Design and Implementation of a Federated Health Record Server

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Introduction

This paper describes the practical implementation of a federated health record server based on a generic and comprehensive public domain architecture and deployed in a live clinical setting.

The authors, working at the Centre for Health Informatics and Multiprofessional Education (University College London), have built up over a decade of experience within Europe on the requirements and information models that are needed to underpin comprehensive multi-professional electronic health records. This work has involved collaboration with a wide range of healthcare and informatics organisations and partners in the healthcare computing industry across Europe though the EU Health Telematics projects GEHR, Synapses, EHCR-SupA, SynEx and Medicate. The resulting architecture models have influenced recent European standards in this area, such as CEN TC/251 ENV 13606. UCL has now designed and built a federated health record server based on these models which is now running in the Department of Cardiovascular Medicine at the Whittington Hospital in north London. A new EC Fifth Framework project, 6WINIT, is enabling new and innovative IPv6 and wireless technology solutions to be added to this work.

The north London clinical demonstrator site has provided the solid basis from which to establish "proof of concept" verification of the design approach, and a valuable opportunity to install, test and evaluate the results of the component engineering undertaken during the EC funded projects.

Requirements

There is now an international momentum to establish the means by which patient health record information can be shared between healthcare providers and follow patients as they move between them. Realising the Electronic Health Record is a core target of, for example, the present UK National Health Service IM&T strategy [1]. Ilias Iakovidis, Project Officer for the European Commission's Health Telematics programme, has stated that an important challenge for realising successful EHR implementations at a national or regional level includes "*technology and standardisation: the storage, maintenance, communication and retrieval of multimedia information on heterogeneous and geographically distributed database systems*"[2].

The Health Telematics Research and Development programme of the European Union has recognised many of the health informatics challenges in the development of EHCR systems and sought to address them on a large scale through a set of multi-national projects over the past decade [3, 4, 5]. The main EU projects on electronic healthcare records have included the Good European Health Record (GEHR), Synapses, EHCR-SupA and SynEx projects.

The very extensive investigations of user and enterprise requirements that have taken place over ten years have sought to capture the diversity and specialisation across primary, secondary and tertiary care, between professions and across countries. These requirements have been distilled and analysed by expert groups across Europe in order to identify the basic information that must be accommodated within an EHCR[1] architecture to:

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

A detailed review of requirements for this domain was published by the GEHR project [6, 7, 8, 9], and this set of requirements informed the subsequent work of CEN PrENV 12265 [10] and the Synapses project [11]. The EHCR-SupA project consolidated the European and international published requirements, for example those from GEHR, Synapses, SPRI [12] and the I4C [13] project in Europe and work from Australia (which later formed part of the Health Online report [14]), into a single project deliverable [15]. This publication has been well received by CEN and is regarded as the single most comprehensive resource by the leader of the ISO Work Item on EHCR Requirements. That ISO Work Item is presently in the form of an evolving database of requirements statements, and is expected to be published early in 2002.

Representing Contextual Information

The work of GEHR and Synapses has drawn attention to the essential nature of contextual information captured alongside the individual clinical entries at the time of recording. Although several other projects have each developed their own EHCR information architectures, they share the objective of formalising a set of contexts that may be associated with any healthcare record entry[2].

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

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

[2] A health record entry is considered in this paper to be a quantum of information that is entered into a record, usually constituting a single fact, observation or statement.

Compositional Context

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

Data Value Context

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

Qualifier Context

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

Ethical and Legal Context

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

Care Process Context

Links and pointers:

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

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

Ethico-legal Issues

There are ethical and medico-legal constraints relating to the accountability of institutions for the healthcare records they hold, and accountability to patients for the persons and other institutions with whom they are shared. Patients are increasingly concerned about the extensive range of personnel who purport to have legitimate access rights to healthcare data. The very process of record federation between independent systems, possibly involving several institutions, is bound to extend this range further.

In 1999 European legislation took effect introducing a requirement for institutions to maintain a register of all such Third Party disclosures and to inform these recipients if a relevant record extract has subsequently been amended [16, 17]. This has implications for record federations that extend beyond a single legal healthcare enterprise, since all client accesses to record components across enterprise boundaries could be regarded as Third Party disclosures.

In addition to supporting direct patient care, a healthcare record also provides the documentation of clinical decisions and actions that may be required to demonstrate the competence and quality of a healthcare professional or clinical team. In order for a record to be admissible as legal evidence a sufficiently rigorous methodology is required to track changes made to individual entries as a formal audit trail.

Information Architecture

The Synapses approach to distributed healthcare records utilised the methodology of database federation to a standard and comprehensive schema, the Federated Healthcare Record (FHCR) information architecture, mediated and managed through a set of middleware services [18, 19].

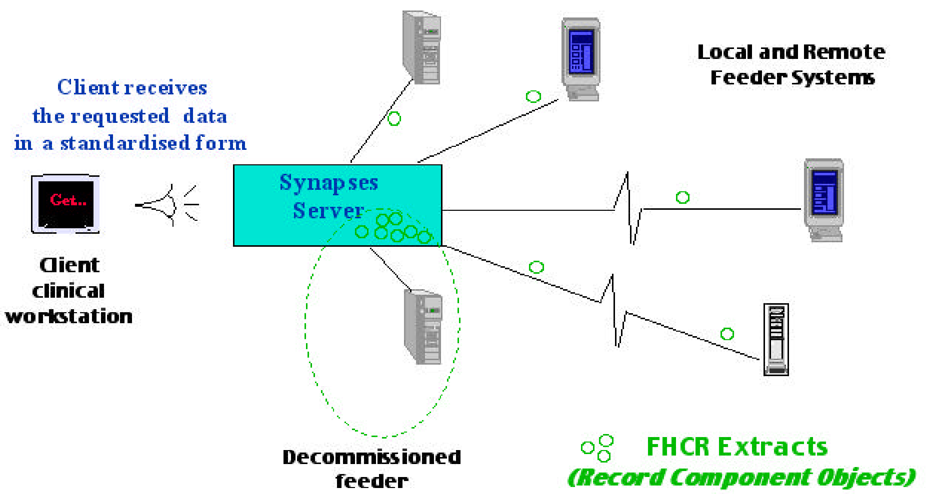

Figure 1: Distributed access to record components within a Synapses federation

In building on the Synapses work, the challenge being addressed by UCL in the design of the federated health record (FHR) information architecture is to provide a formal representation of the generic characteristics applicable to any potential healthcare record entry arising from feeder systems or through clinical applications, now or in the future.

In practice, this challenge can best be addressed through a pair of interrelated information models rather than through a single model.

1. The FHR Reference Model, which represents the global characteristics of healthcare record entries, how they are aggregated, and the general set of context information attributes described as requirements in Table 1. This model corresponds conceptually to the EHCR architecture of GEHR [20] and to the information model of PrENV13606-1 [21]. It is intended to be applicable to any conceivable health domain, in any potential organisational setting. It also reflects the stable characteristics of an electronic health record, and is embedded in the federated record server at a programme code level.

2. The FHR Archetype Model, which extends (and effectively constrains) the Reference Model for particular domains or organisations by specifying particular record entry names, data-types and aggregations of these. This model is used to map the specific data schemata of feeder systems and clinical applications. Such schemata (known as Archetypes) will be subject to frequent change as clinical practice and information systems evolve. This model corresponds conceptually to the Synapses Object Dictionary [22, 23] and to the Archetype concept of the Good Electronic Health Record project [24]. This part of the information architecture is deliberately implemented in a way that facilitates and audits changes to the definition of clinical Archetypes over time within an FHR Archetype Object Dictionary component.

These two information models cannot be described in detail in this paper, but have been documented in their near-final form as part of the SynEx project [3]. The FHR Reference Model, published as the *SynOM* by Synapses in 1999, provided an important input to the drafting of ENV13606. The paired-model approach is now also being reviewed by HL7 in the final drafting of the Version 3 RIM.

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

Middleware Services

The federated health record is derived through a set of services that support access to distributed sources of health records. The FHR Server provides a set of middleware services that enable a requesting service (e.g. a healthcare professional using a client clinical application, or another middleware service such as a decision support agent) to access electronic health record information from a diversity of repository servers (*feeder systems*). These feeder systems may hold clinical data in a variety of different structures, which may range from rigorous electronic healthcare record architectures to quite simple table structures such as those found in departmental systems. The feeder systems may be on-site at an institution or connected remotely through telecommunications services.

The FHR implementation at UCL provides the means by which Record Components

[3] A supplementary paper (UCL-FHR-Models-Annexe) describing these information models is available from the authors on request

(aggregate sets of entries forming part of a patient's federated health record) can be retrieved, added or revised according to a schema defined in the Archetype Object Dictionary. These actions take place in accordance with the user's role-based privilege and the sensitivity of the Record Components involved, and are registered in an access audit trail. The North London demonstrator is utilising the following UCL FHR component services:

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

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

Persons Look-up services: storing a core demographic database to search for and authenticate staff users of the system and to anchor patient identification and connection to the patient's federated healthcare record.

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

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

Component engineering approach

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

- the federated record persistent repository
- the Archetype Object Dictionary (see below)
- feeder system mapping
- client server communications

All of the main components are written in Java. The federated access to distributed clinical databases is managed through a set of directory services accessed via the Java Naming and Directory Interface (JNDI). The components are deployed within a middleware environment managed through Novell Directory Services and JINI™, an open standard service-integration technology. This overall approach allows the ongoing development of flexible and portable applications with high-level graphical user interfaces to be made where such applications can inter-operate across diverse architectures and infrastructures. The services are presently deployed on a Windows™ NT server (to suit local hospital requirements) and a second deployment using Linux™ has been tested. IPv6 web server and servlet runner applications are required for the 6WINIT project (see below) and will be deployed on the Linux™ version.

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

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

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

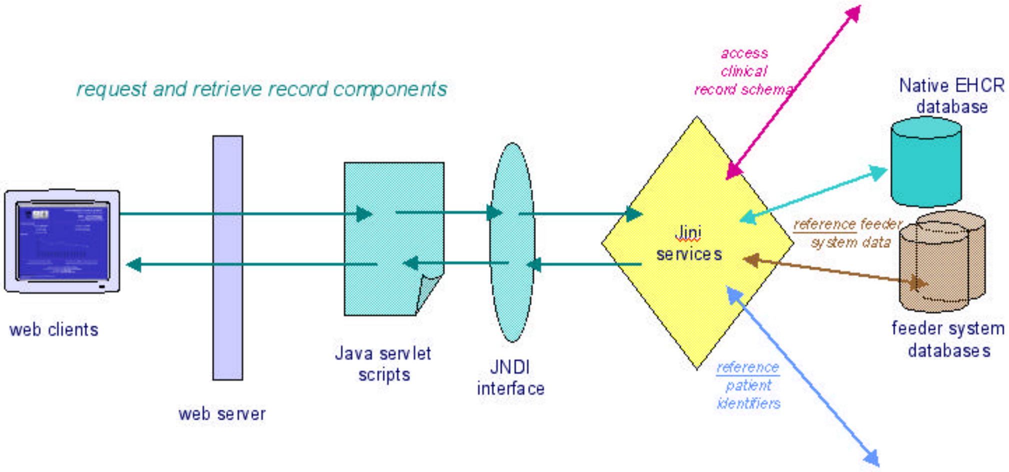

Figure 2: Core FHR components handling the run-time request for and retrieval of patient records

Archetype Object Dictionary Client

The UCL Archetype Object Dictionary Client component:

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

The Object Dictionary Client component has been written entirely using Java Foundation classes and Swing, allowing true cross-platform deployment. It utilises an object database PSE Pro, from Object Design Inc., which is also a Java application and is similarly capable of installation on any platform that supports a Java Virtual Machine.

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

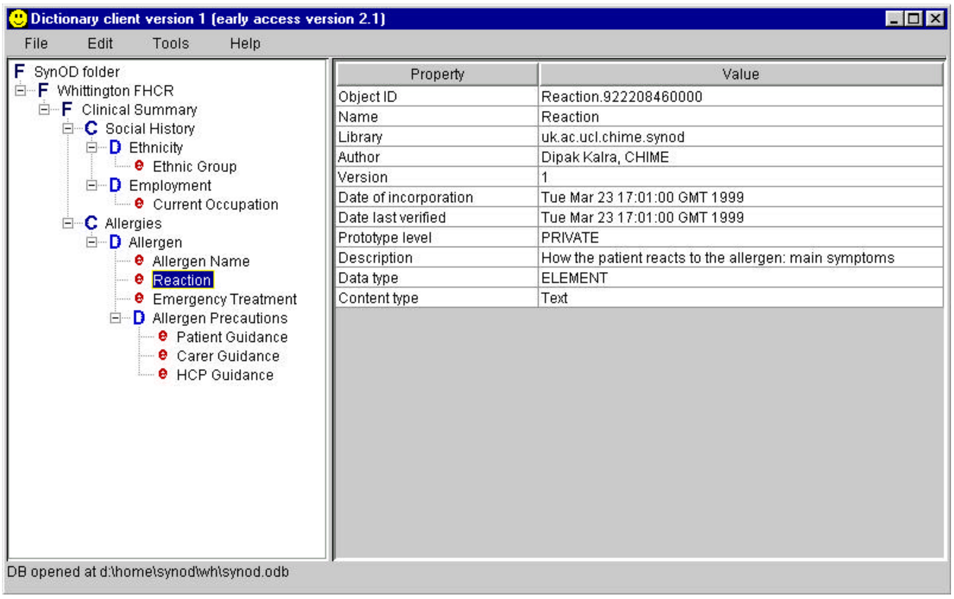

Figure 3: Example screen from the Archetype Object Dictionary Client

Persons Look-up Service

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

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

The 6WINIT Project

The IPv6 Wireless internet INITiative (6WINIT) project is a European IST Framework V initiative involving major European telecom companies, equipment manufacturers, solutions/software providers, research laboratories and end-user hospitals. Its objectives are to validate the introduction of the new mobile wireless Internet in Europe - based on a combination of the new Internet Protocol version 6 (IPv6) and the new wireless protocols (GPRS and UMTS/3GPP). 6WINIT will investigate and validate the set-up of one of the first European operational IPv6-2.5/3G Mobile Internet. This will provide the 6WINIT sites with native IPv6 access points and native IPv6 services in a 3G environment.

The UCL north London demonstrator, based at the Whittington Hospital, is one of three clinical sites chosen to represent the early marketing targets within the healthcare domain. The demonstrator described below is presently being extended to exploit the opportunities presented by wireless Internet services and IPv6, and will be presented in the coming 18 months as the project progresses.

North London Demonstrator Setting

The north London demonstrator comprises a set of primary and secondary care sites working in partnership with UCL. The eventual shape of the demonstrator site will comprise the following healthcare settings.

- The Department of Cardiovascular Medicine at the Whittington hospital
- 2-4 community-based cardiology clinics
- Several GP practices in north London
- Several community pharmacies in north London

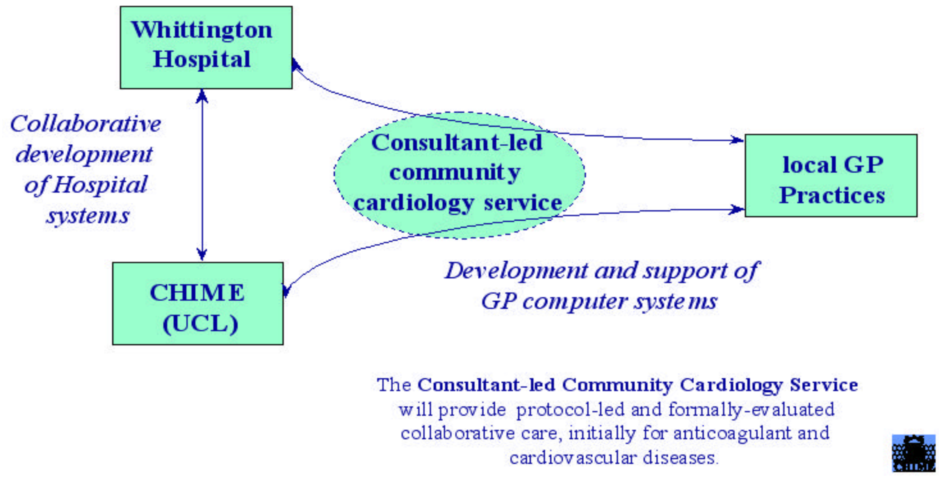

Figure 4: Partner sites in the London 6WINIT Demonstrator

The north London demonstrator vision is to deliver the seamless shared care of patients with cardiovascular illness, in a managed care environment. Patients requiring anticoagulation will have their therapy commenced in the hospital outpatient clinic, informed by background information from their GPs record, guided by electronic protocols and decision support systems. Once stabilised, their care will be transferred into the community and managed under the same protocols with their GP having appropriate access to the hospital records. The care of all patients under anti-coagulation will be subject to clinical and management audits, through interrogation of their federated health care records. Similar managed care scenarios will be developed over time for patients suffering from angina, ischaemic heart disease and cerebrovascular disease.

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

Anticoagulant application

This application provides a set of HTML web clients to enable the management of anticoagulation therapy by clinical staff (or patients) trained to monitor this. The overall application includes forms to deal with requests for and the display of existing data, and also with data entry. The system incorporates drug dosing decision support and recommends monitoring intervals between blood tests. It has been written to replace a legacy application, and is the first live clinical application to test the FHR server. This application is being used daily by staff at the Whittington Hospital, running clinics with up to 70 patients per day. It will shortly be accessed from outside the hospital by a community pharmacist, and it is hoped to include other pharmacists, GPs and patients as users within the next 12 months. Only some of the actual FHR objects and attribute values are shown on user screens, to meet the needs of the users who run the anticoagulation clinics at the Whittington.

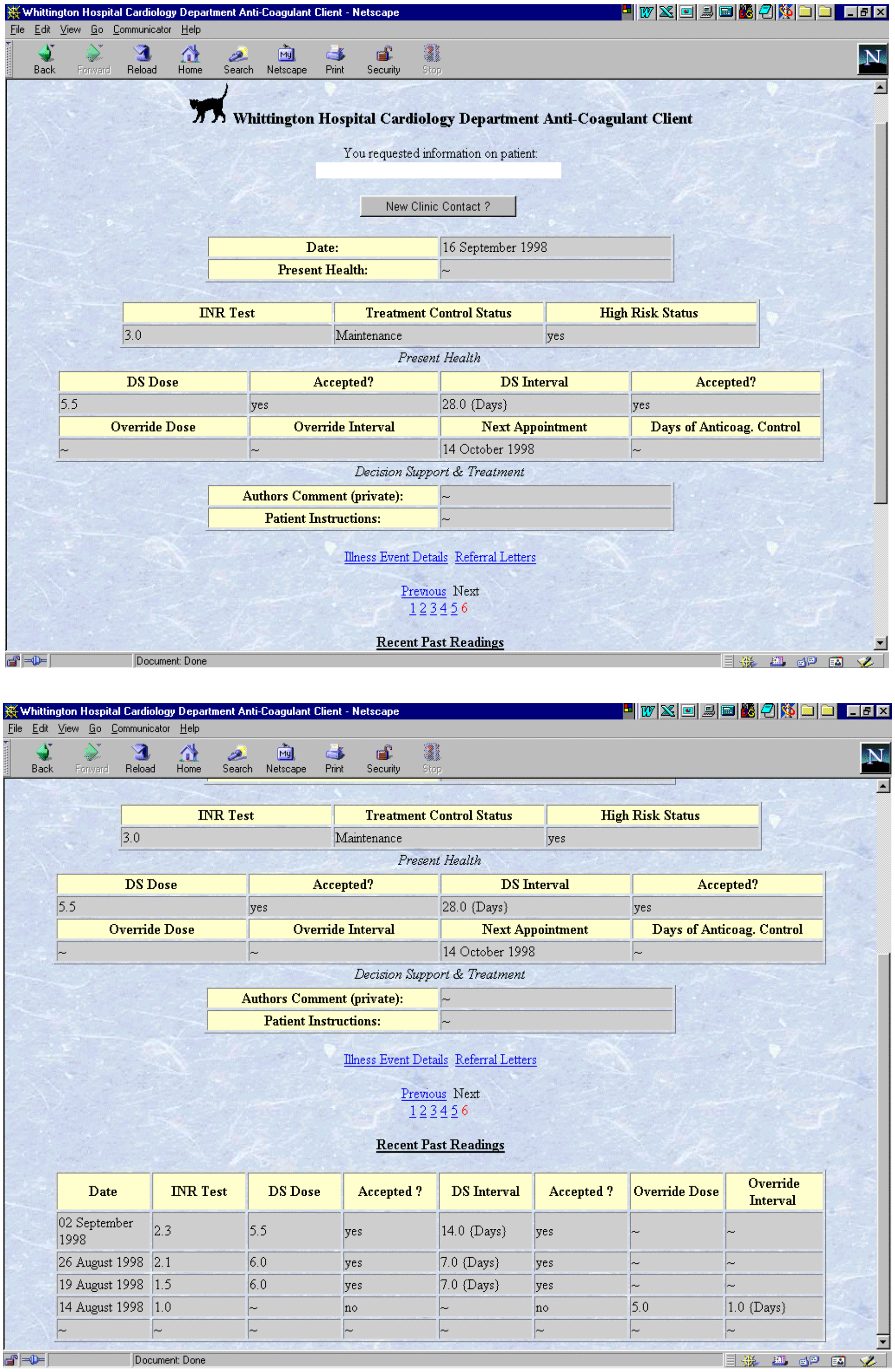

Figure 5: Anticoagulant Client - viewing a clinic contact
(top and bottom half of the web page)

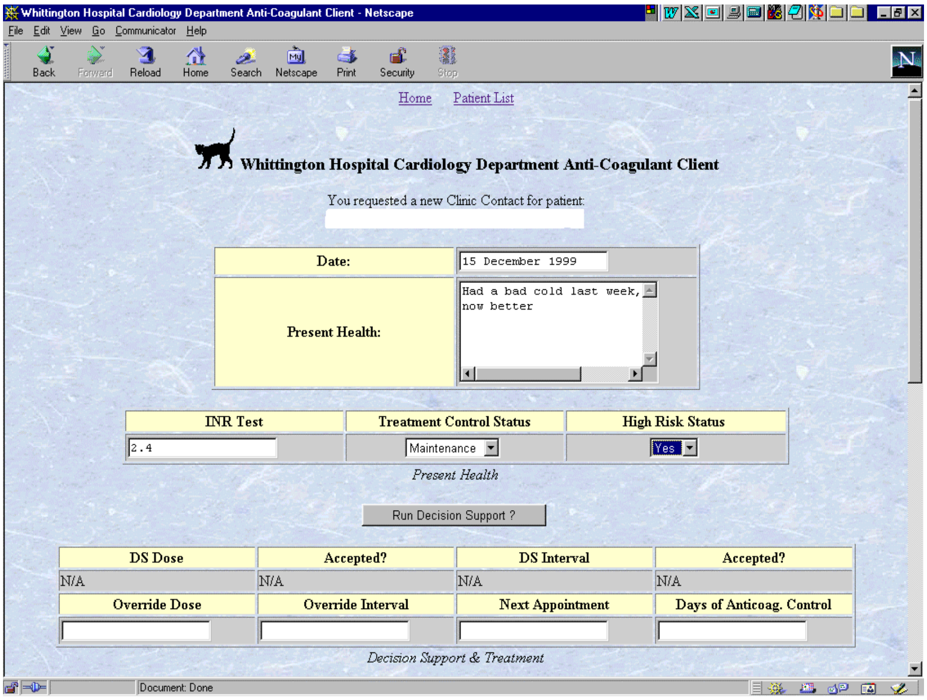

Figure 6: Anticoagulant Client - entering a new clinic contact (prior to running the decision support)

Chest Pain Management

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

Mobile views

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

Further developments

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

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

Conclusion

The north London demonstrator site, embracing the Whittington Hospital and several surrounding general practice and community healthcare sites, provides an important opportunity to validate the design principles of the UCL FHR server.

The experience gained internationally on the design of electronic health record systems is important to communicate widely with in the health service and its related industries. CHIME is now running its third year of an MSc programme in Health Informatics. This course places a strong emphasis on clinical information and systems, including a module on Electronic Health Records.

UCL is in the process of establishing an international foundation (OpenEHR), co-ordinated by UCL and with specific collaborating centres in Australasia and the US [25]. This will operate as a non-profit body to foster high quality electronic healthcare records amongst the purchaser, vendor and user communities. The generic components of the UCL federated health record server described here will next year be offered as Open Source products through the OpenEHR Foundation.

Roger France describes the telematics perspective of the WHO European Region in support of the international WHO Health For All Strategy (HFA) HEALTH21.*"Given the fast rate of technological obsolescence and changing price-performance ratios, countries will benefit from closer collaboration on the development of technological standards, compatibility, open architecture, competitive prices and pilot applications"* [26]. It is hoped that OpenEHR will reflect that spirit.

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

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