providing intuitive access to federated healthcare records - securely

Software Components

being developed by

University College London

for the

SynEx Project
&
London Demonstrator Site

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Component Overview
The main components are written in Java™ and deployed within a middleware environment managed through directory services. This will allow the development of flexible and portable applications that can inter-operate across diverse architectures and infrastructures.

These components have been developed by UCL or other SynEx Consortium members, and demonstrated in north London through the provision of seamless cardiology shared care, initially for patients requiring anticoagulant therapy.
The heart of the London SynEx demonstrator is a set of directory services accessed through the Java Naming and Directory Interface (JNDI), utilising Novell NDS.

This provides run-time access to:
- the Synapses Object Dictionary
- a set of legacy data feeder systems
- an EHCR Object Repository
- a dictionary of persons and devices
- a dictionary of access permissions
- access to other data services (e.g. terminology, protocols)

Many object sources can be attached to a hierarchy within the SynEx federation, and can return objects and attributes from a lookup. Any authorised client that can see the directory automatically has access to the whole SynEx Object Dictionary and patient record databases. The demonstrator site will utilise the JNDI service SPI and probably Enterprise Java Beans as the methodology for supporting the uniform distributed access to all SynEx data component services.
**Federated Record Service Component Set**

*faithfully combining records from diverse feeder systems*

*building on the work of Synapses and CEN/TC251*

A comprehensive electronic healthcare record repository utilising a directory service and object-oriented engineering approach

- to store any healthcare record information acquired from a diverse range of clinical databases and patient-held devices
- to support the secure, mobile and distributed access to federated healthcare records via web-based services

**Technical Features:**

- A comprehensive and medico-legally rigorous reference model for the federation, based on research within Synapses, GEHR, EHCR-SupA and CEN/TC251, implemented using Java classes and XML DTDs.
- A pure object oriented EHCR database (Object Store, from Object Design Inc.) to store record components in a form native to the federation architecture, offering superior performance for storage, selection and retrieval.
- Tools to facilitate the decommissioning of feeder systems and/or the presentation of their data as XML objects.
- Web Servlet extraction methods, generating generic record clients to provide a base-level approach to the presentation of FHCR data.
- Generic data entry clients to provide basic templates to allow users to create new record instances.
Object Dictionary Service Component Set

managing and mapping the domain-specific user objects required to deliver clinical care

The Object Dictionary identifies the object sets to be retrieved from federated feeder systems in response to a client request, and incorporates references or access methods to the underlying FHCR feeder system data.

- Authoring Component
  - allows end-users to author clinician defined “user objects”
  - enables mapping to the underlying feeder system schemata
  - written using Java, with Swing/JFC as the visual sub-component
  - a hierarchical (tree) display supported by search and management functions
  - object definitions stored in PSE Pro object database (Object Design Inc.)
  - XML generator and parser facilities
  - replication function allows for the synchronisation of object dictionaries within a distributed environment

Future versions will incorporate:
- synonyms, customised for users’ preferred terms and preferred language
- clinical concepts, knowledge tags, links to GALEN services
- qualifiers, CEN/TC251 standard component name categories and annotations
- data entry validation criteria and links to PROforma protocols
- terminology system browsers
- links to a public domain (XML) library of standard objects
**Protocol Components**

PROforma is a set of guideline authoring and run-time software products developed at the Imperial Cancer Research Fund and marketed (as Arezzo™) by Infermed. The authoring tool allows users to create a wide range of nested clinical management guidelines, which are represented in a candidate pre-standard interchange format.

The run-time components are presently being re-authored in Java, to be delivered using web-based services. These products will be deployed the north London, inter-operating seamlessly with the record and object dictionary services.

For further information PROforma about please contact Prof. Jon Fox: jf@acl.icnet.uk

**Security Components**

The north London demonstrator will utilise a range of security software components and devices as part of an integrated security policy framework. Various industry standard components will be deployed alongside others developed within the SynEx Consortium. UCL will publish the specification of its validated approach to EHCR security, including:

- security frameworks and policies;
- security protocols;
- mechanisms for authenticating users;
- protection of the integrity of information;
- data privacy schemes;
- cryptology;
- authentication systems (e.g. Kerberos);
- firewall design and implementation;
- user authentication on NDS (ensuring that login and password information is securely held);
- persons look-up service (patients and healthcare professionals)
The North London Demonstrator

seamless cardiology services

The SynEx London demonstrator comprises a set of primary and secondary care sites in north London working in partnership with University College London.

- The Department of Cardiovascular Medicine at the Whittington hospital, integrating:
  - anticoagulant clinical management system
  - cardiology investigation and monitoring devices (Marquette/General Electric)
  - atrial fibrillation specialist systems
  - coronary artery database and display application
- A consultant-led community cardiology service offering integrated ambulatory patient care, requiring:
  - a comprehensive EHCR system
  - links to electronic guidelines and educational libraries
- 2-4 community-based consultant cardiology clinics
  - communicating within the federation through secure telecommunications links
- Several GP practices in north London
  - integrating data from GP-CARE (UK NHS accredited GP computer system)

Decision Support Components

- based on a clinically validated algorithm for warfarin dosage control
- engineered as a specific service using Java agent
- called from a dedicated client and returning data to this client
The Centre for Health Informatics & Multiprofessional Education (CHIME) was established in 1995 to develop and integrate initiatives in health informatics, education and health services research. CHIME is a collaborative venture between University College London, renowned for its work in biomedical research, and the Whittington NHS Trust, with a reputation for clinical practice and education. CHIME seeks to respond innovatively to local challenges and to changing healthcare needs.

Key activities undertaken by the informatics team at CHIME include the Good European Health Record, EHCR-SupA and Synapses projects within the EU Health Telematics Programme, and representation on CEN TC/251 in the domains of Electronic Healthcare Records and Medical Imaging.

The SynEx Consortium

co-ordinating partner: GESI, Rome, Italy
project main web site: http://www.gesi.it

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providing intuitive access to federated healthcare records - securely

Federated Record Service Components
**Introduction**

**Summary**

The key ingredients of the SynEx-UCL software component set are:

1. A comprehensive and federated electronic healthcare record that can be used to reference or to store all of the necessary healthcare information acquired from a diverse range of clinical databases and patient-held devices.

2. A directory service component to provide a core persons demographic database to search for and authenticate staff users of the system and to anchor patient identification and connection to their federated healthcare record.

3. A clinical record schema management tool (Object Dictionary Client) that enables clinicians or engineers to define and export the data sets mapping to individual feeder systems.

4. An expandable set of clinical management algorithms that provide prompts to the patient or clinician to assist in the management of patient care.

CHIME has built up over a decade of experience within Europe on the requirements and information models that are needed to underpin comprehensive multi-professional electronic healthcare records. The resulting architecture models have influenced new European standards in this area, and CHIME has designed and built prototype EHCR components based on these models. The demonstrator systems described here utilise a directory service and object-oriented engineering approach, and will support the secure, mobile and distributed access to federated healthcare records via web-based services.

The design and implementation of these software components has been founded on a thorough analysis of the clinical, technical and ethico-legal requirements for comprehensive EHCR systems, published through previous project deliverables and in future planned papers.

The north London clinical demonstrator site (based in the Whittington Hospital) has provided the solid basis from which to establish "proof of concept" verification of the design approach, and a valuable opportunity to install, test and evaluate the results of the component engineering undertaken during the EC funded project. New EC Fifth Framework project funding has already been approved to enable new and innovative technology solutions to be added to this work.

**Background**

A major impediment to the progress towards evidence-based medical practice, shared patient care and resource management in healthcare is the inability to share information effectively across systems and between carers. Electronic and paper healthcare records are held in islands of information in independent information systems, each with its own technical culture and view of the healthcare domain. Patient care frequently involves the sharing of clinical responsibility between different professionals working in different departments, sometimes on different sites; the care of any one patient may potentially require a healthcare professional urgently to review the information held in several such clinical systems in a consistent manner.

Health care enterprises and regions therefore have a need to federate a very large number of physically and technically diverse feeder systems that may be scattered across hospital departments, specialised units, primary care and other community settings [1].
UCL has taken the experience and results of the Synapses project (from the EU Health Telematics Fourth Framework) as the basis for the set of federated healthcare record components, described in this report.

**The Synapses Approach**

The Synapses approach to this challenge utilises the methodology of database federation to a standard and comprehensive schema (the Synapses Federation Healthcare Record architecture), mediated and managed through a set of middleware services [2]. The emphasis of Synapses has been to facilitate data sharing between a set of federated clinical systems via the Server, rather than to integrate the specialist systems that supply or use the data [3].

The Synapses results provide the generic specification for a middleware server which will enable a healthcare professional to access clinical information from a diversity of repository servers (*feeder systems*) in response to a request issued through a client workstation. These feeder systems may hold clinical data in a variety of different structures, which may range from rigorous electronic healthcare record architectures to quite simple table structures such as those found in locally developed departmental systems. The feeder systems may be on-site at an institution or connected remotely through telecommunications services. At times the Synapses Server may be involved in the transfer of healthcare information between two servers rather than its presentation to a client workstation.

The Synapses federation therefore contains a set of services which support access to distributed sources of healthcare records. The Synapses approach enables the sharing of healthcare records between different applications, and allow institutions to integrate the clinical information held in a range of existing legacy systems.

Conceptually, a Synapses Server provides a unified and communicable view of a patient’s (distributed) healthcare record, drawn from any number of individual feeder systems which are themselves based on a diversity of data architectures. This harmonised view, the **Synapses Federated Healthcare Record (SynFHCR)**, is the high-level federation schema to which all of the individual feeder system schemata are related. Each Synapses Federated Healthcare Record is the complete logical set of record component objects relating to a single subject of care (the patient) within the federation domain of one or more Synapses Servers.

It is realised in practice, for any one patient, through a series of specific responses to formal object requests for record extracts [4]. Client applications are able to request patient record information in the form of Synapses Objects: these are record

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**Figure 1: Illustration of the functions provided by a Synapses server**

The Synapses federation therefore contains a set of services which support access to distributed sources of healthcare records. The Synapses approach enables the sharing of healthcare records between different applications, and allow institutions to integrate the clinical information held in a range of existing legacy systems.
components that could be, in their simplest form, clinical datasets. The SynFHCR architecture has been informed by the requirements for clinical comprehensiveness and ethico-legal acceptability identified by the GEHR project [5,6]. Its class hierarchy builds on the constructs defined in the CEN pre-standard for EHCR architectures [7].

The SynFHCR for any given patient is therefore a set of distributed Synapses record component objects, which can be communicated rigorously and securely within a standards-based CORBA [8] or DCOM compliant middleware environment. The generic model encapsulating the information content of these objects is the Synapses Object Model (SynOM): this model provides the basis by which SynFHCR extracts are transferred from feeder systems via the Synapses Server to the requesting client. The SynOM defines a set of base (foundation) object classes by which the SynFHCR is modelled and to which feeder system database schemata must be mapped. It is the generic architecture of the federated healthcare record.

In order to share clinical information meaningfully, it is also necessary that the formal definitions of specific clinical concepts and data types found in healthcare records be held in common across the SynFHCR, informing the request and response processes. This common information is contained in a set of dictionaries of object definitions, compositions and other relevant persistent data. This standardised dictionary set, together with a set of internal methods, is the Synapses Object Dictionary. The Object Dictionary classes extend the generic FHCR architecture to define the specific clinical data sets and record structures within each mapped feeder system. It defines the complete set of object templates that will correspond (on instantiation) to the domain of potential components within any individual patient record, and is described separately in this report.

**The SynOM**

The UCL SynOM is based on and fully complies with the set of constructs defined by the Synapses project, which optimise the faithful mapping to and from a wide range of clinical databases and comprehensive EHCR architectures. The work has been refined though early implementation experience, and closely maps to the architecture constructs defined in CEN/TC 251 ENV 13606. (It should be noted that the work of Synapses and EHCR SupA significantly shaped this architecture standard).

The SynOM classes and attributes provide a flexible and comprehensive “universal schema” for clinical data that may be derived from a diversity of feeder systems, and from which more sophisticated healthcare record models and messages can be constructed to suit the needs of individual client domains.

The SynOM models the generic characteristics of the hierarchical organisation of entries within any potential electronic healthcare record, and defines a set of attributes that capture the recording context and medico-legal status of each record component. Clearly record entries will vary enormously, and a separate but complementary approach to defining particular clinical concept hierarchies is described later (the Object Dictionary).

The UCL SynOM is drawn below in two diagrams: the first showing its class inheritance hierarchy, and the second showing its aggregation (containment) hierarchy. The diagram conventions are based on the UML notation. The attributes have been omitted from the overall diagrams below, and are defined later in this section.
Figure 2: Class Inheritance within the SynOM

Figure 3: Class Aggregation within the SynOM
Description of the principal SynOM Classes

RecordComponent

RecordComponent is the abstract base class for RecordItemComplex and RecordItem. It defines the common attributes applicable to all of the major classes of the SynOM for:

- Record authorship, ownership and duty of care responsibilities
- Subject of care
- Dates and times of healthcare 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 SynOM 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 RecordItemComplex and RecordItem constructs respectively represent these two broad categories of aggregation.

RecordItemComplex (RIC)

In the SynOM, RecordItemComplex is the common abstract super-class for the grouping of observations that relate to the health care activities performed. Two broad categories of RIC are defined in the standard, and are reflected in the SynOM through two abstract sub-classes of RecordItemComplex.

1. OriginalRIC: 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. ViewRIC: 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.

OriginalRIC

Three concrete classes of OriginalRIC are defined in the SynOM, to provide for the nested aggregation of original groupings for record entries.

FolderRIC

FolderRICs define the highest-levels of organisation within healthcare 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 FolderRICs include an episode of care, an inpatient stay, or one stage of a disease process. FolderRICs can contain other FolderRICs, and/or ComRICs.

RecordFolder

The RecordFolder class is a special sub-class of FolderRIC. It defines the root folder within a single patient’s healthcare record i.e., a Synapses Federated Healthcare Record must consist of exactly one FolderRIC object.
ComRIC
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 EHCR stores comprise whole ComRICs. This explicitly includes caches and cache mechanisms. The ComRIC also defines the medico-legal cohort for the inclusion of new entries within an EHCR: any new EHCR entry (even if stored on a local feeder) must be a whole ComRIC. ComRICs cannot contain other ComRICs or FolderRICs. 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.

DataRIC
This class is intended for grouping observations under headings within a ComRIC. 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 DataRIC names include presenting history, symptoms, investigations, treatment, drug prescription, needs, or plan. DataRICs may contain other DataRICs and/or RecordItems. They cannot contain ComRICs or FolderRICs.

ViewRIC
Two concrete classes of ViewRIC are defined in the SynOM, to provide for two differing mechanisms by which views may be generated.

ViewRIC1
The ViewRIC1 provides a means for grouping entries within ComRICs, at a similar hierarchical level in a record to the DataRIC. However, the data within a ViewRIC1 is derived through the use of a predefined query procedure i.e. a ViewRIC1 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 ViewRIC1 class is presently being developed. At present, as in ENV 12265, the query procedures may only return RecordItems.

ViewRIC2
The ViewRIC2 provides a static view of original information, through a set of references to the original entries or to groups of entries (i.e. RecordItems, DataRICs and/or ComRICs). It therefore provides a mechanism by which information within one ComRIC may logically appear inside another ComRIC, since the originals of these cannot be nested. This class cannot include object references to other instances of ViewRIC2, to avoid recursive loops of such references.

RecordItem
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 RecordItemComplex classes. This class also provides a means by which point-to-point linkage or linkage nets within a single EHCR can be represented. The RecordItem 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 SynOM 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 managed by a Synapses server 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 as recommendations for good practice.

Subject of care

<table>
<thead>
<tr>
<th>RecordComponent attribute</th>
<th>Mandatory/Optional</th>
<th>Description of intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>SubjectOfCareID</td>
<td>Mandatory</td>
<td>this will identify the patient about whom the record component relates</td>
</tr>
<tr>
<td>SubjectOfInformation</td>
<td>Optional</td>
<td>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 PERMITTED VALUES: {patient, relative, foetus, mother, donor, personalcontact, otherperson, device} DEFAULT = &quot;patient&quot;</td>
</tr>
</tbody>
</table>

Record authorship, ownership and duty of care responsibilities

<table>
<thead>
<tr>
<th>SynOM attribute</th>
<th>Mandatory/Optional</th>
<th>Description of intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>RecordingHealthCareAgent</td>
<td>Mandatory</td>
<td>the healthcare agent responsible for including this record component into the patient’s source record (NOT the end-user requesting it as a Synapses Object)</td>
</tr>
<tr>
<td>ResponsibleHealthCareAgent</td>
<td>Optional</td>
<td>the healthcare agent responsible for authoring this record component and taking medico-legal responsibility for it</td>
</tr>
<tr>
<td>LegallyResponsibleHealthCareAgent</td>
<td>Mandatory</td>
<td>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</td>
</tr>
<tr>
<td>RevisedBy</td>
<td>Optional</td>
<td>the healthcare agent responsible for the current version of this record component, if the current version is an amendment</td>
</tr>
<tr>
<td>InformationProvider</td>
<td>Optional</td>
<td>the person providing healthcare information if not the subject of care (e.g. a family member, friend, another clinician, an electronic device)</td>
</tr>
<tr>
<td>ContactWithHealthCareAgent</td>
<td>Optional</td>
<td>The name of the person who has provided health care to the patient, if not the recording HCA or the information provider</td>
</tr>
<tr>
<td>EHCRSource</td>
<td>Optional</td>
<td>the legal source enterprise (the &quot;owner&quot;) of the EHCR to which these record components relate; in a multi-enterprise federation it will be necessary to distinguish legal ownership to comply with EU regulations on disclosure</td>
</tr>
</tbody>
</table>
### Dates, times, locations of healthcare actions and of their recording

<table>
<thead>
<tr>
<th>SynOM attribute</th>
<th>Mandatory</th>
<th>Optional</th>
<th>Description of intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>RecordingDateTime</td>
<td>Mandatory</td>
<td></td>
<td>the date and time this record component was included in the patient’s source record (NOT the date and time it was retrieved by the Synapses Server)</td>
</tr>
<tr>
<td>HealthcareActivityBegin</td>
<td>Optional</td>
<td></td>
<td>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)</td>
</tr>
<tr>
<td>HealthcareActivityEnd</td>
<td>Optional</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ObservationBeginDateTime</td>
<td>Optional</td>
<td></td>
<td>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</td>
</tr>
<tr>
<td>ObservationEndDateTime</td>
<td>Optional</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HealthcareActivityLocation</td>
<td>Optional</td>
<td></td>
<td>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)</td>
</tr>
</tbody>
</table>

### Version control

<table>
<thead>
<tr>
<th>SynOM attribute</th>
<th>Mandatory</th>
<th>Optional</th>
<th>Description of intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>RevisedVersion</td>
<td>Optional</td>
<td></td>
<td>a reference mechanism for linking versions of an amended record component; proposed as a triplet comprising the RC_UID of the (first) original version, the RC_UID of the previous version (if any), and the RC_UID of the successor version (if any)</td>
</tr>
<tr>
<td>AuthorisationStatus</td>
<td>Mandatory</td>
<td></td>
<td>PERMITTED VALUES: {unattested, attested, obsolete, revision}</td>
</tr>
</tbody>
</table>

### Access rights

<table>
<thead>
<tr>
<th>SynOM attribute</th>
<th>Mandatory</th>
<th>Optional</th>
<th>Description of intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>AccessAmendRights</td>
<td>Mandatory</td>
<td></td>
<td>PERMITTED VALUES: {admin, audit, clinical, team, profession, hcp}  This set of values reflect an ordered set of sensitivity levels. The anticipated default in most EHCR 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 within a single EHCR, and are supplementary to any restrictions on overall access to each patient’s EHCR as a whole.</td>
</tr>
</tbody>
</table>

### Emphasis and presentation

<table>
<thead>
<tr>
<th>SynOM attribute</th>
<th>Mandatory</th>
<th>Optional</th>
<th>Description of intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emphasis</td>
<td>Optional</td>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>
### Class identifiers

<table>
<thead>
<tr>
<th>SynOM attribute</th>
<th>Mandatory/Optional</th>
<th>Description of intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>ClassName</td>
<td>Mandatory</td>
<td>this attribute preserves the actual name of the record component used in the original source record; this may be identical to the corresponding Object Dictionary name, but might not be in the case of synonyms</td>
</tr>
<tr>
<td>RC_UID</td>
<td>Mandatory</td>
<td>an internal reference identifier for each record component, provided by the Synapses Server</td>
</tr>
<tr>
<td>SynapsesObjectUID</td>
<td>Mandatory</td>
<td>The unique identifier of the Synapses Dictionary Object that provides the template for this set of record components (Note: the Name attribute may not always be identical to the Synapses Object name)</td>
</tr>
<tr>
<td>ParentRC</td>
<td>Optional</td>
<td>The primary information context, i.e., it is a reference to the record component at the next higher level in a record structure. The object referred must be an OriginalRIC.</td>
</tr>
</tbody>
</table>

### Other Attributes

<table>
<thead>
<tr>
<th>SynOM attribute</th>
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<th>Description of intended use</th>
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</thead>
<tbody>
<tr>
<td>AuthorsComment</td>
<td>Optional</td>
<td>a free-text comment associated with the record component as a whole (not primarily with its value), intended for use by the author</td>
</tr>
<tr>
<td>RCULink</td>
<td>Optional</td>
<td>the RC_UID(s) of other record component(s) in the EHCR linked by the author (e.g. to relate an allergic rash to a previous drug prescription) Note: these other components must already be in the record, and therefore will be from the past or an accompanying present entry</td>
</tr>
<tr>
<td>RCULinkBackToSource</td>
<td>Optional</td>
<td>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 EHCR systems may not permit the retrospective editing of record components to insert this attribute.</td>
</tr>
</tbody>
</table>
**RecordItem**

This (abstract) class defines structure of the individual clinical entries within a record. It is defined in the standard as "the smallest unit of information which remains meaningful as an entry in a healthcare record". The RecordItem class hierarchy provides a means to represent compound and element clinical concepts, using the concrete classes CompoundItem and ElementItem respectively. A set of context description attributes is associated with the RecordItem objects, which are largely derived from the CEN EHCR Domain Termlist standard ENV 13606-2. The RecordItem class also inherits the medico-legal attributes defined in the RecordComponent class, with the option to override the value of any of these at a local level.

![Record Item Class Hierarchy Diagram]

An important aspect of the ElementItem is the binding of a name (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 CompoundItem 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.

An additional child object of RecordItem is LinkItem. This class provides a means by which point-to-point linkage or linkage nets within a single EHCR can be represented. From an aggregation perspective, LinkItems behave as ElementItems: they are leaf nodes in an EHCR object hierarchy.
Content Classes
The ElementItem supports a range of data types for the content value that may be assigned to any element entry. These generic classes are a distillation of the original foundation work of GEHR and the recent proposals in CEN/TC 251 ENV 13606.

![Figure 5: Object model of Element Item content](image)

Separate dictionaries for units and for referencing terminology systems are under development. The model for persons and devices above will reference the richer demographic information stored in the Persons and Devices Dictionary. The name strings are also included for medico-legal safety, to ensure that these attributes of a record component’s content can be interpreted even if connection to the Persons and Devices Dictionary 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 SynOM deliberately does not define specific record objects of this nature: they are instead capable of being defined in and implemented through the Object Dictionary. This approach attempts to separate the most stable aspects of a healthcare record model (through the SynOM) from those where local variation or evolution over time are most likely to occur (via the Object Dictionary).
**Engineering Overview of the FHCR Service Components**

**Middleware Computing Environment**

The heart of the London SynEx demonstrator is a set of directory services accessed through the Java Naming and Directory Interface (JNDI) and a distributed set of record and other expert knowledge services delivered via JINI™, providing the run-time access to:

- the Synapses Object Dictionary
- a set of legacy and newly developed data feeder systems
- an EHCR Object Repository
- a dictionary of persons and devices
- a dictionary of access permissions
- access to other knowledge services (e.g. decision support, protocols)

These are shown schematically in Figure 6 below.

**Figure 6: Data services delivered through Directory Services and JINI**

**Directory Service Approach**

The federated access to distributed clinical databases is managed through a set of directory services accessed via the Java Naming and Directory Interface (JNDI). This environment provides the run-time access to the record objects defined within the Object Dictionary Client (ODC), drawn from legacy and newly developed data feeder systems.

The whole computer industry in general is investigating the problem of locating and federating distributed data. In particular, Novell, Netscape, Sun and Microsoft have considered rival technologies as an answer to the problem of locating information about people and things. Netscape and Microsoft have favoured a technology called LDAP (Lightweight Directory Access Protocol) for accessing directory-oriented information. Novell have provided an LDAP interface to their own NDS directory
system. Sun has created a technology for Java called JNDI (Java Naming and Directory Interface) that can access any directory-oriented service including LDAP. Directory Services are therefore now becoming the industry preferred method of locating objects within containment hierarchies.

It is important to note that the LDAP and JNDI are not aimed at database access, but at the arena of enterprise naming schemes. The directory service is accessed in a completely uniform way, independently of the type of storage (a file system, a database, or anything else can be represented as an object) and the data can be accessed irrespective of the database’s preferred access mechanism (SQL, OQL, etc.). A particular client may use SQL to access and update a particular feeder system but JNDI gives the power to extract data however it is stored. It also provides a way of getting the database schema should it be required.

Many federated object sources can be attached to a hierarchy, and can return objects and attributes from a lookup. Feeder system “signup” is the process of attaching objects to the directory. Any object source on the network can attach to the directory; Synapses federation therefore follows from the use of the service. Any client that can see the directory automatically has access to the whole Synapses Object Dictionary and patient record databases (within appropriate security frameworks).

JNDI provides a uniform access to the set of SynEx data component services. These and other SynEx services (such as decision support and terminology) have been successfully integrated and presented for client access through JINI (a new technology delivering seamless and unsupervised access to services, see below). The directory service component set comprises a specification for the configuration and deployment of these emerging industry standards, together with tools to facilitate the process of feeder system sign-up. The demonstrator shows how patients, clinicians and the anti-coagulant EHCR record objects can be accessed in this way.

![JNDI Interfaces to Clients, Data Sources and to a CORBA Transport Layer](image)

**Figure 7: JNDI Interfaces to Clients, Data Sources and to a CORBA Transport Layer**
**JINI**

JINI, pronounced 'genie', is the latest API from Sun and promises to be nothing short of spectacular. The idea behind it is relatively simple and in fact several companies are known to have been working on something similar. But they have all had to wrestle with the architecture independence issue. Either one must assume the ubiquity of one's own technology, which other manufacturers are reluctant to do, or some way must be found to abstract every architecture.

JINI provides a mechanism by which any item of hardware or software can make itself available to every other item on a network without any intervention from a human network manager. The idea is a derivative of the networked PC model of computing where every aspect of the PC is either able to join the network in its own right or be proxied by something else which is. The first and most obvious conclusion is that the need for device drivers is far less because everything has a standard way of making itself available. This should reduce the problems associated with device failure such as non-functioning printers and so forth.

The second conclusion however, and more pervasive, is that even 'non-computer' machinery such as heart monitors etc., can be added as services on a network and can demand services from other machines. The monitor might demand access to patient record software to add data to it while a cardiologist attaches the output to a visual display unit on his desk so that he can keep watch on the patient while working elsewhere.

For interest, consider the evolution of computing as shown in figure 2. JINI really is a new paradigm for the provision of services in a workgroup. We can envisage that a class file is a unit of development for a software engineer, a JavaBean is a unit of assembly for a system provider, and a JINI service is a unit of usage, a component that users will be comfortable with.

![Figure 8: The three evolutionary stages of computing](image-url)
Figure 9: Engineering Overview of the FHCR Services
The federated healthcare record is a high-level abstract model, enabling the federation of records from a diversity of feeder systems. In essence, it is the generic schema to which all federation feeder systems are mapped.

The federated healthcare record architecture adopted for the UCL components and for the London demonstrator slightly extends and refines the model developed by the Synapses project (the SynOM), informed by the work of EHCR-SupA¹. It is based on a rigorous object model formalism; it incorporates the representation of content types and placeholders for ongoing work on the integration of medical knowledge (GALEN) and protocol (PROforma) services. It also enables the generation of record extracts and messages conformant to the latest CEN/TC251 standard for Electronic Healthcare Record Communication: ENV 13606.

The FHCR architecture has been implemented as a set of Java classes (and capable of conversion to an XML DTD) that provides a reference model for:

- the object dictionary (see below)
- feeder system mapping
- the EHCR object repository
- client server communications

**EHCR database**

As well as accessing distributed feeder systems, the UCL FHCR services incorporate a principal EHCR database 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 stores record components in a form native to the federation architecture.

For functional and performance reasons, Object Store (from Object Design Inc.) has been chosen as the core database of the server environment. In the demonstrator site, the existing anti-coagulant databases were transferred to this Record Object Repository as Java objects. An example set of tools to facilitate the decommissioning of feeder systems and/or the presentation of their data have been developed.

Object Store (from Object Design Inc.) has been chosen for this as it provides:

- compatibility: an object-oriented programmatic interface is provided through Java. Java objects can be stored directly without translation.
- scalability: caching and replication is utilised in order to meet the requirement for large numbers of simultaneous object requests.
- robustness: features such as automatic recovery, on-line backup, roll-forward and failover enable continuous operation.
- tools: schema can be modified, databases populated with sample data and examined through a range of command-line and graphical user interface style tools.

Object Store has been implemented by installing it both on Solaris 2.5.1 and Windows NT 4.0 SP3. Within the framework clients of the EHCR database communicate with a wrapper-class to ObjectStore, insulating them from its exact operation. This wrapper-class is itself an RMI (remote method invocation) listener node executing continuously, so that clients can run in their own processes and/or remotely. Instances of any classes that are stored in ObjectStore need to have been

¹ EHCR-SupA is a Fourth Framework support action that has taken forward the work of GEHR and other EHCR architecture implementation feedback
'post-processed'. This procedure adds and inserts methods to facilitate timeliness and memory-management so that data in the object graph is only retrieved from persistent storage when the corresponding 'get' method is called. The data requirements could be achieved through the creation of just two of these classes.

**Web Servlet Approach**

A set of web servlet scripts has been written, using Java, to extract single or multiple instances of patient record objects from ObjectStore. The servlets map the output object attributes to cells within html tables. This provides a means to verify the information content of each object, and provides a simple record display, but is not intended to provide a clinically suitable client interface.

Java servlets have become increasingly popular as they enable the functionality of the web server to be extended for the dynamic creation of content. Being written in Java they are secure, cross-platform, re-usable and offer good performance through the convenient use of threads. Engines for servlets exist either as integral to the server or as pluggable modules. Servlets were an obvious choice here with so much already being implemented in Java. The servlets here talk to the database and dynamically generate the HTML that is sent to the web browsers of the system users. Likewise they handle any requests e.g. to add a patient or to change their details, sent by users. Servlets can be written by anyone with a moderate understanding of Java, HTML and the HTTP protocol. Java Server Pages (JSP) provide a higher-level script-based technique for developers, which utilise servlets as their underlying technology.

**Anticoagulant Decision Support Components**

Some middleware components have been authored specifically for use in the management of anticoagulation therapy. The existing 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 returning data to this client. Their deployment in other settings will be openly reviewed, but these components are presently only being actively promoted for potential commercialisation as part of the anticoagulant application. Future work on their generalisation will be considered later.

**Anticoagulation Client Screens**

This successor application has drawn on an existing Visual Basic application, and initially provides a set of HTML web clients. The overall application includes forms to deal with requests for and the display of existing data, and also with data entry. Java applets will in the future be used as necessary to provide end-user graphic objects not supported by the core HTML standard.

An example client screen is shown below, captured from a web browser as the application is in practice being accessed by the clinical team. A full set of screens, assembled as a user manual, is given in Annexe A of the SynEx London Demonstrator Final Report, available from the authors of this report.
Figure 10: Anticoagulant Client - authoring a new treatment plan
providing intuitive access to federated healthcare records – securely

Persons Look-up Service
Components
Introduction

The UCL Persons Look-up Service is a component providing information on the identification of patients, healthcare professionals and other staff to the other FHCR 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 EHCR or to authenticate access rights to a given set of record components.

The data repository uses and extends Novell NDS objects and its metadirectory, and is accessed via Java Naming and Directory Interface (JNDI) APIs. Work is in progress to configure the NDS tree and its class models to optimise it as an object repository for user identification. For deployment purposes, Novell eDirectory has been used as the product to provide and manage the NDS services.

Persons dictionary

The persons dictionary provides a means of registering staff and patients within a consistent repository. The information model for the persons dictionary 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).
In practice, to improve performance and ease of data importation, the model has presently been implemented within NDS as a single person class with all of the attributes of the inherited classes. Separate constructor methods are being developed for each of the sub-classes shown here to ensure appropriate attributes are populated.

The Feeder/Pat ID information has been shown here for completeness. It is being implemented through a separate directory service use of NDS.

Software and devices dictionary

This model for information provider devices and software is based on proposals in CEN/TC 251 ENV 13606 (EHCR Communication). It is intended to provide a registry of all electronic sources of EHCR information (such as monitoring devices and decision support software). Some of these may also require controlled access to other EHCR data.

This model will be implemented later within NDS.
**Population of the NDS Tree**

The default NDS Schema has been modified in order to populate the NDS directory with staff and patient demographic information. This includes the addition of new attributes (e.g., for carer information, date of death).

The relevant NDS classes (e.g., Organisational Person) are also amended to incorporate the additional attributes.
For deployment at the Whittington (north London) site, it has been possible to import the complete database of General Practitioners for England and Wales (34,000) and all consultants working in hospital trusts in the north London area. For ease of future updating and integrating with NHS databases, these have been grouped in sets by UK Health Authority Area. The importation functions utilise JNDI methods.

Each consultant in north London (Area QAT) is listed by their National Health Service identifier, which has been used as the Synapses Person ID for this demonstrator site.
The available demographic information (sparse at this stage, reflecting the source NHS database), is displayed through a series of forms.
A similar set of importing classes and methods have been used to establish directory nodes for each patient registered within the anticoagulant application at the Whittington Hospital. The application’s internal UID has been used for the Synapses Person ID on this occasion.

In the screen below the patient’s name has been replaced by asterisks to preserve confidentiality.

Further work is needed to automate updates to this tree. An additional look-up service will later permit record components to contain direct references to NDS tree nodes (persons), in addition to textual descriptions of persons (such as the recording HCP) as at present.
Access Control Services

A requirements analysis is in preparation to define the access control model that should be applied to a distributed FHCR service. This will incorporate user profiles and an approach to match the sensitivity of individual record components to the access privileges of healthcare professionals and patients as users of the service.

The engineering approach to be adopted for this and other security services will be documented elsewhere.
Object Dictionary Component
**Introduction**

The classes and attributes of the SynOM have deliberately been defined at a high level of abstraction, to provide an information model that can be applied to any potential healthcare record entry. It can represent a healthcare record generated in primary, secondary or tertiary care, in any speciality and by any healthcare professional. However, the individual feeder systems providing data through a Synapses Server are likely to be highly specific to the local requirements of individual sites, to specialities and to groups of professionals. There is a need for client applications to generate precise requests for named aggregates from a given patient's federated healthcare record, and to receive these back from the server as objects in a predetermined form.

The Object Dictionary component provides the formalism by which the specific clinical data sets and aggregates normally found in healthcare records and in contemporary feeder systems can be defined. Any such dictionary entry utilises the SynOM classes as basic building blocks, extending the classes 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 Object Dictionary contains the formal definitions of the clinical constructs which may be requested by client workstations. This set of definitions of healthcare objects can be mapped onto those data representations used in each of the individual synapsed feeder systems. This may be done through a set of access methods, defined through a collaboration between the developers of each feeder system and the developers of the Synapses Server at each validation site. The references to the access methods are integrated within the Synapses Object Dictionary during the sign-up process by which each feeder system is connected to the Synapses federation. A request by a client application for a Synapses Object will result in the invocation of the relevant method(s) by the FHCR Service in order to retrieve the necessary health care record data from a feeder system.

The Object Dictionary Client component:

- provides an authoring tool for clinical objects 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 FHCR services are connected;
- ensures adequate version control and maintenance procedures to accommodate revisions of the Object Dictionary itself over time.

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.
**Object Model of the Synapses Object Dictionary**

The formal object model of the Synapses Object Dictionary is closely related to the SynOM. It extends the RecordComponent class of the SynOM 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 synonyms and medical knowledge concept tags.

**Figure 11: Information model of the SynOD**

**ObjectDefinition Class**

The ObjectDefinition class contains the attributes relevant to managing the library entries associated with each Synapses Object. 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 Synapses Objects over time; this might mean recording if this particular object is the current definition, and the identification of its predecessors and/or successors.

Each Synapses Clinical Object has a unique identifier and a unique object name, and these provide the necessary handles by which a client can request the Synapses Object(s) it requires.

**SynonymDictionary Class**

This dictionary enables a client application to reference a Synapses object through the use of a locally-defined label, and abbreviated name or a language translation of it. If multiple synonym names exist for different objects, a preferred object may be indicated.
**Concept Dictionary Class**

This dictionary has been proposed to enable a client application to identify the set of available objects that correspond to a clinical subject heading. This class is a placeholder for the methodology by which Synapses Clinical Object definitions can be appropriately linked to GELEN medical terminology services.

**Instantiation Rules Class**

This class, which is still undergoing evaluation, is a placeholder for the expression of rules regarding the validation of instance values for element objects, or the interdependence of values on other components of a RecordItem or RecordItemComplex. 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 is a placeholder for the methodology by which Synapses Clinical Object definitions can be appropriately linked to Proforma guidelines and to other decision support services.

---

**Engineering Overview of the UCL Object Dictionary Component**

The Object Dictionary Client (ODC) 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 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.

<table>
<thead>
<tr>
<th>Feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>ODC Class Hierarchy</td>
</tr>
<tr>
<td>ODC Object Properties</td>
</tr>
<tr>
<td>Creating New Object Entries</td>
</tr>
<tr>
<td>Cardinality on Instantiation</td>
</tr>
<tr>
<td>Validation Criteria</td>
</tr>
<tr>
<td>Data Retrieval Methods</td>
</tr>
<tr>
<td>Copying and Pasting Objects in the Hierarchy</td>
</tr>
<tr>
<td>Publicising Objects</td>
</tr>
<tr>
<td>Deleting an Object</td>
</tr>
<tr>
<td>Marking an Object Obsolete</td>
</tr>
<tr>
<td>Revising an Object Definition</td>
</tr>
<tr>
<td>Reviewing the Version History</td>
</tr>
<tr>
<td>Tracking Objects with Multiple Parents</td>
</tr>
<tr>
<td>Exporting the Database</td>
</tr>
<tr>
<td>Saving the Database</td>
</tr>
<tr>
<td>Help about screen</td>
</tr>
</tbody>
</table>
Overview
The Object Dictionary Client (ODC) version 1 provides the means to create, amend, browse, search and share (export) EHCR sub-hierarchies.

The ODC creates and manages its own database files (the name is shown on the status bar bottom left, on opening the application). Future versions will allow users to select from a range of such databases.

The ODC provides a hierarchy viewing pane (on the left) together with a set of property, validation and method details panes (on the right).

The database hierarchy may be expanded by “clicking” on any plus signs to the left of the object names. Hierarchies may similarly be collapsed by clicking on minus signs.
**ODC Class Hierarchy**

The “bullet” used for each dictionary entry indicates the SynOM class from which it inherits, as shown in the table below.

<table>
<thead>
<tr>
<th>Bullet legend</th>
<th>SynOM class name</th>
<th>Permitted parents</th>
<th>Permitted children</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
<td>Folder RIC</td>
<td>Folder RIC</td>
<td>Folder RIC, Com RIC</td>
</tr>
<tr>
<td>C</td>
<td>Com RIC</td>
<td>Folder RIC</td>
<td>Data RIC, Compound Item, Element Item</td>
</tr>
<tr>
<td>D</td>
<td>Data RIC</td>
<td>Com RIC, Data RIC</td>
<td>Data RIC, Compound Item, Element Item</td>
</tr>
<tr>
<td>c</td>
<td>Compound Item</td>
<td>Data RIC, Compound Item</td>
<td>Compound Item, Element Item</td>
</tr>
<tr>
<td>e</td>
<td>Element Item</td>
<td>Data RIC, Compound Item, Element Item</td>
<td>None</td>
</tr>
<tr>
<td>l</td>
<td>Link Item</td>
<td>Data RIC, Compound Item, Element Item</td>
<td>None</td>
</tr>
<tr>
<td>V1</td>
<td>View 1 RIC</td>
<td>Folder RIC, Com RIC, Data RIC</td>
<td>None</td>
</tr>
<tr>
<td>V2</td>
<td>View 2 RIC</td>
<td>Folder RIC, Com RIC, Data RIC</td>
<td>None</td>
</tr>
</tbody>
</table>

The aggregation rules dictated by the SynOM model are shown below, and are applied by the application during object creation.
**ODC Object Properties**

Each object has a set of properties, which include its SynOM class, a name and a description, the circumstances of its authorship or revision, its cardinality and its distribution status.

When any object in the hierarchy pane is selected with the mouse (single click) it becomes active, and its properties are shown on the right. The screen above shows the properties of a Data RIC ("data type" = "DATA"), and the one below shows an Element Item.

The Element Item additionally shows a Content Type (here, a NUMERIC) to indicate which SynOM content class it may contain on instantiation.
Creating New Object Entries

A new object definition may be added at any point in the database hierarchy, provided that the addition will constitute a valid aggregation.

First click on the intended parent in the hierarchy pane to select it as the highlighted object. Then select the {New Object} option from the {File} menu, or type "Ctrl+N".
This prompts a new window in which the object name and other information can be added.

Some authorship information is already added directly from the preferences data set (see later), but may be amended for this entry if necessary. After typing in the proposed object name, a description should be added. This field is not used by any of the applications, but is intended to help ensure that different organisations and clinicians can share a common interpretation of its intended use with patient records.
It is possible to indicate:

- if this new object definition is intended to be kept privately (i.e. on this database only and not to be included in any export files),
- if it may be shared but is not intended for real-time clinical use (e.g. for definitions that are still being confirmed amongst a set of users who wish to share their ideas but not yet go live with the object), or
- if it is suitable for public dissemination. In this last category an object is considered sound for real clinical use for the creation of EHCR entries, and is also appropriate for wide distribution.

A mechanism exists whereby objects can be “promoted” from private to sharable, or from sharable to public. The ODC creates new objects as Private by default. It should be noted that Private objects may be permanently deleted from the database, but others may only be marked obsolete or revised.

The user should then select the SynOM class from which this object dictionary entry should inherit. Invalid choices are rejected by the application, and in future versions more on-screen help with the choice of SynOM classes will be offered.
If an Element Item has been chosen, the Content Type drop-down list becomes active, to enable the user to select the kind of content that this object will contain on instantiation.

Once the new object entry window has been completed, click OK and the new object will appear in the hierarchy window as the last child object of the parent originally highlighted. The order of the children in the hierarchy is not of functional importance, and does not have any bearing on the way in which EHCR information may be displayed to end users of clinical applications.
**Cardinality on Instantiation**

Clinical record data set templates will vary as to whether some components are intended to be populated with a single value or multiple values. For example, a left posterior tibial (foot) pulse is likely to have only one value during a physical examination, but several drug items may be included on one drug prescription. The ODC allows the author of dictionary objects to indicate the cardinality of an entry at any point in the hierarchy. From a selected object, choose the {Cardinality} option from the {Edit} menu.

The user has a range of choices; the system default is “ONE-OR-MORE” for RIC classes and “ONE AND ONLY ONE” for Compound Items, since these are anticipated to be the most commonly required cardinalities. This menu option is only needed in cases where the default is not appropriate. Some choices (e.g. “ONE AND ONLY ONE”) have the effect of defining this object as mandatory on instantiation. Please note that this does not automatically mean that EHCR systems will enforce this.
Validation Criteria

Clinical users, and authors of guidelines and protocols, frequently wish to specify data entry validation criteria that should be applied to new EHCR entries. For example, it may be appropriate to state that a systolic blood pressure can never be over 500 mmHg.

ODC provides a validations window that allows users to enter specific criteria or general statements. At present there are no international or European standards relating to the syntax for expressing such criteria, and Version 1 therefore provides a general text field in which one or more individual validation statements can be entered. It is assumed that local applications may be able to utilise the statements as method arguments or executable code fragments, or that users may prefer only to use the validations pane to store human-readable descriptions of the intended criteria.

New validation entries can be made by first highlighting the appropriate object in the hierarchy pane, and then selecting the {Validations} option from the {Edit} menu.

Each validation statement is associated with an intended action to be performed by the EHCR system.

Reject implies that values outside the scope of the criterion are not possible, and must be the result of a typing error or misinterpretation. The intention is that the value offered by the clinical client should be rejected and the object not instantiated. (E.g. systolic blood pressure > 500 mmHg).

Confirm implies that the value offered is unusual, or outside a physiological range, and that the user should be invited to confirm that this is in fact the value intended. (E.g. systolic blood pressure > 300 mmHg). If the end user does confirm the value, the object should then be instantiated.

Accept implies that the value is an acceptable candidate with which to instantiate the object. The option is provided in order to allow permitted values to still generate a message to the end user, such as a prompt or reminder.

Each object may have multiple validation criteria.
Version 1 of the ODC permits the entry and removal of validation criteria, but does not perform any syntax checking.

It is intended for validation criteria to be tested in the following order:

1. Reject criteria
2. Confirm criteria
3. Accept criteria

Testing proceeds though all of the criteria until the first response is triggered.

Future versions of the ODC will allow users to link each validation criterion to a user-managed library of messages that are appropriate to return to the clinician if that exception is triggered.

If the ODC is deployed alongside the UCL FHCR service components, Java logical expressions within the validations window will be utilised as code fragments by a set of client servlets still under development. An additional sub-project is developing a standard syntax for validation statements that can be utilised by the ProForma protocol run-time component. These will be incorporated later.

A syntax by which criteria can be expressed that test for the values of other pre-existing record components within an EHCR is also being explored, together with a technical methodology by which such validations could be executed.
**Data Retrieval Methods**

The ODC provides a means of entering mapping information that could be used by feeder system extraction methods to retrieve instances of each object from distributed EHCR sources. The UCL FHCR components utilise JNDI methods to extract data from nodes parented in an established directory service (e.g. Novell NDS). The precise mapping information to the appropriate set of nodes for each object may be stored in the ODC.

New database references can be added by first highlighting the appropriate object in the hierarchy pane, and then selecting the (Methods) option from the (Edit) menu.

Version 1 of the ODC permits the entry of free text, which is intended to be used by other execution code as appropriate. Future versions of the ODC will support a generic example of the entry of references specifically for the JNDI and NDS distribution environment. An API (service) to report the database reference methods for any object in the dictionary will be provided later.
Copying and Pasting Objects in the Hierarchy

Many objects defined at the level of RecordItems (i.e. Compound and Element Items) are each constituents of several different composite (higher-level) RecordItemComplex objects. For example, the components of a general physical examination might include pulse, blood pressure, chest auscultation and abdominal palpation. These individual components would normally be represented as RecordItems. This particular set of RecordItems might occur as the constituents of several different RecordItemComplexes, such as cardiac clinic assessment, diabetes annual assessment, anaesthetic assessment and routine hospital admission assessment.

The ODC permits users to copy objects (individual elements or whole hierarchies) from one location to another, provided that the destination is a valid containment structure. In the example screens shown here the Element Item object Condition Name is being copied from its existing location as a child of Clinical Condition.

Having first highlighted the appropriate object in the hierarchy pane, the object may be copied to the clipboard by selecting the {Copy} option from the {Edit} menu or pressing "Ctrl-C" as the keyboard shortcut.
The Clinical Condition object may now be pasted to a new location, for example as a child of Family Condition. Again, the appropriate parent is first highlighted.

Clinical Condition is now a child of both parents. The object has been "reused", and its description, together with any access methods or validation criteria, are shared by both containment hierarchies. Whole hierarchies may be copied and pasted in this way. In such cases, amendments to the contents of a pasted hierarchy (e.g. adding a new child object) are replicated in all locations.
It should be noted that, in cases where an object has more than one parent (i.e. occurs in multiple points in the hierarchy) the cardinality may be set differently for each occurrence. The cardinality list window states the context in which the cardinality is being changed.

Publicising Objects

The Private, Private Sharable and Public status of objects has been described earlier for the creation of new object entries. Existing objects might frequently become “promoted” from Private to Private Sharable, once early definition work is complete. Similarly, most Private Sharable objects will eventually become Public for real clinical use. (This may not occur for some data sets that remain in use for teaching or research purposes.)

The {Publicise object} option from the {edit} menu promotes the selected object by one status level. In the example above Family History starts with a status of PRIVATE, and becomes PRIVATE_SHARABLE.
A further run of the (Publicise object) menu option promotes the object to PUBLIC.
Deleting an Object

If an object is PRIVATE, it may be deleted by choosing the {Delete} option from the {File} menu. The object is then lost from the hierarchy in which it was highlighted. If the same object exists in other hierarchy locations these others are retained. The object definition is therefore only fully lost when all occurrences are deleted. If the object is not a leaf node, its children are also deleted.
Marking an Object Obsolete

If an object is PRIVATE_SHARABLE or PUBLIC, it cannot be deleted. If it is no longer required it can be marked as obsolete. It will still be exported, since record components might exist within EHCRs that have been created according to that object definition.

Obsolete objects may be hidden from routine view through the (Preferences) option of the {Edit} menu. They remain in their former hierarchical position greyed out.
Revising an Object Definition

An existing object may need to be revised, for example to amend its name or description. This can easily be carried out by highlighting the existing object in the hierarchy pane, using any of its occurrences (if more than one), marking it as obsolete, and then selecting the {Reversion} option from the {File} menu.

This prompts a Reversion window, which is initially filled with the original information but with revised authorship and date information.

The name and definition can be amended, for example changing condition to problems and then committed by selecting "OK".
The revised object will be visible in the hierarchy pane.
Reviewing the Version History

It is possible to review the version history of any object, by highlighting it and then selecting the {Versions} option from the {Tools} menu.

This option generates a pop up window listing the previous obsolete versions. Future releases of the ODC will allow a richer inspection of the revisions audit trail.
Tracking Objects with Multiple Parents
The ability to copy and paste objects from one hierarchy to another has been described earlier. In a complex database it may become difficult to keep track of which objects have been used several times, and where. For any highlighted object it is possible to generate a list of other uses from the {tools} menu.

This option generates a new window with a list of the parents of, in this case, Drug Strength.

Future versions of the ODC will include more extensive searching and navigation tools, to include interactive assistance when entering new object names.
Exporting the Database

The object definition database can be exported as a single XML document, the DTD of which is included later in this section. The entire database can be exported by selecting the {Export DB} option from the {File} menu.

This generates the complete database XML document file as a new window.

This is a long file, and two extracts from this are shown above. The whole text can be selected at once (Ctrl-A) and copied (Ctrl-C) into any other application for further processing.
The PUBLIC subset of the database can also be exported, via a related menu option. This is intended to allow individual authorship installations each to contribute confirmed objects to a central “live” repository, for clinical or academic purposes, whilst maintaining an ongoing developmental subset within the same database.

Note that any PUBLIC part of a hierarchy will only be exported if its parent is also PUBLIC. The content below any non-public object will not be exported, since a recipient system would not be able to attach the object to a valid parent in its local hierarchy. For any objects to be exported in this way, the highest level objects in the hierarchy must be PUBLIC.

**Saving the Database**

Changes made during an editing session are not automatically saved to the PSE Pro database. The amendments may be saved explicitly from the {File} menu or by confirming the wish to save changes after selecting {Exit}.
**Work In Progress**

The next phase of the development work includes the incorporation of synonyms and clinical concept links. This will include a look-up service to the GALEN Terminology Server, to allow the ODC to be browsed remotely and for end-users to link their objects to core concepts to support audit, teaching and research.

The ODC database has already been revised to allow GALEN or other concepts such as language variants and synonyms to be stored for each dictionary object. The Swing client will shortly updated to provide a user interface to access these functions. A mock screen is reproduced below to illustrate the intended user view of this feature.

Other planned areas of work include demonstration examples of the use of feeder system methods and validation criteria.

Further work is also needed to enable the ODC to generate code fragments that can be used to provide a set of dictionary look-up services.
Help About

Please watch for future releases of the UCL Object Dictionary Client!
The following DTD can be used to represent a full SynOD. This DTD may be later
subsumed into a Record DTD to give a complete self-contained transfer.

```xml
<?XML version="1.0" standalone="no" encoding="UTF-8"?>
<!-- Preliminary XML representations 05/02/1999 -->
<!DOCTYPE DICTIONARY [
  <!ELEMENT DICTIONARY (GRAPH, SYNOD*)>
  <!ELEMENT GRAPH (LINKID*)>
  <!ELEMENT LINKID (EMPTY | LINKID+)>  
  <!ELEMENT SYNOD (LIBRARY, NAME, ID, DOI, VERSION, PREVIOUS?,
                 DESCRIPTION, ORG, DLV, OBSOLETE?, CONTENT?, DATA)>  
  <!ELEMENT LIBRARY (#PCDATA)>  
  <!ELEMENT NAME (#PCDATA)>  
  <!ELEMENT ID (#PCDATA)>  
  <!ELEMENT DOI (#PCDATA)>  
  <!ELEMENT VERSION (#PCDATA)>  
  <!ELEMENT PREVIOUS (#PCDATA)>  
  <!ELEMENT PROTOTYPELEVEL (EMPTY)>  
  <!ELEMENT DESCRIPTION (#PCDATA)>  
  <!ELEMENT ORG (#PCDATA)>  
  <!ELEMENT DLV (#PCDATA)>  
  <!ELEMENT OBSOLETE (#PCDATA)>  
  <!ELEMENT CONTENT (#PCDATA)>  
  <!ELEMENT DATA (#PCDATA)>  
  <!ATTLIST LINKID SYNAPSESOBJECTID CDATA #REQUIRED>  
  <!ATTLIST DOI LOCALE CDATA #REQUIRED>  
  <!ATTLIST PROTOTYPELEVEL (PUBLIC | PRIVATE_SHARABLE | PRIVATE)
             "PUBLIC">  
  <!ATTLIST DLV LOCALE CDATA #REQUIRED>
]>  
```

Document Type Definition for a full SynOD