

# Information Architecture for a Federated Health Record Server

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## Introduction

This paper describes the information models that have been used to implement a federated health record server and to deploy it in a live clinical setting.

The authors, working at the Centre for Health Informatics and Multiprofessional Education (University College London), have built up over a decade of experience within Europe on the requirements and information models that are needed to underpin comprehensive multi-professional electronic health records. This work has involved collaboration with a wide range of health care and informatics organisations and partners in the healthcare computing industry across Europe through the EU Health Telematics projects GEHR, Synapses, EHCR-SupA, SynEx and Medicate. The resulting architecture models have fed into recent European standardisation work in this area, such as CEN TC/251 ENV 13606. UCL has implemented a federated health record server based on these models which is now running in the Department of Cardiovascular Medicine at the Whittington Hospital in North London. The information models described in this paper reflect a refinement based on this implementation experience.

## Requirements

The very extensive investigations of user and enterprise requirements that have taken place over ten years have sought to capture the diversity and specialisation across primary, secondary and tertiary care, between professions and across countries. These requirements identify the basic information that must be accommodated within an EHCR<sup>a</sup> architecture to:

- capture faithfully the original meaning intended by the author of a record entry or set of entries;
- provide a framework appropriate to the needs of professionals and enterprises to analyse and interpret EHCRs on an individual or population basis;
- incorporate the necessary medico-legal constructs to support the safe and relevant communication of EHCR entries between professionals working on the same or different sites.

A detailed review of requirements for this domain was published by the GEHR project [1, 2, 3, 4], and this set of requirements informed the subsequent work of CEN ENV 12265 [5] and the Synapses project [6]. The EHCR-SupA project recently consolidated European and international published requirements into a single project deliverable [7].

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<sup>a</sup> The Terms Electronic **Healthcare** Record (EHCR) and Federated **Healthcare** Record (FHCR) have been used by many projects and publications over the past decade and are used here when referring to historic work. The preferred adoption of the term Federated **Health** Record (FHR) in this paper reflects a slightly wider scope to include the recording of aspects of a patient's health that might not result in health care services being provided.

This publication has been used as the starting point of a new ISO Work Item on EHCR Requirements.

### **Representing Contextual Information**

The work of GEHR and Synapses has drawn attention to the essential nature of contextual information captured alongside the individual clinical entries at the time of recording. Although several other projects have each developed their own EHCR information architectures, they share the objective of formalising a set of contexts that may be associated with any health record entry<sup>b</sup>.

The term "context" has been widely used by different projects and organisations to describe certain aspects of the inter-relationships between parts of a set of record entries or to describe the constituent parts of an individual entry. Each group appears to have identified a specific data set for context, so that, when the work of EHCR architecture, medical knowledge, and terminology groups is compared, several different kinds of contexts emerge. In practice most of these need to be represented within an EHCR, while a few are more applicable to a medical knowledge service interfacing with a population of patient records. Table 1 below summarises the overall set of contexts that the authors believe need to be mapped to classes and attributes within an EHCR architecture.

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<sup>b</sup> A health record entry is considered in this paper to be a quantum of information that is entered into a record, usually constituting a single fact, observation or statement.

**Compositional Context**

- Record entry names to provide a label for each data value
- Compounding hierarchies of clinical concepts to express complex concepts
- Grouping hierarchies for sets of clinical concepts with common headings, to:
  - preserve the way in which entries were originally organised by the author
  - identify the way in which the clinical concepts relate to the health care activities and processes surrounding the patient

**Data Value Context**

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

**Qualifier Context**

- Presence / absence
- Certainty
- Severity
- Site and laterality
- Prevailing clinical circumstances (e.g. standing, fasting)
- Justification, clinical reasoning
- General comments
- Knowledge reference (e.g. a journal reference)

**Ethical and Legal Context**

- Authorship and duty of care responsibilities
- Subject of care
- Dates and times of healthcare actions and of their recording
- Version control
- Access rights
- Emphasis
- Preservation of meaning on transferring the record to another site

**Care Process Context**Links and pointers:

- to other parts of the record, e.g.
  - cause and effect
  - request and result
  - process (act) status (e.g. a test that is requested and subsequently cancelled)
- to a defined problem
- to an episode of care
- to a stage in a protocol
- to a decision support system

**Table 1: The range of contexts that may be associated with health record entries**

## Information Architecture

The Synapses approach to distributed health records utilised the methodology of database federation to a standard and comprehensive schema, the Federated Healthcare Record (FHR) information architecture, mediated and managed through a set of middleware services [8, 9].

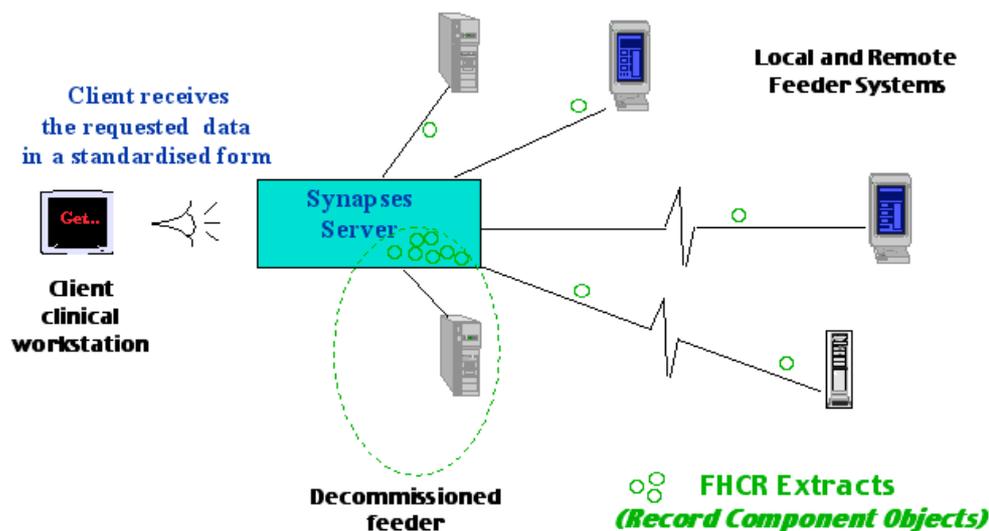


Figure 1: Distributed access to record components within a Synapses federation

In building on the Synapses work, the challenge being addressed by UCL in the design of the federated health record (FHR) information architecture is to provide a formal representation of the generic characteristics applicable to any potential health record entry arising from feeder systems or through clinical applications, now or in the future. In practice, this challenge can best be addressed through a pair of interrelated information models rather than through a single model.

1. The FHR Reference Model, which represents the global characteristics of health record entries, how they are aggregated, and the general set of context information attributes described as requirements in Table 1. This model corresponds conceptually to the EHCR architecture of GEHR [10], the Synapses federation schema (the SynOM) [11] and to the information model of ENV13606-1 [12]. It is intended to be applicable to any health domain, in any potential organisational setting. It also reflects the stable characteristics of an electronic health record, and is embedded in the federated record server at a program code level.

2. The FHR Archetype Model, which extends (and effectively constrains) the Reference Model for particular domains or organisations by specifying particular record entry names, data-types and aggregations of these. This model is used to map the specific data schemata of feeder systems and clinical applications. Such schemata (known as Archetypes) will be subject to frequent change as clinical practice and information systems evolve. This model corresponds conceptually to the Synapses Object Dictionary [13, 11] and to the Archetype concept of the Good Electronic Health Record project [14]. This part of the information architecture is deliberately implemented in a

way that facilitates and audits changes to the definition of clinical Archetypes over time within an FHR Archetype Object Dictionary component.

These two information models are described in the next two sections of this paper.

### FHR Reference Model

The UCL Federated Health Record Reference Model (FHR-RM) defines a set of classes and attributes that represent the clinical context and medico-legal status of health record entries as a hierarchical set of Record Components. The goal for this model, in contrast to the Archetype Object Dictionary, is to represent the generic and domain-independent characteristics of Record Components.

The UCL FHR-RM is drawn below showing its class inheritance hierarchy (in red), and its aggregation (containment) hierarchy. The diagram conventions are based on the UML notation. The attributes have been omitted from the overall diagram below, and are defined later in this section.

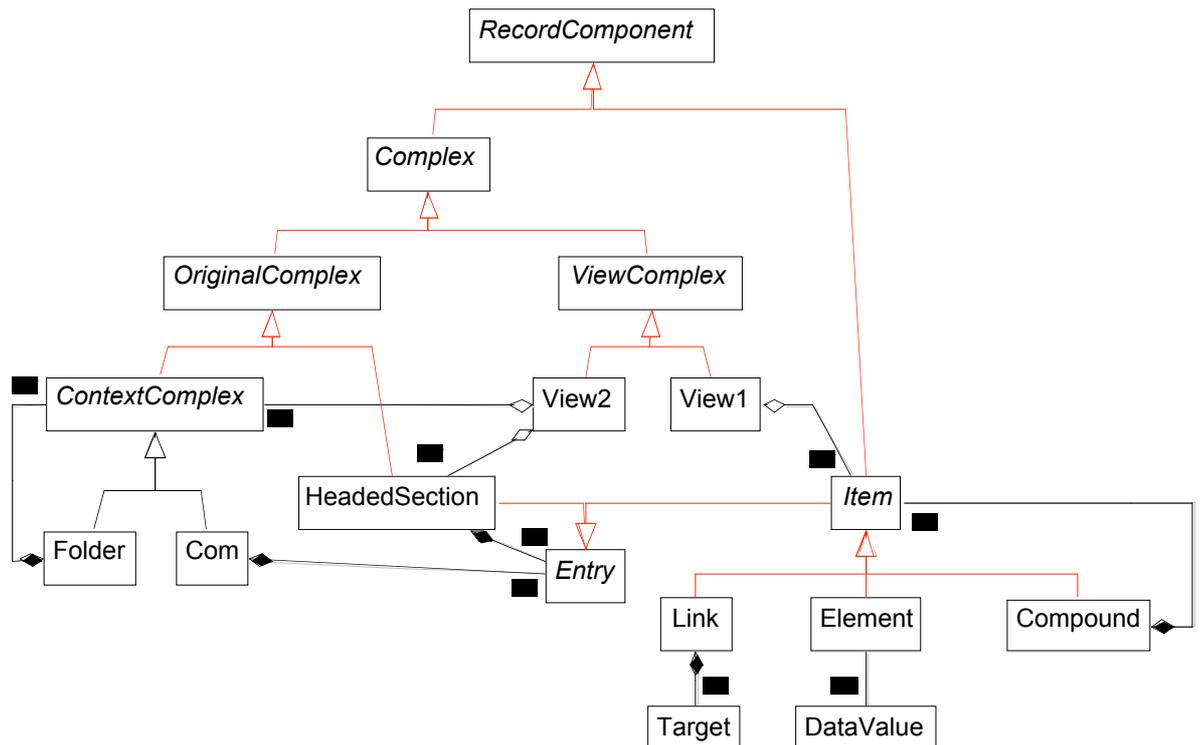


Figure 2: Class Inheritance and Aggregation within the FHR-RM

## Description of the principal FHR-RM Classes

### *RecordComponent*

RecordComponent is the abstract base class for Complex and Item. It defines the common attributes applicable to all of the major classes of the FHR-RM for:

- Record authorship, ownership and duty of care responsibilities
- Subject of care
- Dates and times of health care actions and of their recording
- Version control
- Access rights
- Emphasis and presentation

The complete set of attributes and their data types is presented later in this section.

The FHR-RM distinguishes between the aggregation necessary to convey compound clinical concepts and the aggregation within a record that provides a way of grouping observations that relate to the health care activities performed. An example of the former would be *blood pressure*, which is a compound concept composed of *systolic* and *diastolic* values. An example of the latter would be the grouping together of observations under a general heading of *Physical Examination*.

The Complex and Item constructs respectively represent these two broad categories of aggregation.

### *Complex*

In the FHR-RM, Complex is the common abstract super-class for the grouping of observations that relate to the health care activities performed. Two broad categories of Complex are reflected in the FHR-RM through two abstract sub-classes.

1. *OriginalComplex*: this set of classes represents the original organisational structure (grouping) of sets of record entries, as defined by the author(s) of those entries; it provides the medico-legal representation of the underlying information.
2. *ViewComplex*: this set of classes provide the means by which alternative groupings and sub-sets of the original information may be organised and preserved as permanent views in a patient's record, unlike those generic views provided in an ad hoc way by a client system.

### *OriginalComplex*

Three concrete classes of *OriginalComplex* are defined in the FHR-RM, to provide for the nested aggregation of original groupings for record entries.

### *Folder*

Folders define the highest-levels of organisation within health records. They will often be used to group large sets of record entries within departments or sites, over periods of time, or to demarcate a prolonged illness and its treatment. Examples of Folders include an episode of care, an inpatient stay, or one stage of a disease process. Folders can contain other Folders, and/or Coms.

### ***Com***

A medico-legal set of record entries required by the author to be kept together (to preserve meaning) when information is physically moved or copied to another persistent store. This is to ensure that all persistent EHR stores comprise whole Coms. This explicitly includes caches and cache mechanisms. The Com also defines the medico-legal cohort for the inclusion of new entries within an EHR: any new EHR entry (even if stored on a local feeder) must be a whole Com. Coms cannot contain other Coms or Folders. Examples include:

- the data entered at one date and time by one author (similar to a GEHR Transaction);
- the information gathered through the use of a protocol or template;
- a serialised set of readings taken over time but contributing to one examination;
- the definition of structures corresponding to electronic documents.

### ***HeadedSection***

This class is intended for grouping observations under headings *within* a Com. It therefore provides for the fine granularity grouping and labelling of record entries with names that relate the clinical concepts to the health care activities and processes surrounding the patient. Examples of HeadedSection names include presenting history, symptoms, investigations, treatment, drug prescription, needs, or plan. HeadedSections may contain other HeadedSections and/or Items. They cannot contain Coms or Folders.

### ***ViewComplex***

Two concrete classes of ViewComplex are defined in the FHR-RM, to provide for two differing mechanisms by which views may be generated.

#### ***View1***

The View1 provides a means for grouping entries within Coms, at a similar hierarchical level in a record to the HeadedSection. However, the data within a View1 is derived through the use of a predefined query procedure i.e. a View1 comprises a query that generates a set of entries dynamically at the time of a client request. The mechanism by which search criteria can be defined in a generic, durable and portable manner within the View1 class is presently being developed.

#### ***View2***

The View2 provides a static view of original information, through a set of references to the original entries or to groups of entries (i.e. Items, HeadedSections and/or Coms). It therefore provides a mechanism by which information within one Com may logically appear inside another Com, since the originals of these cannot be nested. This class cannot include object references to other instances of View2, to avoid recursive loops of such references.

### **Item**

This abstract class provides an aggregation construct for clinical concepts that are composed of one or more individual named clinical values (e.g. *pulse*, *blood pressure*, *drug dose*, *heart sounds*). These entries may be aggregated within a hierarchy to represent complex clinical concepts, but such a composition is distinct from the record structure grouping hierarchy provided by the Complex classes. This class also provides a means by which point-to-point linkage or linkage nets within a single FHR can be represented. The Item class hierarchy is described later in this section.

### **The Attributes of the RecordComponent Class**

The tables below list the attributes of the RecordComponent class. These are inherited throughout the FHR-RM class hierarchy and may acquire instance values at any level of a hierarchy of record entries. Some of these attributes have been defined as mandatory, and must be incorporated within any FHCR in order to comply with this specification. If mandatory information is not present in the underlying feeder system data then a null attribute value must be included within the Record Component object. Other attributes, marked as optional, have been included to meet published requirements or on the basis of implementation and deployment experience.

The attribute data types are all of a base type; complex attribute data types have deliberately been avoided to ease implementation and the processability of federated records. The cardinality of all Mandatory attributes is 1, and that of Optional attributes is 0 or 1.

### **Subject of care**

| RecordComponent attribute | Mandatory<br>Optional | Description of intended use  | Type   |
|---------------------------|-----------------------|--|--------|
| SynPatUID                 | Mandatory             | This is the "Subject of Care" attribute and will identify the patient about whom the record component provides information.  | STRING |
| SubjectOf Information     | Optional              | This will identify the person about whom the information in a record component relates if not the subject of care e.g. if the information is about a family member, such as the patient's father or mother.<br>PERMITTED VALUES:<br>{patient, relative, foetus, mother, donor, personalcontact, otherperson, device}<br>DEFAULT = "patient". | STRING |

Note: the values for SubjectOfInformation are taken from ENV13606-2 (Domain Termlist)

### **Record authorship, ownership and duty of care responsibilities**

| FHR-RM attribute          | Mandatory<br>Optional | Description of intended use   | Type   |
|---------------------------|-----------------------|---|--------|
| RecordingHealth CareAgent | Mandatory             | The healthcare agent responsible for physically including this record component into the patient's source record. | STRING |

|                                   |           |  |        |
|-----------------------------------|-----------|--|--------|
| ResponsibleHealthCareAgent        | Optional  | The healthcare agent responsible for effecting the care and for authoring this record component.   | STRING |
| LegallyResponsibleHealthCareAgent | Mandatory | The healthcare agent with senior clinical responsibility for the patient at the point of care documented by this record component e.g. Consultant in charge. | STRING |
| InformationProvider               | Optional  | The person providing healthcare information if not the subject of care (e.g. a family member, friend, another clinician, an electronic device).              | STRING |

Note 1: information passed to the record server is deemed to be from authenticated sources. Digital signatures are not considered to be part of the FHR information model, but might be stored within an EHR server on an enterprise-specific basis.

Note 2: although countersignature is sometimes required for health record entries, these are usually handled at an application level and do not necessarily form part of the FHR. In cases where more than one actioning healthcare agent needs to be recorded the UCL team have so far proposed that two from the available set of healthcare agent attributes above should be used, such as the RecordingHealthcareAgent and the ResponsibleHealthcareAgent.

***Dates, times, locations of health care actions and of their recording***

| FHR-RM attribute            | Mandatory<br>Optional | Description of intended use   | Type     |
|-----------------------------|-----------------------|---|----------|
| RecordingDateTime           | Mandatory             | The date and time this record component was included in the patient's source record (NOT the date and time it was brought into the federation).   | DATETIME |
| HealthcareActivityBeginTime | Optional              | The date and time of the health care activity to which this recording relates (this may differ from the RecordingDateTime if a delay occurred before a record could be authored e.g. a home visit at night).  | DATETIME |
| HealthcareActivityEndTime   | Optional              |   | DATETIME |
| ObservationBeginTime        | Optional              | The date and time (or intervals) of any health or care acts which occurred in the past but are being recorded at the present e.g. an operation performed several years ago.   | DATETIME |
| ObservationEndTime          | Optional              |   | DATETIME |
| HealthcareActivityLocation  | Optional              | The enterprise, department or other location at which the patient is receiving the care documented in this entry (for audit, management, financial or access rights purposes).  | STRING   |
| AcquisitionTimeDate         | Optional              | The date/time at which this Record Component was added to a Federated Record if its origin was elsewhere e.g. if received as a message from another record system; this attribute is necessary because the RecordingDateTime would represent when the original entry was recorded, not when it was received into the federated health record. | DATETIME |

|        |          |  |        |
|--------|----------|--|--------|
| Locale | Optional | To document the time zone and geographical location of the recording clinical system, for example permitting international interpretation of other dates and times recorded. | STRING |
|--------|----------|--|--------|

Note 1 : the UCL implementation of Healthcare Activity and Observation attributes (using the Java Calendar class) permits the recording of begin or end times to be specified to an arbitrary granularity, permitting an author, for example, to record that observation occurred between 1960 and 1965.

### ***Version control***

| FHR-RM attribute     | Mandatory<br>Optional | Description of intended use   | Type   |
|----------------------|-----------------------|---|--------|
| RevisedVersion       | Optional              | A reference to the version of this Record Component that replaces this version, if it has been revised (referenced via its RC_UID). | STRING |
| RevisedBy            | Optional              | A backward reference to the Record Component that this version has replaced, if it has been revised (referenced via its RC_UID).    | STRING |
| Authorisation Status | Mandatory             | PERMITTED VALUES: {unattested, attested, obsolete, revision}.   | STRING |

### ***Access rights***

| FHR-RM attribute   | Mandatory<br>Optional | Description of intended use   | TYPE    |
|--------------------|-----------------------|---|---------|
| AccessAmend Rights | Mandatory             | PERMITTED VALUES: {admin, audit, clinical, team, profession, hcp}<br>This set of values reflects an ordered set of sensitivity levels. The anticipated default in most EHR systems will be “clinical” i.e. the record component is accessible to all staff involved in the clinical care of the patient. This attribute is used to differentiate sensitivity levels <i>within</i> a single FHR, and are supplementary to any restrictions on overall access to each patient’s FHR as a whole. | INTEGER |

Note: this attribute permits a sensitivity level to be assigned to Record Components at any level of granularity, as part of a broader approach to access control summarised later in this paper.

### ***Emphasis and presentation***

| FHR-RM attribute | Mandatory<br>Optional | Description of intended use   | Type    |
|------------------|-----------------------|---|---------|
| Emphasis         | Optional              | At present this attribute is limited to a Boolean. If set to true the information in this record component was emphasised by the original author. | INTEGER |

Note: there is some debate about the importance of representing more detailed aspects of presentation within the FHR. The view taken by the authors is that the specification

of presentation characteristics is not necessary nor feasible for all entry instances within the records of individual patients. Where enterprises wish to retain a medico-legal reference to information display characteristics used for a given time period by certain applications, for example through a pointer to an XML Stylesheet, these ought to be retained by each enterprise or by the developers of clinical applications.

### *Class identifiers*

| FHR-RM attribute | Mandatory<br>Optional | Description of intended use  | Type   |
|------------------|-----------------------|--|--------|
| Name             | Mandatory             | This attribute preserves the actual name of the record component used in the original source record; this may be identical to the corresponding Archetype name, but might not be in the case of synonyms.                                  | STRING |
| RC_UID           | Mandatory             | An internal reference identifier for each record component, provided by the FHR server.  | STRING |
| SynObjectUID     | Mandatory             | The unique identifier of the Archetype that provides the template for this set of record components (Note: the Name attribute may not always be identical to the Archetype name).  | STRING |
| ParentRC         | Optional              | The primary information context, i.e. it is a reference to the record component at the next higher level in a record structure.  | STRING |
| EHCRSource       | Optional              | The unique identifier of the feeder system contributing this record component to the federated health record; this is important for medico-legal reasons, including the ability to link all parts of the FHR to relevant Data Controllers. | STRING |

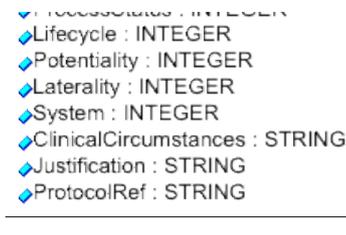
### *Other Attributes*

| FHR-RM attribute | Mandatory<br>Optional | Description of intended use  | Type   |
|------------------|-----------------------|--|--------|
| AuthorsComment   | Optional              | A free-text comment associated with the record component as a whole (not primarily with its value), intended for use by the author; it might be used by a revisor to explain the rationale for the revision.   | STRING |
| RcuLink          | Optional              | The RC_UID(s) of other record component(s) in the FHR linked by the author (e.g. to relate an allergic rash to a previous drug prescription).<br>Note: these other components must already be in the record, and therefore the references will be to past or accompanying present entries. | STRING |
| RcuLinkBack      | Optional              | This reference represents the reciprocal of the above link, from an historic target record component to the source: it will therefore point forwards in time. Some EHR systems may not permit the retrospective editing of record components to insert this attribute.                     | STRING |

Note: The RcuLink and RcuLinkBack sttributes have been implemented using the Java Vector class to permit multiple targets to be specified. The RCU link attributes overlap in function with the Link class described below. This is deliberate to reflect the varying way in which internal links are represented by different feeder systems at present.

### **Item**

The Item abstract class hierarchy provides a means to represent compound and elemental clinical concepts, using the concrete classes Compound and Element respectively. A set of context description attributes is associated with the Item objects, which are largely derived from the CEN EHR Domain Termlist standard ENV 13606-2. Other attributes such as Justification and ProtocolRef permit both a human and a software reference to the rationale behind a clinical entry, including the specification of a protocol or step in a protocol that was used during that part of clinical care. The Item class also inherits the attributes defined in the RecordComponent class, with the option to override the value of any of these at a local level.



**Figure 3: Item Class Hierarchy**

An important aspect of the FHR-RM, including the Element, is the binding of a Name attribute (acting as a label) to each content value, providing the individual quantities, dates, images or clinical terms with a primary context in any given record entry.

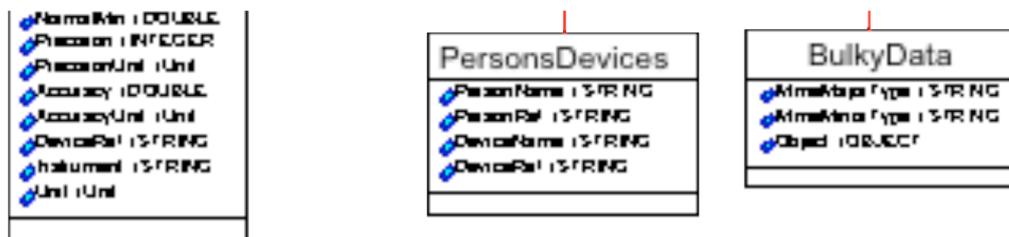
The Compound class provides an aggregation construct for clinical concepts that are composed of one or more individual named clinical values (e.g. *pulse*, *blood pressure*, *drug dose*, *heart sounds*). These entries may be aggregated within a hierarchy to

represent complex clinical concepts, but such a composition is distinct from the record structure grouping hierarchy provided by the RecordItemComplex classes such as the HeadedSection.

An additional child class of RecordItem is Link. This class provides a means by which point-to-point linkage or linkage nets within a single EHR can be represented. From an aggregation perspective, Links behave as Elements: they are leaf nodes in an FHR object hierarchy.

### *Content Classes*

The Element supports a range of data types for the DataValue that may be assigned to any element entry. These generic classes are a distillation of the original foundation work of GEHR, EHCR-SupA, and CEN/TC 251 ENV 13606.



**Figure 4: Object model of Element content**

Separate dictionaries for units and for referencing terminology systems are under development. The model for persons and devices above will reference the richer information objects in the Persons Directory Service (see below), which will later also

include a register of devices. The name strings are also included in the `PersonsDevices` class for medico-legal safety, to ensure that these attributes of a record component's content can be interpreted even if that Directory Service is somehow unavailable.

It should be noted that ENV 13606-4 defines a set of specific content models for commonly used objects such as drug prescriptions. The UCL FHR-RM deliberately does not define specific record objects of this nature: they are instead capable of being defined in and implemented through the Archetype Object Dictionary. This approach attempts to separate the most stable aspects of a health record model (through the FHR-RM) from those where local variation or evolution over time are most likely to occur (via the Archetype Object Dictionary).

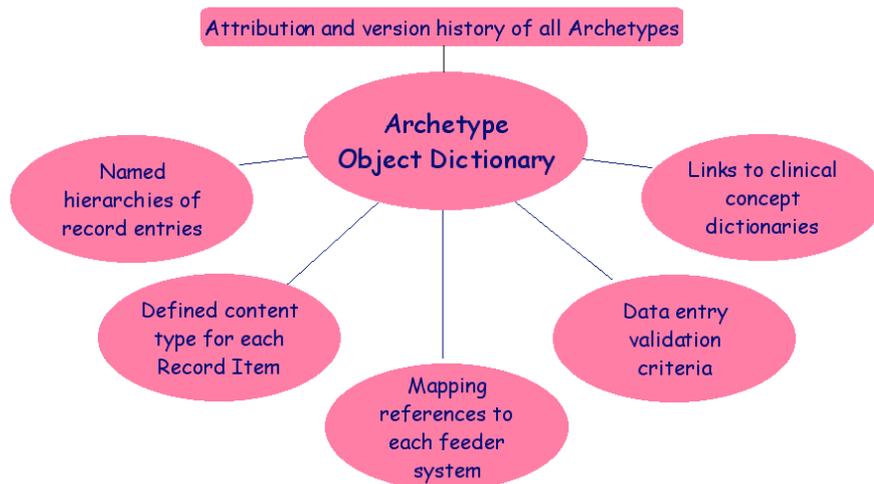
### **FHR Archetype Object Dictionary**

The classes and attributes of the Reference Model, described in the previous section, are deliberately defined at a high level of abstraction to provide an information model that can be applied to any potential health record entry. However, the individual feeder systems providing data to the FHR server are likely to be highly specific to the local requirements of individual sites, to specialities and to groups of professionals.

The Archetype Object Dictionary provides the formalism by which the specific clinical data sets and aggregates normally found in health records and in contemporary feeder systems can be defined. Archetype entries utilise the FHR-RM classes as basic building blocks, using the Name attribute of each class instance to generate specific clinical hierarchies that can be directly mapped to feeder system data schemata and can be the target of a client request.

The Archetypes can be mapped onto the data representations used in each individual feeder system through a set of access methods. These might be defined jointly by the developers of each feeder system and the developers of the FHR server at each installation, or might be derived from published interface specifications. The references to the access methods are logically integrated within the Archetype Object Dictionary during the "sign-up process" by which each feeder system is connected to the federation. In a "live" federation, a request by a client application or middleware service for a set of Record Components will result in the invocation of the relevant method(s) by the FHR service in order to retrieve the necessary health care record data from a feeder system.

Other features of the Archetype Object Dictionary are the mapping of Archetypes to clinical concept tags, and the inclusion of validation criteria that might be used to verify the instantiation of a Record Component's candidate data value. These are shown diagrammatically below.

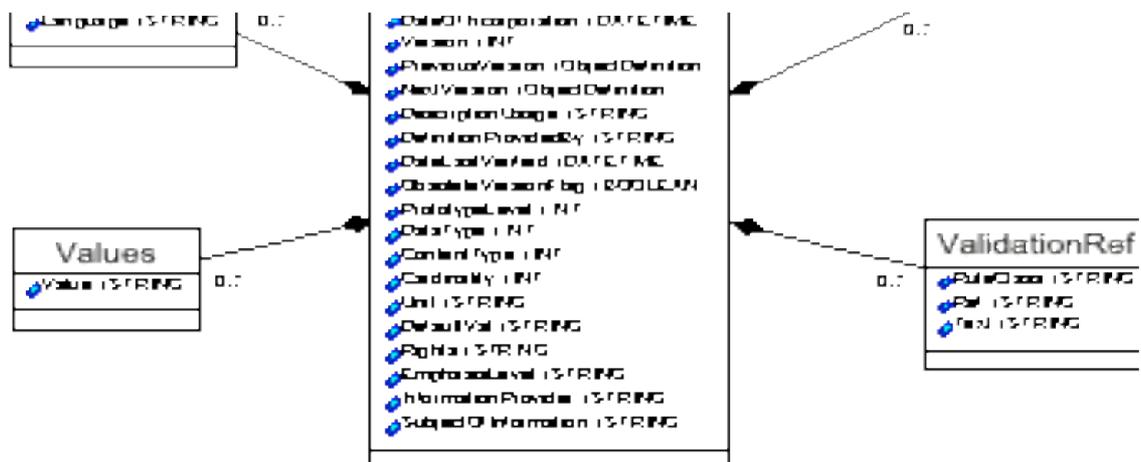


**Figure 5: Functional sub-components of the Archetype Object Dictionary**

The Archetype Object Dictionary Client component is described in a later section of this paper on Middleware Services.

### Object Model of the Archetype Object Dictionary

The formal object model of the Archetype Object Dictionary is closely related to the FHR Reference Model. It extends the RecordComponent class of the FHR-RM through the addition of one compound attribute that is used to represent the information about the creation, versioning and use of each library definition, and supports the mapping of that definition to a set of medical knowledge concept tags.



**Figure 6: Information Model of the Archetype Object Dictionary**

### **ObjectDefinition Class**

The ObjectDefinition class contains the attributes relevant to managing the library entries associated with each Archetype. This includes the formal definition, author identification and version of any local or national standardised data sets within the Dictionary. In addition, some descriptive text (a definition or explanation) may be provided to clarify the intended clinical use of the object. It will also be necessary to store information about changes that occur to Archetypes over time; this might mean recording if this particular object is the current definition, and the identification of its predecessors and/or successors. The individual attributes of ObjectDefinition are described below.

| ObjectDefinition attribute | Mandatory<br>Optional | Description of intended use   | Type            |
|----------------------------|-----------------------|---|-----------------|
| LibraryName                | Mandatory             | Archetypes are authored within libraries to permit traceability and the managed distribution of these within multi-agency domains.                                      | STRING          |
| SynObjectName              | Mandatory             | This is the standard preferred name by which the Archetype is known.  | STRING          |
| SynObjectUID               | Mandatory             | This UID is used to uniquely identify this Archetype within Record Components.  | STRING          |
| DateOfIncorporation        | Mandatory             | When the Archetype was authored in this Library.  | DATE            |
| Version                    | Mandatory             | The version number.   | INT             |
| PreviousVersion            | Optional              | A reference to the previous version if this is a revision.  | ObjectDefiniton |
| NextVersion                | Optional              | A reference to the successor version if this Archetype has been revised.  | ObjectDefiniton |
| DescriptionUsage           | Optional              | A textual description of how this Archetype was intended to be used for record entries, intended as guidance for those mapping feeder systems or clinical applications. | STRING          |
| DefinitionProvidedBy       | Mandatory             | The reference source guiding this Archetype definition, such as a clinical guideline.   | STRING          |
| DateLastVerified           | Mandatory             | When the reference source was last checked to confirm this Archetype is still valid.  | DATETIME        |
| ObsoleteVersionFlag        | Optional              | To permit Archetypes to be marked as obsolete even if a revision has not been authored.   | STRING          |
| PrototypeLevel             | Mandatory             | This attribute permits selective sharing of parts of an Archetype library to others.<br>PERMITTED VALUES: {0-2}<br>(2=PRIVATE, 1=PRIVATE_SHARABLE, 0=PUBLIC).           | INT             |
| DataType                   | Mandatory             | The FHR-RM class to which this Archetype applies.<br>Permitted Values: {0-7}<br>(0=Folder, 1=Com, 2=HeadedSection, 3=Compound, 4=Element, 5=Link, 6=View1, 7=View2).    | INT             |

|                      |           |  |        |
|----------------------|-----------|--|--------|
| ContentType          | Mandatory | Specifying the Data Value type for Archetypes whose DataType is Element. Permitted Values: {0-5} (0=No_Content, 1=Text, 2=Numeric, 3=Date_Time, 4=Persons_Devices, 5=Bulky).   | INT    |
| Cardinality          | Mandatory | Indicating the number of instances of this Archetype that may be created within any one instance of its parent e.g. 1 to many.   | STRING |
| Unit                 | Optional  | Specifying the unit of recording for Archetypes whose DataType is Element.   | STRING |
| DefaultVal           | Optional  | Providing a default value on instantiation for Archetypes whose DataType is Element.   | STRING |
| Rights               | Optional  | Permitted values for these Record Component attributes may be specified in the Archetype definition, for example in the case of a Family History Archetype to indicate that the SubjectOfInformation may not be the patient. | STRING |
| EmphasisLevel        | Optional  |  | STRING |
| InformationProvider  | Optional  |  | STRING |
| SubjectOfInformation | Optional  |  | STRING |

### ***Values Class***

This class permits the author of the Archetype to specify a fixed possible value list for Archetypes whose DataType is Element.

### ***MethodRef Class***

This class stores a set of method references that may be used to identify feeder system data relating to this Archetype.

### ***Concept Class***

This class enables a client application to reference an Archetype through the use of a locally-defined label, an abbreviated name or a language translation of it. It will also enable an application to identify the set of available objects that correspond to a clinical subject heading. This class is a place-holder for the methodology by which Archetype definitions can be appropriately linked to, for example, GALEN ontology or terminology services.

| Concept attribute | Mandatory<br>Optional | Description of intended use   | Type   |
|-------------------|-----------------------|---|--------|
| Type              | Optional              | The classification system or ontology from which the code has been derived.   | STRING |
| Code              | Optional              | A code referencing the clinical concept within that classification system or ontology.  | STRING |
| Concept           | Optional              | A rubric for that code, included for safety and to permit searches to utilise this class of information if that classification system or ontology is not available as a live look-up service. | STRING |
| Language          | Optional              | The natural language used for the rubric.   | STRING |

### ***ValidationRef Class***

This class, which is still undergoing evaluation, is a place-holder for the expression of rules regarding the validation of instance values for element objects, or the interdependence of values on other components of an Item or Complex. These rules would be used primarily during data entry rather than retrieval. For example, an entry value may be drawn from a pick-list or reference database (such as *drug name*), it may be subject to upper and lower limits (such as *height*), or its value may be restricted by other values in the record (such as the patient's age or gender).

This class contains a set of rules that must be evaluated against any candidate value for an Element conforming to this Archetype. A string text message can be returned to the clinical application if a condition is met. This provides a useful means of providing messages back to end users:

- if the value they have offered is not permitted;
- if they need to re-affirm the value (e.g. it is a rather unusual value, but not impossible);
- if the value is accepted but some further action advice needs to be communicated back to the user.

The three situations map to three sub-types of rule, reflected in three values for the RuleClass attribute: REJECT, CONFIRM, ACCEPT.

If more than one rule has been defined for an Archetype, the provisional intention for the service implementing this class is to evaluate rules in the order:

1. REJECT
2. CONFIRM
3. ACCEPT

This class is a place-holder for the methodology by which Archetype definitions can be appropriately linked to electronic guidelines and to other decision support services.

| ValidationRef attribute | Mandatory<br>Optional | Description of intended use  | Type   |
|-------------------------|-----------------------|--|--------|
| RuleClass               | Optional              | Action to be performed if the rule condition is met.<br>PERMITTED VALUES: {0-2}<br>(0=ACCEPT, 1= CONFIRM, 2= REJECT) | INT    |
| Ref                     | Optional              | The rule string to be evaluated against a candidate value for an Element of that Archetype.                          | STRING |
| Text                    | Optional              | A string to be returned by the Federated Health Record server to the calling application if this rule is met.        | STRING |

### **Middleware Services**

The federated health record is derived through a set of services that support access to distributed sources of health records. The FHR Server provides a set of middleware services that enable a requesting service (e.g. a healthcare professional using a client clinical application, or another middleware service such as a decision support agent) to access electronic health record information from a diversity of repository servers (*feeder systems*). These feeder systems may hold clinical data in a variety of different

structures, which may range from rigorous electronic health record architectures to quite simple table structures such as those found in departmental systems. The feeder systems may be on-site at an institution or connected remotely through telecommunications services.

The FHR implementation at UCL provides the means by which Record Components (aggregate sets of entries forming part of a patient's federated health record) can be retrieved, added or revised according to a schema defined in the Archetype Object Dictionary. These actions take place in accordance with the user's role-based privilege and the sensitivity of the Record Components involved, and are registered in an access audit trail.

The components outlined here are believed to constitute one of the first live implementations of a generic record server that provide proof-of-concept validation of many constructs in the current CEN EHCR standard. Recent work at UCL has resulted in considerable refinements to the Reference Model on the basis of practical experience, including some simplifications, which might helpfully inform the pending first review of ENV13606 by CEN Working Group 1.

The North London demonstrator is utilising the following UCL FHR component services:

**Federated Health Record services:** a scalable run-time FHR environment supporting distributed access to record components from new and legacy feeder systems.

**Archetype Object Dictionary Client and services:** a means of facilitating feeder system sign-up and of navigating a federation environment. It enables clinicians or engineers to define and export the data sets mapping to individual feeder systems, and to relate these to the schema requirements of clinical applications accessing the record server.

**Persons Directory services:** storing a core demographic database to search for and authenticate staff users of the system and to anchor patient identification and connection to the patient's federated health record.

**Expert Advisory (Decision Support) services:** for anticoagulation management, to calculate the patient's next treatment regimen and next monitoring interval.

**Web-based applications:** to provide end-user clinical views and functions.

### **Component engineering approach**

The FHR Reference Model has been implemented as a set of Java™ classes (and an XML DTD) that provides a reference model for:

- the federated record persistent repository
- the Archetype Object Dictionary
- feeder system mapping
- client server communications

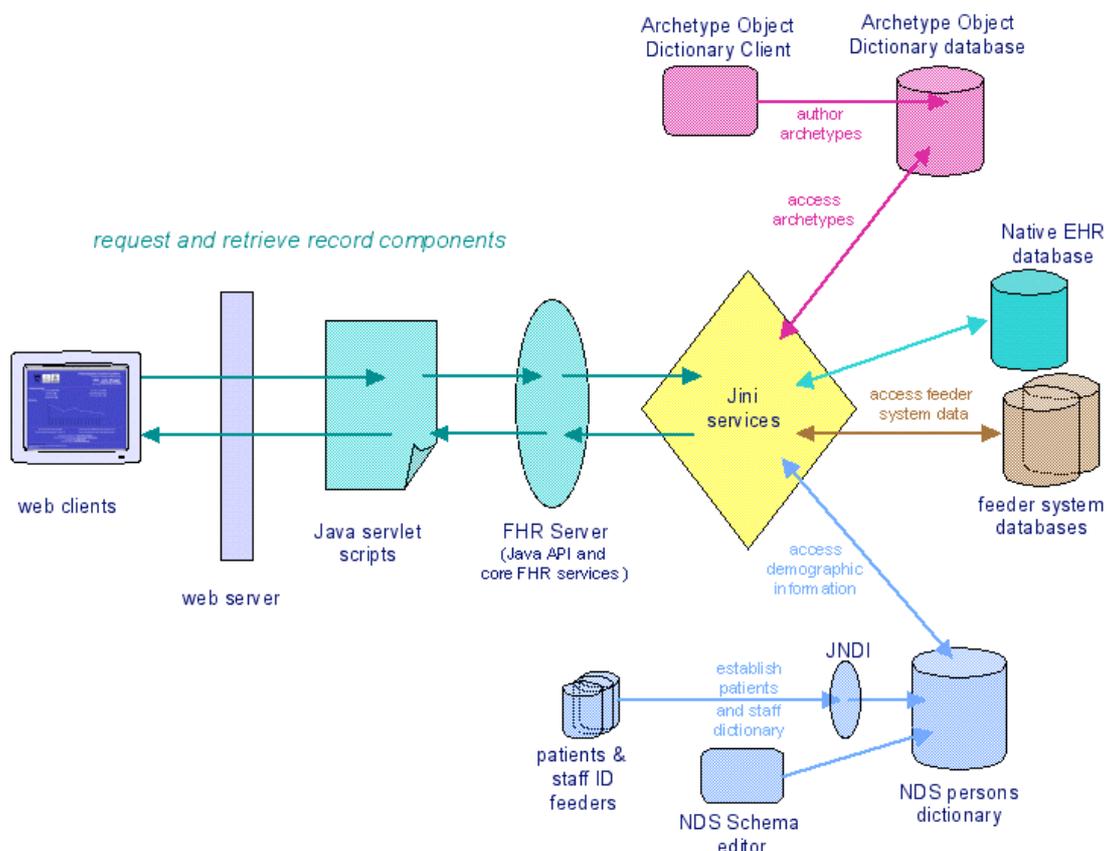
All of the main components are written in Java. The federated access to distributed clinical databases is managed through a set of directory services accessed via the Java Naming and Directory Interface (JNDI). The components are deployed within a middleware environment managed through Novell Directory Services and JINI™, an open standard service-integration technology. The services are presently deployed on a

Windows™ NT server (to suit local hospital requirements) and a second deployment using Linux™ has been tested. IPv6 web server and servlet runner applications are required for the 6WINIT project (see below) and will be deployed on the Linux™ version.

As well as accessing distributed feeder systems, the UCL FHR services incorporate a principal record database, using ObjectStore™ (from Object Design Inc.), that can be used as a local cache and provides a robust repository for data originating from feeder systems that are to be decommissioned. This object oriented database stores record components in a form native to the federation architecture. An Oracle version of the record server has also been developed and will also be tested in live use late in 2001.

New web-based clinical applications have been written, using Java servlets, to provide end user access to the patient records held within the FHR server. The web servlet scripts extract single or multiple instances of patient record objects from the FHR repository and map the output object attributes to cells within HTML tables. At present these applications exclusively use http for client-server communication.

Some additional middleware components have been authored specifically for use in the management of anticoagulation therapy. A previous decision support methodology (i.e. the algorithm and tables for warfarin control) has been re-engineered using Java. This service is now provided through specific agents called from a dedicated client and these return data to this client.



**Figure 7: FHR components handling the run-time request for and retrieval of patient records**

## Archetype Object Dictionary Client

The UCL Archetype Object Dictionary Client (ODC) component:

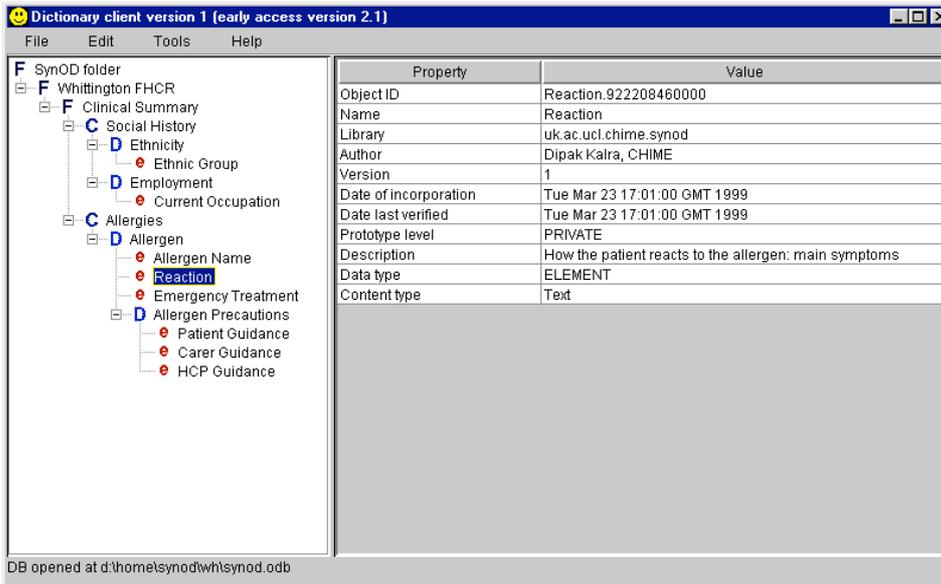
- provides an authoring tool for Archetypes in terms of their constituent compound clinical concepts;
- includes the formal definition, author identification and version of any local or national standardised data sets within the Dictionary;
- incorporates pointers to access methods which can extract data held on feeder systems to which the FHR services are connected;
- ensures adequate version control and maintenance procedures to accommodate revisions of Archetypes over time.

The Archetype Object Dictionary Client component has been written entirely using Java Foundation classes and Swing, allowing true cross-platform deployment. It utilises an object database PSE Pro, from Object Design Inc., which is also a Java application and is similarly capable of installation on any platform that supports a Java Virtual Machine. The licence for PSE Pro permits the distribution of run-time versions alongside the Archetype Object Dictionary application, removing the need to purchase any additional third-party software. The ODC permits the structure of the record object definitions to be captured in a way that the user originally intended for maximum performance and flexibility.

The core features of the ODC are listed below.

|   |
|---|
| <a href="#">ODC Class Hierarchy</a>                             |
| <a href="#">ODC Archetype Properties</a>                        |
| <a href="#">Creating New Archetype Entries</a>                  |
| <a href="#">Cardinality on Instantiation</a>                    |
| <a href="#">Validation Criteria</a>                             |
| <a href="#">Data Retrieval Methods</a>                          |
| <a href="#">Copying and Pasting Archetypes in the Hierarchy</a> |
| <a href="#">Publicising Archetypes</a>                          |
| <a href="#">Deleting an Archetype</a>                           |
| <a href="#">Marking an Archetype Obsolete</a>                   |
| <a href="#">Revising an Archetype Definition</a>                |
| <a href="#">Reviewing the Version History</a>                   |
| <a href="#">Tracking Archetypes having Multiple Parents</a>     |
| <a href="#">Exporting the Database</a>                          |
| <a href="#">Saving the Database</a>                             |
| <a href="#">Help about screen</a>                               |

Future work will enable synonyms for clinical object names to be identified and linked to preferred terms, and offer a multi-lingual set of clinical object names. Data entry validation criteria may also be incorporated, and their linkage to run-time protocol components is being explored.



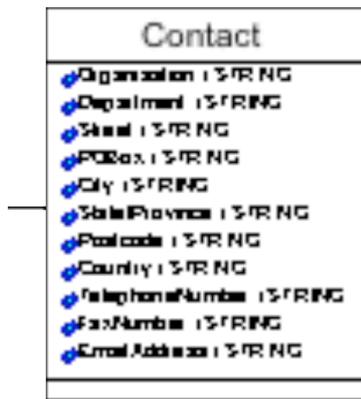
**Figure 8: Example screen from the Archetype Object Dictionary Client**

### FHR Persons Directory Service

The Persons Directory Service is a component providing information on the identification of patients, healthcare professionals and other staff to the other FHR services. It provides a repository of person names and other demographic information, together with their access rights status, that can be used to identify persons within an FHR or to authenticate access rights to a given set of record components.

The Persons Directory provides a means of registering staff and patients within a consistent repository as part of the FHR. This model has been proposed, and implemented as the Persons Directory Service, in order to provide a means of searching for patients, confirming the correct patient has been chosen, and providing a basic demographic data-set as part of each patient's federated health record. In many situations where an FHR server is deployed there is likely also to be a regional or national directory of patients and also of healthcare agents, which would replace the service described here. The overall engineering approach to the FHR middleware would permit the replacement of the Persons Directory Service with a local alternative quite easily.

The information model builds on the early work of GEHR and Synapses, which has been refined by the EHCR-SupA project. The models proposed here by UCL are a simplified but consistent representation of the Healthcare Agent subsystem defined in CEN/TC 251 ENV 13606 (EHCR Communication). This model is deliberately not intended to mimic a full patient demographic server such as a hospital PAS.



**Figure 9: Information Model of the FHR Persons Directory**

The data repository uses and extends Novell NDS objects and its metadirectory, and is accessed via Java Naming and Directory Interface (JNDI) APIs. This entails some configuring of the NDS tree and its class models to optimise it as an object repository for patient and staff identification. For deployment purposes, Novell eDirectory has been used as the product to provide and manage the NDS services.

A Software and Devices Directory is also being developed using NDS, and is intended to provide a registry of all electronic sources of FHR information (such as monitoring devices and decision support software) that might be referenced within a patient's record.

## **Access Control**

A combination of internal services is used to deliver an overall access control framework governing access to FHR information, reflecting enterprise policies by:

- determining user profiles from available authentication and certification services;
- limiting patient searching within organisational contexts;
- limiting access to sub-categories of the record based on roles e.g. a department or speciality.

Specific structured parts of each patient's FHR can record individual patient consent to:

- map a user's role-based privilege to the sensitivity of individual record components;
- permit access to sub-categories of the record based on roles e.g. for research or teaching;
- exclude named persons from adopting certain roles for accessing individual patient records.

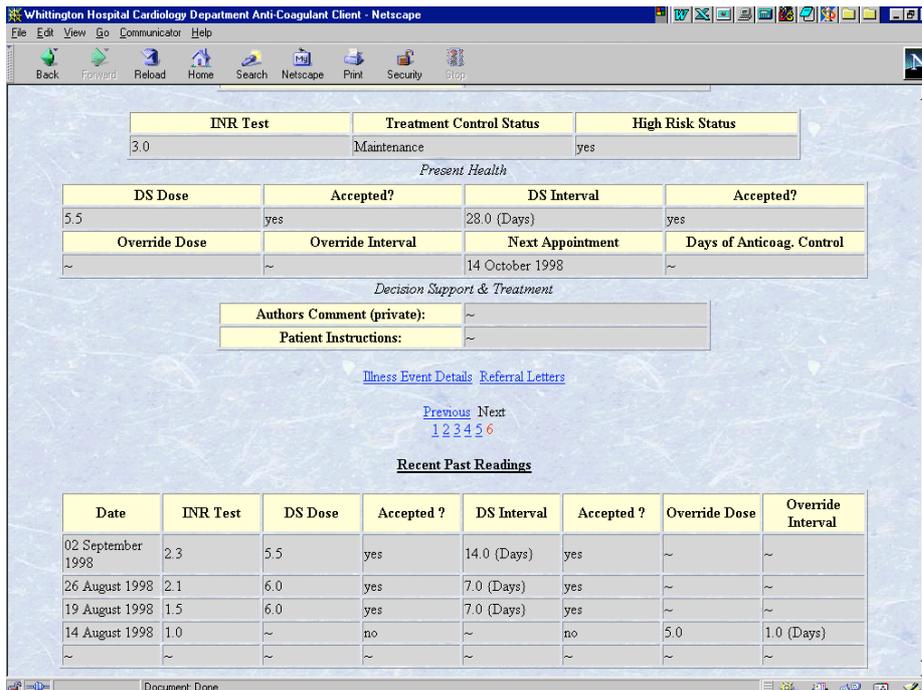
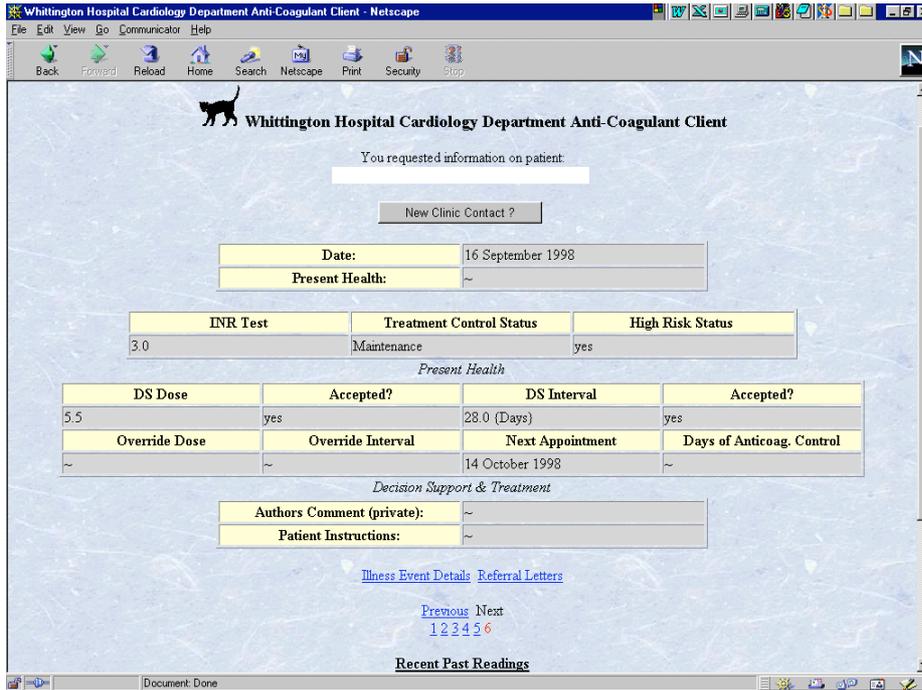
These services are in the process of being implemented and tested, and will be published later.

## **North London Demonstrator Setting**

The UCL FHR components have so far been implemented along with two clinical applications: one in cardiology (anticoagulant therapy management) and one in respiratory medicine (asthma home monitoring). The anticoagulant application is now live, and new applications to capture basic medical summaries and for the management of chest pain clinics and are being designed for deployment during the 6WINIT project lifetime. The asthma home monitoring application is restricted to a research context and is not as yet envisaged as a live clinical service.

### *Anticoagulant application*

This application provides a set of HTML web clients to enable the management of anticoagulation therapy by clinical staff (or patients) trained to monitor this. The overall application includes forms to deal with requests for and the display of existing data, and also with data entry. The system incorporates drug dosing decision support and recommends monitoring intervals between blood tests. It has been written to replace a legacy application, and is the first live clinical application to test the FHR server. This application is being used daily by staff at the Whittington Hospital, running clinics with up to 110 patients per day. It will shortly be accessed from outside the hospital by a community pharmacist, and it is hoped to include other pharmacists, GPs and patients as users within the next 12 months. Only some of the actual FHR objects and attribute values are shown on user screens, to meet the needs of the users who run the anticoagulation clinics at the Whittington.



**Figure 10: Anticoagulant Client - viewing a clinic contact (top and bottom half of the web page)**

*The 6WINIT Project*

The IPv6 Wireless internet INITiative (6WINIT) project is a European IST Framework V initiative involving major European telecom companies, equipment manufacturers, solutions/software providers, research laboratories and end-user hospitals. Its objectives

are to validate the introduction of the new mobile wireless Internet in Europe - based on a combination of the new Internet Protocol version 6 (IPv6) and the new wireless protocols (GPRS and UMTS/3GPP). The UCL north London demonstrator, based at the Whittington Hospital, is one of the three clinical sites. Work in progress is expected to demonstrate applications using wireless and IPv6 Internet services to access FHR services during 2002.

#### *Chest Pain Management*

A new application is being written to provide clinicians with access to the record of patients having non-acute chest pain (i.e. possible heart disease) symptoms. The primary clinical application will be hosted on the same FHR server as the anticoagulant system, and share the same core middleware services. The intention is for this application to be accessed from workstations inside the Whittington Hospital and from selected GP practices.

#### *Mobile views*

Two views of a patient's medical summary will be created, one for emergency care and one for patients who wish to view their own record. For this we hope to utilise 6WINIT mobile networks and PDAs supplied through consortium partners. The emergency view is expected to be a helpful demonstration of secure mobile use of the 6WINIT networks, and is a high-profile strategic goal of the UK Department of Health.

#### *NHS ERDIP Demonstration*

The UCL record server components have been selected by South West Devon ERDIP for the development of a cardiovascular EHR connecting local hospitals and GPs. This work will replicate and extend the Whittington implementation of the record server to suit the requirements of a regional network of collaborating hospitals and general practices.

#### *Further developments*

Further developments planned for the medium term include collaborative work with General Electric/Marquette to incorporate investigation reports (in particular, bio-signals) within the federated record. This integration will explore new facets of live feeder system federation and distributed access to multimedia data.

### **Conclusion**

UCL is in the process of establishing an international foundation (*openEHR*), co-ordinated by UCL and with specific collaborating centres in Australasia and the US [15]. This will operate as a non-profit body to foster high quality electronic health records amongst the purchaser, vendor and user communities. The generic components of the UCL federated health record server described here will next year be offered as Open Source products through the *openEHR* Foundation.

The experience gained to date in the design, implementation and deployment of a generic federation health record server has revealed many issues that still need to be explored and empirically tested before any claim could be made to have met the challenge of delivering ubiquitous and appropriate access to health information. The work described in this paper should be seen as steps on a journey towards that vision,

hopefully with future opportunities to partner a number of organisations internationally in the same way that we have valued so far.

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