The EHR and Clinical Archetypes: time for clinical engagement!

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What is an Electronic Health Record?

“A repository of information regarding the health status of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users.

It has a standardised or commonly agreed logical information model which is independent of EHR systems.

Its primary purpose is the support of continuing, efficient and quality integrated health care and it contains information which is retrospective, concurrent, and prospective.”

What problems does it help us solve?

- Manage increasingly complex clinical care
- Connect multiple locations of care delivery
- Support team-based shared care
- Deliver evidence-based health care
- Improve safety
  - reduce errors and inequalities
  - reduce duplication and delay
- Improve cost effectiveness of health services
- Manage health care resources more effectively
- Underpin population health and research
- Empower and involve citizens
- Protect patient privacy
Where is EHR information needed?

Citizen in the community
Where is EHR information needed?

- Point of care delivery
- Citizen in the community
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- Point of care delivery
- Continuing care (within the institution)
- Long-term shared care (regional, national, global)
- Citizen in the community
Where is EHR information needed?

- Point of care delivery
- Citizen in the community
- Continuing care (within the institution)
- Public health
- Health care management
- Clinical audit
- Long-term shared care (regional national, global)

Implied consent
Where is EHR information needed?

- **Teaching**
  - Research
  - Clinical trials

- **Education**
  - Research
  - Epidemiology
  - Data mining

- **Point of care delivery**
  - **Citizen in the community**
    - explicit consent

- **Continuing care**
  - (within the institution)
  - **Public health**
    - Health care management
    - Clinical audit
    - implied consent
  - de-identified
  - +/- consent

- **Long-term shared care**
  - (regional national, global)
Requirements the EHR must meet: ISO 18308

ISO/TS 18308

ISO TC 215/SC N
Date: 2008-07-07

ISO DIS 18308 draft
ISO TC 215/SC/WG 8
Secretariat: ANSI

Requirements for an Electronic Health Record Reference Architecture

Warning
This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.
4 EHR ARCHITECTURAL REQUIREMENTS

4.1 BUSINESS REQUIREMENTS

4.1.1 Health system requirements

4.1.2 Clinical practice requirements

4.1.3 Citizen inclusion requirements

4.2 REQUIREMENTS FOR THE REPRESENTATION OF CLINICAL INFORMATION

4.2.1 Kinds of health record entries

4.2.2 Structure of health record entries

4.2.3 The representation of context within health record entries

4.2.4 Intra-record links

4.2.5 The representation of data values within health record entries

4.2.6 EHR data retrieval and views

4.2.7 Representation and support of clinical process and workflow

4.3 COMMUNICATION AND INTEROPERABILITY REQUIREMENTS

4.4 ETHICAL AND LEGAL REQUIREMENTS

4.4.1 Support for legal requirements

4.4.2 Subject of care

4.4.3 Identification and authentication

4.4.4 Health care locations

4.4.5 Dates and times

4.4.6 Version management

4.5 CONFIDENTIALITY REQUIREMENTS

3.40.1 Subject access

3.40.2 Access policies

3.40.3 Policy over-ride

3.40.4 Audit trails

3.40.5 Consents
ISO/TR 20514: “...Logical information model independent of EHR systems...”
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- ISO/EN 13606
  - The simplest possible EHR reference model that still meets all of the requirements
  - It is ideally suited for interoperability between heterogeneous and legacy systems
  - It is the world-wide EHR communications standard
ISO/TR 20514: “...Logical information model independent of EHR systems...”

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- **openEHR**
  - The richest available EHR architecture, and is ideally suited for building a comprehensive EHR system
  - It is an open specification, technically validated
  - It conform to ISO/EN 13606 and extends it for maximum completeness
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- Both are based on the use of archetypes
- Both are now being implemented and used across the world
Core properties of the logical EHR model

- the compositional record hierarchy e.g. the document level, folders and the structure of finer grained entries
- the representation of persons, such as the record subject, authorship, signatures and the information provider
- the definition of dates and times, both real world times when events occurred and the time-stamping of when details were recorded
- instance identifiers and version management properties
- data types to represent coded terms, quantities, dates and times, images etc. consistently
- a role based access control approach, with options for jurisdictional profiles of these
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but, deliberately, no clinical domain knowledge
Goals for EHR semantic interoperability

- To support patient safety, quality of care, chronic disease management, extended home-care, patient empowerment
  - enable the safe, meaningful sharing and combining of health record data between heterogeneous systems and actors / care providers
  - enable the integration and safe use of computerised protocols, alerts and care pathways by EHR systems
  - link EHR data to explanatory and educational materials to support patient and family engagement and professional development
  - ensure the necessary data quality and consistency to enable meaningful and reliable use of longitudinal and heterogeneous data for public health, research, health service management
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Clinical meaning (data, information, knowledge) must be capable of being represented consistently
What is a clinical archetype?
What is a clinical archetype?

- a clinical archetype is an agreed, formal and interoperable specification for representing a given clinical entity such as a clinical observation, a finding, a plan or a treatment within an electronic health record.

- invented and maintained by openEHR
- ratified by CEN: EN 13606 Part 2
- being balloted by ISO
- to be quality labelled by EuroRec
What value do archetypes add?

- A user friendly means to capture and collate professional consensus on how clinical data should be represented
- A formal model of clinical domain concepts
  - e.g. “blood pressure”, “discharge summary”, “fundoscopy”
- Can be published and shared within a clinical community, or globally
- Can be imported by vendors into EHR system data dictionaries
- Defines a systematic EHR target for queries and for decision support
How could we make a clinical archetype?

- Option 1: start from common clinical examples
Archetype for clinical concept:

Pain (symptom)
Examples of Pain Symptoms

• 40 year old female complains of intermittent dull pain in lower abdomen since the last 3 weeks.

• Severe pain in the upper abdomen for five days. Epigastric location, burning in nature, especially occurs at night, in bed.
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Onset

Character
Examples of Pain Symptoms

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- **40 year old female** complains of **intermittent dull pain in the lower abdomen** since the last 3 weeks.

- **Severe pain** in the **upper abdomen** for **five days**. Epigastric location, burning in nature, especially occurs at **night**, in bed.

<table>
<thead>
<tr>
<th>Onset</th>
<th>Location</th>
<th>Duration</th>
<th>Variation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Examples of Pain Symptoms

<table>
<thead>
<tr>
<th>Onset</th>
<th>Location</th>
<th>Duration</th>
<th>Severity</th>
<th>Character</th>
<th>Variation</th>
<th>Maximum intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>

- 40 year old female complains of **intermittent dull pain in lower abdomen** since the last 3 weeks.

- Severe pain in the **upper abdomen** for **five days**. Epigastric location, burning in nature, especially occurs at **night**, in bed.
Symptom description

General description of the pain symptom

Occurrences:
Min: 0
Max: 1
Unbounded

Free text or coded

Internal codes
Terminology
Symptom description
Date/time of onset
Character
Location of body
Severity
Duration
Variation
Date/time of maximum intensity
Now, let's add the terms for “character of pain”
Now, let's add the terms for “character of pain”

- Aching
- Burning
- Colicky
- Cramping
- Crushing
- Deep
- Diffuse
- Dull
- Gnawing
- Heavy
- Sharp
- Shooting
- Stabbing
- Throbbing
Now, let's add the terms for “character of pain”

- Aching
- Burning
- Colicky
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- Crushing
- Deep
- Diffuse
- Dull
- Gnawing
- Heavy
- Sharp
- Shooting
- Stabbing
- Throbbing

For consistency, these terms should be drawn from a terminology, such as SNOMED CT.
<table>
<thead>
<tr>
<th>Description Term</th>
<th>Fully Specified Concept</th>
<th>Hierarchy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finding of pain character (finding)</td>
<td>Finding of pain character (finding) (1625020002)</td>
<td>Clinical findings</td>
</tr>
<tr>
<td>Character of pain (416248011)</td>
<td>Character of pain (attribute) (279114001)</td>
<td>Attributes</td>
</tr>
<tr>
<td>Character of pain (attribute) (672358019)</td>
<td>Character of pain (attribute) (279114001)</td>
<td>Attributes</td>
</tr>
<tr>
<td>Description Term</td>
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<td>Hierarchy</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Finding of pain character (finding) (543655014)</td>
<td>Finding of pain character (finding) (162502002)</td>
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<td>Attributes</td>
</tr>
</tbody>
</table>

**Parent(s):**
(Select a parent to make it the "Current Concept".)
Finding of pattern of pain (finding)

**Current Concept:**
Finding of pain character (finding)

**Child(ren):**
(N=2) (Select a child to make it the "Current Concept").
Finding of affective dimension of pain (finding)
Finding of sensory dimension of pain (finding)
Parent(s):  
(Select a parent to make it the "Current Concept").
Finding of pattern of pain (finding)

Current Concept:
Finding of pain character (finding)

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Finding of affective dimension of pain (finding)
Finding of sensory dimension of pain (finding)

**Parent(s):**
(Select a parent to make it the "Current Concept").
Pain (finding)

**Current Concept:**
Finding of pattern of pain (finding)

**Child(ren):**
(N=18) (Select a child to make it the "Current Concept").
Acute onset pain (finding)
Chronic intractable pain (finding)
Chronic pain (finding)
Constant pain (finding)
Delusional pain (finding)
Diffuse pain (finding)
Finding of pain character (finding)
Gradual onset of pain (finding)
Inflammatory pain (finding)
Intermittent pain (finding)
Localized pain (finding)
Mechanical pain (finding)
Night pain (finding)
Radiating pain (finding)
Referred pain (finding)
Rest pain (finding)
Sclerotomal pain (finding)
Somatic pain (finding)
**Parent(s):**
(Select a parent to make it the "Current Concept").

Finding of pattern of pain (finding)

---

**Current Concept:**

*Finding of pain character (finding)*

---

**Child(ren):**
(N = 2) (Select a child to make it the "Current Concept").

Finding of affective dimension of pain (finding)
Finding of sensory dimension of pain (finding)
**Parent(s):**
(Select a parent to make it the "Current Concept").
Finding of pattern of pain (finding)

**Current Concept:**
Finding of pain character (finding)

**Child(ren):**
(N=2) (Select a child to make it the "Current Concept").
Finding of affective dimension of pain (finding)
Finding of sensory dimension of pain (finding)

---

**Parent(s):**
(Select a parent to make it the "Current Concept").
Finding of pain character (finding)

**Current Concept:**
Finding of affective dimension of pain (finding)

**Child(ren):**
(N=4) (Select a child to make it the "Current Concept").
Fearful with pain (finding)
Punishing with pain (finding)
Sickening with pain (finding)
Tiring with pain (finding)
Parent(s): (Select a parent to make it the "Current Concept").
Finding of pattern of pain (finding)

Current Concept:
Finding of pain character (finding)

Child(ren): (N=2) (Select a child to make it the "Current Concept").
Finding of affective dimension of pain (finding)
Finding of sensory dimension of pain (finding)

Parent(s): (Select a parent to make it the "Current Concept").
Finding of pain character (finding)

Current Concept:
Finding of affective dimension of pain (finding)

Child(ren): (N=4) (Select a child to make it the "Current Concept").
Fearful with pain (finding)
Punishing with pain (finding)
Sickening with pain (finding)
Tiring with pain (finding)

Parent(s): (Select a parent to make it the "Current Concept").
Finding of pain character (finding)

Current Concept:
Finding of sensory dimension of pain (finding)

Child(ren): (N=6) (Select a child to make it the "Current Concept").
Catch (finding)
Deep pain (finding)
Exquisite pain (finding)
Griping pain (finding)
Pricking pain (finding)
Superficial pain (finding)
Query: Pain character, Snomed, en-GB, Prune = true

-Tree: -Is a; Root = Passthrough; Burning pain; Default = Select
-Tree: -Is a; Root = Passthrough; Pain character - finding; Default = Select
  -Special Node: Exclude
    -Concept Id: Must Match "Finding of affective dimension of pain"
  -Special Node: HoistChildren
    -Concept Id: Must Match "Finding of sensory dimension of pain"
-Concept: Gnawing pain, Select
-Tree: -Is a; Root = Passthrough; Pain by sensation quality; Default = Select
-Tree: -Is a; Root = HoistChildren; Sharp pain; Default = Select

Excluded Concepts:
-Concept: Burning feet
-Concept: Pain character NOS
-Concept: Shooting headache
-Concept: Dull chest pain
-Concept: Crushing chest pain
How could we make a clinical archetype?

- Option 1: start from common clinical examples
- Option 2: clinical brainstorming and many, comprehensive, examples
Example of a complex symptom

- 56 year old woman, one week prior to admission noticed the **abrupt onset** of **chest pain** which she describes as **dull** and **aching** in character. The pain **began in the left para-sternal area** and **radiated up** to her neck.

  Her discomfort was **accompanied by shortness of breath**, but had **no associated symptoms** like sweating, nausea, or vomiting. The pain **lasted approximately 5 to 10 minutes**. She has had one **additional episode** of pain 3 days back, similar in quality and location to the first onset episode.

  No change in the pain with movement, **no association with** food, no palpable pain.
Detailed symptom archetype: openEHR.org
Too small or too big?

- Symptom description
  - Date/time of onset
  - Character
  - Location of body
  - Severity
  - Duration
  - Variation
  - Date/time of maximum intensity

- Date/time of onset
- Clinical description
- Location
  - Location in body
- Severity
- Current intensity
  - Degree
  - Visual analogue score
- Duration
- Number of occurrences
- Character
- Variation
  - Variation
  - Variation details
- Course
  - Onset type
  - Onset description
- Precipitating factors
  - Common precipitating factor
  - Other precipitating factor
- Date/time of maximum intensity
- Progression
- Modification
- Cessation
  - Cessation description
- Associated symptoms and events
- Features not present
- Previous episodes
Too small or too big?

How many examples do we need to consider before the archetype is COMPLETE ENOUGH?
Too small or too big?

How many examples do we need to consider before the archetype is COMPLETE ENOUGH?

How much of a pain description is USEFUL to SYSTEMATISE?
How could we make a clinical archetype?

- Option 1: start from common clinical examples
- Option 2: clinical brainstorming and many, comprehensive, examples
- Option 3: start from priority use cases
  - identify what most needs to be captured and shared to improve quality and safety
Recommended priority use cases: for safe shared care

- New medication prescriptions
  - requiring comprehensive information on concurrent medication and details of known allergies and conditions (not simple ETP)
- Reminders and prompts
  - for overdue or overlooked health care actions and interventions
- Evidence based care
  - the use of clinical guidelines and other forms of evidence to determine the optimal management strategy and care pathway for a given patient
- Care transfers
  - referrals and within-team workflow such as the degree of urgency and the expectations of the referring clinician from another team member
- Care co-ordination
  - ensuring that a high-level view can be taken of distributed (multi-team) care to protect against duplication, delay and incompatible interventions
- Medical summaries
- Personal Health Records
Example: diabetes mellitus

- High cost and increasingly prevalent condition
- Evidence of improved outcomes and lower costs if control is well managed and complications detected early
- Benefits from multi-professional input
- Care usually managed by many actors on different sites
- Information often not shared well between teams, resulting in inefficient care and gaps
- Good consensus (internationally) on the key indicators of clinical quality and patient risk
- Good consensus (internationally) on the data sets needed to monitor care
Diabetes in the UK (Source: NHS)

- 1.8m people in the UK are diagnosed with diabetes
- Predicted to grow to more than 2.5m by 2010
- Diabetes accounts for an estimated 5% of all NHS expenditure
- Diabetes Continuing Care Reference data set published by NHS, being used to direct systems used to manage diabetes reviews and screenings
NHS Diabetes Continuing Care Reference data set

Demographics
Diabetes diagnosis background
Risk factors and lifestyle risk factors
Current vital signs, weight, BMI
Blood measurements: glucose, HbA1c, Lipids etc.
Urine measurements: protein etc.
Cardiovascular conditions and complications
Cardiovascular risk scores
Eye examination: visual acuity, retinal screening
Foot examination: colour, skin, pulses, vibration, sensation, deformity
Renal failure assessments
Sexual health
Psychological health
Medication
Non-drug therapy
Lifestyle and wellness management
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Non-drug therapy
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openEHR archetype for fundoscopy (retinal examination)

<table>
<thead>
<tr>
<th>Rows</th>
<th>Left eye</th>
<th>Right eye</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Description</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>Red reflex present</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>Description of lens</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>Description of optic disc</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>Papilloedema present</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>Description of macula</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>Description of retinal arteries</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>Description of retinal veins</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>'Cotton wool' artefacts</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>Retinal haemorrhages</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>Description of background</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>Description of Vitreous humour</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>Ease of Visualisation</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
<tr>
<td>Description of visualisation</td>
<td>(Left eye)</td>
<td>(Right eye)</td>
</tr>
</tbody>
</table>
Archetypes need to be quality assured

- 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 is partnering the EuroRec Institute in developing
  - good practice 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)
Archetype development check-points

- Identify a priority clinical use case for shared EHRs
- Identify key stakeholders
- Define the patient journey
- Identify shared care quality and safety needs
- Assemble the evidence
  - especially pre-agreed data sets, established consensus
- Define the archetypes, and bind to terminology
  - collaborate with openEHR Archetype Editorial Group & IHTSDO
- Validate with diverse but realistic examples
- Publish for peer review
  - specifically target key bodies to undertake the review
- Engage vendors to validate implementability
- Seek a EuroRec quality label
Getting clinical engagement right
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- Solve real clinical information gaps
  - join up virtual teams to improve safety and shared care
  - define the benefits right at the start
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Getting clinical engagement right

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Getting clinical engagement right

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- No need to structure everything
  - start by codifying the data that can be computationally exploited
  - narrative is good for human to human communication
Getting clinical engagement right

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- Quality assure archetypes before they are used
Getting clinical engagement right

• Solve real clinical information gaps
  • join up virtual teams to improve safety and shared care
  • define the benefits right at the start
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• No need to structure everything
  • start by codifying the data that can be computationally exploited
  • narrative is good for human to human communication
• Quality assure archetypes before they are used
• Pilot in real settings before wide roll out