

NCRI Workshop

Clinical information standards and health records

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Issues we need to consider

- How does functional genomics research fit in with patient care?
- What do we need to capture in the life-time record of an individual?
- What clinical information does genetic research need to know about its (human) data subjects?

What standards are relevant?

- health data representation
- terminology
 - mainly standards for terminology developers, e.g. term set distribution, conceptual models of clinical domains
 - so really we have standard terminologies used in given domains rather than terminology standards
- archetypes - say more about what this is later
- ontologies (no standards yet)
- ethical and legal standards

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- ethical and legal standards
 - **which must be met by all databases holding personal information**

Distributed access to EHRs is now part of many national strategies

- These strategies are drawing on:
 - 14 years of R&D
 - forthcoming European (CEN) standards for the EHR
 - sets of messages developed by HL7
 - next-generation terminologies
 - open source innovations in EHR design
 - e.g. *openEHR*

Research inputs related to the EHR

1991-2005

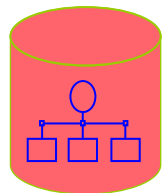
- clinical and ethical requirements
- comprehensive EHR architectures
- federated health record services
- middleware components relating to guidelines and terminology services
- distributed tele-monitoring, decision support, alerting systems
- interaction with security services
- widely distributed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

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

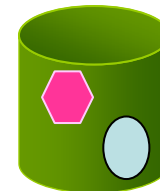
Clinical trials,
functional genomics
and inherited genotype



EHR systems
and servers



Decision support,
knowledge management
and analysis components



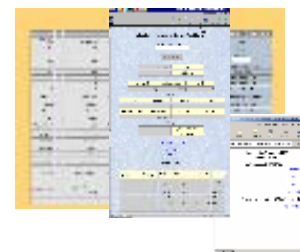
Personnel registers,
security services



Mobile devices

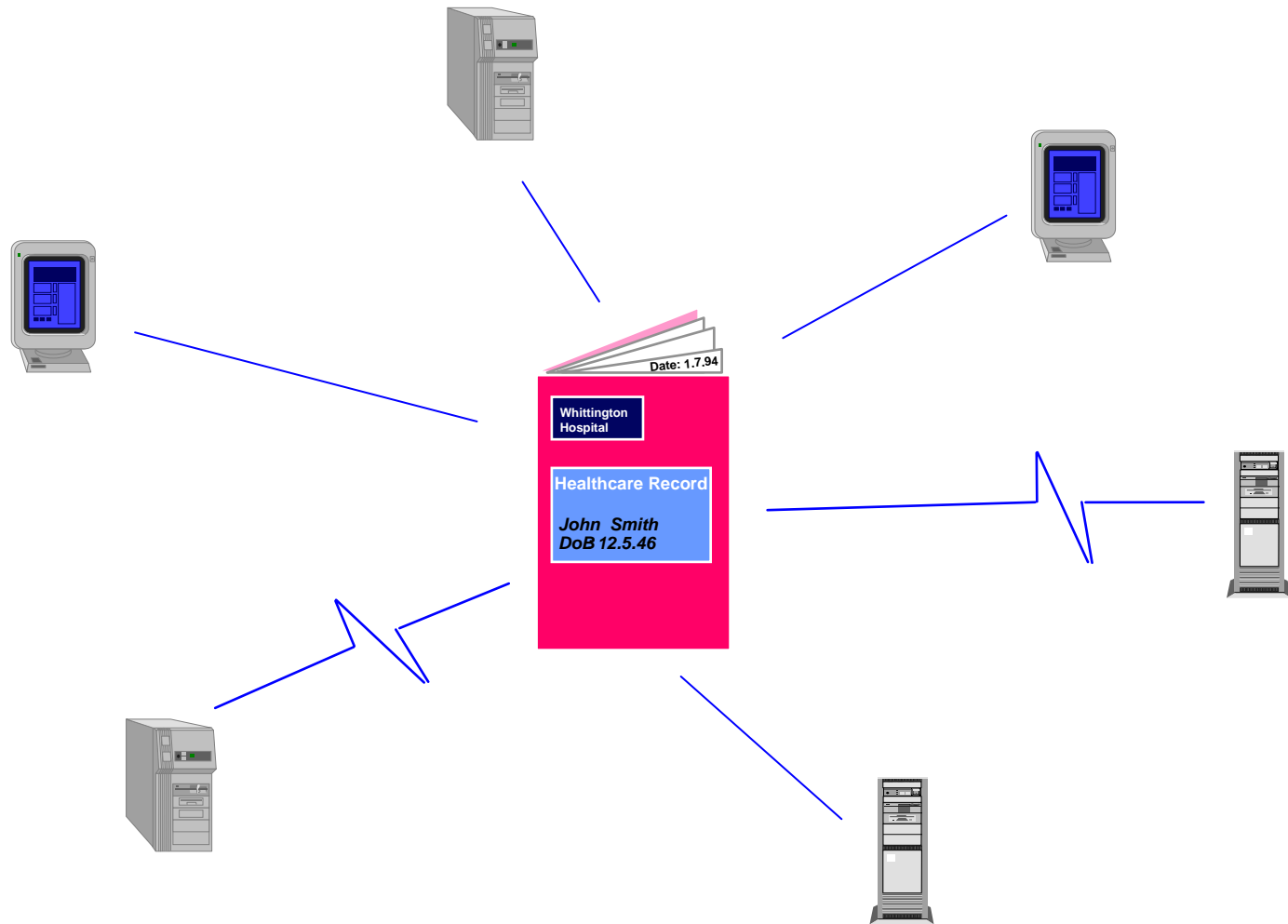


Clinical devices,
instruments



Clinical
applications

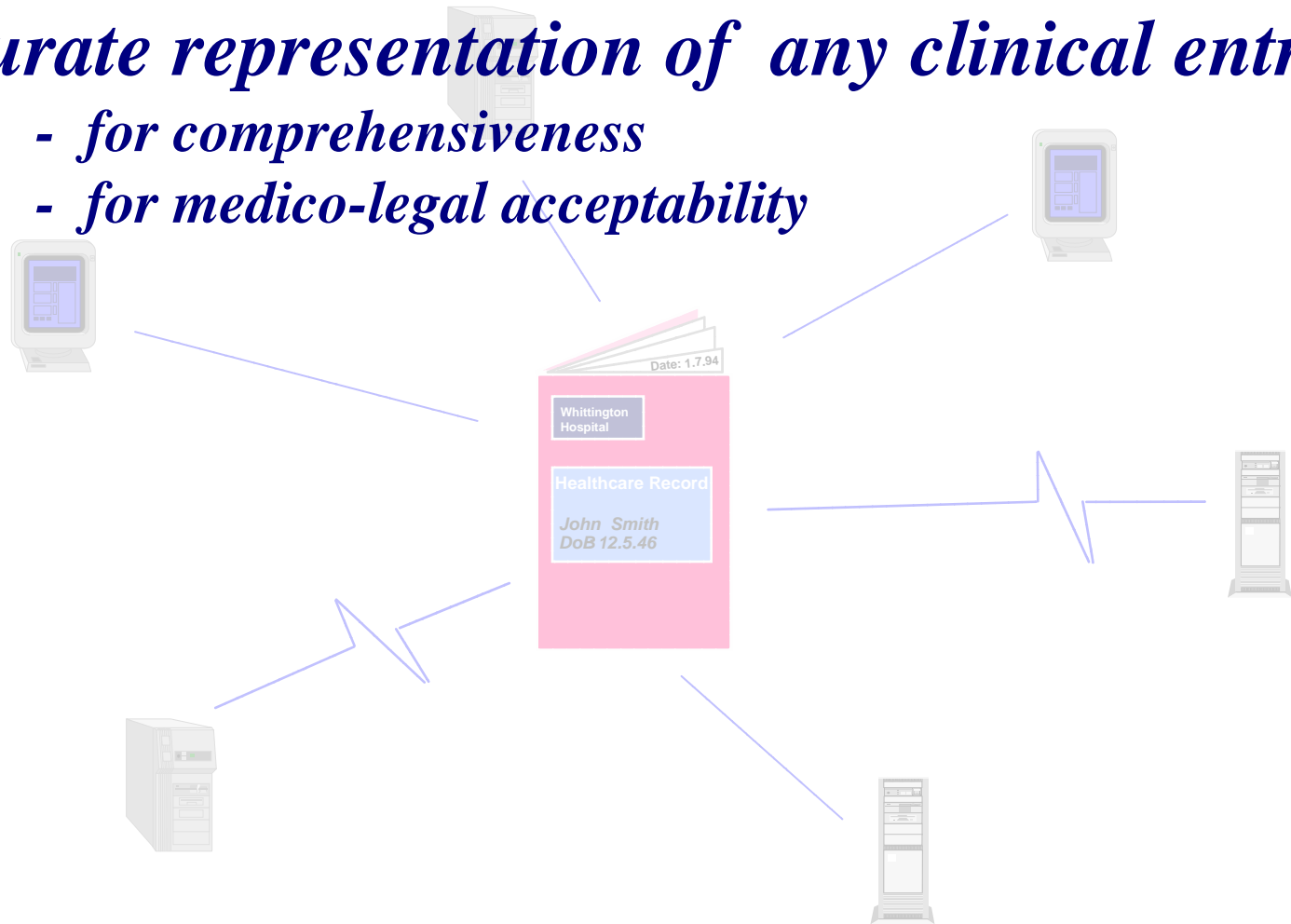
Role of EHR interoperability standards



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Accurate representation of any clinical entry

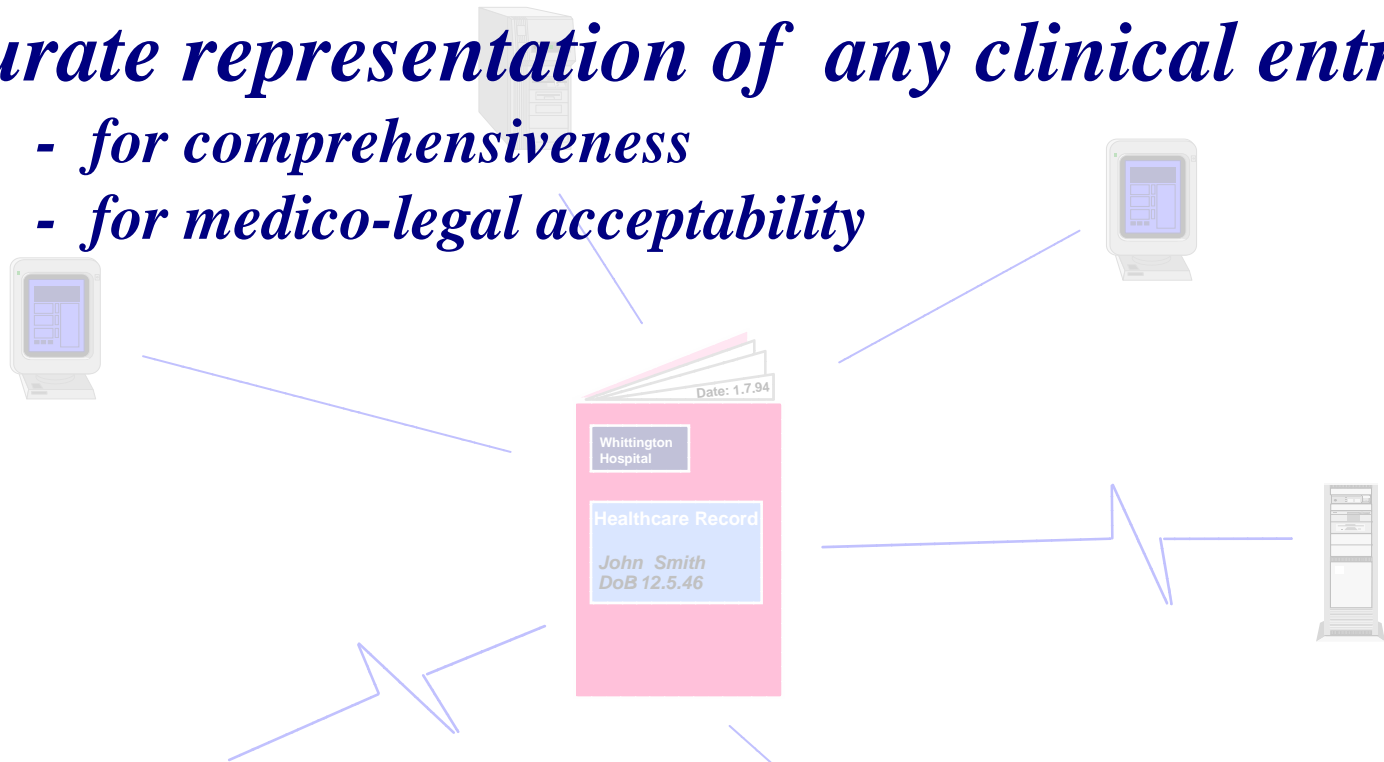
- *for comprehensiveness*
- *for medico-legal acceptability*



Role of EHR interoperability standards

Accurate representation of any clinical entry

- *for comprehensiveness*
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Faithful preservation of meaning and context

- *for analysis*
- *for communication*

Preserving meaning in the EHR

- A formal record structure hierarchy must preserve the way in which entries were originally ordered and grouped by the author
 - using a formal system for defining these hierarchies
- Record entries can be
 - an element e.g. for Weight
 - or a compound e.g. for blood pressure, full blood count
 - or very complex nested data structures
- for each of these there is important additional context that must be represented in a standardised way

Data Value context

- Formal representations for all data types
 - including text, quantities, time, persons, multi-media
- Names of term sets, versions and registering agencies
- Natural language used in a recording
- Accuracy, precision and units for quantities
- Normal ranges

Reasoning context

- Presence / absence
- Certainty
- Prevailing clinical circumstances
 - e.g. standing, fasting
- Justification
 - e.g. the evidence for a finding, conclusion or decision
- Clinical reasoning
 - e.g. why a drug dose has been changed
- Knowledge reference
 - e.g. Medline, drug information database, genomic database

Ethico-legal context (1)

- Authorship and responsibilities
 - who composed the information?
 - who provided it? (e.g. family member)
 - who committed it to the EHR? (e.g. secretary)
 - who was medico-legally responsible? (e.g. consultant)
- Data subjects
 - whose record is this? (who is the patient?)
 - about whom is this observation? (e.g. family history)
- Dates and times
 - when did the event occur?
 - when did the clinician learn about it?
 - when did it get recorded in the EHR?

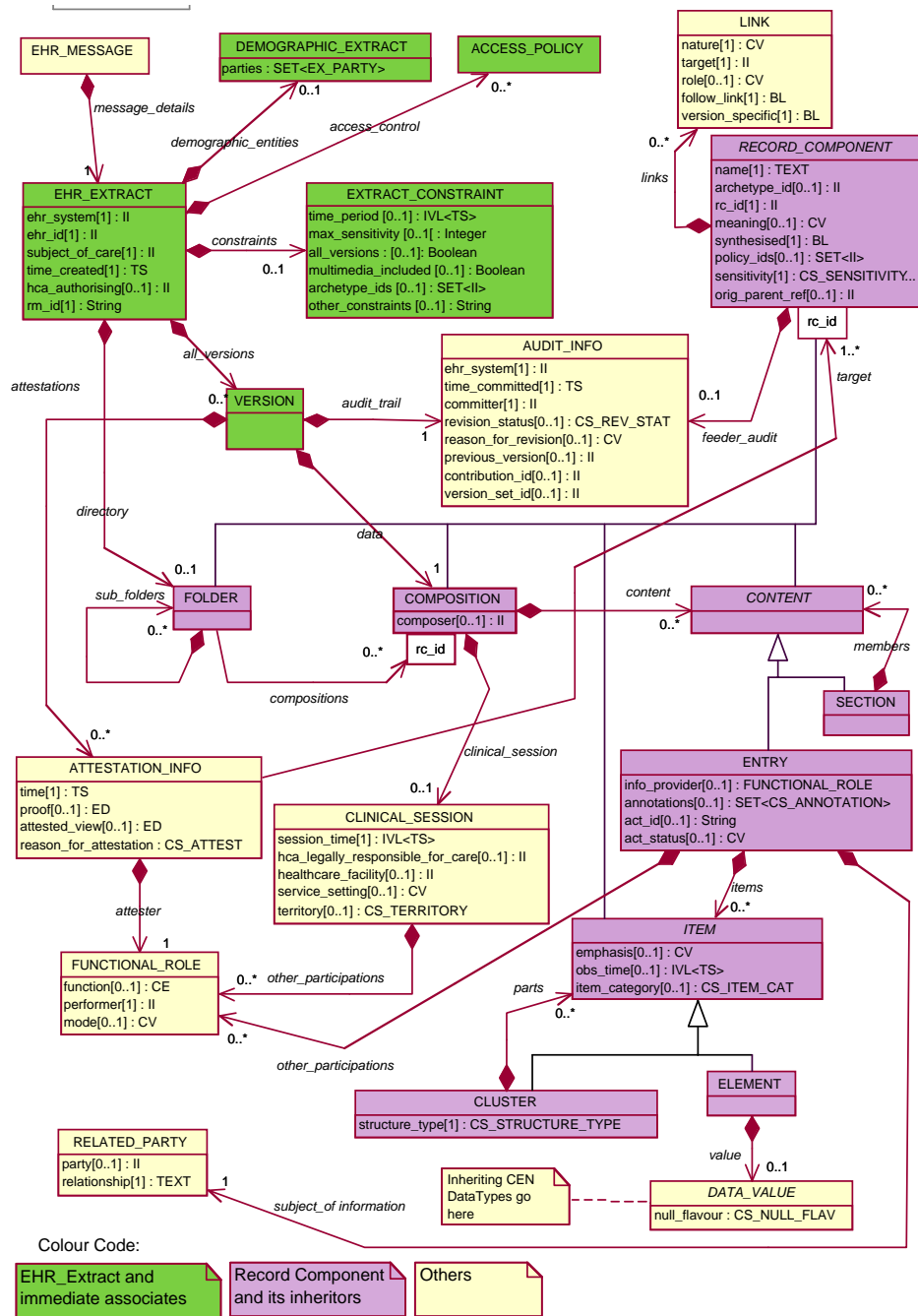
Ethico-legal context (2)

- Version control
 - is this the original version?
 - if not, when was it changed, by whom, and why?
 - if multiple versions exist, what is the sequence of changes made?
- Access rights
 - who should be permitted to access this Entry?
 - who should decide?
 - what about emergency access?

Care Process context

Links and pointers:

- to other parts of the record
 - cause and effect
 - request and result
 - process status
- to a defined problem
- to an episode of care
- to a stage in a protocol
- to a decision support system



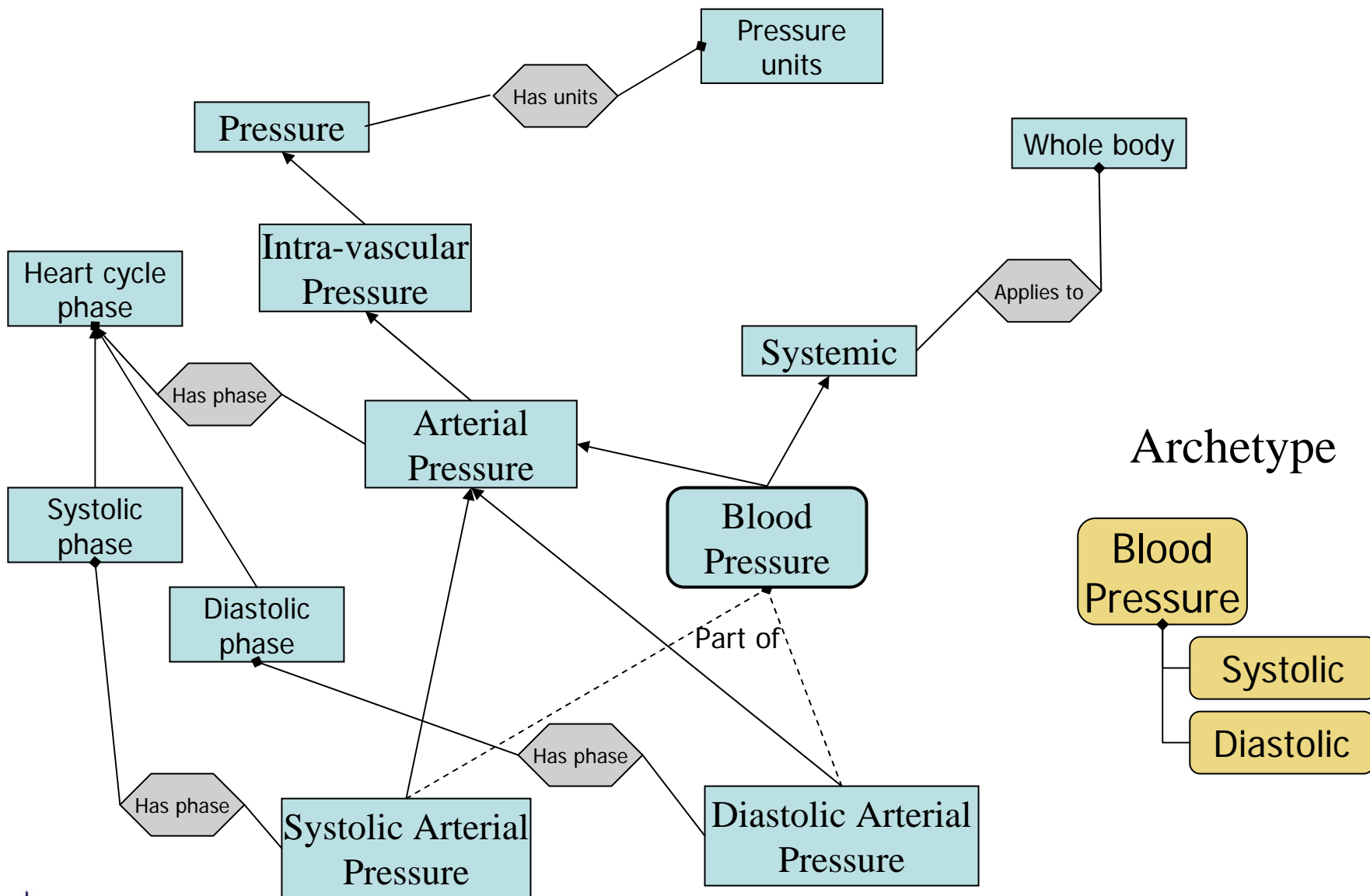
Colour Code:

- EHR_Extract and immediate associates
- Record Component and its inheritors
- Others

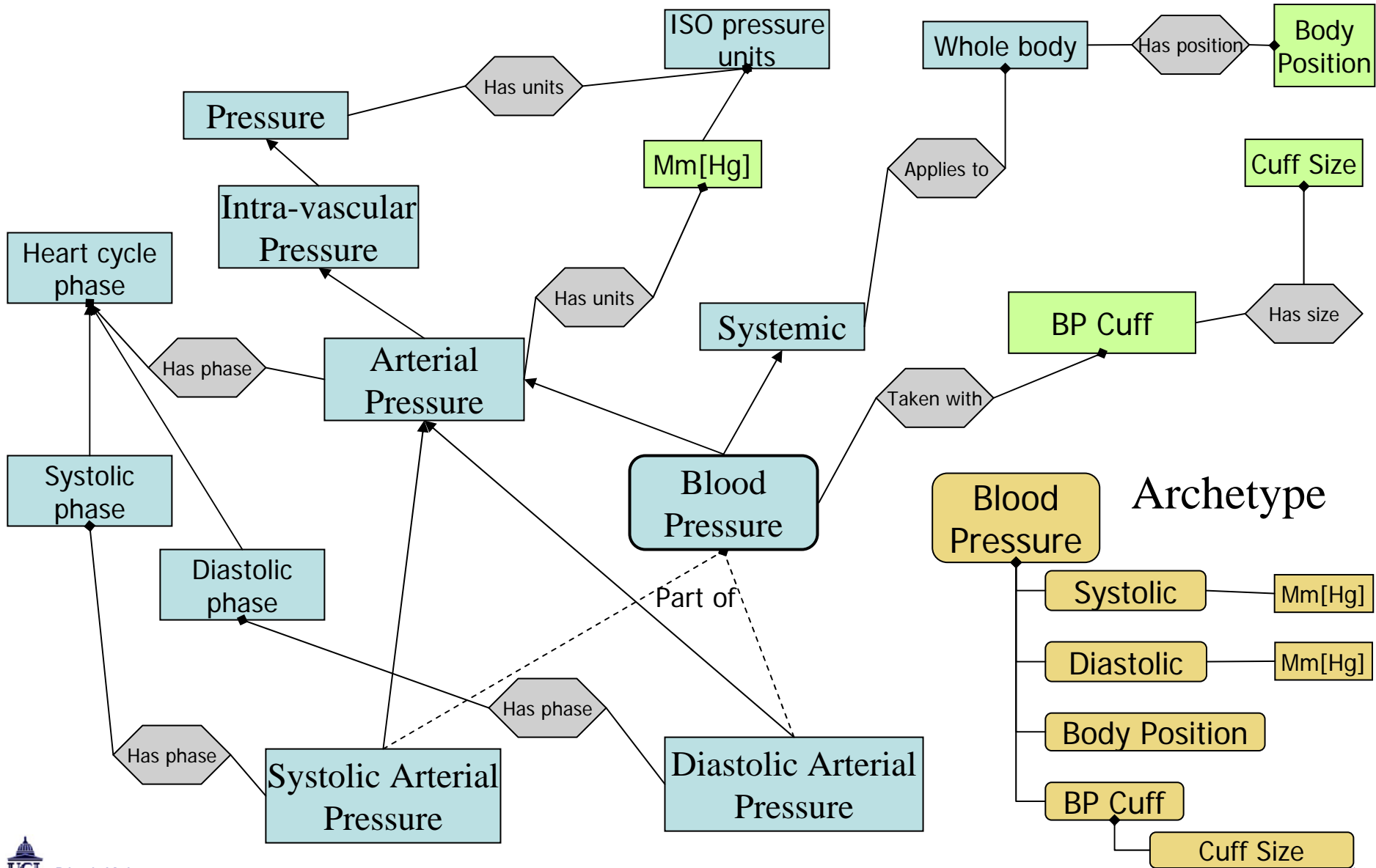
What are archetypes?

- Usually, clinical domain knowledge is embedded within software (e.g. forms), or within information models and database structures
- BUT, clinical practice is diverse and evolving
- We have to systematically separate knowledge from the software and databases to better handle changes in:
 - new research, equipment, tests, drugs, therapies...
 - sociological factors in the practice of medicine and community involvement
- Archetypes are a formalised and interoperable way of representing health care (clinical process) domain knowledge

Medical Knowledge Ontology



Health care (clinical process) ontology



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 so not included here
 - e.g. who took the measurement, on whom, who recorded it, when...

What is an Archetype?

- A formal model of a domain concept, e.g. “blood pressure”, “discharge summary”, “vaccination history”
- Used at runtime:
 - to validate data creation
 - to do intelligent querying
 - to enable knowledge-level interoperability
- Basis of standardisation for health record domain concepts

Constraint Model

- Archetypes thus allow constraints to be placed on the instances of features in the reference model to:
 - represent health-related phenomena in agreed (good) ways
 - enforce clinical, professional, and enterprise policies
 - help ensure consistent EHR data (“data quality”)

*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

CEN 13606 Task Force (EHRcom)

- Developing a comprehensive standard for EHR interoperability and communication
- Working with *openEHR* e.g. on archetypes
- Support from HL7 to harmonise with v3 RIM, CDA and Templates
- Due for publication during 2005-6
- Current Work Item ballot in ISO

CLinical E-science Framework - CLEF

- MRC e-science project(s): 2002-2007
- Collaborating universities
 - Manchester (co-ordinator), UCL, Sheffield, Brighton, Cambridge
- Clinical Centres
 - Royal Marsden and UCLH Foundation Hospitals
- Goals:
 - to provide a research workbench supporting queries on large volumes of anonymised cancer and genetic records
 - applying EHR services, GALEN ontologies, term extraction and language generation to the analysis of clinical narratives
 - to utilise Grid networks to support high volume analyses
- A major part of the work is the development of pseudonymisation policies and tools, and disclosure control

Representing genomic information, usually arising from research

- Accumulating vast volumes of data about:
 - Chromosomes and translocations
 - Allele
 - Gene sequences
 - Gene variations, SNPS, haplotypes
 - DNA Markers
 - RNA etc.
 - Protein information
- What belongs in an EHR?

On what basis does information belong in an EHR?

- it is person specific
- it has a role in supporting health or health care (maybe now or in the future)
- it is relevant to future health care providers
- it is potentially shareable with the patient
- it is trustworthy data
 - on which future care decisions can depend

All acquired data is not EHR data

- With an MRI scan, we don't consider all 1200-2000 images (taken in 35 seconds) to be part of an EHR
 - what happens is selection, annotation, interpretation
 - the original acquired data is significantly filtered: a few illustrative images are included with the report

Genetic investigation results might be handled similarly

- reference to a known chromosomal, genomic, or proteomic pattern
 - which need not be included in the patient's record
 - e.g. reference to a published database entry
- reference to known variations
- specific unique (unreferenced) findings
 - values may need to be included in the EHR
- presence, absence or levels of markers
- interpretations and management plans

What are the challenges?

- Separation of knowledge, reference data and salient personal health record data
- Avoid simple models of phenotypes
 - you may need to refer to anything that might be in a health record
- Recognise that clinical data needs to
 - meet ethical and legal requirements
 - be interoperable: access and contribute to a person's EHR