation experience

Issues requiring further exploration

Education and promotion

Reference implementations
Archetypes need to be quality assured

- If record-sharing communities are to construct safe EHR instances in accordance with archetypes, and to trust EHR data conforming to archetypes, a formal process of verification and certification is needed for archetypes in the same way as EHR systems need to be certified.

- It is important that the design of individual archetypes is an accurate and faithful reflection of good practice for the clinical disciplines in which each of them might be used.
The *openEHR* Foundation

- Oversees the authorship, peer review and governance arrangements for archetype development
- Specifies the requirements for archetype tools and repository services
- Collates and shares the experience of archetype development and use internationally
- Collaborate with other bodies wishing to adopt the archetype approach within products or as part of their e-Health programmes
The contribution of Q-REC

- EuroRec is partnering the openEHR Foundation in developing
  - governance practices for archetype development
  - quality criteria and editorial policies by which certified libraries of EHR Archetypes can be recognised
- The first major analysis of archetype quality criteria and potential certification approaches was published in Q-REC Deliverable 3.3 (July 2008)
Example quality issues

- How can a clinical team lead know that an archetype is clinically trustworthy?
  - is it clear what clinical situations it is to be used for?
  - how inclusive is it of the kinds of patients we treat?
  - is it flexible enough for our needs?
  - what kinds of patients is it intended for? (children?, elderly?)
  - has it been designed with multi-professional input, and with suitable domain experts?
  - what clinical evidence and guidelines does it follow?
  - or, is its model based on an existing well-accepted system?
  - has the archetype been peer reviewed?
  - has it been endorsed by one or more professional bodies?
  - has it been quality labelled by a body that I trust?
Example quality issues

- How can a regional care manager know where an archetype is suitable for use?
  - what clinical use cases has it been designed for?
  - will it be used consistently and safely across care teams?
  - does it align with other archetypes we use: it is clear how they fit together?
  - has it been approved by my national health service?
  - what national data sets does it conform to?
  - what terminologies (and versions) does it bind to?
  - will it align with national audit and governance reporting?
  - how up to date is it?
  - when and who will review and maintain it? how frequently?
  - has it been quality labelled by a body that I trust?
Example quality issues

- How can a CTO or vendor know if an archetype is safe to implement?
  - which use cases and users should have access to it?
  - does it clash with any other archetypes we already implement?
  - does it conform to a technical standard?
  - has it been tested?
  - can I verify the authenticity of the copy I have?
  - can I verify its currency (is it the latest version)?
  - how will I be notified of updates?
  - how are terminology bindings maintained and disseminated?
  - it is published by a certified repository?
  - has it been quality labelled by a body that I trust?
Future contribution of IHTSDO

- Plans for collaboration with IHT SDO
  - to help with implementing governance processes
  - to leverage the semantic structures of SNOMED CT as part of ensuring archetype semantic coherence
  - to help ensure consistency of terminology binding to SNOMED CT
  - to inform the quality processes for SNOMED CT itself