

The Electronic Health Record

CEN 13606, openEHR and Archetypes

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Why do we need EHRs ?

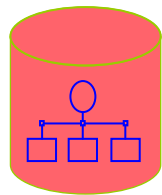
- Manage increasingly complex clinical care
- Connect multiple locations of care delivery
- Deliver evidence-based health care
- Reduce errors and inequalities
- Reduce duplication and delay
- Underpin population health and research
- Empower and involve citizens in their health agenda
- (Maybe reduce healthcare costs)

What makes a good EHR ?

10 quality criteria

1. Comprehensive
2. Faithful
3. Life-long (and beyond)
4. Medico-legally rigorous
5. Educating
6. Supporting diverse cultures and professions
7. Capable of evolution
8. Empowering and respecting
9. Appropriately ubiquitous
10. Capable of interoperability

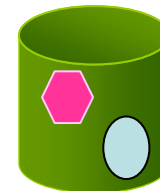
Clinical trials,
functional genomics
and inherited genotype



EHR systems
and servers



Decision support,
knowledge management
and analysis components



Personnel registers,
security services



Mobile devices



Clinical devices,
instruments



Clinical
applications

Many things are maturing together

- Distributed access to EHRs is now part of many national strategies
- A new generation of health informatics standards is emerging
- Open source reference EHR systems will stimulate confidence in solutions and stimulate the market
- Archetypes will help broker semantic interoperability

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Scope of EN 13606

- To produce a rigorous and durable information architecture for communicating the EHR
- in order to support the interoperability of systems and components that need to interact with EHR services
 - as discrete systems or as middleware components
 - to access, transfer, add or modify health record entries
 - via messages or distributed objects (services)
 - preserving clinical meaning
 - protecting confidentiality

Parts of EN 13606

Part 1: Reference Model

- comprehensive, generic model for communicating part or all of an EHR

Part 2: Archetype Specification

- adopting the *openEHR* archetype approach
- constraint-based approach for defining clinical “business objects” that are built from the Reference Model

Part 3: Reference Archetypes and Term Lists

- initial set of archetypes for use across Europe
- vocabularies for the Part 1 model

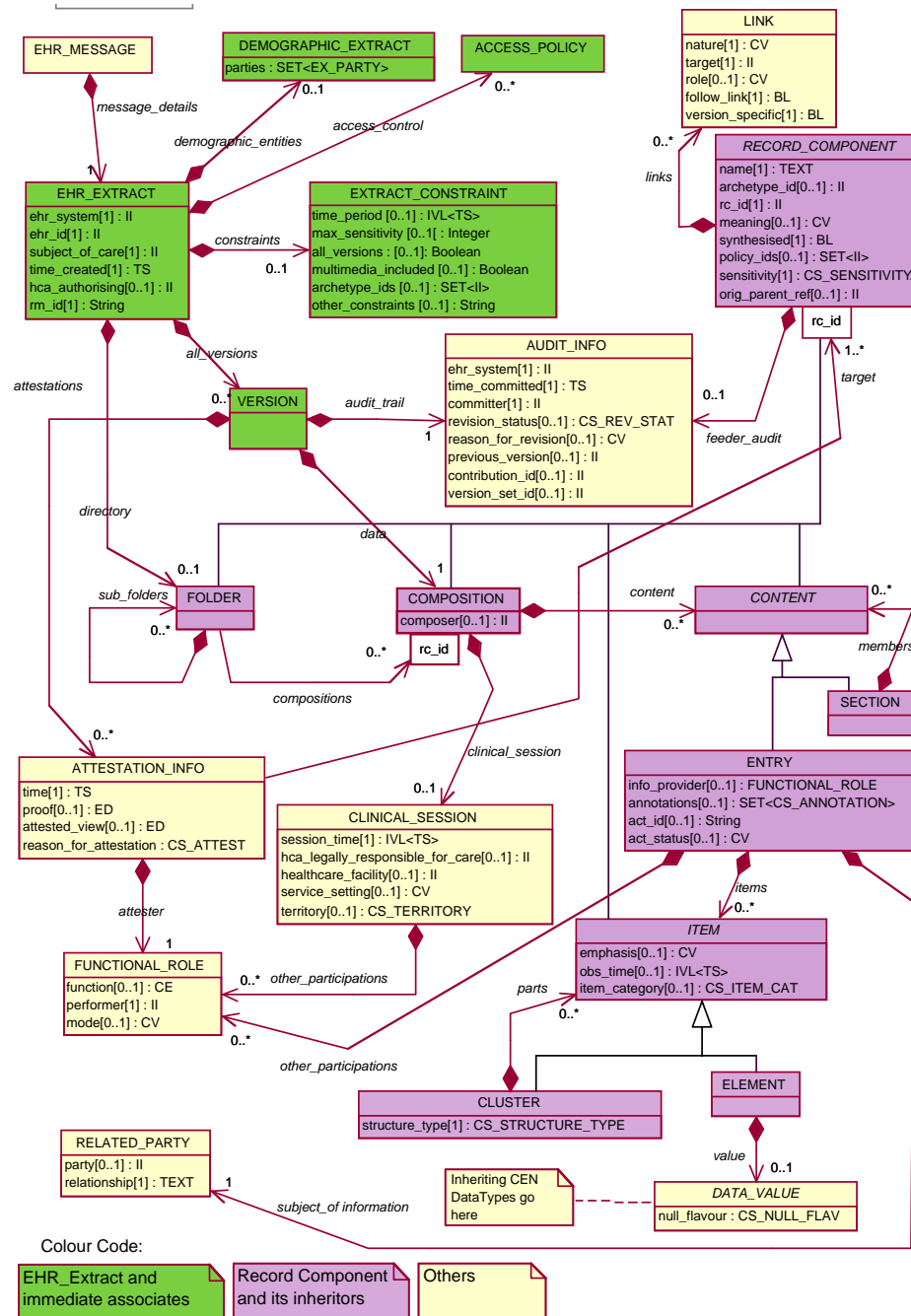
Part 4: Security

- measures to support access control, consent and auditability of EHR communications

Part 5: Exchange Models

- message and service interfaces to enable EHR and archetype communication

13606-1 Reference Model



On what basis has 13606 been developed?

- Research results
- Implementation experience
- Formal statements of requirement
- Previous EHR standards
- Feedback on successive drafts via an RFC process
- Review of, and harmonisation with, complementary CEN, ISO and HL7 standards

research results

design of the
13606
EHR reference
model

Example EHR research projects 1991-2005

- GEHR requirements and architecture
- EHCR SupA recommendations to CEN
- Synapses and SynEx federated health record services
- HANSA and its ancestors (RICHE, Nucleus, EDITH)
- InterCare and PICNIC tele-health record systems
- I4C integrated cardiac records, based on ORCA
- Domain specific work: DIABCARD, TELENURSE, MEDICATE
- HARP security and record components
- PROREC - EHR requirements, vendor and user networks
- New research projects in bio-informatics and genomics
- Many other projects....

Research inputs related to the EHR

1991-2005

- clinical and ethical requirements
- comprehensive EHR architectures
- federated health record services
- middleware components relating to guidelines and terminology services
- distributed tele-monitoring, decision support, alerting systems
- interaction with security services
- widely distributed services, wireless, IPv6, the Grid
- clinical data repositories, public health and research
- bioinformatics, genomics and clinical trials

research results

implementation
experience,
vendor input

design of the
13606
EHR reference
model

Examples of vendor experience/input

Based on ENV13606 (1999-2003)

- DocuLive (Siemens, Norway)
- Integrated Care Systems France (France)
- Systematic (Denmark)
- Ethidium (US)

Generic EHR systems

- Health.one (Belgium): most recently used as the EHR for the Special Olympics
- Microdata (Luxembourg)
- Distributed Systems Technology Centre (Australia)
- Ocean Informatics (Australia)
- Royal Marsden Hospital (UK)

Academic implementations of ENV13606 with live clinical use

- University College London: Java record server: cardiology
- University of Athens: Janaemia system
- Trinity College Dublin: intensive care monitoring
- University Hospital of Geneva (DIOGENE: main record cache)

Plus many national projects

openEHR implementation experience

1992

Clinical and ethical requirements, generic EHR architecture



Java record server and
(Archetype) Object Dictionary
Oracle and ObjectStore storage
Legacy data migration

Eiffel record server kernel
Matisse storage

Visual Basic Archetype Editor

Web and WAP applications
Anticoagulant advisory system
Chest pain & heart failure system
Live clinical use

GP system interfaces

OACIS hospital laboratory
database migration

2004

IPv6 and grid demonstrators

Diabetes shared care

openEHR specifications

input to and drawing from the CEN 13606 work

research results

implementation
experience,
vendor input

design of the
13606
EHR reference
model

published requirements

Requirements specifications

- ISO TS 18308 Requirements for an Electronic Health Record Architecture has been the main requirements basis for 13606
- Complementary requirements have been reviewed from published literature
- HL7 EHR Functional Specification
 - Infrastructure Requirements are most pertinent to the EHR Reference Model

Mapping to ISO TS 18308 defined within Annex E

prEN 13606-1:2004 (E)

Annex E (informative)

Mapping to statements of requirement

	<i>Recording dates and times</i>	
MEL1.1	The EHRA shall support measures to ensure an accurate reflection of the chronology of clinical events and information availability in the EHR. (6.3)	Composition.Audit_Info.time_committed, Composition.Audit_Info.contribution_id, Record Component.Audit_Info.time_committed
MEL2.7	The EHRA shall support measures which ensure that every record entry is dated, and its author identified. (6.1.6)	Composition.Audit_Info.time_committed, Composition.Audit_Info.contribution_id, Record Component.Audit_Info.time_committed
STR3.15	The EHRA shall support the recording of contextual data associated with the date/time the event was committed to the record	Composition.Audit_Info.time_committed, Record_Component.Audit_Info.time_committed
STR3.14	The EHRA shall support the recording of contextual data associated with the date/time the event occurred	Composition.Clinical_Session.session_time
	<i>The Amendment of Health Record Entries</i>	
PRO2.1	The EHRA shall support clear and consistent rules for entry, amendment, verification, transmittal, receipt, translation, and obsoleting/superceding of data. This requirement does not imply that it is necessary for a given implementation to allow deletion of EHR content. Local data retention rules will apply. (3.3.1)	each version is a new Composition instance, with Composition.Audit_Info attributes defining the new point of committal and referencing the previous version and including a reason for the revision
MEL7.1	The EHRA shall support versioning at the granularity at which information is attested (6.8)	Whole set of committed entries must be re-attested if parts of content are revised. Version.attestations point to data within a single Composition version, and are not automatically redirected to a revised one

(containing collaborative multi-disciplinary care and care management across different healthcare sectors and settings (e.g. primary care, acute hospitals, allied health, home-based care)) (5.2.3) Entry other participations

EHRS It must be possible to identify the source (code system) for any entry in a patient's EHR

research results

implementation
experience,
vendor input

design of the
13606
EHR reference
model

published requirements

previous
& current
CEN
standards

CEN standards inputs

- 2 generations of CEN EHR interoperability standard
 - ENV12265 (1995)
 - ENV13606 (1999)
- CEN cross working group activities
 - information models
 - concept representation (archetypes)
 - continuity of care
 - security

research results

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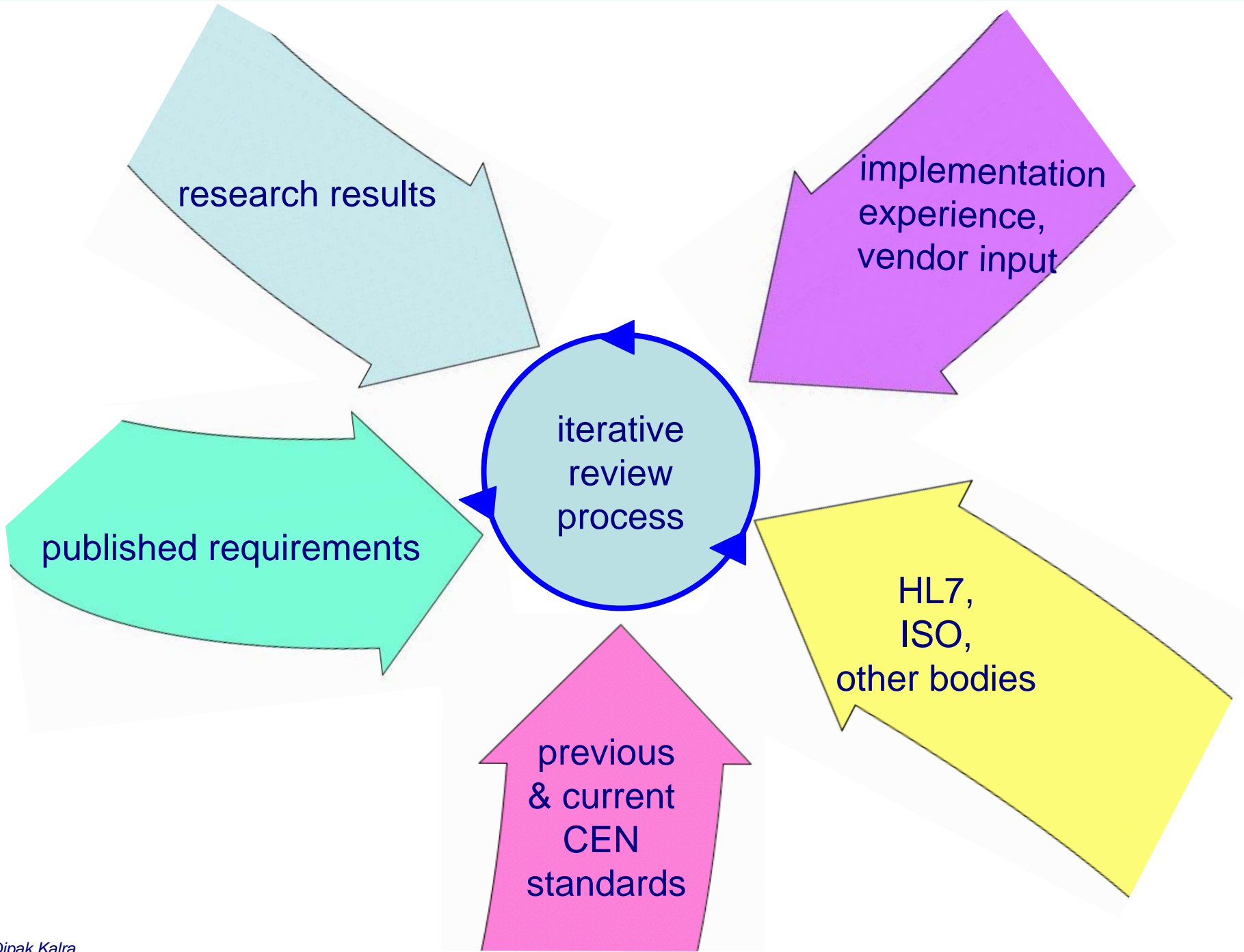
published requirements

HL7,
ISO,
other bodies

previous
& current
CEN
standards

Wide standards inputs

- HL7
 - Clinical Document Architecture
 - Clinical Statement model
 - Template requirements, representations, registry
- ASTM: CCR
- CORBAmed: COAS
- ISO
 - Privilege Management and Access Control
 - 17799: guidelines for use in health care



Harmonisation with other related standardisation efforts

- CEN
 - Healthcare Information Systems Architecture (HISA)
 - Systems of concepts for continuity of care (CONTSYS)
 - General Purpose Information Components (GPICs)
 - CEN data types
- ISO
 - ISO TS 18308 requirements adopted as the official requirements basis for the standard
 - 13606 has been related to concepts defined in ISO DTR 20514
 - Access control approach maps to Privilege Management and Access Control draft standard

Harmonisation with other related standardisation efforts

- HL7
 - Clinical Document Architecture: detailed cross-mapping
 - A formal 13606-1 HL7 D-MIM has been produced
 - 13606 is being mapped into Patient Care Provision message
 - Templates: working together on a joint CEN/HL7 archetype specification
 - Clinical Statement model: contributing to its design
- IHE
 - XDS specification: mapping to registry metadata
 - XDS supports the EHRcom Composition & Folder

Many things are maturing together

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- A new generation of health informatics standards is emerging
- **Open source reference EHR systems will stimulate confidence in solutions and stimulate the market**
- Archetypes will help broker semantic interoperability

Why *open*EHR ?

A good quality open source EHR reference implementation is needed

- to promote a non-proprietary approach to the representation and communication of EHRs
- to grow international (technical and clinical) communities of interest in the promotion of good EHR systems
- as a highly-visible proof that the generic information architecture approach is valid and scalable
- to establish implementations in diverse settings (and learn from them)
- to show how the interoperable EHRs can be implemented
 - offered as a basis from which industry can build commercial equivalents

*open*EHR Foundation

www.openehr.org

- a non-profit organisation
 - jointly formed in 2000 by UCL (UK) and Ocean Informatics (AUS)
- uniting an international community working towards the realisation of electronic health records which are:
 - clinically comprehensive and ethico-legally sound
 - interoperable and standards-based
 - implemented as open-source components
- to support seamless and high quality patient care

*open*EHR methodology

*open*EHR

Requirements

Design principles

Formal models

Open Source reference implementations

Demonstrator sites

Evaluation

EuroRec
relationships with
user communities

CEN, HL7, ISO
development and
use of standards

*open*EHR research pedigree

1992

Good European Health Record: requirements and EHR architecture



EHCR SupA:

revised requirements and architecture

Synapses:

FHR and Clinical Object Dictionary

SynEx:

middleware component architecture

Medicate:

remote asthma monitoring and alerts

Good Electronic Health Record

GPGC project (1):

EHR kernel services

GPGC project (2):

legacy data transformation

GPGC project (3):

diabetes extraction and merge

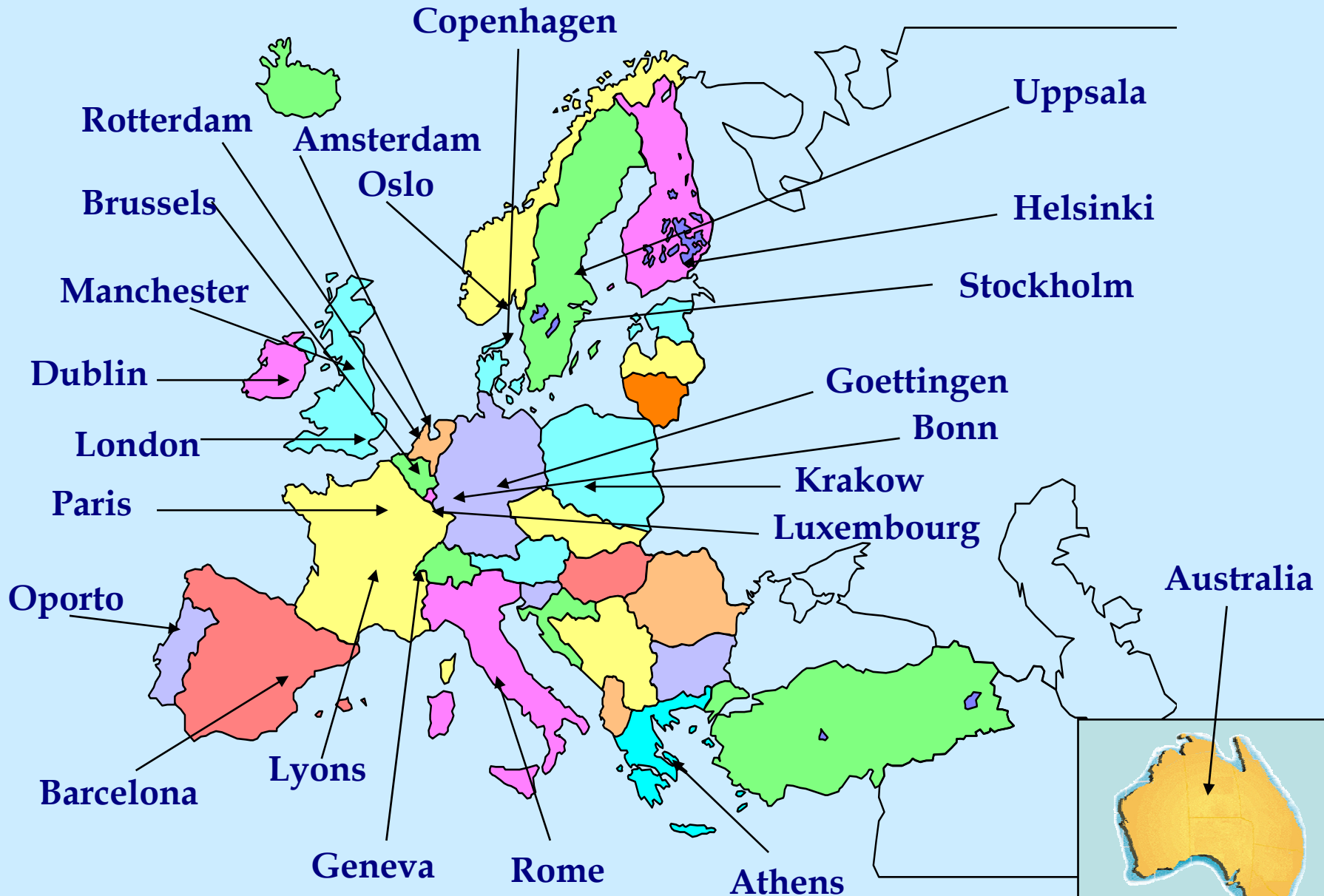
2004

6WINIT: wireless IPv6

mNET: wireless demonstrator

*open*EHR

Contributing EHR demonstrator sites



Engaging with standards

- Key membership and leadership of EHR standards development:
 - CEN 13606 EHR Communications
 - CEN TS 14796 Data Types
 - ISO TS 18308 (EHR Requirements)
 - ISO DTR 20514 (EHR definition and scope)
 - HL7 EHR Functional Specification
 - HL7 Templates specification
 - HL7 Clinical Document Architecture
- Adopting standards within *openEHR* components
- Contributing to next-generation standardisation

openEHR architecture features

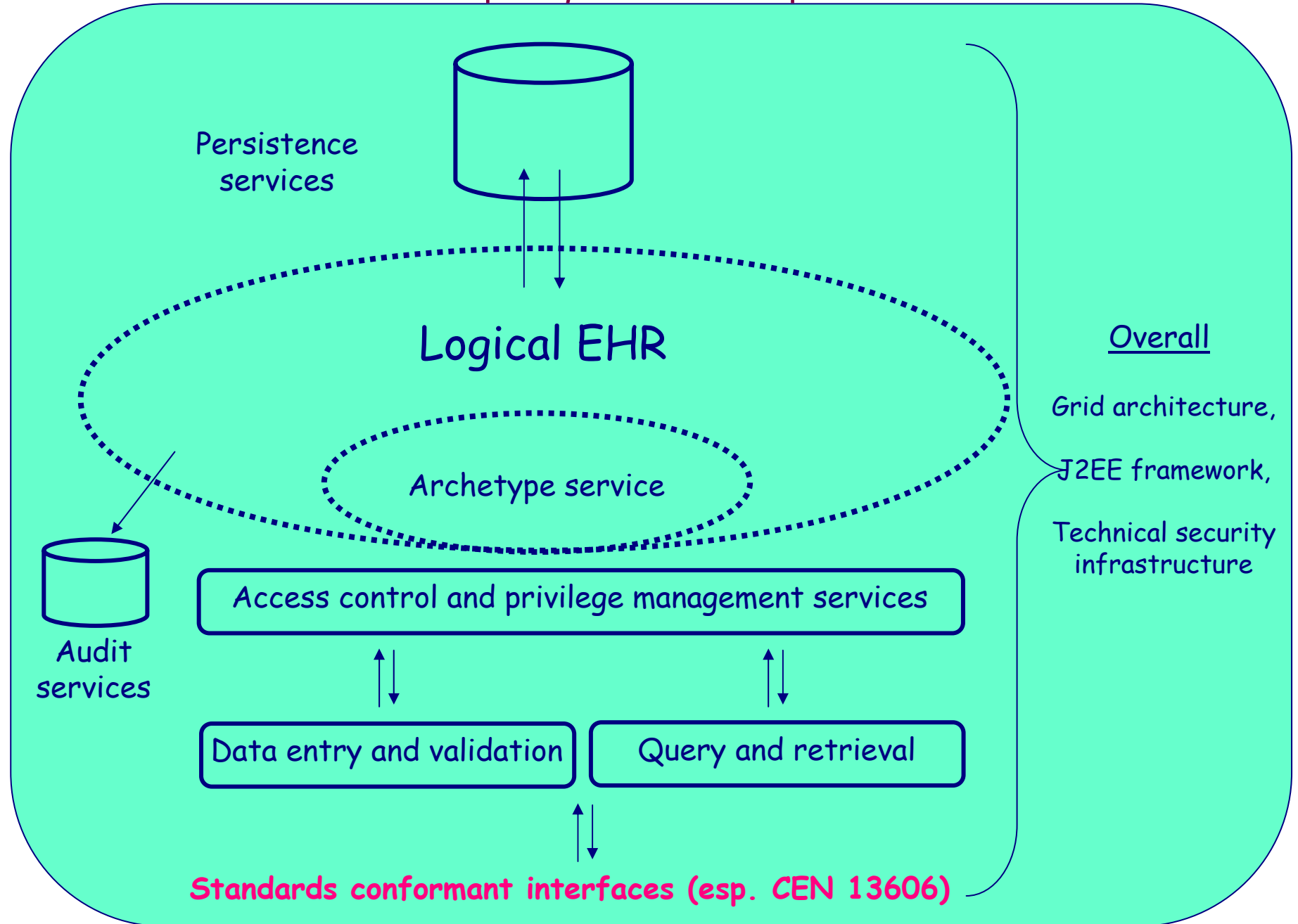
- Separation of EHR context and clinical knowledge: two-level approach
 - Reference Model and Archetypes
 - (approach also adopted by CEN TC/251)
- A multi-layer semantic model of record content
 - Folder, Composition, Section, Entry, Data Structure, Data Type
 - (also adopted by CEN TC/251 and HL7)
- A rigorous representation of EHR “context” attributes
 - e.g. medico-legal, clinical workflow process
- Generic data structures, which take into account temporal and spatial complexity in real clinical data

EHR core services
level

Knowledge services
level

Clinical application services
level

Principal *openEHR* components



Knowledge services level

Directories

e.g. patient demographics
personnel profiles
other resource services

Knowledge
resources

e.g. clinical terminology
published evidence
educational materials

Mediation
(e.g. inference)
services

e.g. clinical guidelines
decision support
alerts, clinical audit,
workflow and act mgmnt

Requirements are largely in academic publications
or, for example, as CORBA specifications
(HL7 beginning to take forward)

Clinical applications services level

(Applications used for providing or supporting direct patient care)

Ubiquitous

e.g. order-comms
appointments/scheduling

Profession-
specific

e.g. medical notes
nursing care
SOAP notes
physiotherapy

Domain-
specific

e.g. chemotherapy
ICU
coronary care
dialysis

Service
department

e.g. laboratory
radiology

Requirements will vary
between health services
internationally

HL7 EHR Functional Spec
now encouraging convergence

Other
perspectives

e.g. personal health

Where are we now?

- Community of nearly 500 international members
 - Active discussion lists
- Published specifications and tools
 - Design principles
 - Reference Model, including demographics and data types
 - Archetype Model, language, editor, parser
 - Exchange formats and interfaces
- Formal document and source code repository
- Changes overseen by Architecture Review Board
- Increasing wealth of publications and educational materials

Who is using the *openEHR* specifications?

- Australian *openEHR* trial for federal HealthConnect project: proving a success
- Canadian Infoway investigating *openEHR*
- US Veterans Health Administration reviewing the specifications
- CEN TC/251 has incorporated archetypes into EN13606
- Many developers have expressed interest in joining in the open source engineering
- Several SMEs have indicated they will use *openEHR* software inside their next clinical systems

Next steps: deliverables for 2005

- Full reference implementation (Java)
 - EHR server
 - Demographics service
 - Archetype service
 - Archetype repository
 - Security and access control components
 - Grid enabled infrastructure
- To be published under the Mozilla triple licence
- International developer community is gathering momentum
- Several demonstrator sites are emerging

Membership of *openEHR*

- Membership of *openEHR* implies a commitment towards realising the vision of high quality, interoperable EHRs, and a willingness to share ideas and experience
- Membership is free
- Visit www.openEHR.org
 - and join in our discussion lists !

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Semantic interoperability is vital

- to enable the meaningful sharing of health record data between systems
- to enable interoperability with modern terminology systems and medical knowledge databases
- to enable the integration and safety of protocols, alerts and care pathways electronically
- ensure the necessary data quality and consistency to enable secondary uses of longitudinal and heterogeneous data: public health, research, health service management

What is an Archetype?

- A formal model of a clinical domain concept
 - e.g. “blood pressure”, “discharge summary”, “fundoscopy”
- Uses classes defined in the Reference Model
 - allows data quality constraints to be placed on the organisation and content of record entries
 - e.g. specifying which constructs are to be used
 - e.g. defining mandatory items, data values, code sets etc.
- Maps to the specific information in each clinical (EHR) system
- May incorporate rules that enact steps within care pathways

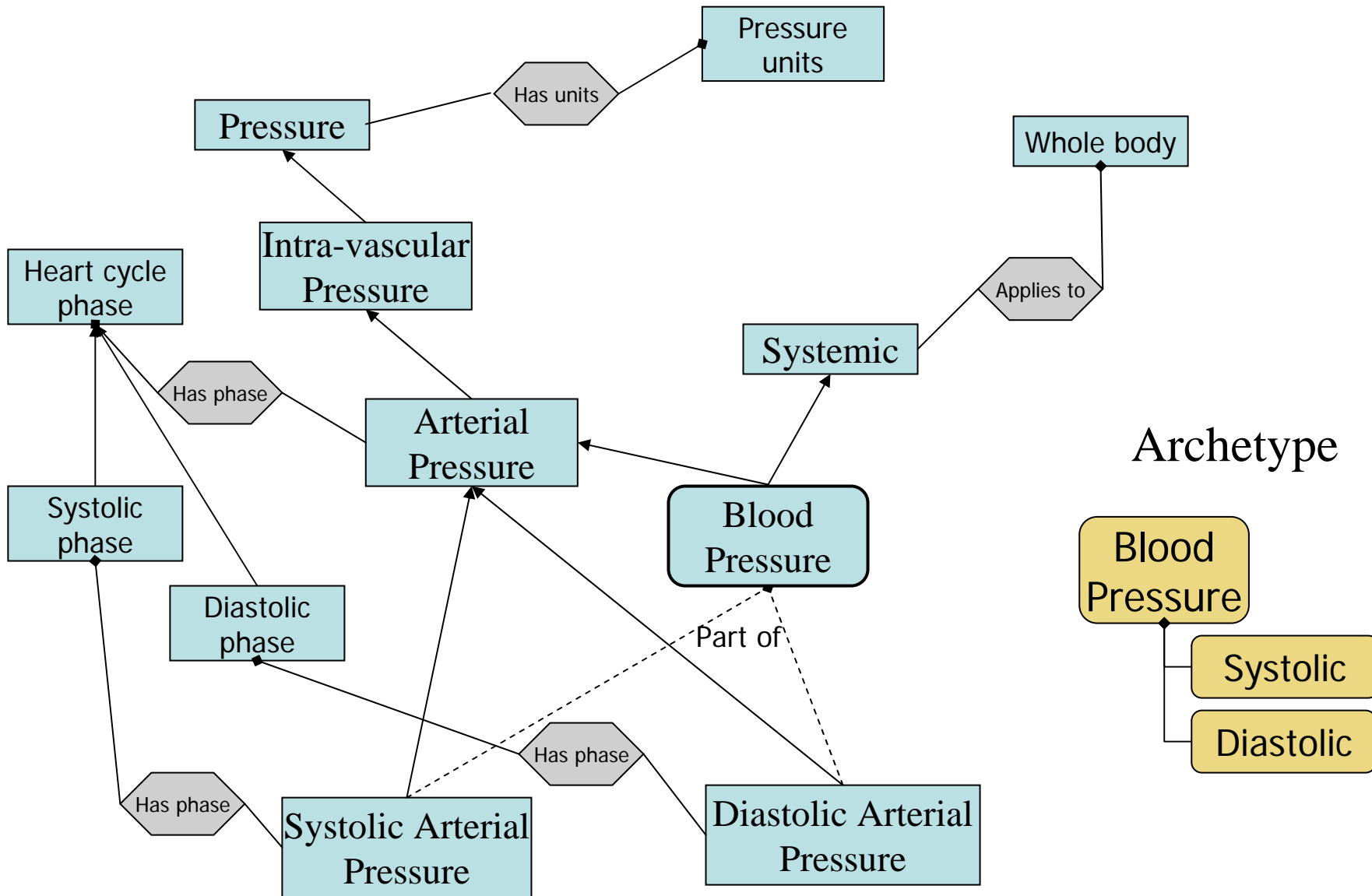
Archetype repositories

- Standardised clinical domain concepts
 - represent health-related phenomena in agreed (good) ways
 - enforce clinical and health service policies
- Used in real time (on-line):
 - to validate data creation
 - to enable care pathways
 - to do intelligent querying (even over legacy data)
 - to provide knowledge-level interoperability

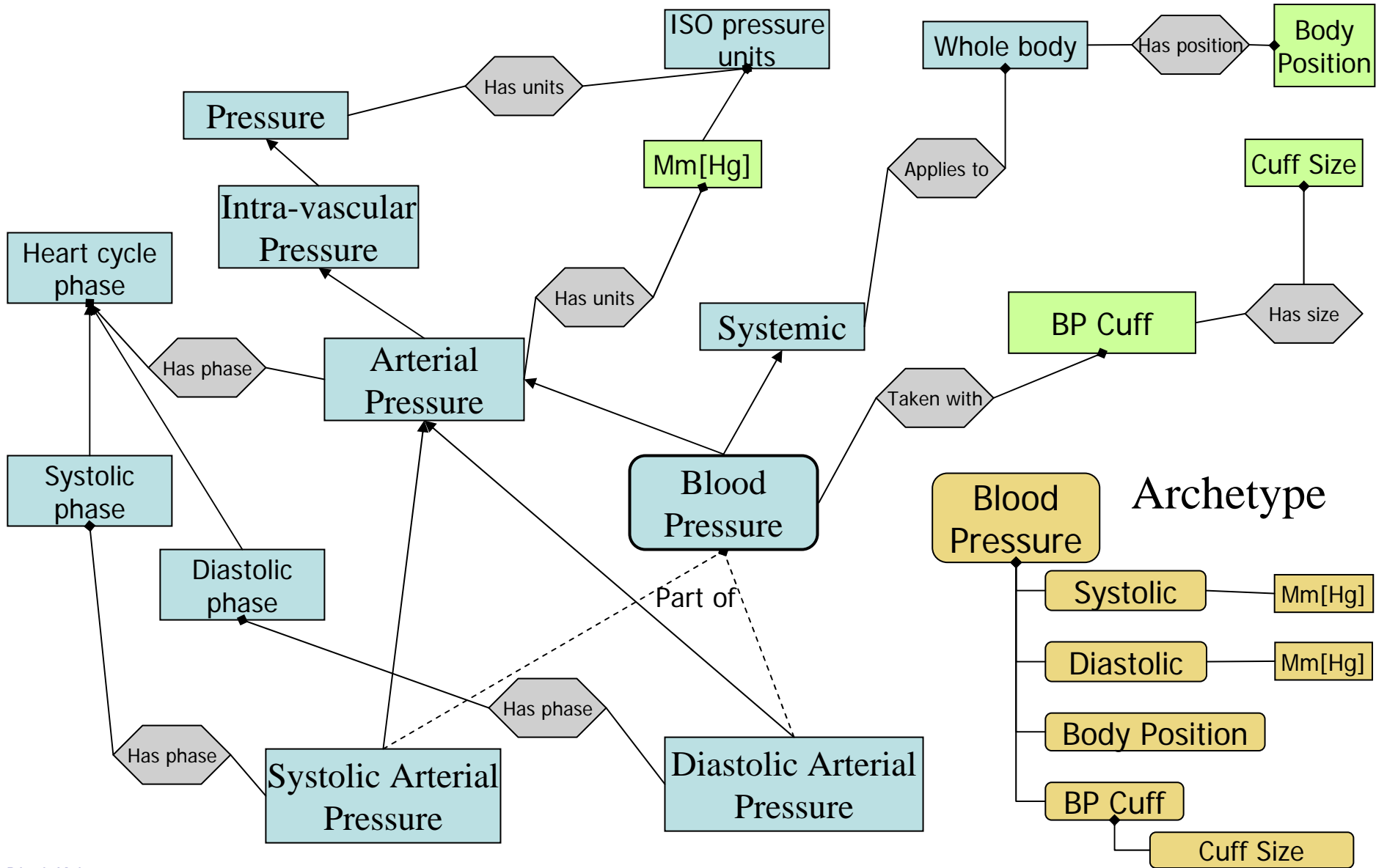
Value of Archetypes

- Empowerment of healthcare professionals
- Enable managed clinical and health service evolution
- EHR carries the identity of each Archetype used with the data created using it
 - aids future interpretation, analysis, computation

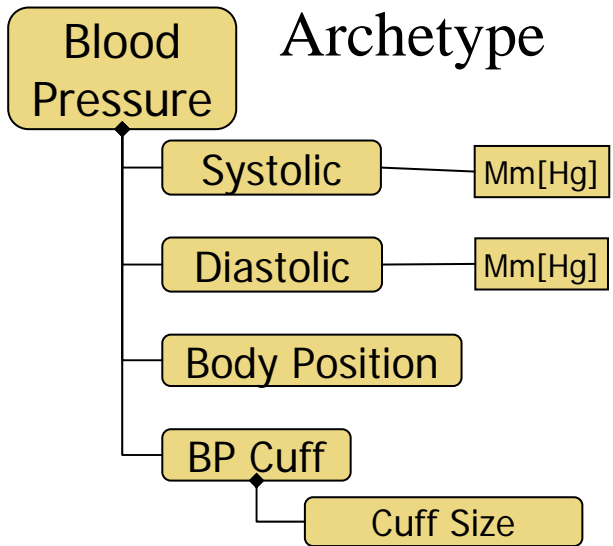
Medical Knowledge Ontology



Health care (clinical process) ontology



Archetype



Fuller list of BP 'characteristics'

- Systolic Arterial Pressure
- Diastolic Arterial Pressure
- Units of measurement
- Physiological ranges
- Exercise state
- Body Position
- Measuring Instrument, details
- Number of times the BP was taken
- Optionality
- Cardinality
- Why this measurement was taken

- Other context is not specific to BP but is part of the Reference Model
 - e.g. who took the measurement, on whom, who recorded it, when...

Constraint Model

- Archetypes allow Constraints to be placed on the instances of features in the Reference Information model to:
 - represent health-related phenomena in agreed (good) ways
 - enforce clinical, professional, and enterprise policies

Formal Model

- but.. in order to express these constraints across the whole of health care, in a rigorous and interoperable way, we need a formal model.

Archetype requirements

- Definition
- Description sets
- Publication status
- Node constraints
- Term and concept bindings
- Attributes, associations and context
- Data value constraints
- References to EHR instances

Definition

- globally unique identifier
- id of repository maintaining this archetype
- health informatics domain (e.g. EHR)
- underlying RM
- concept (scope) code or phrase
- natural language
- parent archetype
- predecessor, reason for revision, successor

Description sets (multiple)

- providing party & organisation
- natural language
- scope: concept code, clinical speciality, types of patients, keywords
- intended use, potential erroneous uses
- reference to knowledge source (e.g. url)
- detailed explanation of purpose, notes
- url or references to explanatory materials

Publication status

- Tentative
- Draft
- Private
- Public
- Preferred
- Former
- Deprecated
- suggest adding Test
- date, authorising party & organisation
- review or validity date

Node constraints

- Explicit node
- Reference:
 - to part or all of another archetype
 - internal
 - external
 - constraints defining an inclusion or exclusion set

Explicit Node constraints

- internally-unique id
- Reference Model class
- inclusion or exclusion constraints (e.g. for existence, multiplicity)
 - logical
 - related to environmental parameters
 - related to other EHR node values to be instantiated within the same archetype
 - related to EHR instance data or workflow or care pathway processes

Binding to terms

- Principal concept (mandatory: the “meaning”)
- Term binding
- Synonym
- Language translation

- for each term:
 - code, rubric, coding system and version, language in which mapping made

Attributes and associations

- common label
- attribute/association name
- optionality
- multiplicity
- if ordered
- if unique
- data value constraints
- other dependencies and constraints

Attributes and associations

- includes constraints on contextual information e.g.
 - subject of information
 - potentiality (present, absent, possible, probable, risk, goal, expectation, etc.)
 - process (done, is in progress, is planned to be done, has not been done, should not be done, etc.)

Data value constraints

- inclusion and/or exclusion criteria
- null, null flavour values
- default value
- fixed value
- list of values
- data type specific constraints
e.g. value range, units, term set, date ranges
- logical conditions and other constraint rules
(and formalism used)

References to EHR data (1)

- the archetype identifier
- the archetype node identifier
- the attribute or association name
- the occurrence in the instance hierarchy e.g.
first, most-recent, any,
n ordered by y,
highest value, lowest value,
one or more instances within a (definable)
recent time interval

References to EHR data (2)

- the intended relationship between this specified instance value and the data value being constrained e.g.
 - the same value as
 - a subset or substring of
 - greater than, greater than or equal to, less than, less than or equal to
 - earlier than, later than, etc.
 - if ... then...
 - must not be the same as

13606-1 profile for archetypes

13606 RM class	Context Area	Corresponding 13606 RM attribute
FOLDER	Meaning	Meaning
	Link	LINK
COMPOSITION	Meaning	Meaning
	Link	LINK
	Participation	composer CLINICAL_SESSION.other_participations
SECTION	Meaning	Meaning
	Link	LINK
ENTRY	Meaning	Meaning
	Link	LINK
	Participation	other_participations
	Subject of information	subject_of_information
	Act status	act_status
	Temporal relationship	Annotation (to be confirmed)
	Potentiality	Annotation (to be confirmed)
CLUSTER	Meaning	Meaning
	Link	LINK
	Structure	structure_type
	Observation time	obs-time
ELEMENT	Meaning	Meaning
	Link	LINK
	Observation time	obs-time

Archetype Model - General

- This is **not** a data model but essentially a **Constraint** model.
- Describes **generic** ways of specifying and managing Archetypes.
- This is a model applying to **all** archetypes

Archetype model

- Designed to be independent of the EHR reference model used
 - So that CEN, HL7 and *openEHR* can share a common model
 - archetypes for other (non-EHR) models will be compatible
 - needed to underpin the design of archetype services, supporting EHR services at “run-time”

Main parts (packages)

- Archetype Identification
- Meta data for Archetype description and management
- Constraints
- Ontologies
- Primitive types
- Domain-specific types

Archetype Identification

- Identification
- Concept
- Parent
- Language

Meta data

- Audit
 - Committers and organisations
 - Revision
- Description
 - Authors and organisations
 - Lifecycle details
 - Use, misuse
 - Where to find this archetype
 - Copyright and other details

Specifying Constraints

- UML but we are modelling constrained Objects
- Any archetype description = instance of C_COMPLEX_OBJECT, which represents a tree structure of any depth. Has features and invariants.
- Generic structure in triangle of C_COMPLEX_OBJECT, C_OBJECT, and C_ATTRIBUTE.
- Here 'Attribute' can be 'normal' attribute or an association in UML terms.
- Single, Multiple attributes
- Primitive types and leaf nodes
- Archetype slots (with assertions) to support 'building block' approach
- Internal Ref, Constraint Ref.
- Special extensions to data types for Clinical Domain

Ontologies

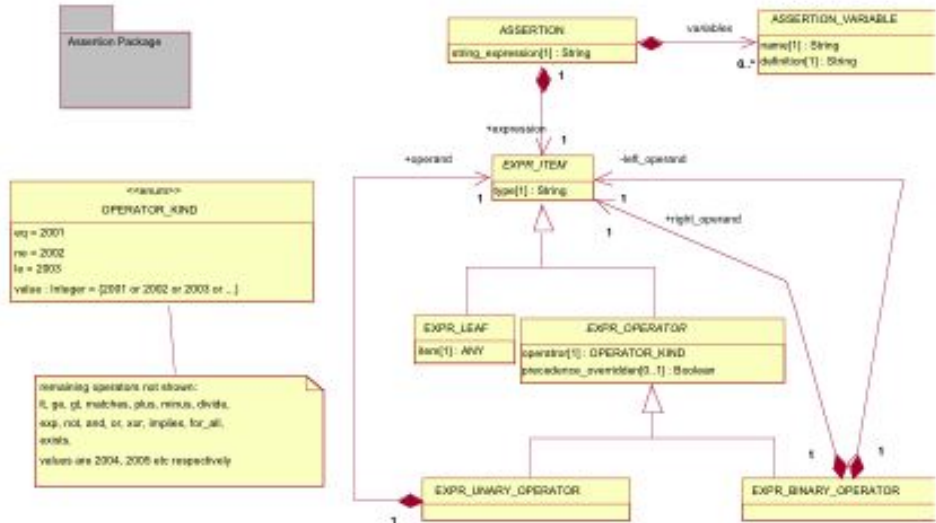
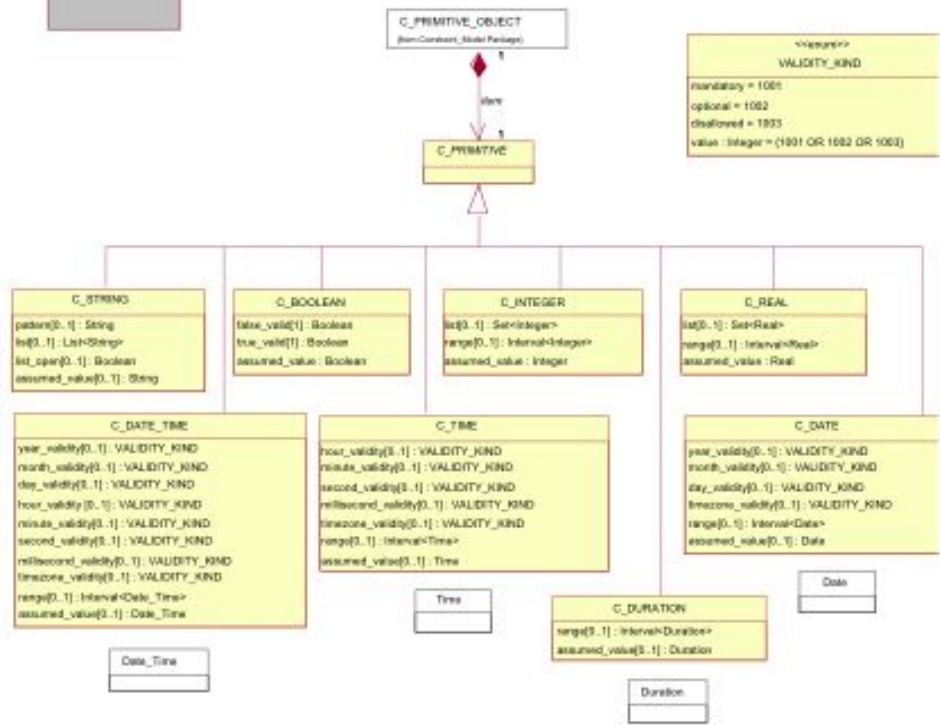
- Available terminologies
 - With term or constraint bindings
- Specialisation depth
- All codes for EHR hierarchy node names
- All constraint codes
- ‘Attribute’ names in ontology terms
- Owning archetype.

Primitive types

- Boolean
- String
- Numeric
- Times, dates, durations

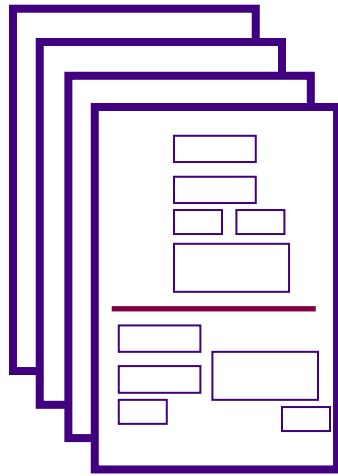
Domain-Specific Extensions

- A small number of domain types

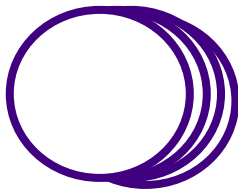


remaining operators not shown:
 lt, gt, gt_matches, plus, minus, divide,
 exp, not, and, or, xor, implies, for_all,
 exists.
 values are 2004, 2006 etc respectively

proposed joint project *openEHR*, CEN, HL7 + new EU project



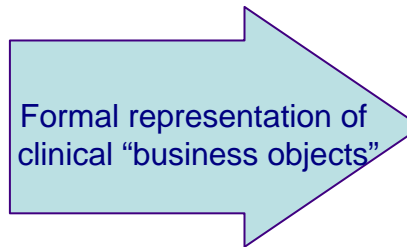
Templates, forms, data sets
used in real, diverse health settings



Data element inventories

catalogue,
synthesise

develop
guidelines &
rules for "good"
archetypes
and templates



Formal representation of
clinical "business objects"

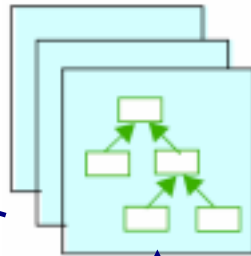


mapped to and used within:
openEHR Reference Model
CEN 13606
HL7 R-MIMs

Archetype formalisms

for the design of
archetype services
supporting EHR
services at “run-
time”

Archetype model



*optionally
communicated as*



XML Schema

conforms to



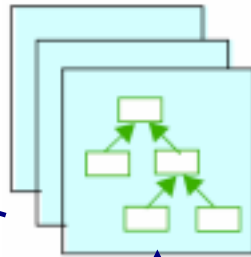
ADL archetypes

for the authoring of
archetypes and
their validation,
+ an ideal form for
archetype libraries

Archetype formalisms

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Archetype model

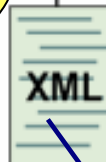


mapping

conforms to

Archetypes in
abstract OWL

RDF



translations

for the authoring of
archetypes and
their validation,
+ an ideal form for
archetype libraries

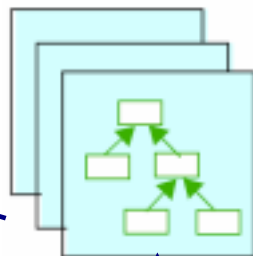
ADL archetypes

for linking with
other ontologies

Archetype formalisms

for the design of archetype services supporting EHR services at “run-time”

Archetype model



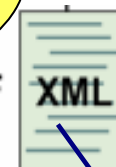
mapping

for use with decision support components and knowledge reasoners

Tools like Protege

Archetypes in abstract OWL

RDF



conforms to

translations

for linking with other ontologies

for the authoring of archetypes and their validation, + an ideal form for archetype libraries

ADL archetypes



Bridging the Ontologies

