

# **Quality requirements for EHR Archetypes**

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# What is an Electronic Health Record?

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- **“one or more repositories, physically or virtually integrated, of information in computer processable form, relevant to the wellness, health and health care of an individual, capable of being stored and communicated securely and of being accessible by multiple authorised users, represented according to a standardised or commonly agreed logical information model. Its primary purpose is the support of life-long, effective, high quality and safe integrated health care”**

- Kalra D, Editor. Requirements for an electronic health record reference architecture. ISO 18308. International Organisation for Standardisation, Geneva, 2011

# Interoperability standards relevant to the EHR

## Business requirements

ISO 18308 EHR Architecture Requirements  
HL7 EHR Functional Model  
ISO EN 13940 Systems for Continuity of Care  
ISO EN 12967-1 HISA Enterprise Viewpoint

## Information models

EHR system reference model *openEHR*  
EHR interoperability Reference Model ISO/EN 13606-1  
HL7 Clinical Document Architecture  
Clinical content model representation *openEHR* ISO/EN 13606-2 archetypes  
ISO 21090 Healthcare Datatypes  
ISO EN 12967-2 HISA Information Viewpoint

## Computational services

EHR Communication Interface Specification ISO/EN 13606-5  
ISO EN 12967-3 HISA Computational Viewpoint  
HL7 SOA Retrieve, Locate, and Update Service DSTU

## Security

EHR Communication Security ISO/EN 13606-4  
ISO 22600 Privilege Management and Access Control  
ISO 14265 Classification of Purposes of Use of Personal Health Information

## Clinical knowledge

Terminologies: SNOMED CT, etc.  
Clinical data structures: Archetypes etc.

# The semantic interoperability challenge

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- **To support patient safety, quality of care, chronic disease management, extended home-care, patient empowerment**
- **Many clinical systems can today achieve semantic interoperability using data that has been captured within their own applications, because the organisation and meaning of the data can be dictated in advance by each system designer**
- **Semantic interoperability is most needed when EHR data are to be shared and combined from different systems (or across modules within a large system)**

# What is a clinical archetype?

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- **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 in Europe EN 13606 Part 2**
- **then internationally ISO 13606 Part 2**
- **to be quality labelled by EuroRec**

# What value do archetypes add?

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- **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**
- **Defines a systematic EHR target for queries and for decision support and facilitate EHR interoperability**

# Examples of Pain Symptoms

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- **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.**

# Examples of Pain Symptoms

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- 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.

Duration

Location

Onset

Maximum  
intensity

Character

Severity

Variation



Archetype file name:

openEHR-EHR-EVALUATION.Symptom\_pain.v1draft



Header **T** Symptom description

Data

Tree



Constraint Details

Occurrences

Min:  Max:   Unbounded

Description:

Runtime name constraint:

Free text or coded  Internal codes  Terminology

**T** Symptom description

**T** Date/time of onset

**T** Character

**T** Location of body

**T** Severity

 Duration

**T** Variation

 Date/time of maximum intensity

## Now, lets add the terms for “character of pain”

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

For consistency, these terms should be drawn from a terminology, such as SNOMED CT

## Example of a complex symptom

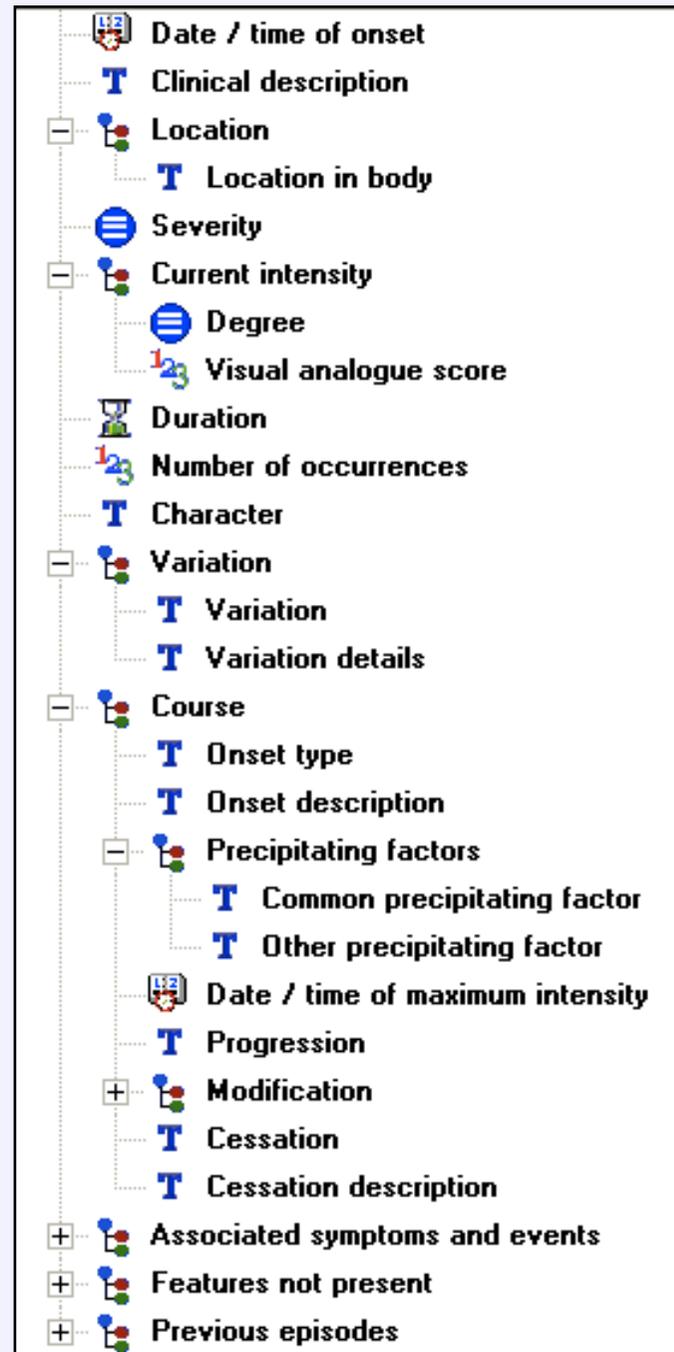
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56 year old woman, one week prior to admission noticed the **abrupt onset** of **chest pain** which she describes as **dull** and **aching** in character. The pain **began in the left para-sternal area** and **radiated up** to her neck.

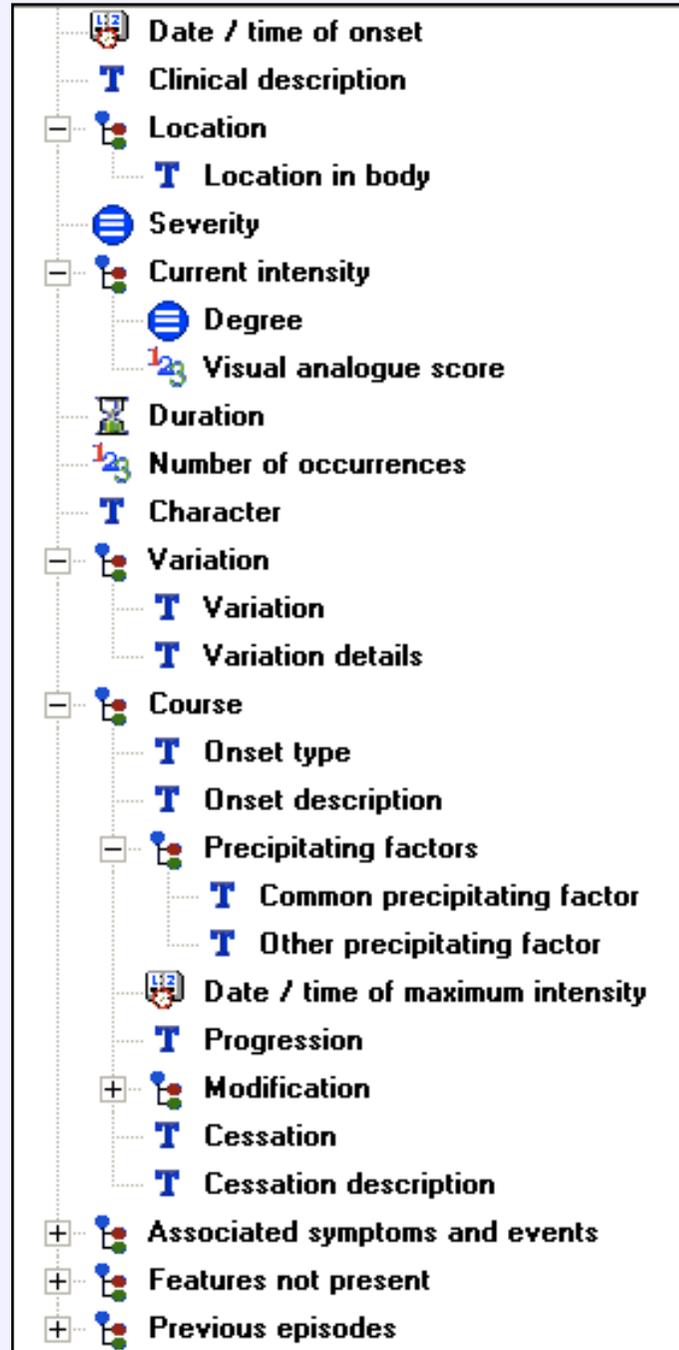
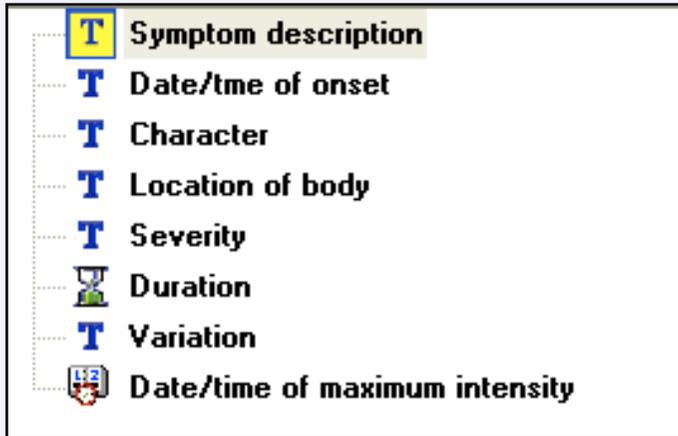
Her discomfort was **accompanied by shortness of breath**, but had **no associated symptoms** like sweating, nausea, or vomiting. The pain **lasted approximately 5 to 10 minutes**. She has had one **additional episode** of pain 3 days back, similar in quality and location to the first onset episode.

No change in the pain with movement, **no association with** food, no palpable pain.

# Detailed symptom archetype: *openEHR.org*



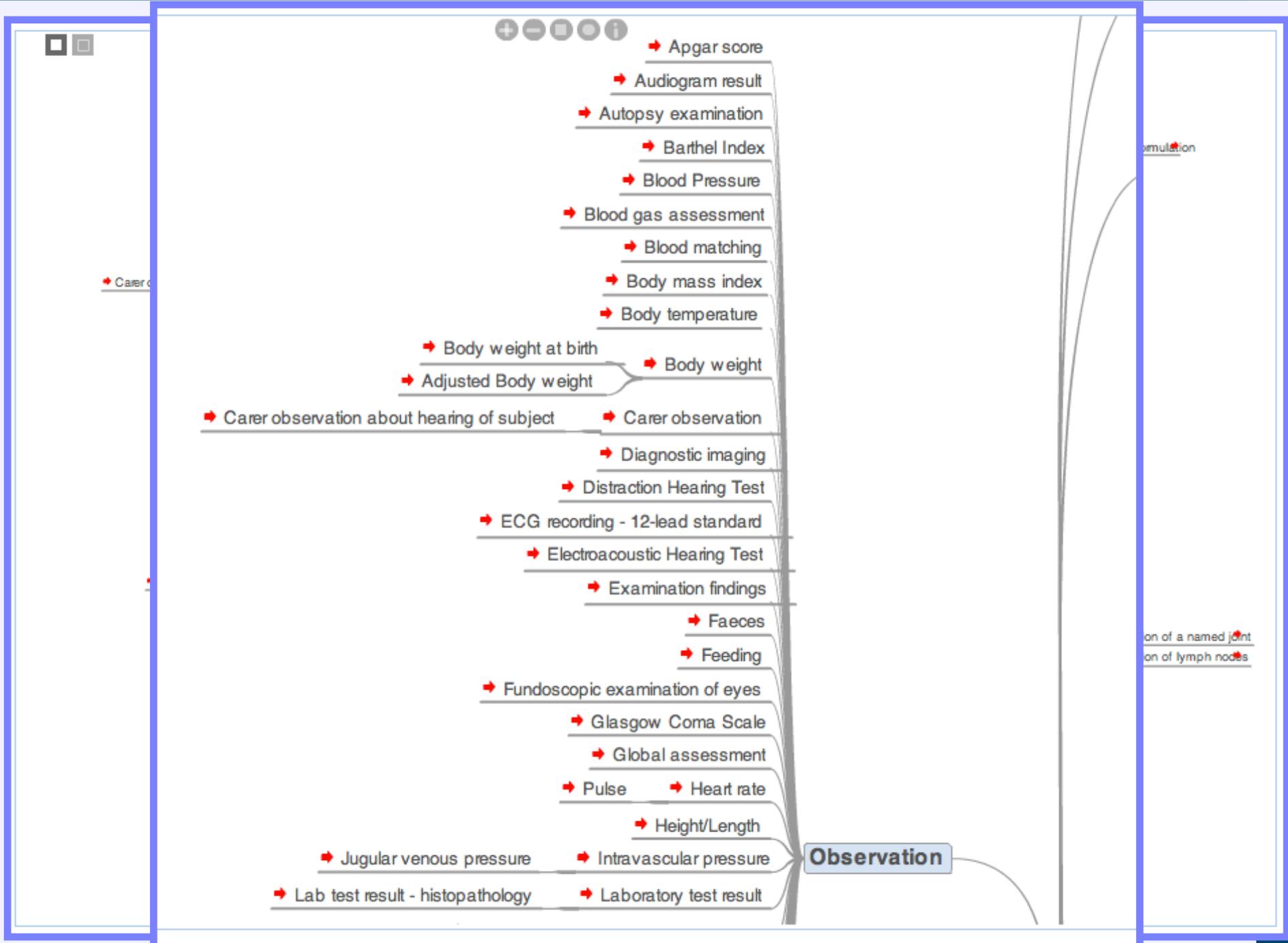
# Too small or too big?



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

How much of a pain description is USEFUL to SYSTEMATISE?

# A growing library of archetypes



# Archetypes need to be quality labelled



- **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**

# 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

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- **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?

# Archetype development checkpoints

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- **Identify priority clinical use cases for shared EHRs**
- **Involve a wide range of working clinicians and encourage multi-professional input**
- **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
- **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**