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Disease Management System

**Design Specification,
System Verification and
Administration**

**Complete Medicate System Test
Report**



University College London

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1. Executive Summary

The vision of MEDICATE is a scalable and widely applicable solution to the challenge of providing mobile patients with rapid and distributed access to evidenced based, personally tailored, medical advice in the management of chronic illnesses, to complement and support the direct care management provided by their usual clinicians [1].

The MEDICATE project has taken the specific demonstrator field of asthma, using two test sites in London (Whittington Hospital) and Barcelona (Manresa Hospital). The demonstrator takes advantage of a new patient-held asthma monitoring device (produced by Jaeger-Toennies). These are examples of the generalised MEDICATE approach.

This report provides a functional description of the Disease Management System (DMS) components of the MEDICATE solution. In essence these components provide the means of federating any number of potential clinical databases within a comprehensive electronic healthcare record (EHR), and of implementing clinical management algorithms (protocols) that may be applied to newly acquired and/or previously stored record information. The EHR services provide distributed (potentially mobile) access to the complete patient EHR, by appropriate clinicians and by patients themselves. The clinical management components can generate clinical alerts, patient messages and/or supplementary information for the patient records. The components described in this report are capable of extension to a wide range of disease areas, to multiple management protocols, and of deployment to support large regional or trans-national networks of patients and clinicians.

This report introduces the requirements for the federated EHR system and for the disease management components. It specifies the functions of the DMS in delivering the MEDICATE scenario, and the alerts incorporated within it. The DMS web application is explained with accompanying screen captures. This report also describes the functions of the individual DMS engineering components and sub-components, including their underlying information architecture. The report also describes how the system was verified, including end-to-end testing of the MEDICATE system, and how the DMS will be administered and maintained. This report therefore combines deliverables 3.3, 3.4 and 5.2 as defined in the Medicate Technical Annexe.

The DMS components have now been deployed and validated in their definitive environment: a secure server hosted by Cable & Wireless and protected by Licore security components.

2. Functional Requirements

Introduction

The key ingredients of the MEDICATE-UCL Disease Management System 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 expansible set of clinical management algorithms that provide prompts to the patient or clinician to assist in the management of patient care, including the generation of patient-specific alerts sent to the responsible clinician by e-mail.

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 EHR components based on these models. The demonstrator systems described here utilise a directory service and object-oriented engineering approach, and 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 EHR systems. This requirement basis is described in this section of the report.

Background

Health services internationally are grappling with the evolution from paper-based records to comprehensive electronic healthcare record systems.

Present day clinical information systems in hospitals and in general practice are not yet adequate for the challenges of delivering effective and evidence-based healthcare, in which teams of clinicians on different sites are working in partnership and collaboratively with patients [2]. Electronic and paper healthcare records are held in islands of information in independent information systems, each with its own technical characteristics and view of the healthcare domain. The available evidence on good clinical practice, existing as publications and guidelines, is often too generalised to be applied to individual patient groups, and is isolated from the relevant known facts about any particular patient's medical and social background [3]. This evidence is difficult to retrieve at the time and in the location where needed. It has been estimated that 15% of the resources of an acute hospital are currently spent in gathering and processing information, accounting for up to 25% of doctor

and nurse time [4]. So there is clearly much scope for improving the efficiency of clinical information management.

The primary purpose of the healthcare record is to support patient care [5], which subsumes many different functions including the documentation of a historical narrative account of the health care given and supporting the communications between healthcare professionals [6].

Healthcare professionals need to document and to review increasing volumes of information, as patients receive increasingly complex care, involving a range of data-intensive examinations, investigations and treatments. The majority of clinical detail in records and in communications, on which such care depends, is still on paper [7, 8]. Clinicians need to share healthcare information with a wider range of professional colleagues on multiple sites. The care of any one patient can require a healthcare professional to review the information held in several distributed clinical systems in a consistent manner [9]. They also need to keep rigorous records to demonstrate their competence [10, 11] in case of future litigation, which is increasing in frequency each year, and in order to justify their use of healthcare resources.

Clinicians and patients also require high quality tools to analyse the data within individual electronic healthcare records [12] in order to:

- observe trends and patterns in the health of a patient;
- enable the use of clinical guidelines and decision support systems as part of evidence-based practice;
- perform clinical audit;
- inform management and commissioning decisions;
- support epidemiology, research and teaching activities.

The need for a clear organisational structure to healthcare records, whether on paper or on a computer, has been discussed on many occasions [13, 14, 15, 16], but it has proved difficult to encourage clinicians to abandon paper records in favour of a fully computerised healthcare record system [17, 18, 19]. There are clear advantages to clinicians themselves of well-organised electronic healthcare records for improving the completeness of the information they elicit from the patient [20], the scope for the subsequent analysis of that data [21], for supporting shared care between clinicians [22, 23], and to demonstrate clinical competence [24, 25]. Improving the ease with which EHR applications can be learned and used [26] and developing more efficient means for clinical data entry [27] have both been suggested as solutions. However, the inherent diversity and complexity of medical data [28] and the need to use rich and varied descriptive terms [29, 30, 31] are held by many clinicians to be a fundamental obstacle to adopting more formal recording structures. The lack of an appropriate architecture for healthcare records has been identified as a major impediment to progress in this area [32].

Clinicians and patients need high-quality information systems to connect an individual person or healthcare record to a repository of the knowledge that is relevant to the care provided. This should include relevant background information about the patient (from their healthcare record or records) and evidence-based management protocols that can be directly applied to the care of individuals.

MEDICATE proposes one approach to this challenge, in particular to support the remote care of patients in their homes or when mobile. Such a solution has the potential to benefit patient care by providing healthcare professionals and patients with relevant personal health record information coupled to alerts, prompts and guidance on care management drawn from evidence-based sources.

Patient involvement in health care

Patients can acquire considerable expertise in managing their own health if they are given useful and appropriate information [33, 34]. The ability to tailor such health information to individual needs, and to make it available at times and in locations suitable to each patient are important for the success of modern shared care. Feedback to patients and to clinicians is also vital if such information is to result in lasting health improvement.

Figure 1, from an article by Smith [35], suggests that traditional models of healthcare services have been associated with inefficient and inequitable healthcare, where expensive specialised interventions are favoured, as characterised by the upper triangle. At the same time, some more useful measures, to provide support for patients and families at home, are under-resourced. It suggests that information technology may enable a new concept of service as illustrated in the lower triangle, aiming to correct this balance by creating a more patient and information-centred view of healthcare. Quality measures would focus more on individual patients' needs and experiences of care they received. Services would be encouraged which met these needs through involving the patient fully in their individual self-management and which were delivered as near to the patient's home and community as possible. This would open many new choices for patients, with resources and professional roles structured to support these choices. Such a model depends on the capacity of information technology to support people, communications and workflow in the highly distributed teams and interventions that are implied.

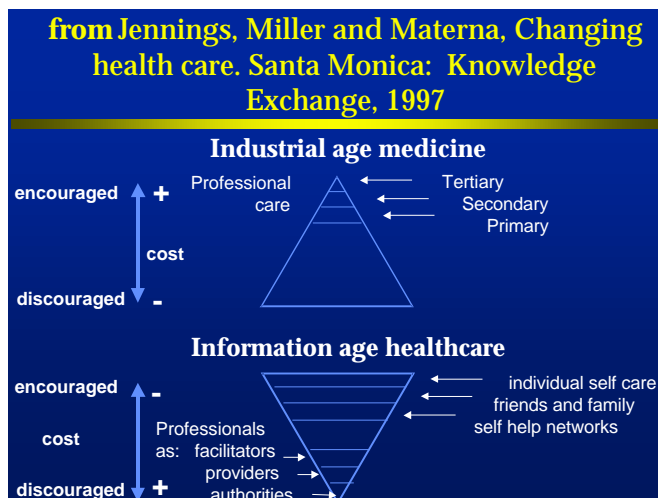


Figure 1: Evolution from the traditional hospital-centred view towards a patient-centred and distributed view of healthcare services, supported by information technology

The MEDICATE approach, by providing a means to deliver near-patient clinical management services, fits well with this new perspective of “information age healthcare”. It has the potential to improve patient care and to reduce healthcare costs.

Requirements research activities

The Health Telematics Research and Development programme of the European Union has recognised many of these health informatics challenges and sought to address them on a large scale through a set of multi-national projects over the past decade [36, 37]. The Clinical Management System developed by UCL builds on a long pedigree of such European research, principally the Good European Health Record (GEHR) and Synapses projects.

The GEHR project carried out over three years of research (1992-5) within the third framework of the European Health Telematics research programme (Advanced Informatics in Medicine). GEHR has developed and published a common health record architecture for Europe [38]. The project consortium comprised 21 organisations in seven EU countries and included clinicians from different professions and disciplines, computer scientists in commercial and academic institutions, and multi-national industrial partners. The project explored the clinical requirements for the wide-scale adoption of Electronic Healthcare Records instead of paper records within primary and secondary care and across specialities. It also developed and evaluated prototypes based on a proposed standard architecture in these settings.

Doctors, nurses and other allied professions from across Europe were involved in deriving a set of clinical and technical requirements covering:

- comprehensive recording of healthcare data for a full range of disciplines in primary and secondary care [39];
- portability of healthcare records between hardware platforms, operating systems and applications [40];
- transfer of healthcare records via telecommunications networks or smart cards [41];
- ethical, medico-legal and security issues which arise when EHRs are the sole medium for capturing, storing and communicating patient-related information [42];
- education, at undergraduate and postgraduate level, to enable the clinical workforce to utilise these new technologies [43].

The most important publication from the GEHR project was a rigorous formal model of health record architecture, based on the specific clinical requirements referenced above. The GEHR requirements have contributed into subsequent European standards work in the field [44], and successor EU telematics projects such as EHCR-SupA and Synapses have built on these foundations.

A fourth Framework Support Action, EHCR-SupA, commenced in October 1997 to refine the GEHR architecture through input from other EHR projects and in the light of implementation experience gained to date.

The Synapses Project, also in the fourth framework (1996-9) has extended the original GEHR requirements work to incorporate the distribution requirements of federations of intercommunicating EHR systems. Research in Synapses has addressed the harmonisation of diverse healthcare record systems to enable clinicians to access information from any institution with electronic records about their patients [45]. Synapses has published a federated healthcare record schema (architecture) together with an object dictionary methodology for defining the specific healthcare record extracts to be communicated between individual systems. The Synapses approach ensures that the original clinical meaning of an entry is preserved when it is transferred to or viewed through another healthcare system [46].



The GAMES II project (1992-4) developed a generalised and comprehensive architecture for the design of medical expert systems [47]. These are now known as knowledge based systems, to reflect an increasing focus on the role of knowledge in medical decision making. UCL (including an author of this report) was responsible for the implementation of an asthma demonstrator of the GAMES II methodology, based on the British Thoracic Society guidelines [48].

Ongoing work in the SynEx project (1998- 2000) [49] is exploring some of the semantic and syntactic issues in the formal preservation of clinical meaning when information is shared between different EHR systems. One specific aspect of the work is the integration of evidence-based guidelines, protocol services and medical knowledge environments with EHR services. The project is also developing tools to deliver the appropriate security and access control framework to a distributed healthcare record environment.

Electronic healthcare communications must take place within an appropriate professional and technical security framework. The EU Projects SEISMED [50, 51] and ISHTAR [52] have investigated the clinical and legislative requirements and the available products across Europe. This work has informed drafting of the EU Data Protection Directive and related national legislation on patient-related data [54, 55].

Much of the work and experience gained in these projects has informed progress on standards through CEN and now in the International Standards Organisation. A four-part EHCR pre-standard (ENV 13606) was published in June 1999 [53]. The Project teams and titles are shown in Table 1.

PT-26	ENV13606-Part 1: Extended Architecture and Domain Model for the Electronic Healthcare Record
PT-27	ENV13606-Part 2: Domain Termlist
PT-28	ENV13606-Part 3: Distribution Rules
PT-29	ENV13606-Part 4: Messages for Exchange of Information

Table 1: Project Teams responsible for the new 4-part CEN standard on EHCR Communication (ENV 13606)

Each of these projects has undertaken a set of formal requirements-gathering activities, and the rest of this chapter provides a distillation of this work. The authors of this report have largely led the European clinical and technical teams involved in GEHR and Synapses, and are primarily responsible for co-ordinating the methodologies adopted and for collating the results obtained. Other published requirements reviewed by the authors include reports from the US Computer Based Patient Record (CBPR) Institute, the Swedish Patient Record Institute (SPRI) and recent work (to be published shortly) from Australia.

Overview of EHR Requirements

Good healthcare records are not just a scattered accumulation of health related data about individuals. Entries are made as formal contributions to a growing and evolving story, through which the authors are accountable for health care actions performed or



not performed. At any point in time a patient's healthcare record provides the information basis against which new findings are interpreted, and its integrity, completeness and accessibility have always been of paramount importance.

When migrating to electronic healthcare records, it is important to acknowledge the wealth of clinical and contextual information that can be expressed very elegantly on paper. Electronic Healthcare Record (EHR) systems need to offer a flexible framework for recording the consultation process, and accommodate the individuality of the clinician as well as the patient.

The interpretation of individual healthcare descriptions, findings or actions can only be faithfully made from their context within a set of entries, contained within the complete patient record as it was availed during that patient encounter.

Clinical practice requires a rich and varied vocabulary to express the diversity and complexity of each patient encounter. An EHR system must be underpinned by a common terminology to express clinical content, that can accommodate such freedom of expression, whilst supporting the need for structured and semi-structured interpretation of each entry.

The way in which individual clinical statements are hierarchically nested within a record confers an important context for their interpretation. A comprehensive EHR system must enable statements to be grouped together under headings and sub-headings in a clinically meaningful way. Aspects of certainty, severity and the absence of findings must be capable of rigorous and unambiguous representation. For example, a patient with only a family history of diabetes or in whom diabetes has been excluded must not erroneously be retrieved in a database search for diabetic patients.

Electronic healthcare records must be medico-legally acceptable, for example as legal evidence, with a rigorous audit trail of authorship and amendments. They must be implemented within a formal security and access framework that ensures only the appropriate persons connected with the care of the patient can retrieve and edit their record.

In a teaching setting, it must be possible for medical, nursing and other healthcare students to have access to and to contribute to healthcare records, such that their student status is explicit. The patient (and possibly their families) must themselves be valid authors of record entries to allow them to contribute their own impressions of health status and needs.

EHR systems must be implemented within a secure communications infrastructure that allows for the seamless integration of existing (legacy) computer systems whilst these remain in use, and for the ongoing inclusion of new-generation systems. Healthcare information must be transferred between sites in a secure manner and comply with both NHS [54] and European [55, 56, 57] directives.

Mutual distributed access, within a secure authorisation framework, to the various records for a patient held on different sites is an attractive alternative to formally generated letters and standardised electronic message. It has the potential to allow for the correct interpretation of individual healthcare record entries within the context of the record that originally contained them, and for the aggregation of data sets drawn from a range of individual EHR systems to provide a richer overview of a patient's health status and care.

Key requirements for the MEDICATE- UCL Disease Management System

From the results of these background projects and standards, a number of requirements are applicable to the information model and the services provided by the federated EHR and decision support system implemented within the MEDICATE project. These are being documented in full by UCL and will be published later.

The broad areas of requirement are listed in the tables below.

GENERAL FUNCTIONALITY
A generic, open and standards-compliant means for combining healthcare records consistently, simply, comprehensibly and securely, to enable the sharing of data between different information systems in different places.
Generic methods, hardware and software products to enable individual computer systems or devices to exchange healthcare data with each other whether on the same site or accessed by secure telecommunications links.
Generic methods to allow clinical protocols to be implemented as management algorithms applied to underlying patient EHRs, to generate alert messages or additional EHR entries.

ETHICO-LEGAL ISSUES
Accountability, attribution Access rights, amendment rights and confidentiality Federation of access rights frameworks Rigorous patient identification Healthcare professional identification Integrity & permanence of patient records Versioning, duplicate persistent storage

EHR ARCHITECTURE REQUIREMENTS
Accommodation of all required data types: <ul style="list-style-type: none">term sets (source organisations and versions)free text (natural languages)charts, tables, diagramsaccuracy, normal ranges, instrumentationmultimedia-media (e.g. images signals, drawings) Flexibility for dealing with <i>ad hoc</i> (loosely structured or unstructured) entries Preservation of original meaning when data is transferred from its original (feeder system) architecture Preservation of context within and between record entries: <ul style="list-style-type: none">original entry groupingsqualifiers, including uncertainty & negative findingsinternal (labelled) links, references, viewsprotocols, references to external knowledgeminimum grouping of record entries for safe transfertemplate frameworks
Clinical Functionality Requirements Support of searching, filtering & analysis requests, including: <ul style="list-style-type: none">the record object request processfilters to customise overviews of recordretrieve personal/team/speciality/problem dataautomatically generate alerts, messages, reportsenable audit Allow monitoring of patient progress, effect of interventions Provide rigorous basis for decision support, links to knowledge

TECHNICAL IMPLEMENTATION REQUIREMENTS
Feeder systems Feeder sign up Managing the clinical database federation Diversity of feeder systems Maintaining mapping schemata Optimising object reuse Local data repositories: synchronisation with the principal EHR database Decommissioning of feeders
Persons and Clients User registration (single sign on) Patient ID reconciliation Client application registration Adaptation of clients
Security Secure communications channels and encryption tools Audit trails Access and amendment records Alert and disease management message register 3rd party disclosure register Authorisation and authentication Access control management Time out management
Other Interfaces to other components Performance Exception handling systems Backup systems

These requirements have formed the basis of the components developed by UCL for MEDICATE, which build in particular on the R&D results of GEHR, EHCR-SupA, GAMES, Synapses and SynEx.

3. DMS Functional Specification

Introduction

This section provides a functional overview of the Disease Management System (DMS) produced by University College London and the way it fits into the overall MEDICATE deployment scenario.

Functional Components of the DMS

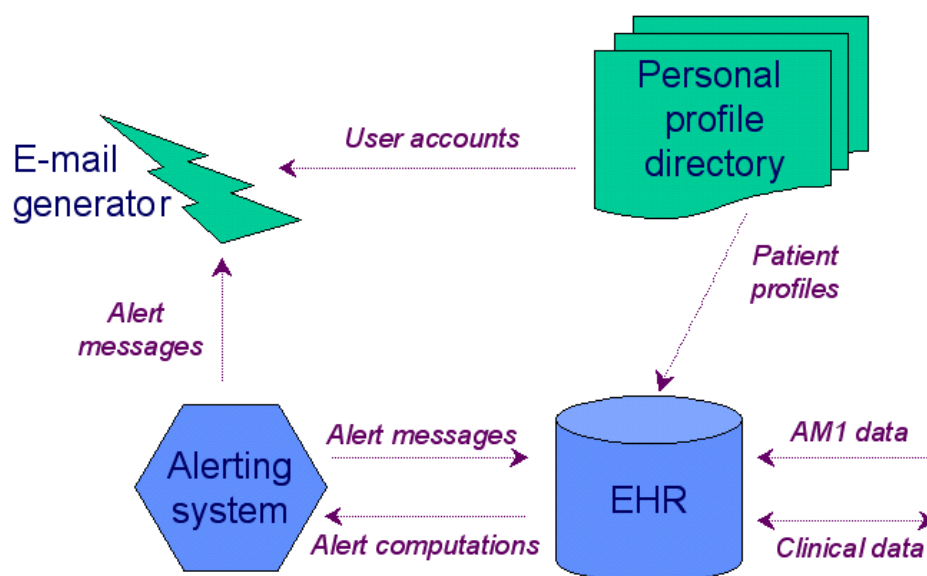


Figure 2: Functional components of the DMS

The DMS comprises a set of software components (written as Java code packages, connected to other software products such as databases and World Wide Web servers). Their structural configuration, information architecture and other technical features are documented in later sections of this Deliverable. From a functional perspective, the DMS provides four key services to its end users.

- The EHR provides a permanent and durable record of all clinical information held on MEDICATE asthma patients, including their home monitoring readings and other clinical information explicitly stored there by clinicians.
- The Alerting System compares the periodic downloads of home monitoring readings (coming via modem from patients' homes) with threshold values and alert configurations within each patient record in order to identify and mark aberrant readings or symptoms. It also scans recent readings from the download

together with previous records in order to identify concerning trends or the absence of readings for an interval.

- The Alerting System communicates with an E-mail Generator that sends a structured e-mail to the recipients nominated for each patient with details of the alerts that have recently been triggered. (A copy of each alert is also stored permanently in the patient's record.)
- The Personal Profile Directory stores demographic information and access rights for all staff and patients registered in the Medicate system. Patient profiles are held in a context related to their healthcare organisation. Staff can similarly be associated with a healthcare provider context and be fed by external databases, but in MEDICATE staff profile information is held by Web Correspondent¹ and communicated directly to the DMS at run time with each instance of initial user access.

Initial Registration

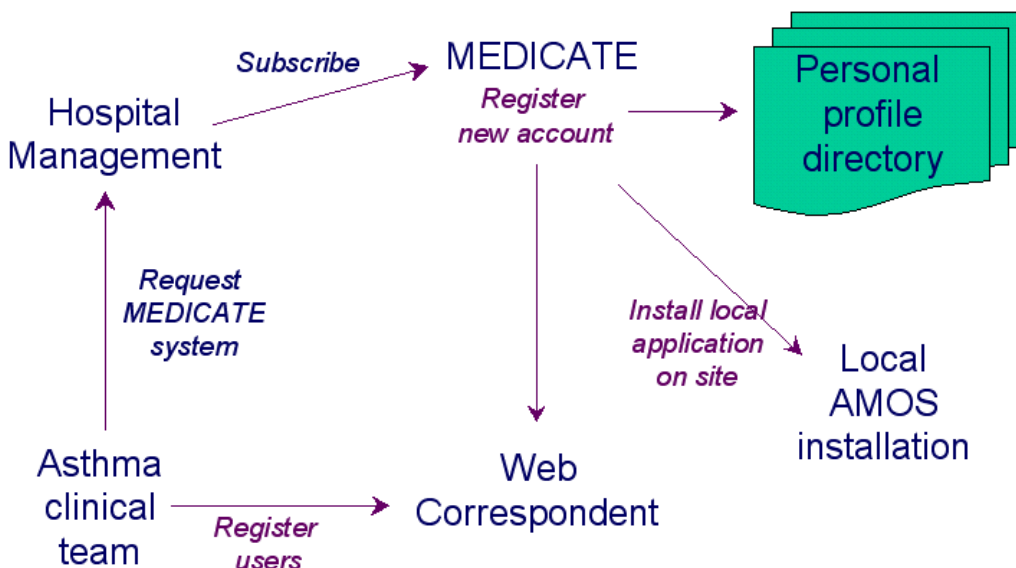


Figure 3: Initial set up of a new MEDICATE healthcare provider account

The process by which a healthcare organisation becomes a registered Medicate account, and the usage units for subscription and billing, have still to be confirmed. Web Correspondent offers a user interface by which a nominated local authority for each healthcare site account is permitted to register and maintain the details of the local clinical team who may access Medicate e-mail messages and EHRs. New healthcare provider account information is passed on to the DMS Profile Directory in order enable new patients registered by that provider to be correctly contextualised, and subsequent clinical authors in the EHR to be correctly attributed. User

¹ Web Correspondent is a component developed by Licore Associates for MEDICATE: it stores user profile information, manages user log in to the server and hosts each user's e-mailboxes. It provides a secured pathway for user access to the DMS.



authentication to the DMS is ensured by restricting access to it to users already authenticated by Web Correspondent.

The access control model for Medicate has been proposed to be simple to administer and to reflect the most likely requirement for healthcare sites. An example is shown diagrammatically below.

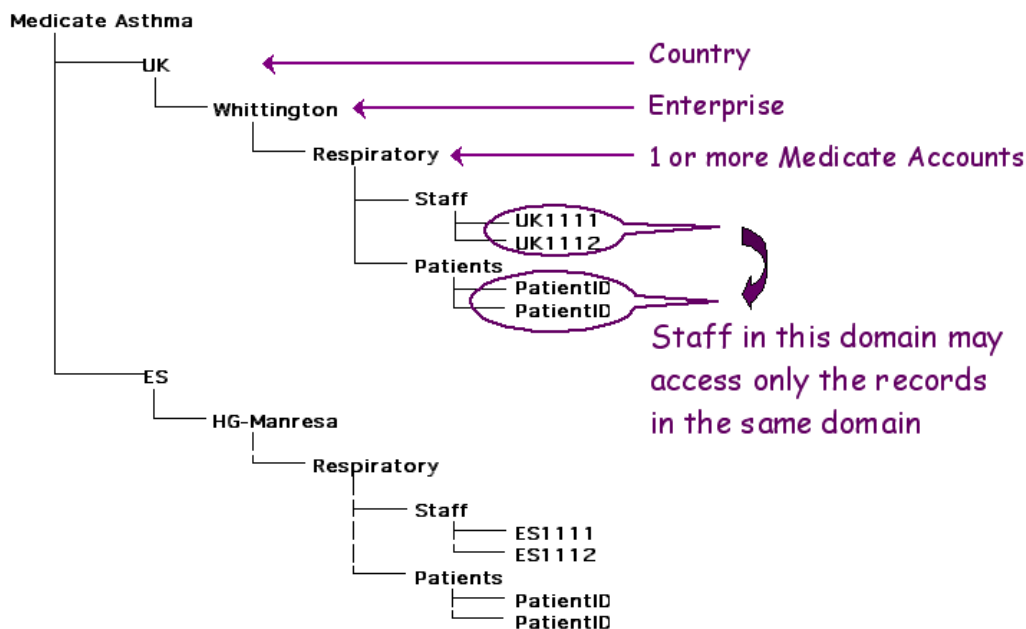


Figure 4: Example of the context hierarchy that governs access control to patient EHRs within the DMS

It has not yet been possible for staff profiles to be synchronised directly with Web Correspondent, as implied by the above figure. However, the DMS has been configured in a way that allows the same user name and password to be used for both access to Web Correspondent and the appropriate patients' EHRs within the DMS, with a single logon to the whole Medicate system.



Data Flows through the DMS

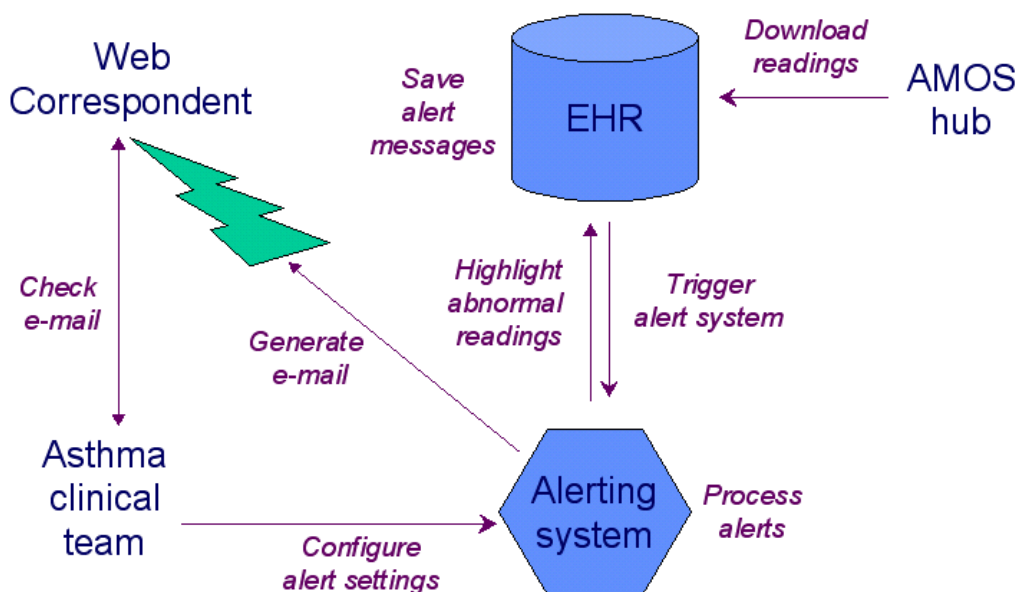


Figure 5: Data flows involved in processing asthma monitoring readings

The initial process for using the DMS in a given patient is their registration, the issue of a hand-held AM1 device² and the configuration of the alert settings. Configuration includes defining the baseline thresholds below which readings are considered to be of concern and choosing which alerts should be active for each patient. Patient registration and alert configuration are performed via the web browser interface to the DMS, enabling new patients to be “signed up” in a wide range of locations including their own home. However, at this stage the issue of a new AM1 device to a patient requires the use of locally-installed software and a cable-based connection from a PC serial port to the new AM1 device. This final stage of patient initialisation therefore presently needs to be performed in the proximity of dedicated machines.

In the definitive MEDICATE scenario, periodic modem uploads of home monitoring readings, medication usage and symptoms will take place as at present, by direct connection to an AMOS Hub Server³ installed by Jaeger-Toennies. This may be to a local healthcare provider running an AMOS hub server, or possibly in the future to a single dial-up location, using a low-cost or free-phone number. The AMOS Hub Server forwards the newly-acquired patient files to the DMS (via an XML interface).

After incorporation into the EHR, the readings, medication usage and symptoms are analysed by the alert system as indicated by the patient-specific configuration. Each time a result triggers an alert a predefined alert message phrase is added to the patient’s record in a dedicated message table and added to the text of an e-mail message. Once all of the downloaded results have been checked, a secondary

² The AM1 device is a handheld electronic respiratory flow meter developed by Jaeger-Toennies and used within the MEDICATE project for asthma home monitoring.

³ The AMOS Hub Server, developed by Jaeger-Toennies, is the dial-up recipient of modem communications from patients’ AM1 devices.

analysis of the patient's EHR takes place looking for trends or missing readings over a specified time period. A summary of the alert checking pathway is shown below.

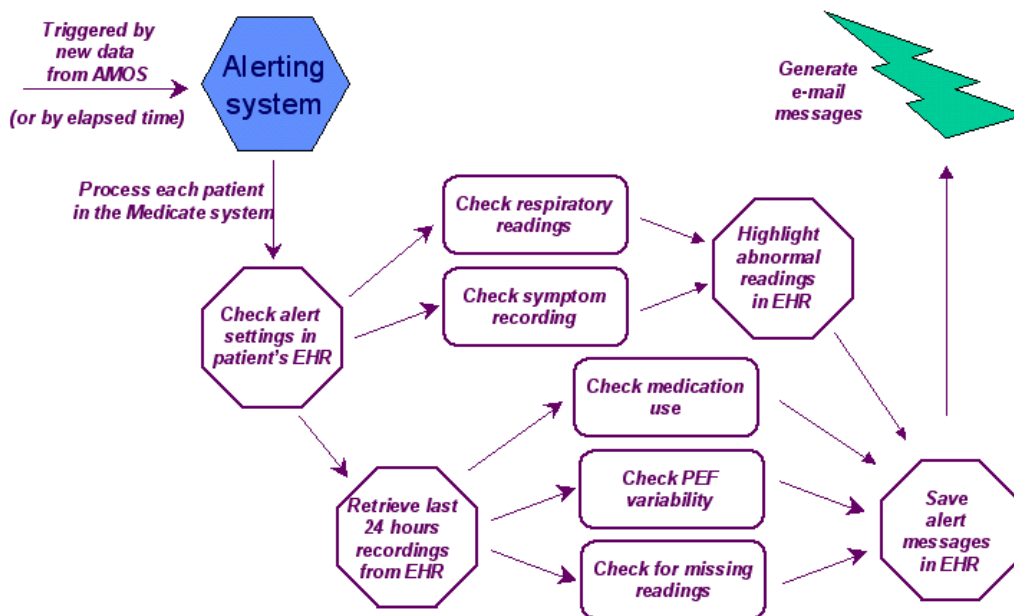


Figure 6: DMS alert checking pathway

The complete set of alert phrases generated for each patient are sent to Web Correspondent as an e-mail message, to the nominated clinical alerts e-mail account for that healthcare provider.

It is recognised that a personal e-mail alert message is not a safe option, since staff absences do not always occur in a planned way. It has been proposed that each clinical team account has an additional generic mailbox, and that the checking of this is handled by a personnel rota system that ensures it is reviewed regularly. That account is established by Web Correspondent and is the Administrator e-mail account for that healthcare provider organisation.

The alert messages may be accessed by clinicians on checking their nominated Medicate e-mail account and/or by reviewing the alert message screen in the EHR. The latter, being permanent, provides a medico-legal record of the alerting process.

Accessing the EHR

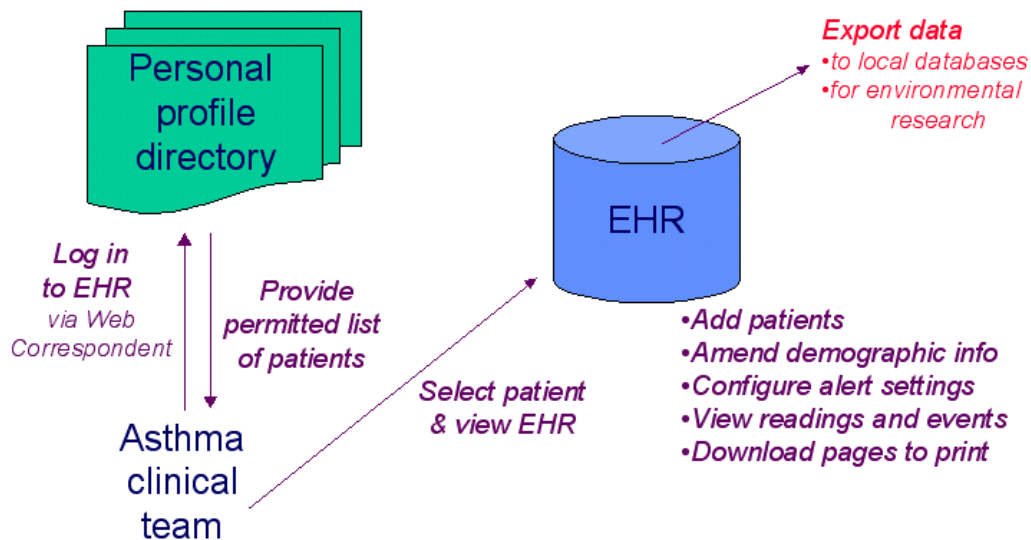


Figure 7: Process by which the DMS EHR can be accessed and used

In response to an alert message, or for general review purposes, the set of registered clinicians can view the Medicate EHR of the patients in their Medicate account. For security reasons, the patient data export functions shown in Figure 7 above will only be available to a limited subset of users, through mechanisms to be confirmed.

4. DMS Alert conditions and messages

Introduction

The implementation of the core DMS functions described in Section 3 builds on a set of Federated Healthcare Record (FHCR) services (described below in Section 6). As well as providing access to the core asthma record for each MEDICATE patient, the FHCR serves as a base environment from which clinical management prompts and alerts can be generated, recorded and communicated.

The DMS incorporates an alerting service, specified as a set of algorithms and executed as functions performed on newly received asthma monitoring data or performed periodically on the global set of asthma records held in the DMS. The functions have therefore been implemented as a Java service capable of direct interaction with the EHR database held in ObjectStore.

DMS Asthma Monitoring Alerts

A series of alert conditions has been defined in negotiation with the clinical trial teams.

- 1) Test newly received peak flow readings from a patient device (imported from the AMOS system) against the two thresholds set for each patient to trigger:
 - a yellow alert if the reading is lower than the “serious threshold”;
 - a red alert if the reading is lower than the “critical threshold”.

Both thresholds are capable of being set individually for each patient, based on their predicted peak flow (calculated by the DMS) or based on a best peak flow entered by the clinician.

- 2) Warn if the patient has been making excessive use of their beta2 agonist inhaler. This alert may be customised for each patient to be triggered if the patient has taken over 10, 15 or 20 puffs per day.
- 3) Warn if the patient has indicated a moderate or severe asthma symptom related to
 - shortness of breath
 - wheeze
 - cough

For each symptom category, the alert can be customised to be triggered by a moderate or a severe symptom event.

- 4) Warn if the patients peak flow readings show significant variability (a.m. to p.m.).
This alert may be customised to be triggered if the variability exceeds 20% or 30% on any day.
- 5) The set of records held in the DMS are checked every 24 hours to identify any patients from whom no data has been received within a specified time period.
This alert can be set for any patient to be triggered after one day, three days or seven days.

It is possible for any or all of the alerts to be deactivated for a patient.

The serious (yellow) and critical (red) alerts are determined by readings falling below a threshold value, which is in turn based on either a predicted peak flow or an alternative best value entered by the clinician.

The AM1 asthma-monitoring device from Jaeger-Toennies collects respiratory function readings to a predefined data set. The device offers a set of other "event" buttons whose use can be agreed between patients and clinicians on an individual basis as appropriate. In general, these have been used to record the occurrence of symptoms related to asthma, and the timing of medication usage. However, in order to provide any generic alerting systems for MEDICATE, the usage of these additional buttons must be standardised. The table below shows the MEDICATE specified use of the event buttons.

Event	Value =	0	1	2	3
1	Cough	No cough	Mild cough	Some disturbance	Night waking
2	Dyspnoea	None	On climbing stairs	On walking	At rest
3	Wheeze	No wheeze	Mild wheeze	Some disturbance	Night waking
4	Location code	0	1	2	3
5	Medication	No puffs	1-2 puffs	3-4 puffs	>=5 puffs

Actions performed by the DMS Alerting Component

When an alert condition has been met, the DMS Alerting Component will:

- generate amendments to the healthcare record entry (Record Component, see Section 6) for the reading or symptom of concern, by:
 - a) setting the Emphasis attribute to true (the default value is false), thereby flagging up that this reading is of particular concern;
 - b) setting the Authors Comment attribute to an alert text specific to the alert condition that has been triggered;
- generate an e-mail to the MEDICATE clinical mailbox for that patient's healthcare organisation;
- add a new entry to the alert message archive (to provide a permanent and indelible medico-legal record of the alert).

The Java web servlets which generate the DMS Web Application (see Section 5) have been adapted to amend the client display html page of monitoring data, by



changing the background colour of the relevant table cell to highlight readings of concern:

- for readings below the serious or critical threshold to yellow or red respectively;
- for alerted symptom events to blue.

An example screen is included within Section 5 below.

Single-Event Alerts

These alerts are processed as individual values – abnormal ones can be identified singly, cells in the table on screen can be coloured red/yellow/blue and a message generated for each triggering instance within the data downloaded from AMOS.

a) Red Alert: PEF less than critical threshold

PEF reading is below the value set for the Red Threshold in “Settings”. This threshold is calculated as 50% of predicted or best PEF.

Values are displayed in cells coloured red.

Alert Message: “PEF below Red alert threshold”

b) Yellow Alert: PEF less than severe threshold

PEF reading is below the value set for the Yellow Threshold in “Settings”. This threshold is calculated as between 50% and 80% of predicted or best PEF.

Values are displayed in cells coloured yellow.

Alert Message: “PEF below Yellow alert threshold”

c) Severe night cough (value = 3) or Some disturbance from cough (value = 2)

Any instance of Event.Event = 1 and Event.Value = 3 or = 2 (depending on alert setting)

Values are displayed in cells coloured blue.

Alert Message: “Night waking from cough recorded by the patient”

Or “Some disturbance from cough recorded by the patient”

d) Dyspnoea at rest (value = 3) or Dyspnoea on walking (value = 2)

Any instance of Event.Event = 2 and Event.Value = 3 or = 2 (depending on alert setting).

Values are displayed in cells coloured blue.

Alert Message: “Severe dyspnoea at rest recorded by the patient”

Or “Dyspnoea on walking recorded by the patient”

e) Severe night wheeze (value = 3)

Any instance of Event.Event = 3 and Event.Value = 3 or = 2 (depending on alert setting)

Values are displayed in cells coloured blue.

Alert Message: “Night waking from wheeze recorded by the patient”

Or “Some disturbance from wheeze recorded by the patient”

Time Period Alerts

These alerts are based on a computation of values over a time period. The latest download will be posted to the patient record, and then the set of readings and/or events for the past 24 hours retrieved. These will need to be run on all patients irrespective of whether a download has just been processed for them.

f) Bronchodilator medication item used over 10 puffs in 24 hrs or over 15 puffs in 24 hrs or over 20 puffs in 24 hrs

For all medication events (Event.Event = 5) over the past 24 hours:

if Event.Value = 0 then score 0 puffs

if Event.Value = 1 then score 1.5 puffs

if Event.Value = 2 then score 3.5 puffs

if Event.Value = 3 then score 5 puffs

If the total score over 24 hours > 10 or 15 or 20 (depending on alert setting) then trigger the alert. No individual values are coloured in the table.

Alert Message: "Bronchodilator inhaler used more than 10 puffs in 24 hours"

Or "Bronchodilator inhaler used more than 15 puffs in 24 hours"

Or "Bronchodilator inhaler used more than 20 puffs in 24 hours"

g) Variability > 20% or Variability > 30%

From all PEF readings over the most recent calendar day (unless only one reading available, in which case the preceding day), find the max and min values.

$$\text{Variability} = \frac{(\text{max} - \text{min})}{\text{max}}$$

If Variability > 0.2 or 0.3 (depending on alert setting) then trigger the alert.

Alert Message: "24 hour PEF Variability over 20%"

Or: "24 hour PEF Variability over 30%"

h) No readings received for over 1 day or 3 days or 7 days

This alert might be run at the end of a complete file download/import. Query each patient record and check if the date/time of last reading is > 28 hours, 76 hours or 172 hours ago (depending on alert setting). (Add 4 hours to each number of days to allow for minor delays in the patient connecting through the modem.)

Alert Message: "No monitoring readings received in the last 1 day"

Or: "No monitoring readings received in the last 3 days"

Or: "No monitoring readings received in the last 7 days"

E-mail Message Structure

The MEDICATE DMS directs alert messages to relevant clinicians via a secure e-mail service developed by Licore Associates. Longer term experience will confirm if an e-mail approach is the most appropriate, given the present limited habit of checking personal e-mail for urgent clinical communications. The UCL Decision Support components can later be adapted to communicate alert messages via other channels if required.

The general structure of the e-mail alert messages is illustrated below.

To:

As indicated by the patient's healthcare provider e.g. admin.whitt@medicate.co.uk

Subject:

"MEDICATE asthma alert for <first name> <surname> <national identifier>"

Body:

The text will display as a series of one-line alert phrases e.g.

The following Medicate asthma alert messages have been issued for this patient.

PEF below Yellow alert threshold
PEF below 70% of predicted value
Night waking from cough recorded by the patient

Generated by: Medicate DMS Version 3.1
On Tuesday 29th February 2001, 11:45 am

5. DMS Web Application

Introduction

This section, incorporating a set of screen captures, is intended to give readers and potential end users a basic understanding of the web pages available within the UCL Medicate Disease Management System (DMS). The heart of the DMS contains an electronic healthcare record that has the potential to store a wide range of patient clinical data-sets and an alerting system for marking entries of concern and for generating electronic mail messages about them. The visible portion of the DMS serves primarily to provide:

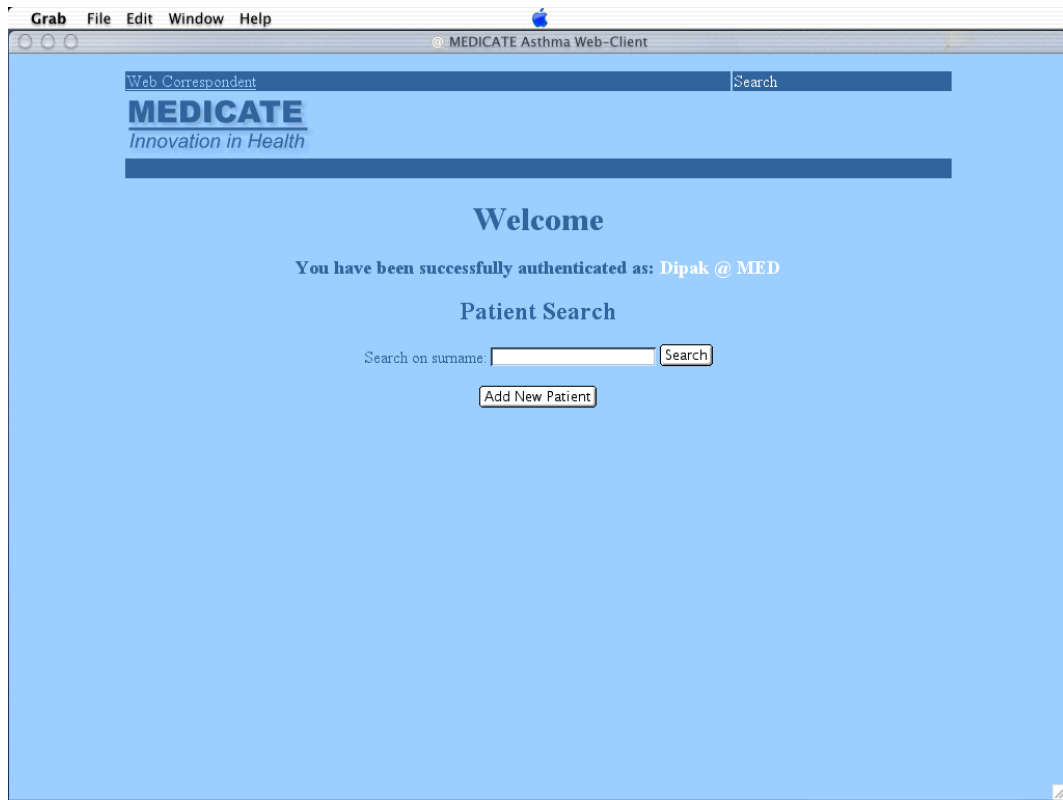
- a) a basic demographic record to confirm the patient's identity and optionally to store contact information about them and their GP for use if their main medical records are unavailable;
- b) a screen to capture the desired trigger settings for the DMS alerting system and AM1 device;
- c) a display of the home monitoring readings, incorporating a graph developed by Jaeger resembling the one within their current desktop application, and a tabular display providing a chronological record of the actual readings, symptoms and medication events downloaded from the patient's device;
- d) a list of the e-mail alerts that have been generated on each patient over time.

The engineering approach to the design of the asthma electronic healthcare record and the servlet based web application are described in Section 6.

You can only access the DMS on the Brentford Server if you are a registered Medicate user. You must first log in to Web Correspondent on the Medicate Web Site: <http://www.medicare.co.uk/> and reach your normal mailbox home page. The DMS can be accessed by the link near the top of the screen marked "Patients".

A working demonstrator of the DMS for interested parties who are not registered Medicate Users is described towards the end of this section of the deliverable.

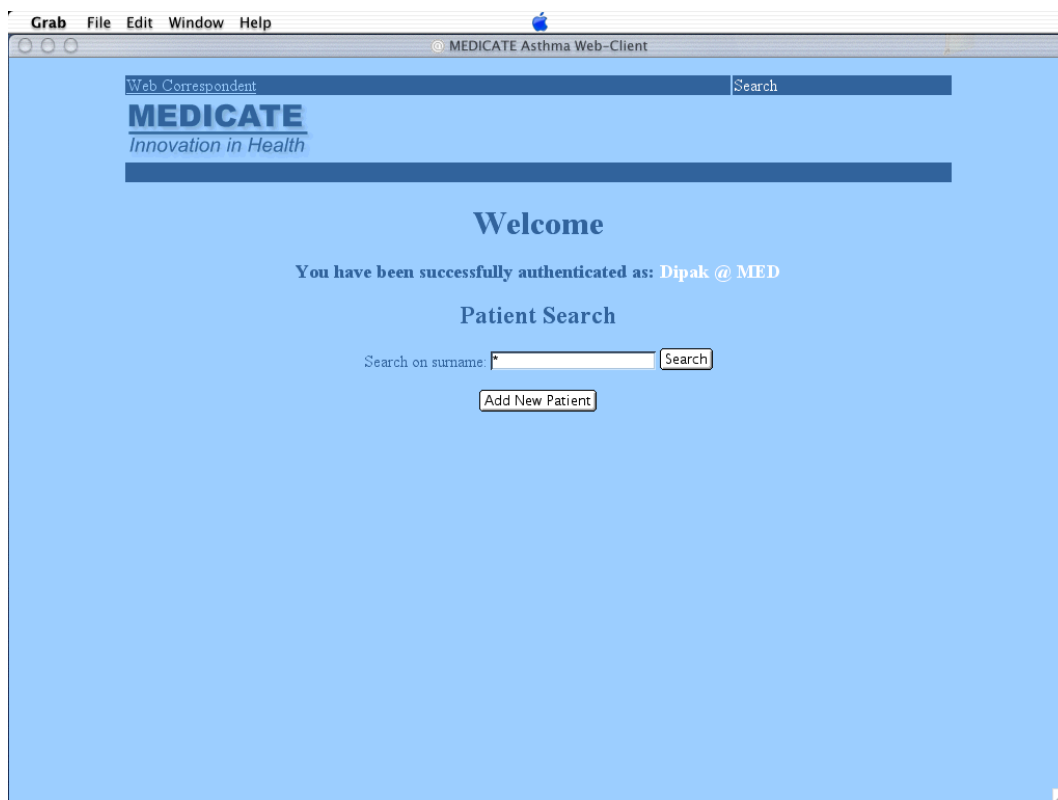
Patient Search



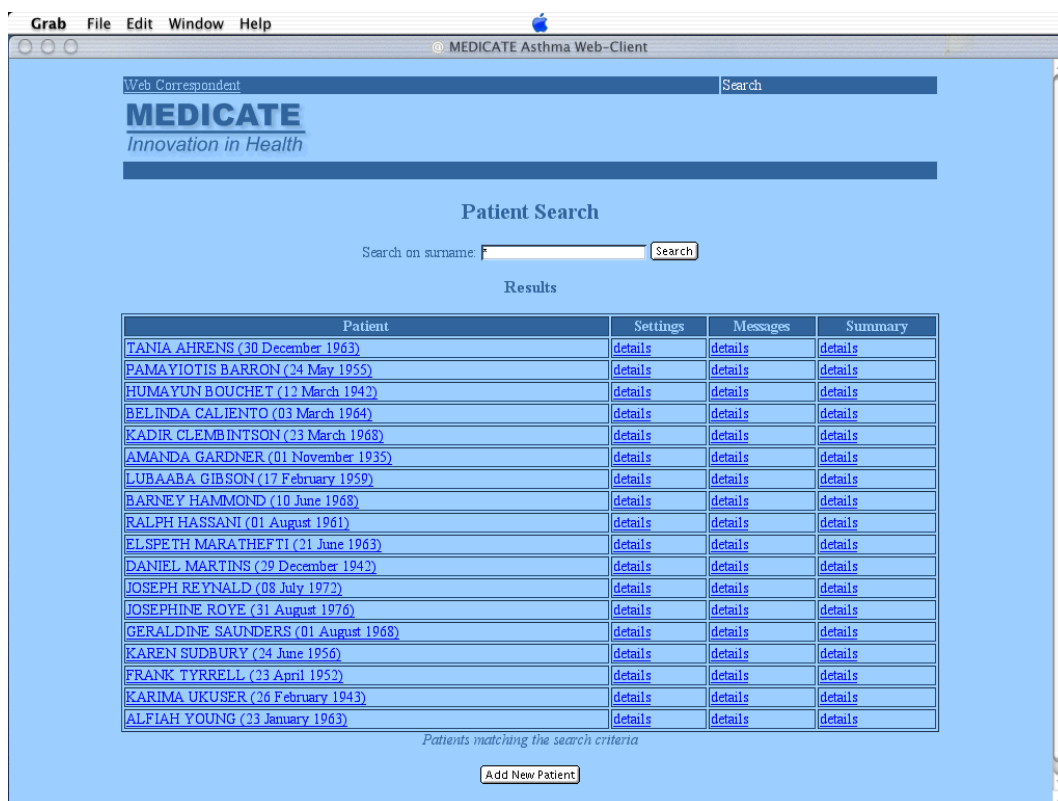
Once logged in, you are taken to the patient search screen. The screen confirms your user identity and account. From this page the "Web Correspondent" link at the top of this page will take you back to your personal home page (containing your e-mails). This should enable you to go back and forth between the two systems easily.

You may search for a patient by Surname only at present. We will add a search by Date of Birth and National Health Service number later. As there are only a few patients in the system, you are unlikely to find a match by typing in letters. The search field accepts a wild character (*), and at present it may be easiest just to type this as the only search criterion. That search gives you a full list of patients registered at your organisation's account.

You can also add a new patient from this screen.



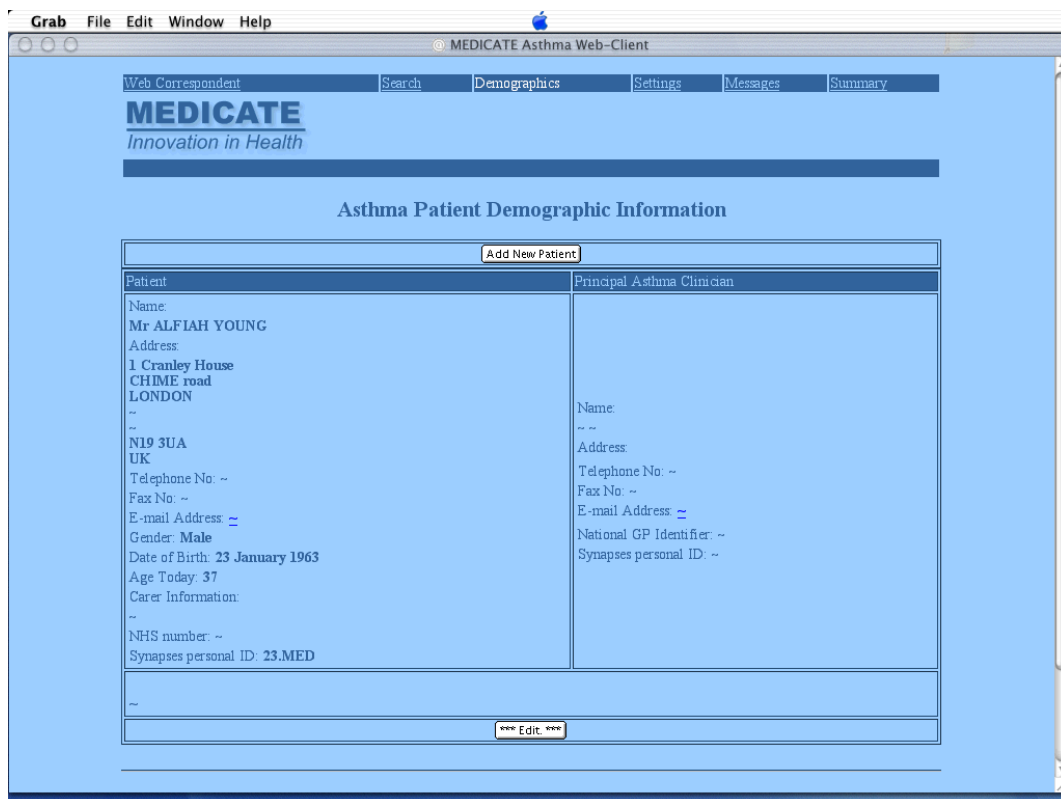
The search generates a list of patients, and gives you a basic identification for each one. If you click on a patient's name you are taken to their demographic screen. The other tables in their Medicate record are shown as hyperlinks, so that you can go directly to the screen of your choice from here.



The option to add a new patient is still available at this point.



Demographic Screen



The demographic screen provides for a basic contact data set about the patient. A placeholder approach exists for the management of hospital-issued numbers, but a generic handling of this is a fairly complex task and will be added as a later function. A National Health Service number can be added now, and will become a searchable field in the near future.

This screen contains links to the other main pages of the patient's Medicate clinical record, as do the other patient record screens.

You may amend the demographic details of the patient, or change their registered GP, by clicking the Edit button. The editing screen will indicate the fields available for you change by a white background. The method for changing a GP is identical to that for entering details for a new patient, described below.

All changes to the patients details must be saved and confirmed (by clicking OK a second time) before they are saved in the record.

Adding a new patient

The choice of adding a new patient can be made from several points in the DMS, including the patient search screen and an existing patient's demographic record.

The screenshot shows a web browser window titled "MEDICATE Asthma Web-Client". The page header includes the MEDICATE logo and the tagline "Innovation in Health". The main heading is "Asthma Patient Demographic Information", with a sub-heading "Patient Registration Details". A message states "You are adding demographic details for a new patient".

The form is divided into two main sections: "Patient" and "Principal Asthma Clinician".

Patient Section:

- Name: Title, First Name, Surname
- Address: Multiple text boxes for street address
- Postcode
- Telephone No., Fax No., E-mail Address
- Gender: Male (selected), Female
- Date of Birth
- Carer Information: NHS number

Principal Asthma Clinician Section:

- Name
- Address
- Telephone No., Fax No., E-mail Address
- National GP Identifier
- Synapses personal ID

At the bottom, there is a "Search for GP" section with a "Search" button and a "GP Description" section with a text box and a "GP description" label. At the very bottom are "OK", "Reset", and "Cancel" buttons.

At present, and to accommodate a wide range of address structures, the fields offered here are open text boxes. In the future more prescriptive form designs will be considered. However, in general, the duplicate entry of information already held in other existing systems is undesirable, and in time UCL will develop other ways of directly importing this kind of information from these core institutional systems. The layout of this screen might also be adjusted with time, but it should be noted that the layout of the fields on this particular screen vary considerably between browsers and platforms (a rare casualty of the web-based approach!) and that a definitive reproducible design may prove impossible.

MEDICATE
Innovation in Health

Asthma Patient Demographic Information

You are adding demographic details for a new patient

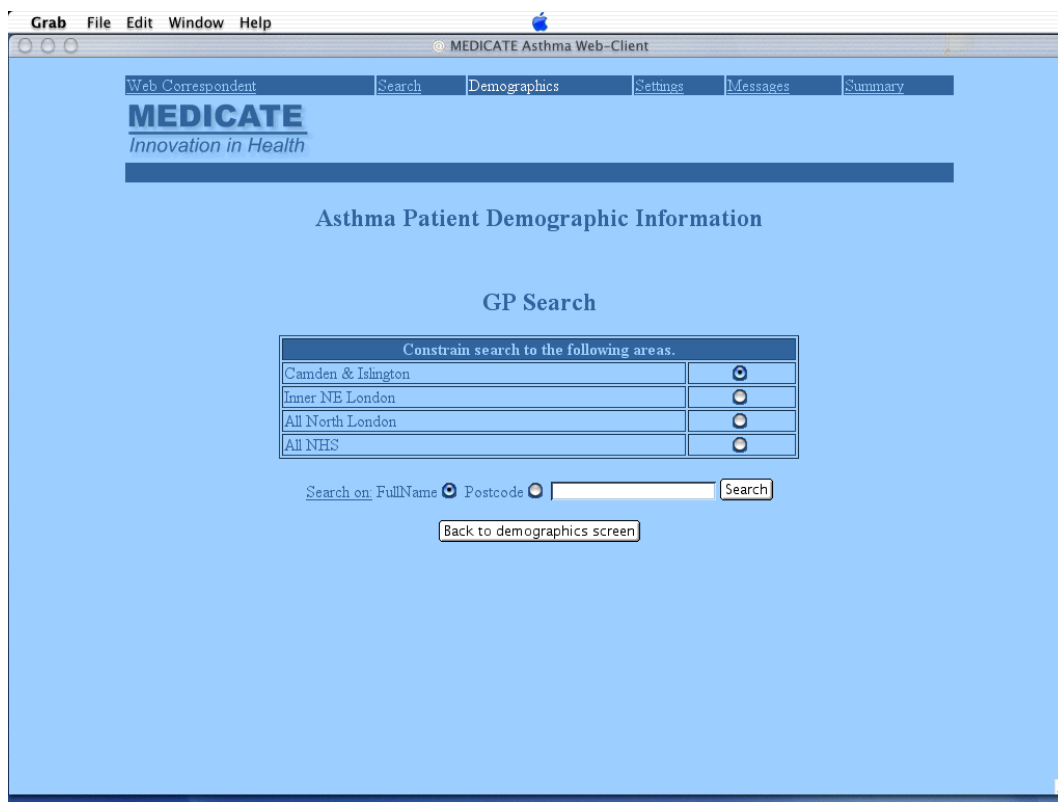
Patient Registration Details

Patient	Principal Asthma Clinician
Name: Title: <input type="text"/> First Name: <input type="text" value="Opak"/> Surname: <input type="text" value="Kaira"/>	Name: ~ ~
Address: <input type="text" value="CHIME"/> <input type="text" value="Holborn Union Building"/> <input type="text" value="Highgate Hill"/> <input type="text" value="London"/>	Address: ~ ~
Postcode: <input type="text" value="N19 3UA"/>	~ ~
Telephone No.: <input type="text" value="020 7288 3362"/>	~ ~
Fax No.: <input type="text"/>	~ ~
E-mail Address: <input type="text" value="j.kaira@chime.ucl.ac.uk"/>	~ ~
Gender: <input checked="" type="radio"/> Male <input type="radio"/> Female	~ ~
Date of Birth: <input type="text"/>	~ ~
Carer Information: <input type="text"/>	~ ~
NHS number: <input type="text"/>	~ ~

Search for GP	GP Description
<input type="text"/> <input type="button" value="Search"/>	<input type="text" value="GP description"/>

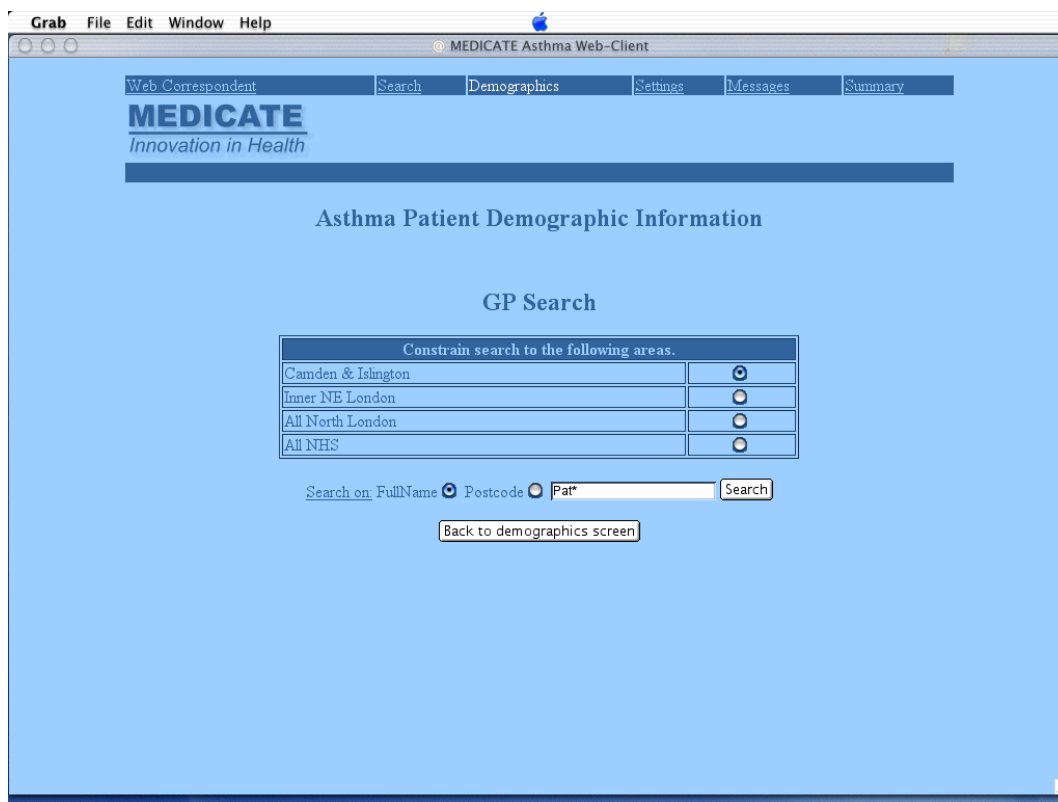
To speed up data entry the tab key can be used to progress from field to field.

General Practitioner details can be entered either as free text or from a look-up database of GPs. At present this contains all of the GPs in the UK NHS, and other national registers can be added as these are obtained. The search button in the lower portion of this screen takes the user to the GP database search screen.



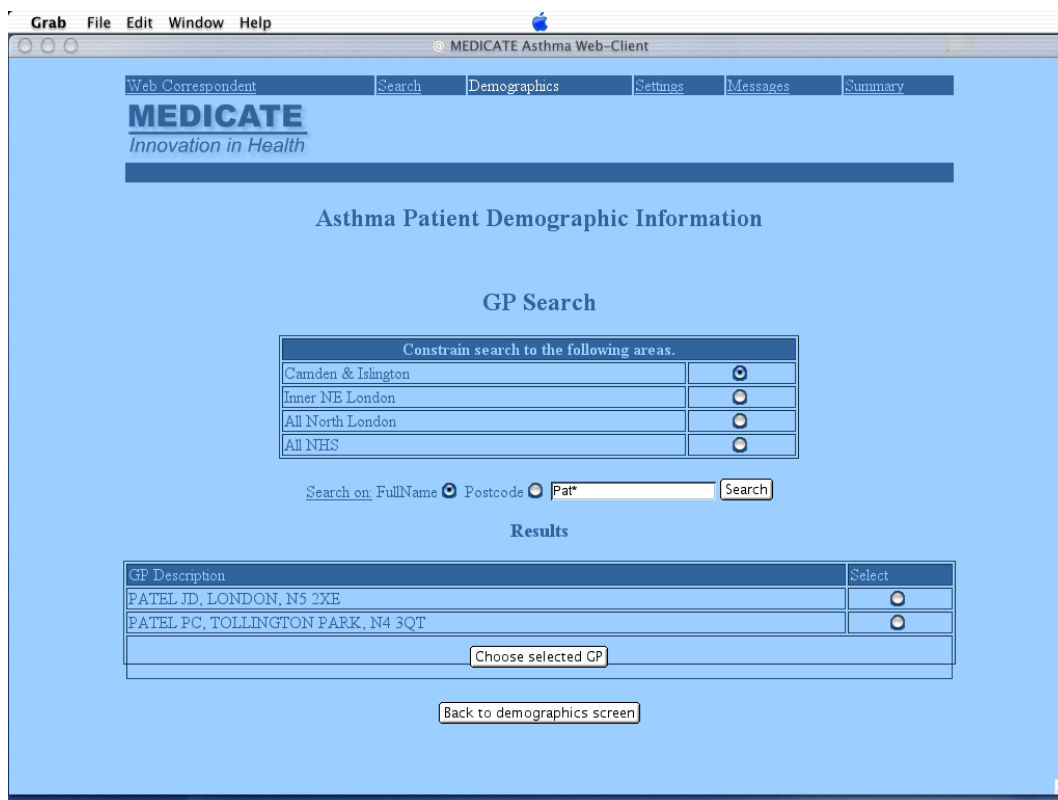
This screen is presently customised to the local needs of north London, offering to limit the search to neighbouring GPs. This is primarily to reduce the search time, since the servers presently available to the Medicate project are quite slow when all 40,000 UK GPs are in the search path. As server performance improves this screen will probably be modified to limit the search to the national context of the users organisation, and could therefore be rewritten more generically for a multi-national deployment.



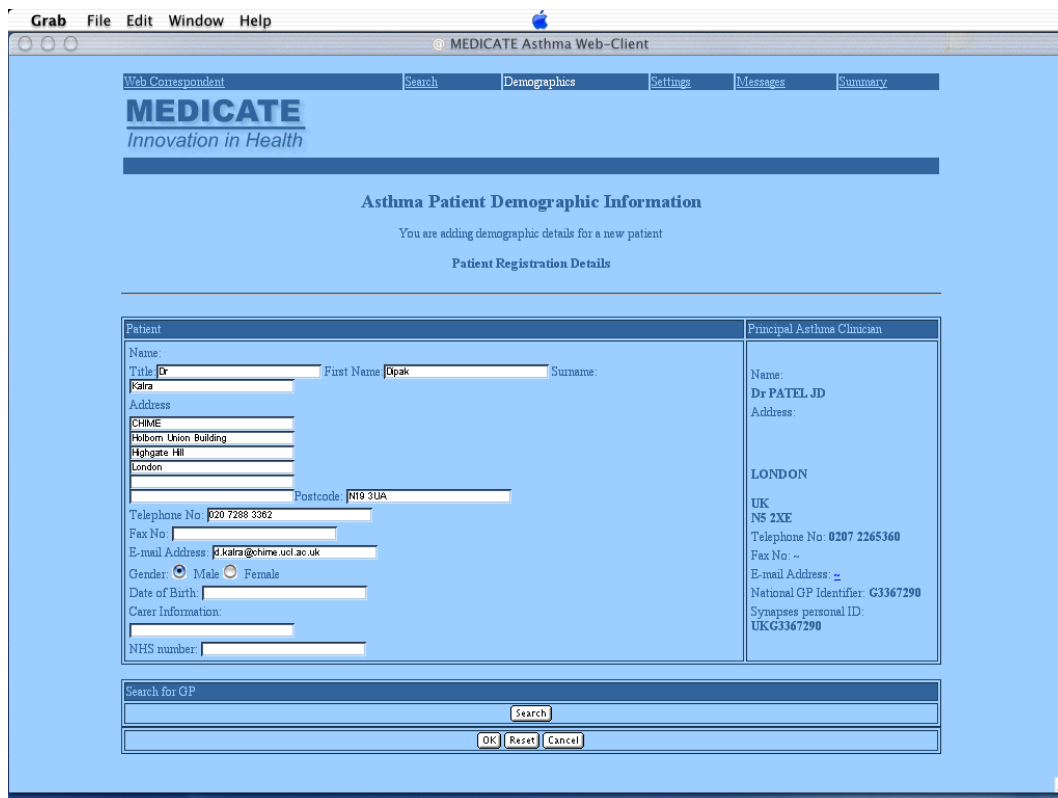


The GP search string, like that for patient surnames, allows the wild-character symbol (*) to be used at the beginning or end of the search pattern. A search by Postcode has been added here as this may be more precise for common surnames. Limiting the search to local GPs is faster. The first search performed in a user session takes an extra minute whilst the database search functions are loaded up.

A search of practice names has not been provided because of the chaotic nature of the UK register provided by the NHS. Should this improve, or other national registers prove better structured, this facility will be added.



A GP can be selected from the resulting list.



If the user is able to locate the correct GP, they can select the person by clicking on the "radio button" to the right of their name, and clicking "Choose selected GP". If the correct GP is not located the search can be repeated using different letters, or switching between surname and postcode. If the correct GP is not in the database, the user can either click none of the radio buttons but still click "Choose selected GP", or click the "Back" button on the browser. If the correct GP for the patient cannot be found in the database, it may be that they are a new GP; in this situation the user is automatically offered the option of typing their details as free text in the GP Description box.

The healthcare provider context ascribed to every logged in user of the DMS ensures that new patients are registered with the correct healthcare provider. This context dictates the subset of patients accessible to each user when they conduct a patient name search.

Asthma Alert Settings

This screen provides the means by which clinicians can indicate the kinds of alert they would like to be active for each individual patient, and for some alerts also choose the reading thresholds to be used. This is therefore a critical screen, which connects to the alerting software of the DMS and also provides the basic data needed by Jaeger-Toennies' AMOS-Setup to configure a patient's AM1 asthma monitoring device.

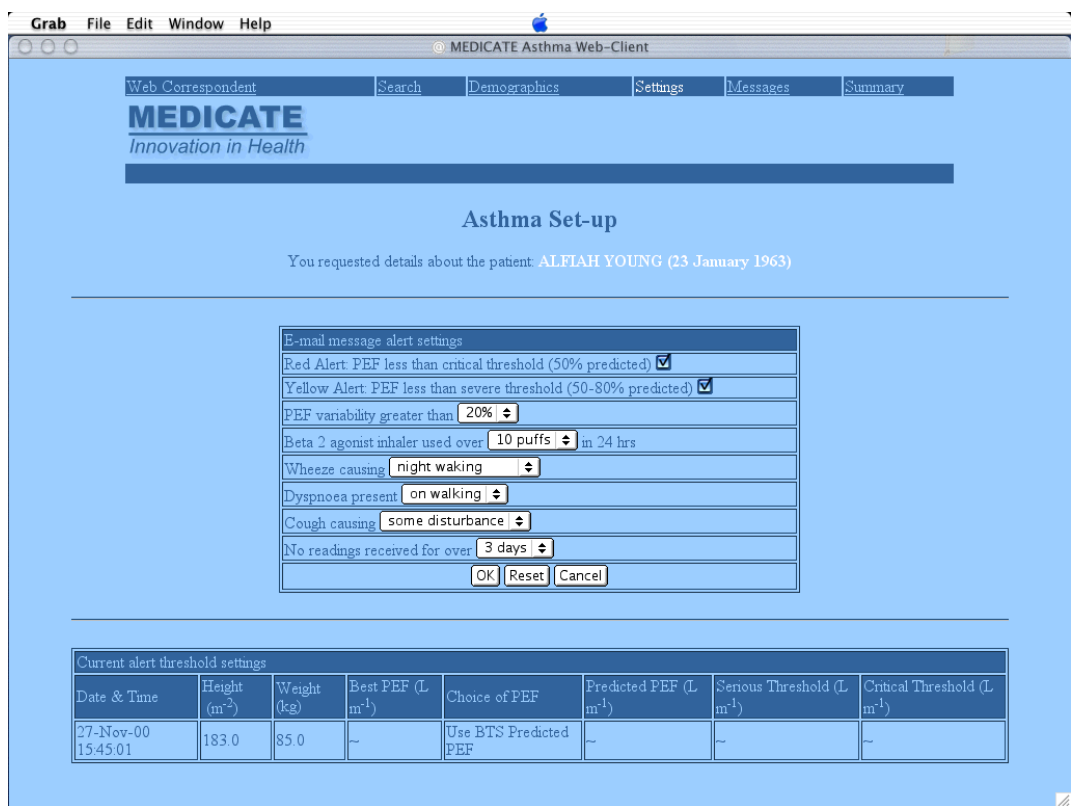
The screenshot shows the 'Asthma Set-up' interface for patient ALFLAH YOUNG (23 January 1963). The interface includes a navigation bar with 'Web Correspondent', 'Search', 'Demographics', 'Settings', 'Messages', and 'Summary'. The 'Settings' tab is active. Below the navigation bar is the 'MEDICATE Innovation in Health' logo. The main content area is titled 'Asthma Set-up' and contains a form for 'E-mail message alert settings'. The form includes several rows with checkboxes and dropdown menus for various alert conditions. Below the form is a 'New Settings' button. At the bottom of the screen is a table for 'Current alert threshold settings' with columns for Date & Time, Height (m), Weight (kg), Best PEF (L), Choice of PEF, Predicted PEF (L), Senous Threshold (L), and Critical Threshold (L).

E-mail message alert settings							
Red Alert PEF less than critical threshold (50% predicted)	<input checked="" type="checkbox"/>						
Yellow Alert PEF less than severe threshold (50-80% predicted)	<input checked="" type="checkbox"/>						
PEF variability greater than	20%						
Beta 2 agonist inhaler used over	20 puffs	in 24 hrs					
Wheeze causing	night waking						
Dyspnoea present	on walking						
Cough causing	some disturbance						
No readings received for over	3 days						
<input type="button" value="New Settings"/>							

Current alert threshold settings							
Date & Time	Height (m)	Weight (kg)	Best PEF (L)	Choice of PEF	Predicted PEF (L)	Senous Threshold (L)	Critical Threshold (L)
27-Nov-00 15:45:01	183.0	85.0	-	Use BTS Predicted PEF	-	-	-
<input type="button" value="New Settings"/>							



The first half of the screen lists the set of possible alerts. The screen is first displayed in a mode that allows users to view the contents of each drop down list, but any changes accidentally made are not stored. These alert settings can be changed by selecting the New Settings button at the bottom of the upper table.



Once the New Settings button has been pressed the upper table becomes sensitive to changes, the buttons at its base change to OK, Reset and Cancel. Please note that at this point the lower table can no longer be edited - only one table can be changed at one time on this screen, to ensure that committed data is kept consistent with the requirements of the various dependent programmes and the AM1 device.



Asthma Set-up
You requested details about the patient: ALFIAH YOUNG (23 January 1963)

E-mail message alert settings

Red Alert: PEF less than critical threshold (50% predicted)

Yellow Alert: PEF less than severe threshold (50-80% predicted)

PEF variability greater than: 20%

Beta 2 agonist in last 24 hrs: 10 puffs

Wheeze causing: night waking some disturbance

Dyspnoea present:

Cough causing: some disturbance

No readings received for over: 3 days

OK Reset Cancel

Current alert threshold settings							
Date & Time	Height (m ²)	Weight (kg)	Best PEF (L m ⁻¹)	Choice of PEF	Predicted PEF (L m ⁻¹)	Serious Threshold (L m ⁻¹)	Critical Threshold (L m ⁻¹)
27-Nov-00 15:45:01	183.0	85.0	~	Use BTS Predicted PEF	~	~	~

Changes can be made to each of the alert settings (as previously documented in the DMS Specification). To turn off an alert the user should uncheck the red or yellow alert check-box, or choose a blank value in the appropriate drop down list.

The changes should be saved (pressing OK) and confirmed (pressing OK again). The settings will then be saved in the patient's record and are effective immediately for the next download of monitoring data. For medico-legal reasons amended setting information cannot be applied to retrospective monitoring data.

The lower table provides the means to set the thresholds for red and yellow alerts that will be used both to display a colour coded response to the patient on their AM1 device and on the results summary screen, described below.



Web Correspondent Search Demographics Settings Messages Summary

MEDICATE
Innovation in Health

Asthma Set-up

You requested details about the patient: ALFIAH YOUNG (23 January 1963)

E-mail message alert settings

Red Alert: PEF less than critical threshold (50% predicted)

Yellow Alert: PEF less than severe threshold (50-80% predicted)

PEF variability greater than

Beta 2 agonist inhaler used over in 24 hrs

Wheeze causing

Dyspnoea present

Cough causing

No readings received for over

Current alert threshold settings

Date & Time	Height (m ²)	Weight (kg)	Best PEF (L m ⁻¹)	Choice of PEF	Predicted PEF (L m ⁻¹)	Serious Threshold (L m ⁻¹)	Critical Threshold (L m ⁻¹)
27-Nov-00 15:45:01	183.0	85.0	~	Use BTS Predicted PEF	~	~	~
- / -	<input type="text"/>	<input type="text"/>	<input type="text"/>	Use BTS Predicted PEF	<input type="text"/>	<input type="text"/>	<input type="text"/>

Calculate PEF

OK Reset Cancel

In this table, only four fields are offered for data entry. The height is required to calculate the Predicted Peak Flow and should be entered in centimetres. The weight is offered as an optional field. The Best Peak Flow field allows the clinician to indicate a different target value from the one that would be calculated for their age, gender and height.

If the gender or date of birth have not been entered on the demographic screen, the user is first prompted to enter these (and offered a direct link to that page, for convenience).



Explorer File Edit View Go Favorites Tools Window
@ MEDICATE Asthma Web-Client

Web Correspondent Search Demographics Settings Messages Summary

MEDICATE
Innovation in Health

Asthma Set-up

You requested details about the patient: ALFIAH YOUNG (23 January 1963)

E-mail message alert settings

Red Alert: PEF less than critical threshold (50% predicted)

Yellow Alert: PEF less than severe threshold (50-80% predicted)

PEF variability greater than

Beta 2 agonist inhaler used over in 24 hrs

Wheeze causing

Dyspnoea present

Cough causing

No readings received for over

Current alert threshold settings

Date & Time	Height (m ²)	Weight (kg)	Best PEF (L m ⁻¹)	Choice of PEF	Predicted PEF (L m ⁻¹)	Serious Threshold (L m ⁻¹)	Critical Threshold (L m ⁻¹)
27-Nov-00 15:45:01	183.0	85.0	~	Use BTS Predicted PEF	~	~	~
- / -	183	87	470	Use BTS Predicted PEF	~	~	~

Calculate PEF
OK Reset Cancel

Use European Predicted PEF
Use Best PEF instead of Predicted

The user is able to select if the red and yellow PEF alert thresholds should be based on a predicted or best peak flow. Predicted PEF is calculated from the height, age and gender of the patient, at present using the formula published by the British Thoracic Society (BTS); the European algorithm will be added later. When the Calculate PEF button is pressed the last three columns of the table are filled in automatically.



Asthma Set-up

You requested details about the patient: ALFIAH YOUNG (23 January 1963)

E-mail message alert settings

Red Alert: PEF less than critical threshold (50% predicted)

Yellow Alert: PEF less than severe threshold (50-80% predicted)

PEF variability greater than

Beta 2 agonist inhaler used over in 24 hrs

Wheeze causing

Dyspnoea present

Cough causing

No readings received for over

Current alert threshold settings

Date & Time	Height (m ²)	Weight (kg)	Best PEF (L m ⁻¹)	Choice of PEF	Predicted PEF (L m ⁻¹)	Serious Threshold (L m ⁻¹)	Critical Threshold (L m ⁻¹)
27-Nov-00 15:45:01	183.0	85.0	-	Use BTS Predicted PEF	-	-	-
- / -	183	87	470	Use BTS Predicted PEF	650.3057	520.2446	325.1529

Calculate PEF

OK Reset Cancel

All PEF readings on this screen are shown in litres per minute. This contrasts to the AM1 monitoring data that stores measurements in litres per second. The above choice for DMS display has been made on clinical request as litres per minute is a more familiar measurement unit in clinical practice.



MEDICATE
Innovation in Health

Asthma Set-up

You requested details about the patient: ALFIAH YOUNG (23 January 1963)

E-mail message alert settings

Red Alert: PEF less than critical threshold (50% predicted)

Yellow Alert: PEF less than severe threshold (50-80% predicted)

PEF variability greater than

Beta 2 agonist inhaler used over in 24 hrs

Wheeze causing

Dyspnoea present

Cough causing

No readings received for over

Are you sure that you wish to commit the new settings?
Press "OK" to confirm your intentions

Current alert threshold settings							
Date & Time	Height (m ²)	Weight (kg)	Best PEF (L m ⁻¹)	Choice of PEF	Predicted PEF (L m ⁻¹)	Serious Threshold (L m ⁻¹)	Critical Threshold (L m ⁻¹)
27-Nov-00 15:45:01	183.0	85.0	-	Use BTS Predicted PEF	-	-	-
- / -	183	87	470	Use BTS Predicted PEF	650.3057	520.2446	335.1529

Calculate PEF

OK Reset Cancel

As with all entries in the DMS, pressing OK requires a confirmation before the data is stored as an indelible part of the patient's record. The date and time of this entry are added automatically at the point when the data is added to the record. At that moment the data is available for use to prime a new AM device for a patient or will constitute the replacement settings for an existing patient's device when they next dial up to download data.

Setting up the AM1 device

At present there is no means to push data to Jaeger's AMOS Setup software in order to prime a new AM device for a patient. This AMOS Setup software must be installed on a machine local to the clinician, and run specifically to set up a device for issue to a new patient. However, the DMS record for that patient need not be set up on that same machine, and can be done from any web browser prior to priming the device.

AMOS Setup, when run, will contact the DMS to obtain a list of patients for that organisation, from which the clinician should select the required name. AMOS Setup will again contact the DMS to obtain the settings for that patient, and will then send them down a connected cable to the AM1 device. Subsequent changes to the settings can be communicated to the AM1 device via the same modem connection used by the patient to download their readings.

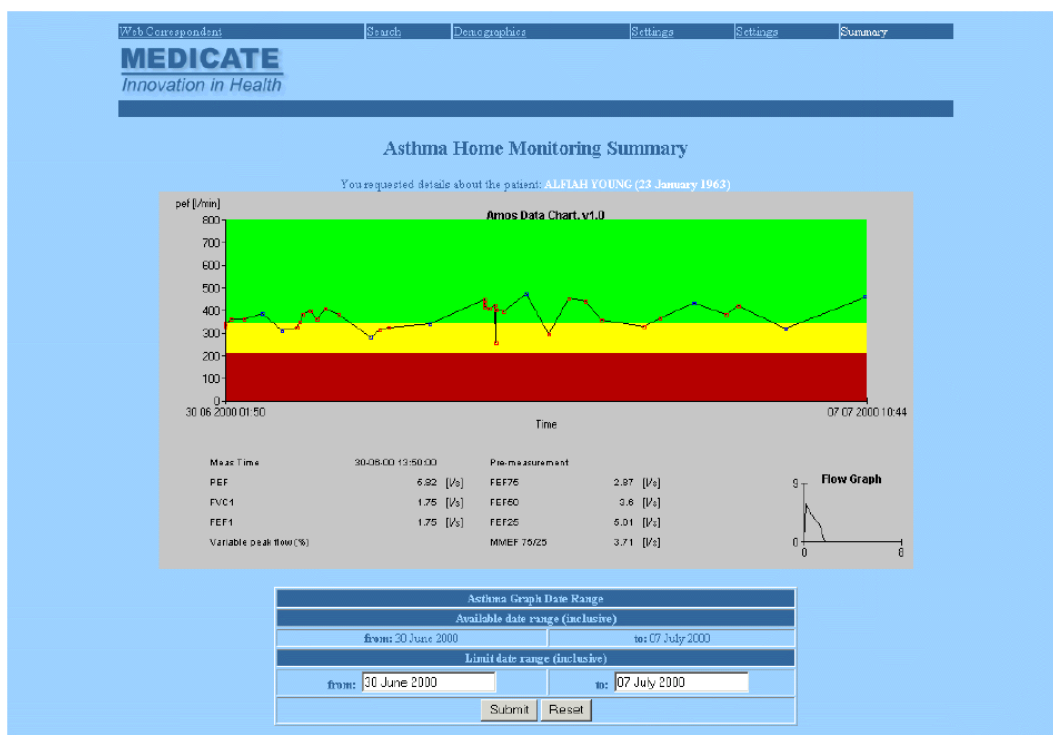
In this process the DMS is providing the information, and the AMOS Setup is acting as a communications channel to the AM1. Once any changes are saved in the DMS they are immediately available for subsequent requests for data from AMOS Setup. Jaeger-Toennies are developing new protocols for communicating with an AM1 device which will simplify some of these steps in the future.



Asthma Monitoring Summary

This screen provides displays of the numeric readings, symptoms and medication usage information collected by the AM1 device. Two formats for display are provided:

- 1) a graph resembling the Jaeger-Toennies graphical display in their existing desktop software.
- 2) a tabular arrangement of all AM1 entries, in reverse chronological order



The upper portion of this summary screen displays a graph (generated by a Java Applet, developed by Jaeger-Toennies in collaboration with UCL). The main part of the graph displays peak flow readings (distinguishing pre- and post-medication readings by a small coloured circle) on a background colour representing the serious and critical thresholds that were active at the time of each reading. Clicking on any individual peak flow measurement dynamically generates a flow graph and a list of the other respiratory function readings that were captured by the AM1 device at the same time as the peak flow reading.

On first loading the page, the graph is displayed with the all of the readings held for that patient.

The applet is followed by a date entry form that allows users to select the date range that should be displayed by the graph. For user convenience, the whole date range for readings available in the current patient's record is also shown. At present users need to enter dates in the format illustrated by the whole record date range (i.e. the month as a full word and a four digit year); a set of rapid entry options for selecting date ranges will be developed in the near future, in discussion with the clinical teams.

It has been noted that the graph presently displays only numeric information, and that symptom and medication usage information is desirable; this is being considered by Jaeger-Toennies for future versions of the graph applet.



The tabular display lists all historic readings chronologically in descending order, including symptoms and medication usage. This should allow the viewer to rapidly note the most recent information. Values that have triggered an alert are presented in cells coloured red and yellow for red and yellow alerts respectively. Please note that, as in the alert set up screen, peak flow readings are shown in litres per minute.

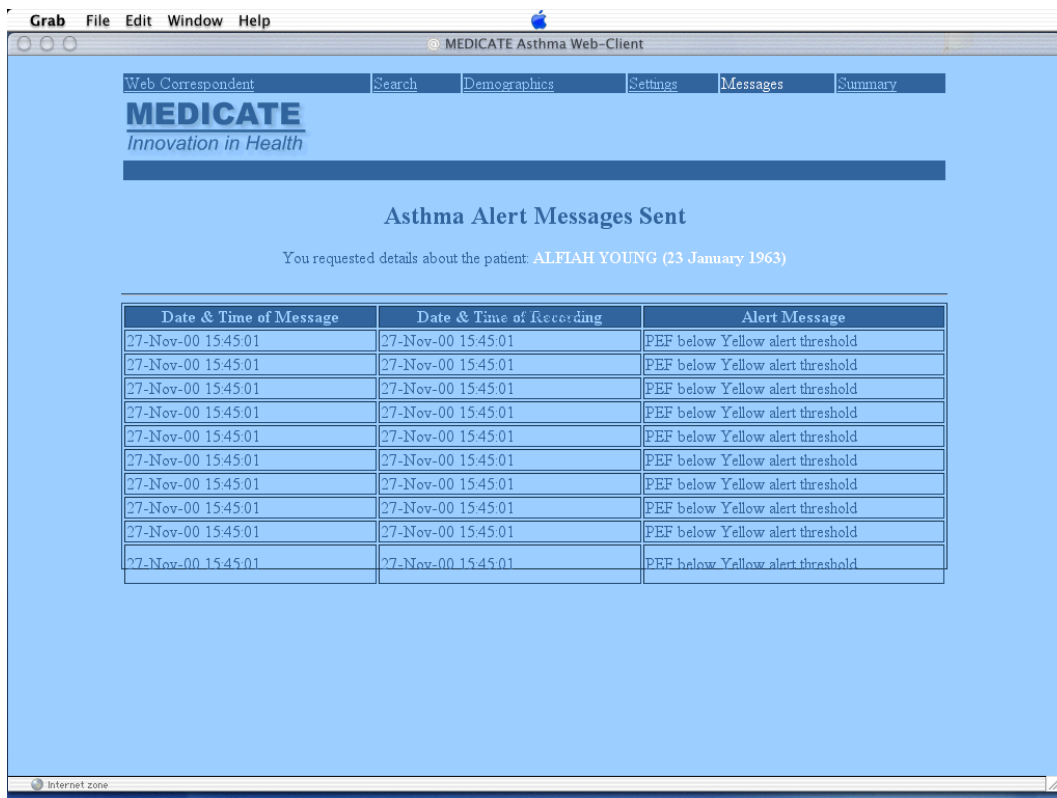
In order to limit information overload, at present the initial table loaded by the DMS displays the most recent entries received from the patient's AM1 device. Historic readings are indicated and accessed via a set of hyper-linked pages presented in the same way as the results of a web search using conventional search engine such as Yahoo. This is intended to provide a means of focusing attention on recent results whilst allowing rapid navigation to earlier ones and giving users a feel of the total record size. The present number of results per page (ten) can be changed in the light of clinical feedback.

It is possible to select date ranges for the graphical display and tabular display independently: for example, if the graph date range is amended and the screen refreshed, the users choice for viewing the tabular display is retained.



Asthma Alert Message Log

For medico-legal purposes, and as a convenient reference within each patient record, the screen below lists all of the alerts that have been generated and sent by e-mail. Two date/times are shown, one when the original reading was taken by the patient, and one when the alert was actually generated (in most cases a few seconds after the data was downloaded by the patient).



This screen is presented for viewing only, sorted to show the most recent messages first. The table presently shows some rather artificial test alerts that were generated by sample data. In reality it is expected that only a few messages would be generated per week for most patients.

It might later be possible to link this screen to a page of advice about each alert for the benefit of patients reading this, or for clinical training purposes.



Medico-legal context information

The complete record object, even for simple elements, contains a set of medico-legal attributes corresponding to those values inherited from the Record Component class and Record Item class of the SynOM. For information only, a screen showing part of this information is shown below. The complete set of attributes is quite large.

(This information view is presently not enabled in the DMS, but may be reactivated in the future if it is felt to be of value).

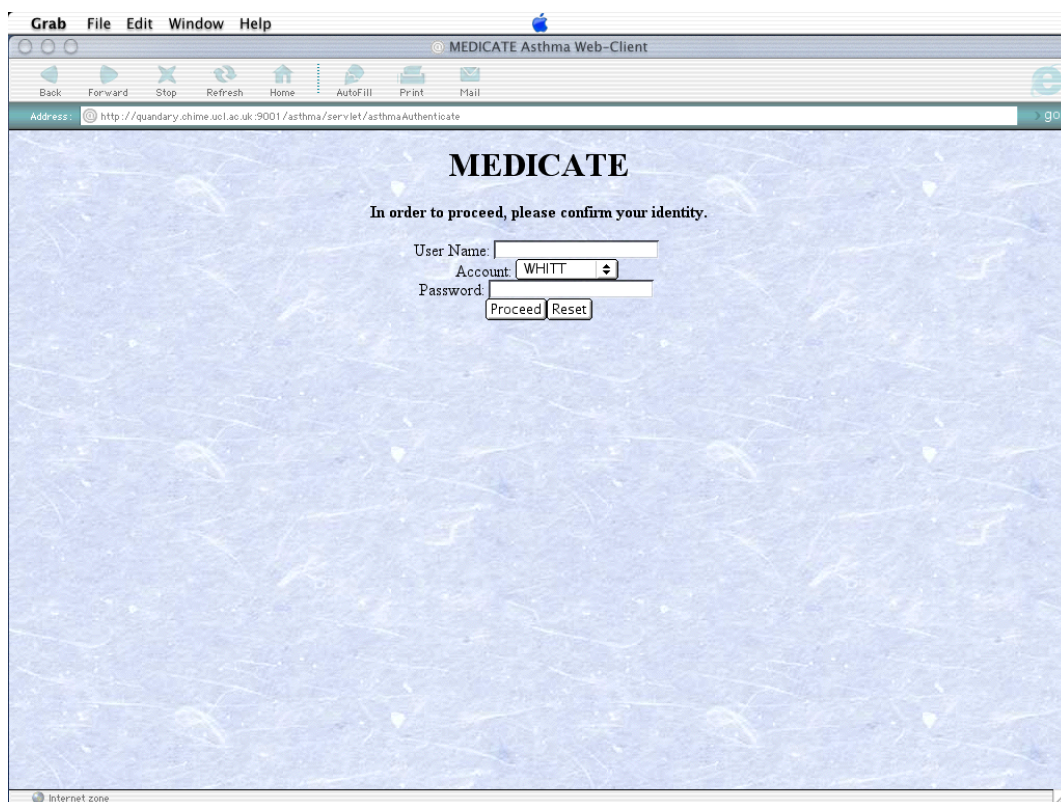
Data information	Data value
for patient:	1
class is:	uk.ac.ucl.chime.synom.ElementItem
id is	uk.ac.ucl.asthma.24
object id is	PEF 939736500000
ehcr source is	uk.ac.ucl.asthma.AMOSTEST.MDB
name is	null
authors comment was	Red Alert
healthcare activity location was	Home
recording healthcare agent was	null
responsible healthcare agent was	null
legally responsible healthcare agent was	Dr S. Lock
information provider was	PATIENT
locale was	en_GB
emphasised?	true
associated rights were	3
authorisation status was	1
subject of information was	4
healthcare activity begin time	null
healthcare activity end time	null
observation begin time	null
observation end time	null
lifecycle was	0
potentiality was	0
process status was	0
negation was	0

Demonstration version of the DMS

A working demonstrator of the DMS has been made available for interested parties to view without having to register as a formal subscriber to the MEDICATE system. This is for illustration only, and the demonstrator may contain some developmental code which runs imperfectly or differs from the description given in this Deliverable.

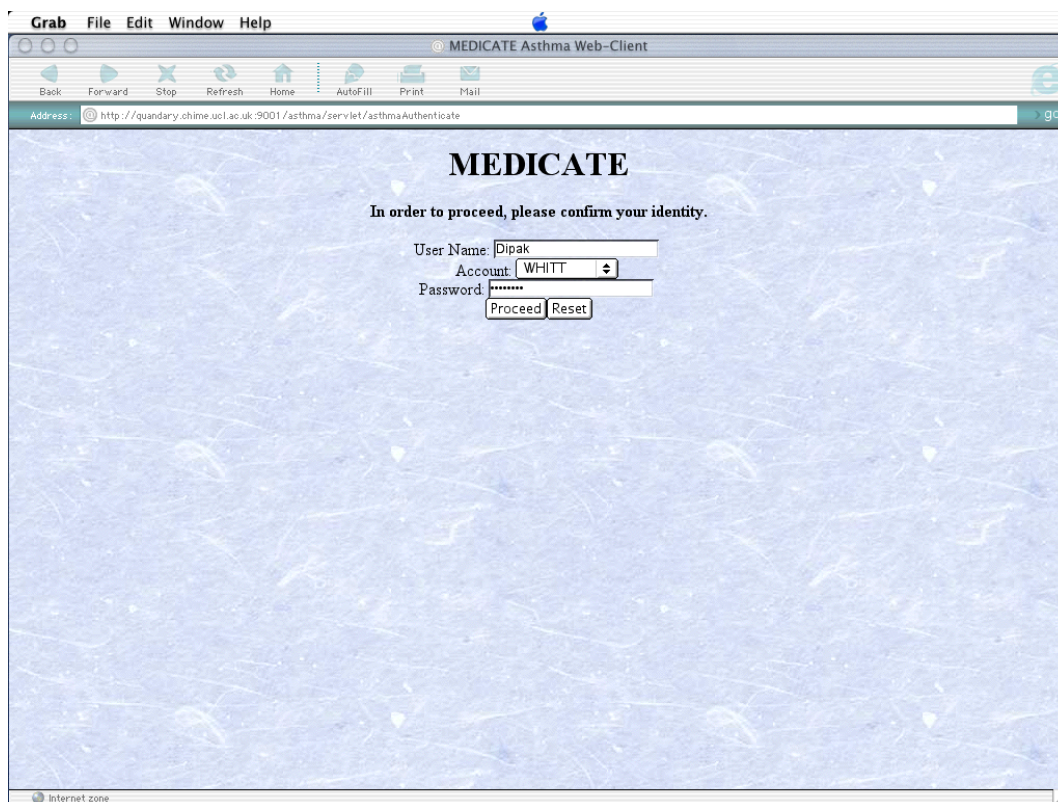
The DMS demonstrator can be accessed by typing in the URL:

<http://quandary.chime.ucl.ac.uk:9001/asthma/servlet/asthmaAuthenticate>



This demonstrator screen simulates the information that is passed between Web Correspondent and the DMS. Please type in any User Name of your choice. Your password must be "iam" (in lower case, without the quotes) followed by the same User Name again. Your User Name must be typed in with the same use of upper and lower case letters each time

e.g. User Name = Dipak
Password = iamDipak



You may choose any of the accounts in the drop down box for fun, but at present there are only a few test patients in the system, mainly in the *MED* account. If you use another account you should not be able to list these *MED* patients, although other test patients will appear in the future!

The account a Medicate user officially belongs to will be the healthcare provider account for their organisation when it registers with the Medicate Project. The definitive Medicate system does not include this screen, as users are co-authenticated to the DMS when they log in to Web Correspondent. They are instead taken directly to the patient search screen described early in this section of the deliverable.

Once you have passed this screen, the demonstrator version of the DMS functionally resembles the Medicate version described earlier.

6. DMS Federated Record Service Components

Introduction

This section describes the rationale, approach, information models and engineering approach to the federated electronic healthcare record middleware components that underpin the clinical data handling and storage by the DMS.

The Synapses Approach

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 [58].

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 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 [59]. 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 [60].

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.

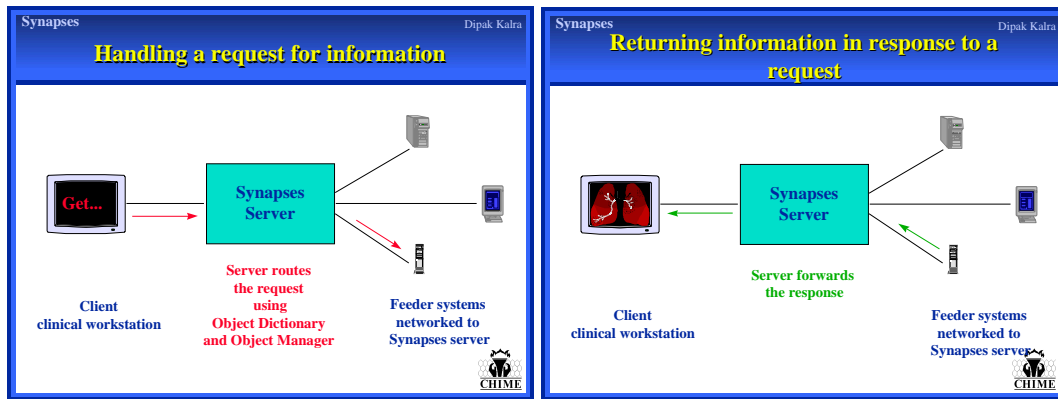


Figure 8: Illustration of the functions provided by a Synapses server

The Synapses federation therefore contains a set of services that support access to distributed sources of healthcare records. The Synapses approach enables the sharing of healthcare records between different applications, and allows 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 [61]. Client applications are able to request patient record information in the form of Synapses Objects: these are record components that could be, in their simplest form, clinical data sets. The *SynFHCR* architecture has been informed by the requirements for clinical comprehensiveness and ethico-legal acceptability identified by the GEHR project [39, 42]. Its class hierarchy builds on the constructs defined in the CEN pre-standard for EHCR architectures [44].

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 [62] 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 EHR architectures. The work has been refined through early implementation experience, and closely maps to the architecture constructs defined in CEN/TC 251 ENV 13606 [63]. (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.

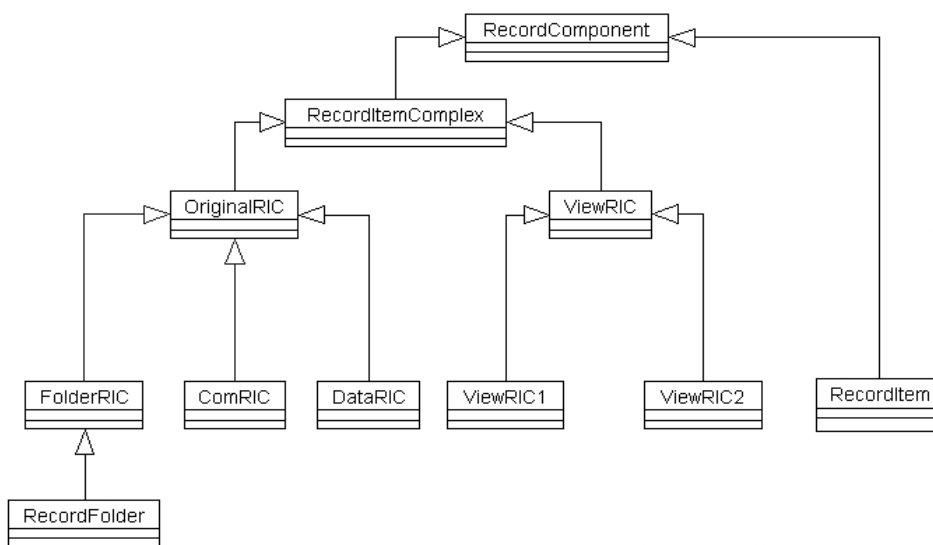


Figure 9: Class Inheritance within the SynOM

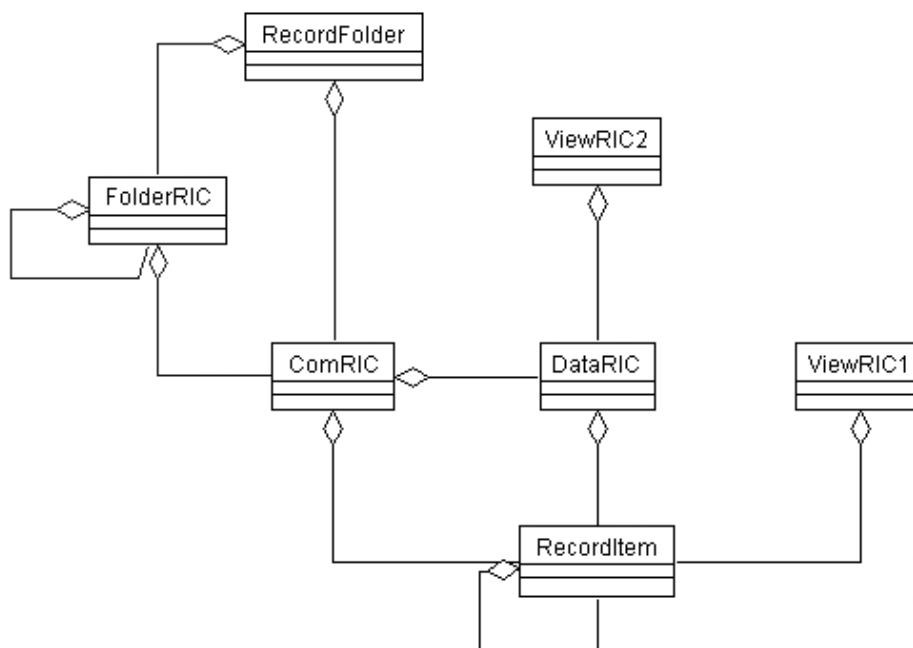


Figure 10: Class Aggregation within the SynOM

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 EHR 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 EHR: any new EHR 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 EHR 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 FCHR 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.

Permitted values have been provided for some of the attributes. These are drawn from the Domain Termlist part of ENV 13606 [64]. Their use allows compliance with this part of the standard.

Subject of care

RecordComponent attribute	Mandatory Optional	Description of intended use
SubjectOfCareID	Mandatory	this will identify the patient about whom the record component relates
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 PERMITTED VALUES: {patient, relative, foetus, mother, donor, personalcontact, otherperson, device} DEFAULT = "patient"

Record authorship, ownership and duty of care responsibilities

SynOM attribute	Mandatory Optional	Description of intended use
RecordingHealth CareAgent	Mandatory	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)
Responsible HealthCareAgent	Optional	the healthcare agent responsible for authoring this record component and taking medico-legal responsibility for it
LegallyResponsible HealthCareAgent	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
RevisedBy	Optional	the healthcare agent responsible for the current version of this record component, if the current version is an amendment
Information Provider	Optional	the person providing healthcare information if not the subject of care (e.g. a family member, friend, another clinician, an electronic device)
ContactWith HealthCareAgent	Optional	The name of the person who has provided health care to the patient, if not the recording HCA or the information provider
EHCSource	Optional	the legal source enterprise (the "owner") 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

Dates, times, locations of healthcare actions and of their recording

SynOM attribute	Mandatory Optional	Description of intended use
RecordingDate Time	Mandatory	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)
HealthcareActivityBegin DateTime	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)
HealthcareActivityEnd DateTime	Optional	
ObservationBegin DateTime	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



ObservationEnd DateTime	Optional	
HealthcareActivity Location	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)

Version control

SynOM attribute	Mandatory Optional	Description of intended use
RevisedVersion	Optional	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)
Authorisation Status	Mandatory	PERMITTED VALUES: {unattested, attested, obsolete, revision}

Access rights

SynOM attribute	Mandatory Optional	Description of intended use
AccessAmend Rights	Mandatory	PERMITTED VALUES: {admin, audit, clinical, team, profession, hcp} 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 EHR, and are supplementary to any restrictions on overall access to each patient's EHR as a whole.

Emphasis and presentation

SynOM attribute	Mandatory Optional	Description of intended use
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.

Class identifiers

SynOM attribute	Mandatory Optional	Description of intended use
ClassName	Mandatory	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
RC_UID	Mandatory	an internal reference identifier for each record component, provided by the Synapses Server
SynapsesObjectUID	Mandatory	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)
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. The object referred must be an OriginalRIC.

Other Attributes

SynOM attribute	Mandatory Optional	Description of intended use
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
RCULink	Optional	the RC_UID(s) of other record component(s) in the EHR 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
RCULinkBackToSource	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.

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.

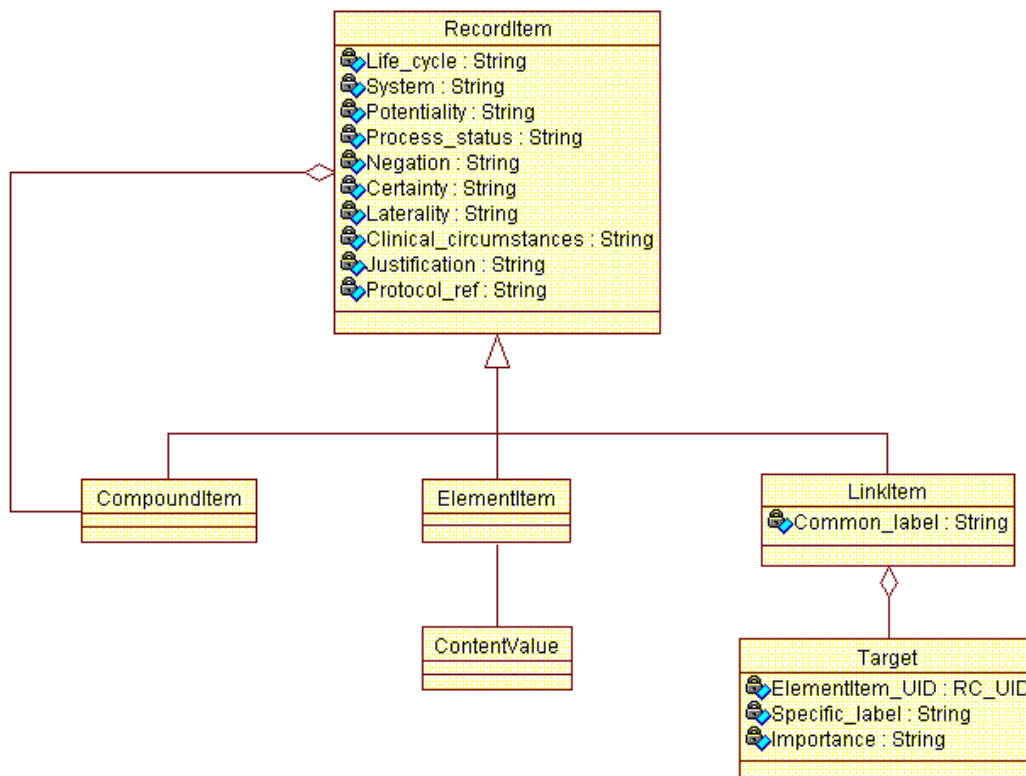


Figure 11: Record Item Class Hierarchy

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 EHR can be represented.

From an aggregation perspective, LinkItems behave as ElementItems: they are leaf nodes in an EHR 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.

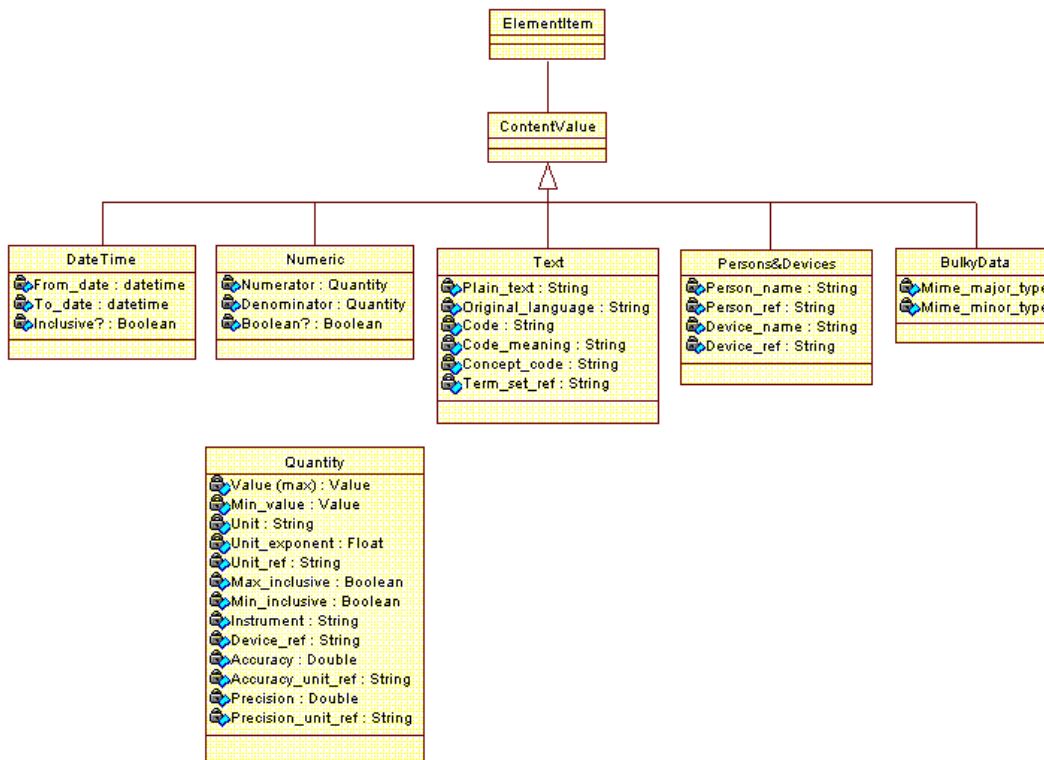


Figure 12: Content Class Hierarchy

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 Medicate DMS 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 EHR 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 13 below.

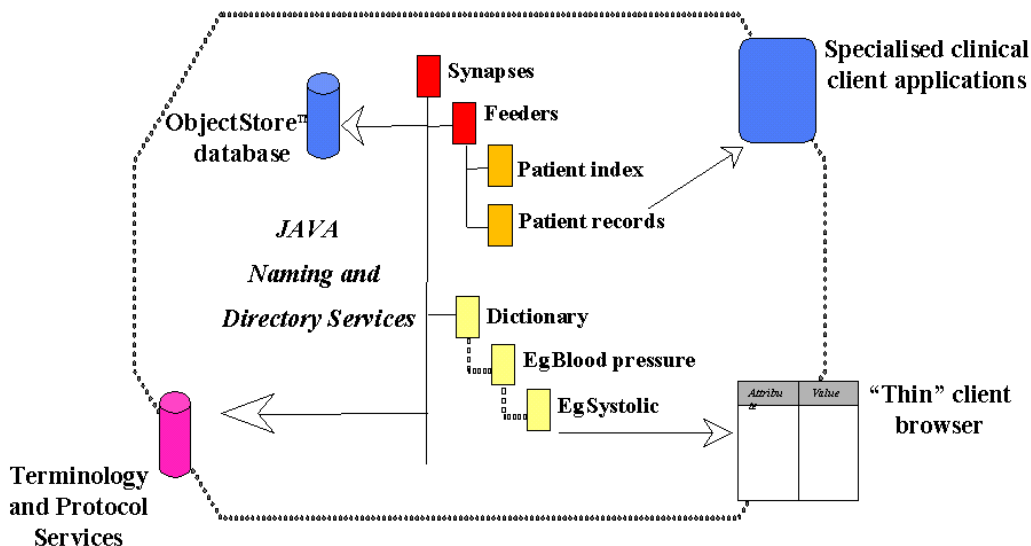


Figure 13: Data services delivered through Directory Services and JINI

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 DMS data component services. These and other DMS services (such as decision support algorithms) 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.

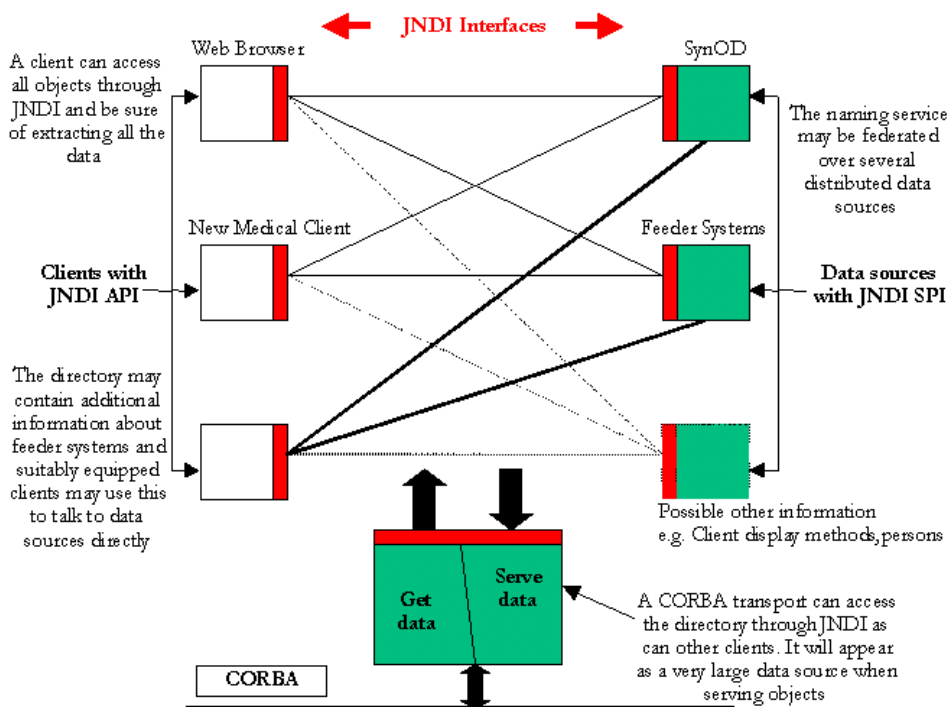


Figure 14: JNDI Interfaces to Clients, Data Sources and to a CORBA Transport Layer

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 driver 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 15. 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.

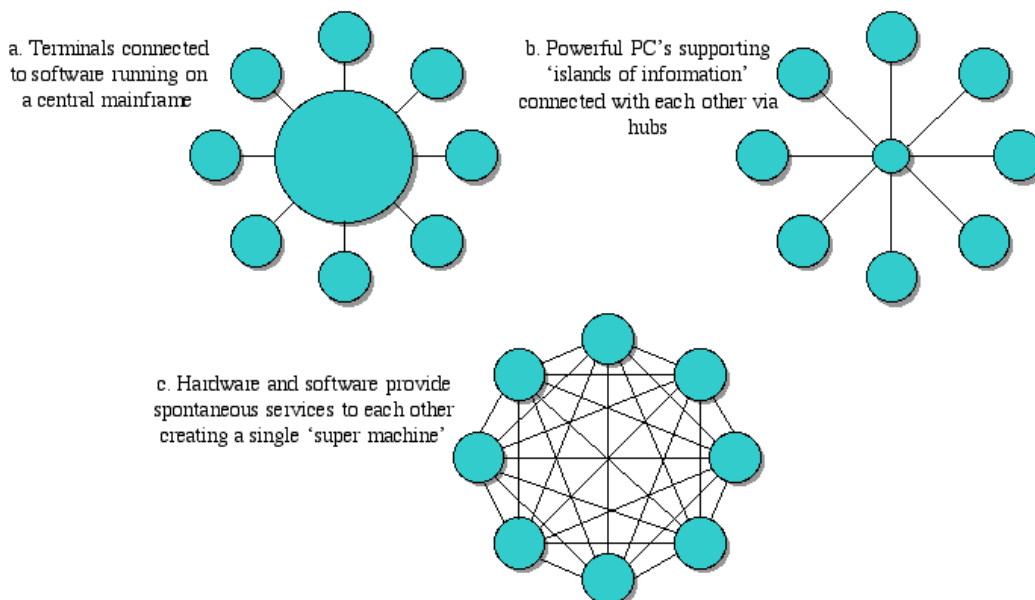


Figure 15: The three evolutionary stages of computing

Federated Record Service Component Set

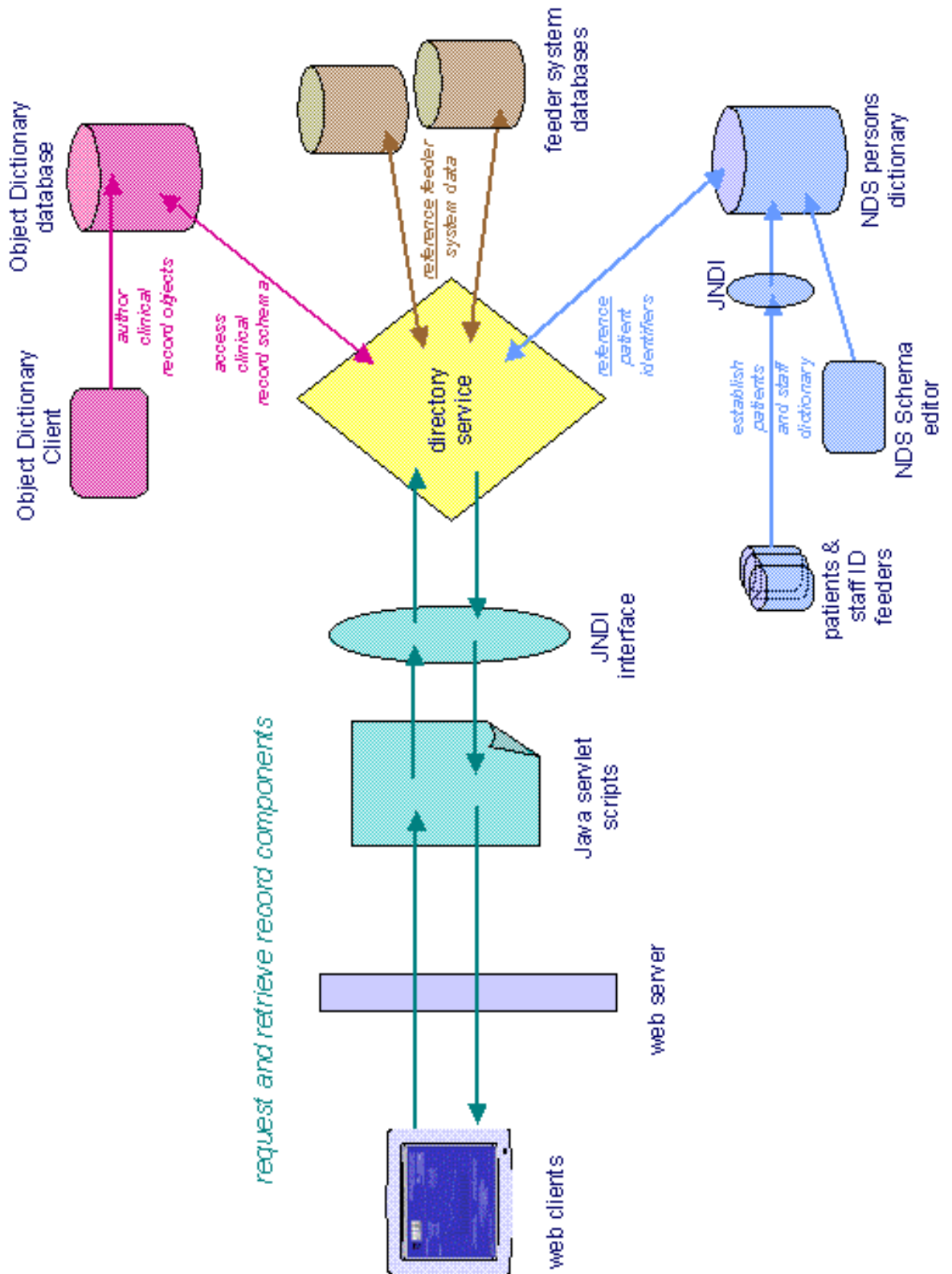


Figure 16: Engineering Overview of the FHCR Services



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-SupA⁴. It is based on a rigorous object model formalism; it incorporates the representation of content types and placeholders for ongoing R&D work in UCL on the integration of medical knowledge and protocol 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 EHR object repository
- client server communications

EHR database

As well as accessing distributed feeder systems, the UCL FHCR services incorporate a principal EHR 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 EHR database communicate with a wrapper-class to ObjectStore, insulating them from its exact

⁴ EHCR-SupA is a Fourth Framework support action that has taken forward the work of GEHR and other EHR architecture implementation feedback



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 '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.

7. 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 EHR 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).

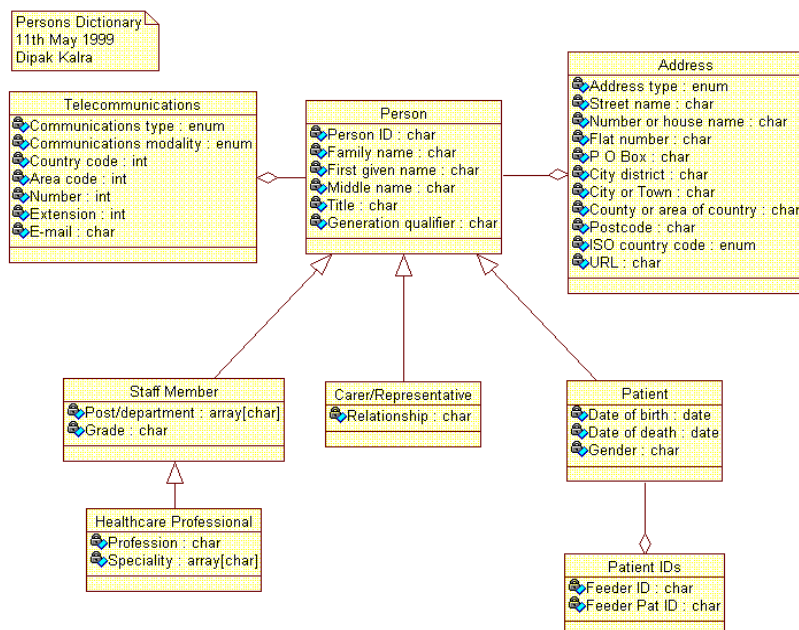


Figure 17: Class Hierarchy of the Persons Dictionary



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 have been 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 EHR information (such as monitoring devices and decision support software). Some of these may also require controlled access to other EHR data.

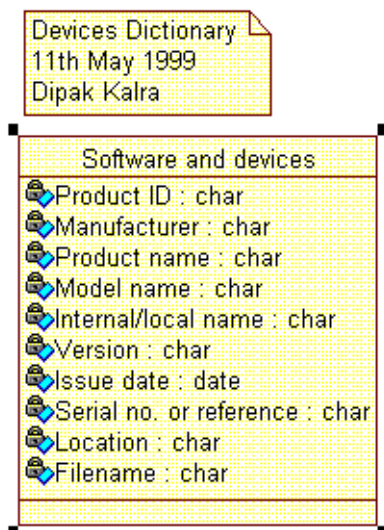
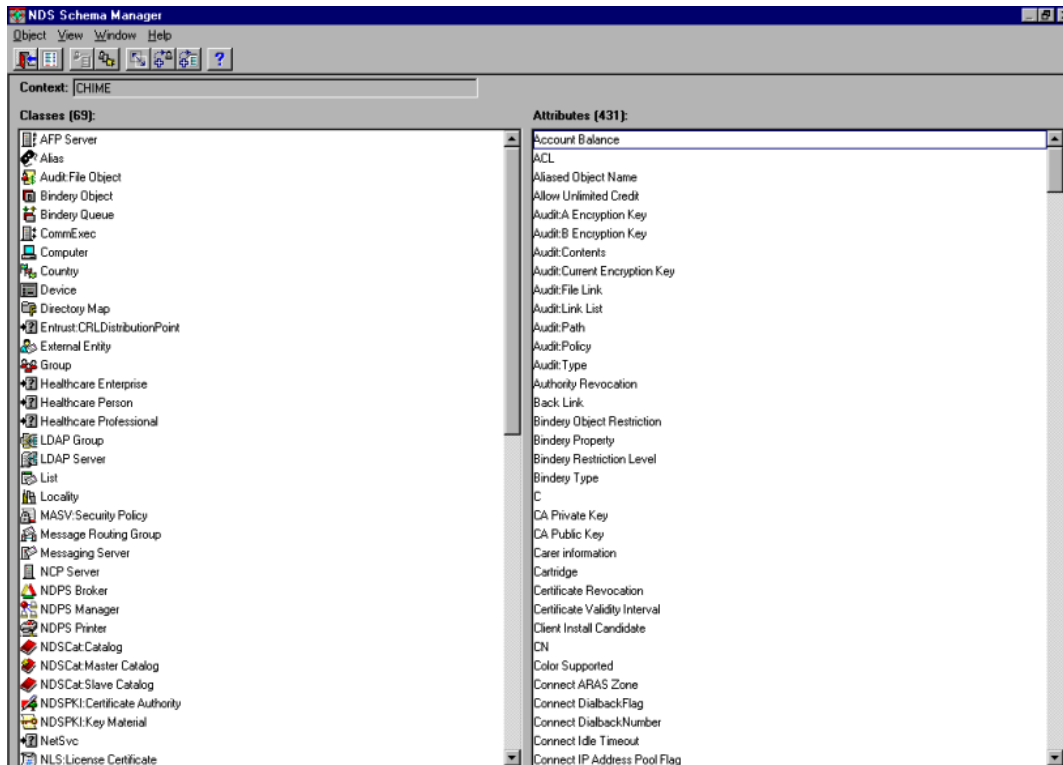


Figure 18: Class Hierarchy of the Devices Dictionary

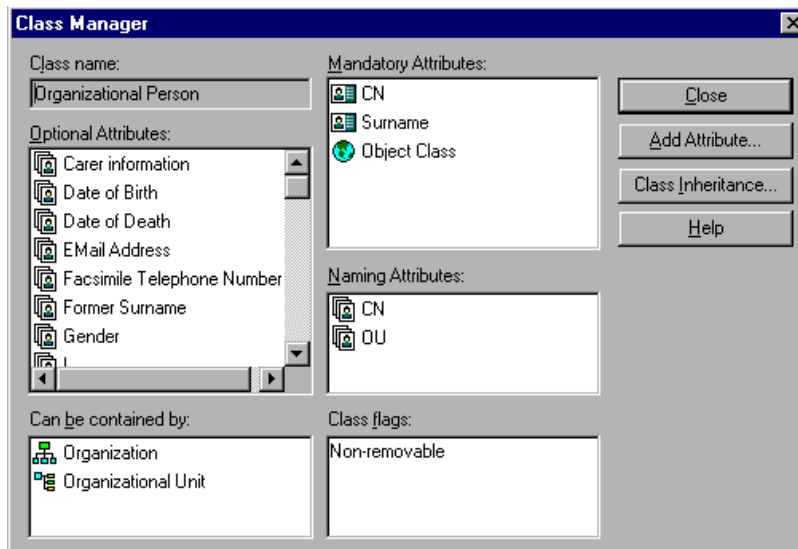
This model will be implemented later within NDS.

Configuration 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).

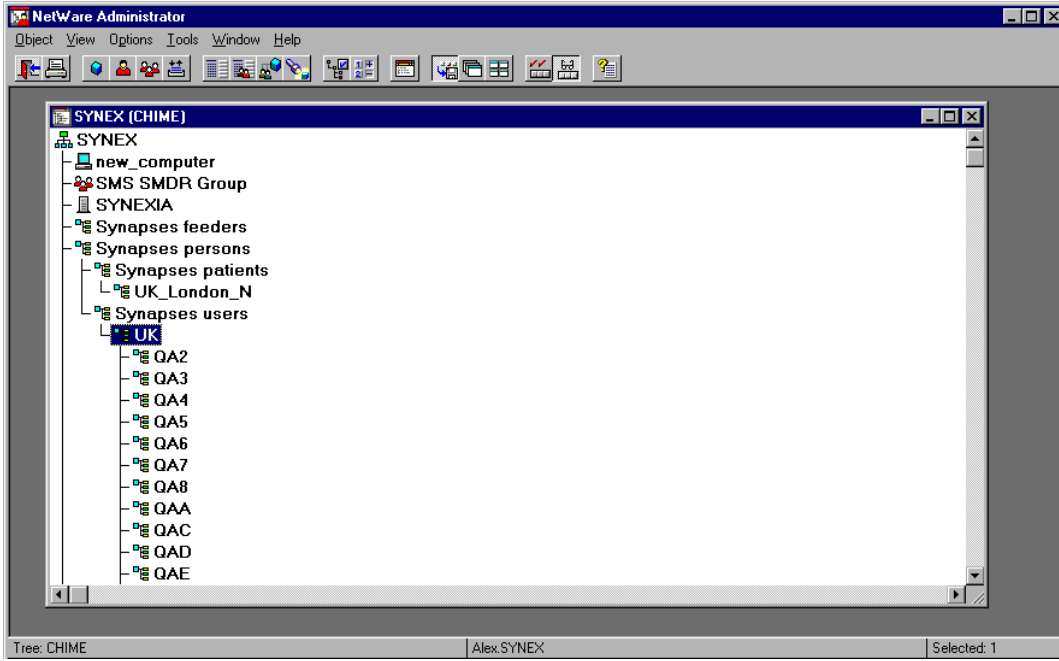


The relevant NDS classes (e.g. Organisational Person) are also amended to incorporate the additional attributes.

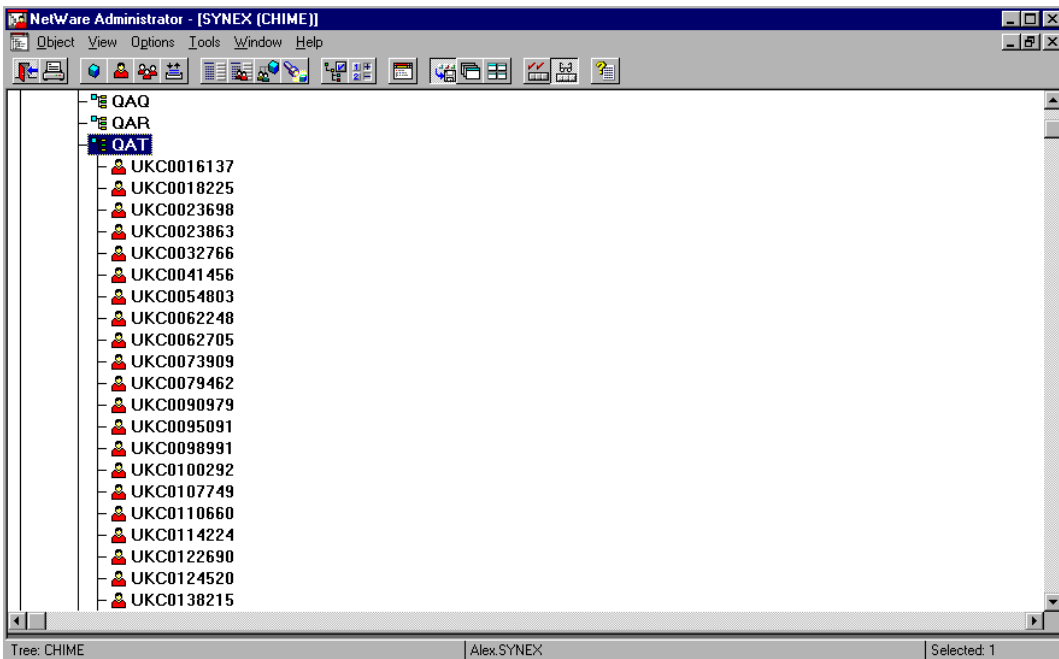


Population of the NDS Tree

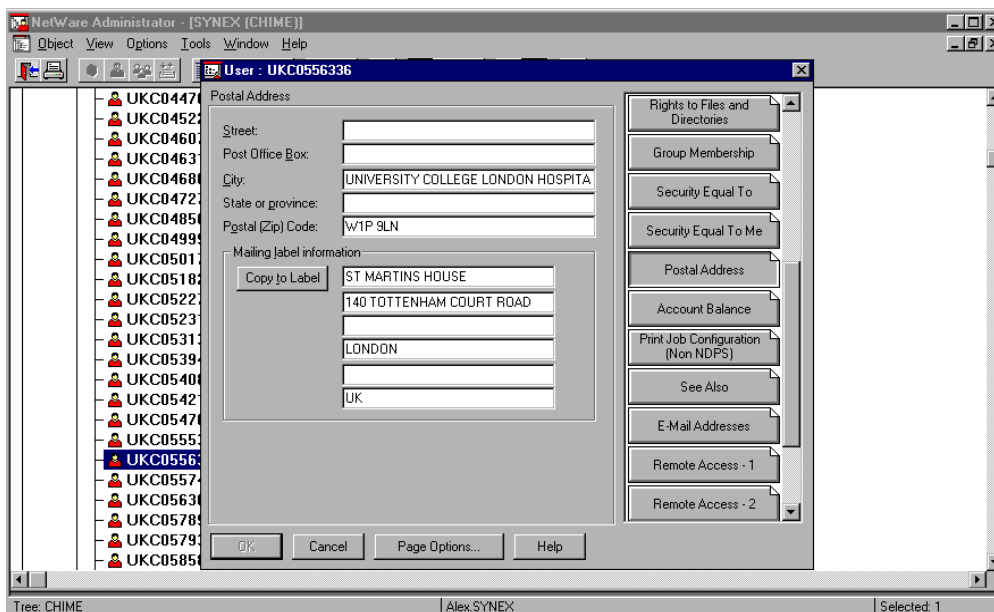
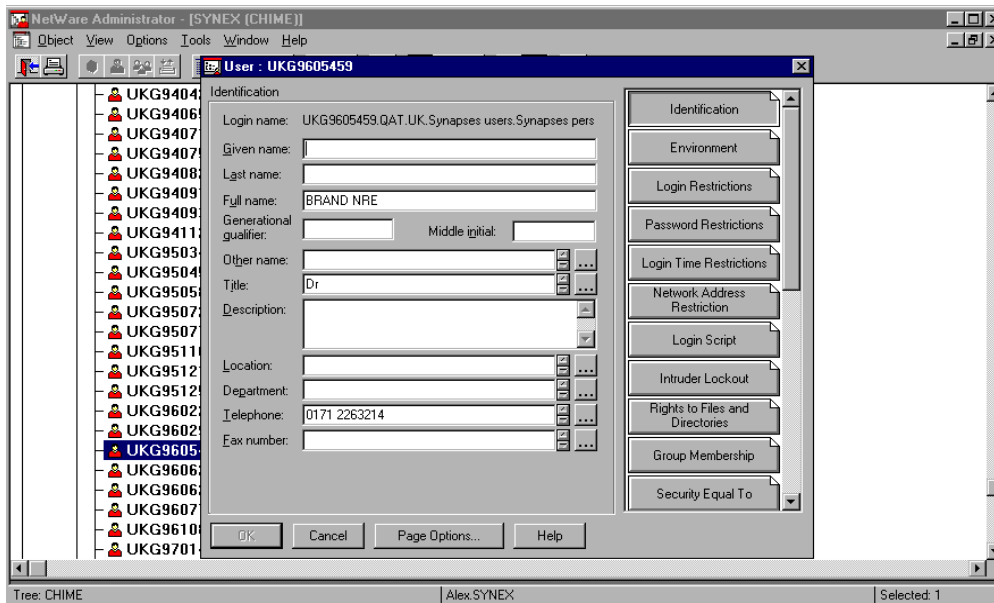
For deployment at the Whittington (north London) site, it has been possible to import the complete database of General Practitioners for England and Wales (40,000) and all consultants working in hospital trusts in the north London area. For ease of future updating and integrating with NHS databases, 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.



The population of the NDS tree has been verified by using the JNDI look-up service to extract the demographic data of sample persons.

A look-up service allows record components to contain direct references to NDS tree nodes (persons), in addition to the textual descriptions of persons (such as the recording HCP).

Additional databases of GP details for other national health services can be imported, and a Spanish set will be incorporated as soon as this is available.

Access Control Services

A dynamic connection is required to the LICORE authentication service, to provide registered end-users with remote access to patient records. This has been achieved by installing the whole DMS inside the MEDICATE firewall protection on the secured server and by running the DMS services in process with the secure Internet services. A mechanism has been defined whereby the profile of a pre-authenticated user can be passed directly to the DMS. This provides the users organisation context, to enable the correct sub-population of MEDICATE patients to be shown to the user, and enables the user to be logged as the author of any changes made to the alert settings in the DMS.

8. 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 that 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 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

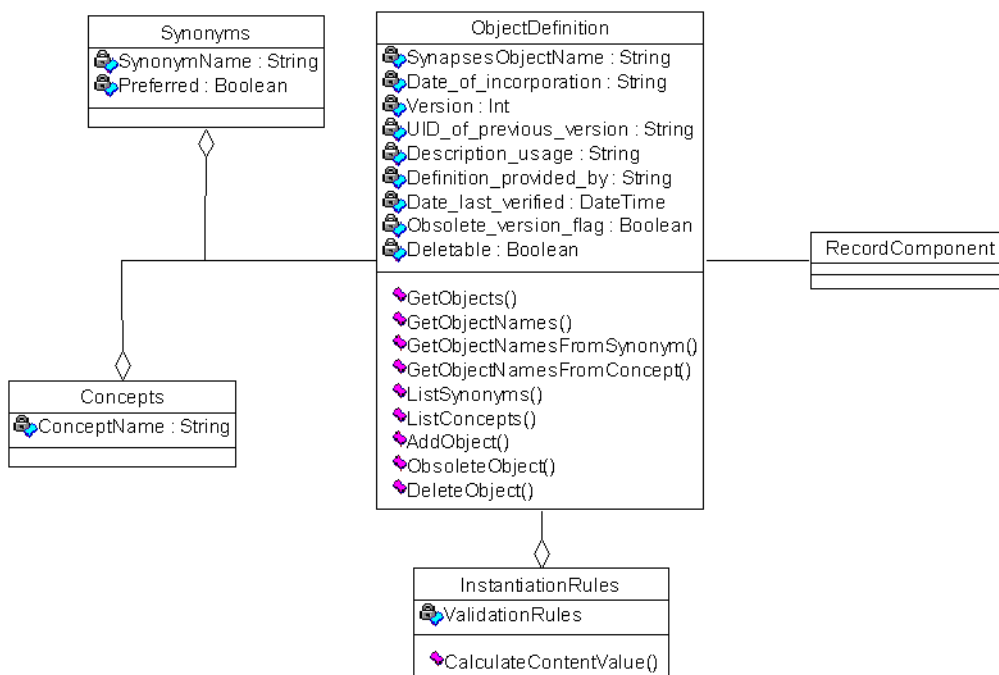


Figure 19: Aggregation hierarchy of the Object Dictionary

The formal object model of the Synapses Clinical Object Library 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.

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

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.

ConceptDictionary

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 GALEN medical terminology services.

InstantiationRules

This dictionary, 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 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 in the table below.

ODC Class Hierarchy
ODC Object Properties
Creating New Object Entries
Cardinality on Instantiation
Validation Criteria
Data Retrieval Methods
Copying and Pasting Objects in the Hierarchy
Publicising Objects
Deleting an Object
Marking an Object Obsolete
Revising an Object Definition
Reviewing the Version History
Tracking Objects with Multiple Parents
XML Export of the Database
Saving the Database

Table 2: List of Features within the Object Dictionary Client Tool (ODC)

SynOD XML Document Type Definition

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 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 SYNAPSEOBJECTID CDATA #REQUIRED>
<!ATTLIST DOI LOCALE CDATA #REQUIRED>
<!ATTLIST PROTOTYPELEVEL (PUBLIC | PRIVATE_SHARABLE | PRIVATE)
"PUBLIC">
<!ATTLIST DLV LOCALE CDATA #REQUIRED>
]>
```

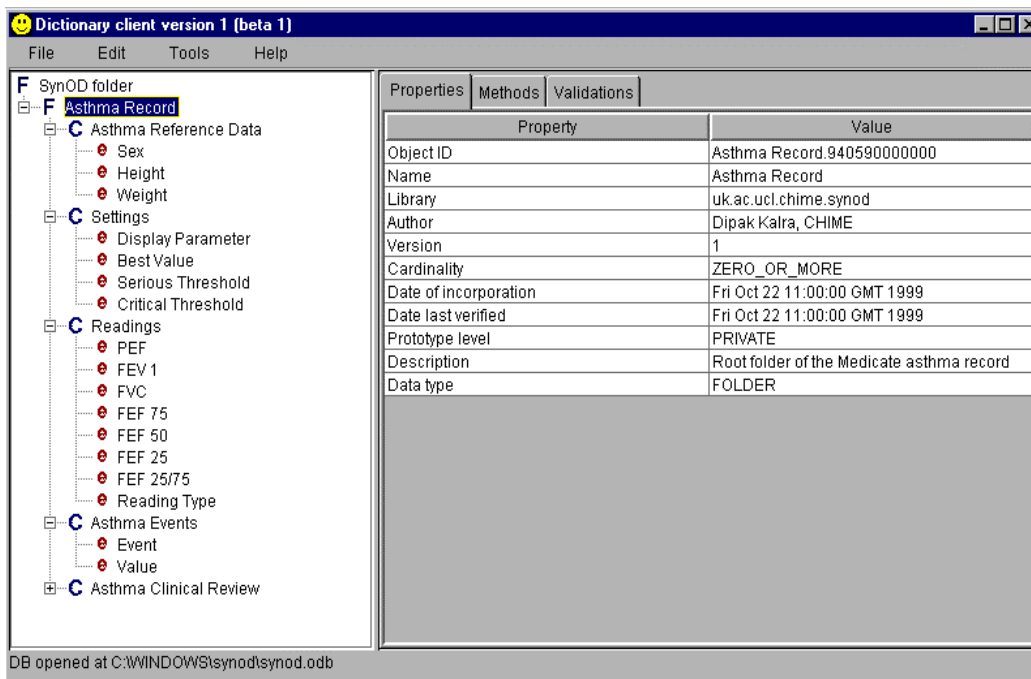
Document Type Definition for a full SynOD



AMOS Data Sign-up

Whenever individual patient peak flow devices are connected via a modem to download their latest sets of readings the AMOS hub server receives this new data. It has historically forwarded this to a J-Lab database for local storage and access by their original desktop applications. The native J-Lab database is not ODBC conformant, and has an awkward proprietary interface for direct connection. Jaeger-Toennies originally implemented a proxy SQL interface to their native one, by producing a mirror database in Microsoft Access. This latter database is populated with readings data in synchrony by the AMOS hub, and was used as the initial feeder system for MEDICATE. It has been the methodology by which the clinical trials of the AM1 device have been technically managed.

The file format of the Access database was initially reconstructed using the Object Dictionary Client (ODC). The screen below shows the class hierarchy of the Record Components that comprise the EHR data schema mapping the AMOS database.



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

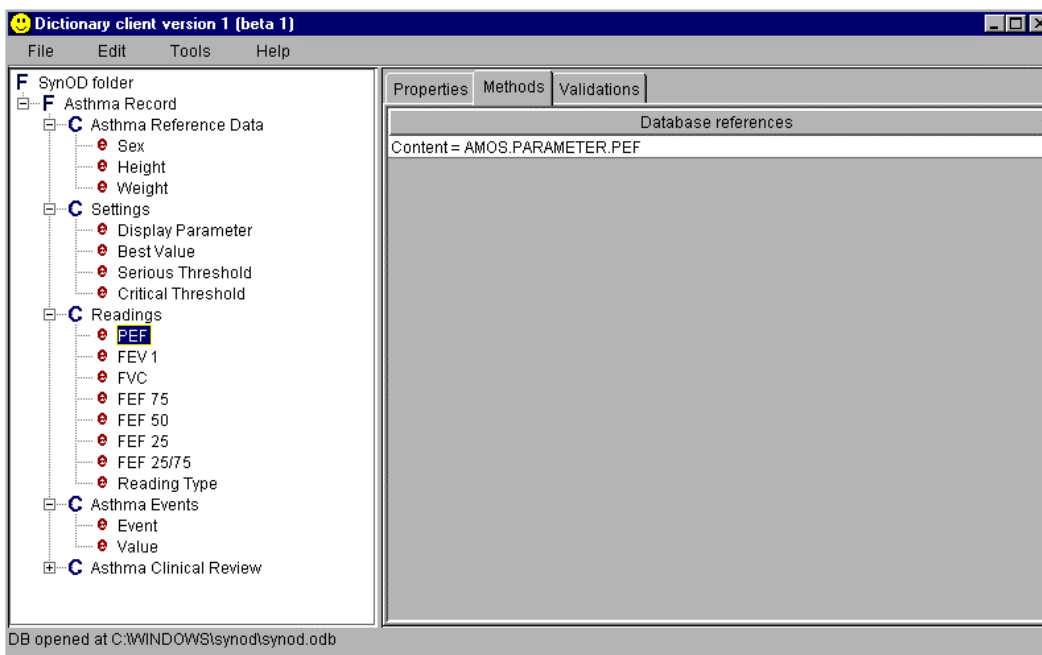
The “bullet” used for each dictionary entry indicates the SynOM class from which it inherits, as shown in the table below. It may be noted that only a few of the SynOM classes were used for the mapping of the AMOS database.



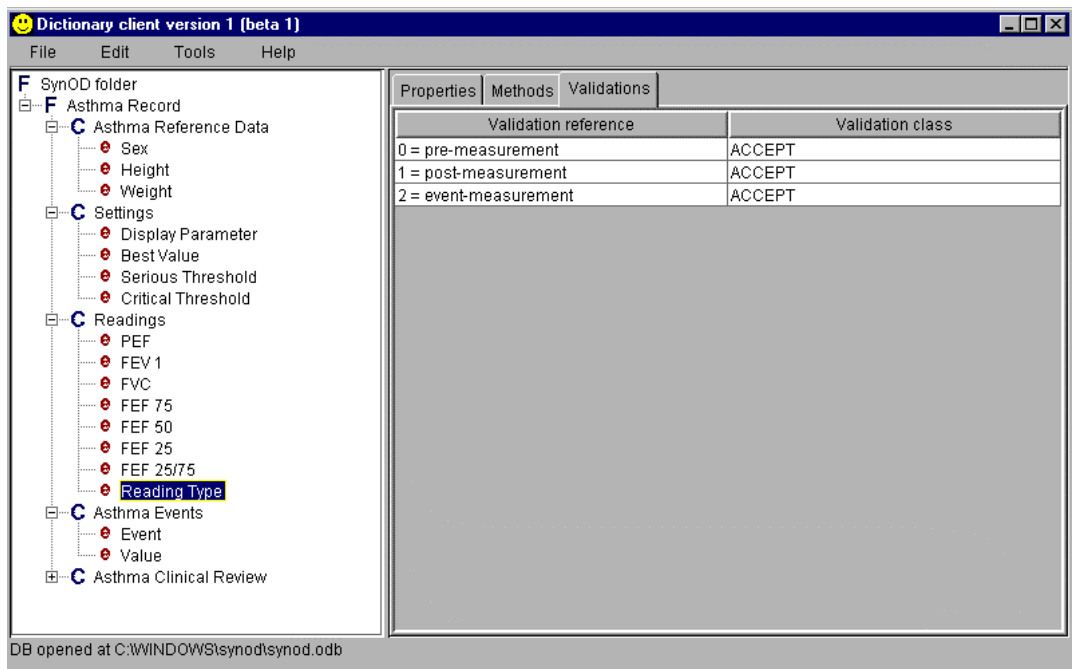
Bullet legend	SynOM class name	Permitted parents	Permitted children
F	Folder RIC	Folder RIC	Folder RIC, Com RIC
C	Com RIC	Folder RIC	Data RIC, Compound Item, Element Item
D	Data RIC	Com RIC, Data RIC	Data RIC, Compound Item, Element Item
c	Compound Item	Data RIC, Compound Item	Compound Item, Element Item
e	Element Item	Data RIC, Compound Item, Element Item	None
I	Link Item	Data RIC, Compound Item, Element Item	None
V₁	View 1 RIC	Folder RIC, Com RIC, Data RIC	None
V₂	View 2 RIC	Folder RIC, Com RIC, Data RIC	None

Table 3: Legend used to indicate the SynOM class of each entry in the ODC

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 EHR sources. The screen below shows an example of the mapping information stored by the ODC to assist in the construction of methods to import the AMOS MS Access data into ObjectStore.

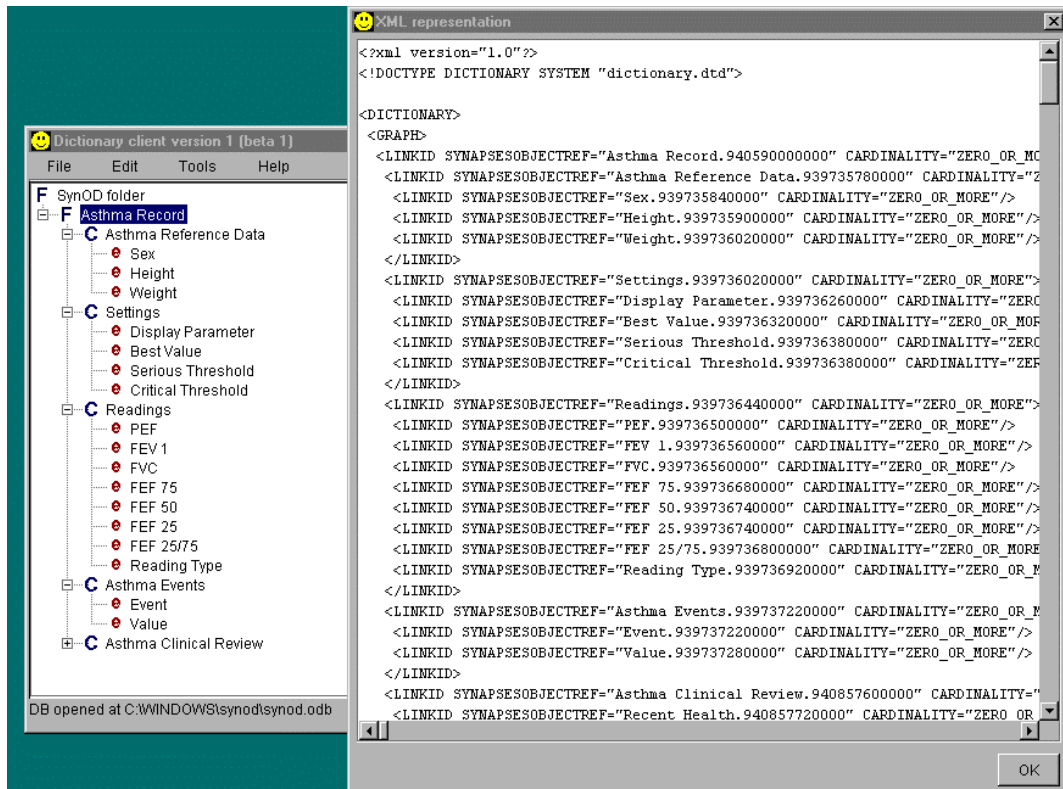


The validations window has been used on this occasion to indicate those objects whose instance values are members of an enumerated list. The validations window in the screen below shows the decoded textual meaning of the integer values for one example database field.



Once the ODC has been populated with the structures and mapping information required to compose the definitive asthma EHR, the entries are exported to an XML file. This provides the core skeleton of information required to author the Java import mapping and servlet extraction code. The XML export function is activated through a simple menu choice in the ODC.

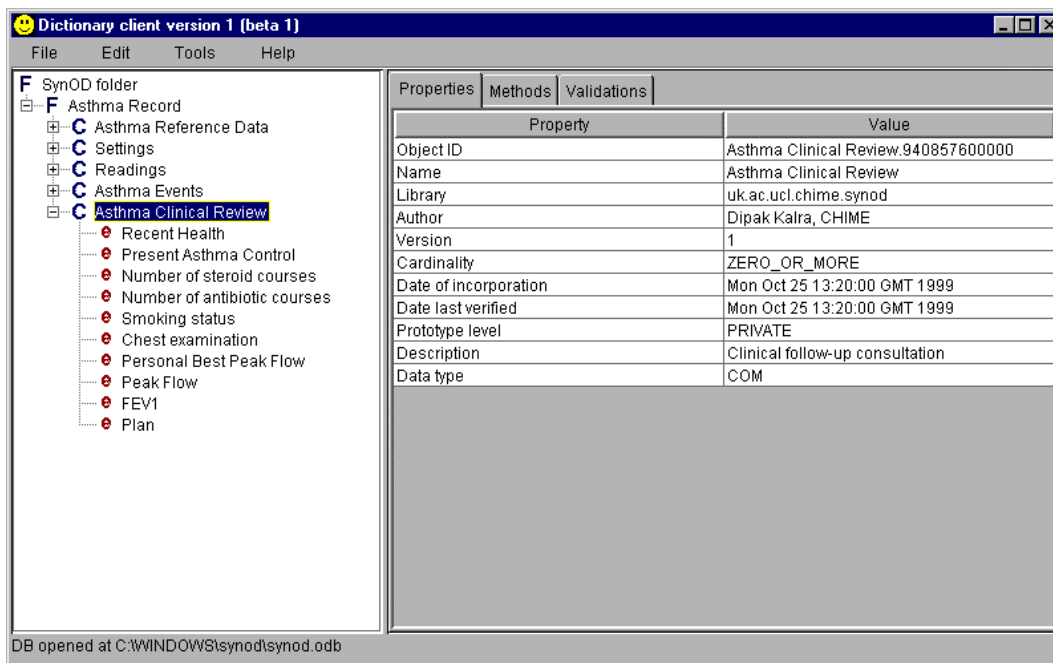




Later in the MEDICATE project Jaeger-Toennies redesigned their data export interface (originally a closed connection only to the native database) to generate a set of XML strings, each representing a single record set instance of the readings, symptoms or medication events captured by an AM1 device. Because a considerable investment has been made by then on the implementation of the DMS according to the original ODBC-compliant schema, it was agreed to retain this as the endpoint representation of the asthma monitoring record. An HTTP formatting class was developed jointly between UCL and Jaeger-Toennies to allow the XML strings to be passed directly to the DMS via a TCP/IP interface.

Future work

In addition to the core patient device data coming from the AMOS database, each of the future MEDICATE hospital sites may wish to capture some additional clinical record information about their patients. Whilst the creation of a comprehensive asthma medical system is not within the scope of MEDICATE, a sample of clinical entries has been included as additional clinical objects in the ODC, shown in the hierarchy below.



The process of creating the web application screens to create and to review the patient record entries related to this part of the schema will be considered later if resources permit.



9. Installation and testing of the DMS components

Overview

The final deployment of the DMS components has been on a Windows NT v4 server located in the secure premises provided by Cable and Wireless in Brentford, London.

The MEDICATE DMS has also been installed and tested in CHIME (UCL) on two servers connected to a sub-domain of the CHIME academic network: a development server running Windows NT (v 4, SP6) and a demonstration server running Windows 2000.

The Windows NT/2000 server provides the platform for:

- Novell eDirectory (holding the demographic database of patients and GPs);
- ObjectStore (the object database enterprise product of Object Design Inc. holding the patient healthcare records);
- the web server and servlet runner applications;
- JNDI and Jini services;
- Java code packages providing the EHR, object dictionary, persons dictionary, decision support and e-mail generation services
- Java web application servlet scripts

A Sun Solaris server also operates on the CHIME network sub-domain to provide a source code repository and a shadow ObjectStore installation, for backup and developmental purposes.

Component testing has taken place throughout the developmental process, and in addition it should be noted that some UCL components have also been used in other projects and been subject to clinical field testing in those other clinical domains. The formal specification of the validation process undertaken and the results obtained is complex, and is being separately documented as part of a set of UCL academic outputs within PhD theses. The key endpoint verification milestone for each sub-component of the DMS is summarised in the rest of this deliverable section.

Third Party Engineering Components

Object Store (Enterprise Edition)

This object database, developed by Excelon Corporation, was originally licensed to UCL for a set of R&D demonstration sites in 1998. ObjectStore 5 has been subject to a set of upgrade and bug fix releases over the years, and the UCL team have studiously maintained all installations to the latest release version of the product. The team has an annual maintenance and support contract with Excelon and is therefore notified of any new technical issues.

Object Store has now been used extensively round the world for critical systems and high volume storage. UCL has tested its own installations with large volumes of cardiovascular records, with regular data access over several months. It is considered to be a suitable long-term storage solution for the Medicate Project.

Novell e-Directory

This product is an evolution of an original Directory Service product (NDS) from Novell. UCL has purchased individual site licences for NDS for each of its installations. The Java and JNDI-supporting class libraries and the administration tools for e-Directory have been upgraded periodically though licensed downloads from the Novell site.

UCL has maintained an identical installation environment, including the modified schema documented in Section 7 of this deliverable, on each of four servers over several months. All four servers have held entries for over 40,000 persons over this period, and the trees have been upgraded (when new address information is obtained from the UK NHS) on many occasions without problem.

UCL is concerned that some GP search routines can take over 1-2 minutes, and is investigating this. Otherwise, the experience of using e-Directory as a directory service to store demographic information has been positive.

Microsoft Internet Information Server

This web server is utilised by Web Correspondent, and it was necessary for the DMS to use the same web server environment to ensure a seamless "in process" handshaking between the components for security purposes. Some adaptations were needed to the DMS to enable it to operate consistently within this environment: this work has been completed and several weeks of continuous running on the Brentford Medicate server have so far demonstrated no problems.

e-Wave Unify Servlet Exec

This product was purchased to provide a Java web servlet running environment that is capable of running "in process" with Microsoft IIS above. Whilst the DMS had previously run successfully with another (industry standard) product Tomcat, it was regrettably found that running Tomcat in process with MS IIS was theoretically possible but not achievable in practice. The installation and configuration of Servlet Exec was not itself an easy task, and (undocumented) Java version incompatibility problems took some time to be rectified. An interoperability problem with Novell e-Directory also generated a significant workload.

The eventual configuration has now been installed on three different servers, and has been started and stopped on numerous occasions (with and without server reboots) without problem. All aspects of the DMS (documented below) have been tested in this definitive environment.

Java Development Toolkit

Although the DMS has also been fully tested on JDK/JRE 1.3, the present decision has been to run the DMS using JDK 1.2.2, for reasons described above to do with incompatibility problems between third party products and the 1.3 environment. The full set of DMS functional tests have been performed whilst running JDK 1.2.2.

Web Browsers

The DMS web application conforms to the HTTP specification and should run on any conformant web client.

Server Operating System

The choice of Microsoft NT v4 as the server operating system was mandated by the requirements of Web Correspondent. The DMS core services have also been previously demonstrated on Sun Solaris, using a similar set of third party software products. Object Store, e-Directory and Tomcat are available for both platforms, and also for Linux. The DMS is therefore potentially deployable on any of these three operating systems in the future, with the requirement only to purchase additional third party licences from Novell and Excelon. The core DMS Java code is server operating system independent.

UCL engineering components

EHR architecture

The architecture of the EHR developed and used by UCL in the DMS is the evolution of significant R&D within the GEHR, Synapses, EHCR-SupA and SynEx projects over nearly ten years. The architecture has contributed to two CEN standards, which offers some peer-review validation of its constructs. Implementations based on the latest CEN standards are few, and the UCL contribution here is therefore also a validation of much of CEN ENV13606-1.

Persons dictionary

This work draws on the results of GEHR, Synapses, EHCR-SupA and CEN ENV 13606. The schema has been used consistently for two EU project demonstrators: SynEx and Medicate, and maintained with external data feeds from a range of demographic database sources. Although not itself externally evaluated, the results of the deployments to date indicate the model is fit for purpose and capable of limited cross mapping with relevant EU standards. It has been considered appropriate by UCL team to delay any further work in this field until new standards in this area are published by ISO.

The implementation in e-Directory has been tested on several servers to import and update large volumes of demographic data over nearly two years. The contextual organisation of the persons into organisational groups has also been tested for a similar period. The present hierarchical arrangement of patient and GP information for Medicate is therefore well-tested.

However, limitations of the AM1 device to a 10-character patient ID, the inability to store a separate healthcare provider ID and the lack of any intrinsic device ID for each AM1 device have required a compromise arrangement for the expression of patient identifiers. These have been limited to four characters, and whilst these will be assigned uniquely within each healthcare provider account, these are not globally unique identifiers. A new design of AM device with the capability to store the above identifiers is being prototyped and will later be interfaced to the DMS to resolve this issue.

EHR server

The EHR server specification has been published and critically reviewed by several European and Australian groups leading parallel research in this field. The server has been successfully running a shadow cardiovascular application for some months, and has been a test repository of asthma legacy data extracted from original Jaeger-Toennies databases for over a year.

The asthma data schema was originally designed in September 1999 to match the data sets held within Jaeger-Toennies' J-Lab database. Subsequent specifications for the format of the XML data exchange between the AMOS Hub Server and the DMS (June 2000) have mirrored that original schema and been found still to represent faithfully the asthma monitoring information acquired by the AM1 device.

The storage of patient information in the record server has been tested through the web application and by XML feeds (i.e. the two primary sources of data within Medicate) and by direct import of legacy data using a separate interface (not formally part of the final Medicate system).

Asthma Decision Support Alert Algorithms

The asthma decision support component provides a set of five import-based and three record-based alerts corresponding to the alert situations requested by the clinical sites in October 1999 and published as a simple list in the DMS Component Manual version 1.0 (November 1999). The algorithms were based on a specification for the alerts published in January 2000 and iterated by the clinical teams over several weeks.

The component is written in Java and interfaces directly to the import interfaces for new data received from AM1 devices, the EHR server and an e-mail generation component. The component was developed in spring 2000 and installed in a development version of the DMS. Once a small set of sample data was obtained from Jaeger-Toennies the alerts component was tested to confirm that the appropriate alerts were generated. This was confirmed by checking that the appropriate readings were highlighted and commented with the correct string message, that a new message object was created in the patient's record (correctly dated and timed with the processing date/time and original reading date/time), and that an e-mail message was generated.

The rigour of the algorithms has subsequently been tested using a larger volume of legacy data from the Whittington Hospital clinical trial. However, it is recommended that a period of live testing is undertaken using new data coming directly from AM1 devices, and with test patients for whom which the result of record-based alerts can be meaningfully verified.

E-mail generation component

The e-mail generation component has been installed and tested in parallel with the alert component above, on CHIME test servers and on the Brentford server. (The component allows e-mails to be directed to any recipient address for debugging purposes, overriding the normal Medicate recipient, and easily to be directed to any specified mail server.) In testing of both the import-based and record-based alerts the right e-mails have been generated, incorporating the correct patient and message details.

Ideally clinical users should receive only one e-mail about each patient who has triggered an alert situation, and not receive one e-mail per triggering reading. (It is likely that a patient who is faring badly will have several readings of concern and or severe symptoms within one download of data). The alert and e-mail generation components have been written to batch up alert messages on a patient and to mail these at the end of a single patient download or after a fixed time (for safety reasons). The AMOS Hub Server is not presently able to indicate the start or end of a new patient download: some batching does take place, but only if a follow on reading is received on the same patient in a short timespan.

It has been most critical to test that important e-mails are not "lost" while waiting for any further readings. Testing so far has not detected any such situations, but a further period of evaluation in Brentford is recommended.

Asthma web application

The clinically-visible part of the DMS is the set of web screens for adding and amending patient demographic data, assigning a GP, setting the e-mail alert conditions and calculating the red and yellow alert thresholds, viewing historic asthma monitoring data in tabular and graphical format, and reviewing the archive of alert messages.

Section 5 of this deliverable describes each aspect of the DMS application: each of the functions and screens has been demonstrated in the final delivered application on the Brentford Server, and therefore provides some "evidence" that the DMS functions have been implemented successfully. Testing has been carried out for each function described in Section 5 on both Brentford and CHIME test servers and found to be satisfactory. A demonstration version of the DMS was made available to the consortium in September 2000 for evaluation. Some modifications were made as a result of feedback, and other (mainly cosmetic) changes may be made in the future.

Component Integration

Interface to Web Correspondent

The DMS can only be accessed on the Brentford Server through a portal authorised by Web Correspondent. A cookie is passed by Web Correspondent to the DMS containing the user name and their organisational account. This enables the DMS to assign new entries to that user, and to ensure the user is able to list only the Medicate patients belonging to their healthcare organisation. A hyperlink from the DMS Home Page takes the user back to their Web Correspondent mailbox home page. These interfaces have been tested in Brentford, and found to work successfully in both directions.

Interfaces to AMOS Setup and the AMOS Hub Server

AMOS Setup is the desktop programme run by a clinical user to initialise or modify the patient-specific information stored on an AM1 device, such as the patient identifier or the red/yellow alert thresholds. This programme uses interfaces to the DMS to obtain the list of Medicate patients registered at the local healthcare provider, and to obtain the threshold settings for any selected patient. These interfaces have been tested using sample commands, and a test installation of the AMOS Setup. The specific testing of the transfer of data from AMOS Setup to an AM1 device has been carried out by Jaeger.

The AMOS Hub Server receives downloaded data from a patient's AM1 device and passes any new information to the DMS. The interfaces to the DMS include requesting the most recent monitoring data-sets from the DMS and providing new data-sets to the DMS. All data-sets include the patient's ID (an organisation code plus an individual ID).

Jaeger-Toennies uses a set of XML strings to communicate with the DMS, and has provided an XML parser with wrapper code for the DMS to enable the communicated data to be readily passed to the DMS. The interfaces between the wrapper code and the DMS have been tested by UCL using sample data. The interfaces between AMOS components and the wrapper data have been tested by Jaeger-Toennies.

General Issues

One technical condition of success is the organisational account code shared by all technical parties within the Medicate system. This must be a unique alphanumeric code of up to five characters, and communicated with case specificity. It has been recognised that a critical role for the successful administration of the Medicate system is the issuing of such a unique code and its communication to the administrators for the DMS, Web Correspondent and the AMOS Setup programme. This will need to be managed by the organisation established to manage subscription to Medicate system, presently under discussion.

Although each component and each interface has been tested on demonstrator servers and at Brentford, full end-to-end testing of the whole Medicate system has only recently been possible. This is primarily because of time consuming integration challenges involving third party software products.

Administration and maintenance of the DMS

Accessing the Brentford Server

Licore Associates has enabled a remote administrative pathway to the server itself through the use of PCAnywhere (Symantec Corporation). This will be used by UCL to administer and to maintain the DMS.

Adding new Organisation accounts

As the number of new organisations signing up to Medicate is likely to be small, UCL has left open a human operator step for the addition of new healthcare provider accounts. This is a quick task carried out using Novell NDS Administrator, and can be done via PCAnywhere. In future, a programmatic interface for this task may be developed, which could also be automated.

Maintaining the GP register

The UK general practice register is issued by the NHS Information Authority every two to three months on a CD, but represented as a series of files with slightly inconsistent internal formats. UCL has developed a means of consolidating that release format into a single homogenous database that can be used by a specially written programme to update the e-Directory trees containing GP demographic data. This task at present needs to be run from the Brentford server itself, but a means will be identified to perform this remotely in the future.

Updating the DMS itself

Changes to the DMS itself may be needed for a variety of reasons: to eliminate errors, to improve look and feel, to add or amend alerts, to modify the e-mail arrangements or to improve performance. All of these changes should be possible remotely through PCAnywhere by the file transfer of revised code. The individual DMS services can be remotely stopped and restarted to read in the new code.

Web interface changes

Changes to the web servlet environment can largely be performed via a password-protected web interface.

Changes to individual patient records should only be made through the DMS itself.

10. End to end demonstration

Figure 20 below shows the installation set-up that was used to provide final end to end verification of the overall Medicate technical system. This test incorporates a live walk-through of all functions within the Medicate system, involving components from Licore, Jaeger-Toennies, UCL and utilising the servers and networks managed by Cable & Wireless in Brentford.

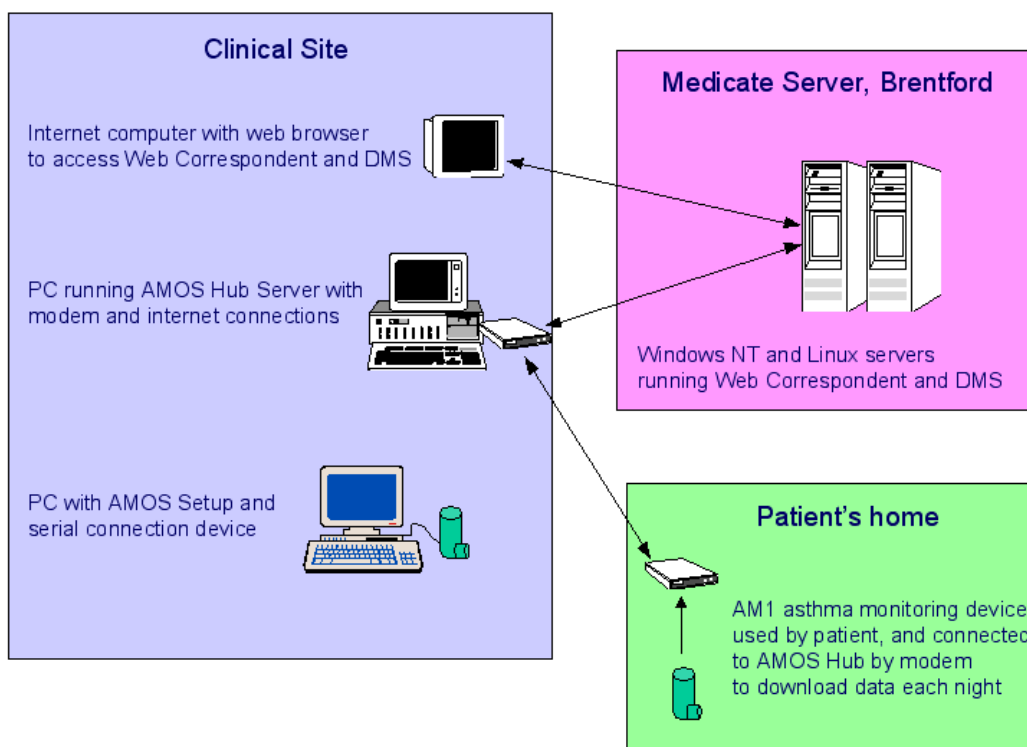


Figure 20: Overview of the technical configuration used for end-to-end testing of the Medicate system

Note: the three computers shown in the clinical site are functionally distinct; however, in practice a single computer was used for these functions

Method

For testing purposes, a fictitious provider organisation has been created named Medicate with an account code of MED. This account was created in Web Correspondent, and a matching Organisational Unit context named MED was created in Novell e-Directory within the DMS. Test users were also created within in Web Correspondent.

From a networked workstation at the test site (initially a mock clinical setting from the offices of Jaeger-Toennies, Wurzburg, Germany and subsequently repeated from the respiratory medicine clinic at the Whittington Hospital in north London, UK), a fictitious patient was created in the DMS with plausible demographic details. Alert settings were chosen to trigger for several alert situations, and the BTS predicted peak flow for the patient was used to calculate the appropriate red and yellow alert thresholds.

At the AMOS workstation, the AMOS Setup programme was run first to obtain a list of patients, and then to select a particular test patient. The programme was able to initialise a new AM1 peak flow monitoring device with that patient's identity and settings.

The peak flow monitor was taken away and used regularly by a volunteer for a few days, who recorded periodic respiratory flow (including some deliberately poor recordings), plausible symptoms and varying inhaler medication usage. The volunteer kept a note of all entries on paper for later verification.

The volunteer connected their monitoring device to their configured HC1 modem at home, which downloaded their data nightly to an installed AMOS Hub Server at the clinical test site.

Verification

1. Respiratory readings, symptoms and medication usage information was received and processed by the DMS. No readings were found to be missing when compared with the volunteer's paper record.
2. The appropriate low respiratory readings were emphasised in the DMS through the correct background display colour: red or yellow.
3. The appropriate low respiratory readings, severe symptoms and excessive medication usage generated an e-mail alert with the correct text message, to the correct mailbox, and a corresponding entry in the alert messages archive.

11. Conclusion

Although many sub-components of the DMS were developed prior to Medicate, such as the EHR server, the persons dictionary and a basic web interface, much of the contribution of UCL in this project has been the development of new functions and components that were specific to Medicate, such as the asthma alerting and e-mail notification components and the alert-setting user interface. The specification of these was not available in advance, and had to be drafted iteratively with the clinical teams during the project lifetime.

Inevitably the DMS, and therefore the UCL team, has been at the heart of technical integration issues. The integration between partners' components has been a journey of discovery and adaptation, and at times required the revisiting of previously working components to accommodate new requirements.

The integration of third party "off the shelf" products and the solution of undocumented interoperability problems has added a considerable workload to UCL unmatched by its limited resources.

Despite human and technical obstacles, UCL has remained committed to the vision of Medicate as a specific instance of a generic approach to safe and monitored near-patient care. The team has more than doubled its human resource input to achieve the end results.

Given the complexity of the DMS and of the overall integration work, without prior clinical or technical specification, the Medicate results represent a considerable achievement for the timescale and resources available. Once a final short evaluation of the overall system is completed the Medicate system promises to be a high quality and robust solution to the challenge of monitoring patients with moderate or severe asthma in their own homes.

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