Clinical Foundations and Information Architecture for the Implementation of a Federated Health Record Service

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Dedication

This Thesis is dedicated to my loving wife Kathryn
and my two sons Rishi and Ravi
whose love and support has made this work possible

Also to my mother Santhosh and my late father Jagdish
who so prioritised the education of their children

Abstract

Clinical care increasingly requires healthcare professionals to access patient record information that may be distributed across multiple sites, held in a variety of paper and electronic formats, and represented as mixtures of narrative, structured, coded and multi-media entries. A longitudinal person-centred electronic health record (EHR) is a much-anticipated solution to this problem, but its realisation is proving to be a long and complex journey.

This Thesis explores the history and evolution of clinical information systems, and establishes a set of clinical and ethico-legal requirements for a generic EHR server. A federation approach (FHR) to harmonising distributed heterogeneous electronic clinical databases is advocated as the basis for meeting these requirements.

A set of information models and middleware services, needed to implement a Federated Health Record server, are then described, thereby supporting access by clinical applications to a distributed set of feeder systems holding patient record information. The overall information architecture thus defined provides a generic means of combining such feeder system data to create a virtual electronic health record. Active collaboration in a wide range of clinical contexts, across the whole of Europe, has been central to the evolution of the approach taken.

A federated health record server based on this architecture has been implemented by the author and colleagues and deployed in a live clinical environment in the Department of Cardiovascular Medicine at the Whittington Hospital in North London. This implementation experience has fed back into the conceptual development of the approach and has provided "proof-of-concept" verification of its completeness and practical utility.

This research has benefited from collaboration with a wide range of healthcare sites, informatics organisations and industry across Europe though several EU Health Telematics projects: GEHR, Synapses, EHCR-SupA, SynEx, Medicate and 6WINIT.

The information models published here have been placed in the public domain and have substantially contributed to two generations of CEN health informatics standards, including CEN TC/251 ENV 13606.

Acknowledgements

The work reported in this Thesis has been inspired, guided and supported by David Ingram throughout my informatics career. It has been the result of a close and longstanding working partnership with David Lloyd, realised through the engineering skills of Tony Austin working alongside Alex O'Connor and Vivienne Griffith, and through clinical partnership with David Patterson.

Many clinical and informatics colleagues internationally have worked alongside me as part of collaborative projects. They have provided me with ideas, understanding and much valued support with the research journey reported here.

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Preface

The work described in this Thesis builds on a 30-year history in the field of health informatics, and specifically on ten years of research projects evolving the proposed approach to the federated health record. This Thesis therefore covers a broad field of interpretation, including practical implementation and proof of concept testing in real life.

The author entered the discipline of health informatics from a background of ten years working as an east London general practitioner, mainly as a partner in a deprived-area urban practice.

Since 1988 he has been involved in the development of a GP Computer System that is still being used by several practices in east London and is fully accredited to the latest NHS standards. His early contributions included exploring the functional requirements within general practice for computerised information systems and the development of several software modules. In later years his role has evolved towards the management of a small GP software development team and the liaison with user, health authority and NHS Information Authority representatives.

In 1992 he was invited to join the Good European Health Record project being co-ordinated by Professor David Ingram through St Bartholomew's Hospital Medical College, and a few months later to manage the project under his directorship and to lead its clinical task group. Since moving to University College London in 1995, under David Ingram, he has been involved as a workpackage leader and demonstrator site co-ordinator in further EU projects: Synapses, SynEx, Medicate and 6WINIT. Through all of these projects he has been responsible for the lead authorship and editing of many peer-reviewed deliverables and publications. He has also contributed to deliverables within the EHCR-SupA project. These projects have formed the cornerstone of his informatics research, and are referenced within several chapters of this Thesis.

In addition to his core R&D activities, he has been involved in European standardisation work as a member of CEN/TC 251 Project Team 27, which drafted part of the current European standard for EHCR Communication: ENV 13606. He is now leading a CEN Task Force to revise ENV 13606, with the expectation that the work will be adopted as a full standard (EN) in 2004.

Between 1990 and 1996 he also chaired the City and East London Medical Audit Advisory Group, and has since then served as a member of the Camden and Islington MAAG committee. Since 1987 he has been an active member of the North East London Faculty of the Royal College of General Practitioners, having served both as Hon. Secretary and Hon. Treasurer during this period. He is a Fellow of the RCGP.

Chapter 1. Introduction

This Thesis proposes an information architecture for representing the comprehensive, longitudinal and multi-enterprise electronic health record (EHR) for any patient, meeting clinical and ethico-legal requirements. It is aimed at supporting the interoperability of clinical information systems and components that need to interact with electronic health record services to access, transfer, add or modify health record entries.

The hypotheses that this work sets out to validate are:

- that it is possible to derive a set of *generic* requirements for the representation and communication of EHR information (i.e. requirements that are generally applicable across a wide range of healthcare professions, specialities and countries);
- that it is possible to define a set of information models and data dictionaries (an information architecture) that meets these requirements;
- that this information architecture is implementable (i.e. that it is possible to implement a set of computing services conforming to the information architecture, and that these services can be deployed and used in a live clinical setting).

The principal results of the work are a set of generic EHR requirements that the information architecture must meet, and a set of information models to represent the EHR as a logical federation of one or more persistent repositories of personal health data: a federated health record. The work described here builds on a decade of research and development activities involving and partly led by the author within a series of European Commission sponsored projects.

A practical implementation of the proposed information architecture has been deployed within the Cardiovascular Medicine department of the Whittington Hospital in north London, enabling its proof-of-concept validation and providing a rich environment from which to identify areas for future refinement. A further demonstrator is in progress in South West Devon as part of an NHS Electronic Records Development and Implementation Programme (ERDIP) project.

1.1. Description of the problem being addressed

Patient care increasingly requires clinical practitioners to access detailed and complete health records in order to manage the safe and effective delivery of complex and knowledge-intensive health care, and to share this information within and between care teams. Patients nowadays also require access to their own EHR to an extent that permits them to play an active role in their health

management. These requirements are becoming more urgent as the focus of health care delivery shifts progressively from specialist centres to community settings and to the patient's personal environment.

However, much of the fine-grained clinical information on which future care depends is still captured into paper records or within isolated clinical databases. Healthcare facilities have widely differing information systems, which have been written in different application languages, and store the data in different structures. Even very modern computerised health information systems limit the ability of users to extract clinical details in a form that can be communicated to other such systems, and few products can import clinical information received from external systems.

The main way in which integrated health care has been managed up to now, apart from via paper-based letters and reports, has been through defined sets of electronic messages, transmitted for example using EDIFACT or HL7. Most national health services have adopted a suite of these messages to support purchaser-provider communications, organisation and service administration, billing, and to communicate health care interventions for public health purposes. However, few such messages have been developed to support the clinical shared care process itself and, where they have been, these tend to be condition-specific such as for the management of diabetes or for antenatal care.

The problem is complex because much of clinical meaning is derived not from individual data values themselves but the way in which they are linked together as compound clinical concepts, grouped under headings or problems or associated with preceding healthcare events during the act of data entry or data extraction. The medico-legal nature and accountability of health care delivery places additional requirements on the rigour with which health record entries are attributed, represented and managed. The ability to communicate this information efficiently in a mutually comprehensible way is crucial to achieving progress towards shared care, improved quality of care and effective resource management.

Over a decade ago it was recognised that a suitable generic representation is required for the communication of arbitrary health record information between systems, and in Europe this has resulted in a succession of EU sponsored R&D projects and two generations of CEN Health Informatics standards. These projects and standards have sought to define the generic characteristics of EHR information and to embody these in information models and message models that could provide a standard interface between clinical systems. The vision of such work has been to enable diverse and specialist clinical systems to exchange whole or parts of a patent's EHR in a standardised way that can rigorously and generically represent the data values and contextual organisation of the information in any originating system. A complementary goal has

been to accommodate the evolving nature of medical knowledge and the inherent diversity of clinical practice.

1.2. Terms to describe the EHR

The Terms Electronic **Healthcare** Record (EHCR) and Federated **Healthcare** Record (FHCR) have been used by many European projects and publications over the past decade; US publications often refer to a similar concept as the Computer Based Patient Record (CBPR or CPR), the Electronic Medical Record (EMR). The UK NHS has recently distinguished the Electronic Patient Record (EPR) from the Electronic Health Record (EHR) although that distinction has not been taken up elsewhere. When referring to published work the terms used by the original authors have generally been retained. The preferred adoption of the terms Electronic **Health** Record (EHR) and Federated **Health** Record (FHR) for work specifically reported in this Thesis reflects a slightly wider scope to include multi-professional use and to include the recording of aspects of a patient's health that might not result in health care services being provided.

The term *clinician* has been used to represent any healthcare professional who may be involved in providing care to a patient, and thereby creating or using health record information. It is deliberately intended to be interpreted multi-professionally.

1.3. Overview of the Chapters in this thesis

Chapter 2 summarises the overall methodology adopted to develop the proposed requirements and information architecture. This includes brief overviews of the research projects undertaken over the past ten years and the way in which other work in the field (including published literature) has been surveyed. The ISO Open Distributed Processing viewpoint model is proposed as the framework for specifying the information architecture.

Chapter 3 examines the needs for and the visions of an EHR that have been portrayed by a range of authors and classic publications. Some example national strategies for managing health information are considered. The roles for the EHR in support of today's health care services and systems are examined.

Chapter 4 looks at the evolution of record systems, from paper based records to pioneering computer-based record systems. The various clinical systems used in different settings are reviewed, with selected examples of their functionality and evaluations drawn from published literature.

Chapter 5 reviews the results of a wide range of R&D projects that have tackled the representation of health record information, including those involving the author, and the major European and

international standards applicable to EHRs. The EHR cannot be considered in isolation from other information systems and services, and the chapter also includes an overview of the major advances in terminology and electronic decision support systems to examine the features that may be required in the EHR to enable interoperability with such services. The ethical and legal aspects of EHR access and usage are considered together with the main data protection legislation applicable.

Chapter 6 focuses on the requirements for the FHR information architecture, referring to specific investigations and publications dealing with domain-independent requirements. A set of requirements that have been collated by the author over a ten-year period is presented.

Chapter 7 proposes the Reference Model for the FHR: the domain-independent information model for representing any arbitrary set of entries within a patient's health record. The federation approach to the logical integration of clinical feeder systems is also described.

Chapter 8 proposes the archetype methodology to represent the domain specific characteristics of an FHR, including its hierarchical organisation and constraints that may be specified on the values of Reference Model constructs when entries are instantiated.

Chapter 9 outlines the approach proposed for managing the control of access to EHR entries. This aspect reflects work that is still in progress, but a basic outline of the intended strategy is given as this issue is of major concern to health services, to the clinical professions and to the public.

Chapter 10 describes the approach taken to design the specific archetypes needed for the north London demonstrator and provides some other illustrative examples.

Chapter 11 summarises the practical implementation of the FHR server and the steps taken to enable the live deployment of the server in the Whittington Hospital. These have included the creation of web applications through which users could interact with the record server and the importing of several years of legacy clinical data into an FHR repository. A full engineering description of the server is not the subject of this Thesis and only an outline of the key features of the technical architecture is given.

Chapter 12 offers additional evidence in support of the proposed information architecture, such as its impact on relevant European standards.

Chapter 13 discusses some of the key lessons learned in relation to the architecture, its implementation and the principal setting in which it has been deployed. The limitations of this demonstration are also considered.

Chapter 14 concludes by considering what is needed to further validate and refine the approach, and to include the requirements of additional care delivery sectors that collaborate with healthcare services to support the health of citizens.

Chapter 15 provides a glossary of terms.

Chapter 16 lists the cited references.

A set of annexes is also included, providing screen captures and descriptions of the archetype authoring tool and of the web applications implemented during the work. These are listed in Chapter 16 and presented in a separate volume.

Chapter 2. Methodology

2.1. General approach to the investigation

The heart of the work presented here was undertaken at the UCL Centre for Health Informatics and Multiprofessional Education (CHIME). It reflects a continuous research investigation through a series of EU sponsored projects dealing with the requirements, information models and prototypic implementation of a federated electronic health record server. This work started in 1992 with initial investigations of user requirements, and has continued through to the established implementation of a federated health record server meeting these and capable of supporting a live clinical service. These projects are outlined here to help explain the overall research journey undertaken; they are described more fully in Section 5.2. The specifc role of the author in each of these is also outlined, as work contributing to this thesis.

The Good European Health Record project (Project No. A1024, 1992-5) explored the clinical and ethico-legal requirements for the comprehensive adoption of electronic records in place of paper systems, and proposed a first generic information model for the EHR. With colleagues the author undertook a series of investigations of clinical and ethico-legal requirements, and was responsible for collating these across the consortium. He contributed to the information model from a requirements perspective.

The Synapses project (Project No. HC1046, 1996-8) extended the GEHR results to include the realisation of a longitudinal and multi-enterprise EHR through a federation of clinical databases and systems: a federated health record (FHR) server. The author co-ordinated the user requirements and clinical scenarios at each site, and had lead responsibility for the information model and data dictionary that specified the federated health record architecture. These information models underpinned Synapses implementations at five European validation sites.

The EHCR Support Action (Project No. HC3001, 1997-2000) developed a detailed and complete information model for the EHR, contributing to the Synapses FHR design. The author contributed to a major review of published EHR requirements, which collated and classified these from a wide range of EHR-related projects and national publications.

The SynEx project (Project No. HC4020, 1998-2000) provided a middleware and component-based framework for the implementation of an FHR server at UCL, and its demonstration in the domain of cardiology at the Whittington Hospital. The author was responsible for the design of that implementation, and contributed to the overall SynEx middleware architecture from a records perspective.

The same FHR approach was demonstrated in the domain of asthma home monitoring during the Medicate project (Project No. TEN-45608, 1999-2001), for which the author had a significant role in the overall system architecture and the specific asthma monitoring application.

The 6WINIT project (Project No. IST-2000-25153, 2000-2002) is now providing the opportunity to consolidate the components of the UCL FHR service using IP version 6 and wireless network infrastructures, and to support the secure access to an extended range of cardiovascular applications by mobile end users. The author is co-ordinating the three project clinical sites and their collaboration with the engineering partners to develop the demonstrators.

Each of these projects, in drawing on the preceding work, has contributed to iterations in a cyclical evolution of requirements, specifications, prototypes and implementation experience shown diagrammatically in Figure 1 below.

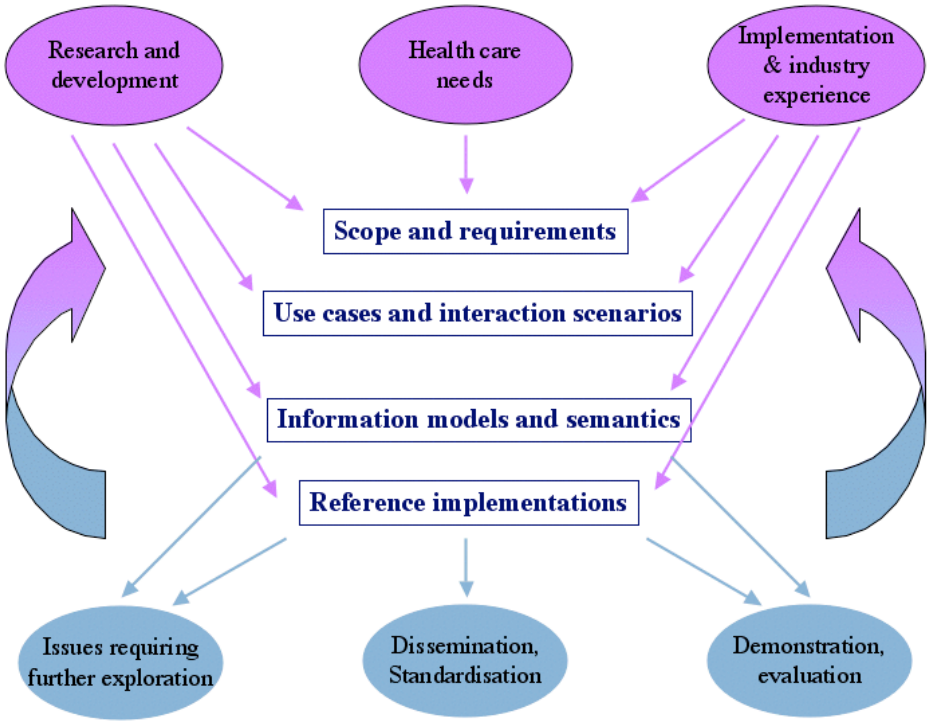


Figure 1: Cyclical evolution of the FHR Information Architecture

This cyclical evolution is typical in many areas of health informatics. The work presented in this Thesis therefore consolidates several such iterations of development, resulting in the live clinical adoption of the FHR service and its contribution to health informatics standards. The specific components of the work, and their relationship to the Thesis chapters, are shown diagrammatically in Figure 3 below, including the input feeds and the demonstration outputs.

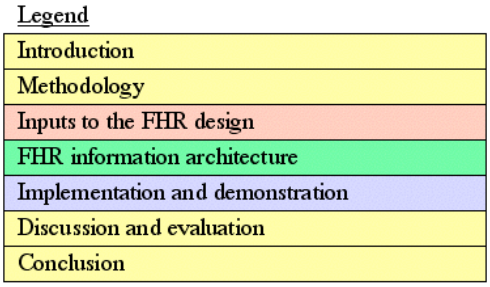


Figure 2: Legend relating to Figure 3

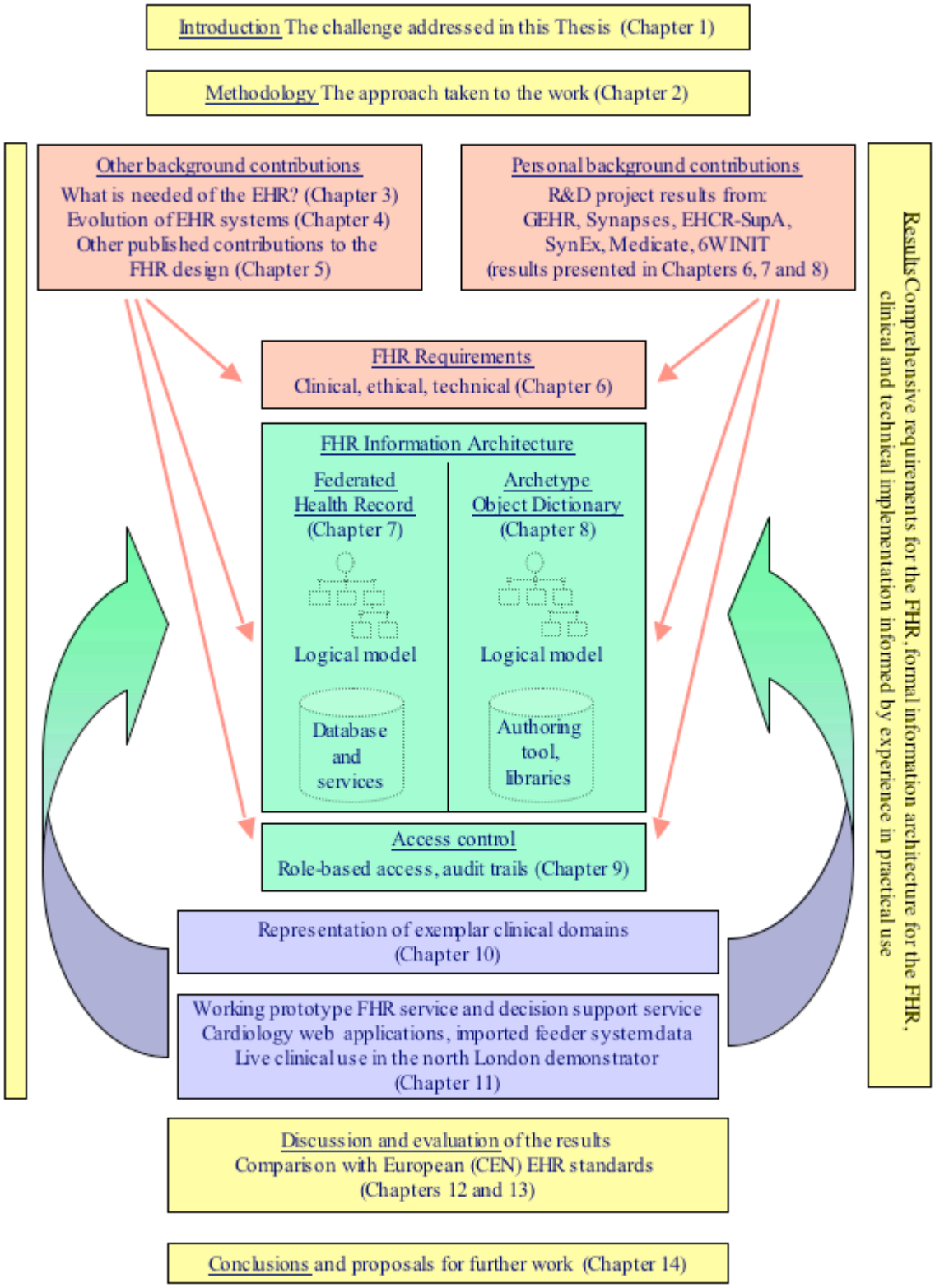


Figure 3: Chapters of the Thesis and their relationship to the results presented

The regular contact with the cardiovascular clinicians at the Whittington Hospital through the north London EHR demonstrator site since 1996 has been of great importance to the clinical validity of this work. It has been an important means of identifying and testing the information requirements of a real clinical team as it evolves a seamless shared-care partnership with GPs and pharmacists in the north London community.

The author has worked within a research team at CHIME whose members have contributed significantly to the information models and are responsible for the actual implementation of the record server and web applications. The interactions that have taken place over many years with these team members have been an invaluable contribution to the work presented here. Professor David Ingram has directed the project activities of the research group over this period and played a pivotal role in the author's understanding of and participation in this field.

2.2. Literature review

Most publications indexed by Medline under the term *Electronic Health Record* (or its well-known synonyms) describe the details of a specific clinical application or decision support system used for an individual study. Work on the general requirements for or representation of EHRs is not often the subject of a journal article in the medical literature.

In 1999 Moorman and van der Lei reviewed 1832 papers dealing with electronic patient records published since 1990, and found that a significant part of the literature was found in ten journals (Moorman and van der Lei 1999). In an update to that paper (still being drafted) the authors have found that the volume of publications has continued to rise but that the list of core journals has largely remained the same (personal communication). The authors used Medline as the resource for their initial search, but noted that Medline does not index some important scientific literature in this field.

A substantial number of important contributions have not been published as academic papers, but as official or *ad hoc* reports issued through a wide range of organisations. Tracing significant new work within this growing "grey" literature is a challenging task, but has been helped by the recent improvement in web search engines and the author's contact networks. The author has therefore adopted a mixed strategy to identify important contributions to the literature.

1 A physical reference library has been maintained of reports and project deliverables acquired by the author and his research team since 1992, through specific collaborations or as direct purchases. These are indexed within a bibliographic database (Procite).

2 All papers cited within any publications or deliverables produced by the research team have similarly been kept and indexed in Procite.

3 Leading health informatics journals were hand searched (going back on average for five years). Relevant papers were selected, by reading the title and abstract, if they were dealing with:

- electronic health records or comprehensive clinical databases;
- projects or pilots utilising federation, message based communications or other remote monitoring technologies to support shared care or patient home monitoring;
- formal approaches to the representation or communication of clinical data;
- health service strategy or policy on health records;
- medical knowledge representation and terminology (except for papers relating purely to the development of coding schemes or to the indexing of medical literature);
- ethical and legal aspects of health record systems;
- security policies and components (except for those dealing with the technical detail of individual components from an engineering perspective).

Papers reporting a lack of success were deliberately included, as these often communicate important lessons that have been learned (Friedman and Wyatt 2001). The main publications systematically reviewed are listed below.

- JAMIA (American Medical Informatics Association)
- Methods of Information in Medicine (Schattauer Press)
- International Journal of Medical Informatics (Elsevier)
- Computers in Biology & Medicine (Elsevier)
- MD Computing (Springer-Verlag)
- Computer Methods and Programmes in Biomedicine (Elsevier)
- British Medical Journal (British Medical Association)
- British Journal of General Practice (Royal College of General Practitioners)
- British Journal of Healthcare Computing (BJHC Limited)
- Health Informatics Europe (BJHC Limited)

4 Additional journals were identified for searching from the health informatics and software engineering sections of the British Library. These journals were less formally reviewed (e.g. selecting papers only via the table of contents of each issue).

5 The principal proceedings of major health informatics conferences were searched, going back at least five years if available.

- MEDINFO
- AMIA Fall Symposium
- Healthcare Computing
- Toward an Electronic Health Record Europe

- British Computer Society: Primary Health Care Specialist Group AGM

6 For all papers reviewed through methods 4-6 above, relevant citations within those papers (usually going back up to twenty years) were short-listed for retrieval. Cited key relevant authors and projects were also short-listed for further searching, which was often performed using Medline or the Internet.

7 Major project and organisational web sites have been searched for relevant publications and "white papers".

This multi-strategy methodology is similar to that advocated by the NHS Centre for Reviews and Dissemination (University of York). The results of this literature review, combined with the author's historic accumulation of publications, is too large a set of resources to be cited comprehensively here. The author has therefore filtered this literature, focusing primarily on those publications that have, in the opinion of the author, had a significant impact on the field and on the results reported. Others have been included as representative examples of a larger body of work.

2.3. Requirements analysis

The author has been responsible for the investigation of requirements within many of the projects outlined above. A wide range of methodologies exist for eliciting requirements from end users or other stakeholders for different target systems. No one of these is ideal for the EHR as a conceptual model, and the author has therefore combined several of these at different stages of the work, includingliterature reviews, questionnaires, clinical and technical scenarios, Use Case diagrams and evaluation questionnaires. These various investigations have permitted confirmation of the requirements statements from multiple sources, and of their ongoing validity over several years. A coherent and classified set of these statements has been maintained throughout this period, including those identified by clinical, managerial and technical users of pilot EHR demonstrator systems. These are documented in Chapter 6 along with summaries of the background research work that has contributed to them.

2.4. Information Models

The information models presented have been derived from work previously published by the author and colleagues through EU projects and CEN standards. The author has been involved in drafting diagrams and summaries of such models on many occasions for project deliverables, reports and formal contributions to CEN. The refinement of the models has been possible through feedback from a range of European demonstrator sites in different clinical settings, and regular (sometimes vigorous) debates on the models moderated by a constant reference back to the

originating requirements. The work presented is the result of many iterations of modelling the EHR, over several years, refined through the detailed implementation and deployment experience of the north London demonstrator.

2.5. Implementation of the Record Server

The early work of the author involved collaboration with demonstrator sites across Europe and in particular with the Royal Marsden Hospital in Surrey. This site has a longstanding history of pioneering the design of clinically-oriented HIS systems, and provided an ideal initial site from which to gather requirements and to test conceptual approaches. That system is outlined in Section 4.2.10.

A critical part of the author's research methodology has been the practical implementation of a complete federated health record server, using Java and object oriented technologies, to provide a proof-of-concept verification of the models and the general approach. This task has required the author to work closely with a small team of developers employed within his department to design the middleware components to conform to the information architecture described in Chapter 7 and Chapter 8. The implementation work required to reach live deployment probably represents at least several person years of effort, and has not only provided validation of the work reported here but provided evidence to a wider international community that this approach to realising the EHR is technically and clinically viable.

2.6. Evaluation

Most classical evaluations of applications or systems focus on the success of the end use of the results. This success can be assessed from user and organisational perspectives, and validation has been undertaken in health care by a variety of techniques, such as:

- technical properties (e.g. conformance, reliability (Goodman and Ahn 1999);
- system walk-throughs accompanied by "think-aloud" protocols (Kushniruk, Kaufman et al. 1996);
- completeness and accuracy of the records available to support teamwork or shared care (van Gennip and Bakker 1995);
- improved data quality and improved access to the data (Milholland 1995);
- qualitative measures such as the functional gain perceived by a clinical team (Heathfield, Peel et al. 1997);
- impact assessment, looking at the long-term effect of a system on clinical care or organisational effectiveness in comparison with expectations (Kaplan 1997), (Goodman and Ahn 1999);
- relative advantage of the organisation through having the system (Dixon 1999).

An engineering approach to technology assessment includes instruments such as the ISO/IEC guidelines (Information Technology - Software Product Evaluation - Quality Characteristics And Guidelines For Their Use 1991). This has a strong focus on the quality assurance measures used during the software engineering process and on product testing. This kind of instrument would be used by industry prior to releasing a product and should ideally be used for prototype software that is intended for use in clinical practice. The evaluation of the FHR service as software will be the focus of another PhD Thesis to be submitted later by the research colleague who has led the implementation.

The results presented in this Thesis are a set of requirements statements and an information architecture.

The requirements statements have no direct clinical end user or target organisation. The validation approach to these has been:

- to assess their consistency through a series of targetted investigations (i.e. that the same requirements recur, elicited in different settings and through different methods);
- to confirm, from the literature, that other groups have identified similar requirements;
- to demonstrate that the requirements statements can be used to underpin the FHR information architecture.

The "end users" of the information architecture are the developers of the FHR middleware components (i.e. the author's research team). The FHR information architecture is only made tangible through the implementation of a middleware service, and this is itself invisible to the end users who interact indirectly with it through a clinical application. The clinical user experiences of "the sytem" as they see it are far too removed from the core information architecture to be valid criteria of success. The author's experience of the clinician feedback on the systems developed through this research, and of any concerns at times expressed by the staff about the system, have almost exclusively related to the look and feel of the web application or to overall (system and network) performance.

The Synapses project, recognising the difficulty of evaluating the design for middleware, proposed to use the methodology developed during the KAVAS project (O'Moore R., Doyle O. et al. 1995). The KAVAS evaluation approach is based on the division of the entire software development life cycle into four dynamically interacting evaluation phases that are integrated with the software product development process. The four iterative phases are illustrated in Figure 4.

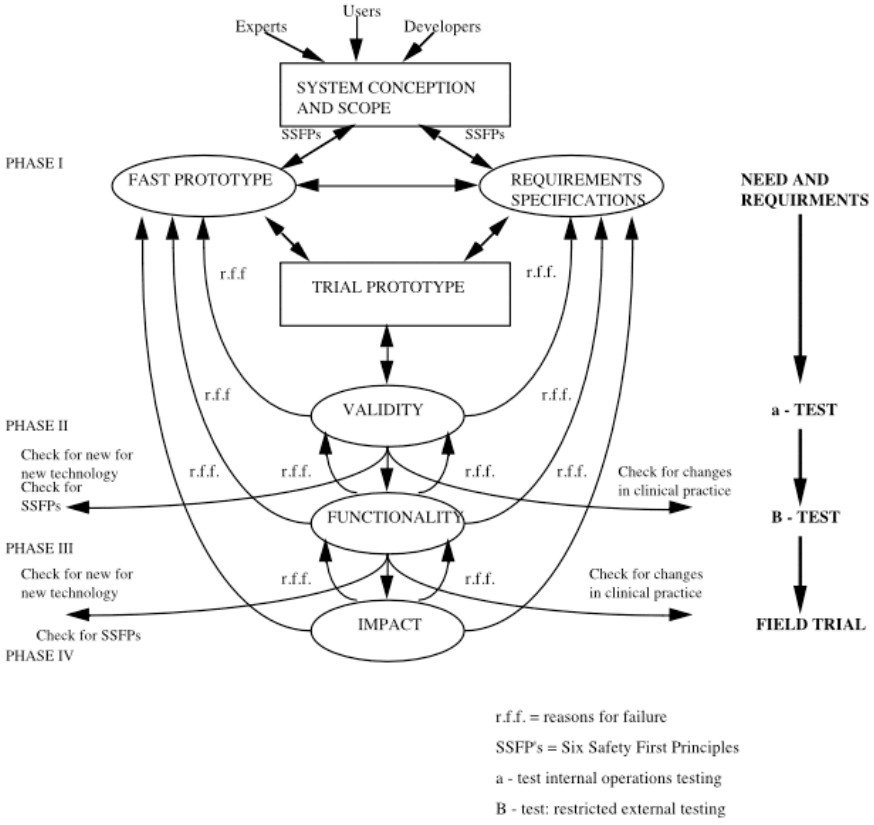


Figure 4: The KAVAS project evaluation methodology

The cyclical journeys through clinical settings, requirements, information models, implementation and demonstration experience, as advocated by the KAVAS project, is the methodology that has been adopted by the author here, and historically through the succession of projects described as background inputs to this present iteration.

The criteria for success of the proposed FHR information architecture have been:

1 that middleware services conforming to it are demonstrated to be implementable;
2 that the schemata of existing clinical data bases can be mapped to the information architecture and that legacy data can be migrated into the implemented FHR server;
3 that new clinical applications, specified by end users, can be mapped to the information architecture and that the implemented applications correctly retrieve imported legacy data and satisfactorily commit new clinical entries to the FHR server;

4 that this approach finds acceptance within the international informatics and standards communities as a valid contribution to the field.

It can therefore be seen that, whilst quantitative end user satisfaction with the clinical applications would not contribute to these criteria, the goal of achieving a live and clinically usable deployment (incorporating legacy data migration and new web applications) does confirm that criteria 1-3 have been met. The requirements and the information architecture build on previously published and peer-reviewed antecedents, and have been compared with parallel independent work in this field. These evaluations, and their limitations, are discussed in Chapters 12 and 13.

2.7. Formalisms used in writing this Thesis

2.7.1. Open Distributed Processing Reference Model

The rapid growth of distributed systems has led to a need for a co-ordinating framework for their specification. The Open Distributed Processing model for developing information systems is an international (ISO) standard method for defining any distributed computing environment from different perspectives (ISO/IEC Information Processing Systems, Open Systems Interconnection, Basic Reference Model of Open Distributed Processing 1990).

The ODP framework includes five viewpoints for specifications. The viewpoints each focus on different aspects of an ODP system.

Enterprise	the purpose, scope and policies for that system.
Information	the semantics of information and information processing.
Computational	modelling distribution through functional decomposition of the system into objects, which interact at interfaces.
Engineering	the mechanisms and functions required to support distributed interaction between objects in the system.
Technology	the choice of technology in that system.

Within the ODP Reference Model, user requirements form the basis of the Enterprise Viewpoint. The architectures developed from them, often expressed as object models, comprise the Information Viewpoint. This can be used to describe aspects of the way health records and medical knowledge can be represented purely as information, independently of any computer-based implementation of them.

For a generic FHR service, the Enterprise and Information viewpoints should ideally be relatively stable and common across different clinical settings. Both of these levels of expression can support

implementation in a diversity of computational and engineering methodologies: each vendor or healthcare enterprise site may identify different computational designs, engineering approaches, hardware platforms and software products with which to build their FHR systems, whilst remaining conformant to a single enterprise model and a single information model.

The Enterprise and Information Viewpoints best characterise the results reported in this Thesis, although the author has worked at the Computational, Engineering and Technology levels in order to implement and to refine these contributions.

The Synapses project adopted the ODP five-viewpoint framework to specify the Synapses Federated Health Record Server, described in Section 5.2.3. The final project deliverables have been published specifically as five viewpoint reports (The Synapses ODP Specfication 1999). Frandji et al have also shown the applicability of the ODP reference model for the specification of the RICHE Reference Architecture as an open framework for health information systems (Frandji, Schott et al. 1994), see Section 5.4.2. More recently Beeler has argued for the use of the ODP framework for the design of the Reference Information Model of HL7 version 3 (Beeler 1998), see Section 5.6.1.

2.7.2. Unified Modelling Language

The Unified Modelling Language (UML) (Odell and Fowler 1998) is now used extensively as the formalism for representing the Enterprise and Information Viewpoints in a rigorous and unambiguous way.

For the Enterprise Viewpoint, Use Case diagrams are the most well known way of describing the functional roles of various system components from a user perspective. The Federated Health Record service is described in this way in Section 6.10. Data Flow Diagrams can also be used to describe the information flows between components required to deliver the Enterprise Viewpoint; and the main data flows to and from the FHR service are shown in this way in Section 11.1.

UML class diagrams are now the industry standard way of depicting the structure and relationships of the information that is managed by or between components, and has largely replaced previous diagramming notations for entity-relationship models. This formalism has been used within Chapter 7 and Chapter 8 to present the information architecture itself.

Although XML has recently been widely publicised and adopted as a representation of information for communication purposes, this is a specific engineering approach and is not implementation independent. In addition, it has some limitations in its expressive power making it insufficiently rigorous. Although XML has a role within the implementation work described here, it has not been used within the FHR specification.

Chapter 3. What is needed of the EHR?

3.1. Challenges facing health care services

The application of information technology to modernise health services has become a key political issue. In his 1997 State of the Union address, President Clinton declared that "*we should connect every hospital to the Internet, so that doctors can instantly share data about their patients with the best specialists in the field.*" (Clinton 1997). The present UK Labour Government has promised NHS modernisation. For example Health Secretary, Alan Milburn, has recently pledged that every adult will soon be able to access his or her own at-a-glance electronic healthcare record.

> *"The EHR, which would hold key summarised data about patients, would be securely protected, created with patient consent, and changeable only by authorised staff. Mr Milburn predicted that up to five million people would have their own lifelong EHR by 2003, rising to around 25 million by 2004, and covering every person treated by the NHS by March 2005."* (EHR Fanfare Masks Complicated IM&T Spending Plan 2001)

There are many challenges and cultural changes facing health care services today. In the opinion of the author, those that have the greatest impact on the expectations of an EHR are:

- the requirement to limit healthcare costs and to optimise resource utilisation;
- the shift of care from specialist centres to community settings;
- the requirement to deliver evidence-based and quality-assured care;
- the growth of consumerism and patient active participation in health care;
- equity of access and public involvement in priority setting;
- an increasing complexity of health care provision;
- an increasingly distributed and mobile clinical workforce;
- changes in the working patterns and accountability of healthcare professionals;
- the overwhelming growth of medical knowledge;
- a critical reliance upon comprehensive patient records;
- increasing concerns about the confidentiality of patient records.

Some of these challenges as presented by other authors, and their implications for the EHR, are discussed in the rest of this chapter.

(Smith 1997) suggests that traditional models of healthcare services have been associated with inefficient and inequitable health care, favouring expensive specialised interventions over some more useful measures to provide support for patients and families at home. He suggests that information technology may enable a more patient-centred approach to healthcare: quality measures focused on individual patients' needs and experiences of care; services actively involving

each patient in their self-management and providing care close to each patient's home and community. This is illustrated in Figure 5 below, reproduced by Smith from Jennings K, Miller K, Materna S. Changing health care. Santa Monica: Knowledge Exchange, 1997.

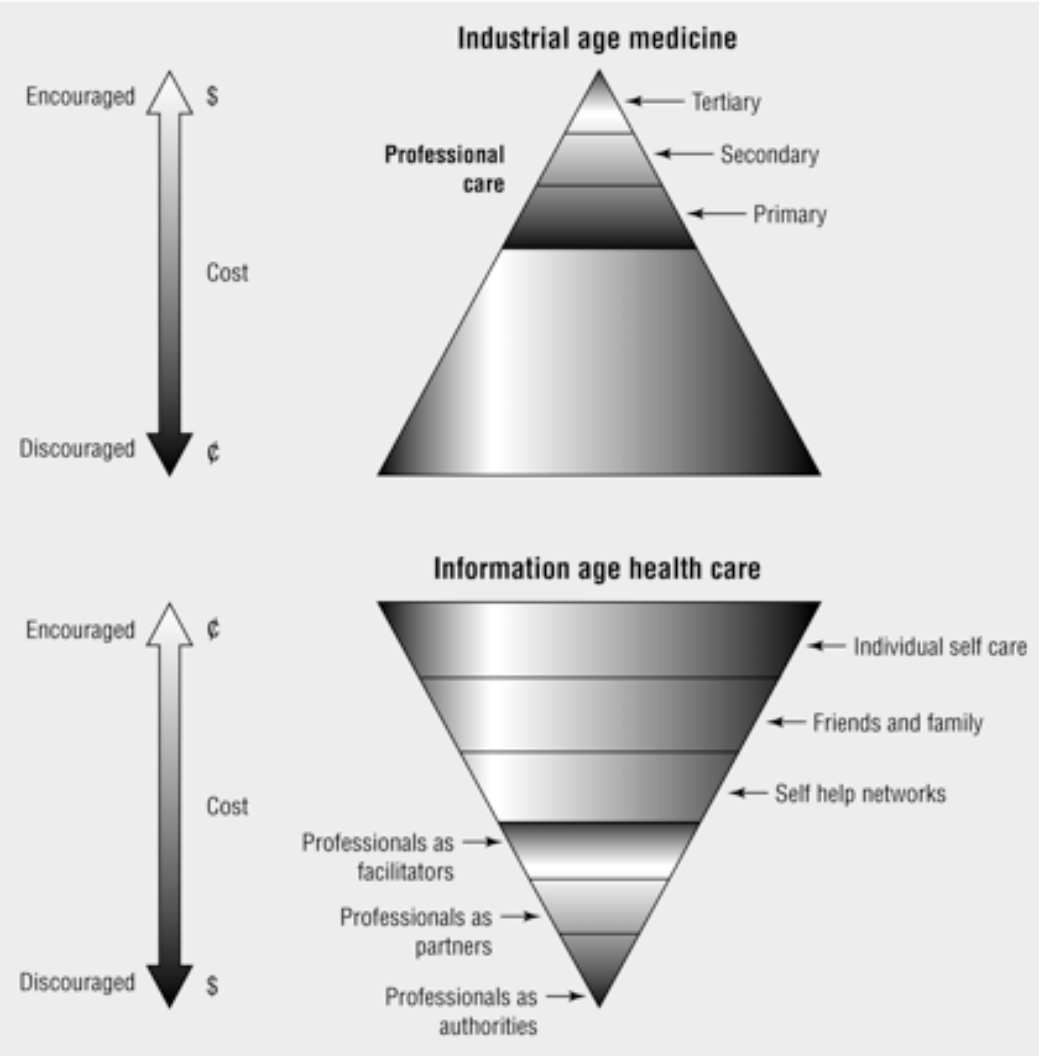


Figure 5: Transformation from industrial age medicine to information age healthcare

Reproduced by Smith from Jennings K, Miller K, Materna S. Changing health care. Santa Monica: Knowledge Exchange, 1997

Such a model depends on the capacity of information technology to support people, communications and workflow in highly distributed teams. It also requires a change of emphasis from the top-down specification of data collection serving a contractual model of healthcare delivery to the facilitation of data collection supporting the seamless flow of each patient between care providers and the continuity of their care over a lifetime.

The challenge of providing clinicians of any profession or speciality with an integrated view of the complete health and health care history of each patient under their care has so far proved difficult to meet. This need is now widely recognised to be a major obstacle to the safe and effective delivery of health services, by clinical professions, by health service organisations and by governments internationally.

In 1997 a White Paper from the UK Department of Health launched a new clinically-focused quality agenda for the National Health Service: Clinical Governance (The New NHS: Modern, Dependable 1997).

> *"Every patient who is treated in the NHS wants to know that they can rely on receiving high-quality care when they need it. Every part of the NHS, and everyone who works in it, should take responsibility for working to improve quality".*

The Clinical Governance agenda was heralded as the catalyst for the development of a culture that recognises and upholds the maintenance and improvement of quality at the heart of health care delivery. It is considered by far the most ambitious quality initiative implemented by the NHS (Scally and Donaldson 1998). Implementing clinical governance depends upon changing everyday clinical practice (Baker, Lakhani et al. 1999). Achieving its goals depends upon the development of new roles and skills within clinical practice and new clinically focused information systems to guide and support them.

European and US legislation of the past several years has recognised the rights of individuals over the information held on them by others, and the consequent responsibility of organisations such as health services to protect the accuracy and confidentiality of the records they hold. A practical means of capturing and applying patient consent for the disclosure of personal health data is now an issue of major concern (for example (Mandl, Szolovits et al. 2001), (Baker, Shiels et al. 2000), (Oswald M. 2002)).

(Roger France 2000) describing the telematics requirements to deliver the WHO Health For All Strategy (HEALTH21), argues that the main goals of future telematics developments, such as electronic health records, must be:

- to facilitate the equity and cost-effectiveness of regional and national health care systems;
- to enable the systematic review of information on health outcomes;
- to empower patients and their support communities (including patient groups) with information on their health and its management;
- to enable the education and training of health care and public health professionals.

3.2. Challenges facing clinical care

Much is changing at the core of clinical practice, and the health record is today facing challenges for which paper systems are not adequate.

Healthcare professionals need to document increasing volumes of information, as patients receive more complex and data-intensive care. More detailed records are also needed to demonstrate competence, to cover the increasing risk of litigation, and to justify use of healthcare resources (Southgate, Berkson et al. 1989), (Southgate 1999), (Summerton 2000), (Pringle 2001), (Good Medical Practice 2001).

The delivery of safe and effective (i.e. evidence based) health care is a challenge for all clinicians, particularly as the extent of medical errors is becoming apparent. The US Institute of Medicine report "To Err is Human" has estimated that 100,000 US citizens die each year through medical errors (Kohn,Corrigan et al. 2000). These possibly rank as the eighth leading cause of death in the US, and contribute 4% ($37.6 billion) to the cost of US healthcare (Anderson 2000c). Surprisingly high rates of missing or erroneous information have been confirmed in a number of studies. For example, in two London hospitals Vincent et al found that adverse events occurred in around 10% of patients, a third of which were moderate, severe or fatal and around half of which were preventable (Vincent, Neale et al. 2001). (Haughton 2000) describes a large study within managed care programmes that identified over 20% of patients with potential misdiagnoses, possible drug interactions, a lack of follow-up or missed screening tests. (Wagner and Hogan 1996) found that around 10% of elderly patients attending an outpatient clinic had incorrect medication records, mainly due to recent changes not having been communicated or documented. The widescale use of decision support and alerting systems that interact with patient records is considered an essential informatics solution to the prevention of errors (Bates, Cohen et al. 2001).

Weed argues that the expanding wealth of medical knowledge has now exceeded the ability of individual healthcare professionals, however well meaning, to retain and retrieve it appropriately or safely (Weed 1999). He states that

> *"memory based, credential oriented systems, with their "habits of certainty" and obscure dark corners of mystique, must now be abandoned."*

Straus & Sackett argue that consolidating this vast array of knowledge within evidence based guidelines, developed by trusted organisations, is the only way in which individual clinicians can remain safe and optimally effective (Straus and Sackett 1998).

Healthcare professionals need to share healthcare information with a growing range of professional colleagues, often on multiple sites (Vari, Brugal et al. 2000). Patients are often under the care of more than one team or speciality at the same time: for example, a diabetic patient may be under a

diabetologist, an ophthalmologist, a nephrologist, a dietician, a wheelchair clinic, their GP and a District Nurse. The National Health Service in England alone handles 1 million admissions and 37 million outpatient attendances per annum, requiring high quality and efficient communications between 2,500 hospitals and 10,000 general practices. Records also need to be efficiently transferred when a patient moves and seeks care at a new institution.

(Dodd and Fortune 1995) observe that doctors, nurses, and other health care professionals are increasingly working together on clinical audit, guideline development, and outcomes research; this joint working has emphasised the need for comprehensive, accurate, integrated, patient-based health records. However, significant problems can arise in continuity of care if salient information is not communicated. Figure 6 shows the situations of high clinical risk regarded by east London GPs as requiring urgent communication from hospital (Kalra and Spence 1998). East London GPs were asked to indicate the clinical situations in which they perceived their ability to care for a patient safely would be compromised by a delay in receiving notification from hospital. In these circumstances most GP's indicated that the relevant hospital doctor should personally notify them by telephone rather than rely on fax or letter.

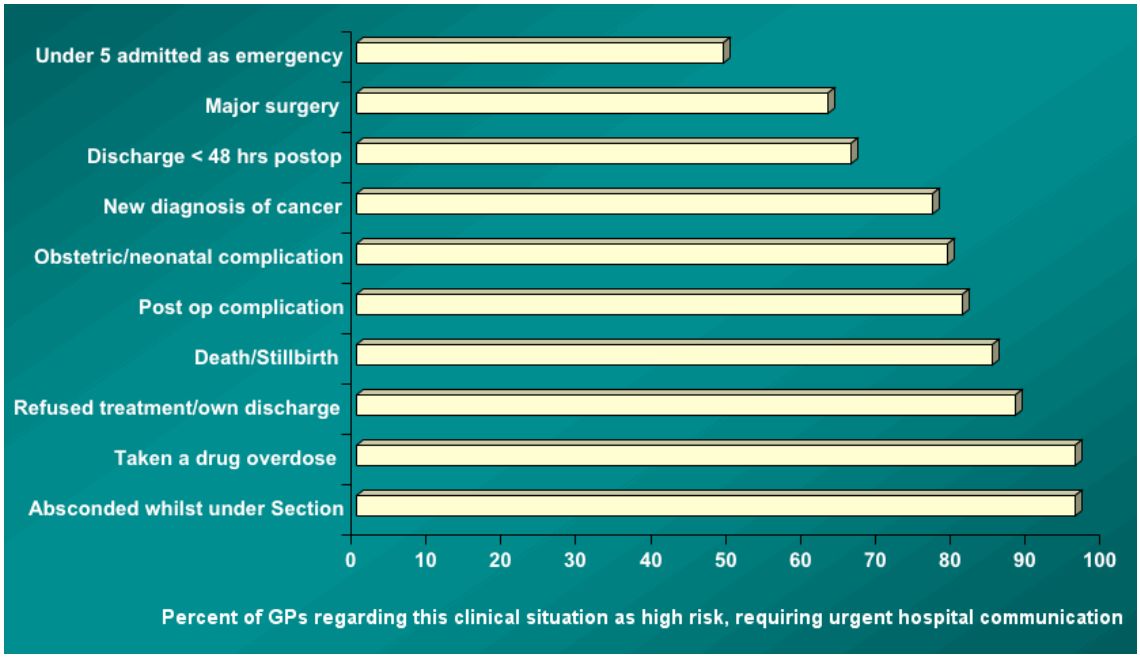


Figure 6: High risk clinical situations requiring urgent communication from hospital to GPs

The clinical requirements for which information technology solutions are needed are in the areas of (Kalra, Ingram et al. 1999):

- improving multi-professional partnerships and clinical decision-making through ethically and legally acceptable access to patient record information and enhanced communication systems;

- developing an integrated knowledge environment that delivers evidence about best practice, clinical guidelines and educational materials directly to the clinical 'coal face';
- promoting systematic clinical practice, for example through data templates, clinical protocols and integrated care pathways, embedded within patient records;
- providing patients with relevant education and support to enable good practice in their own self-management;
- enhancing clinical performance by collecting feedback from patients on the various aspects of their care;
- stimulating a culture of evidence-based practice by linking results from clinical audit with professional educational programmes and resources.

3.3. Challenges facing health informatics and telematics

In 1994 Dean Sittig published ten Grand Challenges for Health Informatics (Sittig 1994), which included:

> *"a complete computer-based patient record that could serve as a regional/national/multi-national resource and a format to allow exchange of records between systems".*

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 (Burns 1998). Ilias Iakovidis, Project Officer for the European Commission's Health Telematics programme, suggests that an important challenge for realising successful EHR implementations at a national or regional level includes (Iakovidis 1998b)*:*

> *"the storage, maintenance, communication and retrieval of multimedia information on heterogeneous and geographically distributed database systems"*

(Rogers 1998), in reviewing the report "Enabling Mechanisms for Global Health Networks" for the G7, suggests that the main challenges to realising a global health information society include data meanings, structures and database navigation.

The adoption of electronic information systems within healthcare is presently very much less than in other public service sectors or other industries. This is partly because the overall percentage of the healthcare budget spent on information and communication technologies (ICT) is relatively low. Across Europe the average healthcare enterprise allocates 0.7% of its expenditure to ICT compared with an average of 3-5% across industry; this is equivalent to only around $400 per employee compared to manufacturing ($1500/employee) or finance ($5000/employee) (Bordoni L, Trends in the European ICT Market, International Data Corporation (IDC), Briefing for the European Commission, March 1996, cited in (Iakovidis 1998a)). More recently the UK Wanless Report has

highlighted the low level of IT spending in the NHS compared with other sectors (see Figure 7) as an impediment to its modernisation (Wanless 2002).

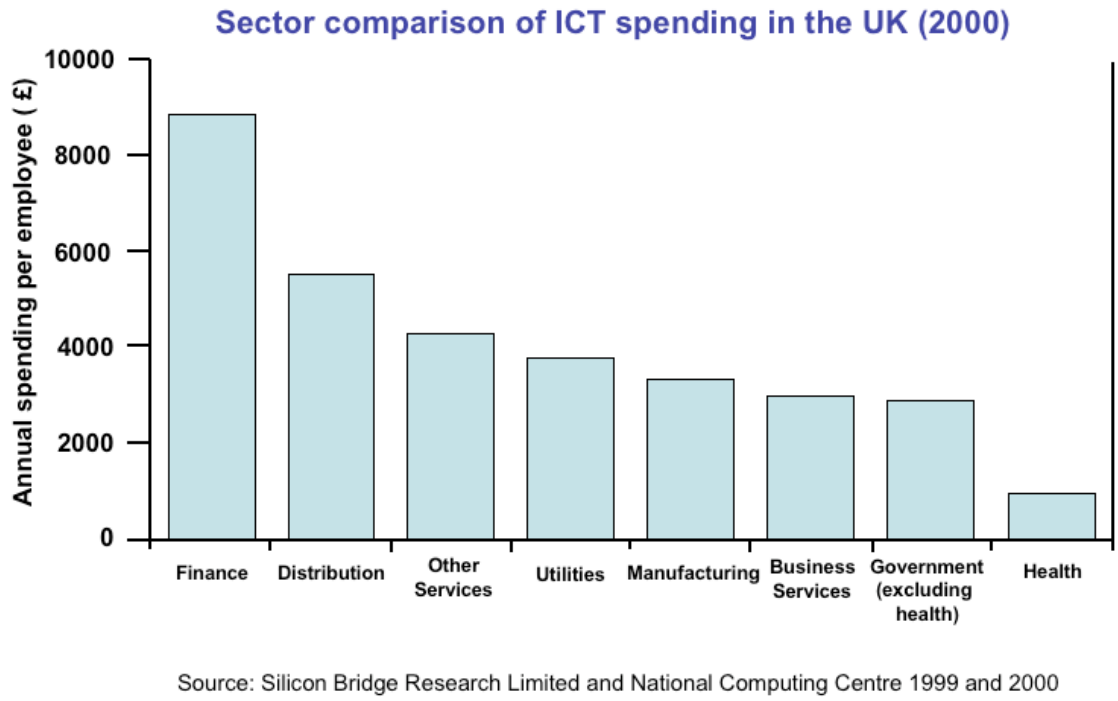


Figure 7: IT spending in the UK by industry sector (reproduced from The Wanless Report)

In contrast, the requirement to manage information systematically in health care is very great. (Amatayakul 2000) cites a 1999 US Department of Commerce study which found that

> *"healthcare's reliance on information is the fourth largest, after telephone & telegraph, radio & television and security brokerage."*

Writing about the organisation and change management requirements for successful software implementation, (Shortliffe 1998) states:

> *"Health care provides some of the most complex organizational structures in society, and it is simplistic to assume that off-the-shelf products will be smoothly introduced into a new institution without major analysis, redesign, and cooperative joint-development efforts."*

(Collen 2000) suggests that healthcare providers now recognise the need for comprehensive and organisation-wide information systems to provide encrypted, secure, comprehensive, and integrated computer based patient records. (McDonald 1997) stresses two major challenges facing the practical delivery of EMR systems: firstly that of integrating clinical information that resides on many isolated islands that have been very difficult to bridge; and secondly how to capture the data from physicians in a structured and computer understandable form.

(Iakovidis 1998b) suggests that human and organisational factors are primarily behind the slow acceptance of telematics solutions across Europe, including a lack of vision on the part of health information managers and health authorities. He proposes six areas of challenge for realising successful EHR implementations at a national or regional level:

1. organisational and cultural issues: the willingness to share records and to trust the records of others;
2. technology and standardisation: the storage, maintenance, communication and retrieval of multimedia information on heterogeneous and geographically distributed database systems;
3. legal, ethical requirements on the confidentiality and security of records;
4. industrial issues: the willingness of industry to invest in good quality record systems, impaired by the low levels of investment in ICT compared with other industrial sectors;
5. national, regional strategies: regrettably often focused on short term cost efficiency requirements for clinical systems and a "wait & see" approach on a comprehensive EHR;
6. human factors: education and training, friendliness of systems, access to workstations and mobile access, data entry & display devices.

Other important issues include the acceptability of and use of record systems by patients.

(de Moor 1998) suggests that the main challenges for international EHR standardisation are organisational, cultural and language problems (terminology) and legal and ethical concerns (security).

3.3.1. Example National IM&T Strategies

UK NHS

The current NHS Information Strategy (Burns 1998) defines a formal commitment to the integration of patient records within hospitals (Electronic Patient Records) and across the wider NHS (Electronic Health Records). Peter Drury, Head of the Information Policy Unit at the UK Department of Health, states that electronic records are

> *"the key to enabling all stakeholders in the care process (patients, professionals and managers) to make informed decisions for improved outcomes."* (Drury 2001)

The NHS vision of the EHR is of 24 hour clinician access to a longitudinal patient record, anchored in general practice and possibly delivered through extensions to present GP systems. It will incorporate health and social care interfaces, supporting seamless care between GPs, hospitals, and the community. EHR systems will conform to NHS technology standards, security and confidentiality policies. They will utilise the existing and planned NHS technical infrastructure:

NHS wide network, the EDIFACT-based strategic messaging service (Love 1994), NHS clinical terms (developed from the Read codes, and in the future to be SNOMED-CT, see Section 5.7.4).

Evaluations of the Electronic Patient Record (EPR) Project (1994-8) at Burton, Wirral (and later Oswestry) highlighted that the active and continual engagement of clinical end users in the requirements, design, implementation and deployment of clinical systems is essential if the hospital medical record is to be fully computerised (Brennan 1996).

17 pilot EHR implementations, within the 2000-2002 Electronic Record Demonstration and Implementation Project (ERDIP) programme, are presently being evaluated with the intention of identifying useful lessons learned about the practical means of realising EHRs within broader health communities.

Examples from other countries

The Health Information Network Australia (HINA) report (National Electronic Health Records Taskforce 2000), published in July 2000, cites several benefits to adopting a national infrastructure approach to the EHR, including:

- better consumer access to their own health information and therefore consumers being able to make more informed decisions about their own health care;
- better provider access to information (with consumer consent) at the point of care;
- increased consumer safety;
- fewer diagnostic tests (including elimination of redundant tests);
- improved warnings and alerts to counter avoidable error;
- better planned and co-ordinated care.

The report proposed the building of a national health information network to permit the systematic collection of clinical and demographic information at the point of care. This would provide for the creation and storage of a summary electronic health record, accessed by authorised users (including health consumers). Although advocating the use of HL7 messages as the primary standard for such a network, it also recommended trials of a comprehensive EHR approach (building on work outlined in section 5.2.7).

The Japanese 'Healthcare Information Strategy 21' emphasises the interoperability, standardisation and security of electronic medical record systems (Toyoda 1998).

As another example, this year the Netherlands has launched a new National ICT Institute for Healthcare, with responsibility for developing an operational Health Information Infrastructure and for the criteria for applications to be able to use it (Freriks, G, personal communication). This

Institute has representation from insurers, healthcare related associations, patient associations, industry and the government.

3.4. Problems with computerised clinical systems

Present day clinical information systems in hospitals and in general practice have not yet proved 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 (Bangemann 1994). The experience of many healthcare professionals (especially in hospitals) is that the clinical computer systems available to them are too slow or cumbersome for use in a realistic consultation time (Drazen 1997). The diversity and complexity of clinical data cannot be captured fully and faithfully on most contemporary systems (Blois 1984), (Rector, Nowlan et al. 1991), (van Ginneken, Stam et al. 1995). Current clinical systems tend to be disease centric rather than patient centric (Haughton 2000).

Duplication of data entry often still occurs because the existing paper folders are usually retained in addition to newly computerised record systems (Derrett, Gordon et al. 1996). In 1998 the American College of Physicians found that most internists used computers for administrative and financial functions but less than 19% had partial or complete electronic clinical functions in their offices (Lacher, Nelson et al. 2000). A more recent Norwegian study suggests that use of computer systems in hospitals remains limited (Laerum, Ellingsen et al. 2001).

Hammond et al describe the present barriers to full information interoperability in healthcare (Hammond, Pollard et al. 1998).

- Existing computer-based patient record systems are primarily derived from hospital information systems (HIS).
- These systems are limited in vision by the current, manual way of using and exchanging data.
- Clinical data still exists in most institutions in different forms and in unconnected bundles of data.
- No common threads of vocabulary exist to permit easy integration of data.
- No consistency of data elements, content and functionality exists to permit easy integration of data, even within one institution.
- Access to knowledge is limited to paper form or independent programs in which the user must query for that knowledge.
- Few systems support real-time use by providers of care.
- Many providers have concerns about patient access to their own healthcare data and about the computer's interference with the process of care.

- Patients are now required to reiterate demographic, reimbursement data, and even clinical data at each different location at which they receive care.

Bleich argues that most existing hospital information systems are procured by managers and maintained by IT staff each trying to meet different agendas from those of the clinical users of such systems (Bleich 1998).

3.5. Visions of a comprehensive EHR

3.5.1. The potential benefits of an EHR

There are many perceived benefits of using EHR systems to acquire, organise and view health record data. Duplicate data entry can be avoided if information is captured, maintained and communicated securely and consistently, in line with clinical needs. The same information can be displayed and viewed in a variety of ways, for example by problem or episode or through summaries, as well as in the traditional chronological order. Standard data sets and templates to assist in their capture and communication can be defined and adapted as practice evolves. A patient record may be accessed from any terminal on a network (even by multiple users simultaneously), and communicated electronically to support seamless shared care. Systems can deliver real-time alerts and decision support on the basis of medical knowledge and information previously documented about each patient.

In 1991 the US Institute of Medicine committee on improving the patient record published a classic report that powerfully endorsed these potential benefits and has shaped US and international thinking about the computer based patient record (CPR) (Dick, Steen et al. 1991) This report defined the CPR as

> *"an electronic patient record that resides in a system specifically designed to support users through availability of complete and accurate data, practitioner reminders and alerts, clinical decision support systems, links to bodies of medical knowledge, and other aids."*

The report proposed the above view of the CPR as the standard for electronic medical records. Its key recommendations were that the CPR:

- contains a problem list;
- supports measurement of health status;
- states the logical basis for decisions;
- can provide a lifelong record of events;
- addresses patient data confidentiality;
- is accessible for use in a timely way at any and all times by authorised professionals;

- allows selective retrieval and formatting of information;
- can be linked to both local and remote knowledge, literature, bibliographic and administrative databases;
- can assist in the process of clinical problem solving;
- supports structured data collection;
- can help individual practitioners and healthcare providers to manage and evaluate the quality and cost of care;
- is sufficiently flexible and expandable not only to support today's basic information but also the evolving needs of each clinical specialty and subspecialty.

The Computer-based Patient Record Institute has since published a number of reports defining the ideal characteristics of patient record systems and discussing issues affecting their adoption, such as (Computer-based Patient Record Institute (CPRI) 1996).

The National Committee on Vital and Health Statistics (NCVHS) 1998 (Information for Health: a Strategy for Building the National Health Information Infrastructure 2002)) describes three types of computer-based health records that are needed to facilitate co-ordination, research, and assessment for clinical care and public health and to permit individuals to participate more actively in their own health care (Humphreys 2000), (Detmer 1998).

1. Patient records "record clinical care and are used by delivery systems in which doctors, nurses, and other health professionals provide an array of hospital, primary care, and other ambulatory and institutional health services." This category includes electronic patient record systems, clinical data repositories and other enterprise data warehouses.
2. Personal or consumer-oriented health records "for individual use, including assessment of health status and linkage with physicians' records." These may include knowledge-based information, such as health education and disease management advice.
3. Population health records are derived "from the health care system and have been made as non-identifiable as possible for public health and research applications. They may also incorporate survey data." This includes monitoring public health, the outcomes of care and health services research.

This view contrasts with other authors who have proposed the electronic health record as a tool to engage patients (citizens) more actively in their health and care decisions in partnership with professionals. This latter approach would favour a single shared record.

3.5.2. Evolving towards an EHR

In 1996 (Waegemann 1996) proposed a five level progression towards Electronic Health Records. This classification is a useful way of reviewing the functional goals of any new EHR design or implementation. His levels are summarised below:

Level 1: Automated Medical Records Still depending on paper-based medical records, although as much as 50% of patient information is computer-generated and stored as computer printouts within the medical record.
Level 2: Computerized Medical Record System Scanning information into a system that offers the same functions as paper-based systems-recording of the health care process and accessibility of previously recorded information. The imaging process does not allow organization of information for users' purposes. For instance, it does not allow data to be transformed into charts or graphs, nor can it aggregate data as is done with computer-generated information.
Level 3: Electronic Medical Records The electronic medical record has the same scope of information as Level 2, but the information is rearranged for computer use. The goal of the electronic medical record is to make the various systems within the institution interoperable. An electronic medical record has the following essential features: (1) an institution-wide system of identifying all patient information, (2) provision of all patient information to all care givers, (3) the use of a common workstation approach including common medical record software, structures, and for patient education.
Level 4: Electronic Patient Record Systems The patient record has a wider scope of information than the medical record. It contains all the health care-related information concerning one person and focuses on the patient and assembles a record that goes beyond the retention period of a particular institution or provider.
Level 5: The Electronic Health Record The more comprehensive term "electronic health record" includes wellness information and other information that is not part of the traditional health care delivery process. Wellness information can include lifestyle and behavioural information captured personally by the individual or by a clinician, parent, or other caregiver.

He estimated then that EHRs for levels 4 and 5 would not surface until 2002. This prediction was clearly optimistic, with work on patient-centred federated systems and patient-oriented health records still at the stage of early demonstrators. Unfortunately the complexity and scale of the task

has often been underestimated, resulting in a tendency towards over-optimistic predictions of how quickly progress can be made.

The UK *Information for Health* definition of an EPR (based on a single institution's records) corresponds to Waegemann's Level 3, whilst the UK vision of the EHR corresponds to Level 4. The distinction between these two terms is now beginning to blur in the UK. However, it is the Level 5 EHR as defined by Waegemann that is required to meet many of the challenges described in this chapter.

3.5.3. Roles of the EHR

The health record is an important tool supporting quality in clinical care. It is today used by personnel trained in different disciplines, working in different settings, on different sites, and in different languages. These include:

- patients themselves and their appointed carers;
- clinicians, in therapeutic or anticipatory care roles;
- groups of clinicians working in primary or secondary care;
- paramedical colleagues working with the patient;
- clinicians and clerical or research staff undertaking clinical audit or quality assurance;
- hospital and general practice managers and health care purchasers (health authorities or insurers) undertaking quality assurance;
- health care planners at hospital, practice, district region or national level;
- legal advisors for the patient or the clinician;
- clinical researchers;
- medical students and medical teachers;
- commercial product developers for market research (e.g. the pharmaceutical industry);
- insurance companies for determining payment, or assessing risk;
- politicians, health economists, and journalists.

Just as there will be many different parties by whom it is accessed, the record can play many roles in the provision of care to individuals and to populations. The following list of roles for the EHR is a consolidated set derived from Shortliffe et al. (Barnett and Shortliffe 1990), the GEHR project (Ingram, Southgate et al. 1992), Health Online (Health Online: a Health Information Action Plan for Australia 1999), the ScopeEPR project (Pringle and Purves 1997), collated by Heard et al (Heard, Grivel et al. 2000).

Supports consumer involvement
Protects personal privacy and reinforces confidentiality
Provides a consumer view of information
Accommodates consumer decision support and self care
Ensures accountability of health professionals
Accesses information for the consumer
Supports consumer health care
Forms the basis of a historical account
Anticipates future health problems and actions.
Describes preventative measures
Identifies deviations from expected trends
Accommodates decision support
Supports communication
Supports continuing, collaborative care and case management
Accesses medical knowledge databases
Allows automatic reports
Supports email generation and electronic data interchange (EDI)
Enables record transfer
Enables record access when and where required
Supports selective retrieval of information
Supports management and quality improvement
Enhances the efficiency of health care professionals.
Supports continuing professional assessment
Facilitates management tasks and reduces routine reporting
Demonstrates and improves cost-effective practice
Accommodates future developments
Provides a legal account of events
Provides justification for actions and diagnoses
Supports population health care
Supports policy development
Provides evidence for development and evaluation of programs
Supports enquiry and learning
Supports clinical research
Assists with clinical audit
Supports medical education

Table 1: Roles for the electronic health record

The list of roles in Table 1 contains many possible conflicts of interest, for example those that would favour a narrative over a structured entry to retain expressiveness. EHR systems will need to support the creation of and access to health records for a wide range of information requirement contexts, whilst prioritising those of direct benefit to individual patients and to the immediate processes supporting their clinical care. These are reflected in the diagram (Figure 8, produced by Ingram D., originally published in (Ingram, Southgate et al. 1992)), which shows the information contexts supporting the care of an individual patient as a set of concentric rings surrounding him/her. The diagram implies that those contexts nearest the centre (i.e. nearest the patient) should be prioritised.

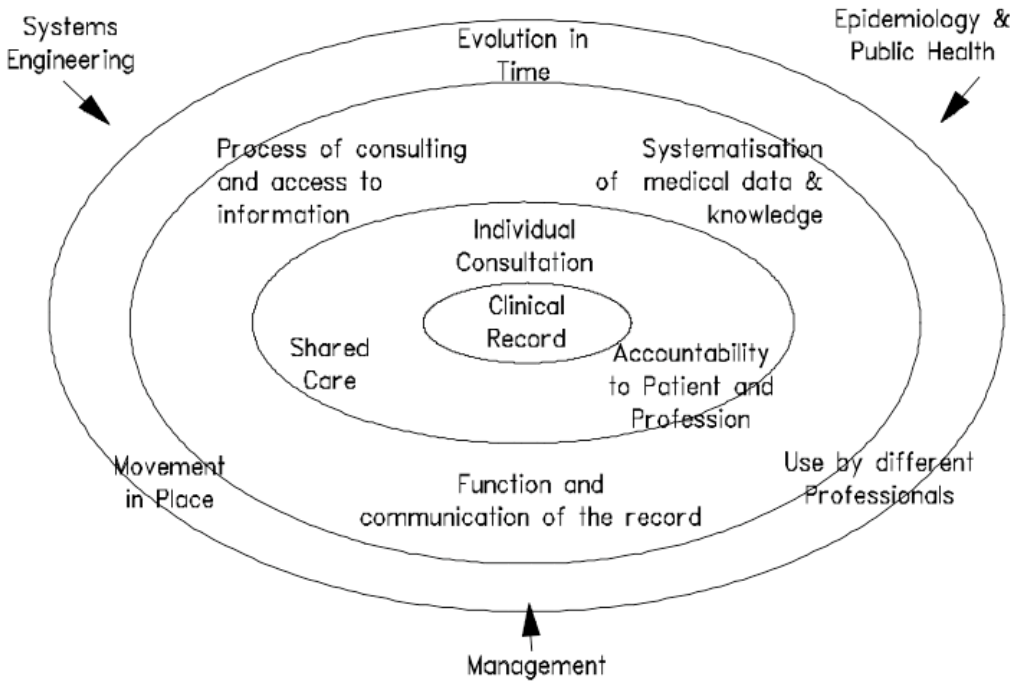


Figure 8: The information contexts surrounding the care of an individual patient

Produced by Ingram D., originally published in (Ingram, Southgate et al. 1992)

(Gordon, Geiger et al. 1998) also propose that the primary focus of the EHR relates to patient care, and that it should be

> *"the logical system that stores detailed information about patients non-redundantly - the single legal version of truth that justified what happened to a patient."*

(Rigby, Roberts et al. 1998) state that

> *"good healthcare delivery, best use of healthcare resources and delivery of a cohesive service …can be achieved only with good communications and a shared clinical perception of a patient's problems and needs – seamless care is difficult to achieve without seamless information."*

In the US Medical Records Institute survey of EHR Trends and Usage (reported by Waegemann in (Waegemann 1999) and on www.medrecinst.com) over 70% of respondents regarded the need to share patient record information between different health care sites as the major clinical driver for EHRs.

(Rigby and Robins 1995) stress the importance of the EHR in supporting team working:

> *" it is important that the enhanced inter-personal communications potential of the networked electronic patient record is exploited by also having a proactive role of supporting, planning, and scheduling activities."*

The EHR needs to represent responsibilities and intentions within the shared care process in order to support effective clinical workflow (Pinciroli, Crippa et al. 2000),(Maij, van Reijswoud et al. 2000), (Boye 1999), (Safran, Sands et al. 1999), (Bricon-Souf, Renard et al. 1998), (Mueller, Ganslandt et al. 1999). (Turley 1995) stresses the need to recognise the differing culture of nurses and doctors in the way information is used even, if the information itself is held in common.

Telemedicine is a major and expanding means of supporting distributed clinical decision making, for example by delivering expertise from centres of excellence to peripheral/community settings. This field of informatics poses requirements for the EHR to capture the substance of a tele-consultation, including the clear accountability for conclusions reached, for determining a clinical management strategy and for confirming the roles and responsibilities for effecting that strategy (Allaert and Dusserre 1998).

Slack suggests that computers offer tremendous opportunities to place patients in control of their own health care (Slack 1998). Lamberts and Hofmans-Okkes propose that the electronic medical record should be anchored in general practice but owned by the patient (Lamberts and Hofmans-Okkes 1996); they have also demonstrated that longitudinal records are important to gain an accurate picture of a patient's health problems (Okkes, Groen et al. 2001). (Richards 1999) stresses the growing evidential, media and legislative pressures to recognise the central role of patients as informed partners in decisions about their own healthcare and in service priority setting. (Brennan 1999) also argues that patients should be regarded as partners in their own health care. Patients can acquire considerable expertise in managing their own health if they are given useful and appropriate material with which to educate themselves (Carl and Gribble 1995), (McKay, Feil et al. 1998), (Jones, Pearson et al. 1999).

(Ramsaroop and Ball 2000) suggest that patients, as consumers of health care, are increasingly expecting to exercise personal and informed autonomy over their health. A third of US home Internet users seek online health advice before calling their physicians (*consumer survey cited by* (Douglas 2001)). The 1997 Eurobarometer Survey found that over 40% of Europeans are interested in on-line access to health information and some services (Flash Eurobarometer 97

1997). More recently the Information Society report found that 23% of Europeans surveyed had searched for health information on the Internet within the past three months (Eurobarometer Special Report 141 2002). (Ball and Lillis 2001) suggest that the Internet can facilitate crucial components of healthcare delivery, including consumer education and disease management. (Kanavos, McKee et al. 1999) suggest that "cross-border healthcare shopping" by EU citizens is likely to emerge to obtain a health care service that is unavailable, poorer or more expensive in their own country.

Analyses of the utilisation of health care resources to investigate cost-effectiveness or equity of care are often limited by the lack of clinical detail to explain the individual circumstances behind a patient management decision. For example GP consultation rates, the admission rates to hospital and length of stay are all influenced by a wide range of socio-economic and health factors other than the patient's primary diagnosis (Black, Morris et al. 1999), (Jankowski 1999), (Giuffrida, Gravelle et al. 1999), (Reid, Cook et al. 1999), (Saxena, Majeed et al. 1999). EHR systems need to be able to identify relevant patient characteristics to inform commissioning decisions and to reduce inequalities in access to service (Smith P. 1999). (Zielstorff 1995) and (Hannan 1999) stress the importance of capturing the data needed to evaluate clinical outcomes. This should include socio-economic information to enable health inequalities to be monitored and corrected (Smeeth and Heath 1999). However, Majeed, in (Gilley and Majeed 1999), points out that most monitoring data required by UK Primary Care Groups on, for example, death, cancer registry and hospital admissions is of variable quality, collected in non-standard ways and not easy to aggregate across practices. An information strategy to tackle this issue is a recognised requirement for Primary Care Groups and Trusts (Proctor and Campbell 1999), (McColl and Roland 2000).

Standard clinical activity data sets have been collected in UK hospital and community settings to inform health service management for nearly twenty years (Korner 1982). Körner codes and minimum data sets were aimed at developing an integrated community and acute care population index, although it has recently been recognised that this kind of information ought to be derived from detailed electronic clinical records (Report on Review of Körner Community Health Services and Cross-Sector Returns 2000).

(Brossette, Sprague et al. 2000) suggest that in the future

> *"the ideal public health surveillance system will include analysis tools that automatically identify, on different time and geographical scales, unusual and interesting patterns from time-slices of raw data."*

The use of selective queries and search tools to analyse health records for reassert purposes is now well established (Murphy, Rabbani et al. 1997), (Vlug, van der Lei et al. 1999), (General Practice Research Database (GPRD) 2002); this issue is also discussed in Section 4.3.5 on clinical data repositories.

3.5.4. Characteristics of the EHR

Good health 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 health record provides the information basis against which new findings are interpreted, and its integrity, completeness and accessibility are of paramount importance. Electronic Health 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. When migrating to electronic health records, it is important to acknowledge how readily the tremendous richness of a clinical dialogue can be expressed on paper (see Figure 9).

In this example, often found useful by the author for teaching, the reader can rapidly deduce:

- that the doctor was not pleased to see this patient, at least at that time of day;
- that the "tonsillitis" is a recurrent reason for attendance;
- that the physical findings are minimal, and not commensurate with that diagnosis;
- that an antibiotic has been prescribed with little or no sound clinical indication;
- that some change in the "usual" consultation for this recurrence has been introduced, by not providing a sickness certificate, with an implication that these have previously been given.

This kind of entry, rich in direct and indirect meaning, might have taken 15-20 seconds to write on paper, whilst an equivalent computerised system might require 1-2 minutes of data entry time. However, it should be noted that the lack of explicit structure has permitted the recording of a consultation in a way that is far from "objective", and the recording system (paper) has passively accepted both a diagnosis and a treatment that is not supported by the clinical evidence. EHR adoption, if it is to meet future challenges, will require a greater clinical attention to data quality.

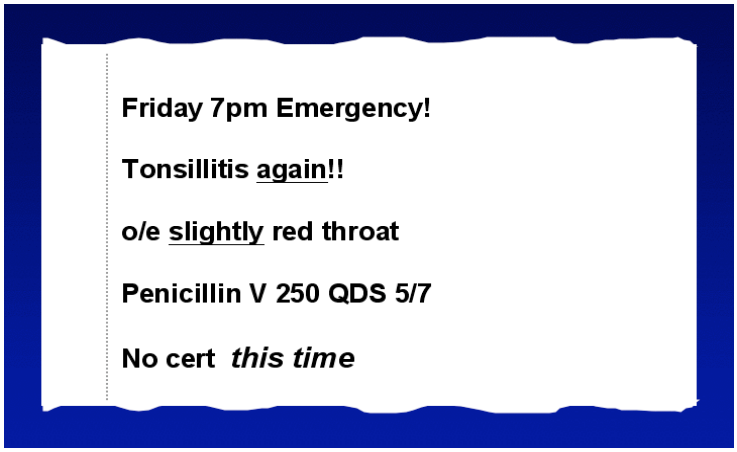


Figure 9: An example narrative record entry, showing the richness that can succinctly be expressed but is full of ambiguity

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 a family history of diabetes or in whom diabetes has been excluded must not erroneously be retrieved in a database search for diabetic patients.

Increasingly clinicians of all disciplines and professions wish to document the rationale behind their decisions, and to share this information with colleagues. Electronic health 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, and within a secure communications infrastructure that allows for the seamless integration of existing (legacy) and new-generation computer systems.

In a teaching setting, it must be possible for medical, nursing and other healthcare students to have access to and to contribute to health records, such that their student status is explicit. Patients (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.

(Rector, Nowlan et al. 1993) stress that the medical record needs to be faithful, which implies that it needs to be:

- attributable;
- permanent (entries can be logically deleted or linked to a corrective comment, but never erased);
- authentic:
- allowing negative and uncertain statements;
- allowing conflicting statements.

(Papagounos and Spyropoulos 1999) suggest that the medical record is not (nor intended to be) a faithful reflection of the life and health of the patient, but is authored by professionals working in an institution whose task is to manage the treatment or prevention of illness. Their perspective will influence what is recorded and how it is expressed.

Chapter 4. History & Evolution of Health Record Systems

This chapter reviews the background and current use of paper health record systems, and the early experiences of the application of computing to clinical information. The present use of clinical computer systems in a range of clinical settings is explored.

4.1. Paper record systems

4.1.1. The evolution of paper records

There has always been a recognised need for those involved in healing to pass on details of successful procedures or potions either by written methods or through an oral tradition. Some of the oldest surviving examples of health care recording are papyri from ancient Egypt, which contain details of surgery and prescriptions.

Until the early 20th century medical record-keeping was erratic and idiosyncratic: most physicians kept some records about each patient but these were often held in personal ledgers. Notes were scattered between homes, hospitals and private clinics and were full of private codes and symbols, deliberately rendering them useless to everybody except the author; at best they served to jog the clinician's memory.

In 1907 the Mayo Clinic and the New York Presbyterian Hospital pioneered the design of a patient-centred record: the Unit Medical Record. Whilst generally popular amongst doctors, problems soon arose regarding the space needed to store, and the staff needed to transport, these files. Sometimes clinicians took to keeping brief additional notes themselves as a backup. The organisation of clinical information within records was also not addressed by this solution. A 1923 textbook noted that "*from the standpoint of scientific record taking, case histories are most glaringly defective in what they fail to record about a patient*" (Pearl 1923).

Since the 1920's attempts have been made to address the issue of data omission, through the use of standard pro-forma to record essential information. When first introduced these were almost universally unpopular, as most physicians demanded that they ought to decide what should be recorded. They insisted that the unique characteristics of each patient and illness required considerable variation and flexibility in the record structure (Reisner 1991). During the mid twentieth century, as medical technology advanced and specialisation increased, the results of x-rays, laboratory analysis, visiting consultant notes and photographs were often pasted in the

margins of records, overlapping each other and sometimes making it difficult to read the original entries. The involvement of different professionals in care has led to records becoming vast repositories of data with little structure to facilitate the processing of these data (Gregson et al. 1991).

The holistic perspective

In 1957 Balint published "*The doctor, his patient and the illness*" which recognised the psychological basis of many health problems (Balint 1957). This book has had a powerful impact, in particular on general practice. This has been reflected in the content of clinical encounter notes, which now tend to contain information relevant to an individual's psychological well-being such as sources of stress, social interactions and perceptions of illness.

The need to value and listen to the story as told by patients is explored in "*Doctors Stories*" (Montgomery Hunter 1991). She suggests that when physicians have a working knowledge of life histories and utilise medical narrative to document the experience of illness they are better able to provide good medical care. The field of narratology is summarised in Section 5.3.4.

The Problem Oriented Medical Record

In his classic paper "*Medical Records that guide and teach*" Weed draws attention to the extent of the disorganisation within hospital paper medical records (Weed 1968a) and (Weed 1968b). He illustrates the way in which a failure to trace the evolution of each problem a patient has can result in unnecessary delays in instigating the correct clinical management or result in needless morbidity. He argues strongly for the advantages of a Problem List as the key organisational structure within patient records, permitting medical problems to be deal with scientifically, improving continuity of care and allowing audit.

In "*Medical records, medical education and patient care*" Weed introduced the Problem Orientated Medical Record (POMR) (Weed 1971). This proposed a format for clinical records consisting of a problem list, a database (history, physical examination and laboratory findings) and, separately for each problem, a plan (diagnostic, therapeutic and educational) and a daily SOAP (subjective, objective, assessment and plan) progress note. The problem list was kept at the front of the medical record and served as an index for the reader so that each problem could be followed through until it was resolved.

The satisfactory functioning of the Problem Oriented Medical Record requires that all data be linked to a problem and be easily retrievable. The POMR has not been widely adopted within paper or early electronic record systems internationally because it has proved too time consuming. In POMR systems the individual note entries are usually classified according to problem but are still

entered sequentially in date order, making it a complex process to acquire a retrospective picture of events within one problem (Feinstein 1973).

4.1.2. Templates, headings and data sets

Well-structured health records improve the completeness of the information documented within a clinical encounter (e.g. (Lilford, Kelly et al. 1992)). In order to support evidence (guidelines) based management, consistent shared care and to allow clinical audit to take place across a range of clinical settings, standardised templates, proformas and summary sheets have increasingly been adopted across all sectors of health care. The design of forms, for paper or computer use, ideally should facilitate rapid and structured data entry catering for the majority of possible responses. This might include the use of anatomical diagrams, tick-boxes, pick-lists and preferred terms; an example is shown in Figure 10 taken from the GP-CARE system developed at CHIME, UCL.

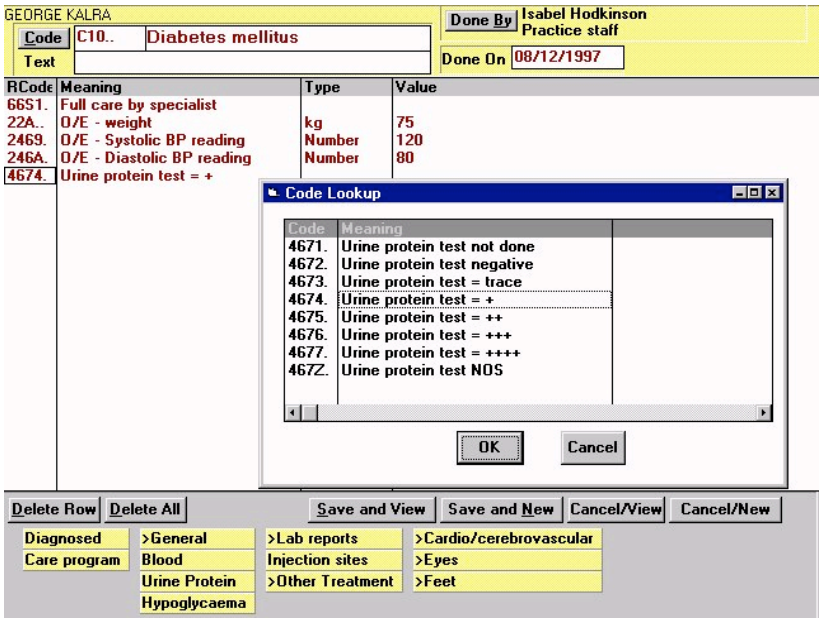


Figure 10: Example computer screen showing pick-lists during data entry within a diabetes protocol

It is important to incorporate some flexibility in the design of these to allow for unique individual findings and for the recording of additional explanatory details. When this flexibility is absent, forms tend not to be completed well and users often revert to using narrative remarks (sometimes using 'white space' on the form to capture this). (Harris, Ellison et al. 1997) have shown that the exact layout of obstetric booking notes affects the accuracy and completeness of the records made. (Leiner and Haux 1996) argue that clinical documents, whether for paper or electronic implementation, must be rigorously designed for the intended purposes and potential uses that will be made of the data. They stress the need to balance the desire for detail with the reality of clinical workflow and workload.

4.1.3. Audit, Quality and Behaviour Change

Clinical audit aims to promote a culture of working to standards and of encouraging clinicians regularly to review the quality of care they provide. This should ideally promote a positive attitude within an organisation towards critical self-appraisal in the context of an open, supportive and learning environment. High quality clinical records are an invaluable resource with which to perform audit. However, the human and financial costs of data collection and analysis for clinical audit are often obstacles to its performance (Lough, Willmot et al. 1999), and clinical audit has proved difficult to integrate into daily practice without specific facilitation (Hearnshaw, Baker et al. 1998).

Present-day computerised systems have hitherto mainly been used to collect easily structured data, such as the reasons for encounters, chronic disease reviews and physiological measurements. Where such information has been entered methodically it provides a valuable resource for audit and for population analyses (for example, Figure 11).

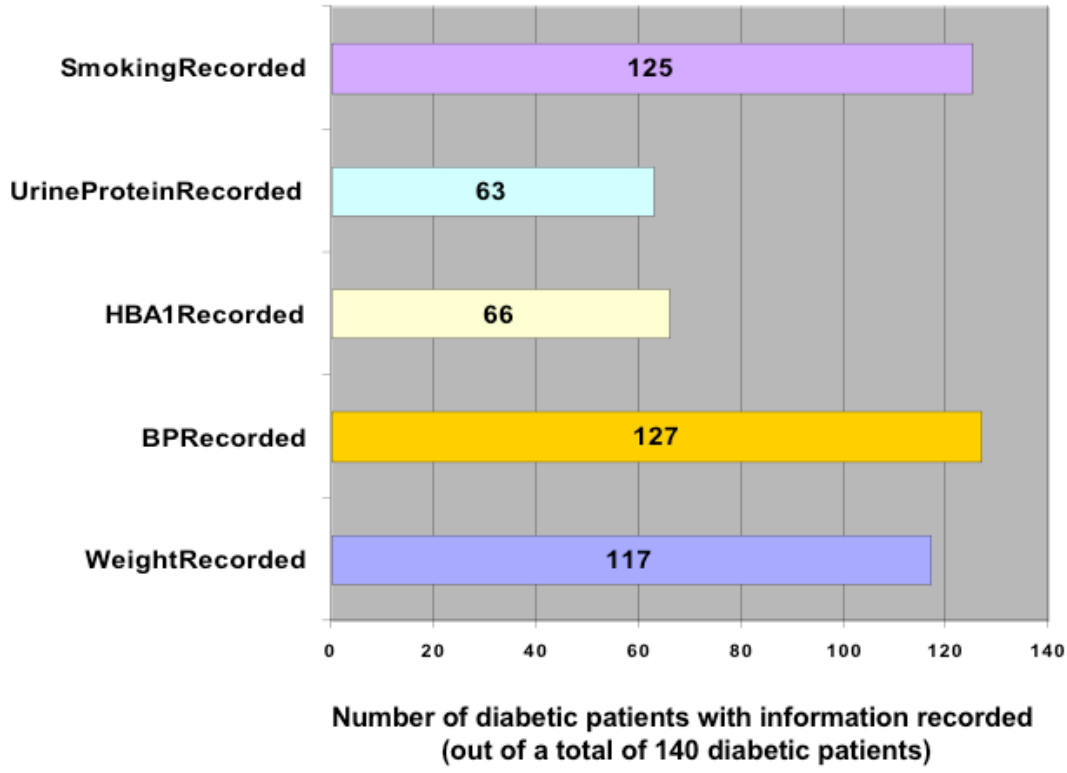


Figure 11: An audit of computerised diabetes records in a London practice

Individual audit activities are nowadays often undertaken in the light of a total quality approach to the care of each patient group. This might include:

- information about and access to a particular clinical service;
- the equipment, training and inter-working of staff;

- adherence to protocols and other evidence of best practice;
- the recording of health care findings and activities (i.e. compliance with standard data sets);
- critical event (clinical risk management) procedures to protect against serious error;
- the safety and security of the environment for staff, patients and their information resources (including patient records).

Ambitious teams sometimes undertake external quality assurance and organisational accreditation, for example under the umbrella of the International Standards Organisation (ISO) 9000 standard (Quality Management and Quality Assurance Standards 1991). More specifically in healthcare, the Health Services Accreditation organisation and The Kings Fund publish standards and undertake formal assessments, such as (Kings Fund 1990), (Kings Fund 1993).

Clinical governance activities require a more detailed analysis of clinical findings and actions than has hitherto been recorded in most computer systems, to present and compare performance and outcomes in ways that are readily understood by a wide range of professionals and by patients. Although the traditional approach of specifying audit data sets can support the evaluation of quality in individual clinical areas, this approach does not scale to the wide range of health care services that good practice now requires to be monitored. The process really needs to be underpinned by a comprehensive and longitudinal EHR.

4.1.4. Integrated care pathways

Clinical guidelines are systematically developed statements designed to assist practitioners to decide about appropriate health care in specific clinical circumstances (Field and Lohr 1990). Most clinical settings nowadays use a range of templates and flowcharts that embody published evidence on clinical effectiveness expressed in the form of algorithmic guidelines. Historically, it has proved difficult to integrate guidelines within everyday clinical practice and to ensure that they remain an effective tool when used during patient consultations (Haines and Feder 1992). Patient encounters are usually hurried, with many agendas to meet within severe time pressures (Ridderikhoff 1993). This makes it a difficult setting in which to think strategically, to practise effectively or to deliver educational messages. Clinical guidelines are renowned for lying on shelves, unread and untouched.

The available evidence on good clinical practice, existing as publications and guidelines, is isolated from the relevant known facts about any particular patient's medical and social background (Smith 1996). Grimshaw and Russell have found that the guidelines are most effective if they deliver patient-tailored advice during a consultation (Grimshaw and Russell 1993). (Smith 1999) questions whether a large body of published guidelines can in itself give rise to a uniform rise in clinical standards. (Woolf S., Grol et al. 1999) observe:

> *"Too often, advocates view guidelines as a 'magic bullet' for healthcare problems and ignore more effective solutions. Clinical guidelines make sense when practitioners are unclear about appropriate practice and when scientific evidence can provide an answer. They are a poor remedy in other settings."*

Feder et al point out that *"the development of good guidelines does not ensure their use in practice"* (Feder, Eccles et al. 1999). (Chu and Cesnik 1998b) suggest that a clinically useful guideline system needs to include links between a patient's problems, activities and target outcomes.

A paper-based, integrated record and guideline approach, known as the *Integrated Care Pathway* (ICP) has been adopted in many hospitals. An ICP combines guidance notes and spaces for capturing the record of care given, and is used by all of the healthcare professionals involved in place of their conventional records. Figure 12 shows a section from an ICP for the management of a fractured neck of femur at the Whittington Hospital in North London.

Assess Pain - F & G Grade A&E Nursing Staff

a) Record Pain Score from diagram below - Pain Score .....score

b) Give Pain Relief as per standing order below

Pain Measurement	Drug	Dose	Route
1-5	Co-dydramol	2 tabs	Orally
5-10	Pethidine	50 mgs	Intra-muscular
Nausea from Pethidine	Prochlorperazine(Stemetil)	12.5 mgs	Intra-muscular

Medication & Dose.....Time Given.....

Complete R_x(Treatment Chart) ☐ .....initials

Assess Pressure Area Risk

a) Record sites of injuries / contusions / pressure areas on Body Diagram below ☐

b) Record Waterlow Score - Waterlow Score: .....score

Pressure Mattress	Given ☐	Not Applicable ☐
Turn Hourly		
1Hour - Yes ☐	2 Hours – Yes ☐	Not Applicable ☐
initial	.....	.....
time	.....	.....

Figure 12: Extract from the Whittington Hospital ICP for fractured neck of femur

The ICP combines medical knowledge, workflow guidance and a multi-professional record within one convenient tool. However, there is considerable variability and volatility in workflow, which can for example be significantly influenced by the temporary absence of one specialist health worker. In an electronic environment these three functions might best be managed as independent but collaborating information systems, with their outputs integrated on screen for the end user. The EHR needs to be able to represent the workflow processes that have given rise to the care acts being documented, and to permit workflow systems to interrogate the EHR from a care pathway perspective.

Although ICPs are gaining in popularity as they integrate the records of multiple professions, they also isolate the information gathered about each clinical problem within individual ICPs. They therefore still fail to provide an integrated health record centred on the patient.

4.1.5. Problems with paper record systems

It has been estimated that 15% of the resources of an acute hospital are spent in gathering and processing information, almost exclusively through paper systems, accounting for up to 25% of doctor and nurse time (The Audit Commission (UK) 1995). A similar proportion of staff time is committed to handling patient data in primary care.

The volume of clinical data accumulated on paper is becoming increasingly complex to manage. (Reinhard, Ohr et al. 1998) report that the University Hospital of Heidelberg (with 1700 beds) creates about 400,000 new medical records per year containing 6.3 million pages and requiring 1.7 km of storage (and growing at the rate of 1500m per annum (Haux 1998)). Physicians create over 250,000 reports and 20,000 procedure reports each year, and service departments around a million results. It is hardly surprising that medical records are not always be available at a point of clinical care, particularly in large institutions. However they are readily portable e.g. to a home visit.

The problems with using paper records are well recognised: poor legibility, disorganised layouts with little or no structure, inconsistent content, difficulties in sharing records within or between sites and difficulties in the navigation, comparison or analysis of the information contained in them, as argued for example by (Weed 1968a), (Rector, Nowlan et al. 1991), (Dick, Steen et al. 1997)). Table 6 below summarises the findings of the 1995 UK Audit Commission that investigated the quality and availability of records within acute hospital trusts (The Audit Commission (UK) 1995).

36% of case-notes were not immediately available at the time of need
75% of hospitals had examples of multiple records for same patient
30% of history sheets were considered to be clinically inadequate
20% of prescriptions were illegible
40% of hand-written discharge letters were illegible

Table 2: Findings of the UK Audit Commission investigation of acute hospital records

More recently, (Kang and Kim 1998) reviewed over 500 paper records in 11 Korean hospitals for completeness and found:

- discharge summaries were completed on average 34 days after discharge;
- less than half of the entries were dated;
- around half of the entries contained illegible statements;

- half of the sheets they reviewed contained an amendment/correction;
- 24% were clearly missing a relevant sheet or form;
- 20% of entries were unsigned;
- 18% of discharge summaries omitted at least one key diagnosis;
- 12% of discharge summaries omitted at least one procedure that had been performed.

(Elson, Faughnan et al. 1997) also stress the disorganised nature of paper records, making them highly unsuitable for information retrieval. However, (Wofford, Secan et al. 356) have shown that there is conflicting evidence for the claims of increased legibility, accuracy or completeness with dictated and transcribed reports over hand-written ones. Collen has suggested that paper and computerised record systems co-exist largely because of the difficulty in capturing complex clinical information electronically (Collen 1993).

Patients and clinicians are generally keen to encourage the sharing of record information in order to enable the best possible clinical management decisions to be made and to minimise the duplication of investigations. In a shared care situation, even if both parties have computerised systems, their likely incompatibility means that valuable clinical time is spent extracting information to prepare letters and reports, and even more frustrating time is sometimes required to enter this data back into the recipient's computer system. Dumont et al, in a survey of 160 staff within two Dutch hospitals, found that communication within and between care teams was considered to be the most important role for the EHR that was poorly fulfilled by paper systems (Dumont, van der Loo et al. 1998). (Branger, van 't Hooft et al. 1998) have shown that the incorporation of ten key data items for diabetes monitoring into an EDIFACT message from hospital clinics to GPs can greatly increase the information available to those GPs for continuing a patient's care when compared with traditional paper clinic letters.

4.1.6. Migrating from paper record systems

Despite the progressive introduction of computerised information systems across Europe, the majority of clinical detail in health records and in communications is still on paper records (Fischer and Stratmann 1980), (Campbell, Ginver et al. 1989), (Tang, Shortliffe et al. 1991), (Emerging Trends in Information Technology 1995), (Dick, Steen et al. 1997), (Wyatt 1995).

The paper health record is a tool that has been progressively refined over centuries. Clinicians, often working under considerable time pressure, have acquired great skill at assimilating salient points from a record folder that is often quite disorganised, and usually without a recent summary (Nygren and Henriksson 1992). Health records contain a rich use of synonyms, abbreviations, symbols and colloquialisms. Whilst making the record efficient to write and interesting as a narrative, this diversity also causes considerable difficulty for effective and reliable communication.

There is increasing pressure on clinicians to code consistently and to use standardised templates to facilitate evidence-based and quality assured care; however there are times when narrative is required to convey ideas faithfully. The health record should ideally be structured in a way that preserves the meaning of the information when it was originally written, so that it can be understood if read by another person elsewhere.

4.2. Pioneering computerised record systems

4.2.1. Origins and early adopters

From the early seventies to the mid eighties several US Academic Medical Centres pioneered the application of computers for the management of clinical information. Many of these have their origins in the acquisition and analysis of laboratory data. As they grew in scope and scale some focussed on capturing the health problems, investigation reports and medication records of individual patients, others had a greater emphasis on capturing best practice and medical knowledge through on-line access to the medical literature, protocols and alerting systems. Some pioneering systems were also developed in Europe during that period. This section summarises the experiences gained by these early adopters.

Possibly the earliest hospital information system was the Technicon Data System (TDS), initially developed as a nursing station system and first installed at the El Camino Hospital, in Mountain View CA in December 1971. By October 1974, 78% of the physicians used the system for either entering orders or reviewing results, and 45% of all orders were entered directly by physicians (Barrett, Barnum et al. 1975) *cited in* (Sittig and Stead 1994). The earliest hospital information system in the UK was the Sperry Univac installed at the Royal London Hospital in the mid 1970's. Examples of the application of computers specifically for clinical care include the renal dialysis computation and graphing software developed at the Charing Cross Hospital in London in 1982 and used in several centres across Europe and North America (Gordon, Venn et al. 1983).

4.2.2. COSTAR

COmputer STored Ambulatory Record was designed at Massachusetts General Hospital by G. Octo Barnett. It was first installed in 1969 within a group outpatient practice and later became the primary hospital-wide system. Its goals were the improved availability of medical information, improved quality of patient care, the support of healthcare research and demonstrated cost effectiveness (Barnett 1984).

Clinical data capture was though encounter reports (initially via paper forms, later through transcription). COSTAR provided an overview of a patient's current medical status, flowcharts of medication and observations, clinical reminders; core record summaries were printed out for

clinical use. An evaluation in 1989 showed good access to the record when needed, particularly to the most recent patient encounter and a current problem list (Campbell, Ginver et al. 1989). Telephone enquiries and prescriptions were better managed, but use of COSTAR was mainly by nursing and clerical staff and not doctors.

COSTAR has been commercialised and installed at several sites internationally. The systems has acquired the reputation of richly supporting end-user queries, using a dedicated query language based on its MUMPS architecture, although only about 10% of queries are related directly to clinical care (Murphy, Morgan et al. 1999). A web interface has now been developed to access the repository containing over 40,000 patient records (Barnett and Chueh 2000).

4.2.3. Harvard Centre for Clinical Computing (CCC)

Slack & Bleich began the development of research-based computer systems in the early 1970's, at Beth Israel Hospital in Boston (Bleich, Beckley et al. 1985). They recognised the potential for a computer system to support clinical practice through the immediate provision of diagnostic test results, access to medical literature, give advice, consultations, alerts and reminders, assist with communication and participate directly in the education of students and house staff. The authors have demonstrated a number of successes of the system (Slack and Bleich 1999):

- user acceptance, particularly amongst voluntary (clinical) users, with increasing access measured over decades and through user satisfaction questionnaires;
- studies of alerts and reminders showing the reduced morbidity associated with antibiotic monitoring and alerting systems;
- reduced outstanding debts and reduced receivables days;
- heavy use by students and interns for learning.

The original system was written in MUMPS, and ran both at the Beth Israel Deaconess Medical Centre and the Brigham & Women's Hospital, in Boston. It is now also used at the Massachusetts General. The system has been used to provide an integrating environment between the Brigham and Women's Hospital and Massachusetts General Hospital, under the Partners HealthCare System (Teich, Glaser et al. 1999), (Sittig, Teich et al. 1997), (Yungton, Sittig et al. 1998).

The categories of clinical data within the Clinical Data Repository are shown in Figure 13 (Glaser 2000).

Partners Clinical Data Repository Contents (1/00)
Dates in parentheses indicate the age of the earliest result

BWH Clinical diagnostic results		*MGH Clinical diagnostic results*	
Specimens and test results for		**Specimens and test results for**	
• Chemistry Imm	(3/89)	• Chemistry	(6/90)
• Haematology	(8/88)	• Haematology	(6/90)
• Microbiology	(6/87)	• Immunology	(10/92)
		• Microbiology	(8/91)
Procedures and text reports		**Procedures and text reports**	
• Radiology	(6/88)	• Radiology	(4/92)
• Pathology	(6/89)	• Pathology	(12/92)
• Cardiology	(8/86)	• Cardiology	(1/93)
• Endo Notes	(2/97)	• Endoscopy	(6/96)
• Discharge Summaries	(11/89)	• Discharge Summaries	(7/92)
• Operative Notes	(11/89)	• Operative Notes	(7/92)
• Pulmonary	(1/90)	• Pulmonary	(9/96)
• Neurophysiology	(7/91)		
• Dialysis	(9/90)		
• GFR	(5/96)		
• Vascular	(7/92)		
Specimens and activity		**Specimens and activity**	
• Blood Bank	(2/89)	• Blood Bank	(12/95)

Figure 13: Categories of clinical data within the Partners HealthCare System

Reproduced from (Glaser 2000)

Users can now access this integrated information via web-based forms (Karson, Perkins et al. 1997). This virtual EHR (called W3-EMRS) requests patient details from all of the federated sites via HL7 request and response interfaces (Halamka and Safran 1998). Initial evaluations show high user satisfaction with performance, layout and information content (Halamka and Safran 1997).

An Online Medical Record (OMR) system at the Beth Israel Hospital (Safran, Sands et al. 1999) is used extensively by clinicians for problem lists and medication, orders and results, transcribed notes but not for clinical encounter details. It is integrated with a large library of prompts, reminders and decision support algorithms, and used in over 60 clinic sites in a 12-mile radius around the hospital. (Sands, Rind et al. 1998) observe:

> *"Although the system was intended to eliminate the need for paper, we have found that it has, in the short term, increased the amount of paper produced."*

4.2.4. TMR

The Medical Record was the vision of William Stead and Ed Hammond at Duke University Medical Centre, where it was initially installed for outpatient clinic use in 1969 and later extended to inpatients. The goals of TMR were to achieve legible records, high data availability, a clinically

focused data display, expert reminders, time saving and the creation of a longitudinal history database (Stead and Hammond 1988).

TMR was intended for the direct capture of data during care episodes, based around a list of problems, diagnoses, procedures. These could be associated with symptoms, physical findings, laboratory data and therapeutic interventions. The system offers views of the data by problem, time, task or encounter, and links to other third party databases, spreadsheets and management information systems. The system includes a data dictionary of data elements, menus, terms, algorithms and decision-making rules.

It is still in active use and has now largely obviated the need to refer to paper records, although these are still maintained (Hammond E, personal communication).

4.2.5. Regenstrief Medical Record System

The Regenstrief Medical Record System (RMRS) originates from a diabetes departmental information system developed in 1972 at the Wishard Memorial Hospital (McDonald 1976). The record system includes patient-specific medical reminders to assist with routine clinical activities such as the most common investigation or treatment for a clinical problem. A pioneering Physician Order Entry (POE) system was able significantly to reduce inpatient charges and hospital costs (Tierney, Miller et al. 1993). An early feature of the system was the use of a data dictionary that governs the schema within the clinical database. This has enabled the clinically driven expansion of the system to cover all aspects of patient care delivered within the three main hospitals of the Indiana University Medical Centre and 30 community-based clinics.

(McDonald 1997) describes the mixed use of paper and electronic medical record systems.

> *"The medical record system now carries records for more than 1.4 million patients, including more than 6 million prescription records, hundreds of thousands of full text narrative documents, nearly 200,000 EKG tracings, millions of orders per year, and 100 million coded patient observations and test results. It includes all diagnoses, all orders, all encounters, all dictated notes, and a mix of clinical variables from selected clinical sites. It does carry a great proportion of what care providers need to know about the patient, but it does not include everything. Physicians still hand-write daily notes in the hospital and most visit notes in clinics, and we don't capture most of that content in the computer. So, we still have a paper chart, but our Electronic Medical Record (EMR) has eliminated most of the need to access it. Physicians always turn to the computer record first."*

Clinicians use the system for inpatient notes 15% of the time, and around 25% of the time for outpatient notes (McDonald, Overhage et al. 1999).

4.2.6. Columbia Presbyterian Medical Centre

The Columbia-Presbyterian Medical Centre has been developing an integrated hospital information system since 1985 (Hendrickson, Anderson et al. 1992). The core components of the current clinical information system are described in (Cimino 1999).

- Central repository: a patient-event oriented relational database schema (Johnson, Paul et al. 1997).
- Data Access Modules: programmes that allow external applications to retrieve data from or commit data to the repository.
- Medical Entities Dictionary: a metathesaurus of coding terminologies linked by clinical concepts (described in Section 5.7.2.).
- Data monitor: reviews incoming and repository data for necessary actions: coded as Arden Syntax Medical Logic Modules (see Section 5.10.2).
- Medical Language Extraction and Coding System: for parsing natural language reports and for deriving coded terms to be passed to external knowledge sources via "Infobuttons" (see Section 5.9).

The Centre has been very committed to the development of secure web-based applications to support distributed access to the clinical data (Cimino, Socratous et al. 1995), (Hripcsak, Cimino et al. 1999), (Jenders, Dasgupta et al. 1998).

4.2.7. HELP

The HELP system at the Latter Day Saints (LDS) Hospital in Salt Lake City was originally developed for the interpretation of cardiac and aortic pressure measurements arising from cardiac investigations (Gardner, Pryor et al. 1999). ICU clinical user experience provided the impetus for systems that gave birth to HELP (Warner, Olmstead et al. 1972), initially as an on-line critiquing system for ordering blood products. It has progressively integrated patient data from several different hospital sources (Pryor, Gardner et al. 1983). Its medical record system was designed to minimise access time to records and to provide flexibility in data use, with the capability to expand its medical vocabulary over time (Pryor 1988).

The HELP system now spans much of the hospital, and interfaces with several third party modules via HL7 messages. It has been evaluated through clinical questionnaire surveys during the early 1990's, involving over 600 doctors and nurses. Ready access to laboratory data and alerts were rated highly, and respondents did not perceive the decision support as a threat or a restriction on their own decision making powers (Gardner and Lundsgaarde 1994).

The growing patient record repository within the HELP hospital information system has been used to detect patients having an unusually long length of inpatient stay given their clinical condition (Nelson, Gardner et al. 1994). HELP has been shown, in outcome studies, to influence antibiotic prescribing: reducing cost, reducing total administered doses, reducing adverse drug reactions (Gardner, Pryor et al. 1999). (Aronsky and Haug 2000) have demonstrated that data routinely present in the HELP system is sufficient to enable computerised decision support for the diagnosis of acute community-acquired pneumonia, including the analysis of free text imaging reports to detect the diagnosis of pneumonia (Gardner 1999).

4.2.8. Diogene

The Diogene system at the University Hospital of Geneva (Borst, Lovis et al. 1998) is sometimes regarded as the most successful European example of a pioneering Hospital Information System. It was conceived by the late Professor Jean Raoul Scherrer in 1977-8 and developed over the past 20 years under his direction as a leading European clinical system and a centre for pioneering health informatics research.

The EHR component, ARCHIMED, is a federal database fed by over 25 departmental clinical applications, usually overnight, which enables real-time clinical access to comprehensive reports and summaries as well as facilitating the statutory reporting requirements of the hospital (Borst, Appel et al. 1999). Several facets of the system are considered in other chapters, as the site has participated as a demonstrator in the Synapses and SynEx projects.

4.2.9. The BAZIS HIS

The BAZIS (HISCOM) HIS originated from a government-sponsored project at the Leiden University Hospital (1972-6) resulting in an operational system with 100 terminals. The system implemented interfaces with Dutch EDIFACT messages and HL7, but through APIs (i.e. HL7 did not drive the specification of the internal data model or end-user applications).

The project had a strong focus on functionality for the clinician, illustrated by their early adoption of a patient-centred databank. The databank initially provided clinical access to laboratory and PACS systems, and had an ambitiously large number of terminals to ensure availability of the information. Later modules included nursing, medication, orders, scheduling, theatres and an evolving EPR. Regular evaluations have shown high system availability and user acceptance, decrease in healthcare costs, improved planning of capacity and research; improved quality of care has also been demonstrated, though improved access to information (Bakker and Leguit 1999).

4.2.10. The Royal Marsden HIS

The Royal Marsden NHS Trust and the Institute of Cancer Research together form the largest comprehensive cancer centre in Europe and the second largest in the world. The hospital spans two sites, one in Central London and the other in Surrey, served by an integrated information system illustrated in Figure 14.

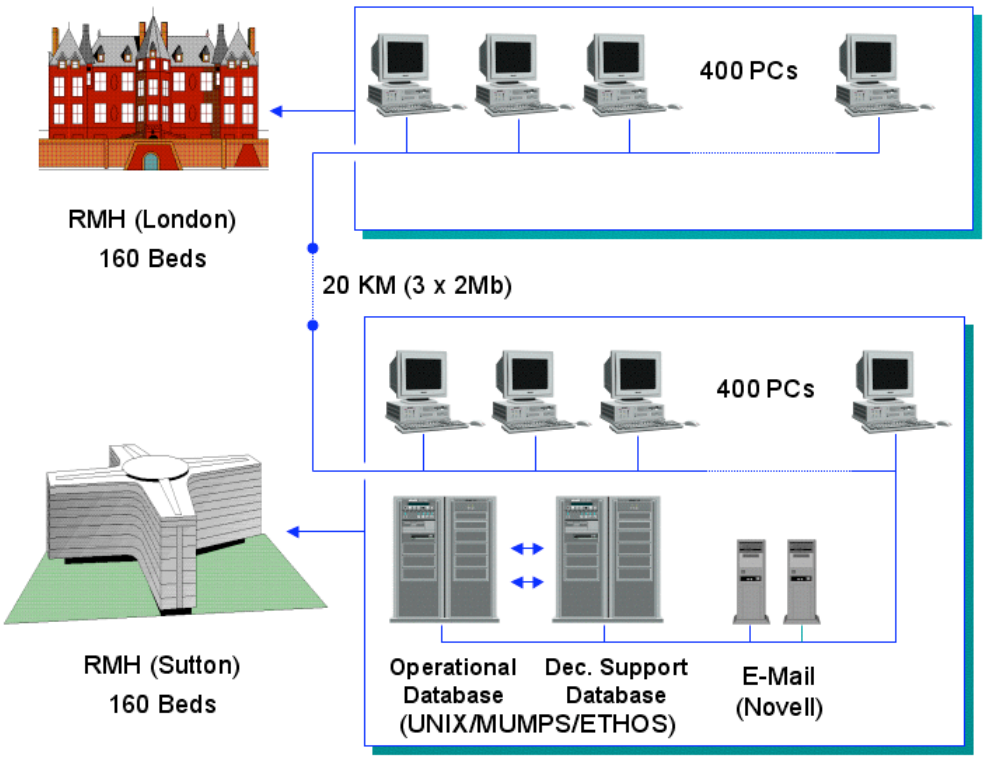


Figure 14: Overview of the Royal Marsden Hospital information technology environment

The Royal Marsden Hospital provided a demonstrator site for the Synapses project (see Section 5.2.3), with which the author was closely involved, and contributed to the validation of the federation approach that subsequently informed the design and implementation of the UCL FHR service.

The hospital information system provides a patient focussed repository containing cancer data elements that meet the needs of patient care whilst enabling this care to be evaluated and costed on an on-going basis. This comprehensive integrated HIS, developed using an in-house tool set, comprises an object-relational database layered onto MUMPS and an active data dictionary with advanced object oriented features (illustrated in Figure 15).

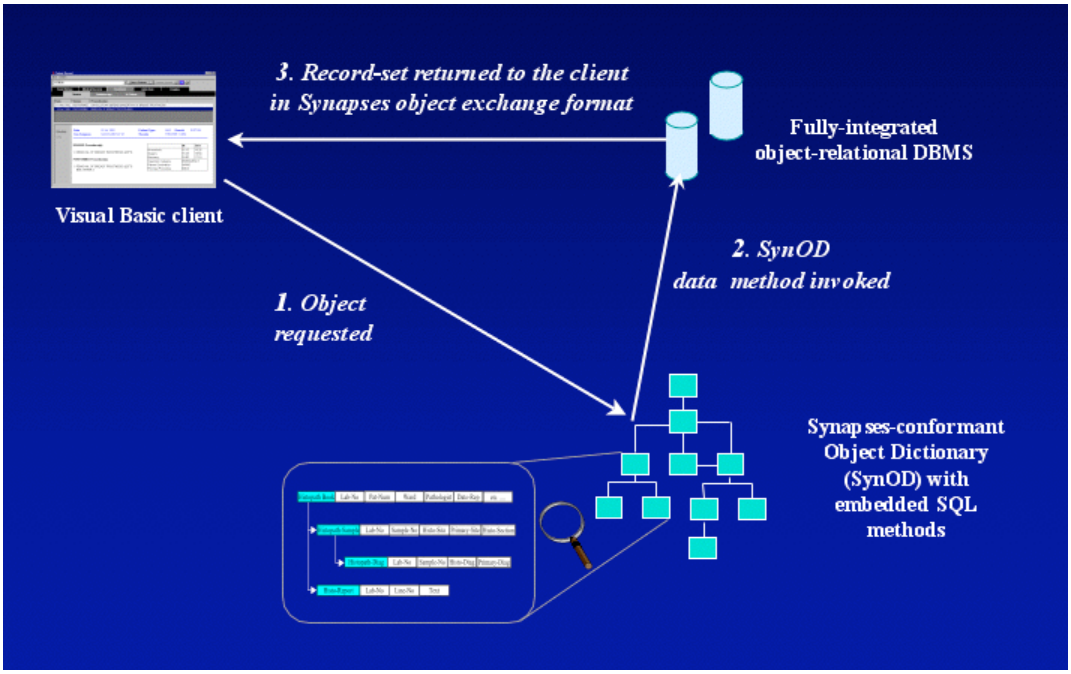


Figure 15: Royal Marsden Hospital system design

The main technical challenges tackled during Synapses were to represent clinical user objects in terms of an active data dictionary, and to provide the client PCs of different user groups with integrated views of these objects via a standardised (Synapses-conformant) interface. The active data dictionary provided a practical example of a scalable metadata driven approach; this is discussed further in Section 5.7.2. Screens from this application are illustrated in Figure 16 and Figure 17 below.

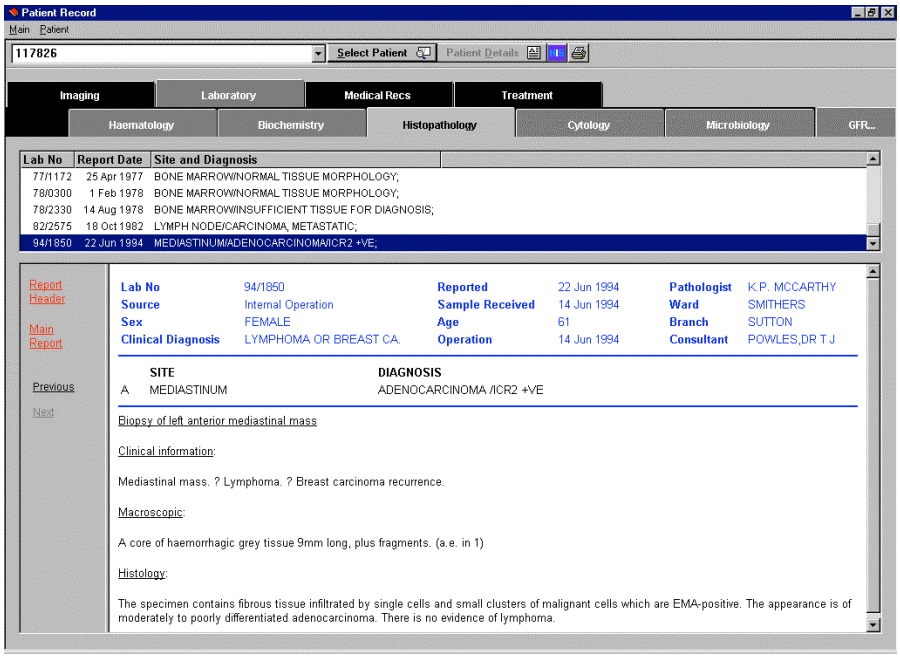
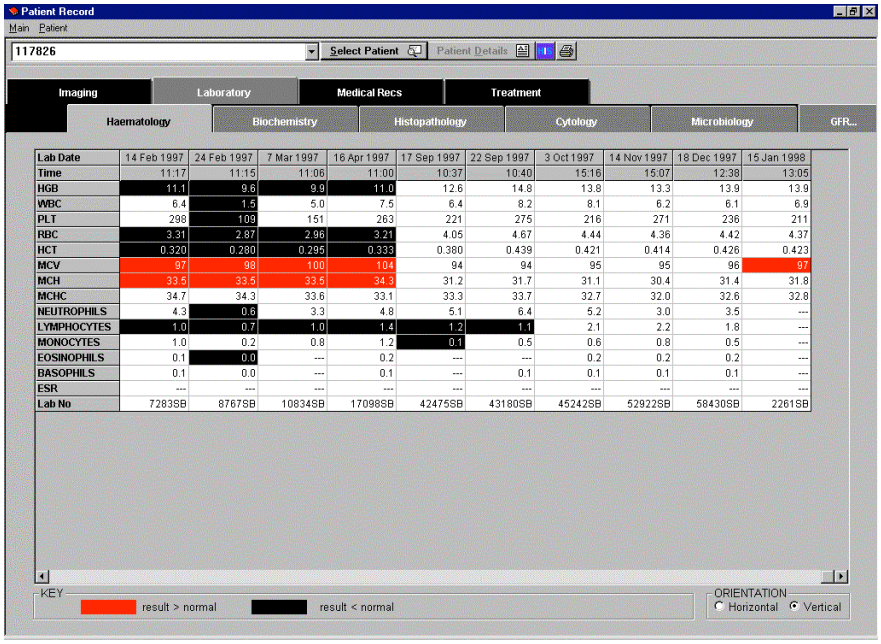


Figure 16: Histopathology report screen from the Royal Marsden Hospital



Lab Date	14 Feb 1997	24 Feb 1997	7 Mar 1997	16 Apr 1997	17 Sep 1997	22 Sep 1997	3 Oct 1997	14 Nov 1997	18 Dec 1997	15 Jan 1998
Time	11:17	11:15	11:06	11:00	10:37	10:40	15:16	15:07	12:38	13:05
HGB	11.1	9.6	9.9	11.0	12.6	14.8	13.8	13.3	13.9	13.9
WBC	6.4	1.5	5.0	7.5	6.4	8.2	8.1	6.2	6.1	6.9
PLT	298	109	151	263	221	275	216	271	236	211
RBC	3.31	2.87	2.96	3.21	4.05	4.67	4.44	4.36	4.42	4.37
HCT	0.320	0.280	0.295	0.333	0.380	0.439	0.421	0.414	0.426	0.423
MCV	97	98	100	104	94	94	95	95	96	97
MCH	33.5	33.5	33.5	34.3	31.2	31.7	31.1	30.4	31.4	31.8
MCHC	34.7	34.3	33.6	33.1	33.3	33.7	32.7	32.0	32.6	32.8
NEUTROPHILS	4.3	0.6	3.3	4.8	5.1	6.4	5.2	3.0	3.5	---
LYMPHOCYTES	1.0	0.7	1.0	1.4	1.2	1.1	2.1	2.2	1.8	---
MONOCYTES	1.0	0.2	0.8	1.2	0.1	0.5	0.6	0.8	0.5	---
EOSINOPHILS	0.1	0.0	---	0.2	---	---	0.2	0.2	0.2	---
BASOPHILS	0.1	0.0	---	0.1	---	0.1	0.1	0.1	0.1	---
ESR	---	---	---	---	---	---	---	---	---	---
Lab No	7283SB	8767SB	10834SB	17098SB	42475SB	43180SB	45242SB	52922SB	58430SB	2261SB

Figure 17: Haematology cumulative results screen from the Royal Marsden Hospital

The health record server at the Royal Marsden has been developed to a point where it acts as a viable substitute for the paper record in many circumstances (Kalra, Milan et al. 1998a). The benefits of this are substantial in an environment where patients are seen frequently and the paper record may be in the hands of many different care providers or research workers. These benefits have sold the value of an electronic record to clinicians who are now actively participating in the process of implementing a structured record.

4.3. The adoption of clinical information systems

The pioneering US and European clinical systems reviewed in Section 4.2 show that user acceptance, efficiency gains and some outcomes benefits can be demonstrated through their use. These systems have all been developed "in house" through a progressive evolution of functionality and scale, usually through close working partnerships between the development teams and clinical champions, over a period of decades. Even then, few successes have yet been reported in achieving complete direct clinical data entry at the point of care.

4.3.1. Experience from other hospital information systems

Kaiser Permanente

(Churgin 1994) describes the introduction during 1993-4 of the EpicCare system at the Chandler Primary Care Clinic in Arizona, which included template based entry screens, coding support, flow-sheets and report generation and laboratory result import interfaces. Nursing staff found that the system enhanced efficiency in assessing patients, was acceptable to patients and reduced time spent

on routine administration. Physicians found that their level of coding improved, and that the average number of lines of transcribed notes fell by 80% within four months. They valued the range of summary views provided in the system and the immediate availability of previous entries when seeing a patient.

(Chin and Krall 1997) describe the process of implementing and adopting the EpicCare EMR system in the ambulatory setting of Kaiser Permanente's Northwest Region, which commenced in 1994. Several departmental systems such as radiology and laboratory, ADT and demographics, transcription reports were fed into a read-only Results Reporting System repository for review as event-based summaries. An evaluation in 1998 showed high user satisfaction with this Results Reporting System (Marshall and Chin 1998). However a newer EpicCare EMR system, requiring direct data capture from clinicians, was seen to take time away from patient contact.

OCIS

The Oncology Clinical Information System (OCIS) at Johns Hopkins Hospital, operational since 1978, has been designed primarily to support clinical care. The system has a repository focused on the individual patient and their accumulated health data, with links to protocols and alerts. It has been developed gradually over fifteen years, in response to user requirements, which the authors believe to have contributed to the wide acceptability and use of OCIS. The system is regarded as critical to their management of patients by over 90% of cancer physicians (Enterline, Lenhard et al. 1994).

Between 1986 and 1991 OCIS was ported from Johns Hopkins to an Australian tertiary cancer care centre in New South Wales (Hannan 1998). Hannan points out that active development on the system ceased in 1991, as administrators saw the system as "complete" and sought a return on investment rather than continuing to invest in its evolution (Hannan 1994). This contrasts with the continual evolution fostered at Johns Hopkins Hospital, and has resulted in the Australian version failing properly to be incorporated into the clinical care process.

UK EPR Project

The UK NHS EPR Project attempted to incorporate a rich clinical information repository in each of two acute hospital trusts between 1996-9, in order to convince managers of the benefits of EPR systems and to influence suppliers to develop the next generation of hospital information technology. A formal evaluation carried out by the Open University showed that the eventual demonstrators were less sophisticated and less ambitious than was originally planned and that there was insufficient user involvement in design and implementation (reported in (Dodd and Fortune 1995)). It was recognised that clinical involvement in the design and adoption of an EHR system is critical to its success.

Veterans Affairs System (VistA)

Open Source software is sometimes considered a means by which organisational IT costs can be reduced. However, Brown reports that the cost of human and technical resources required to deploy a "free" (Open Source) VA system (VistA) at the Veterans Affairs Medical Center, Nashville was $2.6 million (Brown 1999). Three quarters of this was for computing and network infrastructure, and around a quarter for the staff time to champion the system adoption or to deliver training.

Developing integrated hospital information systems

Hospital information systems have evolved during the 1990's to support the capture and analysis of clinical activity in order to manage healthcare costs. Many now use HL7 messages to link modular departmental components such as PAS, radiology, laboratory and pharmacy to clinical applications for the encoding of clinical diagnoses and procedures. However most computer-based patient records in the late 1990s still contained mostly administrative and accounting data, and little clinical data (Collen 2000). As a consequence, many enthusiastic physicians have developed *ad hoc* databases to store clinical details about their patients, for research, educational or audit purposes (Gage 1999).

(Kohane, Greenspun et al. 1996) argue that many hospital information systems are designed to old architectural models, using closed data structures and local coding schemes, which obstruct any attempts to integrate these with any other local or remote systems, including departmental clinical systems. (Covvey and Stumpf 1999) report that the cost of interfacing legacy systems is large (they estimate over $500,000 for interfacing 8 legacy laboratory applications). (Sanders, Mann et al. 1997) also point out the complexity of migrating departmental legacy databases to a modern SQL compliant relational database.

Only 15% of hospitals across Europe have implemented the full integration of their centralised administrative database systems with these departmental clinical systems (Iakovidis 1998a). (Broverman, Schlesinger et al. 1998) suggest that attempts to integrate departmental applications have been hampered by a lack of EHR standards and comprehensive controlled vocabularies. However (Fairey 2000) observed that clinical interest in integrated EPRs at the Royal London Hospital was limited until the late 1990's.

(Hripcsak 1997) advocates a layered and modular approach to integrated hospital systems, using a middleware layer that fulfils a number of mediation services such as message handling, code translation, alert monitoring and access management. Conversely Anderson argues that integration was possible because his Hospital Trust elected to upgrade all of their core information system modules through one supplier (Anderson 2000a). (Chen and Gough 1995) have shown that a near paperless hospital can be achieved in a green-field situation at the National Cheng Kung University Hospital in Taiwan, using a single vendor "turn-key" solution.

(Kuhn, Lenz et al. 1999) suggest that the process of selecting a HIS, whether from a single vendor or assembled from multiple components, is a non-trivial challenge: single-product vendors promise wide ranging functions and comprehensive data integration, while component specialists offer elaborate and specialised functionality. (Weston Smith 2000) observes that up to 50% of a hospital IT project can be consumed by the procurement process. (Stead, Borden et al. 1996) stress the importance of human and organisational factors in planning a long term programme to develop and deploy integrated information management systems.

Multimedia integration

Multimedia integration with clinical systems has focussed on the provision of:

- radiology reports with an X-ray image viewer, usually based on the DICOM standard (see Section 5.6.3), now a feature of many radiology information systems, e.g. (Wang and Starren 2000)
- histopathology reports with photographs of the various tissue sections, e.g. (Frankewitsch and Prokosch 1999);
- biosignal reports, usually presented as an image of the signal trace, e.g. (Ip, Law et al. 1995), (Wang and Ohe 1999), (Norris, Dawant et al. 1997)
- image archives (radiology and/or histopathology) with anonymised and indexed reports for case-based learning or decision support, e.g. (Crowley, Gadd et al. 2000), (Hatton, Woods et al. 1997), (Le Bozec, Jaulent et al. 1999), (Le Bozec, Zapletal et al. 2000).

Example screens of on-line radiology reports are shown in Figure 18 and Figure 19 below.

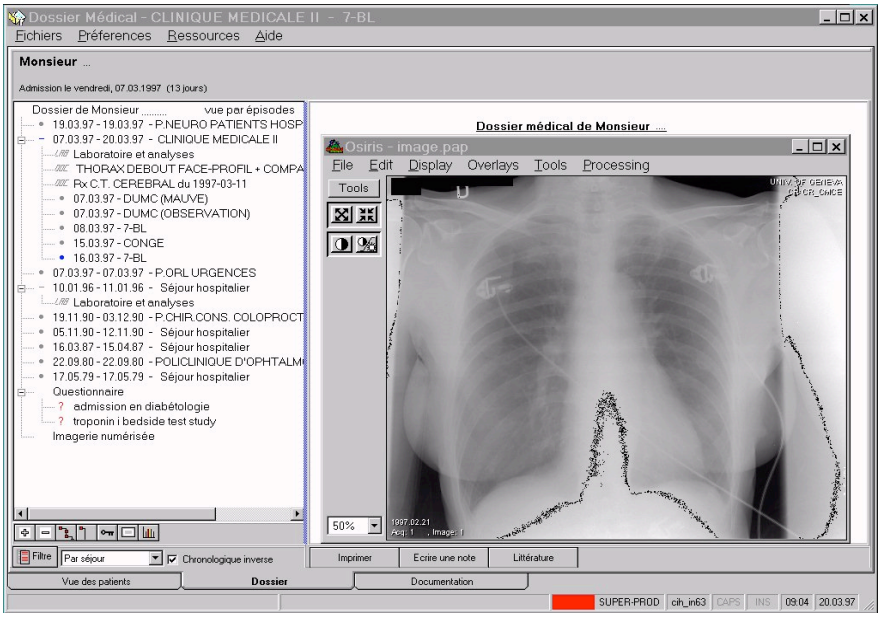


Figure 18: The incorporation of a radiological image (University Hospital of Geneva)

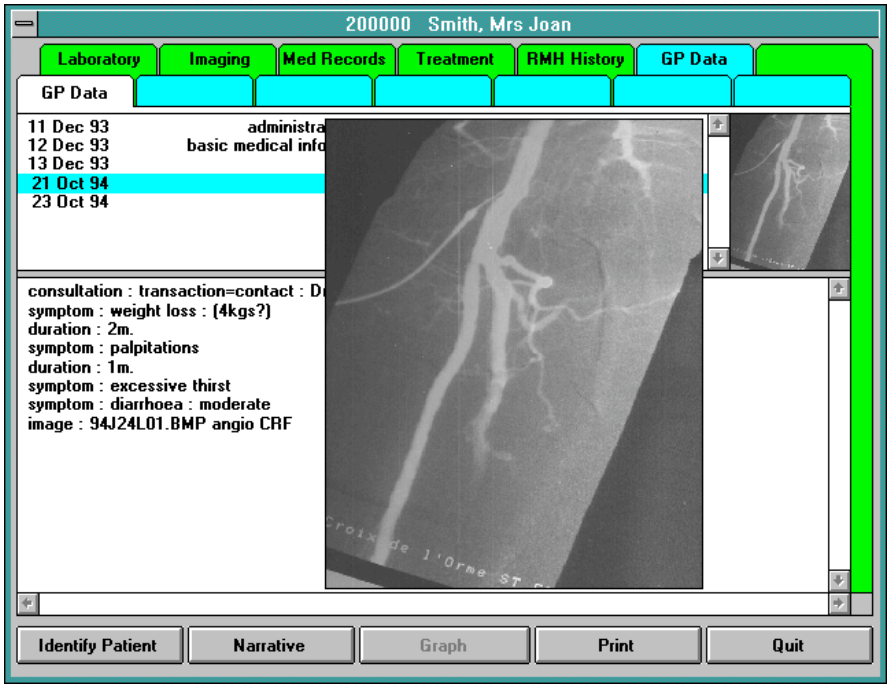


Figure 19: The incorporation of a radiological image

(Royal Marsden Hospital)

Complex data types, such as images and biosignals, play an important role in both diagnosis and treatment. These are increasingly being captured in digital form, and new clinical systems are beginning to exploit direct interfaces to the diagnostic systems used to capture and analyse multimedia data, such as radiology information systems and cardiographic interpretation systems. There is a compelling case for such data to form an integral part of a patient's EHR, included as formally authorised and attributed multimedia reports.

4.3.2. Nursing information systems

In 1996 (Goossen 1996) noted that

> *"the term nursing information system is often used incorrectly: many systems support only data entry, but not data notable for nursing care as a systematic process of assessing, planning, implementing and evaluating care."*

However, some centres have developed modules specifically for nursing assessment and care.

Since the early 1990's The Medical Record (TMR) has been used by nurses to complete automated physical assessment. Evaluation has shown a significant decrease in documentation time and an increase in the number of observations recorded (Minda and Brundage 1994). The Health Evaluation through Logical Processing (HELP) system at Intermountain Health Care has for several years incorporated a complete physical assessment module and the ability for a nurse to

carry forward unchanged assessment findings, to reduce data entry time (Wilson and Neiswanger 1996). The nursing structured data entry and display system at the Columbia Presbyterian Medical Centre utilises templates, fields that can be displayed as blanks within ready-made sentences and prompting rules (Henry, Douglas et al. 1998).

In 1995 the Beth Israel Hospital developed an automated, inpatient nursing assessment system that was found to reduce the repetitive entry of data items, to improve the legibility and availability of information, to increase communication between nursing units and to halve documentation (Bourie, Chapman et al. 1997). Within one year it was used for 96% of emergency unit visits, producing a saving of time and improved patient flow (Bourie, Ferrenberg et al. 1998). (Burkle, Kuch et al. 1999) found positive nursing user acceptance of a hospital information system but no change in workload or nursing activity on two wards at the University Hospital of Gießen. They suggest that systematic changes to nursing practice and workflow should be introduced manually and accepted before equivalent computerised applications are introduced. A recent evaluation of a nursing information system in Heidelberg suggests that although documentation time is greater, computerised records are more complete and care planning can be made easier (Ammenwerth, Eichstadter et al. 2001).

(Marin, Cunha et al. 1998) have elicited the priority functions of a nursing information system.

- medication administration such as dosage calculation based on patient specific data such as weight and age;
- alerts or reminders related to drug effects, side-effect or drug interactions;
- analysis of the content of the nursing assessment in order to provide nursing diagnoses;
- for a given nursing diagnosis, to have a range of suitable interventions that can be selected by nurses for a specific patient;
- automatically generated patient discharge plan based on diagnoses and interventions during hospitalisation;
- nutritional plan based on patient diet needs, medical and nursing diagnoses;
- patient education on topics such as hygiene and post surgical care;
- nursing management functions such as staff scheduling;
- systems to support quality management and effectiveness of nursing care;
- critical path programs to support nursing decision related to categories of care and interventions of diseases.

The development of innovative nursing information systems is an expanding field of informatics in Europe and the US.

4.3.3. General Practice systems

For over 20 years many EU Member States have adopted specific programmes to promote computerisation, through a combination of systems development programmes and financial incentives schemes, but these have been slow to stimulate the clinical computing market place. General Practice has been the most progressive healthcare sector at embracing computer use during patient care, particularly in the UK and in the Netherlands where most GPs now capture some elements of the patient encounter on a computerised record system (Knottnerus 1999).

Growth of GP Systems in the UK

Computers first appeared in UK general practice in the 1960's as *ad hoc* systems developed in university research departments by pioneer enthusiasts, with early commercial systems appearing in the late 1970's sponsored by the Department of Health. In the mid-80's the market grew rapidly through the initiative of two companies offering GP computing systems at no cost in exchange for a commitment of access to aggregated prescribing and contact data. Despite widespread concerns at the ethical implications of this, both companies enjoyed considerable success up to 1991. However these early systems had a strong bias towards drug prescribing and other clinical requirements were later addressed with some difficulty. The revenue from the sale of this data proved to be much lower than anticipated, precipitating the collapse of these free schemes.

In the late 1980's the Department of Health introduced a 50% reimbursement of all computing costs in general practice. This encouraged the growth of the GP computer industry, and at its peak around 50 companies were actively supplying this market (GP Computing 1991 Survey); (Computerisation In GP Practices: 1993 Survey); (Prodigy Project - Computerisation In GP Practices 1996 Survey). UK general practice now has one of the highest levels of computerisation in Europe (now over 95%, with over 70% used in the consulting room (Gillies 2000)), although practices vary in the extent to which the computer system is used (Kalra 1996a).

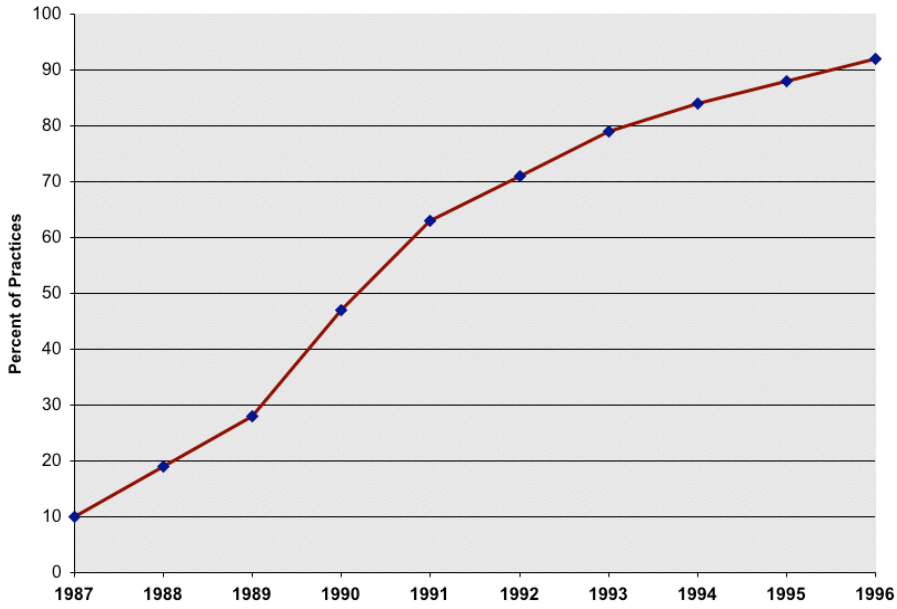


Figure 20: Levels of UK General Practice computerisation from 1987 to 1996

The computer has had a major impact on General Practitioners, allowing them to gain greater insight into their list of patients, and an ability to respond to the preventive health needs of their local population. Figure 21 shows the extent to which GPs used the main clinical functions of their computer system in 1999-2000 in north London, from a survey conducted by the author. The chart indicates the number of respondents who believed they could use the system, those who were confident they could show others how to use it, and those who indicated that they could not use it without help through training.

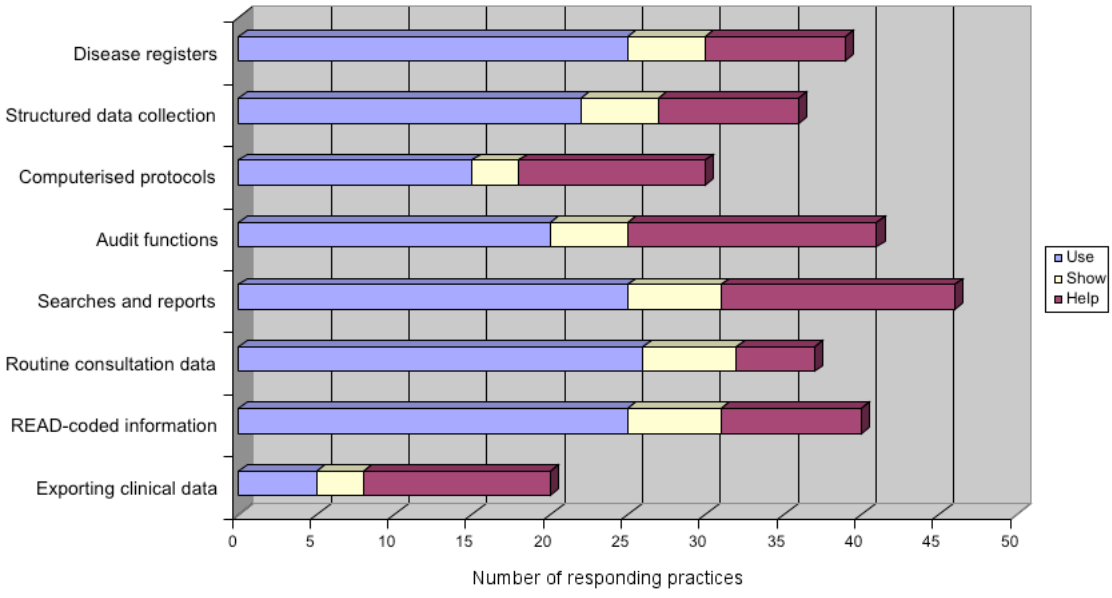


Figure 21: Use made of GP computer systems - survey in east London, 1995-6

New software versions incorporating a graphical user interface have made these systems friendly to use (for example, see Figure 22 below).

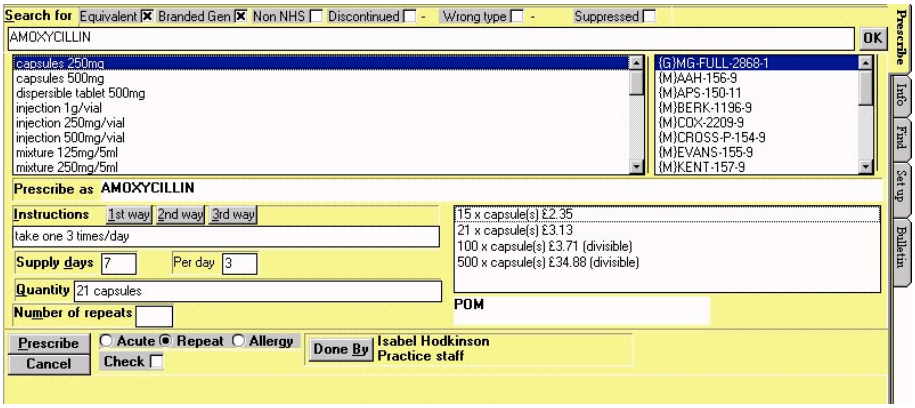


Figure 22: Using a GP drug prescribing screen

Clinical management functions benefiting from structured data are now quite sophisticated, for example drug prescribing includes interaction checking and adverse reaction alerts based on recent diagnoses. Recall systems for health checks such as child vaccinations and cervical cancer screening are also now common place. The analysis of quite simple data sets can yield valuable information with which to review the activity of the practice (see Figure 23 below).

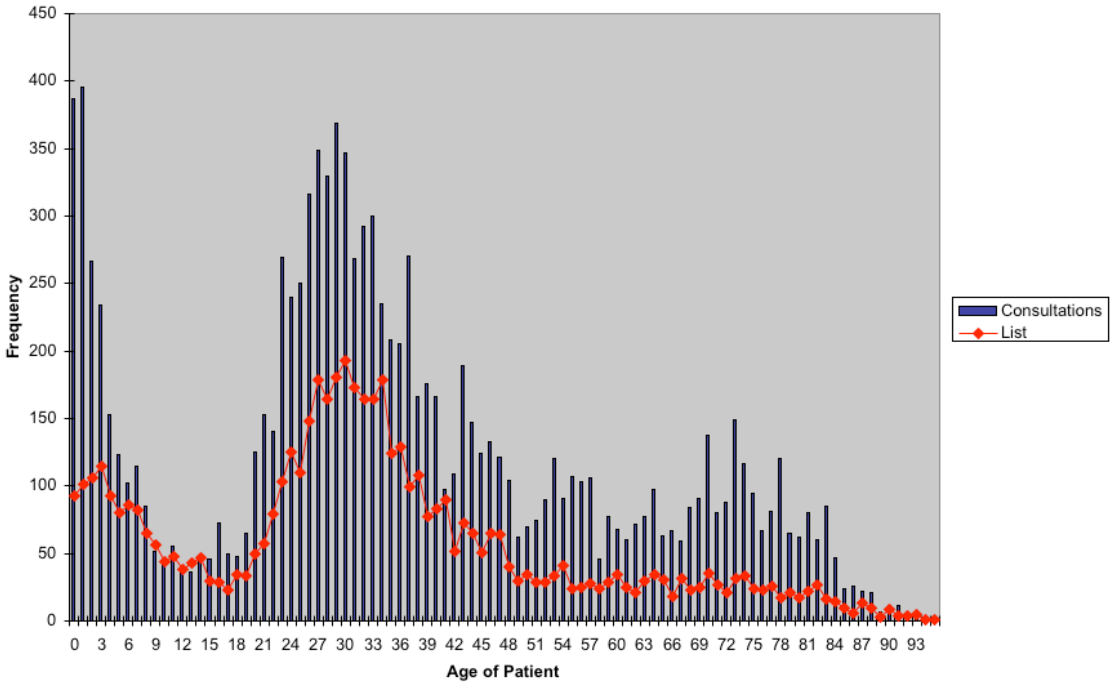


Figure 23: Annual consultations per year by age of patient, and list size by age, in a London practice

UK general practice systems have, over the past ten years, been conformance-tested against progressively more detailed and rigorous functionality and safety criteria. These standards, known

as Requirements For Accreditation (RFA) now require the incorporation of PRODIGY (national prescribing guidelines for a wide range of common primary care conditions) (Purves and Sowerby 1996), (Purves, Sugden et al. 1999) and MIQUEST (a remote access audit and population morbidity data extraction and analysis tool) (Markwell and Hinchley). Clinical data entry is underpinned by the Read Codes (see Section 5.7.4). Most systems support user-definable templates for disease management and health promotion, but the migration to paperless record-keeping is limited to enthusiast practices. The PRIMIS project has for some years facilitated collaborative data collection across practices using MIQUEST and the Read codes, and sought to improve the consistent recording of key clinical conditions (Pringle et al. 2002).

De Wet et al have shown that the principal concerns of South African general practitioners towards the adoption of an EHR relate to organisational and cultural issues, including the process of changing from a manual system, dual systems on paper and the computer and the risks to the relationship of trust with a patient (De Wet, McDonald et al. 1998). (Strasberg, Tudiver et al. 1998), in a questionnaire survey of 46 Toronto community family physicians found that over 80% would prefer the incremental adoption of an EPR, with some overlap period when also using paper records. (Bomba 1998) suggests that the effective adoption of computer systems in primary care requires education, information, training and support, along with financial incentive schemes. He argues that clinical acceptance will also depend upon the ability to generate audit and trend-spotting analyses.

(Dewan and Lorenzi 2000) note that many community-based health organisations such as community nursing services, and agencies tackling problems such as substance abuse, mental illness and developmental disabilities, have adopted computerised information systems independently of GPs, adding to future interoperability problems. Jones et al have shown that many GPs and dentists would favour a combined patient record, as would patients (Jones, McConville et al. 1999). Rigby et al argue that research and pilots are needed to establish the optimal ways in which interoperating information systems should support seamless care in the community (Rigby and Robins 1995).

4.3.4. Message-based clinical communication

Many national health services communicate administrative and clinical data through pre-defined messages (known as EDI, for example using EDIFACT). Message-based strategies in Europe and in the US (where HL7 has been widely implemented) originated in the need to support efficient healthcare administration and billing. The UK NHS has defined over fifty EDIFACT messages to cover the basic purchaser-provider communications to manage commissioned healthcare services.

Data sets of this kind tend to be stable and well structured, with little need for variation between patients or enterprises. This contrasts with the idiosyncratic nature of clinical practice and of most

healthcare record entries. The need for each clinical message to contain a predictable content structure has inevitably led to their introduction for clinical administration, for screening programmes and for the management of well-defined chronic diseases. The German BDT is a successful example of a message set used to compile disease registers and manage population-screening programmes from data derived directly from GP systems. Standardised messages have provided a key mechanism for supporting communications between providers and purchasers, and within the broader context of health service management. They have not played a significant role to date in communicating the level of detail necessary to enable seamless shared clinical care.

In 1995 Branger and Duisterhout argued that EDI has considerable potential to reduce delays and improve patient shared care (Branger and Duisterhout 1995). They noted, however, that much progress is needed on standards for data interchange, information models and coding schemes. They also note the need for privacy measures to be at least as good as for paper systems. (McDonald, Overhage et al. 1998) argue that the purpose of healthcare messages (EDI) should be to enable the communication of patient clinical information (reports) from one system to another. However, they note that messages required by the recent HIPPA legislation include over 1000 fields, which they argue is due to an insufficient degree of abstraction.

> *"The solution is to use more abstract models with fewer, but more expressive, objects. The patient information model has to be simplified and clarified and a uniform and correct level of abstraction must be found... For example, items such as birth weight or haemoglobin concentration should not be found included as named attributes of the model. The specific clinical entities should be represented in a concept/vocabulary data base that is separate from the data model...Such simplification always means moving information from field definitions to master tables."*

They also stress the need not become distracted by choices of technology or syntax (for example, HL7, X12, EDIFACT, ASN1) when defining information models for messages.

The 1999 CEN standard ENV 13606-4 now provides a sophisticated message definition matching the generic approach of an EHR architecture (see Section 5.5.1). HL7 version 3, which is undergoing a series of revisions in draft, is also now attempting a more generic representation of a healthcare record (see Section 5.6.1). These complex messages have yet to be technically and clinically validated.

4.3.5. Developing federated clinical systems

Many health regions are now incrementally piloting a community EHR, often electing to share specifically composed summaries rather than the original record data held by each enterprise because clinical systems cannot usually share this data directly (Kohane, Greenspun et al. 1996). (Kohane 1996) draws a distinction between distributed EMR systems that are:

- local (single institution) in which information is limited to that held by the users institution and is accessible only from inside that organisational firewall;
- full regional or national EMR systems that retrieve data from multiple legacy systems, using an intermediate translation (abstraction) layer comprising a well-defined information model with standard vocabularies.

(Stead 1997) suggests that a common reference architecture is a necessary enabling stage for the multi-enterprise and regional sharing of patient records. (Stead, Miller et al. 2000) suggest that new generation systems need to use interoperability standards such as HL7, standard terminologies such as LOINC, and knowledge ontologies to give the appearance of data integration from diversely represented and encoded entries. (Glaser 2000) states that information systems need to support clinical team integration as each individual patient receives care across provider sites.

Examples of distributed access to integrated clinical data repositories are beginning to appear in the literature. (Wang, Harkness et al. 1998) describe the design of a web-based read only application for accessing the medical record data held in the Johns Hopkins Hospital and for providing a view into the hospital record to referring physicians. (Stewart and Langer 1998) describe the MIND clinical repository at the University of Washington Academic Medical Centres, which integrates demographics, ICD-9 problems, medication, immunisation, investigation results and transcribed reports to form an electronic medical record (Tarczy-Hornoch, Kwan-Gett et al. 1997). This has been positively evaluated by over 600 clinicians. (van Wingerde, Sun et al. 1998) describe the BiliLIGHT system undergoing trial at the Boston Children's Hospital, which combines a computerised bilirubin management guideline (to prevent neonatal jaundice) with patient record information. The EHR data is obtained from the Beth Israel and Brigham and Women's Hospitals (via W3-EMRS, see Section 4.2.3) and the local hospital record server. (Kittredge, Rabbani et al. 1997) report the introduction of a web-based dial up access to Massachusetts General Hospital admission and discharge information by referring physicians. The Geneva University Hospital now offers GPs access to a secure web interface to a subset of their patients' records (Weber, P and Spahni, S Personal communications).

Many other examples exist as early-release commercial products; most still being validated at selected demonstrator sites. Reports of these evaluations are largely unpublished.

Clinical Data Repositories

Integrated repositories have often been developed to support the need for record interrogation outside the immediate care situation, for example for case reviews and audit, or as a source from which to generate a summary prior to a patient encounter. Examples include:

- demographic, financial and cardiac surgery data integrated at the University of Virginia to provide users with graphs and charts of a diagnosis code against demographic data items or length of stay (Scully, Pates et al. 1997);
- an obstetric data warehouse drawn from Duke University's TMR system, to look for factors contributing to pre-term birth (Prather, Lobach et al. 1997);
- a 46,000 patient record repository in Iowa comprising hospital and community minimum data sets accumulated over ten years, to investigate the frequency of nursing diagnoses (Delaney, Reed et al. 2000);
- a minimum basic data set repository at the University Hospital of Freiburg with data on over 450,000 patients (going back to 1986), providing a valuable clinical summary (Klar, Zaiss et al. 1995);
- a logical data repository combining microbiology test reporting and a pharmacy system for antibiotic prescription data at the Henri Mondor Hospital in France, used to detect the early emergence of antibiotic resistance by reviewing short-term trends in organism detection and antibiotic usage (Bouam, Girou et al. 1999);
- radioactive thyroid treatment records captured from paper based worksheets over 35 years at the Burns Medical Hospital in Honolulu (Nordyke and Kulikowski 1998);
- a data warehouse drawn from the data within the COSTAR system at Massachusetts General Hospital; (Murphy, Morgan et al. 1999) were able to determine a data set (comprising coded diagnosis, medication and laboratory results) that would satisfy over 90% of user queries and provide a rapid response.

A number of hospitals or health regions are exploring the potential use of data mining techniques to identify new causal relationships or trends in clinical outcome. Present publications suggest that these are at an early stage, have found only weak associations or have duplicated findings already in the medical literature (Abbott, Quirolgico et al. 1998), (Downs and Wallace 2000), (Mani and Cooper 1999), (Nigrin and Kohane 1999), (Brossette, Sprague et al. 1998). The educational value of such analyses for case-based learning has also been proposed (Kircher, Granfeldt et al. 2000).

These repositories are usually integrated by copying data to a centralised database rather than via a federal mechanism. (Mohr 1998) calculates that, once fully established with cumulative data over some years, around 17 Terabytes of storage will be needed for a population of 10 million patients, and a communications infrastructure to enable the addition of 80-200 million new contacts per annum. Solbrig considers it unlikely that these centralised systems will solve the large-scale problems of integrating multiple heterogeneous health information repositories (Solbrig 2000). An approach in which clinical data are maintained within their originating applications and systems but combined at a logical level through federation might offer a more practical and scalable solution.

4.3.6. Shared care and smart card projects

The use of smart cards has been considered a potential migration path from patient held records on paper and a means of enabling patient-managed distribution of access to a shared health record. However, most pilots of these have had limited success at expanding outside of their initial demonstration domain. A few example projects are summarised in this section.

The UK Exeter Smart-Card project, launched in 1989, aimed to allow the unambiguous communication of information between dissimilar computing systems, to cater for the mobility of both patients and health care providers and to allow patients to hold and to access secure copies of their own medical records (Hopkins 1990). The card was designed to store a global data set from which each health care professional's computer could extract locally required sub-sets, subject to their access rights. The card was issued to 8,500 patients through two general practices, and formal evaluation was encouraging, but hardware cost has been a key reason why the initial trial was not extended.

The DiabCard project (1992-8) has developed and evaluated a Chip Card based Medical Information System for chronic diseases in ambulatory and hospital care, using the exemplar of diabetes (Engelbrecht, Hildebrand et al. 1999). The clinical goals were to:

- provide health professionals with up-to-date and relevant information about a person's health status;
- improve the communication between patient and physician(s) and between the different health personnel involved in the treatment of the patient;
- improve the quality of diabetes health care in Europe;
- enhance quality assurance according to the St Vincent Declaration;
- standardise medical documentation.

DiabCard has used crypto-processor chip cards both for the storage of structured clinical data and to control access to that data. The project has adopted an open architecture and used ISO standards to facilitate the easy integration into existing clinical systems. The card software is based on an existing prototype diabetes system: DiabCare. Pilot installations for the initial validation were performed in Germany, Italy, Greece and Spain. Long-term demonstrator studies are being set up in Austria, France, Germany, Greece, Italy and Spain (now largely funded on a national basis). DiabCard is probably one of the most successful card-based projects internationally.

Other example smart card projects include:

- a Slovenian project, involving the use of cards held by patients (medical summary) and by clinicians (authentication) (Suselj and Cuber 1998);

- a card used in Kyoto, Japan, to hold patient identity, authentication and a basic "emergency" medical summary data set (Alkhateeb, Singer et al. 2000).

(Pinciroli, Nahaissi et al. 2000) argue that personal health smart cards (i.e. carrying actual health data) have the fundamental drawback that a card reader may not be available at the point of care delivery, particularly in emergency settings. They point instead to the wide availability of the Internet as a potentially ubiquitous pathway to access health data, particularly to support emergency care. A recent international survey reinforces the role of the smart card to authenticate and control access to Internet-based health records (Alkhateeb, Takahashi et al. 1999).

4.3.7. Mobile health record systems

Existing pilots of mobile health record systems can be divided into a few broad categories.

1 Laptop computers or large LCD tablets connected via a wireless local area network. These offer portability within a local environment such as a hospital ward or operating theatre, offering users equivalent access to their desktop computer while away from their desk. For example, Kaiser Permanente, Northwest has used laptop computers to access an existing comprehensive EMR in examination rooms (Dworkin, Krall et al. 1999).

2 A handheld device (PDA) connected via a GSM mobile phone or (recently) via a GPRS card permitting use both inside an enterprise and anywhere in the community.

   a Acting as a portable data entry device, for filling in forms. For example, patients and nurses can use a Palm Pilot together at the bedside to capture patient preferences for nursing care and goals for functional health more completely than using conventional paper systems (Ruland 2000), (Ruland 2002); (Blackman, Gorman et al. 1999) describe the use of handheld computers to capture patient activity and diagnoses for billing purposes in a surgical group practice in Oregon.

   b Acting as a browser providing access to the clinical repository of an enterprise. For example, (Buchauer, Werner et al. 1998) report a prototype PDA in Heidelberg accessing patient record documents and medical knowledge databases; (Duncan and Shabot 2000) describe the use of a Palm VII wireless handheld to access a clinical data repository in Los Angeles; (Brazier, Campbell et al. 2001) describe the successful use of a WAP-based access to GP computerised records in Scotland to facilitate out-of-hours care and house calls.

(Sittig, Jimison et al. 2000), through interviews with physicians who were early PDA adopters, found that the top 3 clinical roles for a PDA were perceived to be:

- checking a drug-drug interaction

- checking treatment regimens
- viewing patient data from EMR

They also found that voice dictation was a key feature that physicians wished to have in the handheld.

The 6WINIT Project

The IPv6 Wireless internet INITiative (6WINIT) project (2000-2002) is a European IST Framework V initiative involving telecoms companies, equipment manufacturers, solutions/software providers, universities and 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). The UCL north London FHR demonstrator is one of three 6WINIT clinical sites. The implementation is presently being enhanced to exploit the opportunities presented by wireless Internet services and IPv6 (see Section 11.7).

4.3.8. Patient home monitoring systems

Remote monitoring systems (tele-monitoring) permit clinicians to assess their patients' condition on a frequent basis without the need for the patient to journey to a hospital or GP surgery, offering a new means of communication between patients and clinicians. They can also provide a valuable means to empower patients to play an active role in tailoring their own health care, provided that feedback on the acquired data is offered to them.

(Billault, Degoulet et al. 1995) have shown that providing hypertensive patients with a personal health record (on paper) for regularly collecting lifestyle monitoring data can significantly lower their systolic pressure, reduce complications and improve their lifestyle risk factors within one year. (Edmonds, Bauer et al. 1998), (Riva, Bellazzi et al. 1997) and (Nigrin and Kohane 2000a) have all shown that an improvement in diabetes management can be obtained by providing immediate (computer generated) feedback on patients' home monitoring readings in comparison with monthly reviews of a log book by physicians. (Chen, Liao et al. 1998) describe the use of telephone keypad menu choices and web-based disease management records to support the monitoring of chronic diseases such as hypertension and diabetes in Taiwan. Celler et al report the technical feasibility, user acceptance and satisfactory performance of the remote home monitoring of elderly persons (Celler, Lovell et al. 1995). They have installed a set of movement, light, temperature and water flow sensors in the home of frail elderly persons in Sydney, Australia.

A major drawback to contemporary tele-monitoring devices and systems is their use of a specific data structure to represent the acquired data, and often a specific exchange format for their

communication back to a repository server or processing system (Cai, Johnson et al. 2000). Patients frequently have multiple health problems, and it would be a pity if efforts on harmonising their health record information between enterprises were confounded by a diversity of incompatible information resources around their very person.

4.3.9. Patient participation through their health record

The case for patients being treated as active players in their health management has been discussed in Section 3.5.3. Over a decade ago (Essex, Doig et al. 1990) showed that patient held mental health records can improve continuity of care and aid communication with patients. In order to empower patients in this way records need to be written in a way that is comprehensible to them (Wright). However (Schoop and Wastell 1999) point out that communication problems can arise from the use of patient held records, such as the difficulty of verifying that requested clinical actions have been noted and agreed by another clinician.

(Hingorani, Wong et al. 1999) suggest that patients do wish to know about problems and complications arising within their health care, irrespective of there being any active manifestation of that complication. The findings are consistent with UK General Medical Council guidance that a *"full, honest explanation"* should always be given of any adverse healthcare event (Good Medical Practice 2001).

(Kuperman, Sussman et al. 1998) at the Brigham and Women's Hospital describe the impact of printing a summary of screening, medication and allergy information for patients to read and correct in the waiting room before their outpatients consultation. They reviewed 80 such forms and found that 29% of patients had provided new screening data and 19% had corrected or added medication data. (Porter and Mandl 1999) have demonstrated that parents of ill children bought into an emergency room of Boston Children's Hospital can enter data into a computerised interview touch-screen system as completely as histories taken by a physician. The hospital has piloted a clinical communications application permitting patients at home to view their daily plan, access disease-specific educational materials, and correspond with their physician via secure e-mail (Mandl and Kohane 1999). (Cimino, Sengupta et al. 1998) describe a patient-centred web interface to provide patients with friendly access to their medical records, educational materials and questionnaires. Educated, technically literate and well-motivated patients made good use of such a system, and in particular wished to view the results of laboratory tests (Cimino, Li et al. 2000), (Kushniruk, Patel et al. 2000). (Tanaka, Shibata et al. 2000) have demonstrated the use of electronic questionnaires to gather symptoms from elderly patients attending clinics for health education. (Hunt, Haynes et al. 1997) describe the use of a diabetes self-administered questionnaire to generate patient management advice and suggested education topics for the subsequent clinical encounter. (Shegog, Bartholomew et al. 2001) report a positive impact on self management skills amongst

children with asthma, through the use of a computer educational programme specifically tailored for children.

Web based record systems targeted specifically at patients are becoming popular but as yet exhibit limited functionality and almost no interoperability with clinical record systems (Kim and Johnson 2002).

4.3.10. Impact and user acceptance of clinical systems

(Atkinson and Peel 1998) liken the process of adopting an EPR system to biological growth, requiring stepwise progress and constant change. (Ash 1997) has shown that the primary success factor for the wider adoption of CPR systems is the application of resources to organisational change. (Sittig, Kuperman et al. 1999) have found functional fit with clinical workflow requirements to be a more important success factor than overall system performance. (Luxenberg, DuBois et al. 1997) suggest that individual clinicians must perceive a clear and personal benefit in order to adopt new technology approaches to record keeping.

de Dombal et al have shown that a computerised advisory system for the management of acute abdominal pain can improve diagnostic accuracy by 10-15%, and halve the rate of perforated appendicitis (McAdam, Brock et al. 1990). Structured data collection forms and computer-based teaching can also contribute to improved diagnostic accuracy (de Dombal, Dallos et al. 1991). (Tang, LaRosa et al. 1999) have demonstrated that computerised records are more complete than paper records created for similar patients in equivalent settings, but (Schriger, Baraff et al. 2000) have shown that the recording of key elements of clinical information can decline to pre-computer recording levels if a system is removed.

(Travers and Downs 2000) compare two paediatric clinics in North Carolina that each received a Child Health Improvement Programme that had been developed and used successfully at a local academic practice. One practice with poor pre-existing manual systems, experience of frequent organisational change, and a positive systems champion, has accepted the new system. The other practice, with previously good manual systems and a technology champion who was not supported by the lead figures in the practice, stopped using the system after several months.

(Lorenzi and Riley 2000) concur that organisational factors that play a significant role in the adoption of new health informatics solutions. They suggest that pioneering informatics successes have often been lead by champions and deployed in local and small-scale settings in which benefits could readily be demonstrated.

(Patel, Kushniruk et al. 2000) found that those who used a CPR system for nearly 100% of consultations had quickly adopted a consultation pathway and recording style that elicited

information in the order of headings presented on screen, and were able to enter findings into the computer shortly after eliciting them from the patient. Moderate and minimal users appeared to have adopted an approach of wanting the technology to fit in absolutely with the way they practised; they had long stretches of the consultation when they did not interact with the computer. The study also noted that expert computer users tended to record less psychosocial information about their patients.

The routine use of Physician Order Entry (POE) systems has been regarded as a critical goal in achieving clinical acceptance of hospital computer systems, to increase adherence to guidelines and to reduce cost (Sittig and Stead 1994). In 1996 (Lee, Teich et al. 1996) found the POE system at the Brigham and Women's Hospital to be well regarded by both physicians and nurses, who valued the effect on productivity (i.e. workflow facilitation) over and above any influence on quality of decision making. In contrast (Weiner, Gress et al. 1999) more recently conducted a survey of 271 physicians and nurses at Johns Hopkins University Hospital to evaluate user experiences of a new Physician Order Entry system. Physicians perceived the system as adding to their work, inviting more tests and detracting from patient contact time; nurses perceived the opposite for all three.

Most studies of clinical system introduction have been of an initial system into a traditionally paper based environment. However, (Rotman, Sullivan et al. 1996) found that physicians at the Veterans Affairs Palo Alto Health Care System did not like a new replacement drug interaction and prescribing system because of familiarity with the previous system, which had been very good.

Impact on clinician-clinician relationships

(Coiera 2000) argues that much of clinical communication is preferentially handled by human interaction (talking) than by the use of computerised information sources. He notes that hospital doctors are heavy telephone users and often deliberately seek advice from colleagues in preference to consulting paper documents or computer-based sources. (Parker and Coiera 2000) suggest that the perceived risk of forgetting minor (often repeated) tasks leads doctors to take immediate actions with immediate responses including acknowledgement and/or agreements to take on care responsibilities.

It is difficult to know whether this preference for immediate, personal interaction with clinical colleagues would be altered by the availability of good quality workflow systems incorporating this kind of clinician-clinician interaction and guideline-based advice, underpinned by compehensive EHRs. Clearly any migration towards more systematic electronic workflow support would increase the likelihood that the EHR for each patient is more complete by including those interactions.

Impact on the clinician-patient relationship

Early experience following the implementation of the "First Aid" system in the UK revealed that attitudes toward the system were more positive when patients had actual experience with its use during a clinical encounter (Cruickshank and P.J. 1985). However, when asked to compare their doctor against their ideal doctor, patients' ratings were less positive if the system had been used in their consultation.

(Rethans, Hoppener et al. 1988) reported on the implementation of general practice clinical system in the Netherlands. In this study, patients felt that computer use did not make their care less personal or their communication with the physician more difficult, but conversely felt that the GP was able to assess their overall care more efficiently using the computer.

(Gadd and Penrod 2000) found that physician-patient rapport was a concern to physicians prior to EMR implementation and this concern was increased at the end of six months of use. In contrast, patients did not indicate a sense of loss of rapport with their physicians when an EMR was used.

The general experience of using clinical systems during patient care, discussed throughout this chapter, suggests that well-designed applications do not adversely affect the clinician-patient dynamic, and have significant potential to offer evidence-based advice, workflow support and to enable the EHR to be more complete.

Chapter 5. Published contributions to the FHR Design

This chapter summarises a wide range of research projects and publications, and outlines the health informatics standards relevant to electronic health record information. It focuses on the representation of the EHR itself, but includes reviews in the areas of metadata and terminology, decision support systems, and ethical and legal issues.

5.1. The simple case for a generic record architecture

The diversity and complexity of health record information makes it difficult to capture comprehensively and faithfully on most contemporary systems. The lack of agreed and implemented standards makes it virtually impossible to transfer detailed healthcare information between different systems in a way that supports the rigorous integration of that data within the receiving system. In 1998 (Shortliffe 1998) wrote:

> *"System integration has emerged as a key element in the reinvention of environments for patient data management and health promotion. The ability to achieve the future vision of integrated health records depends in part on current research initiatives related to the role of the global information infrastructure in supporting health and health care."*

(Greenes and Deibel 1995) argue that a number of factors hamper the interoperability of applications and components, including:

- the complexity of the problems addressed by the systems;
- the wide variety of goals to be met;
- the diverse spectrum of users;
- the range of data and information that must be accessed, analysed, and manipulated;
- the numerous, often conflicting, constraints that must be satisfied.

(Dolin 1997) suggests that many contemporary systems lack both detail and uniformity to enable the consistent retrieval of good outcome data across providers. He argues that standards for the information model of an electronic health record are important, but that clinical data can be complex.

> *"Data can be nested to varying degrees (e.g. a data table storing laboratory results must accommodate urine cultures growing one or more than one organism, each with its own set of antibiotic sensitivities). Data can be highly interrelated (e.g., a provider may wish to specify that a patient's renal insufficiency is due both to diabetes mellitus and to hypertension, and is also related to the patient's polyuria and malaise). Data can be heterogeneous (e.g., test results can be strictly numeric, alpha-numeric, or composed of digital images and signals) ... a computerized health record must be able to accommodate unforeseen data."*

5.2. Generic EHR research projects

5.2.1. The European Health Telematics Framework programmes

The increasing limitations of paper-based records, the potential benefits of electronic health records and the acknowledged challenges of delivering these in practice have stimulated a considerable investment in research and development over the past decade. In the last seven years the European Union has provided 47 Million ECU of direct funding support to research projects whose budgets total 76 Million ECU (Iakovidis 1998a). Examples of these programmes include: the Health Telematics Research and Development programme of the European Commission (Text of the Council Decision Adopting a Specific Programme of Research and Technological Development in the Field of Communication Technologies (1990-1994) 1991), (Decision No. 1110/94/EC of the European Parliament and the Council, Adopting a Fourth Framework Programme of European Community Activities in the Field of Research, Technological Development and Demonstration (1994-1998)), (EEurope An Information Society for All 1999).

Realising the electronic health record has been at the heart of the EU Health Telematics programmes (Kalra 1996). Considerable research has been undertaken over the past decade to explore the user requirements for adopting EHRs (e.g. published by the GEHR and EHCR Support Action projects), resulting in the proposal of architecture formalisms to capture healthcare data comprehensively and in a manner which is medico-legally rigorous and preserves the clinical meaning intended by the original author, (e.g. GEHR and the CEN pre-standard ENV 12265). European standards have also been developed to define the core characteristics of a Healthcare Information Systems Architecture (HISA: ENV 12967).

Subsequent research has identified the additional requirements to support the communication of EHRs within federated communities of healthcare enterprises to support shared patient care across sites (the Synapses project) and middleware architectures to integrate across R&D projects (SynEx). All of these projects are summarised in this chapter.

Activities in the field of standardised messages overlap the domains of EHR architectures and medical knowledge representation. Work undertaken through CEN is summarised here: its primary focus has to date been on the generalised specifications for message structures, some of which relate closely to the work on EHR architectures. Other groups that have established extensive information models and clinical data sets (HL7 and CORBAmed) are described under industry standards.

5.2.2. The Good European Health Record project

The Good European Health Record project developed a comprehensive multi-media information architecture for using and sharing electronic healthcare records, meeting clinical, technical, educational and ethico-legal requirements (Ingram D. 1995), (Griffith, Kalra et al. 1995). The research was funded through the EU Health Telematics research programme (Advanced Informatics in Medicine) from 1991-95.

The GEHR project consortium involved 21 participating organisations in seven European countries, and included clinicians from different professions and disciplines, computer scientists in commercial and academic institutions, and major multi-national companies. The project explored the clinical requirements for the wide-scale adoption of Electronic Healthcare Records (EHCRs) in place 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 (Ingram, Griffith et al. 1995). The architecture model, an exchange format, term sets and the specifications of access and integration tools have all been placed in the public domain.

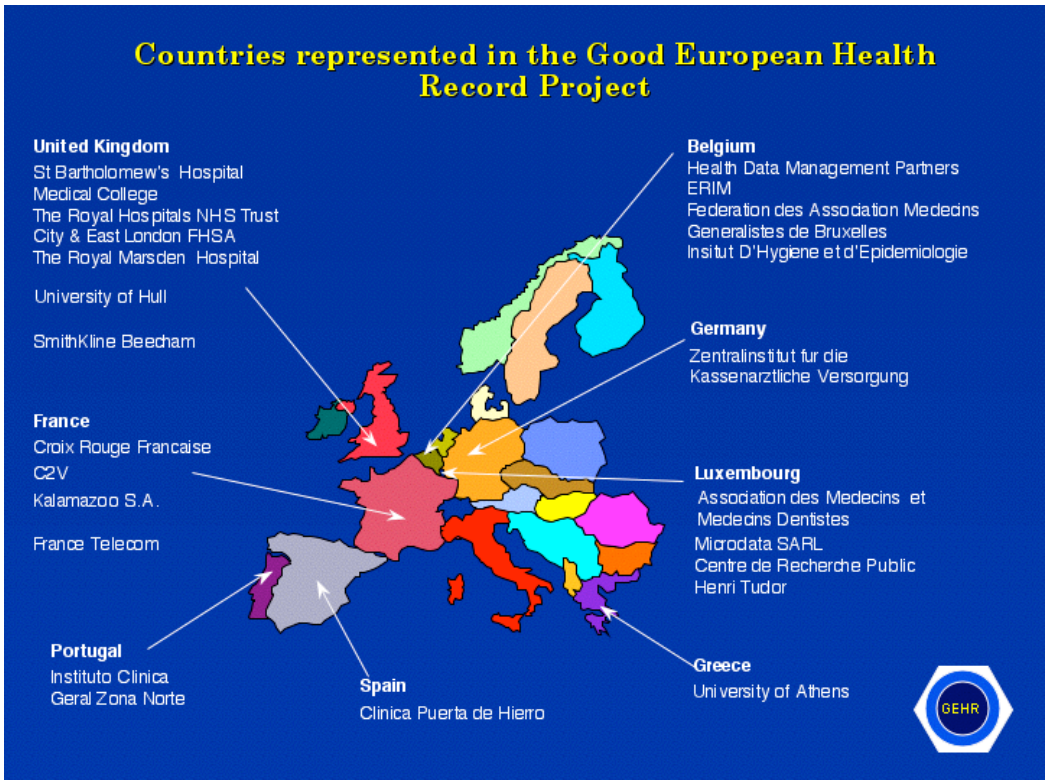


Figure 24: Countries represented in the GEHR project

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

- the requirements for the comprehensive recording of consultations with patients for a wide range of disciplines in primary and secondary care (Ingram, Southgate et al. 1992);

- the requirements for the portability of health records between different institutional systems independently of the technology or of the applications at those sites (Ingram, Hap et al. 1992);
- the requirements for the communication of health records between clinicians involved in sharing the care of patients, whether via telecommunications networks or intermittently-connected devices such as smart cards (Ingram, Lloyd et al. 1992);
- the ethical, medico-legal and security issues which arise when using EHRs as the sole medium for recording and storing patient-related information (Ingram D, Southgate L et al. 1993);
- the educational needs at an undergraduate and postgraduate level in order to enable the clinical workforce to adopt EHRs (Ingram, Murphy et al. 1993).

The results of the project strongly emphasised the primary purposes of the record being to support the continuing care of individual patients, and for clinicians to be able to demonstrate the competence and quality of care they have provided. The final key publication from the GEHR project was a formal model of the health record architecture based on these requirements (Lloyd, Kalra et al. 1995). A description of the GEHR architecture is given in Section 7.2.1 below. Several prototype healthcare record applications were developed within the GEHR consortium, some of which are now commercial systems in clinical use (e.g. Figure 25, taken from the Health.one system developed by Health Data Management Partners, Brussels).

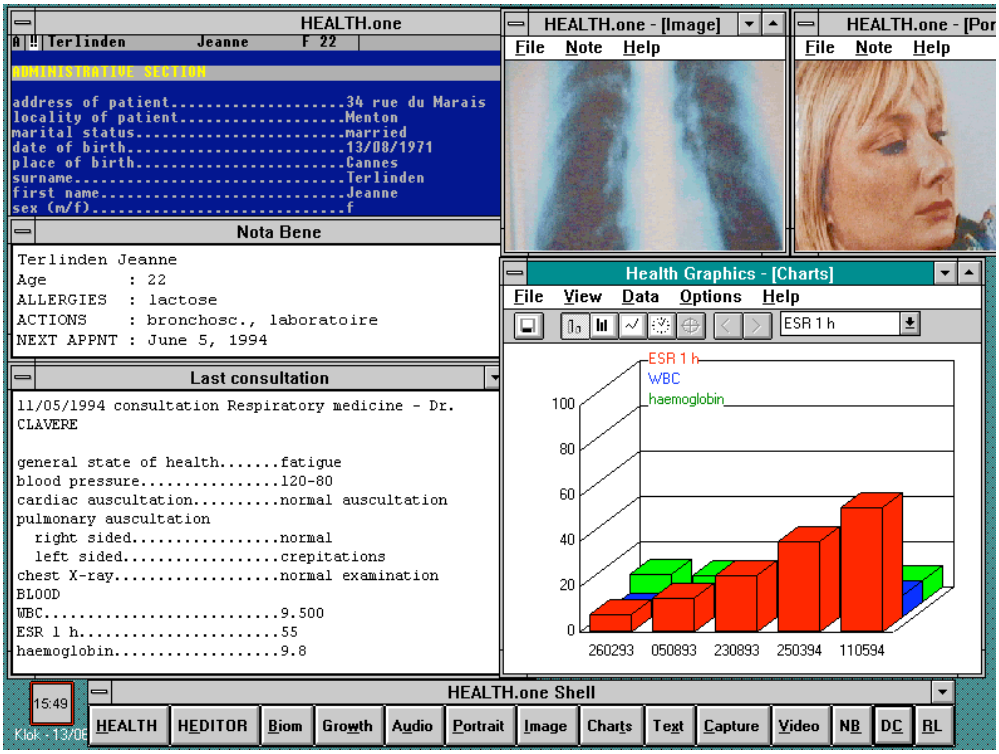


Figure 25: Example screen from Health.one developed during the GEHR project

The GEHR requirements have contributed into subsequent European standards work in the field (Hurlen 1995), see Section 5.5.1, and subsequent EU Health Telematics projects such as Synapses and EHCR-SupA have built on these foundations (as illustrated in Figure 26).

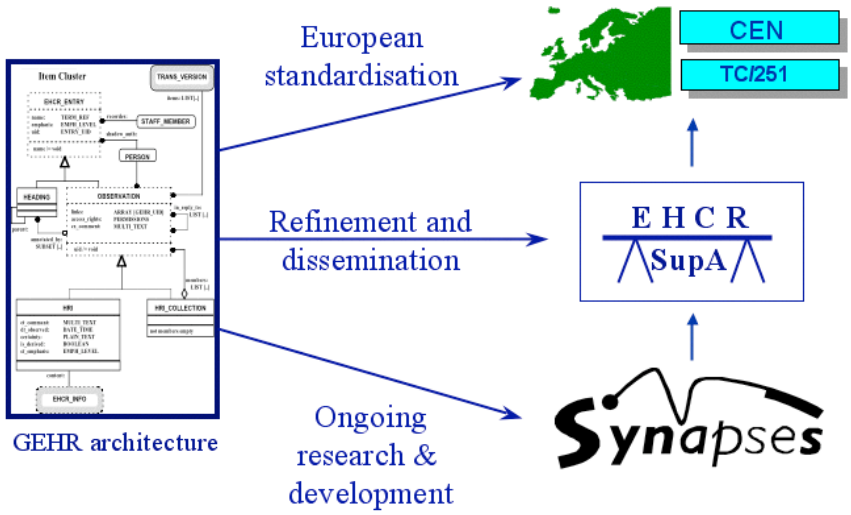


Figure 26: Taking forward the GEHR results

A recent diabetes shared care implementation of GEHR has been developed through the EU Black Sea Telediab project and is being piloted in Romania (Black Sea Telediab 2002).

5.2.3. The Synapses Project

The Synapses project was funded within the EU fourth Health Telematics R&TD framework from 1996-8. Its aim was to develop a generic and open means of providing access to patient record information from diverse and distributed clinical systems. The GEHR approach was taken as the starting point of Synapses.

Health care enterprises and regions need to federate a very large number of diverse feeder systems, which may be scatted across hospital departments, specialised units, primary care and other community settings (Kalra 1996b). The electronically stored information may be distributed over many sites, in a range of legacy databases. Each of these legacy systems store information relating to different aspects of a patient's health or illness. The care of any one patient may potentially require a healthcare professional urgently to review clinical information from several of these in a consistent manner.

The Synapses approach to this challenge utilised the methodology of database federation to a standard and comprehensive schema (the federated healthcare record architecture), mediated and managed through a set of middleware services (Grimson et al. 1996). The emphasis of Synapses has been to facilitate data sharing between federated clinical systems rather than to integrate the

systems that supply or use the data (Grimson and Groth 1996). The specifications of the Synapses information models and interfaces, summarised in Sections 7.2.3 and 11.1, have been placed in the public domain (Grimson, Grimson et al. 1998).

Several healthcare sites prototyped the Synapses results. The Royal Marsden Hospital demonstrator, in which the author was directly involved, has been described in Section 4.2.10. As another example (Weier, Kalshoven et al. 1998) implemented a Synapses server in Amsterdam federating parts of two GP systems with the Academic Medical Centre's diabetes clinic system to support shared care. (Toussaint, Kalshoven et al. 1997) provide a high-level ODP description of that diabetes system. The ARCHIMED server at the at the University Hospital of Geneva has a Synapses-based federating cache repository, bringing homogeneity to a range of heterogeneous databases across the hospital (Thurler, Borst et al. 2000). Trinity College Dublin has piloted the use of a server in the intensive care unit of St James Hospital to federate blood gas and laboratory data (personal communication).

5.2.4. The SynEx Project

The SynEx Project, running between 1998 and 2000 within the EU Fourth Framework programme, defined a middleware architecture for the delivery of collaborating health information components (Kalra, Austin et al. 1999), (Sottile, Ferrara et al. 1999). These included federated health record, terminology, decision support, security and demographic services, as shown in Figure 27 below.

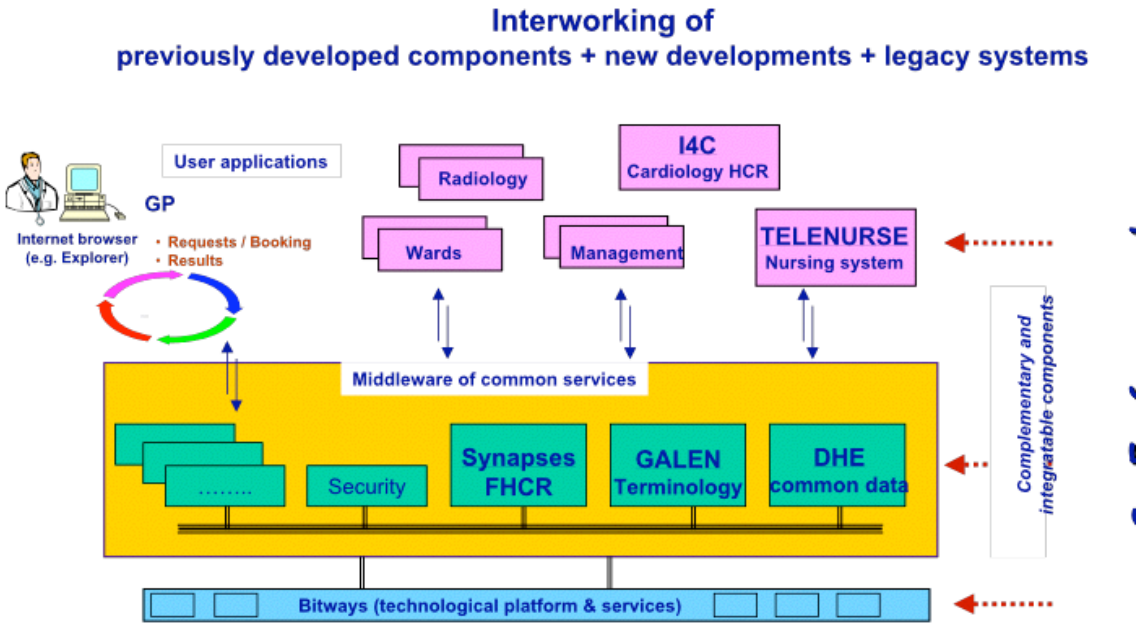


Figure 27: Components and services within the SynEx middleware architecture

The project provided an opportunity for academic and industrial collaborators to migrate individual applications to middleware components with complementary interfaces. The time-scale of the project was unfortunately insufficient to permit both this re-engineering of individual components and their joint evaluation within demonstrator sites. As a consequence each site was only able to demonstrate limited component interoperability.

The UCL FHR Service is one example of a middleware component largely developed during the SynEx project. (Degoulet, Sauquet et al. 1998) have implemented a mediator component at the Broussais Hospital in Paris to translate medical messages between representations. The component has subsequently been enhanced to cross-map between any pair of feeder system schemata (Xu, Sauquet et al. 2000).

5.2.5. PROREC

The PROREC project (PROmotion strategy for European electronic healthcare RECords) was a support action within the EU Fourth Framework Programme. Its goal was to promote and co-ordinate the European wide convergence towards uniform comprehensive, communicable and secure Electronic Healthcare Records. The PROREC approach has been to install a permanent network of centres in Europe focusing on the dissemination of information related to electronic healthcare records. The main active Centres are in Belgium, Spain, Germany and more recently the Netherlands. Other national Centres are planned over the next two years.

The PROREC project has been succeeded by a new follow on project WideNet, which has permitted the original collaborators to extend the number of ProRec centres and to establish a central European Institution on the Electronic Healthcare Record (The EuroRec Institute). Successful EuroRec Conferences have been held in Paris (1997), Rotterdam (1998), Madrid (1999) and Aix en Provence (2001). These have provided valuable opportunities for the results presented in this Thesis to be presented in their evolving stages, and for ideas to be shared with other colleagues in the field.

5.2.6. EHCR Support Action Project

This EU sponsored Support Action within the Fourth Framework programme was established to:

a) disseminate the results of 3rd Framework EHCR Architecture projects and of the standardisation work of CEN to user groups in all countries of the EU;
b) provide expert advice to user groups to encourage good practice in the use of electronic healthcare records;

c) provide a maintenance mechanism to collect feedback of experience of the use of structured EHCRs in the field and to propose improvements to the Architectures to the 4th Framework follow-on projects and CEN.

EHCR-SupA reviewed the experience gained across Europe in the use of early architecture models (e.g. GEHR) and of the first CEN EHCR Architecture pre-standard ENV 12265 in order to develop proposals for a revised version of the standard. It collaborated closely with industrial experts in several EU countries to ensure that the features in the proposed architecture met the requirements both of industry and of users. It also collaborated with PROREC to ensure that the proposed architecture, accompanied by educational materials, could be disseminated within European countries to departments of health, healthcare professional organisations and to healthcare information systems developers.

Amongst the main project results are;

- a consolidated set of requirements synthesising the publications of several EU projects and national bodies ((Dixon, Grubb et al. 2001), summarised in Section 6.1.1);
- a set of recommendations to CEN for the revision of ENV 12265 (Dixon, Grubb et al. 1998);
- guidelines and educational materials on the subsequent CEN pre-standard ENV 13606 (Dixon, Grubb et al. 2000).

The early work of this Support Action fed into the Synapses project as contributions to the federated health record architecture. The deliverables have been widely disseminated for review by colleagues in the field.

5.2.7. The Australian Good Electronic Health Record project

The Good Electronic Health Record project arose in Australia in 1997 through colleagues who were involved with the original Good European Health Record project described above in Section 5.2.2.

In 1997, the Good European Health Record architecture was recommended for use across Australian general practice by a major IBM consultancy commissioned by the Federal Government (IBM Consulting Group Health Practice 1997). This prompted former key GEHR members from London, now living in Australia, to develop an implementation of the GEHR model, refining it in the light of experience (Beale 1999). This was carried out in close collaboration with colleagues from UCL in the UK, including the author. It was agreed at this time to change the word European in GEHR to Electronic in recognition of its spread beyond Europe. This has now been published as an Open Source component and organisations in several countries internationally have expressed an interest in piloting the component and overall approach.

An initial demonstration trial of the GEHR kernel funded by the Australian Federal Government was undertaken during 1999-2000 (Schloeffel, Heard et al. 1999). A second Federally funded project to develop a translation 'wrapper' from an existing hospital clinical data repository to GEHR is currently underway. GEHR has recently been recommended as the underpinning EHR architecture for a major national health IT initiative called HealthConnect which will see the development of an Australia-wide EHR network to be implemented progressively over the next 10 years (National Electronic Health Records Taskforce 2000). Extensive implementation trials of GEHR across a wide range of health settings will be required to prove its suitability for health-wide Australian requirements (Heard 2000).

It is interesting that the Australian GEHR team have independently proposed and defined a knowledge-model for the specification of clinical record structures, known as archetypes, to allow the semantic definition of clinical content to be standardised and separated from the underlying information model of the EHR. This approach is very similar conceptually to the Synapses Object Dictionary (described in Section 8.1.1) and the approach taken by the author in defining the federated health record information architecture.

As part of a planned convergence over the past three years, in 2000 it was agreed to adopt the name *archetype* to describe the concept as developed by both teams. This term has therefore been used within this Thesis to describe the conceptual evolution of the work of the author from the originating Synapses Object Dictionary. The convergence work between GEHR Australia and UCL, and a common commitment to Open Source, has recently led to the formation of an international Open Source Foundation, *open*EHR. This is described in Section 14.2.

5.2.8. ORCA and the I4C Project

Research over many years at the Department of Medical Informatics of Erasmus University in Rotterdam has contributed towards a goal of supporting a flexible approach to structured data entry.

(van Ginneken 1996a) suggests that differing levels of record flexibility are required by generalists and specialists. The design of the ORCA (Open Record of Care) database supports both predictable data entry through structured templates and some flexible data entry in which high-level knowledge model rules govern record entry hierarchies and content data values (Renaud-Salis and Lagouarde Philippe 2002). (Moorman, van Ginneken et al. 1994) have developed a core EHR information meta-model and tools that permit the authoring of domain-related metadata for "descriptional knowledge". This metadata approach is very similar to the Archetype Object Dictionary concept. (van Mulligen, Stam et al. 1998) also report the development of a complementary clinical application that combines scope for structured form-based data entry with

the ability for users to add narrative entries alongside. The tool, now known as Structured Data Entry (SDE), is based on:

- a generic record information model;
- a high-level metadata model that acts as a foundation for decision support code modules;
- a domain-specific knowledge base to permit tailored forms and drop-down lists to be constructed at run-time for a given clinical speciality.

Systems based on ORCA and SDE have been implemented in obstetrics and gynaecology, and paediatrics at Erasmus University Hospital, and in six European centres within the EU 4th Framework I4C project (van Bemmel, van Ginneken et al. 1998b). This research group worked with the author within the SynEx project, during which several common elements of approach were explored.

5.2.9. The Medicate Project

The Medicate project was sponsored by the EU through the Ten-Telecom programme between 1998 and 2001. MEDICATE has aimed to provide 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 care provided by their usual clinicians. Medicate chose the exemplar of asthma for the development and demonstration of a respiratory flow measurement device communicating with a web-based asthma home monitoring record and a set of disease management algorithms. Medicate incorporates the UCL FHR service for the patient record and the advisory algorithms, described in Section 11.8. Patient and clinician acceptance was demonstrated at two hospital sites in London (Whittington Hospital) and Barcelona. The features of the portable respiratory flow meter are summarised in Figure 28 below.

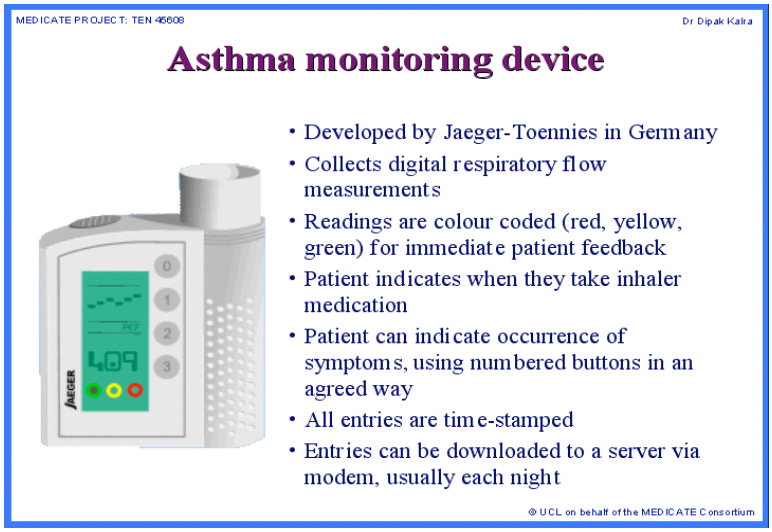


Figure 28: The Medicate asthma monitoring device, developed by Jaeger-Toennies

In the demonstrator, the device was used by patients recently discharged from hospital following an acute asthma attack. Readings were downloaded by each patient nightly and were sent to the FHR server. A set of decision support algorithms was implemented to monitor incoming readings and to generate an e-mail alert to the responsible clinician if any readings were of concern. A web application provided clinicians (and in future patients) with secure distributed access to the whole monitoring history of each patient under their care.

The project ended with good evidence of the acceptance of such monitoring devices by patients, and a technically complete demonstrator, but with no clear research sponsor for broader field trials and no marketing partner through whom the solution could be taken forward. It has therefore provided a technical proof-of-concept validation of the UCL FHR services, but not of its live clinical use.

(Finkelstein, Hripcsak et al. 1998a) have also described a research-funded pilot of the use of a portable digital asthma spirometer for home monitoring, coupled to a PDA and mobile phone for live communication of readings to a monitoring server. Their asthma system also generates alerts and offers a web browser interface to view the patient's monitoring record. Patients could also access their record via the PDA web interface (Finkelstein, Hripcsak et al. 1998b).

5.3. Other research on EHR representation

The projects described above in Section 5.2 have sought deliberately to tackle the representation of EHRs at a generic level to support the capture and communication of any potential health record entry, preserving the original clinical context and medico-legal integrity. Internationally, Europe has dominated this field of research. Other groups have investigated the representation of health information with a requirement to enable communication or interoperability within a specific domain or for a particular kind of data. Nevertheless these pilots often generate requirements or design principles that can be generalised to the EHR itself. Some examples of these design principles, taken from the literature, are summarised below.

(Dolin 1994) has demonstrated that the complexity of patient symptoms, including descriptive attributes and the inter-relationships between symptoms, can only rigorously be represented using a nested polyhierarchy.

(Johnson 1996) argues that the general principles for the design of a clinical record repository should be to represent those characteristics of record information that are consistent across multiple patients.

In 1998 Huff et al described a new clinical data model for the LDS Hospital, underpinning the HELP system (Huff, Rocha et al. 1998). All of the common data types found in clinical practice can

be represented but the model does not formalise the overall structural organisation of the EHR, and its data dictionary does not separate the semantic organisation of the record from the terms that may be chosen as data values by an author.

(Muller 1997) describes the need to represent the context relationships between parts of an electronic patient record, including the interaction between care processes, clinical reasoning and the consequent medical record entries.

(Ferri, Pisanelli et al. 1998) describe a prototype clinical record system (CADMIO) based on a generic information model and a user configurable record folder hierarchy for the clinical review of radiology reports and related encounter notes in an ambulatory care setting.

These results confirm the approach identified by the EU EHR-related projects, described above, of adopting a domain-independent hierarchical representation for the EHR, and the use of a data dictionary for specialising this within each domain.

5.3.1. Specialised information models

A number of research groups have tackled the representation of specialised areas of health information. Some examples of this work for time, units, drug data, images and ECGs are summarised below. These results are important for the requirements and information models of the EHR.

Representing time

(Dolin 1995) and (O'Connor, Tu et al. 1999) stress the importance of relating health care information to time, which may be timestamps on recording, time periods captured by systems over time, or time intervals written by authors. (Das and Musen 1994) describe the approach to representing and processing temporal data within CHRONUS, a decision support engine developed at Stanford. Their model defines each time as a single time-point or an interval between two time-points: vague times can then be expressed as start and end intervals bounding an interval of uncertainty. (Combi, Pinciroli et al. 1995) propose a model for time expressions with three main reference time-points: a start, and end and a duration, all of which have a start and end timestamp and a granularity to indicate the level of specificity (years, months, weeks, days, hours, minutes, seconds).

(Buekens, Ceusters et al. 1993) emphasise the distinction between timed events described relative to a setting (time-point, location, author) and those which are expressed in relation to another event. (Ceusters, Steurs et al. 1998) propose three principal categories for representing temporal events in a healthcare record:

1. by relating situations to a calendar;
2. by relating situations to reference situations;
3. by relating events together in "before and after" chains.

These are reflected in the CEN time standard ENV 12381.

(Nigrin and Kohane 2000b) describe the challenge of performing time series and interval related queries on medical records that only contain individual time-stamped entries. They have developed a query tool allowing users to pose queries relating events to each other in time, such as "How many diabetes type II diagnoses were made prior to obtaining two consecutive raised HBA1 tests?"

Units of measure

(Schadow, McDonald et al. 1999) draw attention to inconsistencies in the abbreviation symbols used for measurement units within US, European and International standards, and to the inconsistent way in which combination (compound) units are represented. The authors propose a base set of seven non-overlapping measures: length, time, mass, charge, temperature, luminous intensity, angle, each based on their SI unit. They have identified 13 compounds of these base units that are sufficient to be the building blocks of all medical measurement units. Their approach should permit a more reliable conversion between units, ensuring that parts of a compound unit are treated correctly.

Drug prescription

(Sene, Venot et al. 1995) report the need for a standardised model for drug prescriptions to support electronic prescribing, prescribing advisory and alerting systems and review/monitoring tools. Their summary of the information model developed in OPADE, an EU Third Framework Health Telematics project, is shown below in Figure 29.

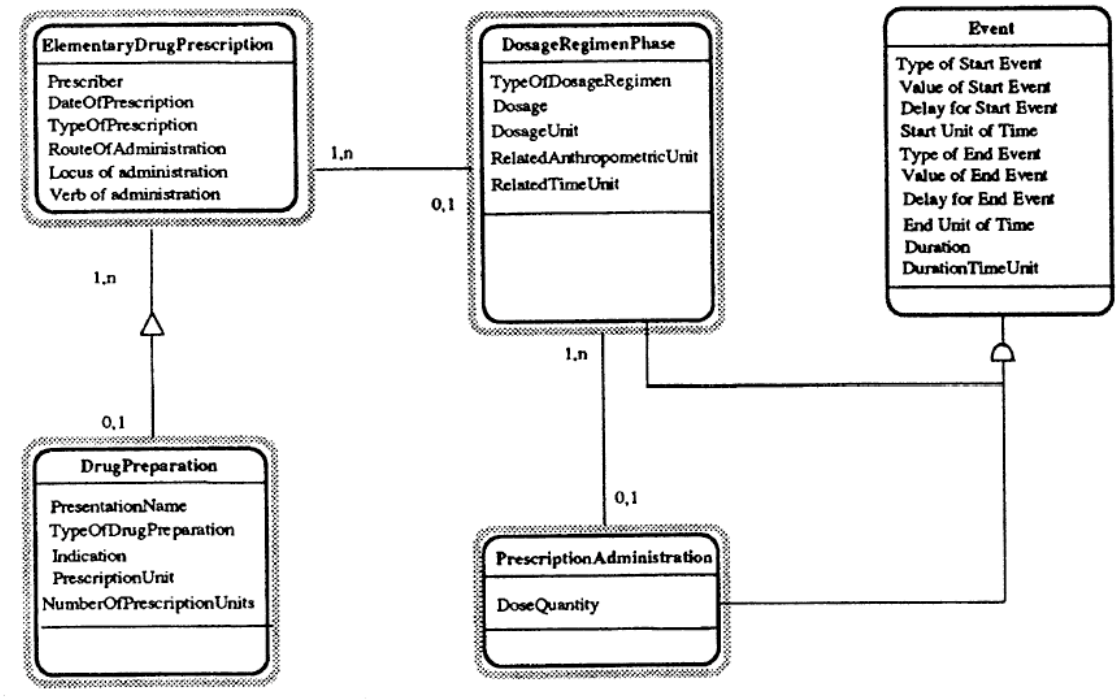


Figure 29: OPADE Project model for drug prescription

Building on the original OPADE work, Duclos and Venot have proposed object models for the representation of drug prescription, prescribing indications and contraindications (Duclos and Venot 2000). Their list of attributes closely resembles those that might also be applied to a diagnosis or rationale for treatment as authored in an EHR.

Medical image reporting

(Huff, Rocha et al. 1995) have designed a conceptual model for the representation of chest X-rays that has been implemented within the data dictionary of HELP system at the LDS Hospital. This LDS pilot was taken forward as a multi-centre project, the Canon Group, to develop a generic representation for chest radiograph reports, with a view in the future to extending this to other diagnostic reports (Friedman, Huff et al. 1995).

(Adelhard, Nissen-Meyer et al. 1999) propose that requests for radiological examinations should be accompanied by relevant clinical findings captured through the order process or from an EHR. This includes previous radiology tests & results, pregnancy status & LMP, basic illness, current illness status, working diagnostic hypothesis and the indication for the requested radiology examination. Additional past illness, renal function, coagulation and allergy information would be needed for specific contrast or invasive procedures.

(Langlotz and Meininger 2000) describe the design of a radiology structured reporting system at the University of Pennsylvania. In small-scale "laboratory" tests the time taken to author a structured report was faster than both conventional dictation and speech recognition.

(Bidgood, Bray et al. 1999) propose a standard set of data items, populated from terms defined in the SNOMED-DICOM Microglossary, which can be used to describe the clinical and technical context of image acquisition. This would permit standardised descriptions of medical images, supporting the development of interoperable image libraries. It is not specifically also a proposal for the imaging report that would normally form part of a patient's record: for example, the interpretation and conclusions of the radiologist are not included in their data set. However, this work has informed the specification of a DICOM Structured Reporting model for that purpose (see Section 5.6.3).

ECGs

The SCP-ECG specification, arising from an EU sponsored R&D project of the same name, has been accepted as the most comprehensive work in this area on both sides of the Atlantic, and future interoperability standards are likely to utilise this work (Zywietz 1998).

5.3.2. Faithful preservation of meaning

(Rector, Nowlan et al. 1991) stress the importance of an EHR that is faithful to the clinical care process. They suggest three kinds of record entries that need to be represented in the EHR.

1. Observation statements: what the patient says and what the clinician sees. This information is attributable to a source, permanent and factual but may include conflicting, uncertain or negative statements, which may be expressed at an arbitrary level of detail;
2. Meta-observation statements: what the clinician thinks, including problems, plans, justifications, reasonings and rationales, analyses, groupings of problems and differential diagnoses.
3. Clinical dialogue: what now ought to happen, including requests and responses relating to investigations, referrals and treatments, the observations and recommendations of third parties.

Berg and Goorman discuss the attraction of secondary uses of medical information as strong drivers for the adoption of EHR systems and for their design (Berg and Goorman 1999). They argue that such secondary uses assume that healthcare data are utilities or commodities that can be extracted, and often aggregated, if their input has been structured and/or coded. The authors describe how entries on a structured form can be influenced by the perceived purpose of the healthcare actions being documented, by the pre-existence of relevant background record information, and by the way in which the authors assume that their entries may in the future be used. The set of information entered at one time and location is proposed as a key principal context for the faithful subsequent re-interpretation of record entries. The authors suggest that it is possible

in most situations to explicitly label the context to a point that permits safe and valid data re-use, but that a considerable effort is required to achieve this.

(van Ginneken and Moorman 1998) discuss the challenge of maintaining clinical meaning within EHRs when terminology systems evolve. They argue that the underlying record entries should not change, but should be clearly marked with term set versions to enable a future query author to choose whether to include older versions of terms in the search path.

The GEHR project identified that apparently simple elements of healthcare information can at times require quite complex recording structures (Ingram, Southgate et al. 1992). For example a blood pressure entry might have one numeric value and one value that is "unrecordable"; it may be measured in different positions (lying, sitting or standing), at different sites (e.g. arm or leg) and by different methods (sphygmomanometer, intra-arterial), which may in turn be further specified (e.g. large cuff). Narrative comments relating to the patient's state of anxiety during the consultation may be important. All of these additional attributes of blood pressure might have clinical significance and may therefore need to be represented in the EHR. They might on occasions have a direct bearing on the way that a single blood-pressure reading is interpreted

Bryant and Norman have demonstrated the wide disagreement about the meaning of commonly used terms to express uncertainty, such as *probably* (Bryant and Norman 1980). It may therefore be difficult to ensure that a subsequent reviewer can correctly interpret the degree of uncertainty expressed by an author.

5.3.3. Narrative versus structure

(Tange 1999) suggests that the flexibility of data entry and support of narratives are major reasons for the retention of paper records by many physicians. He also suggests that, whilst suitable for data entry, the main problem with narrative records is the time spent navigating to relevant record entries and to filter out unwanted detail. The authors have shown that structuring narrative record entries by problem enables faster comprehension by reviewers. Finer grained sub-divisions of the narrative segments tended to slow down information retrieval, probably because the time needed to search among many small segments may outweigh the time needed to read the whole story in a coarse segment, and the content of a single detailed segment may become so restricted that it no longer covers the clinical context needed for a proper understanding (Tange, Schouten et al. 1998).

van Mulligen observes the increasing requirement for the selection and filtering of the large volumes of health information, for reviewing individual patient records and for using the concepts in records as terms with which to search knowledge sources such as Medline (van Mulligen 1999). (van Ginneken 1993) points out that a semantically rigorous and rich extraction from EHRs will

require clinical practice formally to adopt some form of structuring to narrative entries and adhere to it consistently.

In contrast, Berg et al draw attention to the potential for misinterpretation of patient data entered exclusively into highly structured forms, including the problems with interpreting unfilled boxes out of the original context (Berg, Langenberg et al. 1998). They argue for the need for free text to be valued as an important format for capturing the summarised interpretation of the clinician, and of the way in which such mini-summaries are valued as communication tools within teams.

Williams and Morgan describe the need for the structure of information in the EHR to be appropriate to the needs of clinicians (Williams and Morgan 1995). They suggest that EHR systems need to offer users a comprehensive thesaurus of terms, with agreed definitions or clinical consensus on their appropriate use. Data can have varying clinical priority and importance that needs to be noted and represented in some way. Observations may be qualified with a degree of certainty or severity. Information may be organised under headings, negative findings may be recorded, and imprecision may be implied by the phrasing of a diagnosis or management plan. Clinical actions may be intended, planned or carried out. The authors base their conclusions on the experience of the GeneCIS clinical information and management system, and used for the care of 2,000 patients and containing over 15,000 coded entries.

(Lovis, Baud et al. 2000) present the argument for a document-oriented approach to the EHR utilising full text indexing/searching and content-oriented browsing. They propose that this balances the trade-offs between the rich capture of contextual information enabled by narratives and the ability to retrieve or analyse individual items of data. The authors have implemented such a document-oriented EHR system in Geneva. The documents are stored as individual XML document files in directories per patient. Search facilities drill down to patients, their list of documents, and then each individual document. The EHR system has so far accumulated over 1.8 million documents (Jan 2000), and is growing at an estimated 1.5 million per annum. The response times have been less than one second per document requested.

However, Rector argues that marking up narrative text is not sufficient for modern healthcare. He suggests that that medical record information is inherently complex, and that a structure (with some flexibility) is needed to permit useful aggregation and analysis of records (Rector 1993). Narrative entries should ideally be annotations and idiosyncratic additional detail to supplement a core structured and coded record.

This section has highlighted the sociological and clinical complexity that may need to be captured within a health record, and the importance of context surrounding the authorship of individual EHR entries. Achieving the optimum balance between structured and systematised record-keeping

and holistic narrative is difficult, and the EHR must not be prescriptive about this: it needs to accommodate both.

5.3.4. Narratology: patients' stories

(Purves 1995) suggests that the health record is fundamentally a contemporaneous list of observations about an individual's physical, psychological, and social well being. He proposes the adoption of a *Goal Oriented Health Record* for general practice using a set of headings graded for importance to prioritise (for example) the documentation of care plans and of their ongoing evaluation over the recording of basic observations. This could be seen as a more modern general practice variant of the Problem Oriented Medical Record.

(Kay and Purves 1996) argue that conventional medical records abstract and organise the patient's own illness and health story into concepts and strategies in the mind of the clinician. They suggest that in this process critical parts of the patient's story are lost, and may lead to a depersonalisation of health care. They propose a framework for representing the way patient stories and clinician authorship can give rise to a new kind of narratological record. (Kay 1999) argues that the EHCR should ideally capture the interaction between two or more parties from the perspective of each of them rather than only the clinical author.

This approach has to be reconciled with the present day aspirations of good quality health care, which often hinge on consistently structured guideline-based records. It must also be remembered that patient's themselves filter their stories either on the basis of perceived relevance to health care or the kind of health service they wish for.

(Simpson, Wilson et al. 1999) draw parallels between GP record keeping and completing a diary. (Kluge 1996) argues that a patient's story is one perspective on the patient's global information space, whilst a clinician's records might be another legitimate view. (Gremy, Lelaidier et al. 1996) suggest that the medical record is an intertwined system of stories. They suggest that the filtering and selection that takes place from the patient's history and other observations is relevant to the actions that need to be agreed and performed. Hurwitz discusses the way in which time perspectives to a patient can vary significantly from chronological time as it may be perceived by a clinician (Hurwitz 2002).

(van Ginneken 1996b) points out the need to reconcile the individual experiences of a patient with the scientific knowledge and clinical concepts shared amongst healthcare professions. (Rector 1996) points out that a medical record may at times need to be seen as a comprehensive, accurate and legal "log" of healthcare activities, and at times will document hypotheses and filtered abstractions of the healthcare process to support the reasoning of the clinician.

(Berg 1998) stresses the limitations of the idealised image of medical practice as a strictly cognitive process involving gathering observations, testing hypotheses and logically deducing treatments. He suggests that new health data can often undo the reasoning of previously solid historical "facts" and that the clinical picture of a patient is constantly being reconstructed, with no predictable and reproducible basis for weighting one kind of fact over another. He points out that the medical record is not an accurate mirror of the consultation nor an actuarial document, but itself provides a means for organising ideas and contributes to the work of communicating, decision making and sharing with patients. Records contain much reiteration, not because facts are not found elsewhere but to summarise the current focus of thinking. Many entries are brief, concise, and are understood by those who are familiar with the context of that recording, including a familiarity with the author and the clinical setting. Such entries often only note exceptions and emphasised information, and may even omit the routine. Such brevity allows the record to highlight what needs to be known rather than to document all that is known.

5.4. Healthcare Information System Architecture projects

A thread of research running parallel to that on generic EHR representation has been the representation of the health care (business) processes that occur within and between healthcare enterprises. As these projects have included a basic model for health data, and an FHR service will need to interoperate with many of these services, a summary of the main research projects is given below.

5.4.1. The COSMOS Clinical Process Model

The COSMOS project (Cairns, Casey et al. 1992) was funded through the UK National Health Service during 1989-92 to develop a formal model of clinical practice that could inform the development of future computerised patient record systems. The work built on pre-existing models for organ transplantation and donor-recipient matching, but sought to provide a general model applicable to all of clinical practice.

The NHS adopted this approach as its Common Basic Specification for healthcare computing systems (Generic Model and Data Dictionary for the Common Basic Specification 1992). It was revised in 1998 and published as the NHS Healthcare Model (NHS Healthcare Model 1999).

5.4.2. RICHE

Reseau d'Information et de Communication Hospitalier Europeen (RICHE) began in 1989 as a project within the Esprit programme of the European Commission (Kilsdonk, Van de Werff et al 1992.). The purpose of RICHE was

> *"to develop the structure (a framework) of a new-generation of patient-oriented comprehensive open hospital information systems, and to demonstrate this approach through working prototypes."*

The RICHE systems architecture provides an integrated functional model for comprehensive Hospital Information Systems, through a series of interacting component sub-systems. The clinical functions are implemented through the paradigm of *ACT Management*. This defines the transition states through which any healthcare activity may pass and which need to be tracked in order to document the process of healthcare delivery within an enterprise. The RICHE Architecture incorporates a Patient Identification Server, a Patient Dossier Server and an Act Management Server (Frandji, Schott et al. 1994). This Act-based approach to clinical systems has been adopted by a number of systems developers and research projects across Europe. It offers an alternative view to the authored-record approach of ENV 12265 and the main European EHR projects such as GEHR and Synapses.

5.4.3. NUCLEUS

NUCLEUS (1992-4), a follow-on consortium in the EU 3rd Framework, took forward much of the RICHE architecture and its systems component prototypes (Kanoui and Joubert 1995).

The general idea of a NUCLEUS Act-oriented server, with semantic links between parts of the temporal record, resembles the interoperation of care pathway systems with EHR systems, the former being viewed as the "active" monitoring partner and the EHR being the historic repository of "passive" data.

5.4.4. Edith

In 1992 the EDITH special action was launched to build on the previous results of RICHE and NUCLEUS, to specify an open architecture for Healthcare information systems and to verify them in two hospitals in Italy. The main project results include a set of commercial products: a distributed technological platform (the Distributed Healthcare Environment) and several clinical and administrative applications supporting admissions, wards, laboratories, radiology, outpatient clinics and resource management.

5.4.5. HANSA

The HANSA project was launched under the EU Health Telematics Fourth Framework programme to demonstrate the validity of EDITH approach. Its mission, taken from the project proposal, was:

> *"to promote and facilitate the evolution and convergence of the European Healthcare structures towards the new organisational and technological requirements, by permitting the integration, interworking and interoperability of both advanced and legacy information systems through a common and open architectural framework, based on the DHE middleware of common services."*

The DHE middleware, developed by GESI in Rome, still represents the most complete implementation of this kind and is also a reference implementation of the CEN "HISA" standard ENV 12967 (see Section 5.5.2).

Although the Commission-funded HANSA project has ended, the partners continue to promote the DHE and other HISA-compliant middleware solutions internationally. (Burkle, Schweiger et al. 1999) describe the transfer of cancer registry entries for 128 sample patients from a legacy application in Gießen, to an installation of the DHE in Magdeburg. The authors report that an open architecture system such as the DHE, being based on the HISA standard, proved an ideal recipient of the feeder data.

The series of projects described above has treated the EHR as a by-product arising from workflow, and focused on the specification of successful workflow systems. This is in contrast to the EHR research thread that has focused attention on the specific composition of record entries, as deliberately filtered, summarised and organised details that the author deems significant.

5.5. Legislative EHCR Standards

Much of the work and experience gained in the R&D projects described above has informed progress on standards through CEN (see (CEN Technical Committee 251 2002)) and recently in the International Standards Organisation. Such standards can potentially facilitate the interoperability of different vendor products, and enable enterprises to adopt a multi-vendor best of breed solution to local information system requirements whilst remaining consistent with the broader vision of communicable and lifelong health records.

CEN/TC 251 is supported by the European Commission DGIII (industry), healthcare organisations, suppliers of ICT-solutions and users to develop standards that enable compatibility and interoperability between independent systems in healthcare. TC 251 comprises four working groups, which cover: information models; systems of concepts and terminology; security; and technologies for interoperable communication. The overall scope of CEN Working Group I (WGI) focuses on standards for the representation of the Electronic Healthcare Record and standards for messages to meet specific healthcare business needs for the communication of health care information.

5.5.1. CEN EHCR Architecture standards

When the Technical Board of the European Standardisation Committee (CEN) approved the establishment of a Technical Committee for Medical Informatics (TC 251) in May 1990, the Electronic Healthcare Record was regarded as one of the most important and most urgent areas for the establishment of European standards. Working Group I defined the scope and terms of

reference for two work items (WI): WI 1.6 'Electronic Healthcare Record Architecture' (EHCRA) and WI 1.8 'Electronic Healthcare Record Extended Architecture'; these were intended to be the basis for two consecutive project teams.

The Project Team under WI 1.6, PT1-011, developed the pre-standard *ENV 12265 Electronic Healthcare Record Architecture* (Hurlen 1995). ENV 12265 was a foundation standard defining the basic principles upon which electronic healthcare records should be based. Over 80% of its requirements (published in a Supporting Annexe) were derived from GEHR project deliverables. The architecture, summarised in Section 7.2.2, was one key input to the design of the Synapses federated healthcare record architecture and to the UCL Reference Model.

The Project Teams under Work Item 1.8 were convened in 1998 and published a four-part EHCR successor standard ENV 13606 in 1999. This is the current pre-standard for EHCR Communication (ENV 12265 has now been withdrawn). The Project Teams (PT) behind each part of the standard are shown in Table 3.

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

Table 3: Project Teams behind the 1999 4-part CEN standard on EHCR Communication

A healthcare domain model was developed to represent the requirements of clinical practice including professional, ethical, legal and security requirements that must be satisfied by the Extended Architecture, Domain Termlist and Distribution Rules. The model helped to specify the requirements for the other three parts and also provided a background against which to check their content and properties.

The Extended Architecture (Kay and Marley 1999) built on ENV 12265 and defined additional components for describing the structures and semantics in EHCRs conforming to a range of requirements to allow the content of a healthcare record to be constructed, used, shared and maintained. These include those necessary to:

- record such data representations (e.g. text, coded, visual image, signal, sound) as are to be expected in the Electronic Healthcare Record;
- reflect the organisation or grouping of the data;
- enable electronic healthcare record systems to perform the processes required to support clinical practice including care processes, audit and access control.

This part standard is summarised in Section 7.2.5.

The Domain Termlist part of this European pre-standard provided a set of measures to support various degrees of interoperability of the EHCRs created on different systems or by different teams on the same system (Rossi Mori, Kalra et al. 1999). These measures were aimed at enhancing the likelihood that EHCR entries can be accessed or communicated in a way that:

- supports the visual interpretation of original entries by the end-user of a recipient system;
- facilitates record navigation;
- enables the amalgamation of received data to permit the generation of longitudinal views; and
- allows for a limited degree of automated processing, e.g. information retrieval.

This part standard is summarised in Section 5.7.1.

The Distribution Rules specified a set of data objects that represent the rules for defining access privileges to part or whole EHCRs, and the means by which security policies and attributes can be defined and implemented (Hopkins et al. 1999). It also defined the principles that should be employed within an audit trail log.

The part-standard on Messages for the Exchange of Information defined a set of messages to enable the communication of part or whole EHCRs in response to a request message or a need to update a mirror repository of a patient's EHCR (Markwell et al. 1999). These messages were specified in a syntax-independent way (i.e. as message information models) but the publication included an informative XML DTD, which was found to be helpful to a number of implementers.

Implementation experience based on ENV 13606

Since 1999 several demonstrator projects and a few suppliers have elected to use ENV 13606 in an adapted form as their means of EHR interoperability between systems and enterprises. Regrettably the adaptations made to ENV 13606 have been rather *ad hoc*, so the exchange of EHR information between demonstrators or systems is not possible, thus defeating the object of such a standard. Many of these demonstrators are still at an early stage, and documentation about their experiences are not yet available. A few examples of the application of ENV 13606 are summarised below.

(Booth, Jain et al. 1999) describe the TextBase project, an experiment to design an html/XML message based on ENV 13606 to communicate salient patient information between general practices when patients move. The project involved the four main UK GP systems suppliers (potentially representing 13,000 practices, 37 million patients) but has not yet been used in a live clinical setting.

More recently (Markwell, Fogarty et al. 1999) also report the test validation of an XML-EPR message model, based on ENV 13606 part 4, by UK GP system suppliers using sample patient records. The XML renderings were all reviewed by a team of GPs to confirm clinical meaning had been preserved in the transformation process.

Since 1995, ICSF have been developing an electronic medical record system for the hospital sector and a cancer clinical system in partnership with the Institut Bergonié (Cancer Hospital of Aquitaine Region). They have adapted and evaluated the original CEN pre-standard ENV 12265 and ENV 13606 (Renaud-Salis and Lagouarde Philippe 2002). The implementation has been tested at two clinical sites in the region and they have succeeded in demonstrating the XML-based transfer of relevant health record extracts between these sites.

A research group at the University of Athens have developed a web-based application (JAnaemia) using Java that is based on the constructs in ENV 13606 (Deftereos, Lambrinoudakis et al. 2001). The group have critically reviewed the standard in relation to their information requirements, and needed to make a number of adaptations to enable the implementation of a complete and robust application. The system has been installed and supports the clinical care of beta-thalassaemic patients at four Greek hospitals.

A Norwegian Ministry of Health project is funding the development of a comprehensive EHR model (based on ENV 13606) that is to be implemented by several national hospital and GP systems suppliers as an XML interface for record transfers (Glück and Nystadnes, personal communications)

The Danish Ministry of Health is amongst those whose national strategy for EHR information models is loosely based on ENV 13606 but targeting subsets of the overall model. (Bredegaard Kirsten 2000) reports that that the priority areas of health information for which a detailed model is intended are episodes, diagnoses, prescribing and other interventions.

CEN Task Force to revise ENV 13606

In December 2001 CEN TC/251 confirmed a new Task Force, *EHRcom*, to review ENV 13606 and to propose a revision that could be adopted by CEN as a formal standard (EN). The author is leading this new Task Force. The overall mission proposed by the Task Force is to produce a rigorous and durable information architecture for representing the EHR, in order to support the interoperability of systems and components that need to interact with EHR services:

- as discrete systems or as middleware components;
- to access, transfer, add or modify health record entries;
- via electronic messages or distributed objects;
- preserving the original clinical meaning intended by the author;

- reflecting the confidentiality of that data as intended by the author and patient.

The work of the Task Force will build on the existing pre-standard ENV 13606 and on the implementation experience described above. Important aspects of its work will be to examine why the 1999 standard was so poorly and haphazardly implemented, and to align the new standard more closely to the results of contemporary EHR research.

5.5.2. CEN standard ENV 12967

The CEN 'Standard Architecture for Healthcare Information Systems' (ENV 12967, commonly known as "HISA") seeks to enable the development of modular open systems to support healthcare (Ferrara 1998).

The HISA standard builds on the extensive work of RICHE, NUCLEUS, EDITH and HANSA in this field (summarised in Section 5.4). The architecture of any generic healthcare information system is described as a federation of heterogeneous applications, interacting and co-operating through a middleware layer of common services. It specifies the structure of the data maintained and retrieved by each service, without prescribing its internal structure. Both applications and the middleware rely on a set of technological facilities (a bitways layer) to enable the physical connection and interaction of various modules as shown in Figure 30 below.

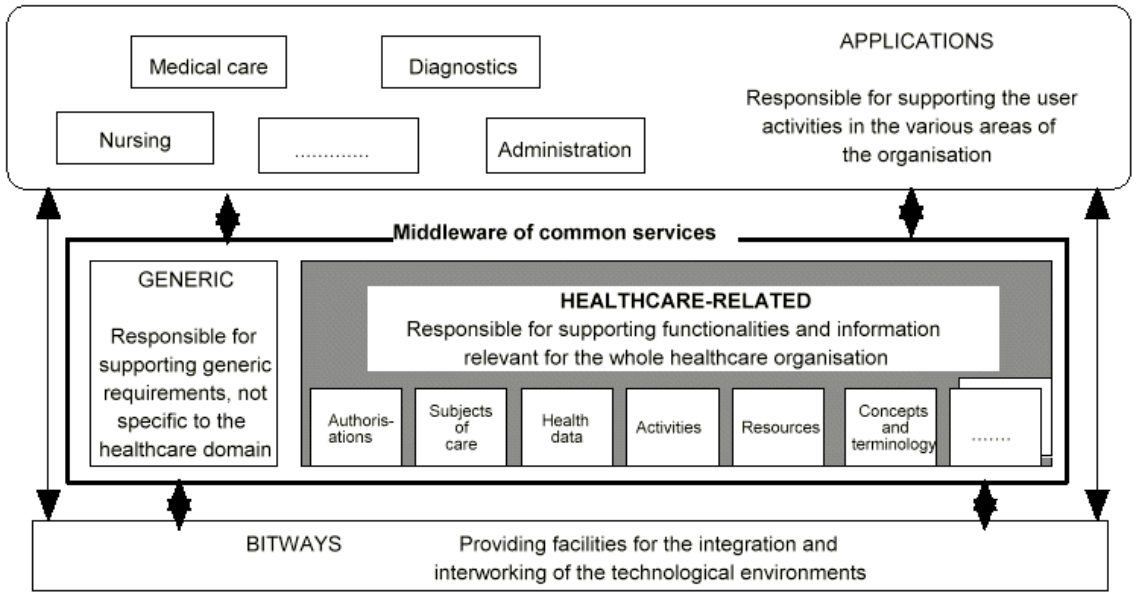


Figure 30: The scope of the HISA standard

Two main classes of common services are identified:

1. Healthcare-related Common Services (HCS) meeting the particular requirements and activities of users in the healthcare business domain. These relate to the subject of care, activities, resources, authorisation, health characteristics, concepts.

2. Generic Common Services (GCS) which may be common to any information system in any business domain.

(Blobel 2000a) supports a systematic, object oriented, component and service based approach to the specification of healthcare system architectures. (Kanoui, Joubert et al. 2000) echo the requirement for open-architecture health information systems and the clinical requirement to manage increasing volumes of new medical knowledge. They have designed a semantic concept model that can provide a high-level framework for mapping the hierarchical contents of a healthcare record (the RICHE Patient Dossier) with the workflow-oriented requirements of an Act Management Service. The complete implementation, known as STIMUS, has been installed and evaluated in Marseilles. (Scherrer and Spahni 1999) describe a HISA-like implementation at the Geneva University Hospital utilising an intelligent request broker. (van der Velde 2000) describes the key service components that would comprise an organisation's health information systems in terms of the HISA standard, but suggests that the EHR business objects could be derived from the work of GEHR and Synapses. In this, he is perhaps one of a few authors who have explored a potential pathway for usefully combining two branches of health informatics R&D and standards: HISA and the EHR.

5.5.3. ASTM Standards

The American Society for the Testing of Materials (ASTM) was established as a non-profit standards organisation in 1898. ASTM is accredited by the American National Standards Institute (ANSI), and has 132 standards writing committees. Committee E-31 on Healthcare Informatics was established in 1970 with a mission

> *"to develop standards for health information systems designed to assist vendors, users and anyone interested in systematized health information. The current standards address architecture, content, portability, format, privacy, security and communications."*

In 1995 the Board of Directors of the American Medical Informatics Association stressed the need for several new standards to support the development of computerised medical records (Standards for Medical Identifiers, Codes, and Messages Needed to Create an Efficient Computer-Stored Medical Record. American Medical Informatics Association. 1994):

- patient, provider, and site of care identifiers;
- computerised health care message exchange;

- medical record content and structure;
- medical codes and terminologies.

They endorsed ASTM E31 as the body with responsibility for the wide-scale standardisation of record structures. Committees under the jurisdiction of E31 include E31.19 (Electronic Health Record Content and Structure), which has been responsible for the production of several standards including the four summarised below.

E1238 Specification for Transferring Clinical Observations between Independent Computer Systems

This standard, published in 1988, was the first published consensus standard in the US for the transfer of clinical data between independent computers and is mainly used for laboratory system interfaces. This standard is technically aligned with the Observations and Results chapter of HL7 (Huff 1998).

E1384-99e1 Standard Guide for Content and Structure of the Electronic Health Record

This standard defines the content and logical structure of a Computer-Based Patient Record (CPR) relevant to the provision of conventional healthcare services in acute care, primary care and long-term residential care. This includes health care descriptions and observations, orders for and reports of investigations and actions performed including medication treatment. A future version of the standard will also include health status measurement, preventive case, and health education.

(Biczyk do Amaral, Hartmann et al. 1999) describe a prototype implementation of a web based EHR using the ASTM-E31-1384 data item dictionary. This has so far been validated against sample case histories from papers published in the New England Journal of Medicine.

E1633-00 Standard Specification for Coded Values Used in the Electronic Health Record

This standard defines the sets of names and data representations to be used for the data elements identified in E1384.

E1744-98 Standard Guide for View of Emergency Medical Care in the Computerized-Based Patient Record

This standard defines the data items necessary to document emergency medical care in a CPR that is part of a paperless patient record system. This is not the equivalent of a patient's summary record, which is seen as the scope of another future standard.

Other examples of ASTM committees relating to the EHR include:

E31.17 Privacy, Confidentiality, and Access
E31.20 Data and System Security for Health Information
E31.25 XML Document Type Definitions (DTDs) for Health Care

E31.26 Personal (Consumer) Health Records
E31.27 Data Capture and Report Generation
E31.28 Electronic Health Records

ASTM standards for XML DTDs for healthcare are expected to concentrate on the definition of domain-specific documents and not formalise a generic underlying electronic health record model (Sokolowski and Dudeck 1999).

The ASTM standards have been used for specific health data transfers between hosptial sub-systems and between purchasers and providers. The recent growth of HL7 in the US, as the new major driver for interoperability (see Section 5.6.1 below), may now mean that ASTM plays a less active role in future health data communications standards.

5.5.4. Messaging standards, EDIFACT and XML

CEN message standards

CEN/TC 251 has developed several message standards to facilitate the electronic exchange of structured information between autonomous computer systems within and between healthcare organisations. CEN has regarded such standards as essential if healthcare services are to obtain the benefits of open systems and avoid the constraints of proprietary interfaces.

The CEN message standards include:

- Message development methodology (CR 1350:1993);
- Registration of coding schemes (ENV 1068:1993);
- Request and report messages for clinical laboratories, including clinical chemistry, haematology and microbiology (ENV 1613:1994);
- Referrals and reports for specialist clinical services, including referrals from general practitioners to hospital specialists, clinic letters and discharge summaries (ENV 12538: 1997);
- Request and report messages for diagnostic services, including diagnostic imaging, including scheduling information (ENV 12539: 1997);
- Medical Imaging Communication (ENV 12052: 1997);
- Messages for the exchange of healthcare administrative information (ENV 12612: 1997).

Much of this work was reviewed and generic parts of it incorporated within ENV 13606 (described in Section 5.5.1 above). The clinical data sets defined within these message standards are, however, more closely related to the other work on common data sets such as HL7 (see Section 5.6.1 below). There is now a close inter-working between CEN and HL7 in this field to ensure compatibility.

Love suggests that the definition of individual communication requirements on a message by message basis, through EDI, is a perfectly valid alternative to the approach of defining a prior domain information model (Love 1995). He argues that user requirements can best be defined and agreed by the parties relevant to a specific message definition rather than the experts who define the overall domain models.

For many years EDIFACT has been the most widely used protocol for EDI messages. Interest in the alternative use of Standard Generalised Markup Language (SGML) has been heightened by the more recent XML family of standards, which significantly extends the HTML specification to facilitate the communication of systematically structured documents via the HTTP protocol over the Internet. Considerable support is also growing for the adoption of middleware component system architectures within healthcare, which will use CORBA (or other industry equivalents such as Microsoft's D-COM and .NET) as the standard for object exchange within and between enterprises. (Dolin, Alschuler et al. 1997) have shown that SGML is a valid alternative to other message representations (e.g. ASTM and EDIFACT). Laforest et al argue for the strengths of XML as a representation of medical documents, and describe work in progress to design an appropriate DTD (Laforest, Frenot et al. 1998).

(Dudeck 1998) argues that healthcare communications standards, such as EDI messages, fail to establish requirements for the internal structure and architecture of the communicating systems. He points out that this requires the information in any one system to be mapped twice: once into the message standard format by the contributing system, and once back into the internal representation of the receiving system. He points out that the diversity of message standards and syntaxes (HL7, EDIFACT, X12, ASTM, DICOM) adds to the complexity of this mapping activity.

In planning the design of an EHR system in Japan, Takeda et al (Takeda, Matsumura et al. 2000) have reviewed the work of GEHR, Synapses, EHCR-SupA and CEN TC/251 on health record architectures and the more document-oriented approach advocated by the HL7 Clinical Document Architecture (described in Section 5.6.1). They consider that XML-structured documents may offer a way of combining these approaches.

However, it is the view of the author that unless a common and fine-grained model of the EHR can be defined and agreed, XML document exchange will not provide for the rigorous and processable transfer of the detail within these documents (i.e. they might be understood only through human interpretation).

5.5.5. International Standards Organisation (ISO)

The ISO Technical Committee 215 (Health Informatics) was formed in late 1999 to support the compatibility and interoperability of Information and Communication Technology (ICT) systems in health care. There are presently five Working Groups:

- WG 1 Health records and modelling co-ordination
- WG 2 Messaging and communication
- WG 3 Health concept representation
- WG 4 Security
- WG 5 Health cards

(Treseder and Williams 1998), in outlining the work programme for ISO TC/215, state the need to balance robust standards against overly prescriptive standards, stressing the need for timeliness, quality and affordability in gaining and sustaining vendor acceptance. Working Group 1 is presently defining the overall scope of the EHR and a set of requirements for EHR information (outlined in Section 6.1.1).

This ISO forum, bringing together such a diverse international set of informatics and health service stakeholders, will probably progress only slowly to define standards for the EHR.

5.6. Relevant Healthcare Industry standards

Comparing industry and legislative standards

Legislative standards can take many years to produce and ratify, and risk being too generic to be of real value (Stokes 1995). However, industry standards and *de facto* standards, whilst often more rapidly developed, risk favouring the originating company (the "owner"). (Korpman and Dickinson 1998) suggest that standards-making bodies, especially if industry-backed, are not entirely motivated to develop true information integration because they have point-to-point integration solutions to sell. One successful alternative is the role of a non-profit industry sponsored organisation, as exemplified by HL7, to broker the potential vested interest of individual vendors within a democratic consortium (Stokes 1998).

In contrast to legislative standards, the Internet Engineering Task Force (IETF) requires that in addition to consensus on a proposal there must be “working code” - an implementation of the proposed technology to demonstrate that the constructs in the proposal are valid - a proof of concept which might also act as a reference implementation.

(Harrington, Melo et al. 1998) suggest that the integration of information systems in a heterogeneous environment is a top health IT challenge, but argue that heterogeneity of standards

is also a fact of life. They suggest that barriers to the operational use of health information standards lie in:

- the lack of a precise complete specification which can be validated;
- the lack of middleware tools supporting implementation, integration and operation.

5.6.1. Health Level 7 (HL7)

Origins of HL7

The Health Level Seven (HL7) organisation was formed in the United States in March 1987. It arose initially to tackle the growing diversity of messages developed within the US health insurance industry. The HL7 protocol is a collection of standard formats that specify the interfaces for electronic data exchange in healthcare environments between computer applications from different vendors. The focus of the HL7 organisation is the interface requirements of large healthcare enterprises. It represents over 1,500 hospital, professional society, health care industry, and individual members including almost all of the major US health care systems consultants and vendors. HL7 is presently being used in the United States, Australia, Canada, Germany, the Netherlands, Israel, Japan and New Zealand. Additional countries are joining each year.

HL7 version 2

HL7 version 2 messages have been developed to reflect standardised reporting data sets for several aspects of a patient's care in hospital:

- patient admission, transfer or discharge (ADT);
- orders for drugs, procedures or tests and their results;
- messages relating to finance and billing information;
- clinical observations focusing primarily on measurements.

The HL7 protocol specifies the precise messaging syntax to be used, including definitions of segments and internal code strings. Because many of these messages have been developed to support the administration of patient care rather than supporting the work of individual clinicians, the clinical content of the messages is often quite limited. It contrasts with the EHR research and standardisation activities within Europe that have placed the support of individual clinicians working directly with patients as the primary concern.

HL7 version 3

Despite its wide uptake internationally, the problems of inconsistent implementations of Version 2 and the unsystematic growth of message segment definitions have limited the realisation of interoperability. A key feature of Version 3 is the Reference Information Model (RIM): a means of

specifying the information content of messages through an information model that clarifies the definitions and ensures that they are used consistently. The RIM is a formal object model, expressed using UML, representing the superset of core classes and attributes that will be required (in various combinations) by the different HL7 version 3 messages. The RIM defines five major classes of information:

- Entities, for example persons, organisations, places and devices;
- Roles, for example that of patient or employee;
- Relationships, for example that between a patient and a clinician;
- Acts, for example the recording of patient encounters, observations, procedures;
- Document structures such as tables and core entries;
- Control classes dealing with the message transaction process.

The Act class structure is intended to represent the kind of information that would be communicated to support clinical shared care. The Patient_encounter class is illustrative of the hospital-based ADT ancestry of this model, and is shown below in Figure 31. The patient encounter attributes are those administrative details typically recorded on a patient's admission to hospital, and could not readily be generalised to any kind of health care encounter.

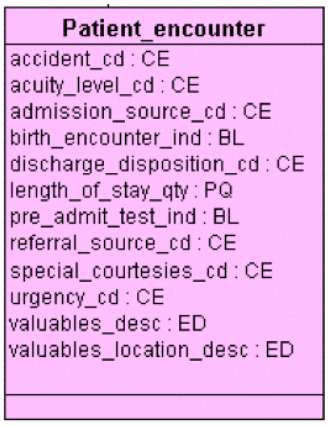


Figure 31: Patient_encounter classs of HL7 version 3 RIM

The HL7 Vocabulary Technical Committee defines the code sets associated with all of the relevant attributes of HL7 including the RIM (Bakken, Campbell et al. 2000).

The RIM will provide the foundation model for the generation of restricted message information models (R-MIMs), which are intended to apply to a particular communications domain, and for common message element types (CMETs), which are reusable generic message fragments. These two derivatives of the RIM will in turn be used to define hierarchical message descriptions (HMDs) that are a syntax independent representation of the HL7 version 3 messages. These might, for example, be implemented using EDIFACT or XML. (Dolin, Rishel et al. 1998) have demonstrated

that XML can be used to represent the content of HL7 version 2 and version 3 messages, although the authors admit that the resulting messages might be 40-100% larger than at present.

The RIM has been informally considered by some HL7 members as a candidate for EHR communication, but this has yet to be validated. It is therefore seen as an important competing alternative to the European EHR approach as adopted by the author. This issue is discussed in Section 13.3.

Unified Service Action Model

The Unified Service Action Model (USAM), which was developed as an adjunct to the early versions of the RIM, defines an action centred model as a means of managing cost and efficiency (Russler, Schadow et al. 1999). This model has contributed to a simplification of the initial RIM by clarifying the necessary relationships between persons and other agents and their authorship of observations, medications, procedures etc. in a record. Most of its constructs are now included within the RIM Action class.

The Kona Proposal

The Kona proposal was the result of a one-week brainstorming session involving the HL7 SGML Special Interest Group, including industry representatives. Its outcome was a preliminary proof of concept method by which a number of the aims and mechanisms of HL7 could be realised in SGML applications. This takes the form of a multilevel architecture comprising four levels corresponding to the granularity of SGML-tagged structure within the data. This is illustrated in the diagram below (The Kona Proposal 1998).

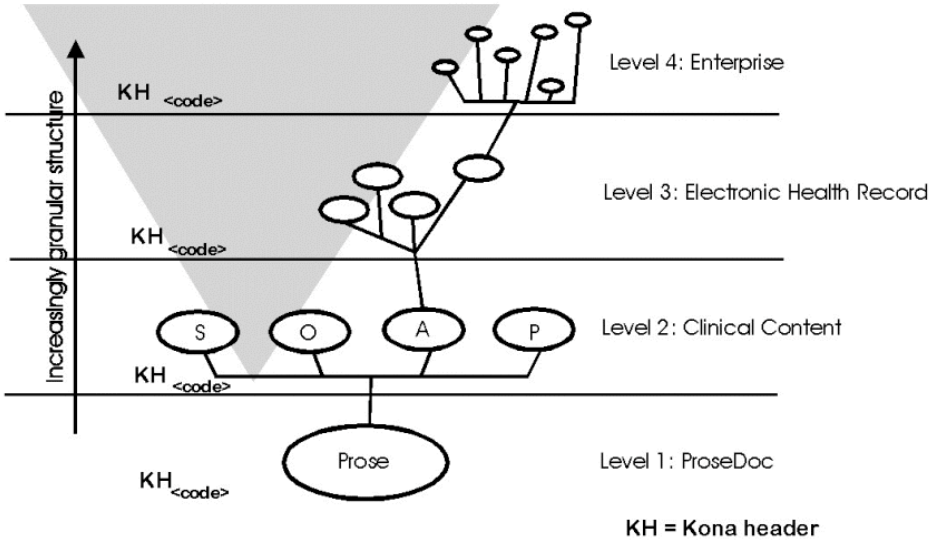


Figure 32: The Kona architecture

From (The Kona Proposal 1998)

Kona Level One

The coarsest level of detail is Level One, which is really a Kona metadata "wrapper" for electronically rendered documents. This is envisaged as the first step towards the adoption of the architecture, as it requires only the addition of metadata (high level descriptions of the document) but leaves the content of the legacy forms and reports unchanged (e.g. as scanned document images).

Kona Level Two

Level Two, "Clinical Content", seeks to encode the structure of documents used for clinical care. This could be relevant to multiple institutions with similar clinical interests: for example several health insurers could implement the same DTD for communicating with a wide range of hospitals. The SOAP classification (Subjective, Objective, Analysis, Plan) has been included at this level as a candidate generic structure for such contents.

Kona Level Three

The third level is "Electronic Health Record", which represents a fully encoded health record capable of transmission or export to other systems. The proposal recommended that HL7 concentrate on developments at this level.

Kona Level Four

The fourth level, named "Enterprise", was envisaged as being internal to a specific organisation and thus customised for its particular needs. It seemed unlikely to the group that common consensus standards for Level Four DTDs would be relevant or helpful.

The Kona proposal was accepted by the HL7 SGML SIG and fed into the Version 3 proposals, where it was initially taken forward named the Patient Record Architecture (PRA). Is has now been further developed under the name of the HL7 Clinical Document Architecture.

HL7 Clinical Document Architecture

The HL7 Clinical Document Architecture (CDA) is a proposal for the generic structure of clinical documents, based on the original 4 Kona levels, and is sometimes regarded as the HL7 equivalent of a record architecture (Dolin, Alschuler et al. 1999). Only Level One of the CDA has at present been ratified. This XML-based specification includes a header with document authorship information, organisational origin and patient identifiers, and a body whose basic structure is loosely defined at this stage (Dolin, Alschuler et al. 2000). Data types are taken from HL7 V3 RIM. The authors recognise that a more detailed specification will take time to agree and adopt, but suggest that this level of specification will enable a rapid basic level of interoperability between document-based systems (Dolin, Alschuler et al. 2001).

CDA Level 3, proposing a fine-grained document structure, will resemble the inner structure of an EHR. The work of this group over the next 1-2 years, as Level 3 candidate specifications are reviewed and debated, will therefore be an important contribution to future iterations of the representation of the EHR.

5.6.2. CORBA Health Domain Task Force

Object Management Group

OMG was founded as a non-profit corporation in May 1989 by eight companies: 3Com Corporation, American Airlines, Canon, Inc., Data General, Hewlett-Packard, Philips Telecommunications N.V., Sun Microsystems and Unisys Corporation. OMG is committed to *"developing technically excellent, commercially viable and vendor independent specifications for the software industry"*. The consortium now includes over 800 members.

Health Domain Task Force

The HDTF, formerly known as CORBAmed, has over fifty members representing vendors, health care providers, payers and end users. HDTF is developing standardised object-oriented interfaces between healthcare related services and functions, to provide compatibility for a wide range of software components and to provide software developers with access to larger markets. The work of the group spans the Information and Computational ODP Viewpoints, and therefore overlaps with the development of EHR architectures, messages, classifications and term sets. The activities within HDTF are not restricted to the implementation of object oriented systems. The main CORBA HDTF specifications potentially relating to or interfacing with EHR services and systems are listed below in Table 4.

Roadmap	Global perspective and direction for HDTF standardisation activities (as a set of healthcare specific functional areas).
Person Identification Service (PIDS)	Services to identify and locate a person and their associated records across systems, be subject to the confidentiality concerns and the right for anonymous care.
Clinical Observations Access Service (COAS)	Query, retrieval and display of clinical observations.
Decision Support Services (DSS)	Integration of decision support technology
Lexicon Query Service (LQS)	Common access to medical terminology resources.
Security	Identify and implement security requirements specific to the security and confidentiality profile of medical domain.
Pharmacy	Common access to pharmacy resources.

Health Level 7 (HL7)	Seamless CORBA object interoperability with HL7 messages.
Workflow	Work flow and event passing between medical components and activities.
Schedule and Calendar	Physician, patient and resource scheduling
Electronic Commerce Payment Facility	Payment of electronic medical claims
Biomedical Imaging	Object oriented access to radiology, endoscopy and related imaging technology.
CORBA/M (Mumps) Interoperability	Wrappers and IDL bindings to integrate Mumps-based systems into a CORBA-based environment.
Transcription	

Table 4: CORBA HDTF specifications potentially interacting with an EHR

Clinical Observations Access Service (COAS)

COAS defines a set of services that may be offered by a clinical application or data repository to enable other components or applications to request and to receive one or more clinical observations on a patient (CORBA Health Domain Task Force 2001b). COAS is underpinned by a basic information model of an observation, which is a simple hierarchy comprising name value pairs (ClinicalDataElements) that may be grouped under a Header and may have links to other ClinicalDataElements via ItemRelation and ItemRelationSeq classes. Each ClinicalDataElement may have a data value that is drawn from a comprehensive set of data types defined in the specification. This information model is relatively simplistic in comparison with the EHR information models proposed by the European research projects described above in Sections 5.2. The service itself relies upon other CORBA HDTF services such as the PIDS to confirm the identity of the patient about whom observations are requested, and the LQS to determine the rubrics and knowledge relationships of the terms within any textual observation.

Person Identification Service (PIDS)

This specification defines the interfaces that organise person identity management to meet healthcare needs (CORBA Health Domain Task Force 2001a). These services identify and locate person identifiers and their associated records across facilities, enterprises and systems, subject to the confidentiality concerns and the right for anonymous care. (Forslund, Smith et al. 2000) have, for example, used the CORBAmed PIDS services as a means of federating multiple patient master index systems.

Lexicon Query Service

The Lexicon Query Service (also known as Terminology Query Service - TQS) defines a specification to support the use of multiple vocabularies in a heterogeneous application

environment, based on the notion of a terminology service (CORBA Health Domain Task Force 2000). This specification has been informed by demonstrator terminology servers such as those produced by GALEN and the Mayo Clinic MetaPhrase terminology server (Chute, Elkin et al. 1999).

Although the CORBAmed PIDS and TQS are regarded as good middleware specifications, uptake of these has been limited. Almost no implementations of COAS have been developed outside research contexts. These specifications are now being reviewed by HL7 but little active work appears to be taking place inside the HDTF itself.

5.6.3. DICOM

The Digital Imaging and Communications in Medicine (DICOM) standard was first published in 1993 jointly by the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA), building on two previous ACR-NEMA specifications originating from 1985. It addresses the issue of vendor-independent data formats and data transfers for digital medical images. Both CEN and ANSI have adopted DICOM by reference in their imaging standards. DICOM is presently in version 3, comprising 14 chapters relating to the acquisition, storage and communication of different kinds of image data.

(Brown, Britton et al. 1998) stress the importance of the data that may be associated with medical images. Although strong standards exist for the technical data associated with image acquisition (e.g. DICOM, HL7), they suggest that the clinical and descriptive data elements also need to be profiled to enable interoperability with clinical systems to support patient care. (Bidgood 1997) describes the requirement for a standardised information architecture to facilitate the exchange of imaging procedure descriptions and DICOM image interpretation reports. He has led the development of a standard information model for the representation of medical image structured reports (DICOM-SR). This work is related to a controlled vocabulary for reporting imaging studies to permit their semantic analysis. This has been published as the SNOMED DICOM Microglossary (see Section 5.3.1).

The DICOM-SR specifications provide a simple generic structure for an electronic report document that is also a candidate for inclusion within the EHR. However the present model, in the view of the author, is not sufficiently rich in medico-legal and revision attributes to satisfy the requirements documented in Chapter 6.

The inclusion of multimedia data within the EHR is of great importance to clinicians. The authors of DICOM-SR and others in the field are collaborating with HL7 on the RIM and Clinical

Document Architecture, and with European research and standarisation groups in order to advance current EHR specifications to include multimedia reports.

5.7. Metadata: representing EHR domain knowledge

In parallel with the work on EHR architectures over the past decade, formalisms have been investigated by which the medical knowledge necessary to interpret and to process health record entries can be represented. The term *metadata* is sometimes described as "data about data", and commonly illustrated by the schema of a database. However the term is also used for the indices and knowledge models that describe the data content of a statement, a document or a database entry.

There are several published formalisms for the representation of metadata that can be applied to the information model of the EHR. Three specifications are discussed below in this section: the Dublin Core Metadata Specification, ISO/IEC 11179 and Categorial Structures. These are examples of developments focused on a formal and generalised information model to represent metadata. A larger number of specific data dictionaries have been developed to support health care record systems, often within large hospitals. This latter group have often been empirically driven with a principal focus on the accumulation and exploitation of the clinical semantic content; the information models underpinning them are often tightly coupled to the local clinical systems at those sites and so not readily migrated to other settings. They are discussed in Section 5.7.2.

Dublin Core Metadata Specification

The Dublin Core Metadata specification defines a set of header tags that can be used to systematically index and reference the content of web pages (Dublin Core Metadata Initiative 1995). The Dublin Core elements include: title; creator; date; subject; publisher; type; description; contributor; format; source; rights; identifier; language; relation and coverage.

(Munoz and Hersh 1998) have used the Dublin Core elements and terms from the MeSH thesaurus (as rubrics and codes) to capture document subject index terms and other relevant header information from clinical (web based) documents. They have developed tools to include this information as a "meta-header" to the html page for web indexing and searching tools, potentially to enable a Medline-like search facility for the web (Malet, Munoz et al. 1999).

This metadata specification is relatively general, and has recently been adopted in the UK as part of the e-Gov programme to support metadata registries in local government. It is too general to be applied directly to EHR metadata repositories.

ISO/IEC 11179

The ISO/IEC 11179 Specification and Standardisation of Data Elements proposes a standard approach for the construction of a metadata dictionary. This is a framework standard rather than a populated dictionary of healthcare elements. The attributes for Data Elements (still in draft form) are listed in Table 5 below. This list resembles those attributes proposed by the author to register archetype definitions in the FHR Archetype Model, described in Section 8.2.

Name	Label assigned to the Data Element
Identifier	Unique ID assigned to the Data Element
Version	Version of the Data Element
Registration Authority	An organisation authorised to register the Data Element
Language	Language in which the Data Element is specified
Definition	A statement that clearly represents the concept and essential nature of the Data Element
Obligation	Indicates whether the Data Element is required to always or sometimes be present (mandatory, conditional, optional)
Data type	Indicates the type of data that can be represented in the value of the Data Element
Maximum Occurrence	Indicates any limit to repeatability of the Data Element
Comment	A remark concerning the application of the Data Element

Table 5: Attributes for Data Elements proposed in ISO/IEC 11179

(Solbrig 2000) notes that, after an initial wave of enthusiasm, work on this standard is progressing slowly. The XMI (XML Metadata Interchange) specification to be published by the World Wide Web Consortium (W3C) may facilitate the standardisation of tools and APIs in this area. The new W3C enterprise business XML (ebXML) specification for metadata registries might also overtake the ISO work in this area.

Categorial structures

(Rossi Mori and Consorti 1999) have carried out an extensive review of the headings and entries within a wide range of clinical documents, in order to populate a three-tier semantic structure that can be used to classify and compare the content of patient records from a semantic perspective:

1. documents and sections;
2. clinical statements;
3. systematic details within statements.

They have proposed methods for representing clinical meaning in each of these three tiers, called categorial structures. The authors propose these as an alternative to standards like ENV 12265 for representing clinical statements (Rossi, Galeazzi et al. 1997). They argue that a basic record structure allows variability in the granularity and hierarchical organisation of a clinical statement because Record Items can be named arbitrarily and populated from any clinical terminology (Rossi Mori and Consorti 1998).

(Harris, Graves et al. 2000) argue that systematic evaluations must be performed of the extent to which categorial structures accurately and completely represent nursing and other non-medical domains.

(Rossi Mori, Consorti et al. 1998a) also describe a system of tags that could be used to represent formally the implied context for the interpretation of a health record entry within its original record system. Such context can easily be lost if data items are communicated to other record systems in isolation. They also point out that it may prove difficult for clinicians to accept a standardised set of record structures or headings, and that their alternative should be sufficient for the "safe" communication of records and for some local processing. The authors suggested system of tags is given below.

C0 Nature: tags to identify the nature of data;
C1 Safety context: essential tags that convey the main context of data;
C2 Interpretation: tags about interpretation of data in the original context by the original user;
C3 Intention: additional tags to make explicit the links that reveal a sender's intentions and goals;
C4 Organisation: further tags to show the organisation of the original record.

This work fed into and was refined by CEN/TC 251 and published as the CEN Domain Termlist standard ENV 13606-Part 2 in 1999. This is discussed in Section 5.7.2 below. The view of the author is that this system of tags should form part of rather than replace a formal information model for the EHR.

Concepts underlying continuity of care

CEN standard ENV 13940 defines a set of concepts for health care parties, threads of care and mandates (responsibilities) that are needed to ensure the complete documentation of continuing shared care (Mennerat and Booth 2002). These concepts need to be represented consistently and communicated between clinical information systems to support safe and high-quality care. The author, and the lead authors of ENV 13940, believe that the EHR needs to be able to cater for all of these concepts, most of which would be represented through the archetype approach presented in Chapter 8.

5.7.1. CEN ENV 13606-2: Domain Termlist standard

The 1999 CEN/TC 251 pre-standard ENV 13606 has been summarised in Section 5.5.1. The Domain Termlist proposals provide a high-level and coarse-grained representation of the clinical meaning of one or more entries that can be applied in a consistent manner even if a diversity of information models are used to represent the EHR. The standard does not attempt to provide a complete and rigorous semantic "mirror" of the detailed clinical entries themselves. Although necessitating some duplication of information within EHRs, the proposals are intended to attach a set of safe and consistent tags to the clinical data that can assist human interpretation, can support record navigation and enable a limited degree of processing for information retrieval purposes. The measures in the standard include:

- a simple classification for clinical documents or other high-level entries in the EHR representing a single patient encounter;
- a simple classification for clinical headings that may convey an important context within a clinical document;
- a system of component annotations, building on the tags described in Section 5.7 above, to indicate the existence of modifiers or qualifiers within an EHR entry that significantly alter the way that the core term should be interpreted;
- a simple classification system for links between EHR entries.

The author was a core member of the CEN Project Team that developed this standard, and has regarded the component annotation approach as an important contribution to the goal of preserving clinical meaning between heterogeneous systems within the FHR. Several of the annotations are included as attributes of the FHR Reference Model described in Section 7.4.

5.7.2. Example Data Dictionary approaches

Standard data sets are often used to enable a range of goals including consistent patient care and faithful message-based communication, as previously discussed in Section 4.1.2. Examples of the widespread adoption of such data sets have also been described, such as the DiabCard project (Section 4.3.6). These data sets are rarely founded on a generic information model for the underlying health care record, and data sets originating from one setting cannot usually be used in others. These prolific but rather individual specifications have not been considered further in this section, which focuses on work to develop generalised representations for medical knowledge or health record data-sets.

Within the Columbia Presbyterian Medical Centre

The Medical Entities Dictionary (MED) is the repository of concepts, terms, relationships and cross-maps that anchors the knowledge functions of all clinical systems at the Columbia

Presbyterian Medical Centre. In 1994 Cimino et al reported a MUMPS implementation of the MED with 32,000 terms, which included links to the UMLS thesaurus, facilitating the automatic classification of laboratory test reports (Cimino, Clayton et al. 1994). By 2000 the MED had grown to comprise a semantic network with 60,000 concepts, 208,000 synonyms, 84,000 hierarchic relations, 114,000 other semantic relations, and 66,000 mappings to other terminologies, including the UMLS and LOINC (Cimino 2000). An object formalism is now being used to help with its maintenance (Gu, Halper et al. 1999).

Terms are drawn from laboratory, pharmacy, radiology, and billing systems. The relationships in the network provide definitional knowledge about the individual terms (Cimino 2001). The dictionary has been used to support direct clinical encoding (via a terminology browser), smart querying of records (DxPlain), just in time education (including "Infobuttons"), expert systems, data mining and more recently the integration of legacy systems.

(Cimino 1995) performed a comparison between the MED and the UMLS Semantic Network (USN) in 1995, and found much in common with the way these two conceptual models had evolved. Both classify terms from a medical knowledge perspective but, unlike the MED, the USN does not contain the knowledge or attributes necessary to represent the way a term has been recorded, contained or linked within a patient's EHR. The MED has been used to enable users to construct queries (Wilcox, Hripcsak et al. 1997). Most queries are successful and searches usually return with a manageable list of options (7-15) within an acceptable time frame (mean 0.75 seconds) (Cimino, Patel et al. 2001).

(Kannry, Wright et al. 1996) have shown that a considerable manual effort is needed to migrate a Medical Entities Dictionary from one institution to another. When migrating the laboratory and pharmacy entries in MED to Yale University Hospital the authors found a match within the local systems for only 73% of pharmacy terms and 53% of laboratory terms.

Within the DIOGENE system

(Breant, Borst et al. 1999) describe the construction of a Clinical Findings Dictionary (CFD) built on and extending ICD and which, for every term, defines the name, local code, data type, optional units, optional (coded) enumeration list, link to ICD term. The authors have used the CFD to design several data collection templates for use within the hospital. They describe the challenge of attempting to integrate the valuable clinical information from over 50 discrete and geographically distributed departmental databases within the University Hospital of Geneva (Breant, Borst et al. 2000). They suggest that the historic inability of DIOGENE (and other comparable hospital systems) to provide a coherent clinical data repository and the availability of personal computers have fuelled the growth of such systems. The clinical data models, value sets and reference

terminology systems differ widely across these databases, challenging any attempt to harmonise the patient medical data they contain. The CFD is the key semantic component of their solution to this.

The CFD entries correspond closely to the entries for Elements in the UCL Archetype Object Dictionary (see Section 8.2). The hospital has participated in the Synapses and SynEx projects, and this work has similarities to the design features of the Synapses Object Dictionary.

Within the Royal Marsden Hospital information system

The information system at the Royal Marsden Hospital has been summarised in Section 4.2.10. This system is unusual in being underpinned by a comprehensive data dictionary that defines all of the clinical and managerial concepts that may be required by individual screens, reports or analyses. These are associated with very powerful methods to derive data values from other raw values, to compare values or trends or to initiate new processes. An example extract from this data dictionary, for histopathology reports, is shown in Figure 33. Although some of the data element names are not readable terms, this extract gives a sense of the complexity of the overall schema.

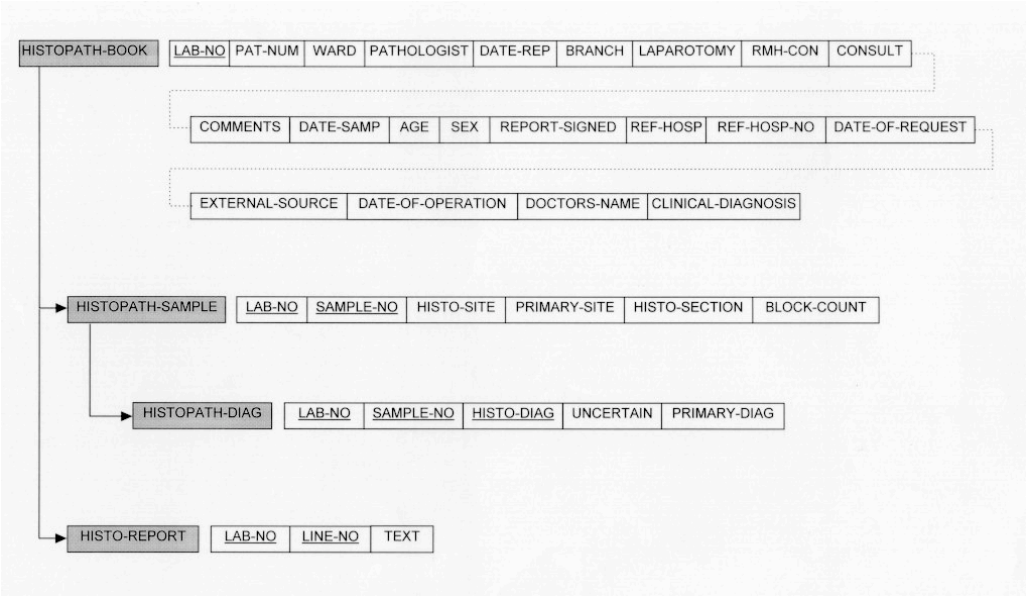


Figure 33: Representation of an extract from the Royal Marsden Hospital data dictionary

This data dictionary differs from the other metadata approaches described here in being primarily like a highly sophisticated data schema rather than a knowledge model. The developers of the system have found this approach much easier to maintain than a conventional database schema as changes to the dictionary can usually be made without a significant programming effort. This system provides important evidence of the scalability of a metadata-like approach to the design of a complex clinical system. Being a dictionary driven system has also allowed the development of user-friendly analysis tools permitting users to construct queries using dictionary elements (illustrated in Figure 34 below).

(Information for this section has been supplied by Dr Jo Milan, Director of Computing at the hospital).

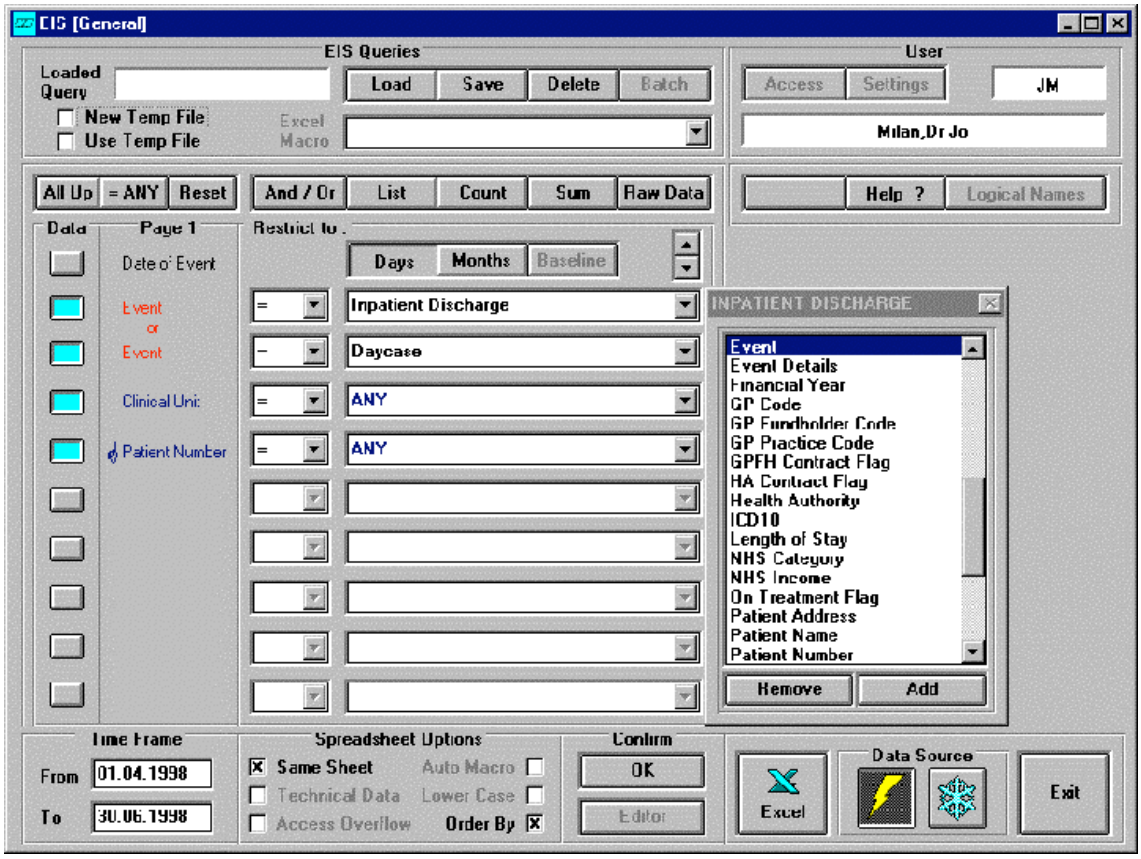


Figure 34: Analysis tool at the Royal Marsden Hospital

(Graeber 1995) has also advocated using a dictionary of objects and methods (services), which they are starting to convert into an active dictionary for the HIS at the Saarland University Hospital.

The Helios project

The HELIOS project has prototyped an architecture to facilitate the reuse and interoperability of components and sub-components (Dore, Lavril et al. 1995). The architecture includes a Medical Concepts Dictionary that enables developers to be precise about the kinds of health data that their component handles. This common library of concepts enables health data to be managed consistently within the HELIOS computing environment. The co-ordinators of HELIOS were partners in the Synapses project and contributed to the design of the Synapses Object Dictionary (see Section 8.1.1).

Within guideline and protocol systems

The work at Stanford on PROTÉGÉ is a well recognised contribution to the design and development of modular decision support systems which separate the generic handling of algorithms from the domain specific knowledge required for specific decisions (e.g. (Park and Musen 1998)). This is an important example of the separation of a "reusable" engineering approach to generic core middleware (based on a domain-independent specification) from a formal methodology for representing domain knowledge (e.g. disease aetiology) (Musen, Gennari et al. 1995).

Other examples

Yamazaki et al describe a "Template-assisted" EHR system, which offers users a problem oriented view of the EHR as a template containing recent historical data values and permitting new instances to be added (Yamazaki, Satomura et al. 1995). The templates are structured around a data dictionary, mapped to SNOMED codes to permit future cross-language implementations. The authors suggest that a standardised representation is needed for the structure of medical templates (Yamazaki and Satomura 2000).

Hannan et al describe the challenge of delivering a systematic electronic approach to the management of health information in a rural clinic setting in Kenya (Hannan, Rotich et al. 2000). The system design draws on the experience of the authors in the design of the Regenstrief Medical Record System (RMRS), and of the porting of a John Hopkins cancer system to Australia. It is underpinned by a data dictionary that lists the data elements that can be captured in the system, their data types and any associated value sets. This again illustrates the need to distinguish the architecture of the core clinical database from the more dynamic clinical schema used in specific healthcare settings.

(Burkle, Ruan et al. 1998) describe the use of the Medical Data Dictionary in Gießen, (which is based on the US HELP system) to provide context sensitive access to several discrete knowledge sources that have been integrated via the hospital's Intranet.

The various approaches described here have highlighted the value in separating out a relatively stable core information model from a more dynamic and adaptable data dictionary (metadata repository) for clinical data sets, record hierarchies and value sets. However there has been little work outside that on generic EHRs to define the optimum boundary between these two (i.e. the systems described here have not adopted a rigorous requirements-based approach to defining the generic health data model or the metadata model).

5.7.3. Clinical Headings

The UK project Headings for Communicating Information for the Personal Health Record identified a core set of headings to provide a generic classification of the information included within clinically-authored communications to support shared patient care (Severs 1999). It was originally anticipated that these headings would be used to sub-divide and label parts of a narrative letter or report, such as a discharge summary, on paper.

The investigation to derive these headings was largely empirical; they were subsequently refined by a multi-professional steering committee (Severs 1997). The headings were published with formal definitions and associated synonyms to assist an author to identify the most appropriate heading for each entry. The prototype headings were further revised following an extensive evaluation performed during 1998-9, to which the author contributed three distinct reviews (Kalra, Lloyd et al. 1998), (Kalra 1998a), (Kalra 1998b). The evaluations showed that the headings were largely unsuitable to structure electronic health record entries. Thirteen further investigations have recently been performed, nine of them in practical clinical use (Severs et al. 2002); the results of these are presently being evaluated. The consensus view within the NHS, with which the author concurs, is that these headings are suitable for human navigation but are too broad and imprecisely used to govern the structure of an EHR.

(Ahlfeldt, Ehnfors et al. 1999) report the work of a two year multi-site and multi-professional study investigating the clinical headings used by different healthcare groups. Despite a wide range in the actual headings used, the authors found six high level concepts shared across all professions: anamnesis or patient history, status, analysis or diagnosis, goals, actions, and results. However, doctors tended to use anamnesis to refer to information provided by the patient and status to indicate the current assessed state of the patient through observations and measurements; nurses tended to use anamnesis to classify information about the past health and care of the patient, and status to classify the present state of the patient whether subjectively or objectively derived. The authors conclude that considerable further work in this field is needed before headings can be used and interpreted consistently within a multi-professional EHR.

5.7.4. Terminology and coding systems

The knowledge of clinical concepts and the way in which they inter-relate has traditionally been implemented in healthcare applications through coding systems. These have, at their most basic level, provided nomenclatures, controlled vocabularies and simple hierarchical classifications of diseases, aetiologies and treatments to facilitate the entry and analysis of healthcare data (Chute 2000). Examples of this include ICD, ICPC, SNOMED and Read (earlier versions). The coding schemes associated with these terminologies were primarily required to assist with the subsequent analysis and aggregation of the data within clinical systems. Unfortunately many of these

terminologies have historically failed to distinguish the requirements of a classification system from that of a clinical vocabulary.

Over the past decade a number of research consortia and coding centres across Europe have sought to extend these basic representations of medical knowledge. The UK NHS Centre for Coding and Classification has designed and populated a rich thesaurus of clinical terms cross-referenced against underlying concepts and associated with basic qualifiers. The GALEN project has developed formalisms by which the medical knowledge necessary to interpret and to process healthcare record entries can be represented. GALEN-in-Use, a successor project, has more recently implemented robust Terminology Servers, capable of providing both authoring and real-time support with the analysis and the transfer of record entries in a multi-lingual environment.

These developments in terminology systems have interacted with the work on EHR architectures, and therefore influenced the information models underpinning them. However, from its origins in medical terminology, the initial focus of the work on medical knowledge representation has been to extend the richness and precision with which individual clinical concepts can be represented. From a semantic point of view this contrasts with the efforts within the architecture projects, which have been to define the constructs and labels with which such concepts can be organised within health record entries. For example, the emphasis of a terminology service might be to inform a clinician that a *pulmonary embolus* is both a respiratory and a vascular condition, that it can have several causes, can be severe or even fatal, and has a site and a laterality within the lungs. Term lists used to label EHR entries would focus on whether the pulmonary embolus was part of a past medical history, a present finding, a condition being prevented or a concern in the mind of the patient; the basic concept of pulmonary embolus would be the same in each of these cases.

(Rossi Mori, Consorti et al. 1998b) have provided a helpful categorisation of the evolution of terminology systems.

First generation are traditional systems such as ICD and Read v2. Terms are represented in a single hierarchy, usually developed for one primary purpose, and presented alphabetically or by hierarchical position.

Second generation systems allow polyhierarchy, and are combinatorial systems suitable for multiple purposes. New concepts can be created from the atomic components as required, but including illogical combinations. SNOMED, UK Clinical Terms and LOINC are examples.

Third generation systems, such as GALEN, include a universal model with combinatorial rules to constrain and validate any proposed new combinations of atomic terms.

A systematic approach to appraising terminology systems has also been advocated in (de Keizer and Abu-Hanna 2000).

(Bishop 1990) originally published a set of ideal characteristics for a system to represent medical knowledge in 1990:

- a unique code for each term or phrase;
- each coded term is defined;
- each term is independent of others;
- synonyms are equated to the code of a basic term;
- to each code could be attached the codes of related terms;
- the system would encompass all of medicine;
- the system would be in the public domain;
- the format of the knowledge base should be described in functional terms, and be independent of software and hardware.

Reed et al (Reed, Sanderson et al. 1995) stress the importance of recognising the difference between:

terming: assigning a clinical phrase from a controlled vocabulary, to document health care and to facilitate future individual patient care (e.g. the Read codes);
encoding: to assign a term from a classification system to enable population-based analysis, often for statistical and research purposes (e.g. ICD, OPCS);
grouping: to aggregate patients who potentially will need similar kinds of health intervention, to enable service delivery or cost-effectiveness comparisons to be made (e.g. DRG).

The authors argue that the clinical vocabulary chosen for each of these three activities should be different, and even if they contain some common phrases these cannot be taken to have an equivalent meaning.

More recently Cimino has reviewed the differing and evolving roles of a controlled medical vocabulary. He stresses the difference between classification systems used to group and aggregate for statistical and epidemiological purposes and medical vocabularies used to represent the actual concepts intended by an author using the terms closest to their preferred expressions (Cimino 1996) and (Cimino 1998). His twelve desiderata have been widely accepted within the informatics community, and build on published work over many years and the findings of others in the field.

1 Content, content, content
2 Concept orientation
3 Concept permanence

4 Non-semantic concept identifier
5 Polyhierarchy
6 Formal definitions
7 Reject "not elsewhere classified"
8 Multiple granularities
9 Multiple consistent views
10 Beyond medical concepts: representing context
11 Evolve gracefully
12 Recognise redundancy

(Chute, Cohn et al. 1998) describe the need for a standard terminology for health care, in parallel to metric units for weights and measures. (Spackman 1999) points out that the electronic patient record, decision support, outcomes research and many other medical informatics contributions depend upon a structured and shared terminology.

(Oliver and Shahar) stress the pitfalls of adapting a standard terminology or of incorporating terminology release upgrades into an EHR system. The simplistic way in which change management is handled by classical terminology systems such as ICD and SNOMED are contrasted with Read 3, GALEN and UMLS, which aim to ensure the integrity of entries made with legacy codes.

(Brown and Price 1999) describe the challenge of semantically relating pre-coordinated concepts (e.g. streptococcal meningitis) with post-coordinated equivalents (bacterial meningitis, causative organism = streptococcus). The authors have explored the implications of performing such a mapping on 2,627 problems accumulated within a diabetes record system, and found that it is a labour intensive task. However, they have demonstrated the utility of a semantically rich mapping in resolving clinical queries of the database. (Elkin, Tuttle et al. 1998) also discuss the challenges of pre- and post-co-ordination of atomic terms to represent compound clinical concepts, for example for problem list generation. They suggest that such compositional terms ideally should be uniquely identifiable to allow the matching of similar compound expressions.

Rector discusses the challenges facing the delivery of a clinically usable terminology system to support data entry, navigation, interrogation and analysis within EHRs (Rector 1999). He proposes ten reasons why it is "hard" to develop good terminologies for clinical record and decision support systems, and stresses the importance of meeting clinical requirements for practical data entry, presentation and retrieval for clinical tasks. He suggests that further resources and effort alone are not enough: a systematic approach is needed to develop scalable and extensible ontologies of the medical and health care domain, mapped to multiple languages and to existing coding schemes. He

points to work in SNOMED-CT and GALEN as potential ways forward, but recognises that these require further work to demonstrate that they are valid and practical solutions.

The structured EHR functions in part as a hierarchical container of terms taken from terminologies. The EHR information model must therefore be able to represent simple or complex expressions comprising a combination of terms (e.g. including qualifiers) and be able to reference the terminology system from which they have been derived. As these systems grow in complexity (as anticipated for example with SNOMED-CT) the EHR may need to interact with a live terminology service, at run-time, in order to ensure that complex expressions can be faithfully decoded and rendered back to the end user.

5.7.5. GALEN

The GALEN project, a European Health Telematics project from 1991-94, has developed a methodology based on description logic for representing any domain of human knowledge as a formally expressed concept model (Rector, Zanstra et al. 1995). The GALEN Representation And Integration Language (GRAIL) is a set of formal rules for building, using and maintaining such concept models which is independent of natural language. A model can be constructed, through computerised tools and an application interface, from information about the sets of object classes within a chosen domain together with further information about the properties and inheritance rules that apply to each class level. With such background information the GRAIL engine is able to validate statements about class relations as being *grammatically correct, sensible*, and *necessary*. Such a representation schema transcends the traditional restrictions that apply to the hierarchical clinical classification schemes.

Many of the principles and constructs developed by the GALEN project have their origins in the PEN & PAD intelligent user interface project (Nowlan and Rector 1991). This project developed a novel form of knowledge representation: predictive data entry embodied within a general practice clinical application, allowing users only to generate statements which were 'medically sensible' in a given situation. More recently, enhancements to that knowledge-driven interface have been implemented as the Clinergy system.

In the GALEN project the GRAIL formalism was applied to several areas within the domain of medicine to produce the Coding Reference (CORE) model (Rector, Solomon et al. 1995). The work of the project focused on aspects of anatomy, laboratory investigations and surgical procedures. Several specific disease areas, such as the identification of fractures and urinary tract infections, were also covered. Each of the object classes and attributes is named internally within the GALEN project but is mapped to a multi-lingual dictionary of terms which is more likely to be used by healthcare professionals or systems developers. This enables the CORE model to be independent of natural language. The CORE model has been incorporated into a terminology

server together with a set of multilingual dictionaries and a code conversion module mapping to ICD-9 terms (Rogers and Rector 2000). The terminology server is capable of receiving requests for information about a clinical concept and returning the information held about that object. In the example of *cystitis*, an application could interrogate the terminology server in order to discover that cystitis can be associated with several attributes including *severity* and *chronicity*.

GALEN has proposed that healthcare application developers would find such a server useful in order to enable them to offer to clinicians appropriate data entry forms and pick-lists to capture relevant clinical information, for example about cystitis (Rector 1998). (Hardiker and Rector 1998) have also shown that GALEN can be used to represent new terminology systems such as the International Classification of Nursing Practice and can help to identify inconsistencies within the classification.

GALEN-IN-USE, a follow-on project to GALEN project, from 1996 to 1998, promoted the development of Europe-wide institutions to maintain and develop common resources for clinical classifications, terminology and language. The information models and terminology services have now been published in open source through openGALEN. Interoperability between the UCL FHR service and the GALEN terminology server is the subject of new funded research, outlined in Section 14.2.

The recent development of a standardised mark-up formalism for the Semantic Web, (The DARPA Agent Markup Language Homepage) and a formal ontological model (DAML+OIL), is expected to provide an industry-standard framework to the GALEN kind of approach.

5.8. Natural Language Processing

(Baud, Lovis et al. 1998) describe the conceptual approach of applying Natural Language Processing (NLP) to the medical domain, starting from the formal definition of concepts for clinical real world entities and the collection of synonymous words and phrases that describe them. To facilitate the reliable encoding of narrative text entries the ontology must allow for the composition of complex concepts from elementary ones, semantic links between them and for the co-occurrence of concepts. The authors suggest that around half of the concepts believed to exist in the world (500,000) are in the medical domain. 85% of medical record entries in Europe are not in English (Baud, Lovis et al. 1995) and a multi-lingual approach to building a medical concept knowledge base is therefore required, as exemplified by the work of GALEN.

In (Baud, Rassinoux et al. 1995) they point out that critical aspects of a clinical communication may include emotional, hope, certainty information that is variably expressed by clinical authors and therefore difficult to extract reliably from narrative reports and letters. (Hahn, Romacker et al.

1998) warn of the potential loss of meaning that can occur in contemporary natural language processing by ignoring the discourse structures (narrative references) between sentences and paragraphs. (Friedman and Hripcsak 1998) note that many NLP studies have been based on the encoding of text entries drawn from limited samples and checked *in vitro* by one or more domain experts.

A medical language processor (MedLEE) has been developed at the Columbia Presbyterian Medical Centre to automatically encode narrative reports from radiology and electrophysiology departments. (Hripcsak, Kuperman et al. 1998) found that MedLEE was able to match the efficacy of physicians at extracting diagnostic codes from chest radiograph reports. They note that physicians themselves disagreed in 22% of reports. The major source of natural language parsing difficulty included expressions of negation and of uncertainty. MedLEE has recently been adapted to generate XML structured documents from narrative reports (Friedman, Hripcsak et al. 1999).

(Tuttle, Olson et al. 1998) have designed a middleware prototype (Metaphrase) to facilitate the systematic expression and coding of clinical problem lists using entries taken from the Mayo Clinic and Beth Israel Hospital systems.

(Rodrigues, Trombert-Paviot et al. 1998) in Saint Etienne have shown that good French (controlled) natural language can be generated from codes for the description of surgical procedures. The terms originate from a standard French coding scheme, and have been linked to appropriate natural language expressions using GALEN-In-Use tools to limit user selections to semantically correct expressions. The resulting narrative retains a link to the underlying codes to permit structured analysis of the entries for clinical audit and epidemiology.

(Tange, Hasman et al. 1997) suggest that free text reconstruction from structured entries might be a more reliable alternative to the encoding of narratives.

This work shows that it will be necessary for the EHR to represent links from an authored entry to derived codes or to generated text, possibly in more than one language, without altering the original.

5.9. Accessing medical knowledge

(Smith 1996) has shown that clinicians frequently need to access expert knowledge during patient consultations. (Kagolovsky, Freese et al. 1998) cite the ability to selectively search and filter the growing body of published medical knowledge as one of the key challenges facing effective delivery of usable clinical education. Sackett and Straus have shown that medical textbooks and guidelines are regularly consulted on treatment decisions if suitable resources are readily available (Sackett and Straus 1998).

(Safran 1995) has demonstrated that, in outpatient care for HIV patients at Beth Israel, computer based information resources are consulted in 16% of all consultations. The vast majority of these are for the results of diagnostic tests, with a drug information database being second. A significant number of look-ups were also made for online management guidelines.

(Hersh, Brown et al. 1996) have demonstrated the use of a web-based indexing and retrieval system for published medical knowledge based on the MeSH headings. (Baujard, Baujard et al. 1998) describe the methodology by which a software agent can be used to index medical web sites. Working at the University Hospital of Geneva they have developed a component called MARVIN (Multi-Agent Retrieval Vagabond In Information Networks). This has been used to provide search sites for the Health on the Net Foundation (Boyer, Baujard et al. 1997). The ARIANE project, co-ordinated in Marseilles, has developed a generic means of integrating diverse information databases using the UMLS as a common semantic reference ontology (Volot, Joubert et al. 1997), (Aymard, Joubert et al. 2000). The UMLS metathesaurus has been used to provide a uniform conceptual view of the knowledge within local drug databases, PubMed and a gastroenterology web site (Aymard, Fieschi et al. 1998).

(Richards, Colman et al. 1998) suggest that Computer Assisted Learning (CAL) style materials can play an important role in engaging the interest and participation of patients. Goldsmith and Safran have shown that appropriate Internet-based educational materials about post-operative pain self-management can reduce patients' actual experiences of pain (Goldsmith and Safran 1999). (Hunt, Haynes et al. 1998) have shown that a computer-administered health status and educational awareness questionnaire prior to a consultation can identify useful healthcare recommendations.

The metadata dictionary at the Columbia Presbyterian Medical Centre, the Medical Entities Dictionary (MED), has proved a valuable tool to link terms in patient records to medical knowledge sources such as Medline. (Cimino, Elhanan et al. 1997) have developed a user feature known as "Infobuttons" that utilise clinical terms from the active user form to provide a set of answers to common questions, links to on-line medical literature and example case histories, for example on the interpretation of chest x-rays (Zeng and Cimino 1997) and Pap smears (Baorto and Cimino 2000).

Over 10,000 health-related Web sites are now available on the Internet. Much of the material is inaccurate or misleading (Wyatt 1997). Many patient information sites are too introductory, do not provide evidential references for the information, rarely consider medical uncertainties, present prevalence rates in misleading ways and rarely include a publication date to enable currency to be assessed (Coulter, Entwistle et al. 1999). There are strong arguments to establish an accreditation system, with appropriate evaluation, which will enable users to judge the quality of health information (Coulter 1998), (Kim, Eng T. et al. 1999). (Eysenbach, Yihune et al. 2000) point out

that awards and logos, such as a "seal of approval" from a reputable body, can be included by webmasters of other unapproved sites. The EU funded MedCERTAIN project is developing a system to "trustmark" health information sites (MedPICS Certification and Rating of Trustworthy Health Information on the Net).

There can be little doubt that future EHR users (authors and reviewers) will concurrently access other on-line information resources. EHR entries need to be able to preserve links to these, for example, in order to justify or explain the clinical reasoning process, or as educational pointers for subsequent readers.

5.10. Reminders, alerts, and decision support

Systems to compare patient specific observation values with population norms or scientific evidence are now widely used. The use of the term *decision support* is variably applied to:

- simple logical algorithms such as an alert to a user that a patient's screening test is overdue; these are sometimes described as reminder systems;
- calculations derived from one or more clinical observation parameters such as a cardiovascular disease risk score (for example as described in (Hingorani and Vallance 1999);
- algorithms that compare new entries with existing record entries and with reference databases, such as drug prescribing systems; these sometimes function as alerting systems;
- rule-based systems incorporating probabilistic algorithms to determine the most likely clinical decision or pathway from a set of predetermined options, based on informal description logic or formal languages such as Arden Syntax, GLIF, *pro*Forma or Prodigy.

Miller points out that whilst no one generic system is widespread, individual (local) decision support systems are in regular use throughout hospital and primary care, and used by a range of different health care professions (Miller 1994). (Shiffman, Liaw et al. 1999) found that most systems offer recommendations concurrently with patient care, and half offer some explanation of the advice given. Most include prompts to document relevant data items. (Scott and Lenert 2000) consider the differing decision-making roles patients may choose to play in their own health care, ranging from

- paternalistic (health provider knows best);
- informed (health provider provides objective information but no direction);
- deliberative (health provider directs strongly how the patient should interpret the information);
- collaborative (provider offers information and helps patient understand their own values).

They argue that patient-focused decision support systems tend to assume the informed model, and that next generation systems will need to be adaptive to different patient participation roles.

5.10.1. Alerting systems

Systems that can monitor for critical events and generate alerts have proved both readily implementable and clinically valuable. Some successful contemporary examples are listed below.

- A drug prescription interaction and adverse effect alert system has been linked to pagers at the Barnes-Jewish Hospital, a 1,400-bed university teaching hospital in St. Louis, Missouri (Miller, Reichley et al. 1999). The alerting system links a clinical data repository to the pharmacy orders and laboratory systems.
- (Warner, Miller et al. 1998) describe the design of a Clinical Event Manager, which monitors new medical record information within the HIS at the University of Utah. Four hundred alert algorithms have been developed, focusing on laboratory values, drug interactions and contraindications. Physicians receive an average of 14-18 alerts per day: these are felt to be largely useful but occasionally annoying.
- (Shabot, LoBue et al. 2000) describe the design of a pager-based alerting system for physicians looking after intensive care patients in a tertiary care hospital. The alerting system interacts with the main intensive care system repository.
- CADMIUM II is a new system for the image processing and interpretation of mammograms (Alberdi, Taylor et al. 2000). Advice is based on explicit knowledge about the diagnostic process, obtained through an investigation of radiologists' diagnostic reasoning and of their subsequent reports.

5.10.2. Guideline representation formalisms

(Elkin, Peleg et al. 2000) review the various formal representations for electronic guidelines. The paper includes a helpful time line of the evolution of and inter-relationships between the main international guideline models, reproduced below in Figure 35.

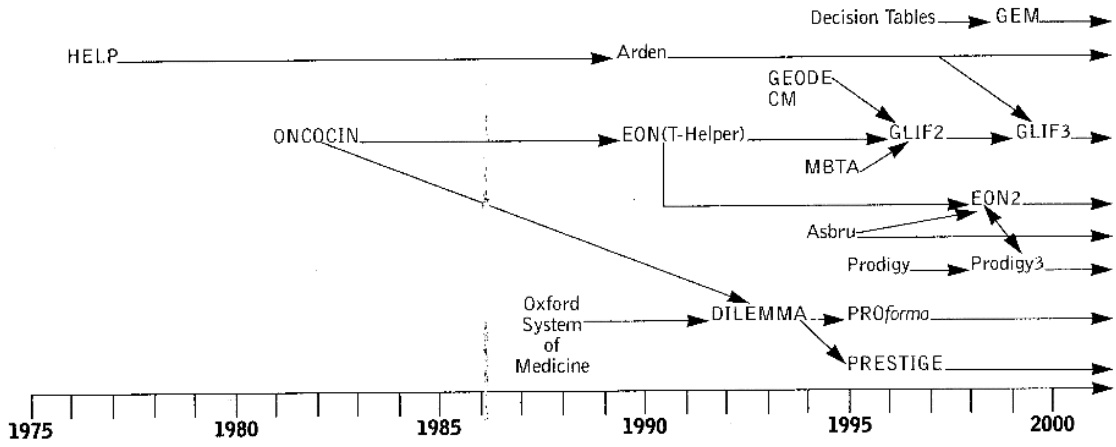


Figure 35: Time line for the development of guideline representation formalisms

From (Elkin, Peleg et al. 2000)

Arden Syntax

The Arden Syntax is a standard for the representation and exchange of medical knowledge and logic used to make clinical decisions (Hripcsak, Ludemann et al. 1994). Any one alert or prompt comprises a set of interacting Medical Logic Modules (MLMs) each of which relates to a single decision step. Examples of such decisions include contraindication alerts, the interpretation of observation values and management advice using treatment protocols. The Syntax evolved from prompting systems developed at the LDS Hospital in Salt Lake City (the HELP System), the Regenstrief Institute in Indianapolis (the CARE System), Columbia Presbyterian Medical Center in New York (the first Arden Syntax system), with input from other academic centres. Version 1.0 was adopted as an ASTM standard in 1997 and taken over by HL7 in 1998 for ongoing refinement.

(Jenders, Huang et al. 1998) report a high maintenance and change management effort for the Medical Logic Modules within the Columbia-Presbyterian Medical Centre. The authors also note that the transfer of decision support modules between institutions requires significant code change to reflect the differing underlying clinical data representations (which can affect up to 40% of MLM code).

GLIF

In 1998 the InterMed Collaboratory, combining the guideline representation experience of Columbia, Harvard (Massachusetts General & Brigham and Women's) and Stanford, proposed a new formal generic representation called the Guideline Interchange Format (GLIF) (Ohno-Machado, Gennari et al. 1998). Attempts are being made to improve this initial specification through implementation experience (Greenes, Boxwala et al. 1999b), (Peleg, Boxwala et al. 2000), including its representation in UML and XML (Dubey and Chueh 2000).

proForma

*pro*Forma is a syntax for specifying the logical components of an electronic guideline, including criteria for making decisions and choosing between optional pathways, weighted arguments for and against the various options and interactions with users or EHRs to obtain clinical information (Fox, Johns et al. 1997). The syntax is computable and the development team at the Imperial Cancer Research Fund have developed graphical guideline authoring software and various run-time enactment components including web-based guideline forms. Some of these tools are available as commercial products.

(Fox and Bury 2000) suggest that the proForma specification is technically more complete and potentially safer than GLIF or the Arden Syntax. The development team have recently founded openClinical, which offers a web-based repository of enact-able clinical guidelines and a resource for sharing international progress in this field.

PRODIGY

(Purves, Sugden et al. 1999) have developed a representation for general practice prescribing recommendations based on clinical indications through the PRODIGY project. In Phase One of the project the system was developed in partnership with UK GP system suppliers and piloted in 183 GP surgeries. Informed by that successful first evaluation the main suppliers have developed a more complete integration of PRODIGY II guidance within their clinical systems (Rogers, Jain et al. 1999) and have undertaken a wider evaluation (Phase Two). PRODIGY has now been adopted as an NHS standard for GP systems.

(Johnson, Tu et al. 2000) describe the design of PRODIGY III as a simple but rigorous representation for guidelines that can be used in general practice for the management of chronic diseases.

EON

EON is the system at the heart of longstanding decision support work at Stanford Medical Informatics (Musen 1999a). It comprises components called "problem solvers" that can apply logical pathways to a particular clinical problem and take a specific protocol as an input parameter. PROTÉGÉ is the key authorship tool that contributes to the EON therapy protocol middleware (Musen 1998b). At run-time EON also interacts with a database mediator (called Tzolkin) to process patient record instance information. This in turn interacts with Chronus (to produce temporal queries) and with RÉSUMÉ (for temporal abstraction of the result sets) (Musen, Tu et al. 1996). The components of EON (RÉSUMÉ, a temporal database, a temporal query handler) are shown diagrammatically in Figure 36 below, with links to domain knowledge acquired and validated by PROTÉGÉ.

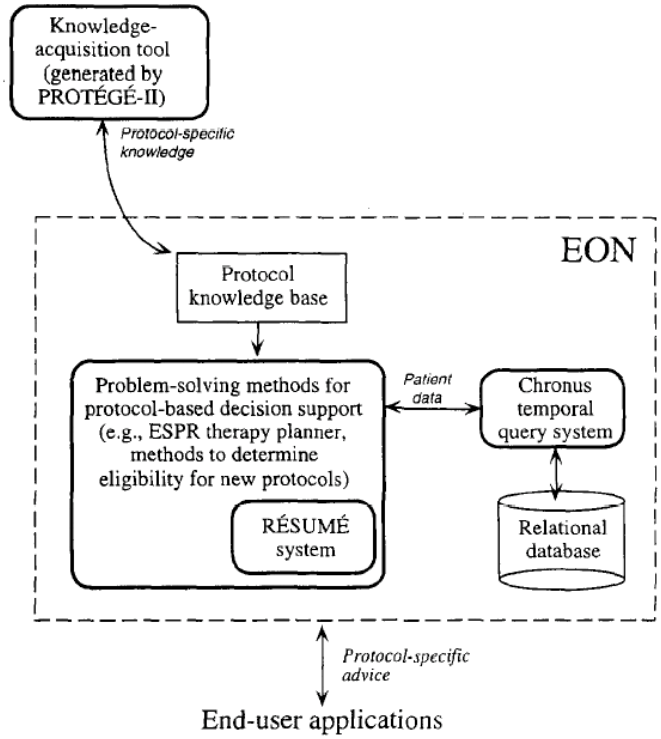


Figure 36: Component architecture of EON

From (Musen, Tu et al. 1996)

The representation of the domain knowledge needed to run EON is itself standardised as a metadata schema, illustrated in Figure 37 below with a subset of the knowledge model for T-HELPER, supporting HIV therapy management.

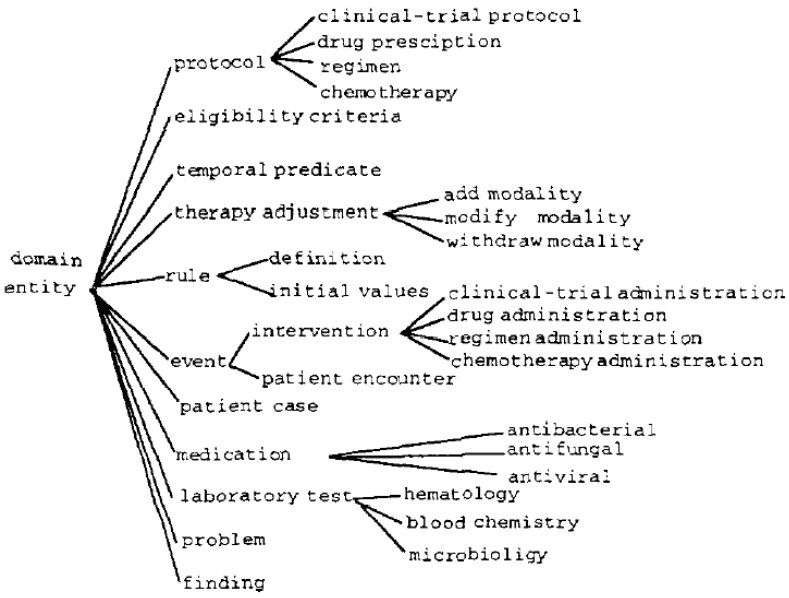


Figure 37: Subset of the domain ontology for T-HELPER

From (Musen, Tu et al. 1996)

Musen argues that the construction and maintenance of complex rule-based decision support applications is difficult, and that the solution lies in having a set of generic problem-solving methods (implemented as generic reusable components) and a standard representation for the domain ontology & knowledge base (Musen 1998a), (Musen 1999b). This parallels the twin-model approach of the FHR information architecture.

5.10.3. Example electronic protocols and guideline systems

A wide range of other protocol and guideline systems have been developed and piloted in a range of clinical settings. Several examples are summarised briefly below.

- The EU Project GAMES II has developed and prototyped a set of generic and reusable components enacting various stages of the clinical reasoning process (Lanzola, Quaglini et al. 1995). These algorithms depend upon domain knowledge represented in a consistent structure but with variable (domain-specific) content.

- The Decision Systems Group in Brigham & Women's Hospital has integrated different sources of information for a reporting clinical workstation in the department of radiology (Greenes, Boxwala et al. 1999a).

- Schilling et al have designed a care pathway system using web-based forms (Schilling, Faisst et al. 2000). Their focus has been on guiding clinicians to confirm that the appropriate evidence-based indications exist within each patient before embarking on potentially costly investigations or treatments.

- (Chu and Cesnik 1998a) describe the design of an object oriented care pathway system for assessment and treatment based on observation parameters, orders, reports and trends.

- (Vissers, Hasman et al. 1998) describe the design of ProtoVIEW: a web based front end and patient record simulator for protocol enactment. The prototype has been developed for emergency care, but has yet to be tested in vitro.

- (Murphy, Ng et al. 1998) describe the use of Java agents to provide decision making and alerting functions within a web-based referral care pathway system.

5.10.4. Evaluations of decision support systems

Most early evaluations of decision-support systems were limited to measures of reliability, accuracy and acceptability (e.g. (Barnett 1984)). A classic systematic review by Johnston et al. found that computer-based decision support can improve clinician performance (Johnston, Langton et al. 1994). More recent studies confirm significant improvements in documentation (ranging from 30-

700% change) and improved adherence to guidelines, e.g. (Chin and Wallace 1999), (Shiffman, Liaw et al. 1999).

(Anderson 2000c) makes the case that clinical decision support and alerting systems have been shown to improve physician performance and clinical outcomes. (Teich and Wrinn 2000) claim that decision support systems have been proven to save lives and to reduce costs "to a remarkable degree", in particular for physician order-entry and drug interaction alerts. Examples of positive outcomes include:

- reducing hospital admission rates (Safran, Rind et al. 1995b), (Safran, Rind et al. 1996b), (Safran, Rind et al. 1996a);
- a rapid response to critical laboratory results or to adverse drug reactions (Rind, Davis et al. 1995), (Kuperman, Teich et al. 1999), (Bates, Teich et al. 1999);
- glycaemic control in diabetes (Balas, Boren et al. 1998);
- immunisation rates (Flanagan, Doebbeling et al. 1999).

However not all evaluations have been positive. (Harpole, Khorasani et al. 1997) at the Brigham and Women's Hospital found that prompts to avoid inappropriate abdominal radiographs on clinical grounds did not alter the request rate. (Rocha, Christenson et al. 2001) at the University of Utah found that staff rarely looked at alerts on microbiological test results, whether on a computer terminal or printed onto paper.

5.10.5. Interoperability with the EHR and other services

The enactment of an electronic guideline and decision support function is of greatest clinical value when it is linked to the circumstances and needs of an individual patient. Guidelines therefore need to be linked to the EHR. An appropriately linked guideline system would, for example, enable a clinical system to:

- accept a random blood glucose of 4.2 mmol/l and pass it directly to the EHR;
- warn the clinician when entering a blood glucose of 7.4 mmol/l, invoking a textual message or initiating a protocol depending upon whether the patient is diabetic;
- reject a blood glucose of 74 mmol/l as a typing error.

(Tierney, Overhage et al. 1995) identify several issues that needed to be addressed if guidelines are to be consistently used with EHRs, including the recognition of co-morbidity and concurrent medication, and the need to indicate the clinical importance of a recommendation. (van der Lei and Musen 1995) draw attention to the need for decision support systems to accommodate the underlying terminology system of the medical record system they interoperate with, rather than incorporating their own controlled vocabulary for domain knowledge.

If decision support and EHR systems are to interoperate safely the metadata defining clinical data elements needs to be held in common, including the permitted data value ranges and the units or terminology systems to be used. The clinical use of a decision support system needs itself to be documented within the EHR, including the origin, name, version and step of the guideline influencing or generating a particular entry, and a copy of any message or recommendation provided to the user.

Decision support systems also need to be much more interoperable than at present, so that a tailored guideline can "follow the patient" as well as their EHR might soon do so.

5.11. Ethical and Legal Issues

GEHR Ethical and legal requirements

Many of the ethical issues in adopting EHRs arise from its purposes: the definition below was proposed by the GEHR project (Ingram D, Southgate L et al. 1993).

- The primary purpose of the patient record is to benefit the patient by providing a record of care that supports present and future care by the same or other clinicians.
- The secondary purpose is to provide a medico-legal record of the care provided and hence support and demonstrate the competence of clinicians.

The foundations of the relationship between a clinician and a patient are the delivery of clinical care to the highest possible standard and the respect for patient autonomy. This inevitably means that the right to informed consent and the right to confidentiality are important moral principles for a 'good' health record system. Patients should exercise as much choice over the content and movement of their health records as is consistent with good clinical care and the lack of serious harm to others. Records should be created, processed and managed in ways that optimally guarantee the confidentiality of their contents and legitimate control by patients in how they are used. It is well recognised that there are few indications for withholding information from patients (Fisher and Britten 1993), (Data Protection Act 1998 1998). The communication of health record information to third parties should take place only with patient consent unless emergency circumstances dictate that implied consent can safely be assumed.

Clinical rights to access an EHR should be on the grounds of direct care provision, with appropriate explicit or implied consent. These rights are normally applied to a clinical team involved in the provision of care to patients, but frequently also extend to non-clinical personnel directly supporting the care providers, such as medical secretaries. The definition of this extended team is unfortunately not consistent and nor usually publicly known for each enterprise. Access for continued professional learning by the care teams involved in direct care, and internal or external

quality assurance, are widely considered to be acceptable practice, although access for research and for teaching beyond the immediate care team are now regarded as requiring explicit informed consent.

The EHR must be a legally acceptable: admissible as evidence in legal proceedings, as well as authorising the validity of prescriptions and other orders. The EHR has to be durable, and the systems interpreting the EHR need to be accurate and safe. The responsible clinician making a recording must accept that he or she is thereby accountable for the care given. Information created or received by a clinical information system must therefore only be considered part of the EHR when an accountable clinician has authenticated it. Some components of clinical competence are closely related to the role of clinicians in the societies in which they practice. The EHR should allow the clinician to express information, ideas and justification for actions fully and without restriction. The health record must not impose the values of one society on the clinical practice of another, although it should promote ways of learning about different styles of clinical practice. The health record must be capable of evolution as society develops and defines new aspects of the common core of practice.

Other contributions on ethical issues

Kluge argues that the advent of advanced patient record systems should be accompanied by a change from paternalistic health care attitudes to a patient autonomous approach (Kluge 1993). He states that the global integration of patient healthcare information is creating a record that functions as the patient analogue in medical decision making space: it affects what is done to the patient and how others relate to the patient (Kluge 1995).

(Kluge 1998) also introduces the concept of a Health Information Professional (HIP) who might include information managers and IT staff at a healthcare enterprise. He proposes that HIPs have duties:

- to protect a patient's right to privacy and confidentiality;
- to control access;
- to correct errors if requested by the patient;
- to ensure data are only collected when necessary and suitably de-identified when appropriate;
- to ensure the integrity and availability of EHR data;
- to foster a security culture within their enterprise.

The "Tavistock Group" (a multi-national working group) is developing a code of ethics for healthcare systems (Smith, Hiatt et al. 1999). (Collste, Shahsavar et al. 1999) suggest that ethical principles should also underpin the design of decision support systems.

(Gaunt 2000) describes the challenge of balancing the differing record access requirements of a wide range of personnel including healthcare professionals, data controllers, data subjects, health insurers, government departments and professional bodies. He argues that the technical measures that can be taken to enable a security policy are probably not the most challenging dimension, but rather that of developing and implementing a workable policy. He cites as impediments to change:

- the attitude and sometimes ignorance of healthcare staff towards security measures they should personally take;
- the conflicting demands on time and financial resources between ensuring information is available and adequately protecting it;
- inadequate technical systems, and inconsistent security policies between organisations that share EHR data.

Other practical challenges include the accreditable training of thousands of staff within any one enterprise, and managing their turnover. He cites the growing use of the fax to communicate information between hospitals and GPs as an example of an easy and "successful" but woefully insecure approach.

Anderson emphasises the major public concern about the protection of EHR information, in particular if this is available in a distributed form such as the Internet (Anderson 2000b). He concludes that systematic US public policy is needed (even post-HIPAA), and suggest that US endeavours lack cohesion and are unnecessarily different from the approaches and legislation in Europe.

These ethical considerations for health records have an important bearing on the requirements for the FHR information architecture: the medico-legal requirements listed in Section 6.4 form a significant proportion of the overall set.

5.12. Confidentiality and Security

5.12.1. Confidentiality

The need to protect information from unintended access is not new, and the practice of encrypting communications builds on a longstanding mathematical pedigree (*reprinted in* (Shannon 1998) from an original paper in 1945).

(Slack 1997) points out that

> *"the best defence against unauthorised intrusion into the paper chart is the illegibility of the doctor's handwriting. Coupled with illegibility is the traditional disorganisation of the paper chart. Since there*

> *is usually no index or table of contents, whatever information can be read is difficult to retrieve and use."*

However, (Lincoln 1993) points out that many breaches of secure electronically-held data do not in fact take place by electronic break-in but through trading information across some informal human network, whether revealed deliberately or inadvertently. Such a threat is identical if paper or electronic record systems are in use.

(Robinson 1994) observes that ready access to information is important for patient care but also threatens the patient's privacy.

> *"Knowledge of some data elements can endanger employment, insurability, and even acceptance in a society. Indications of illicit drug use, sexual promiscuity, psychiatric admissions, and sexually transmitted diseases, especially infection with human immunodeficiency virus (HIV), are harmful for obvious reasons...Perhaps access should not be limited according to type of information, but according to the person attempting to retrieve it."*

(Gardner 1994) notes that hospital departments at the LDS Hospital need access to computerised information acquired by up to 15 other departments in order to manage their care process or to generate reports. Szolovits and Kohane express concern at the potential risks associated with easier database integration through the use of a common patient identifier (Szolovits and Kohane 1994).

In 1995 the British Medical Association (BMA) commissioned the development of a clinical information security policy (Anderson 1996). This states nine principles designed to uphold the core principle of patient consent and to be independent of the details of specific equipment; they have significantly shaped the approach to patient confidentiality within the UK medical profession and the NHS and are reproduced below.

1 Access control Each identifiable clinical record shall be marked with an access control list naming the people or groups of people who may read it and append data to it. The system shall prevent anyone not on the list from accessing the record in any way.
2 Record opening A clinician may open a record with herself and the patient on the access control list. When a patient has been referred she may open a record with herself, the patient, and the referring clinician(s) on the access control list.
3 Control One of the clinicians on the access control list must be marked as being responsible. Only she may change the access control list and she may add only other health care professionals to it.
4 Consent and notification The responsible clinician must notify the patient of the names on his record's access control list when it is opened, of all subsequent additions, and whenever responsibility is transferred. His consent must also be obtained, except in emergency or in the case of statutory exemptions.

5 Persistence No one shall have the ability to delete clinical information until the appropriate time has expired.

6 Attribution All accesses to clinical records shall be marked on the record with the name of the person accessing the record as well as the date and time. An audit trail must be kept of all deletions.

7 Information flow Information derived from record A may be appended to record B if and only if B's access control list is contained in A's.

8 Aggregation control Effective measures should exist to prevent the aggregation of personal health information. In particular, patients must receive special notification if any person whom it is proposed to add to their access control list already has access to personal health information on a large number of people.

9 Trusted computing base Computer systems that handle personal health information shall have a subsystem that enforces the above principles in an effective way. Its effectiveness shall be evaluated by independent experts.

Denley and Weston Smith have demonstrated a practical and manageable implementation of access control lists in three UK hospitals, based on Anderson's nine principles (Denley and Smith 1999). They have also demonstrated that an emergency override facility can be safely administered if staff are warned of the presence of an audit trail which is regularly reviewed before access is granted. More recently (Buckovich, Rippen et al. 1999) have proposed a set of 28 principles, derived from ten leading US sources of privacy and security principles with respect to health data, which are similar to those proposed by the BMA.

(Safran 1996) argues that, despite concerns about confidentiality, the present position is that too little clinical information is shared between direct health care providers for a patient, resulting in missing information such as allergies, test duplication etc. He also suggests that one of the greatest threats of unauthorised disclosure arise from hospital staff themselves. (de Meyer, Lundgren et al. 1998) propose that any request for clinical information ought to include the relation between the patient and the requester, the purpose for which the information is requested and the type of consent given by the patient.

(Anderson and Brann 2000) argue that many present day threats to unauthorised disclosure arise from inside provider organisations, usually from inadvertent mis-posting of confidential databases on an Intranet or the Internet. However they cite several cases of more deliberate financially motivated disclosures, for example to employers, insurance or sales organisations. They also argue that secondary disclosures, however legitimate, may result in data being held by third parties in less stringent security conditions than the original health provider's data repository.

It is difficult to specify a rigorous approach to consent and confidentiality for the EHR that is also scalable, practical and easily maintainable over a patient's lifetime. An approach to this piloted by the author is described in Chapter 9.

5.12.2. Data Protection legislation

(Kluge 2000) distinguishes the generic nature of ethical principles from the differing and sometimes fallible nature of national legislation. The ethical issues outlined in Section 5.11 have contributed significantly to the FHR requirements presented in 6.4. The legislation summarised below has not contributed many new requirements, but is currently influencing health policy on consent to the disclosure of health records in many countries. In some ways an ethical approach is now being derived retrospectively from the legislation, somewhat inappropriately.

EU legislation

The 1995 European Community Directive 95/46/EC took effect for all new processing on 24 October 1998 (On the Protection of Individuals With Regard to the Processing of Personal Data and on the Free Movement of Such Data 1995). The key security requirement (Article 17) states:

> *"the controller must implement appropriate technical and organisational measures to protect Personal Data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where the processing involves transmission over a network, and against all other unlawful forms of processing. Having regard to the state of the art and the cost of their implementation, such measures shall ensure a level of security appropriate to the risks represented by the processing and the nature of the data to be protected."*

Personal Health Data (Article 8) is classified as "high risk" and requires strong security measures, taking the costs into account, such as encryption services, digital signatures and a Trusted Third Party for the management and certification of the encryption keys. The Data Subject's right of access (Article 12) is a cornerstone to the legislation, requiring informed consent for the collection of data and facilities for subjects to view and possibly correct the data that is held.

The principal recommendations of the 1997 Council of Europe Recommendation stress the rights and control of the individual over their data (Council of Europe Recommendation R(97)5 on the Protection of Medical Data 1997).

> *"The respect of rights and fundamental freedoms, and in particular of the right to privacy, shall be guaranteed during the collection and processing of medical data. In principle, medical data should be collected and processed only by health-care professionals, or by individuals or bodies working on behalf of health-care professionals."*

The recommendations specify the purposes applicable to medical data, including the provision of clinical care and compliance with statutory requirements. Protection is given to information provided by or relating to third parties. Specific provisions relate to unborn children and to genetic

data. It also reinforces the requirement for appropriate security measures to be applied to the data. An authoritative review of the requirements, EU legislation and international standards applicable to the security of electronic healthcare records is provided by (Barber 1998).

Data Protection Act

The national legislation that exists across Europe governing the protection of electronic health records (e.g. the Finnish Personal Data File Act (Tervo-Pellikka 1994)) is anchored on the EU Data Protection Directive.

The UK legislation, (Data Protection Act 1998 1998), came into force in 2001 for all new and legacy data and its processing in paper and electronic form (although there are transitional arrangements for paper records till 2007).

The Act states eight Data Protection principles that largely complement the provisions of the EU Directive, and it covers almost all patient information held by the NHS (unless anonymised). Particularly "sensitive" data include racial or ethnic origin, physical or mental health or condition, and sexual life, which constitute most of the data that would be in an EHR.

"Processing" of data is widely defined and covers all manner of use including obtaining, recording, holding, altering, retrieving, destroying or disclosing data; all of these require patient consent. Processing must be necessary for "medical purposes" and, although not defined exhaustively, this includes preventative medicine, medical diagnosis, medical research, provision of care and treatment and the management of healthcare services - but only if the processing is carried out by a health professional or a person with an equivalent duty of confidentiality. Processing without consent is only permitted in order to protect the vital interests of the data subject or another person. The Act also reinforces subject access rights with the exception of anonymised data held for historical or research purposes.

Clearly the EHR needs to permit compliance with each nation's data protection legislation. The EU Directive discussed above is considered internationally to be of a very high standard, and has largely shaped European national legislation. The author has found that a rigorous ethical approach to the EHR already encompasses most of what would be needed at the level of the information architecture, to meet legislative requirements.

HIPAA

The US Health Insurance Portability and Accountability Act (HIPAA) of 1996 provides a legal framework for public-private partnerships in health care, standards for the uniformity of health care data used in electronic administrative health transactions and standards for the privacy and security of individually identifiable health information (Report on H.R. 3103 1996). (Fitzmaurice 1998)

describes HIPAA as a simplification of the diverse electronic and paper transactions between purchasers, providers, social security and other statutory bodies across the US.

A set of HIPAA supporting standards has been defined to facilitate the definition of the above messages, and to enhance interoperability. These include: unique identifiers for each individual, employer, health plan and health care provider; code sets for appropriate message data elements; security policies and the use of electronic signatures (HISB Inventory of Health Care Information Standards Pertaining to the Health Insurance Portability and Accountability Act of 1996 1997).

This act has sometimes been regarded as the US equivalent of the EU Directives described above, but in fact it is broader in scope, more concrete and more prescriptive. In relation to data protection and the implications for the EHR, this Act has tended to bring the US closer to Europe and does not itself add significant new requirements to those necessary to meet the ethical issues described in Section 5.11 and the EU legislation outlined above.

5.12.3. Access control

Access control measures are an important component of ensuring appropriate availability and of denying unauthorised access to EHRs. Rigby et al describe the importance of access control to effect the confidentiality of electronic health records (Rigby, Draper et al. 1999), and propose that clinicians should be able to access records of patients if:

- they have an established history of providing care to the patient;
- they are members of the same department or speciality;
- they are recipient of a referral to provide or advise on care.

They also propose that access should be afforded to those who are currently supporting the work of another health professional who is providing care. This secondary network might be more difficult to define.

(Staccini, Joubert et al. 1999) argue that access to EHR information cannot be based retrospectively on an access control list created when record entries are made, because of the dynamic fluctuation in a patient's care team as their health problems change. (France 1998) suggests that there is an inherent contradiction between the confidentiality that might normally be exercised by a clinician and their patient, and the need to assure continuity of care through relevant communication to colleagues. He argues that privacy is about a relationship between a clinician and a patient, rather than about the information *per se*.

(Hirose 1998) describes a framework for access control to electronic medical records, piloted over five years at the Tokyo Dental Hospital in Japan, which includes "why": the patient-doctor role at

the point of care. (Iversen, Heimly et al. 1995) report a Norwegian approach to access control in which individual users and roles are mapped to a document-level sensitivity scale. Documents may additionally be "sealed" to limit their availability to local departments or to named users, and for which access is specifically audited. (Myers, Culp et al. 1999) describe the use of a metadata approach to managing access control in a new web-based EMR system in Texas. Original electronic record documents are linked to sensitivity and access tags that govern who may see them. Users are also authenticated against profiles including their "need to know". This dual system permits a user's credentials to be cross-mapped against record document access tags.

(Rind and Safran 1998) propose explicit prior consent for clinician access to web-based access to their records, and anticipate this will be obtained in those patients for which emergency access is considered a likely risk. Such an approach might not be scalable to the federated access to multi-site records (whether web-based or not). (Bowen, Klimczak et al. 1997) discuss the challenge of delivering an implementable access control policy in a large institution wishing to provide distributed access to a repository of clinical reports. They contrast the need to balance the availability of appropriately complete information for clinical care with the difficulty of managing access control applied to segments of patient records. They conclude that compartmentalising individual patient records into access control sub-domains may not be feasible on a large scale.

(Malamateniou, Vassilacopoulos et al. 1999) have successfully designed an access control database to store user profiles governing access to clinical documents or data sets via Internet/Intranet based FHR systems, for example comprising a federation of institutional record systems across multiple organisations.

Longstaff et al have proposed a confidentiality model derived from work carried out in Tees (UK) and drawing on inputs from both literature and a range of NHS projects (Longstaff, Capper et al. 1999), (Longstaff, Capper et al. 2000). The authors propose four broad categories of permission or restriction:

- relating to specific agents and specific patients;
- relating to specific agents and to classes of clinical information (for any patient);
- relating to types of agent and specific patients;
- relating to types of agent and to classes of clinical information (for any patient).

The model has been implemented in a web-based demonstrator and is being validated within the Tees Health Community (Thick, M. personal communication).

The PCASSO Project

The Patient-Centered Access to Secure Systems Online (PCASSO) project was a research, development and evaluation project to exploit state-of-the-art security and WWW technology for health care (Masys and Baker 1997). Key aspects of the security policy model that enhance PCASSO's assurance are (Baker, Masys et al. 1999):

role-based access control: individuals may access patient information in ways commensurate with their relationship to the patient;
least privilege: individuals have only the authorisations they require;
explicit authorisation: individuals have no default authorisation.

A more technical overview of the security architecture needed to protect web-based access is given in (Masys and Baker 1998). An access control framework for the EHR proposed by the author is discussed in Chapter 9.

5.12.4. Audit Trails

Section 5.12.1 and 5.12.3 above include several access control approaches that rely upon an audit trail to monitor user access to EHR information and sometimes to publicise the audit trail to patients to prevent abuse of access privileges. (Safran, Rind et al. 1995a) have shown that a comprehensive access audit trail that can be viewed by individual patients deters inappropriate access to patient records by hospital staff.

Few publications have proposed formal specifications for an EHR audit trail. Asaro et al have explored a range of actual and possible breaches of confidentiality within the University of Missouri-Columbia School of Medicine, to derive an appropriate set of data items that could be used to monitor or analyse and access audit trail (Asaro, Herting et al. 1999). Their study suggests several key data items that should be captured by an audit trail system:

- User name, role, enterprise, care team/unit(s)
- Session: connection type, location, start and end times
- Patient identification, care/team/unit(s)
- Record objects requested, and if sensitivity level is higher than default values

Concern has been communicated to the author by several hospital and industrial parties about the potential size of an access audit trail. In 1996 the Columbia Presbyterian Medical Centre clinical system audit trail generated about 100Mb of data per month (Barrows and Clayton 1996), suggesting that these can indeed become quite large.

5.12.5. Security policy and measures

Electronic healthcare communications must take place within an appropriate professional and technical security framework. The EU Projects SEISMED (Barber 1996a) (Barber 1996b) and ISHTAR (The ISHTAR Project 2002) have investigated the clinical and legislative requirements and the available products across Europe. The SEISMED project has published a set of guidelines to facilitate the compliance of health care enterprises with legislation, to enable them to protect against system vulnerabilities, and to deal with practical and organisational issues affecting security policies (Barber, Bleumer et al. 1995). The ISHTAR project has demonstrated working examples of comprehensive security policies in a range of settings across Europe. More recently the TRUSTHEALTH project has piloted the Trusted Third Party certification approach in several European countries (Blobel 2000b). One example is the secure distributed access to a cancer registry network in Magdeburg, Germany (ONCONET).

In 1995, the US National Research Council (NRC) of the National Academy of Sciences conducted an investigation of the practical measures needed to reduce the risk of inappropriate disclosure of confidential health information while facilitating legitimate access to those interested in improving the quality and reducing the cost of care. Their March 1997 report, *For the Record: Protecting Electronic Health Information*, reviews the public policy context and the internal and external threats to organisations holding health information (National Research Council Computer Science and Telecommunications Board 1997). The key technical and organisational measures recommended in the report are listed below.

<u>Measures for Immediate Implementation</u>

- Individual Authentication of Users
- Access Controls
- Audit Trails
- Physical Security and Disaster Recovery
- Protection of Remote Access Points
- Protection of External Electronic Communication
- Software Discipline
- System Assessment

<u>Measures for Future Implementation</u>

- Strong Authentication
- Enterprise-wide Authentication
- Access Validation (role based)
- Expanded Audit Trails (multi-enterprise)
- Electronic Authentication of Records (signature)

(Halamka, Szolovits et al. 1997) report on a proof-of-concept demonstrator of these recommendations using a web-based multi-institutional medical record at the Beth Israel and Deaconess Hospitals (CareWeb). Other authors have also investigated the possible threats and security measures that should be taken to protect health data, e.g. (Barrows and Clayton 1996), (Gritzalis and Lambrinoudakis 2000) with similar findings.

Pilot implementations of Trusted Third Party and Public Key Infrastructure solutions have now been validated in a number of settings (Katsikas, Spinellis et al. 1998), (Gritzalis, Iliadis et al. 1999), (Alkhateeb, Singer et al. 2000). PKI is now predicted to be the universal authentication and encryption key management system for securing healthcare communications, possibly augmented by strong authentication measures such as tokens or biometrics (van Dyk 2000). A comprehensive open source PKI framework has recently been developed by the HARP project (Blobel 2002).

EHR and FHR systems need to be capable of deployment within a comprehensive security architecture. However, technical security measures in themselves have limited impact on the specification of the FHR information models.

5.13. Data Capture Issues

(Rodnick 1990) states that *"the cost of manual data entry is the Achilles' heel of computer stored medical records"*.

(Gregory, Mattison et al. 1995) suggest that *"the complete elimination of unstructured or free text from the entire medical record is neither practical nor desirable"*, but also point out that *"a significant degree of structure is both practical and desirable in most circumstances"*. They suggest that facilitating direct data entry by clinicians represents one of the major challenges to replacing paper charts with electronic health records. (Ash, Gorman et al. 2000) have highlighted the challenge of gaining user acceptance to Physician Order Entry systems, which can be frustrating if the user has to journey through multiple screens or if response times are much over half a second per screen.

Benson et al have shown that the redesign of an anaesthesia information system can enable users to capture quite complex data to a high standard of consistency and completeness (Benson, Junger et al. 2000). (Matsumura, Takeda et al. 1998) describe a template based data entry system using a data dictionary to update dynamically the drop down lists, radio buttons etc. on each screen as a user makes choices. They have found that users can enter chest pain history in an average of 35 seconds (compared with 90 seconds on paper). (Reilly 1999) describes the successful use of a pen-based interface and a laptop computer to capture recent symptom experience from inpatients. Aisaka et al have successfully combined a pen and tablet based user interface with a GUI form design that

resembles the paper forms with which clinicians are familiar. They have shown data entry times that are equivalent to those of the paper forms (Aisaka, Tsutsui et al. 1995). The pen-based input also permitted the use of clinical drawings and sketches to be included within the clinical record.

Speech recognition

(Borowitz 2001) found that dictating paediatric gastroenterology clinic notes into a speech recognition programme on average took one minute longer than dictated reports that were later typed by a human transcriptionist. (Zafar, Overhage et al. 1999) found that the more expensive speech recognition products with rich dictionaries can yield a high recognition rate (98%). (Monnich and Wetter 2000) suggest that switching between a small set of limited vocabularies (for different sub-domains of a specialty) might also improve recognition rates.

A wide range of data input devices are likely to be used for the future capture of EHR information. These will have a greater impact on the design of clinical applications than on the EHR itself. However, as an example, it may be necessary to store both voice data and recognised text, extracted from that speech, as a pair of appropriately labelled values of a single entry.

5.14. Record Navigation and Presentation Issues

Navigation

Vastly more information is now gathered and is more easily available, which does not in itself improve the quality of care. In fact presenting clinicians with too much information can increase the risk to patients (Vincent 2000). Moehr et al warn that the increasing ubiquity of clinical systems and their interconnection may significantly impair the ability to identify relevant data from a mass of record information from diverse organisations, professions and disciplines using different recording styles (Moehr, Kluge et al. 1995).

One of the key challenges for future systems will be to reflect the individuality of different clinicians and to find ways of placing key information and commonly used functions within easy access. The population is increasingly realising the potential for this through personal home pages and web portals, and this issue is an active area of informatics research.

(Miller and Frawley 1995) suggest that long or complex on-line clinical guidelines might helpfully be filtered to the needs of each specific patient, becoming shortened and more readable. A hypermedia tool (DI-ADEM) has been developed in Marseilles to deliver web based clinical information contextualised to the user requirements that are held in a user profile database (Pagesy, Soula et al. 2000). van Mulligen describes a knowledge-based means of filtering, browsing or analysing the content of EHRs by mapping the clinical concept terms in the ORCA database to UMLS terms (van Mulligen 1999). (Zeng and Cimino 1999) have used the Medical Entities Dictionary at the

Columbia Presbyterian Medical Centre to filter and categorise record entries under laboratory tests, medication and problem lists, resulting in a summary subset of around 15% of the total patient record. They are now evaluating a richer "concept-oriented" view of the record (Zeng, Cimino et al. 2002).

Presentation

Health record systems need to support the clinician with clear and user-friendly screens, requiring a short data entry time and providing a rapid display of past and recent health events. However, (Wyatt 1999) argues that information presentation formats should be based on a formal and empirical evaluation and simply not on clinician preferences.

(Staggers and Kobus 2000) have demonstrated that a GUI application can improve the time taken to navigate and assimilate computer-held nursing records and reduce errors of interpretation when compared with a character-based screen. (Hoeke, Bonke et al. 2000) have shown that colour can facilitate recognition of the severity of the deviation of laboratory results from normal ranges.

(Poon, Fagan et al. 1996) in the Pen-Ivory project at Stanford have shown that users perform most rapidly and accurately when presented with a consistent information layout rather than an adaptive and contextually filtered interface. (Elting, Martin et al. 1999) have demonstrated that the format used to display clinical data (e.g. tables, icons, pie charts) can profoundly affect the way the data is interpreted and the conclusions inferred.

(Starren and Johnson 2000) have analysed and classified the diversity of presentation formats used for health data. This provides a useful overview of the options that exist for presenting medical data in the design of clinical applications and for their representation in the EHR.

The way that the EHR is structurally represented needs to accommodate some components that formally define relationships between data objects and others that serve purely navigation or organisation purposes to facilitate context-sensitive searching, filtering and presentation.

5.15. Data quality issues

Data sets and templates undoubtedly contribute to consistent and complete data entry, provided that adequate capacity is provided for narrative remarks. However, adherence to these is not straightforward, and (Stausberg, Kolke et al. 1998) have found that regular feedback of recording quality and completeness is necessary to facilitate better recording of selected data items. For example, the clinical systems of highly-computerised general practices are reliable sources for diagnoses, prescriptions and referrals but not for lifestyle information (Pringle, Ward et al. 1995).

This is almost certainly a reflection of the perceived functional (workflow) benefit of computerising certain classes of information, or the requirement of practices to produce activity reports.

(Marshall and Sumner 2000) have shown that a structured reporting form can increase the recording of problems when compared with free text recording sheets: 130-140% increase using paper and 109% increase using a computerised version. However, the authors observed that fewer psychosocial diagnoses were entered onto structured forms. (Moorman, van Ginneken et al. 1995) compared the use of free text and a computerised structured reporting form to capture endoscopy reports in a controlled experimental situation. They found that the overall completeness of the reports was greater using the structured forms, and that the underlying knowledge base of concepts relating to each part of the form provided suitable guidance in its completion.

(Tai, Nazareth et al. 1999) randomised six general practices to each receive one of two computerised templates, for the review of adults with either asthma or diabetes. They found practice nurses valued the templates as a reminder and data entry interface, but reported that it was more time consuming to use it and perceived it as rigid: they expressed a wish for more capacity to record free text comments. GPs rarely used the template, and either found it too detailed for convenient use during consultations or too prescriptive; however they wished to be provided with more management guidance.

It is sometimes hoped that EHR systems with sophisticated browsing tools will allow users to manipulate an unfamiliar data set and to represent it in their favourite way. Such tools might, for example, enable a diversity of styles of diabetes review entries within a single patient record, perhaps authored on different sites over time, to be presented in a uniform way. There are dangers in manipulating clinical facts and intentions without a rigorous record architecture and a comprehensive semantic formalism. Detaching part of a recorded entry from the original clinical context at the time that it was composed carries the risk that it will be misinterpreted. The amalgamation of data that is inconsistent, from disparate sources or collected for different purposes easily leads to misleading or erroneous interpretations and conclusions.

5.16. Supporting educational use of the EHR

An investigation of the implications for undergraduate and continuing professional education for the adoption of EHRs was published by the GEHR project in 1993 (Ingram D, Southgate L et al. 1993). The conclusions are summarised below.

The basic premise of modern clinical education is to move away from healthcare professionals having to remember vast amounts of information to a situation in which they are able to identify

problems, work out what knowledge they require, and then to seek out relevant information. It is argued that this process is partly dependent upon a more organised approach to the health record.

Unfortunately students do not usually receive much training in the use of health records and are confused by variations in how they are organised. Surveys of healthcare staff demonstrate great interest and willingness to improve clinical computing skills and frustration at lack of time and resources within the working context to make this possible and worthwhile (Murphy, Errington et al. 1997). As healthcare professionals tend to learn by apprenticeship it is important for students to feel actively involved in, and to some extent responsible for, patient care. An ideal EHR system would permit them to make and retrieve student entries (with patient consent, explicitly labelled and capable of being subsequently corrected and authenticated by a qualified professional). If students learn to be systematic and to code many of their entries they will be able to use the EHR to access clinical decision support systems and for bibliographic and knowledge links. This will enable them to become more independent in their learning. This could also provide them with a valuable case-based learning resource, for personal audit, and to review their experience of different health problems.

Access to anonymised databases of EHRs supports learning by comparing and contrasting similar cases (case-based learning). (Herting and Barnes 1998) describe a Java application that can anonymise a clinical database by replacing identifier and demographic information with random but suitable alternatives and replace keys consistently to maintain relational joins between tables. Yamamoto et al describe the construction of a clinical image library at the Shimane University Hospital based on real patient imaging reports (Yamamoto, Makino et al. 1998). Staff and students can search for (anonymous) images classified by condition as an educational resource.

An EHR repository, suitably and safely anonymised, wil have tremendous value for students and life-long learners. Techniques for developing such a repository directly from a real EHR are being investigated in a new MRC E-Science project, including the author, outlined in Chapter 14.

Chapter 6. Requirements for the Federated Health Record

This chapter presents the proposed clinical, ethico-legal and technical requirements for the Federated Health Record information architecture. These requirements build on the work of the author and colleagues as part of a series of EU projects, literature reviews, empirical observations and interactions with health care settings including the Whittington Hospital, east London general practice and a range of European demonstrator sites. The key published collections of formal requirements reviewed by the author are first summarised in Section 6.1 below. This chapter constitutes the ODP Enterprise Viewpoint specification of the UCL FHR service.

6.1. Sources of published requirements

Several extensive investigations of user and enterprise requirements for the EHR have taken place over the last decade, which have sought to span the information needs of diverse specialties across primary, secondary and tertiary care, between professions and across countries. These requirements have been distilled and analysed by expert groups, mainly within Europe, in order to identify the basic information that must be accommodated within an EHR information 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 EHRs on an individual or population basis;
- incorporate the necessary medico-legal constructs to support the safe and relevant communication of EHR entries between professionals working on the same or different sites.

6.1.1. Principal EHR requirements publications

GEHR

Several investigations were carried out between 1992-3 on the clinical requirements for comprehensiveness within the EHR (Ingram, Southgate et al. 1992):

1. An extensive literature review and a specific investigation of the experiences from several electronic healthcare record projects in Europe and North America.
2. Meetings and presentations in UK, Belgium, Luxembourg, Portugal, France, Greece and Spain with key organisations including the various Departments of Health, professional medical groups and informatics organisations.

3. Two reviews on current paper hospital health records. The first surveyed the structure of medical and nursing notes and the types of headings and subheadings used. The second compared the notes made by different health professionals to identify common content and common structures.
4. Evaluations in France and Belgium amongst users of an early GEHR prototype medical record application in hospital and in general practice. These studies included questionnaire surveys and the anonymised extraction and analysis of data from the prototype architecture.
5. An analysis of words used in free text recording, through dictated letters or free-text clinical records. Over 20,000 letters or notes were examined using specially written software tools for their vocabulary contents.
6. The health record content of asthma consultations in general practice and rheumatology consultations in hospital, as part of a broad study in London. A test site was subsequently established supporting shared care between general practice and hospital by transferring records using a GEHR-based prototype application.
7. A series of evaluations performed on several later GEHR prototypes, including:
   - a direct comparison of the contents of hand-written and computerised records;
   - the development and testing of a clinical drawings application;
   - the incorporation of digital images into an electronic healthcare record.

This narrative-style report was partnered by two other deliverables on educational requirements and on ethical and medico-legal requirements, which were summarised above in Sections 5.16 and 5.11 respectively. These three were synthesised into a single set of requirements statements in work largely co-ordinated by the author (Ingram, Southgate et al. 1993). This consolidated set provided the foundation for the final GEHR Architecture, published in 1995 ((Lloyd, Kalra et al. 1995), which is described in Section 7.2.1 below).

Synapses

The Synapses project extended the scope of the GEHR requirements to consider the federation of multiple heterogeneous clinical databases and record systems. The consortium included several hospital computing departments from across Europe (as demonstrator sites) and three vendors of Hospital Information System products. The author lead a significant set of investigations, published in (Kalra 1996b). The methodology for this work included:

1 a consolidation of the publications of GEHR and the Nora project on clinical and technical requirements, supplemented by input from the vendors and hospital departments;
2 a review of recent publications on data protection and security policy (including the EU Directives and the projects summarised in Section 5.12).

3 a set of clinical and technical scenarios developed by each of the demonstrator sites including specific information requirements, feeder systems and example patient case histories;
4 proposed audits to evaluate the impact of Synapses server at each site.

These requirements were later synthesised into a formal Software Requirement Specification (Grimson and Groth 1996), conforming to (IEEE Recommended Practice For Software Requirements Specifications 1993). A subsequent revision of these statements was edited by the author as a chapter in the final Synapses ODP Enterprise Viewpoint Specification (Toussaint 1998).

EHCR-SupA

In May 2000 the EHCR Support Action project (summarised in Section 5.2.6) published a consolidated set of requirements applicable to the design of an EHCR information architecture (Dixon, Grubb et al. 2001). The editing team, including the author, reviewed publications in this area from a range of European research groups and projects including CEN/TC 251, GEHR, I4C, NIVEMES, NUCLEUS, PRESTIGE, RICHE, SPRI, STAR and SYNAPSES. Some of these projects have been summarised in Chapter 5. The topics covered by this report are summarised in Table 6 below to give an indication of its scope.

Responsibility Of The EHCR	Multimedia And Externally Referenced Data
Subject Of Healthcare	Problems
Identification Of The Patient's Record	Events
Comprehensiveness	Acts
Expressiveness	Requests And Results
Faithfulness	Prescriptions And Drug Administration
Single Record Of Care	References To Non-Patients And Places
Boundaries And Definitions	Alerts , Triggers And Decision Support
Administrative Information	Derived Data
Organisation Of The Record	Dates, Times And Chronology In The Record
Links	Sources And Providers Of Information
Intra-Record Links	Normal And Physical Ranges
Inter-Record Links	Comments In The Record
Preservation Of Context	Certainty
Observations Recorded By Students	Severity
Language	Terminology And Knowledge
Free Text	Synonyms
Numerical And Quantifiable Data	Other Forms Of Data

Table 6: Topics covered by the EHCR SupA Consolidated List of Requirements

The deliverable also covers the requirements for electronic health care record processing and EHCR interchange and the sharing of healthcare information. The report has been well regarded internationally, and has been fed into current work in ISO on EHR requirements.

Nora

An investigation of end-user requirements was performed in Norway by the Nora project during 1987-88 (Skifjeld, Harket et al.). These requirements were developed by a team of 6-8 health care professionals and computer specialists with additional input from larger groups of potential users. A subsequent refinement of these was carried out by a smaller team working at the SiA hospital in partnership with Siemens Nixdorf (Oslo). These requirements were provided to the author during the Synapses project.

SPRI

The Swedish institute for health services development (SPRI) undertook a national investigation of requirements for computer based patient records, published in 1998 (Introducing Computer Based Patient Records: Prerequisites and Requirements 1998). This work covers general requirements relating to the core EHR functions, data presentation, data capture, outputs, legal issues, security and communication. Additional requirements were included to ensure compliance with national policies. The publication was intended to ensure the consistent quality of new procured systems, particularly for hospitals, but was also regarded more widely across Europe as a valuable set of requirements relating to EHRs.

I4C

The I4C project has been described in Section 5.2.8. One component of the work has been to propose requirements for the EHR that have underpinned the development of the ORCA database for cardiovascular care and the Structured Data Entry client application that interoperates with it. Several papers from this group have been sited in Chapters 3-5 describing their view of the role and functions of the EHR. Their approach on the representation of EHR information is summarised in (van Bemmel, van Ginneken et al. 1998a). A formal set of requirements were published in (User Requirements and Functional Specification) early in the I4C project. Many of these requirements correspond closely with those published by GEHR, reflecting a common general understanding of the EHR.

Health Information Network for Australia

The Australian National Electronic Health Records Task Force was established during 1999 to propose the approach that should be taken towards EHR systems and realising a health information network. One element of that investigation was a literature review of the key benefits and difficulties associated with adopting such a national approach, and a survey of comparable

experiences from other countries (Heard, Grivel et al. 2000). This report included a review of the purposes of an EHR and its main requirements.

ISO Work Item

In June 2000 Technical Committee 215 of ISO approved a Work Item to produce a set of requirements for an EHR reference architecture. This work is now at an advanced stage (Schloeffel 2002), and its editor has accumulated a database of nearly 600 requirements statements drawn from many original publications including those described above. Because of the common pedigree of original sources few significant new requirements were found on reviewing this publication but the degree of overlap has provided a degree of verification of the completeness of the set presented below. The final draft of this chapter is being offered back as a contribution to the ISO work, due for publication later in 2002.

6.1.2. Other examples of published requirements

(Hayes 1997) discusses the variation in user requirements that exist for an electronic medical record, in particular between hospital specialists and general practitioners. He draws attention to the differing granularity of clinical observation and problem specification that is commonly found between disciplines, and the evidence that highly structured clinical systems tend to be more acceptable to users in hospital settings. He argues that a single medical record might not be feasible across all disciplines, but does acknowledge that a common information model might be found to underpin their core requirements.

van der Meijden et al describe the development of a departmental EHR system for a stroke unit in Maastricht (van der Meijden, Tange et al. 2000). The primary feeds into the design were an analysis of the use made of pre-existing paper records and the attitudes of staff towards a future electronic record system. The authors found that, even in apparently unstructured records, users have expectations of the order in which to find information, how it might be laid out and how to decode annotations, marginal notes and colour usage. The summarising that takes place during a recording process provides a weighting context that clinical readers learn how to interpret. The paper includes a discussion of a number of requirements that, although derived from the paper record, could be applied to any generic EHR.

(Lovis, Baud et al. 2000) have published a list of clinical functional requirements that have informed the design of the DIOGENE system at the University Hospital of Geneva. Mooney et al investigated the requirements for the effective migration from paper-based records to multi-professional and holistic EHRs through a questionnaire and interview survey of users at the Hospitaller Order of St. John of God in Ireland. (Teich, Sittig et al. 1998) consulted a panel of physicians at Brigham and Women's Hospital in Boston on their priorities for clinical applications.

The requirements identified for clinical documentation (entry of notes, observations, orders) and data review (results, summaries) were used to inform the development of a new Partners Healthcare system to support 7 hospitals and many practices covering 800,000 patients. (Korpman and Dickinson 1998) propose a list of over 150 functions and features to be considered in the design of EHR systems. This list includes many features applicable to a clinical system rather than an EHR information model or a middleware service. The author has used it as a checklist to confirm complete coverage of the core EHR requirement themes presented below.

The author has reviewed many other papers reporting requirements, but has not found that they incorporate any additional significant generic requirements.

6.2. Introduction to the structured set of requirements

The requirements listed below, adapted from work by the author through several projects, reflects the functional requirements of an open distributed system providing secure and ubiquitous access to patient health records. These requirements include the federation of multiple EHR sources to form the federated health record.

The requirements listed below have been categorised under four main headings:

- functional requirements, relating to the overall goals of an FHR service and the high level characteristics of a federated health record;
- ethico-legal requirements, relating to the purposes for creating record entries, policies for their disclosure and other policy aspects of security;
- clinical requirements, relating to the overall culture of clinical practice, the acts of record entry creation, amendment, communication and access, and the fine-grained requirements for representing and processing health record information itself;
- technical requirements, relating to the middleware computing environment in which the service is deployed, including network connections and technical security features.

The individual requirements statements listed below have been collated and refined by the author over a ten-year period, drawn from:

- the formal analyses published by GEHR, Synapses and EHCR SupA;
- the process of implementing an FHR server according to the information architecture presented in Chapters 7 to 9;
- experience of the live clinical deployment of the FHR server at the Whittington Hospital, as described in Chapter 11;

- the design and implementation of general practice systems in east London and nationally over the past twelve years, including the author's own general practice;
- working in the primary and secondary care sectors with involvement in clinical audit and in the quality assessment of paper record systems;
- reviews of major published requirements by other European projects and other published literature; the key influential original publications are summarised in Sections 6.1.1 and 6.1.2 of this Chapter.

Statements of requirement should ideally comply with the IEEE specification (IEEE Recommended Practice For Software Requirements Specifications 1993), and should be verifiable, traceable, unambiguous, correct and relevant. The author has used this framework during the Synapses project and has endeavoured to frame the statements below in this way. Many of the requirements, particularly those in the medico-legal category, come under the SRS heading of *Constraints* for which the IEEE specification is less precise.

Ideally each statement below should also reference the original published sources of the requirement. Although the author has maintained some record of this, in practice the formal attribution of individual requirements to sources on this scale is neither practical nor faithful. In the ten year period since the first publication of the early GEHR requirements deliverables and the US Institute of Medicine report there has been much subsequent cross-fertilisation of ideas and cross-inclusion of requirements in newer publications, with some improvement and updating as the scope of electronic health records has evolved. Secondly, individual publications often cover similar requirements themes to a different level of granularity or stress different perspectives. In collating the statements below an attempt has been made to express each requirement in the most generic way possible, whilst many of the original publications have been targeted at the needs of one country, a professional group or an envisaged implementation.

The statements below therefore represent a symbiosis of thinking, primarily within Europe, and are the result of much valued interaction with many colleagues over the last decade.

6.3. FHR functional requirements

Key concepts

The federated health record (FHR) service is intended to enable health record data about patients to be retrieved from distributed clinical systems (feeder systems) for presentation to a requesting application or other process. This does not include handling the editing, deletion or creation of such data on these feeder systems; these are processes to be managed by clinical applications on those feeder systems. A set of entries will be provided by the FHR service (as *FHR extracts*) in

response to an authorised access request for part or all of a patient's FHR. Access does not necessarily imply that the recipient will utilise another persistent store: information will more commonly be requested for transient display or computation. The underlying common information model for representing EHR information within the federation is referred to as the *FHR Reference Model*. The FHR will need to contain an object dictionary of metadata defining the (hierarchical) structural organisation of potential federated health records, the data types that instance values may take, constraints on permitted values, and a mapping to the feeder systems that contain instantiated parts of the FHR for each patient; these definitions are referred to here as *archetypes* and the middleware services managing archetype definitions as the *FHR Archetype Object Dictionary*.

Long term goals of a federated health record service approach

GOAL.1 The FHR should support the improvement of patient care by enabling healthcare professionals to access health record information more readily from whichever system and in whatever format it is originally stored.

GOAL.2 The FHR should enable healthcare professionals to access healthcare record information that is relevant, complete, and immediately and appropriately available.

GOAL.3 The FHR should enable the communication of healthcare information efficiently in a mutually comprehensible way to support shared patient care, improved quality of care and effective resource management.

GOAL.4 The FHR should help ensure that patients receive the most appropriate care as quickly as possible, by:

- enabling more rapid diagnoses and more appropriate treatments;
- avoiding any unnecessary duplication of examinations, tests and other procedures;
- avoiding any increased risk to patients;
- assisting with tasks such as producing order forms, discharge letters etc.;
- transferring information about the care and progress of patients between hospital teams, general practices and other community care professionals;
- supporting individual patients in the self-management of their condition;
- improving medical outcomes;
- demonstrating clinical effectiveness;
- helping to meet patients' expectations of confidentiality, integrity and continuity of care across providers.

GOAL.5 The FHR should enrich audit & research activities within healthcare enterprises, by:

- providing information for audit of individual clinical cases, and for quality assurance relating to services and outcomes;
- providing information for research studies into best care practices for specific categories of patients.

GOAL.6 The FHR should support strategic planning decisions, by:

- enabling the monitoring of the quality of care provided, including the achievement of standards of care specified in contracts;
- enabling the monitoring of costs, e.g. by providing tools for evaluating cost-per-pathology or DRGs;
- contributing to an overall reduction in the cost of health care provision and to reducing litigation costs.

GOAL.7 The FHR should support continuing health professional learning, by:

- supporting the review of personal care provision to enable case-based learning;
- offering better facilities for learning through anonymised cases and audit data.

The federation mechanism

FHR.1 The FHR must facilitate the creation of a single logical electronic healthcare record for each patient within a healthcare enterprise or region, by enabling distributed and legitimate access to the set of EHRs and other clinical data held by or available to that healthcare enterprise.

FHR.2 Each FHR applies to an identified subject of care (the patient).

FHR.3 The FHR must be clinically comprehensive and medico-legally acceptable.

FHR.4 The FHR must be able to represent a longitudinal health record reflecting the contributions of multi-professional HCPs and other carers from multiple organisations and countries through a patient's life.

FHR.5 The FHR must support the communication of EHR data between healthcare enterprises, both by enabling remote EHR sources to act as feeder systems and by enabling requests from one site to be forwarded and processed by another FHR server at a remote site.

FHR.6 The FHR must ensure that the autonomy and ownership of individual EHR sources is preserved when data are communicated between healthcare enterprises.

FHR.7 It must be possible for feeder systems to contribute only a subset of their data schema to the FHR.

FHR.8 It must be possible for users to obtain an overview of what information legally resides within a patient's EHR at an institution, particularly if this is distributed across several servers.

FHR.9 It must be possible to identify the source feeder system for any entry in a patient's FHR.

FHR.10 Healthcare professionals must be clear what record information is available to them during patient care, and whether it is held locally by their own healthcare enterprise or may be available on request from a remote site.

6.4. FHR medico-legal and security requirements

Subject access rights

SUBJ.1 The FHR design must enable an institution to comply with national and international mandates and directives on the protection of healthcare data.

SUBJ.2 The FHR must be legally acceptable: admissible as evidence in legal proceedings, as well as guaranteeing the validity of prescriptions and other orders.

SUBJ.3 The FHR service must provide facilities to enable patients or their representatives to view any or all of the personal health data that forms part of the FHR. (The FHR should be presentable in a form that avoids unnecessary jargon.)

SUBJ.4 Data subjects (patients) must be able to make or to authorise amendments to their health record to correct errors, including amendments to the disclosure policy for entries.

SUBJ.5 Patients must be able to contribute to their own record as active participants in their own health care.

SUBJ.6 Any correction, erasure or blocking of health record entries must be notified to Third Parties where it has occurred.

SUBJ.7 The FHR service must have the facility for keeping a "Third Party Disclosure Register" so that subsequent updates or corrections can be notified to them.

Confidentiality and access control

ACC.1 The FHR must be able to represent the extent of the consent specified by a patient or other party for the disclosure of his or her FHR; this might include the specific relationship of user roles to levels of access.

ACC.2 The FHR service handling of the processes of request and response must be consistent with access control requirements, even though such features may be invisible to the end-user.

ACC.3 The FHR must support a multi-level access level framework, in which levels may be defined according to profession, position, speciality or role, and which may only be valid for individual patient records or parts of patient records for certain periods of time.

ACC.4 Health care enterprises utilising FHR server(s) to federate clinical systems must have a formal mechanism whereby explicit or implied patient consent can be documented for the access rights framework that will be applied to their record.

ACC.5 Patients should be made aware of which professionals have "clinical care" status at a healthcare enterprise and consequent access to their FHR.

ACC.6 The access control policy that applies for non-clinicians, such as secretaries or managers, to access the FHR should be available to patients.

ACC.7 Research utilising healthcare records should be by informed consent: the design and purpose of the research must be communicated to patients.

ACC.8 Computer systems engineers should not normally have access to the actual FHR data held on their system, although if there are technical problems this may at times be necessary.

ACC.7 It must be possible to associate access rights to individual health record entries.

ACC.9 An institution receiving an extract into its EHR system must be aware of the security access framework of the donor site, and be capable of mapping this into its own such framework. (The security status of different staff should ideally be consistent at a national or European level.)

ACC.10 The FHR service must ensure that the transfer of record extracts between systems complies with both the donor and the recipient access level frameworks, to ensure that users only have appropriate access to FHR data.

ACC.11 It is sometimes argued that users must be clear if their view of the record is restricted for security reasons; this is not practical as the revelation that parts of the record have been denied is itself a disclosure that relevant information exists.

ACC.12 Clinicians providing health care services must have sufficient access to the entries within an FHR to enable them to deliver care safely.

ACC.13 A set of entries made by one author at one date and time should only contain data associated with more than one different level of access rights if the responsible healthcare professional is satisfied that the view derived through any one of those access levels does not seriously misrepresent the meaning of that whole set of entries.

ACC.14 It must be possible for healthcare professionals to mark health record information as potentially harmful for the patient to access, and for the FHR service not to disclose it if the user is known to be the patient.

ACC.15 The restriction of record entries from access by the patient's guardian may need to be distinguished from restrictions applied to patient access.

ACC.16 The purposes for which an FHR extract is retrieved or analysed should be consistent with the consent (explicit or implied) for which the data is being held on about a patient. This may at times mean that a given user is able to access a patient's record for providing clinical care but not for teaching or research activities.

ACC.17 Communicating the FHR or parts of it to Third Parties that have a legal or other legitimate interest in the record should involve explicit and documented consent by the patient and a clear undertaking by that Third Party to use it for specified purposes.

Emergency over-ride

EMRG.1 The FHR service must accommodate the over-riding of normal access rights in a medical emergency situation.

EMRG.2 Emergency over-ride exceptions must be explicitly documented within the FHR service itself (for example, specifically labelled within the audit trail) to support subsequent investigation.

Audit trails

AUD.1 The FHR service must contain the necessary features to enable an audit trail of the creation and amendment of patient information.

AUD.2 A formal audit trail of all requests for record entries must also be kept by the FHR service (since a patient's FHR itself will usually only contain a record of new or amended entries).

AUD.3 The audit trail must be able to rigorously track the distributed access to FHR services.

AUD.4 The audit trail must record at minimum the identification of the requesting end user and the role assumed, the patient whose FHR has been accessed, the set of entries accessed, and the date and time of access.

AUD.5 The audit trail must be protected from modification or erasure at least as securely as any federated health records.

AUD.6 Facilities must exist for the authorised inspection and interrogation of the audit trail as a whole, and for presenting the accesses pertaining to an individual patient's FHR.

Unambiguous identification of patients

PAT.1 The FHR must allow for the recording of attributes necessary for accurate patient identification.

PAT.2 The link between a patient and his or her record cannot depend only upon the patient's name, but must be via one or more unique identifiers that are independent of demographic details.

PAT.3 The FHR service must minimise and monitor the risks of the erroneous identification of patients and of providing data about the wrong patient to an end-user.

PAT.4 The FHR service must be able to store and cross-reference a series of patient identifiers for several institutions involved in any patient's care, and allow for these to change over time.

PAT.5 If a patient can be identified in more than one way, these different identities should be capable of being linked together in order to always provide a comprehensive view of the patient's medical record data.

PAT.6 The FHR must be able to represent patient demographic information in a way that permits configuration to allow for local naming conventions, and also allow for these to change over time.

PAT.7 The FHR must allow for international person name conventions. For example, the system may need to try matching with the surname and forename interchanged to allow for Asian names entered incorrectly.

PAT.8 The FHR must support the recording of more than one name for a patient (e.g. maiden name, married name).

PAT.9 The FHR service must permit patient records to be retrieved on the basis of a range of demographic characteristics and healthcare identifiers.

PAT.10 In the event of a confirmed duplication of patient identities in the FHR a rigorous method for the merger of two FHRs must be available.

User Authentication

AUTH.1 Authentication mechanisms should be facilitated: there must be a rigorous method to identify and to authenticate the author of an entry or of a request for a record extract.

AUTH.2 The FHR should facilitate the use of technical solutions for the attribution and non-repudiation of the author of a record entry.

AUTH.3 End user authentication should not require specific user profiles to be permanently maintained on portable connection devices (e.g. PDA, laptop), but utilise trusted third party (PKI) services that are not compromised if the portable device is lost or stolen.

AUTH.4 End-users should require authentication only once for each session, unless that session has timed out.

AUTH.5 The FHR service interfaces should allow access to be controllable, e.g. on a 'time and station' basis.

AUTH.6 The FHR service interfaces should allow 'time-out' to be configured, e.g. on a station basis.

FHR security

SEC.1 There should be an agreed set of information associated with every entry including the origin and authorship of the information and who is permitted to view it.

SEC.2 Appropriate technical and organisational measures must be implemented to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access.

SEC.3 Measures to guard against falsification of date and times should be considered; the FHR must enable the use of verifiable time-stamping services

SEC.4 Security measures within the FHR service must prevent unauthorised reading, copying, alteration or deletion of information during the communication of record entries.

SEC.5 Encryption services must be used for FHR data sent over open or uncontrolled networks. (This might involve the use of digital signatures to ensure the integrity of the data and to authenticate its origin as well as encryption for confidentiality. It may be necessary to include a Trusted Third Party for the certification of the encryption keys.)

6.5. FHR clinical requirements

Fulfilling the role of the record

ROLE.1 The FHR must contain or reference all information thought to be clinically relevant to the care of a patient.

ROLE.2 It must at least fulfil the two major roles of the traditional health record: supporting the ongoing health care of the patient and providing evidence of competent care.

Faithful reflection of clinical practice

PRAC.1 The FHR must be able to represent opinions, suggestions and hypotheses as well as firm factual knowledge about a patient.

PRAC.2 The FHR must permit an author to express a degree of uncertainty about a hypothesis; this may change as hypotheses are tested or as new information is acquired.

PRAC.2 The FHR Reference Model must permit an author to explain or justify their reasoning or assertions, and optionally to reference external sources as the basis for a conclusion or strategy.

PRAC.3 The FHR Reference Model must be flexible and generic enough to allow for the individual and professional variations in the interpretation of health and illness, and therefore in record entries.

PRAC.4 The FHR Reference Model must be flexible and generic enough to allow for regional, national and cultural variations in health expectations and health care, and therefore in record entries.

PRAC.5 The FHR Reference Model must be flexible and generic enough to allow for the future evolution in the understanding of health and for innovations in health care, and therefore in record entries.

Authorship of health record entries

ATHR.1 All entries within an FHR must be associated with the identifier of the authorising party, the institution owning the EHR source, and the date/time of the entry.

ATHR.2 The authorising party must either be a healthcare professional (HCP) with responsibility for the care of that patient, or a party authorised by the patient who might be a carer, a guardian or the patient him- or herself.

ATHR.3 The identification of responsible HCPs must be internationally recognisable, and their professional status must be clear to any future user.

ATHR.4 There should be an agreed, ideally internationally, set of information recorded every time information is authored within the FHR. This might include the time and date, definition of time zone, identification of provider (personal ID, name, position, speciality, physical location, health care organisation), identification of language and coding system used, definition of ownership of the information and its level of sensitivity for disclosure.

ATHR.5 The person responsible for authoring the entry, if not the responsible HCP, must also be unambiguously identified. (It must be possible for medical secretaries, students and patients to be recorders of FHR entries; these must still be authorised by a responsible HCP.)

ATHR.6 Test results or other information not yet seen by a responsible healthcare professional should be regarded as external to the FHR even if held on the same information system.

ATHR.7 The FHR must accommodate the assignment of a specific authorisation status (e.g. "not signed") to data that needs to be entered into an FHR by a device, computer programme or third party, prior to its authorisation; it should not be widely available to other users until it has been authorised.

ATHR.8 Once data has been entered into the record by the responsible healthcare professional, it should still be possible to identify the laboratory or diagnostic department/institution that carried out the test.

ATHR.9 Any extract incorporated into an FHR system (e.g. from a feeder system) should identify the HCP responsible for incorporating it into the FHR for that patient or confirm the patient's authorisation, and the date and time it was incorporated.

ATHR.10 It must be possible to identify the institution that is the source of each entry within the FHR.

ATHR.11 It must always be possible to confirm the content of an institution's record as it was at any previous moment.

ATHR.12 A legally-responsible HCP must always be identified with every FHR entry, whether it has been authored by a person or automatically incorporated from a device, software or other EHR system.

ATHR.13 The FHR must be able to represent the identification of a second authorising HCP for any entry. (Certain kinds of record entries need to be countersigned by a second authorising HCP, for example the dispensing of drugs in a hospital context, and a number of legal forms.)

Identifying students

STUD.1 Student interactions with the FHR must be identifiable as such.

STUD.2 Student entries must be distinguishable from authorised entries, excluded from analyses and decision support queries, and not transmitted to external institutions.

STUD.3 The FHR should allow qualified professionals to validate a student's entry, document that they agree with the student's notes and change the status of the student's notes to that of qualified professional.

Identifying third parties

THRD.1 The FHR must be able to represent information provided by a patient about a third party without relying upon access to information held externally to that patient's record, for example information in the health record of the third party.

THRD.2 Responsible parties (e.g. authors and care providers) must be unambiguously identified within each FHR. (A mechanism is required to enable HCP authors to be identified longitudinally within FHRs as they change organisation, role, speciality and possibly name; national professional registration numbers may facilitate this.)

THRD.3 If information is provided by a third party (e.g. family member), another institution (e.g. laboratory) or a physical device (e.g. cardiac monitor), it must be possible to distinguish that information source from the author of the entry itself.

THRD.4 The roles and responsibilities of agents should be definable in the FHR.

Identifying healthcare and patient locations

LOC.1 The FHR should cater for the appropriate identification of locations including the relationship of these to the subject of care.

LOC.2 It must be possible to record the physical location pertaining to a health record entry, for example the facility at which health care was provided.

Recording dates and times

DATE.1 At the time of saving a set of entries in a patient's record, a "point of commitment", these must become unchangeable and be indelibly preserved. The set of entries, including all relationships between terms and any attributes of the individual data elements must all be saved unambiguously.

DATE.2 Health record entries must be associated with a recording date and time unless these are not known.

DATE.3 Users must be made aware if they are accessing record entries for which the recording date and time are unknown.

DATE.4 The date and time at which health information was acquired by a person or a device may not coincide with the recording date and time, and may need to separately documented; this may be a time period or an instant.

DATE.5 The date and time at which a health or health care event took place may not coincide with either the date and time at which that health information was acquired by a person or a device nor with the recording date and time, and may need to separately documented; this may be a time period or an instant.

DATE.6 The date and time at which new data were acquired in a patient's FHR may need to be recorded, for example to indicate the acquisition of information via EDI messages or new feeder systems.

DATE.7 The locale at which a date and time entry is made must also be recorded to permit its safe international interpretation.

The Amendment of Health Record Entries

AMND.1 Amendments must be new versions of the original entry.

AMND.2 It must be possible for an authorised user to create or update a record entry, but impossible to alter or erase an original entry.

AMND.3 Each version of an entry must document the amending responsible healthcare professional and an amendment date and time.

AMND.4 Amended entries should include the rationale for the amendment.

AMND.5 When transferring a health record or extracts of it, only the most recent version of each entry should normally be sent. (Mistakes or details that the patient did not agree to have in the record would therefore not automatically be propagated.)

AMND.6 If versions of an FHR or of some entries exist on more than one feeder system, modifications made on each must be capable of subsequent reconciliation to ensure that the overall FHR reflects the most recent modifications.

Faithful representation of health record entries

ENTR.1 The FHR information architecture must preserve the clinical meaning of record entries as they were originally recorded.

ENTR.2 Unless specifically labelled otherwise, health record extracts must contain data relating to a single subject of care.

ENTR.3 The FHR service must enable health record extracts to be derived and combined from one or more feeder systems.

ENTR.4 The FHR must be able to represent any healthcare record entry, potentially created by any health professional of any specialty from primary, secondary, tertiary, community or complementary health care enterprises.

ENTR.5 The FHR must allow records and record entries to be combined even if they have been created on different computer hardware configurations, different operating systems or different EHR applications.

ENTR.6 The FHR should enable record related information to be extracted from feeder systems, and support various predefined and *ad hoc* combinations of this information for end user applications.

ENTR.7 Although individual EHR systems will display healthcare data differently, it must be possible to obtain an overview of all of the data entered at any one date and time by one person at one institution, and in its original language. This view should reproduce, as accurately as it is feasible to do so, the way that the information was organised at the time of its creation.

ENTR.8 The transfer of the record, or extracts of it, between independent EHR systems must comprise exchanging whole medico-legal cohorts of entries: the set of entries made by an author at one date and time about one patient.

ENTR.9 In many situations data sets rather than whole cohorts of entries will be requested by end users and client applications, for display or analysis (as opposed to transfer for subsequent storage).

ENTR.10 Data sets should only become part of an enterprise EHR if a healthcare professional has vouched for their clinical validity as an extracted data set.

ENTR.11 The FHR must preserve the authorship, creation and amendment audit trails, original information providers and clinical/legal responsibilities identified in a feeder system record extract.

ENTR.12 The data contained in an extract must be capable of manipulation, representation and storage by the end-user application in ways appropriate to local requirements.

ENTR.13 The FHR service should facilitate the generic rendering of any health record extract or of the whole record, to enable readable access to a patient's record if no clinical application is available; an XML rendering of the patient's FHR would be an example of this.

The structure of health record entries

STRC.1 The FHR must preserve as much as possible of the original context of a health record entry as represented by the originating clinical application or feeder system.

STRC.2 The FHR must preserve original organisation of compound clinical concepts and hierarchies and any defined relationships between record entries.

STRC.3 FHR entries must preserve faithfully:

- narrative and structured (e.g. problem orientated) methods of organising clinical data;
- the grouping structures used to organise element and compound clinical concepts into record entries;
- headings and sub-headings used to organise sets of record entries;
- longitudinal partitions of health records, for example episodes of care, which might be defined retrospectively;
- terms from a wide range of term sets, free text, measurements, drawings or diagrams, images or photographs, biological signals, sound, video or other data types;
- the qualification of entries by negation, degree of certainty, severity, accuracy or precision;
- entries which are associated with a free-text comment;
- features relating to emphasis (e.g. for unexpected findings or abnormal results);
- references to externally-held data such as bulky images;
- information provided by a third party (such as a family member), another institution (e.g. providing a laboratory result) or a physical device (such as a cardiac monitor);

- the links between activities and information generated by the activities (e.g., that a test result originates from a specific request);
- other linkage networks within a record such as problem links, disease progression or therapy programmes;
- the rationale for clinical decisions, including attribution to protocols, knowledge databases, bibliographic references or decision support systems.

STRC.4 It must be clear what language has been used in an original record entry. An extract should always be transferred to another EHR system in its original language.

STRC.5 There may be occasions when an extract includes pointers to information held elsewhere in a patient's record. They should be durable on transfer if all of the relevant parts of the record have been included in the extract.

STRC.6 If diagrams, drawings, tables or graphs are present, these structures as well as their data content must be preserved in the record extract.

STRC.7 Data should not be made available to a recipient end-user without any accompanying template structures if these give meaning to those data.

STRC.8 The FHR must be able to represent an ordered list of values such as, but not limited to, a time sequence.

STRC.9 The FHR must be able to represent the life-cycle status of a healthcare activity; this is usually one of: established, validated, requested, accepted, scheduled, started, transferred to another care team, provisionally reported, completed, cancelled, refused, suspended, abandoned.

STRC.10 It must be possible to document and to communicate information about the role played by decision support tools, protocols and bibliographic databases in a patient's care.

Authors' Comments

COMM.1 The FHR must be able to associate a narrative author's comment with a record entry of any data type.

Categories of clinical information

CAT.1 The FHR must faithfully represent the structure and content of any class of health information pertaining to a patient's health or health care.

CAT.2 Many published requirements specify categories of record information that must be included, for example the ISO draft report Requirements for an Electronic Health Record Reference Architecture (Schloeffel 2002) includes the following list of categories:

- patient history
- physical examination
- psychological, social, environmental, family, and self care information
- allergies and other therapeutic precautions
- preventative and wellness measures such as vaccinations and lifestyle interventions
- diagnostic tests and therapeutic interventions such as medications and procedures
- clinical observations, interpretations, decisions, and clinical reasoning
- requests/orders for further investigation, treatments, or discharge
- problems, diagnoses, issues, conditions, preferences and expectations
- healthcare plans, health and functional status, and health summaries

CAT.3 There must be a mechanism to provide an alert to key information (warning/ priority messages) all users should see before taking clinical decisions.

CAT.4 The FHR should allow for pre-birth and post-death entries.

CAT.5 (It has been proposed that appointments for health care activity need not be part of the FHR; this view is not universally held.)

CAT.6 The FHR must cope with variable numbers of reports for a particular test data acquisition.

CAT.7 Prescribing and drug administration entries in the FHR need to be supported and differentiated.

Textual entries

TEXT.1 It must be possible to include free text entries and narrative comments in the FHR, ranging in length from a single word to a long narrative. (The FHR should allow clinicians to use a rich and varied vocabulary.)

TEXT.2 The FHR must cater for information recorded in different languages, whether this be individual entries or complete sections of the record.

TEXT.3 The FHR must indicate wherever information has been translated from its original language.

Coded terms

CODE.1 Terms should be stored in a record within a context that preserves their meaning, and allows computation.

CODE.2 Where an author has entered information from a term set, the term set name (and version) must also be included.

CODE.3 Term set entries must always be retained with their original codes, and any mapping to other term sets must always be from this original.

CODE.4 The FHR must be capable of identifying coding schemes by means of a CEN or ISO health care coding-scheme designator.

CODE.5 Locally-defined terms must be capable of representation within the FHR.

CODE.6 The FHR must be able to represent both a term-set code and its rubric as part of a record entry.

CODE.7 Pre- and post-coordinated term combinations must be faithfully represented in the FHR.

CODE.8 Term set entries may be qualified with negative, probability, severity or risk statements. Probability or certainty may be expressed as a scale, percentage or a term; severity might be a term or a scale.

CODE.9 Drug prescription data must be transferred in a manner that enables their interpretation by users in another country, who may have access to identical or similar generic drugs under a different brand name.

CODE.10 Proper nouns, synonyms and abbreviations will represent a substantial proportion of textual entries; these must be represented faithfully in their original language.

CODE.11 The model of the FHR and any associated dictionaries must be able to accommodate future evolution in classification systems, and the addition of new terms.

Quantities and numeric data

QUAN.1 The FHR must be able to represent complex numeric values including ratios with differing units.

QUAN.2 The FHR must be able to represent numeric values expressed as percentages.

QUAN.3 Where calculated information is used for clinical decisions the actual result rather than the formula should be stored in the record. If a derived value calculated today is used for a clinical decision, this must not be able to change invisibly through changes made in other parts of the record (e.g. the correction of an erroneous weight).

QUAN.4 The FHR must be able to represent data derived from other data by formulae.

QUAN.5 The FHR must be able to represent units of measurement (including compound units), precision and accuracy.

QUAN.6 The FHR must be able to represent the information defining an instrument or device from which clinical observation readings are obtained.

Reference ranges

REF.1 The FHR must be able to represent a reference range or normal physiological range as defined at the time that a value entered into the record was observed.

Time and other sequences

TIME.1 The record must be able to cope with sequences of similar measurements, as in vital signs monitoring.

TIME.2 The FHR must be able to represent complex (multi-dimensional) ordered organisations of clinical observations, each potentially with distinct recording or contextual properties.

TIME.3 Time may need to be expressed in absolute terms, as a duration or as an expression relative to other times, events, or conditions.

Graphical and multimedia data

MULT.1 Drawings, symbolic diagrams and stylised symbols are often used in health records and communication between clinicians and patients; they must be capable of representation within the FHR.

MULT.2 The FHR must be able to represent a comprehensive range of multimedia data types.

MULT.3 Radiological images, bio-signals, video, sound and other multimedia data must be stored and accessible in a manner that permits the information to be viewed or played to a quality compatible with the individual clinical context.

MULT.4 The FHR must be able to represent any specification for the presentation of image data that is necessary for its faithful rendering.

MULT.5 Charts, tables, drawings and diagrams must be supported and faithfully transferred, as must the ability to incorporate more complex material produced by graphics applications.

MULT.6 The authors of graphical or image entries must be able to add annotations to these, and be able to synchronise their appearance with other parts of the visual material within a time series.

Externally referenced data

EXT.1 The FHR must be able to represent data elements of an 'external reference' type which point to storage elements that are appropriate for containing data of any type not suitable for incorporating directly in the record.

Intra-Record Links

INLK.1 The FHR must be able to represent the many functional and logical links that exist across all data for a patient.

INLK.2 The FHR must be able to represent problem lists, often originating from more than one health care activity.

INLK.3 The FHR must be able to represent the association of one or more components of the FHR (i.e. events) with each change of life cycle status.

INLK.4 It must be possible to modify or to logically remove links.

INLK.5 If part of a record is accessed which has a link to one or more other parts that have not been accessed, the recipient must be able to determine the presence of the link and provided with sufficient information to determine the importance of specifically retrieving those other parts.

Linkage between patient FHRs

Note: this sub-section requires further investigation and has not yet been incorporated within the FHR architecture specification.

EXLK.1 The subject of the FHR will usually be an individual but there will be occasions where the subject is a group (e.g. a family); the FHR must cater for the situation where the subject of an access request is a group rather than an individual.

EXLK.2 Individual patients' FHRs should be linkable to other patients' FHRs; examples of such links include genetic or household links.

EXLK.3 The inclusion of links between any two FHRs requires at least the consent of both subjects of care, and may require the consent of other parties whose information is contained in or referenced from either of the two FHRs.

EXLK.4 If a link exists between two FHRs, the rights of disclosure of either subject of care to the other FHR must be rigorously defined and represented; similar disclosure policies must also exist for the range of parties who have access to each FHR.

EXLK.5 If intra-record links involve more than two FHRs then the access control policies to parts or all of each FHR, including the links themselves, must be consistent, agreed by all subjects of care and independently associated with each FHR.

Support of evidence-based care

EVID.1 The FHR must be able to reference the use of decision support services, knowledge services and of bibliographic databases for patient care.

EVID.2 The FHR must support the derivation of alert and trigger conditions from health record information.

EVID.3 The FHR must support interoperability with terminology services to support the use of coded concepts.

Retrieval and analysis of FHRs

ANLY.1 It must be possible to perform analyses both within an individual patient's record and on a population of patients for epidemiological purposes.

ANLY.2 It must be possible to obtain a chronological overview of the entire FHR for a patient, as well as other views.

ANLY.3 The structure and content of the FHR Archetype Object Dictionary should support requests for a wide range of archetypes (i.e. clinical data sets and record structure hierarchies).

ANLY.4 It must be possible for the computer systems engineers and the end-users at a healthcare enterprise to interrogate their local FHR Archetype Object Dictionary in order to identify the appropriate archetype(s) for any relevant purpose.

ANLY.5 The structure and content of the FHR Archetype Object Dictionary should enable instances of archetypes for a patient to be retrieved from one or more appropriate feeder systems to which the FHR service is connected.

ANLY.6 An FHR Archetype Object Dictionary must enable two or more FHR servers to forward requests and extracts between each other in appropriate circumstances.

ANLY.7 It must be possible to request record extracts with similar properties and content to the structures found in paper records, e.g. discharge summary, nursing chart, medical notes.

ANLY.8 The process of requesting FHR extracts must enable users to search for entries:

- of a particular type;
- authored by a particular responsible person or professional group;
- occurring in a particular department, institution or country;
- recorded at a particular point in time;
- containing a particular term or terms;
- containing particular data types;
- with particular contextual values, such as a lifecycle status.

ANLY.9 Health care professionals should be able to monitor the progress of the actions of care undertaken, in a comprehensive way.

ANLY.10 It must be possible to request information to varying levels of detail.

ANLY.11 It must be possible to define archetypes of requisite granularity to optimise the preservation of clinical context in the record extract.

ANLY.12 The record extract request process should enable users to:

- obtain extracts of records or selectively to browse the FHR itself;
- analyse FHR data for clinical audit, for continuing professional education, and for case-mix or resource management;
- reproduce national and local data sets and incorporate data into standard reports;
- generate summaries of health problems or of episodes of care, which are accessible to other services, applications or databases.

ANLY.13 It must be possible to interface the FHR service with a range of other middleware services and end user applications to support the authorised request and retrieval of record entries.

ANLY.14 Aggregated population data must be clearly identified as being derived from more than one patient.

ANLY.15 It should be possible to create suitably-anonymised databases of federated health records as a teaching resource.

ANLY.16 It should be possible to ascertain which actions, recalls and reviews are pending for a patient, related to care provided by different professionals, and clearly to identify those which apply to the current user and to that institution.

The FHR information models

INFM.1 The FHR Reference Model should be generic and not the standardisation of a particular model of health care.

INFM.2 The constructs in the FHR Reference Model need to be sufficiently flexible to represent, within extracts, the original organisation of health record entries from a diversity of feeder system architectures.

INFM.3 The constructs in the FHR Reference Model and FHR Archetype Object Dictionary need to be sufficiently rigorous to ensure that health data from a diversity of feeder systems can be mapped accurately and consistently within extracts.

INFM.4 The FHR Archetype Object Dictionary must allow for the future evolution of common data sets, message types, clinical practice and the culture of health care.

INFM.5 The FHR Reference Model and FHR Archetype Model must be capable of representation as formal object models, and of implementation within both relational and object-oriented computer systems and in an open-systems environment.

INFM.6 The FHR Reference Model and FHR Archetype Model constructs must avoid implementation-specific features.

INFM.7 Record extracts must be able to have methods as well as data associated with them.

INFM.8 The FHR Reference Model and FHR Archetype Model constructs must be specified in a way that permits consistent implementations to be derived directly from them.

INFM.9 The constructs of the FHR Reference Model must demonstrate the unambiguous mapping of classes and attributes to any applicable European or international EHR architecture standard.

INFM.10 The constructs of the FHR Reference Model should facilitate the adoption of good security policies at implementation sites.

INFM.11 The constructs of the FHR Reference Model should facilitate the easy and accurate mapping from the data representations used in diverse legacy feeder systems.

INFM.12 The classes in the FHR Archetype Model must map rigorously to the classes pertaining to record instances in the FHR Reference Model.

INFM.13 The constructs of the FHR Archetype Object Dictionary must support archetype definitions that can be shared between FHR servers.

INFM.14 Mechanisms must exist whereby a local site can update archetype definitions to provide new or modified feeder system mapping information.

INFM.15 The FHR Archetype Model and Dictionary service must support the representation of data value constraints applicable to record instances.

INFM.16 The FHR Archetype Model and Dictionary service must support the mapping of archetypes to clinical concepts in published terminologies or knowledge ontologies.

INFM.17 The authorship and revision of archetypes must be managed with the same medico-legal rigour as federated health records.

INFM.18 The FHR Reference Model and the FHR Archetype Model must be capable of revision over time without risk of damage or loss to data held or communicated using earlier versions.

Conformance to International Standards

STAN.1 The FHR must allow for compatibility with existing European and international standards (including industry standards) wherever possible and appropriate.

STAN.2 Where possible and appropriate, existing standards must be adopted for:

- the FHR information architecture itself;
- data interchange and medical message exchanges (e.g. EDIFACT, XML);
- open systems and computing environments;
- security and data protection;
- data sets, classification and coding (e.g. drug descriptions);
- data standards and definitions (e.g. laboratory and image standards).

6.6. FHR technical requirements

General Service Requirements

SERV.1 The FHR server should contain the necessary features to facilitate safe exchange of patient records and record components between information sources holding patient information.

SERV.2 The FHR server should be capable of accepting and responding to requests for patient records from end-user applications.

SERV.3 The FHR server should be capable of generating an output to the end-user application corresponding to the original request.

SERV.4 The FHR server should be capable of managing requests from more than one client application.

SERV.5 The FHR server and server-side applications must be capable of receiving and responding to end user client applications from a diversity of locations and physical devices, via any appropriate communications connection.

SERV.6 The FHR server should make information accessible to end user applications in a safe and secure way.

The Availability of the FHR

AVAL.1 The FHR services must be capable of being implemented in such a way that the federation process is completely transparent to the end-user.

AVAL.2 Health records must be available at all times at any appropriate points of care; this will increasingly include a requirement for wireless access.

AVAL.3 The FHR service must be able to provide end-users with the most accurate and complete data available in response to their request.

AVAL.4 The FHR server should aim for 100% availability.

AVAL.5 Appropriate backup facilities must exist to enable continued access health records when the FHR service is "down" or fails.

AVAL.6 If parts of the record are lost, damaged or unavailable (for any reason) this fact must be made apparent to the end-user.

Performance

PERF.1 The time required to retrieve the components of an individual patient's FHR should be appropriate to the time available for the clinical encounter (e.g. less than one second).

PERF.2 The FHR service must support the basic information-processing activities required by healthcare professionals at least as well and as quickly as the current paper and computerised record systems.

PERF.3 The FHR service must be able to restore any required EHR data from backup within a time appropriate to the clinical context.

Concurrent use

CONC.1 The FHR service must allow multiple users to have concurrent access to the same patient record at different locations.

CONC.2 Only one person at the time must be allowed to change a specific piece of information in a given record.

CONC.3 Any changes to a patient record must update the original EHR source and update other users' views of it within the record federation immediately.

Version control

VERS.1 The FHR must minimise the possibility of retrieving contradictory or inaccurate health information because of the inadequate version control of amendments to entries (on a feeder, between two feeders, or through the FHR service itself).

VERS.2 Updates and corrections to any existing entries must be offered to any Third Party healthcare enterprises that have a copy of the original entries.

Persistence services within the FHR

PERS.1 If data are persisted by the FHR service, the architecture of that repository must enable its contents to be requested and extracted in conformance with the FHR Reference Model and its local Archetype Object Dictionary.

PERS.2 If identical data are held both by the FHR persistence service and other existing feeder systems, a rigorous version control mechanism must be in place to ensure that future requests are returned the most up-to-date record entries.

PERS.3 Data stored by the FHR service must never be deleted unless the data are known to be stored elsewhere within the record federation or are known to have been retained in their original form by the site that created it.

General interface requirements

INTF.1 Mechanisms must exist whereby an authorised user can modify, in a safe, secure and friendly manner, the archetype definitions, patient indices, end-user authorities and access-control frameworks held by the EHR server.

INTF.2 The FHR server interfaces should allow the 'registration' of feeder systems to be managed.

INTF.3 The FHR server interfaces should support connection between multiple applications and the server.

INTF.4 The FHR server interfaces should allow the 'registration' of end-user applications to be managed.

INTF.5 The FHR server must be able to manage patient identifiers, allowing for these to change over time.

Exceptions and Errors

ERR.1 The FHR server should be capable of detecting data conflicts or errors and notify the end-user application and administrator.

General server procurement requirements

PROC.1 The FHR service components must:

- be easy to configure for local use at a site and to integrate with existing information systems;
- be provided with a comprehensive educational programme for technical users and health service end-users;
- be configured, installed and maintained within an institution in accordance with a formal procurement process and a formally-costed project plan;
- be evaluated formally from safety, quality and cost-effectiveness perspectives;
- comply with relevant CEN standards to ensure maximum interoperability with other commercial and research products utilising the standards.

6.7. FHR educational requirements

EDU.1 Computerised records should support developments in medical education, in particular self-directed learning and problem based learning.

EDU.2 Computerised medical records should be accessible to students at an early stage in their medical education. The user interface should be designed so as to make it easy for the inexperienced user to find his/her way around the system.

EDU.3 Students should be able to identify patients they have followed during their training.

EDU.4 Adequate safeguards need to be established to ensure privacy, confidentiality, and data protection. For instance, there may need to be methods of stripping records of personal identifiers.

EDU.5 The relationship between data quality and patient care should be apparent so as to encourage students to take responsibility for patient data.

EDU.6 The FHR must interoperate with decision support tools, educational software and bibliographic databases.

6.8. FHR managerial requirements

MAN.1 Computerised healthcare information systems must be able to:

- support individual patients in choosing their treatment, the self-management of their condition and the assessment of the outcome;
- underpin good communication between clinical staff and patients;
- improve clinical outcomes through improved patient access to healthcare information;
- help meet patients' expectations of confidentiality, integrity and continuity of care across providers.

6.9. Representing Contextual Information

The work on the requirements for representing health record information has drawn attention to the essential nature of contextual information captured alongside the individual clinical entries at the time of recording. Although several research projects and standards have each developed their own EHR information architectures, they share the objective of formalising a set of contexts that may be associated with any health record entry. (A health record entry is considered here to be a quantum of information that is entered into a record, usually constituting a single fact, observation or statement.)

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 EHR 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 FHR, while a few are more applicable to a medical knowledge service interfacing with a population of patient records.

These contexts can perhaps best be illustrated by an example: the entry in a health record of a diagnosis of supra-ventricular tachycardia (SVT). This entry could be associated with several kinds of context within an EHR, illustrated in Figure 38 below.

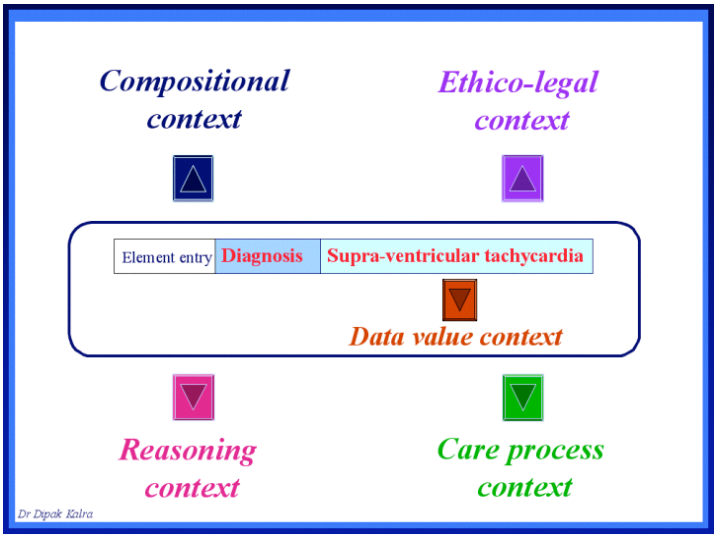


Figure 38: The kinds of context associated with a health record entry

In the absence of these sets of contextual information the reader of this health record entry could not tell if this is a new diagnosis or a longstanding problem, nor the certainty with which it has been made. He or she could not be sure even if this diagnosis had been made on the patient or on a relative, recorded as part of a family history.

Compositional context

This context refers to the way in which the diagnostic entry of SVT relates to other information entered along with that finding (the history and examination findings), and the higher level of those entries within the health record of that patient.

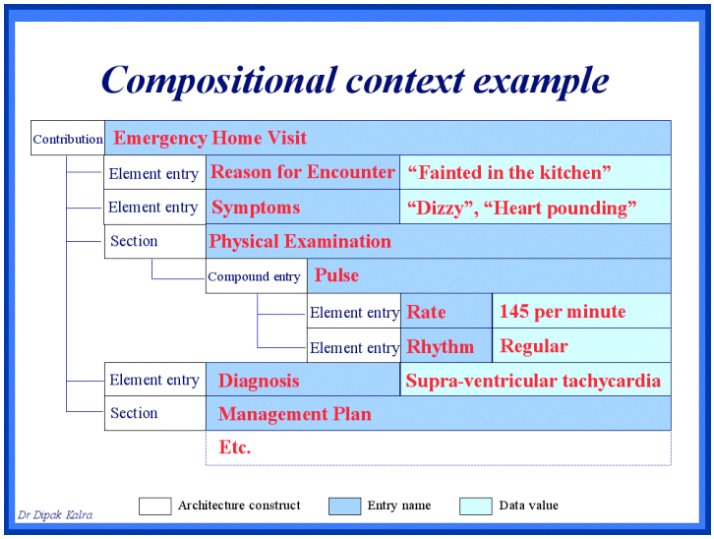


Figure 39: Illustration of the compositional context

From the information in Figure 39 the reader can infer that the consultation has taken place in fairly rushed circumstances, with the patient possibly quite distressed about having fainted. The diagnosis has been made without the benefit of an ECG, but perhaps on reasonable clinical grounds. It would appear to be a brand new diagnosis for this patient. By naming the entry *Diagnosis* the reader is able to ascertain that this is a condition that has now been ascribed to the patient by the author; were it an entry of one or more named *Differential diagnoses* a different inference would be made. There are several facets to this context.

- Every record entry must be able to have a name that provides a label for each data value.
- Record entries can be:
  - an element e.g. for Weight;
  - or a compound e.g. for Blood Pressure.
- A formal record structure hierarchy must preserve the way in which entries were originally ordered and grouped by the author.
- The record architecture must define the minimum medico-legally acceptable cohort of data from which FHRs must be constructed.

Data value context

This context refers to the fine details associated with the chosen value itself. In this case, a term has been chosen from the Read code term set that is commonly used within GP systems in the UK.

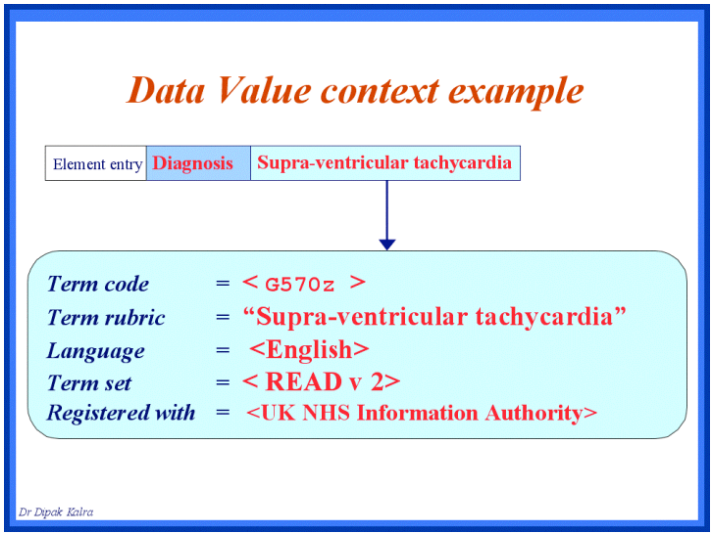


Figure 40: Illustration of the data value context

The EHR clearly needs to be able faithfully to represent a comprehensive range of data types, including:

- text, quantities, time, persons, multi-media;
- names of term sets, versions and registering agencies;

- natural language used in a recording;
- accuracy, precision and units for quantities;
- normal ranges.

Ethico-legal context

The requirements listed in Section 6.4 stress the importance of documenting, for example, the authorship and dates and times associated with each entry.

Figure 41: Illustration of the ethico-legal context

In this example the reader can determine that this entry is a revision of an original version, implying that an error of recording had been made that has now been corrected. (Access to that original version might be more restricted than to the current version). This context may include:

- identifying authorship, authorising agents and those with legal responsibility for the documented health care;
- identifying the subject of care, and the subject of the information within each entry;
- dates and times of record authorship, care delivery and of the events being recorded;
- version control;
- access rights, amendment rights.

Reasoning context

This context refers to information that might be associated with the entry to explain how or why it applies to the patient in this particular instance.

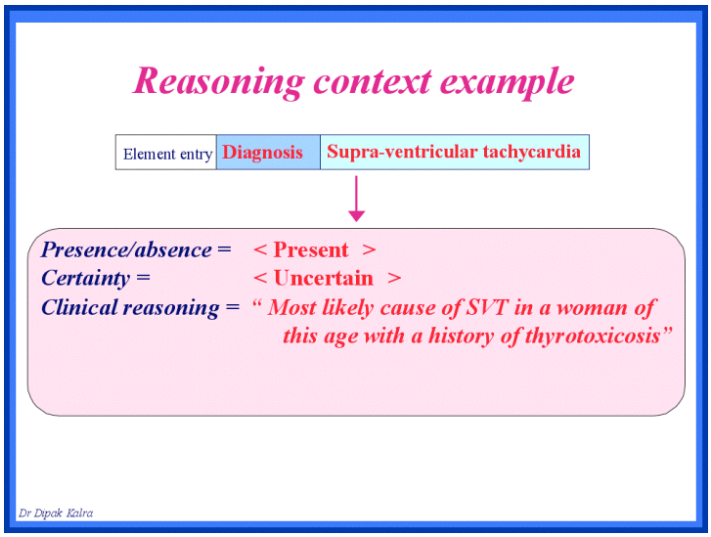


Figure 42: Illustration of the reasoning context

In this case, the reader can see that the author has acknowledged uncertainty in the diagnosis, but has also provided some explanation of the clinical reasoning. In the future it may become commonplace for such reasoning to refer explicitly to an external source of medical knowledge, as illustrated in Figure 43.

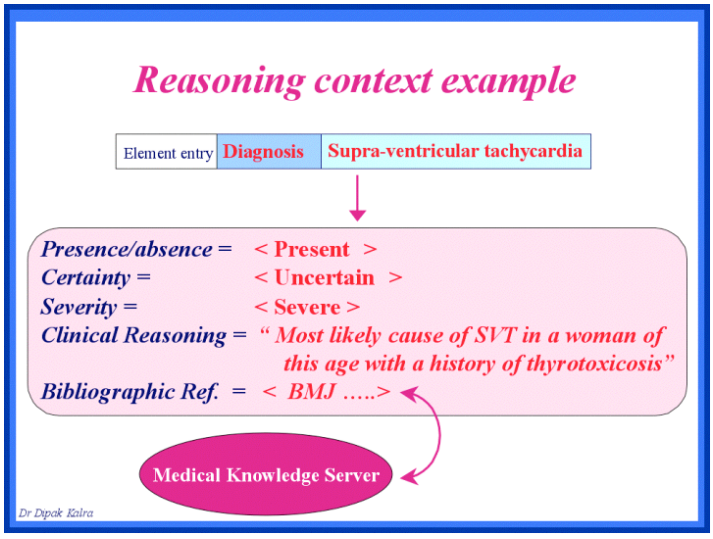


Figure 43: Illustration of a context link to a Medline reference

The author is aware only of a few pioneering centres where such linkage is presently implemented within clinical systems. The reasoning context might include:

- presence / absence;
- certainty;
- prevailing clinical circumstances (e.g. standing, fasting);
- supplementary comments made by the author;
- emphasis of exceptional or abnormal observations;

- justification or clinical reasoning;
- knowledge reference (e.g. Medline).

Care process context

Clinical entries are rarely isolated in the longitudinal evolution of health problems and of care delivery. This context relates to the sets of links and pointers that help to represent the non-chronological organisation of health records.

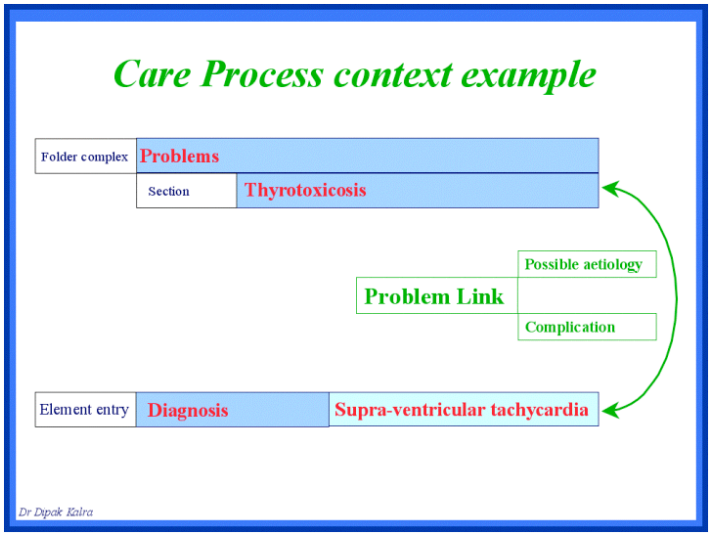


Figure 44: Illustration of the care process context

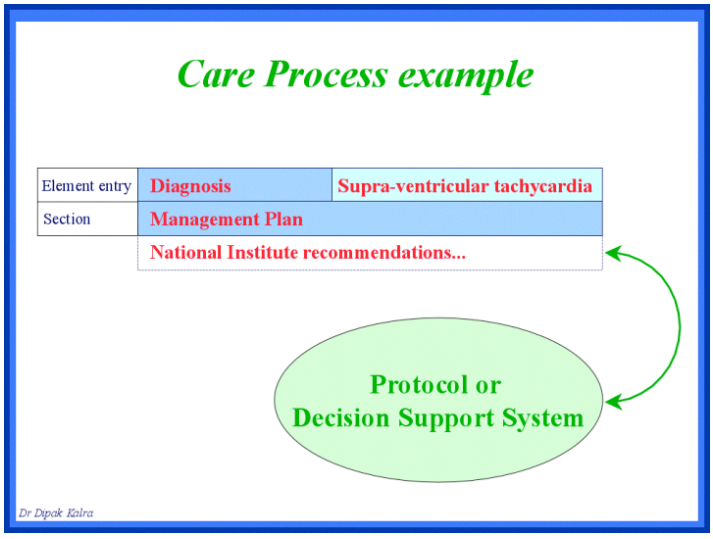


Figure 45: Illustration of a context link to a protocol

The potential links and pointers to other parts of the record that might need to be represented in a health record include:

- 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.

These sets of contexts all need to be mapped to classes and attributes within the FHR architecture.

6.10. Interaction Diagrams

The following Use Case scenarios summarise the likely principal interactions between end-users of clinical applications and a Federated Health Record server, for example as deployed at the London demonstrator site (see Section 11.4). Each case is described in general terms, since the actual users in any enterprise setting may vary. A set of more specific example users and interactions is given in Section 6.10.2.

6.10.1. Use Case Diagrams

A federated health record service is regarded here as a being accessed through a generic EHR system. Users may wish to request certain classes of clinical data and to view those that exist in the FHR of a given patient. They might wish to modify existing entries or to add new health care entries. Some users will be authorised to register new users or patients. Certain kinds of authorised expert user may wish to make changes to the clinical data sets that are defined within their FHR setting, or to "sign up" new feeder systems to the federation by indicating the mapping of data set elements to tables and fields in the feeder system. Each such Use Case is outlined below; these have informed the overall definition of the UCL FHR service.

Request/response

An end user for this scenario may typically be a doctor or a nurse providing care to a patient, or a medical secretary generating out-patient clinic letters or discharge summaries. A further class of users is hospital management staff, who will wish to review individual patient record information for financial (e.g. billing) purposes, or aggregate data for clinical audit or quality assurance purposes. An additional special case of this scenario is when patients wish to view their own health record, which must be permitted through their own levels of access rights.

End-users will typically wish to:

a) log in to their computer workstation, and thereby declare their appropriate level of authorisation to EHR services;

b) select a patient by providing identification information (such as their surname and first names) and receive confirmation of the patient by seeing a fuller demographic data set;

c) review the contents of the patient's healthcare record through a series of drill-down and drill-up requests for record entries.

NOTE: In each of the use case diagrams (a) to (c) the user Healthcare Professional could be replaced by a Healthcare Manager or a Patient.

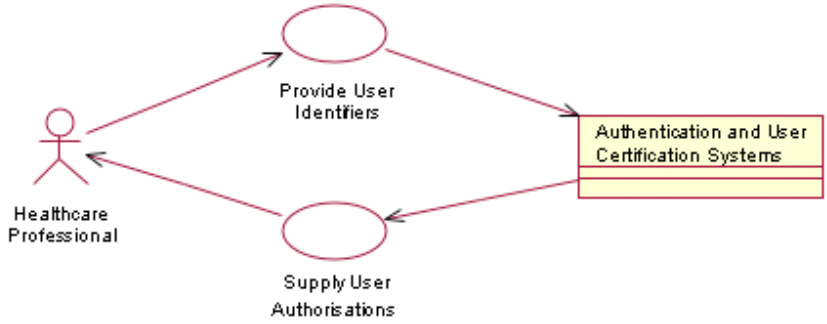


Figure 46: Request and response Use Case

(a) logging in to the EHR server

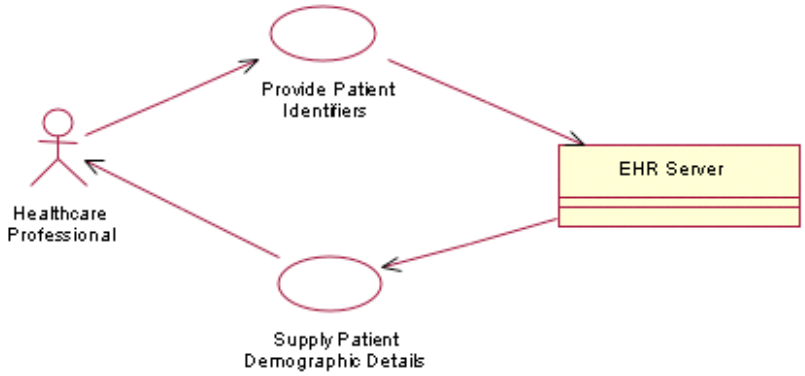


Figure 47: Request and response Use Case

(b) identifying a particular patient

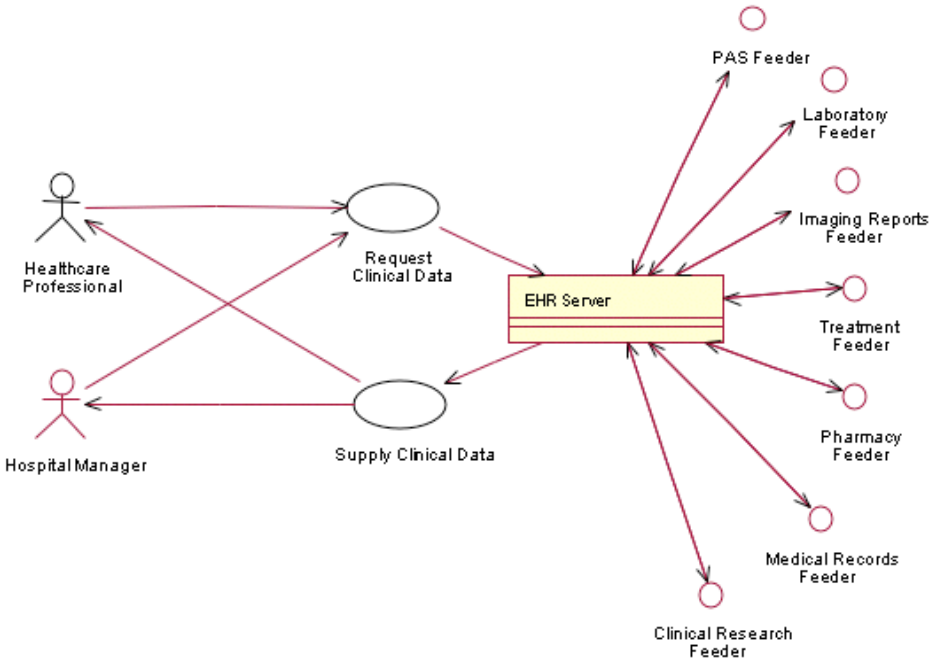


Figure 48: Request and response Use case

(c) requesting and retrieving parts of a patient's record

Add or amend record entries

Although the main purpose of the UCL FHR service is to provide access to pre-existing distributed and heterogeneous health record information, it is recognised that there may at times be a capability for the FHR to receive new data from end users (through clinical applications) and for this to be stored within a dedicated FHR cache or occasionally updating a feeder system. This Use Case caters for this situation, in which a user might provide health record entries that are either new entries or revised versions of existing entries.

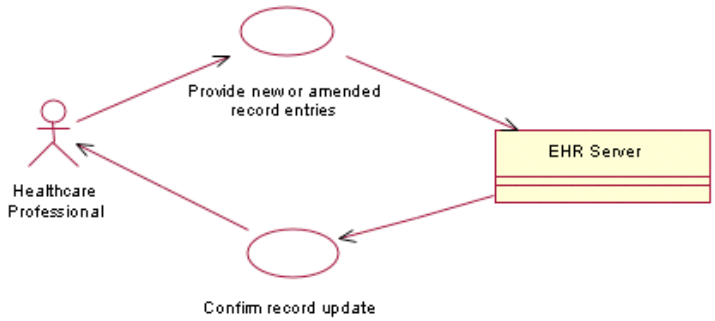


Figure 49: Add or amend record entry Use Case

User Registration

Given the broad range of feeder sub-systems that will be accessible through an EHR federation, the process of user registration will need to be carefully managed. The process of defining named end-

users and of associating them with a default set of authorisations may for example be handled by a hospital's computing department or personnel department.

NOTE: In the diagram below the Healthcare Professional could be replaced by a Departmental Administrator or Personnel Officer.

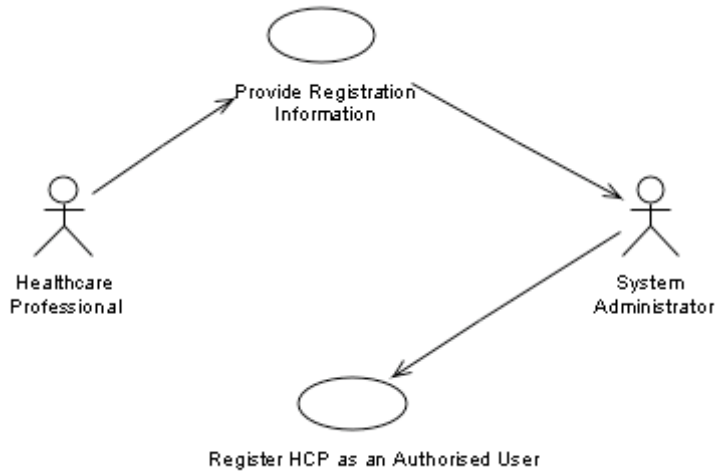


Figure 50: User registration

Patient Registration

Each patient whose records are contributing to the EHR federation at any healthcare enterprise will need to be uniquely and unambiguously identifiable by the EHR server. A mechanism is required for this, although it may initially draw on existing patient master index systems, in order to allow the federation to incorporate multiple sites.

NOTE: In different settings a wide range of different end-users may be involved in the process of patient registration. The diagram below is therefore an example case.

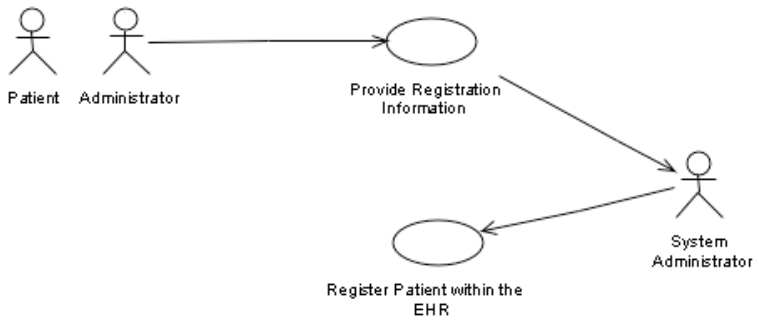


Figure 51: Patient registration

Browse or Modify Clinical Data Sets

End users may wish to review the formally defined data sets and other clinical aggregates that have been established for their use to create or review patient records. Within acceptable limits, they may wish to modify these or to create new entries in such dictionaries. This will be particularly true for views or queries to be generated for individual or sub-populations of patients. Very occasionally it may be appropriate to declare a clinical data set definition obsolete, or to delete its entry. It will be necessary to define specific end-users with an authorisation to perform these activities, for example within a hospital's computing department.

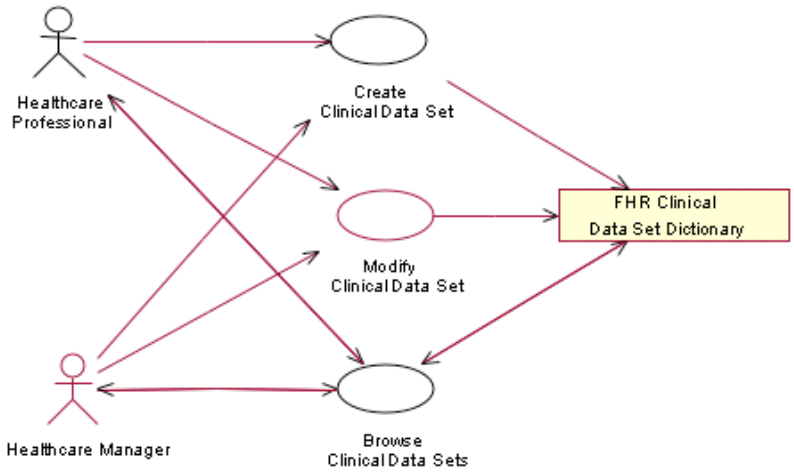


Figure 52: Browse, modify or delete clinical data sets

Sign-up Feeder Systems

Each feeder system or sub-system will need to be signed-up to the record federation. In particular, the data sets and other record information that are held on each feeder would need to be represented as clinical object definitions. The process of sign-up may include the matching of end-user authorisations and of patient identifiers.

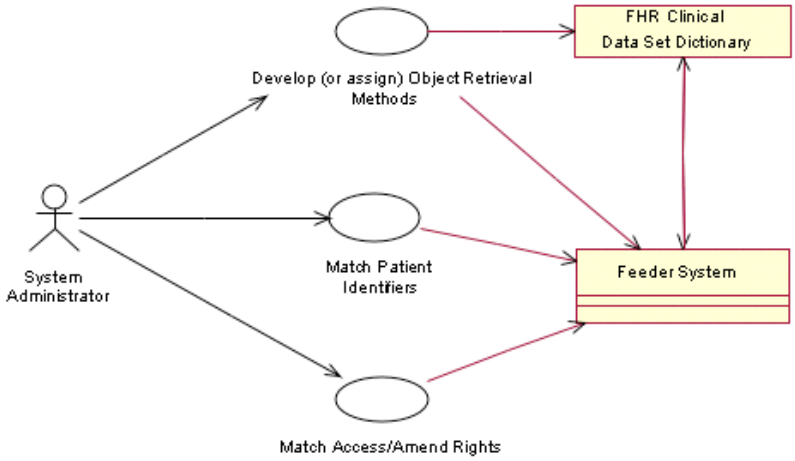


Figure 53: Sign-up feeder systems

6.10.2. End Users and Their Activities

The above Use Cases have described potential users and their interactions with an FHR service in very generic terms. To provide some more tangible examples of likely users of the FHR service, Table 7 lists some end users, their locations, and the kinds of activities they might need to perform through the FHR. The Whittington Hospital Department of Cardiovascular Medicine and the author's former general practice were used as the sources for gathering these examples.

End User	Locations	Activities
Health Care Professional: e.g. Doctor Nurse Medical Secretary	Hospital clinic or ward, including intensive care units; GP surgery or health centre; Patient's home; In their car or at roadside	Review patient records, including: out-patient clinic consultations, medical history taking, clinical examinations, laboratory test requests & results, radiology requests & results, biosignal requests & results, angiography records & diagrams, operation notes, anaesthetic records, nursing observations, dietary history, education by specialist nurses, outpatient clinic letters, discharge summaries. Revise data sets and templates for research or clinical care purposes. Audit the clinical care of patients or groups of patients.
Patient	Home, office, in transit	Review personal record, annotate personal record
Administrator	Hospital office or GP surgery office	Register new patients, amend patient registration details. Arrange admissions, clinic appointments.
Personnel Officer	Hospital office or GP surgery office	Register new clinical staff, amend staff details.
Hospital Manager	Hospital office or GP surgery office	Analyse the overall management, costs and clinical care of patients or groups of patients.
Computing Department Information Scientist	Hospital IT department, clinic or ward; GP Surgery	Register new clinical staff, amend staff details. Register new patients, amend patient registration details. Revise data sets and templates for research or clinical care purposes. Analyse the overall management, costs and clinical care of patients or groups of patients.

Table 7: Examples of end users and their potential interactions with an FHR service

Chapter 7. The Information Architecture of the FHR

This chapter describes the federation mechanism for the integration of heterogeneous clinical databases, and the approach taken to define a reference model for the federation schema. The concept of federation is outlined in Section 7.1, and the principal published information models for representing the EHR that served as input to the FHR Reference Model are summarised in Section 7.2. The detailed reference model proposed and used as the basis for the implementation and demonstration is described in Section 7.4. The complementary model for specifying the metadata associated with any specific federation environment is dealt with in Chapter 8. An approach for representing access control is described in Chapter 9. These three chapters together constitute the ODP Information Viewpoint specification of the UCL FHR service.

7.1. The Federation approach

The federation approach adopted by the author and colleagues was initially developed during the Synapses project (1996-8, summarised in Section 5.2.3). In a database federation a desired set of classes of information are created by combining the available information from a network of individual database systems (Grimson and Bell 1992). The individual contributing systems, known as feeder systems, retain their autonomy by continuing to be accessed locally through their own applications and by electing which parts of their local database are to be accessed by the federation as a whole. In a healthcare setting this might be realised as a hospital federating a set of departmental clinical databases or as a regional healthcare network federating the set of hospital, GP and community systems within its geographical area. A national health care network might practically be delivered as a super-federation of such regional federated health records.

Individual requests for information coming from an authorised end user application or other system component to the federation service are brokered across the federation. This relies upon knowledge stored centrally of which classes of information are held on each feeder system; this metadata dictionary is described in Chapter 8.

The federation can exist either as a logical integration, with the information required to meet a request extracted from the relevant feeder systems on demand, or using a physical store to cache in advance the desired common data from all participating feeder systems. In practice it is likely that any federation will employ a mixture of these to suit local requirements, taking into account the characteristics of the various feeder systems. There are strengths and weaknesses associated with each approach: live federation places considerable demands upon network and server performance and requires the constant and reliable availability of all participating feeder systems; a caching

mechanism places a reliance upon potentially large repositories and upon regular version checking to ensure that updates to each feeder system are forwarded to the cache repository in real time to avoid the risk of a requesting client receiving out of date or incorrect information.

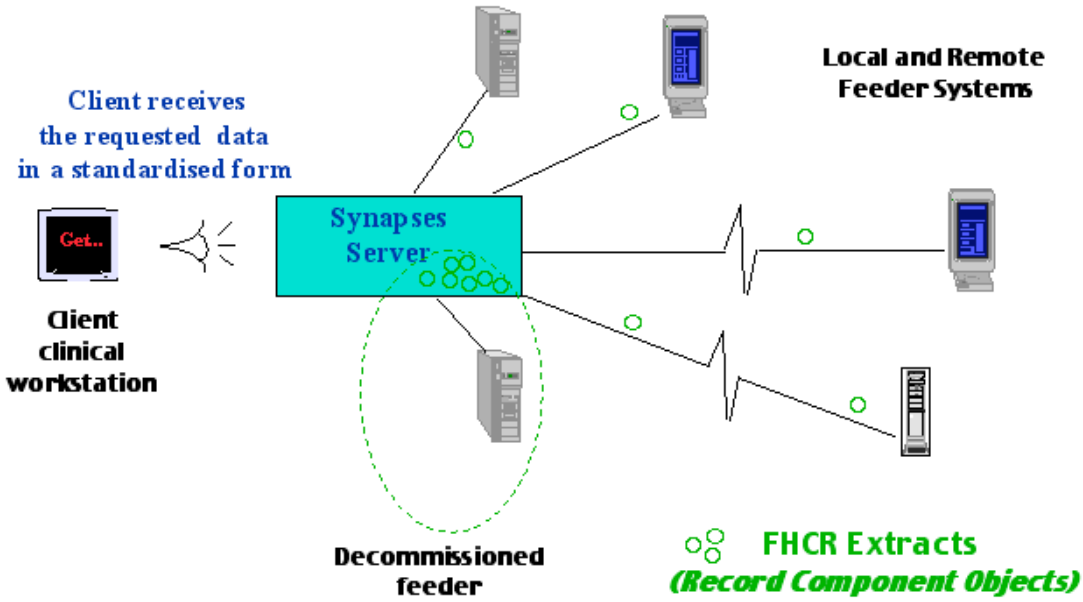


Figure 54: Distributed access to record components within a Synapses federation

The approach taken in Synapses was to regard each feeder system as a data provider, and not to attempt to develop a means by which feeder system databases can be remotely updated with new information from the federation. Each feeder system would therefore only be updated through its own local applications. This can be described as a read-only federation, and was piloted in healthcare prior to Synapses in the Jupiter project (Grimson and Murphy 1995). Updating feeder systems remotely is recognised in computer science to be a complex challenge and highly dependent upon the availability of update interfaces offered by each feeder system application; in practice these rarely exist in legacy applications and ought ideally to be developed only by the original vendors of those applications to ensure that the internal integrity of their databases is preserved.

A key component in developing a database federation is specifying the federation schema: the unifying information model to which the diverse feeder system schemata are mapped. This requires a single mapping exercise to be performed for each feeder system, and avoids the alternative combinatorial explosion of mappings that are required were each feeder to develop a direct communication to all other relevant feeders. However, it requires that the federation schema is

sufficiently generic and rich to represent faithfully the underlying information that could be extracted from any possible contributing feeder system.

The challenge in a health care context is to develop an information model for the federation service that can represent any conceivable health record entry or a partial or complete EHR that might be contributed by any clinical database or EHR feeder system, now or in the future. This challenge has strong parallels with the research work to develop a generic EHR information model, and that work was therefore used as the basis for defining the federation schema in Synapses and later by the author in defining the UCL FHR Reference Model.

The following section summarises the major published EHR or FHR information models that provided input to the author in defining the FHR Reference Model documented in Section 7.4. The author has significantly contributed to those published models, which can be regarded as an evolution in thinking leading up to the model that was adopted for the implementation.

7.2. Published generic EHR architectures

The strength of the approach taken in Europe on the EHR architecture (spanning GEHR, EHCR-SupA, Synapses, SynEx and complementary standards from CEN) has been the development of a rigorous generic representation suitable for all kinds of entries, and the requirement for all labelling information to be an integral part of each construct. Provided that the core architecture is common to both a sending and a receiving information system, any health record extract will contain all of the structure and names required for it to be interpreted faithfully on receipt even if its organisation and clinical content have not been "agreed" in advance.

7.2.1. GEHR architecture

The GEHR representation of the EHCR treats all information in a given EHCR as implicitly relating to the care of one person, the patient, even if it describes another person such as a family member. Within each patient record, the GEHR architecture preserves both the original structure of the data and how the entries in the record are grouped (Lloyd, Kalra et al. 1995). Every effort was made to propose an architecture that is as generic, flexible and non-prescriptive as possible. However, where clinicians identified the need to be prescriptive (e.g. in situations where medico-legal security must be maintained) the architecture incorporates features that may be utilised for this purpose. The main constructs of the GEHR architecture are summarised in Table 8.

EHCR provides the container for all data about a particular patient
Transaction provides most of the features needed for the medico-legal aspects of healthcare data provides the mechanism for the control of amendments represents the smallest amount of data which can safely be transferred between EHCR systems
Health Record Item (HRI) provides the structure for recording the content values of EHCR entries
HRI Collection provides for aggregation of HRIs and other HRI Collections provides the means of changing the scope (data subject) of the data
Heading provides annotation for groups of HRIs/Collections

Table 8: Principal GEHR architectural components

Each of these constructs is further elaborated using attributes that address aspects of identification, content and context.

GEHR proposed that there should be a clear boundary to entries in an electronic healthcare record. This is formalised through the concept of a Transaction. The Transaction will commonly be recognised as a patient contact or a consultation, but may at times reflect an interaction with the record when the patient is not present, such as filing a test result or a letter. Each Transaction is authored by a clinician who accepts responsibility for the accuracy of the information added to it, encapsulating the cohort of information that has been entered through one 'interactive session' with the record of one patient. GEHR proposed that an electronic healthcare record should comprise only a set of such Transactions. For medico-legal reasons it must also be possible to determine the date and time at which Transactions have been added to an EHCR, whether created at that institution or received from another EHCR source.

- the healthcare record is composed of a set of transactions
  - a single logical record of care
- only whole transactions are transferred when information is shared
  - remote access and merging of records
- transactions are subject to a formal version control process
  - amendment of transactions

Figure 55: Features of the GEHR Transaction class

The fundamental GEHR architectural constructs Health Record Item (HRI) and the HRI Collection allow for the documentation of any chosen hierarchical arrangement of fine grained clinical concepts, and can accommodate any textual, quantity, coded or multi-media data type. The Item construct was originally developed and implemented in the late 1980's by Maskens A. in his clinical record system HEALTH.one, which has been used in primary and secondary care sites in several European countries (Maskens 1992). HEALTH.one was adapted during the GEHR project to provide an early prototype for many of the proposed architectural features.

- a construct for the representation of a health record entry
  - "a meaningful quantity of information when considered alone" [CEN: TC/251 PT 1-011]
- composed of identification, content, and context attributes
  - IDENTIFICATION: eg. item name = symptom
  - CONTENT: eg. value = pain in epigastrium
  - CONTEXT: eg. recorded by = Dr R Dixon

Figure 56: Features of the GEHR Health Record Item class

- term, quantity, free text or multi-media object
  - will often draw from registered term sets eg. ICD-10, ICPC
  - will accommodate multi-media objects in standard formats eg. DICOM

Figure 57: Features of the GEHR Health Record Item Content class

The GEHR Heading provided an additional construct for the logical grouping of HRIs and HRI Collections into higher-level hierarchical sections within a Transaction.

The GEHR project developed two formal definitions in support of the architecture: the GEHR Object Model and the GEHR Exchange Format. The Exchange Format was been published in Abstract Syntax Notation (ASN.1) as this was then considered to be a suitable and rigorous engineering formalism. To support the development of healthcare record systems incorporating the GEHR architecture, the project produced a term set of 2,000 HRI names available in 9 European languages, and a comprehensive set of 47 anatomical drawings. The architecture, term sets and drawings have all been placed in the public domain (Lloyd, Kalra et al. 1998). Several prototype

healthcare record applications were developed within the GEHR consortium, some of which are now commercial systems in clinical use.

7.2.2. ENV 12265

The 1995 CEN pre-standard ENV 12265 (Electronic Healthcare Record Architecture, (Hurlen 1995)) proposed two "information elements".

Record Item is "*the smallest unit of information that remains meaningful as an entry in the record*", for example one or more numbers, tables, text strings, images (including film), or recorded sound. Each Record Item has several attributes including a Record Item Name.

Record item complex to represent how the information elements are organised, applicable both to the information elements already recorded and to potential future additions.

Along with GEHR, the pre-standard regarded the structural organisation of entries as part of the record, not as part of a record system. This allows a record system to contain records with very different structures, and is a prerequisite for being able to receive records from other systems with previously unknown structures.

Often, data are logically present in more than one part of a record. The architecture allows this to be described through defining two types of Record Item Complexes: Original and View. The Original Record Item Complex represents the original information context for a Record Item. The View Record Item Complex represents other use of this information in the record. Figure 58 was provided by Hurlen P. to the author during the Synapses Project.

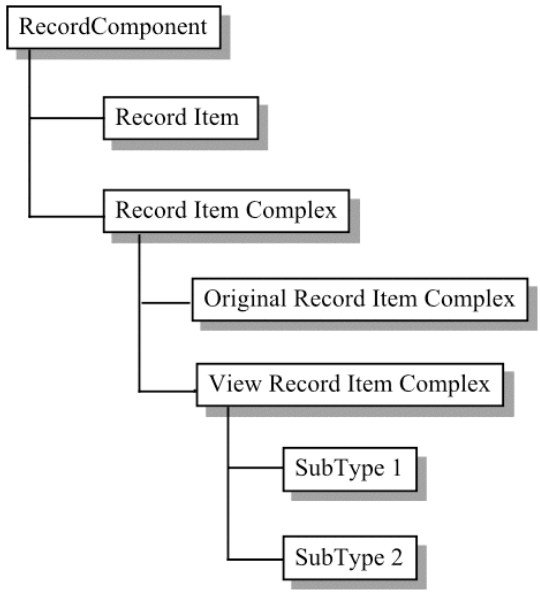


Figure 58: The concept hierarchy of PrENV 12265

7.2.3. The Synapses SynOM

The Synapses approach to distributed health records applied the methodology of database federation to develop a standard and comprehensive schema, the Federated Healthcare Record (FHCR) information architecture, mediated and managed through a set of middleware services (Grimson et al. 1996), (Grimson and Groth 1996).

The federation approach requires two information formalisms to be specified (Kalra 1997):

1 a federation schema that defines the abstract generic model of all FHCR extracts; in Synapses this was called the SynOM;
2 a metadata Object Dictionary that defines the hierarchy of named entries, headings and folders, and the data types of the leaf nodes in each hierarchy, which comprise the domain clinical information held within any specific deployment of the Synapses server; in Synapses this dictionary was called the SynOD.

The SynOM defines a set of base (foundation) classes by which the FHCR is modelled and to which feeder system database schemata must be mapped. The SynOM was developed using the then newly published EHCR architecture standard ENV 12265. Drawing on the richer and more formal GEHR architecture, the basic ENV Record Item and Record Item Complex classes were extended into several specialised sub-classes with specific structural roles within the FHCR.

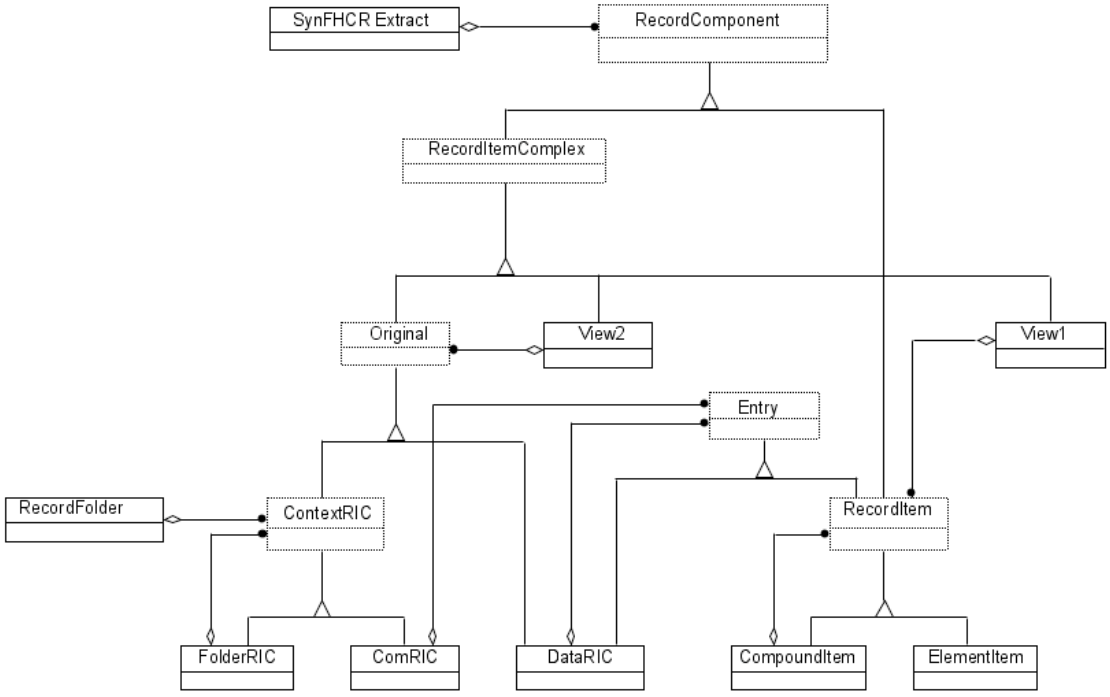


Figure 59: Class inheritance and aggregation within the SynOM

The SynOM has several features to facilitate the rigorous preservation of the original meaning of a record entry as clinical concepts within a structured record:

- every Record Item has a Name attribute which provides a label for each content value
- a formal Record Item Complex (RIC) hierarchy preserves the way in which Record Items were originally ordered and grouped by the author
- the Data RIC provides a mechanism for grouping Record Items under headings
- the Com RIC defines the minimum medico-legally acceptable cohort of data which may be transferred between sites

The final version of the Synapses SynOM (Kalra 1998) provided the starting point from which the author began the development of the FHR Reference Model described in Section 7.4 below. It is therefore not described in more detail here.

7.2.4. EHCR Support Action

Overlapping with the later part of Synapses, the EHCR-SupA project sought to integrate the EHR information modelling work of GEHR and Synapses with additional experience that had been gained within Europe by a diverse range of complementary research projects and national EHR pilots.

An important project deliverable was set of recommendations to CEN for the revision of ENV 12265 (Dixon, Grubb et al. 1998), using inputs from the final GEHR architecture and other EHR research across Europe. Although this architecture differed from the then contemporary work of Synapses, a strong tie between these projects was maintained by the author and the EHCR-SupA co-ordinator, who is a member of the same UCL team. For example, Synapses agreed to adopt the data value class system as the equivalent part of the SynOM. A cross mapping of these two models was also maintained by the team to ensure consistency and to permit possible future interoperability. The EHCR SupA model provided the second major input to the design of the FHR Reference Model described in Section 7.4.

7.2.5. ENV 13606

In late 1997 Project Team 26 of CEN/TC 251 was appointed to revise the EHCR Architecture pre-standard ENV 12265. This project team was responsible for developing Part 1 of the four part-standard ENV 13606 (Kay and Marley 1999), summarised in Section 5.5.1. The team considered a range of available inputs and publications: the major work on EHR architectures at the time came from Synapses and EHCR-SupA. These projects drafted specific material for the project team (for example, (Dixon, Grubb et al. 1998)) and provided early access to advanced drafts of forthcoming deliverables. The overall architecture of ENV 13606 Part 1 is largely derived from a synthesis of

these two inputs, moderated and adapted by the Project Team and in response to feedback from other parties.

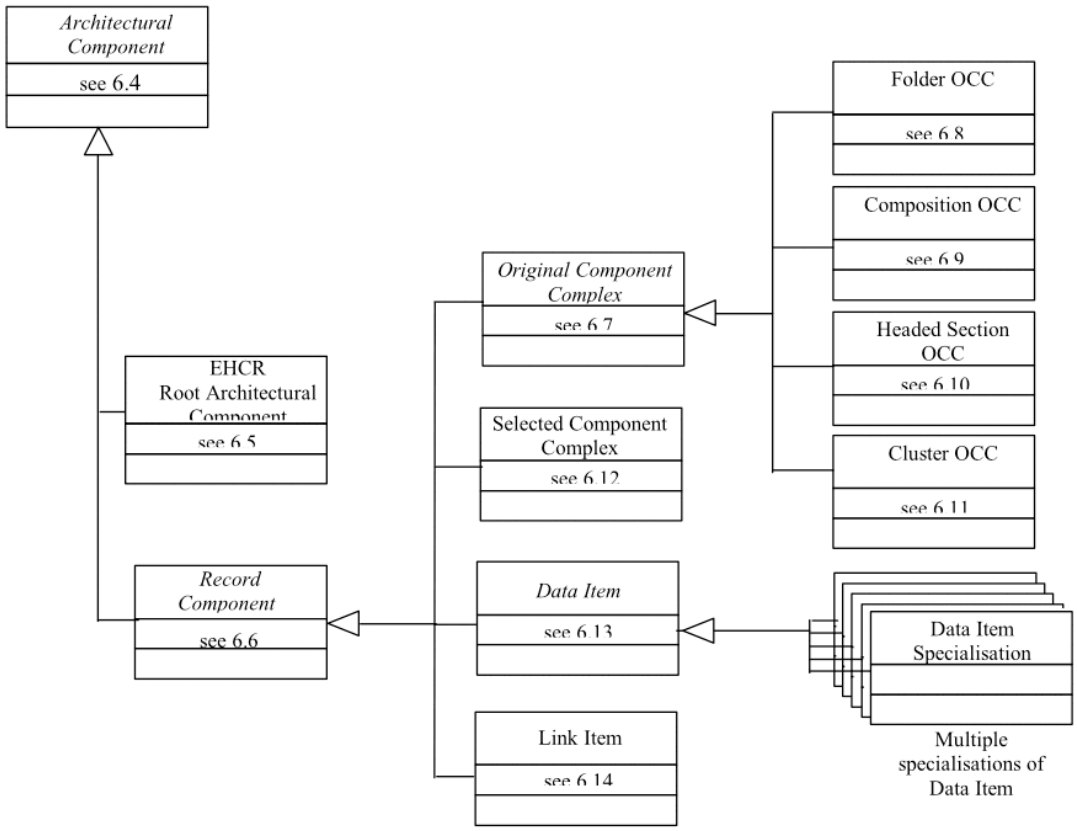


Figure 60: High-level class structure of the ENV 13606 EHCR architecture

The high-level class structure shown in Figure 60 above resembles closely the equivalent presented in Section 7.4 below. The various working drafts and final version of this standard were published during 1998-9, and were reviewed in detail by the author, partly to provide comments back to PT26 and partly to compare the new standard with the author's own FHR Reference Model. These models are compared in Section 12.3.1.

7.3. The Federated Health Record Architecture

In building on the Synapses work, the challenge addressed in the design of the UCL 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. This challenge can best be addressed through a pair of interrelated information models rather than through a single model, mirroring the duality of the Synapses SynOM and SynOD.

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, the Synapses SynOM and to the information model of PrENV 13606-1. 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, and is explained in Chapter 8.

These two information models are described below in Sections 7.4 and 8.2 respectively.

7.4. FHR Reference Model

The Federated Health Record Reference Model (FHR-RM) defines a set of classes and attributes that represent the clinical context and medico-legal status of health record entries as a hierarchical set of Record Components.

The Reference Model described below is the result of a close interaction between the author and a small implementation team working to develop the prototype federated health record server. The main benefit of such iterative development has been the simplification of an otherwise rather complicated model to produce an end result with minimal compromises and satisfactory performance. The model presented below has fewer classes than GEHR or ENV 13606, and almost no compound attributes. The data value classes have little internal hierarchical composition to facilitate the ability to search for record entries of specific values or ranges of values. Inevitably in such iteration it is difficult to avoid some computational perspectives influencing the information model, although every effort has been made to keep the model independent of the computational approach used. Where specific Java features have been exploited these are described in notes below each class or attribute table.

The FHR-RM is drawn below showing its class inheritance hierarchy (in red), and its aggregation (containment) hierarchy. The class diagrams in this chapter have been drawn by Lloyd, D., a member of the UCL research team, using the UML notation. The attributes have been omitted from the overall diagram below, and are defined later in this section.

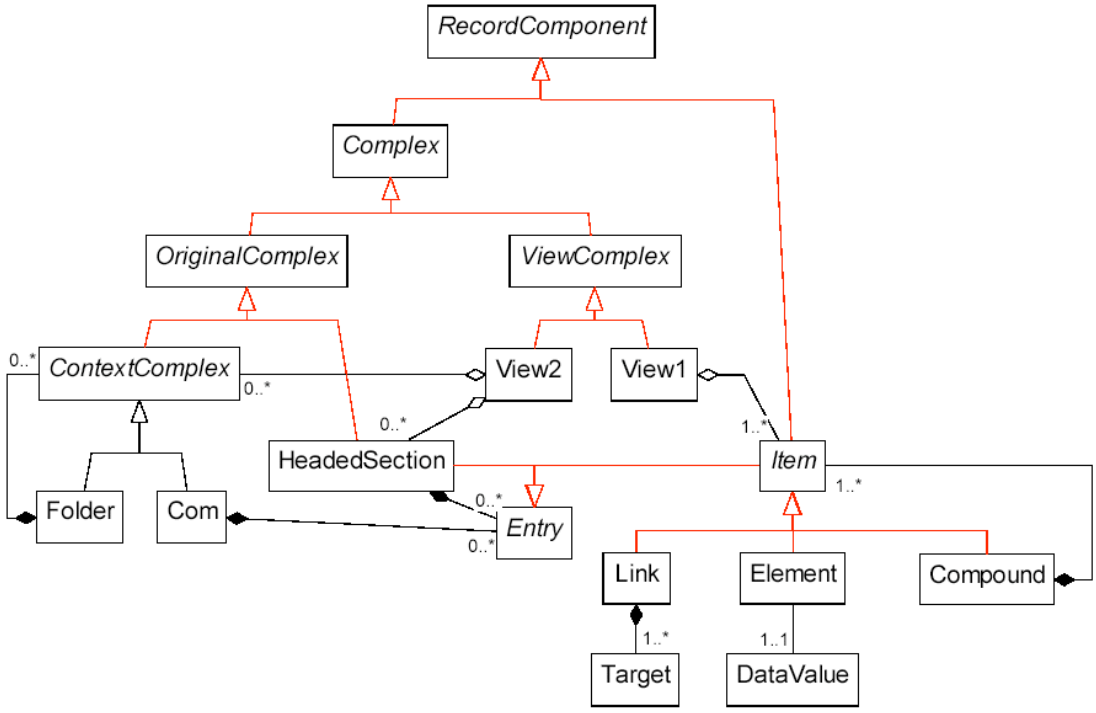


Figure 61: Class Inheritance and Aggregation within the FHR-RM

RecordComponent

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

- record authorship, ownership and duty of care responsibilities;
- subject of care;
- dates and times of health care actions and of their recording;
- version control;
- access rights;
- emphasis and presentation.

The complete set of attributes and their data types is presented later in this section. The FHR-RM distinguishes between the aggregation necessary to convey compound clinical concepts and the aggregation within a record that provides a way of grouping observations that relate to the health care activities performed. An example of the former would be *blood pressure*, which is a compound concept composed of *systolic* and *diastolic* values. An example of the latter would be the grouping together of observations under a general heading of *Physical Examination*. The Complex and Item constructs respectively represent these two broad categories of aggregation.

Complex

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

1. OriginalComplex: this set of classes represents the original organisational structure (grouping) of sets of record entries, as defined by the author(s) of those entries; it provides the medico-legal representation of the underlying information.

2. ViewComplex: this set of classes provide the means by which alternative groupings and sub-sets of the original information may be organised and preserved as permanent views in a patient's record, unlike those generic views provided in an *ad hoc* way by a client system and not stored in the record.

OriginalComplex

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

Folder

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

Com

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

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

HeadedSection

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

ViewComplex

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

View1

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

View2

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

Item

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

7.4.1. The Attributes of the RecordComponent Class

The tables below list the attributes of the RecordComponent class. These are inherited throughout the FHR-RM class hierarchy and may acquire instance values at any level of a hierarchy of record entries. Some of these attributes have been defined as mandatory, and must be incorporated within

any FHR in order to comply with this specification. If mandatory information is not present in the underlying feeder system data then a null attribute value must be included within the Record Component object. Other attributes, marked as optional, have been included to meet published requirements or on the basis of implementation and deployment experience. The attribute data types are all of a base type; complex attribute data types have deliberately been avoided to ease implementation and the processability of federated records. The cardinality of all Mandatory attributes is 1, and that of Optional attributes is 0 or 1.

Subject of care

RecordComponent attribute	Mandatory Optional	Description of intended use	Type
SynPatUID	Mandatory	This is the "Subject of Care" attribute and will identify the patient about whom the record component provides information.	STRING
SubjectOfInformation	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".	STRING

Note: the values for SubjectOfInformation are taken from ENV 13606-2 (Domain Termlist)

Record authorship, ownership and duty of care responsibilities

FHR-RM attribute	Mandatory Optional	Description of intended use	Type
RecordingHealthCareAgent	Mandatory	The healthcare agent responsible for physically including this record component into the patient's source record.	STRING
ResponsibleHealthCareAgent	Optional	The healthcare agent responsible for effecting the care and for authoring this record component.	STRING
LegallyResponsibleHealthCareAgent	Mandatory	The healthcare agent with senior clinical responsibility for the patient at the point of care documented by this record component e.g. Consultant in charge.	STRING
InformationProvider	Optional	The person providing healthcare information if not the subject of care (e.g. a family member, friend, another clinician, an electronic device).	STRING

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

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

FHR-RM attribute	Mandatory Optional	Description of intended use	Type
RecordingDateTime	Mandatory	The date and time this record component was included in the patient's source record (NOT the date and time it was brought into the federation).	DATETIME
HealthcareActivityBeginTime	Optional	The date and time of the health care activity to which this recording relates (this may differ from the RecordingDateTime if a delay occurred before a record could be authored e.g. a home visit at night).	DATETIME
HealthcareActivityEndTime	Optional		DATETIME
ObservationBeginTime	Optional	The date and time (or intervals) of any health or care acts which occurred in the past but are being recorded at the present e.g. an operation performed several years ago.	DATETIME
ObservationEndTime	Optional		DATETIME
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).	STRING
AcquistionTimeDate	Optional	The date/time at which this Record Component was added to a Federated Record if its origin was elsewhere e.g. if received as a message from another record system; this attribute is necessary because the RecordingDateTime would represent when the original entry was recorded, not when it was received into the federated health record.	DATETIME
Locale	Optional	To document the time zone and geographical location of the recording clinical system, for example permitting international interpretation of other dates and times recorded.	STRING

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

Version control

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

Access rights

FHR-RM attribute	Mandatory Optional	Description of intended use	TYPE
AccessAmendRights	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 *within* a single FHR, and are supplementary to any restrictions on overall access to each patient's FHR as a whole.	INTEGER

Note: this attribute permits a sensitivity level to be assigned to Record Components at any level of granularity, as part of a broader approach to access control summarised in Chapter 9.

Emphasis and presentation

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

Note: there is some debate about the importance of representing more detailed aspects of presentation within the FHR. The view taken by the author is that the specification of presentation characteristics is neither necessary nor feasible for all entry instances within the records of individual patients. The role of this Emphasis attribute is to represent that the author wished to

indicate that the observation or conclusion was in some way exceptional or unexpected, and needs to be highlighted to subsequent readers. Where enterprises wish to retain a medico-legal reference to information display characteristics used for a given time period by certain applications, for example through a pointer to an XML Stylesheet, these ought to be retained separately by each enterprise or by the developers of clinical applications.

Class identifiers

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

Other Attributes

FHR-RM attribute	Mandatory Optional	Description of intended use	Type
AuthorsComment	Optional	A free-text comment associated with the record component as a whole (not primarily with its value), intended for use by the author; it might be used by a revisor to explain the rationale for the revision.	STRING

RcuLink	Optional	The RC_UID(s) of other record component(s) in the FHR linked by the author (e.g. to relate an allergic rash to a previous drug prescription). Note: these other components must already be in the record, and therefore the references will be to past or accompanying present entries.	STRING
RcuLinkBack	Optional	This reference represents the reciprocal of the above link, from an historic target record component to the source: it will therefore point forwards in time. Some EHR systems may not permit the retrospective editing of record components to insert this attribute.	STRING

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

7.4.2. Item class hierarchy

The Item abstract class hierarchy provides a means to represent compound and elemental clinical concepts, using the concrete classes Compound and Element respectively.

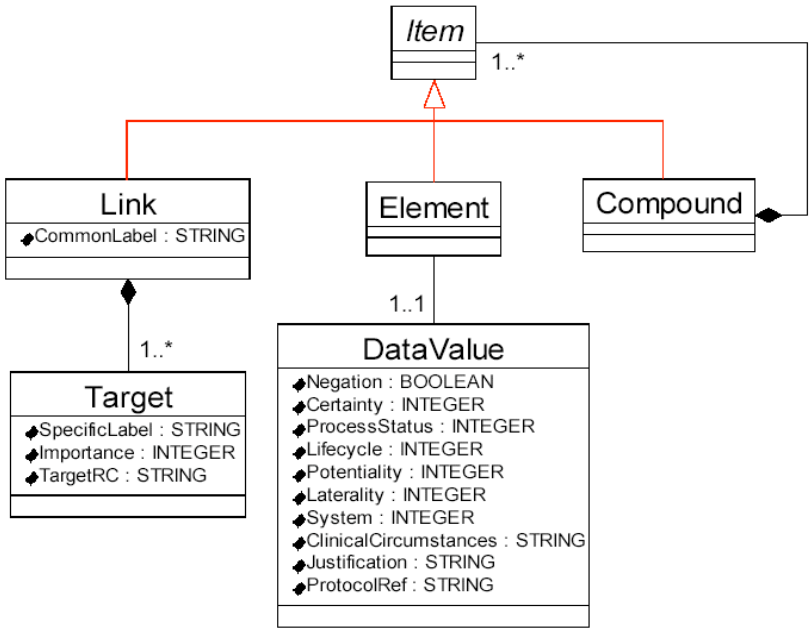


Figure 62: Item Class Hierarchy

An important aspect of the FHR-RM, including the Element, is the binding of a Name attribute (acting as a label) to each content value, providing the individual quantities, dates, images or clinical

terms with a primary context in any given record entry. The Compound class provides an aggregation construct for clinical concepts that are composed of one or more individual named clinical values (e.g. *blood pressure, drug dose, heart sounds*). These entries may be aggregated within a hierarchy to represent complex clinical concepts, but such a composition is distinct from the record structure grouping hierarchy provided by the Complex classes such as the HeadedSection. An additional child class of Item is Link. This class provides a means by which point-to-point linkage or linkage nets within a single EHR can be represented. From an aggregation perspective, Links behave as Elements: they are leaf nodes in an FHR object hierarchy.

A set of context description attributes is associated with the Item, which are largely derived from the CEN EHR Domain Termlist standard ENV 13606-2. According to the standard these are intended to "*provide a means to summarise in a standardised form the key contextual information pertaining to an elementary or compounded entry, primarily to assist in its safe interpretation*" and "*to represent the information that exists about a clinical entry external to the terminology system that has been used*". The list of permitted values for each of these attributes is given below.

Domain Termlist attributes of the Data Value class

DataValue attribute	Mandatory Optional	Description of intended use	Type
negation	Optional	PERMITTED VALUES: {0=notapplicable, 120=negation_affirmative, 130=negation_negated}	BOOLEAN
certainty	Optional	PERMITTED VALUES: {0=notapplicable, 140=certainty_certain, 150=certainty_uncertain}	INT
processStatus	Optional	PERMITTED VALUES: {0=notapplicable, 90=processstatus_new, 100=processstatus_ongoing, 110=processstatus_former}	INT
lifecycle	Optional	PERMITTED VALUES: {0=notapplicable, 1=lifecycle_underconsideration, 10=lifecycle_done, 40=lifecycle_exceptionallynotdone, 20=lifecycle_inprocess, 30=lifecycle_planned}	INT
potentiality	Optional	PERMITTED VALUES: {0=notapplicable, 50=potentiality_actual, 60=potentiality_goal, 70=potentiality_predicted, 80=potentiality_atrisk}	INT

laterality	Optional	PERMITTED VALUES: {0=notapplicable, 180=laterality_bilateral, 160=laterality_left, 170=laterality_right}	INT
system	Optional	PERMITTED VALUES: {0=notapplicable, 190=system_general, 200=system_blood, 210=system_digestive, 220=system_eye, 230=system_ear, 240=system_circulatory, 250=system_musculoskeletal, 260=system_neurological, 270=system_psychological, 280=system_respiratory, 290=system_skin, 300=system_metabolic, 310=system_urinary, 320=system_pregnancy, 330=system_genital, 340=system_social}	INT

Clinical reasoning attributes of the Data Value class

DataValue attribute	Mandatory Optional	Description of intended use	Type
clinicalCircumstances		A narrative remark about the circumstances in which an observation has taken place e.g. "standing", "fasting".	STRING
justification		A narrative remark to explain a step in clinical reasoning, perhaps in arriving at a diagnosis or management plan; this might include a free-test description of a guideline that has been used.	STRING
protocolRef		A placeholder attribute for information generated by an electronic guideline component to reference a guideline, version and step in the guideline that has made or influenced this entry.	STRING

The Item class also inherits the attributes defined in the RecordComponent class, with the option to override the value of any of these.

7.4.3. Data Value classes

The value of an Element is singular, and given by one of the DataValue child classes. These generic classes are a distillation of the original foundation work of GEHR, EHCR-SupA, and CEN/TC 251 ENV 13606.

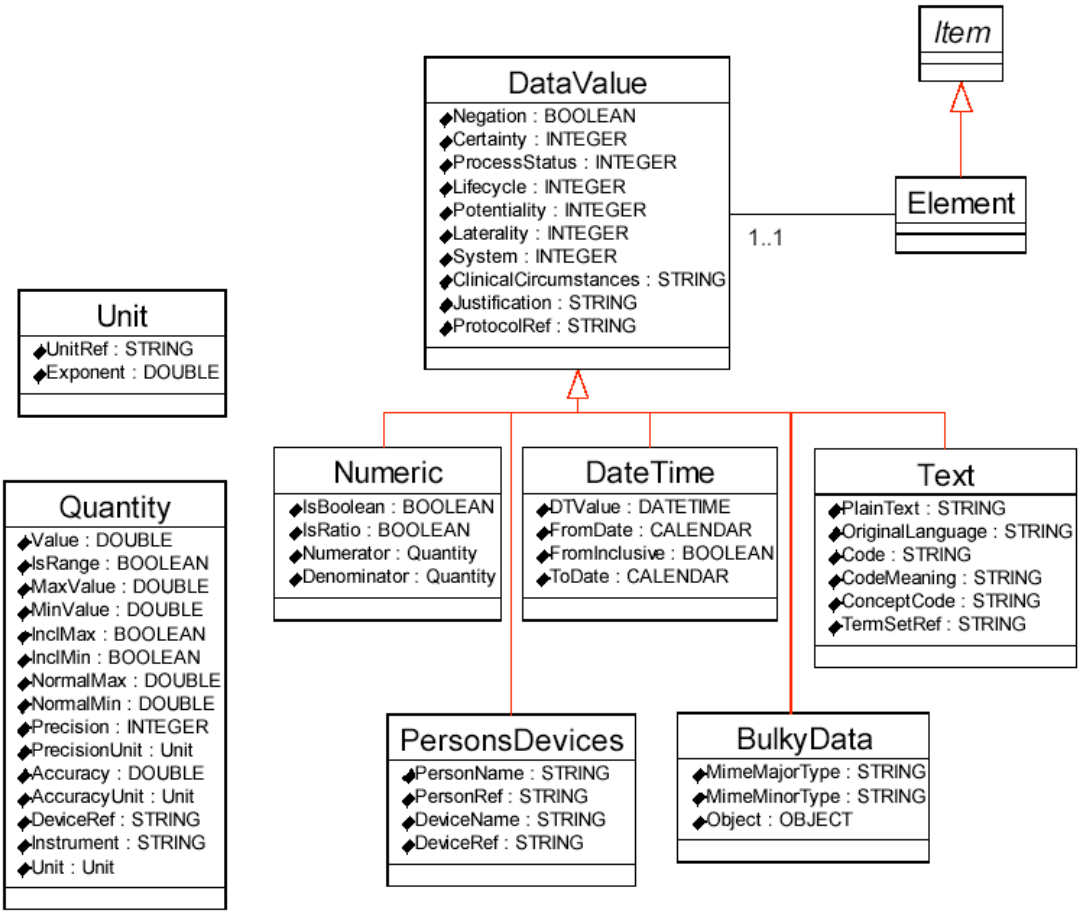


Figure 63: Object model of Element value

A full description of these attributes has not been included as they are reasonably self-explanatory. Separate dictionaries for units and for referencing terminology systems are under development. In the PersonsDevices class above the *PersonRef* and *DeviceRef* attributes reference the richer information objects in the Persons Directory Service (see Section 7.4.4 below), which will shortly include a register of devices. The name strings are also included in the PersonsDevices class for medico-legal safety, to ensure that a person or device name can be identified even if that Directory Service is somehow unavailable. (Please note that any one instance of the implemented class can refer either to a person or to a device, but not both).

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

7.4.4. FHR Persons Directory Service

The Persons Directory provides a means of registering staff and patients within a consistent repository as part of the FHR. This model has been proposed, and implemented as the Persons Directory Service described in Section 11.3.1, in order to provide a means of searching for patients, confirming the correct patient has been chosen, and providing a basic demographic data-set as part of each patient's federated health record. In many situations where an FHR server is deployed there is likely also to be a regional or national directory of patients and also of healthcare agents, which would replace the service described here. The overall engineering approach to the FHR middleware would permit the replacement of the Persons Directory Service with a local alternative quite easily.

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

This directory has been proposed as a minimal but useful set of information that might be held within or closely coupled to the federated health records themselves, to enable the accurate reference to the patient and any other parties specified in each FHR. This part of the information model does not purport to be comprehensive nor to meet the information requirements in an equivalent way to the FHR Reference Model. It has, however, been necessary to define and to implement this model in order to provide a clinically usable application for the Whittington Hospital demonstration site, where federation of the main demographic service of the hospital has not yet been possible.

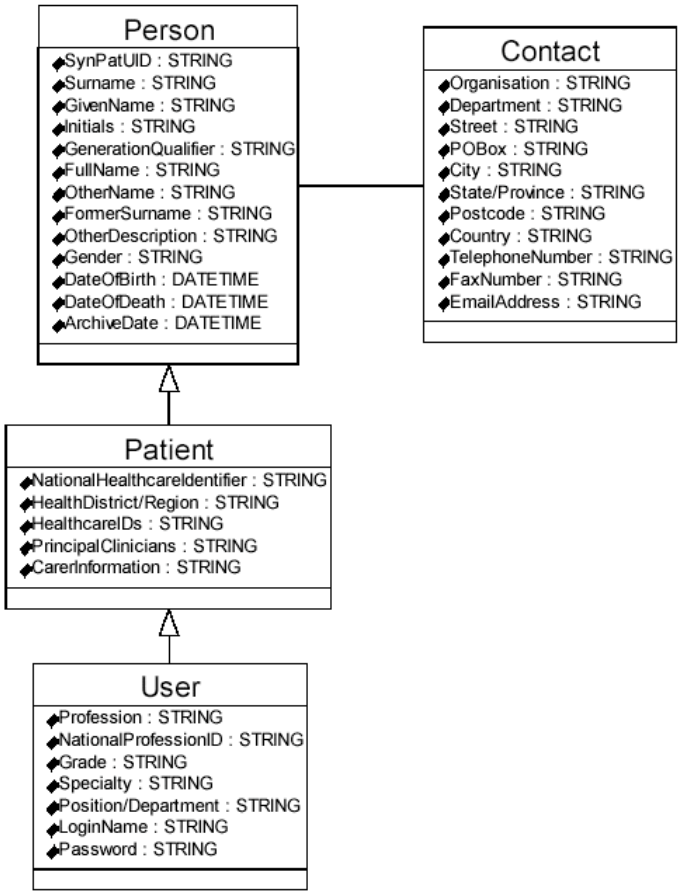


Figure 64: Information model of the FHR Persons Directory

A Software and Devices Directory has also been designed but not yet implemented. It is intended as a registry of all electronic sources of FHR information (such as monitoring devices and decision support software) that might be referenced within a patient's record.

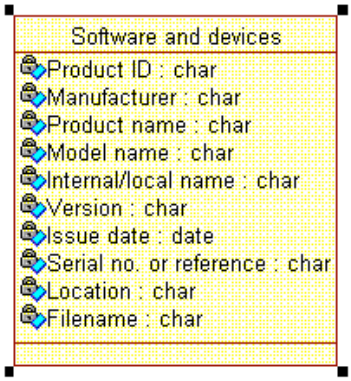


Figure 65: Information model of the FHR Software and Devices Directory

Chapter 8. The Archetype Object Dictionary

This chapter presents the second part of the ODP Information Viewpoint specification of the FHR information architecture.

8.1. FHR Archetype Object Dictionary

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

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

Such schemata (known as archetypes) will be subject to change as clinical practice and information systems evolve. This model corresponds conceptually to the Synapses Object Dictionary (Kalra 1997), (Kalra 1998) and to the archetype concept of the Good Electronic Health Record project (Beale 2000). 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. The individual archetype definitions are represented as metadata entries in that dictionary, and include the mapping of archetypes to clinical concept tags, and the inclusion of validation criteria that might be used to verify the instantiation of a Record Component's candidate data value.

8.1.1. Origins and purpose of archetypes

The Naming of Health Record Entries by GEHR

Although many clinical term sets and coding schemes (such as ICD, ICPC, SNOMED and the READ codes) provide rubrics for the range of possible clinical findings, there is no standardised or comprehensive term set for the names of these record entries. For example, many clinical classification systems include terms to describe the different clinical diagnoses, but do not contain the term *diagnosis* with which such entries might be labelled.

The GEHR project recognised that a term set of this kind would be essential in order for the architecture to be used consistently in clinical practice and by EHR applications. The project produced a term set of 2500 construct names, which were assigned an arbitrary GEHR code and were translated into 9 European languages. Examples of Item names from the GEHR term set are listed in Table 9 below.

aetiology	indications
allergy	problem
auscultation	progress
blood group	proposals
breathing	RBC
complaints	referral
conclusion	surroundings
diagnosis	vaccine
haemoglobin	weight

Table 9: Examples of terms taken from the GEHR term set of HRI names

In order for health records to be interpreted effectively between systems within a federation, and to promote good practice, the structures of compound clinical concepts and record structures need to be agreed and shared. The additional problem of synonyms for these objects often being used differently in each language also needs to be addressed. The author and others within GEHR recognised these requirements but were not able to pursue them within that project for time and resource reasons.

The Synapses Object Dictionary

The Synapses project has been discussed earlier in connection with its core federated health record architecture constructs. In addition to proposing the federated record architecture, Synapses also specified an active dictionary of clinical objects. This work built on the semantic issues identified in GEHR outlined above, and on the federation schema formalisms developed in the Jupiter Project (Grimson and Murphy 1995). These Synapses clinical objects are each formally defined clinical data sets expressed as specific sub-classes of the basic federated health record model (the SynOM), and provide the templates for health record objects to be populated with real patient data.

The Synapses project proposed that, in order to share clinical information meaningfully, it is necessary that the formal definitions of specific clinical concepts and data types found in health records be held in common across the Synapses Federated Health Record, informing the request and response processes and permitting the consistent interpretation of record extracts communicated within the federation. This standardised metadata dictionary set, together with a set

of internal methods, is the Synapses Object Dictionary. The Synapses Object Dictionary is complemented by other persistent data dictionaries for the cross-referencing of term-sets and identifiers that may differ between clients and feeder systems. Examples of these include patient identifiers, end-user identifiers and their access rights to view and to amend the record. This set of dictionaries provides the means by which end-users can unambiguously identify the information they require from a patient's record, and by which a Synapses Server can locate the access methods necessary to retrieve the relevant data.

The resources of Synapses allowed for the population of several Object Dictionary implementations across Europe with locally defined example object definitions, as a proof of concept and to inform guidelines on the future definition of such objects. This work demonstrated that the specification of the dictionary can represent the structure of a wide range of such clinical objects. These structures are not necessarily imposed upon the underlying (feeder system) health record data themselves. Good clinical practice may eventually give rise to data entry templates and protocols to encourage records to be created according to these structures, but this was seen by Synapses as a longer term vision, and secondary to the main project objective of supporting valid data aggregation for review, for analysis and for transfer.

A range of object oriented and relational implementations were piloted, with intentions to demonstrate both message based and CORBA methods of communication between sites. The FHR Archetype Object Dictionary implemented at UCL is the most advanced such implementation, and its information model is a core part of the work reported. It is described below in Section 8.2. The authoring tool is described in Section 8.3.

8.2. FHR Archetype Model

The Archetype Model defines the characteristics that can be used to specify archetypes, which can be regarded as entries within a metadata dictionary. Figure 66 below depicts the functional sub-components of the Archetype Object Dictionary proposed by the author and which has been implemented as an authoring tool and as a run-time service.

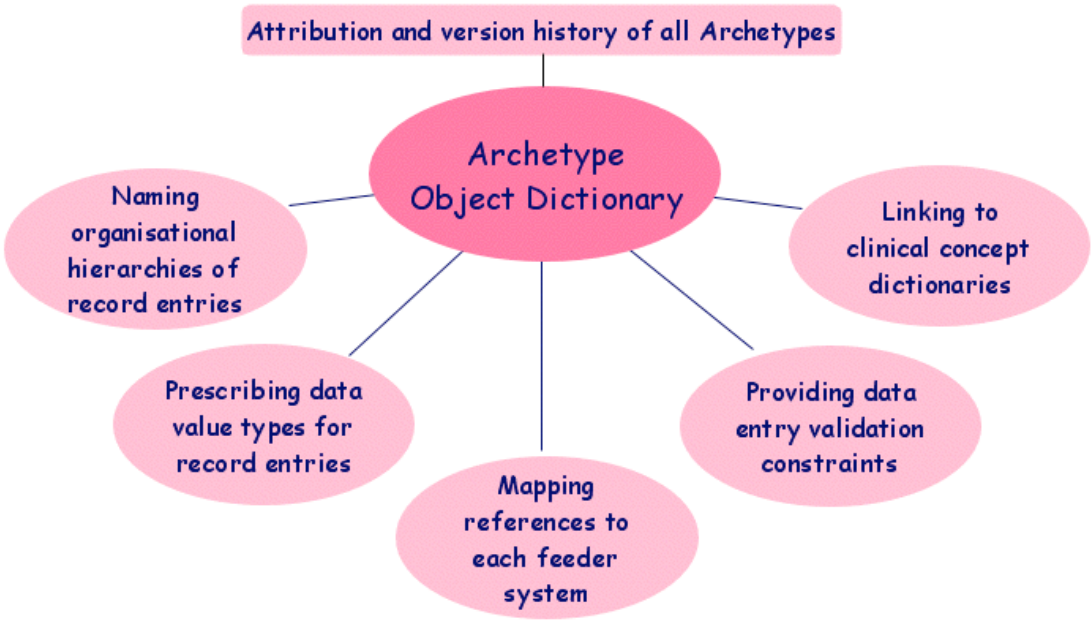


Figure 66: Functional sub-components of the Archetype Object Dictionary

These functional sub-components correspond to parts of the model described in the rest of this section. The Archetype Object Dictionary Client component is described in Section 8.3. The formal object model of the Archetype Object Dictionary is closely related to the FHR Reference Model. It extends the RecordComponent class of the FHR-RM through the addition of one compound attribute that is used to represent the information about the creation, versioning and use of each library definition, and supports the mapping of that definition to a set of medical knowledge concept tags. The overall model is shown below in Figure 67.

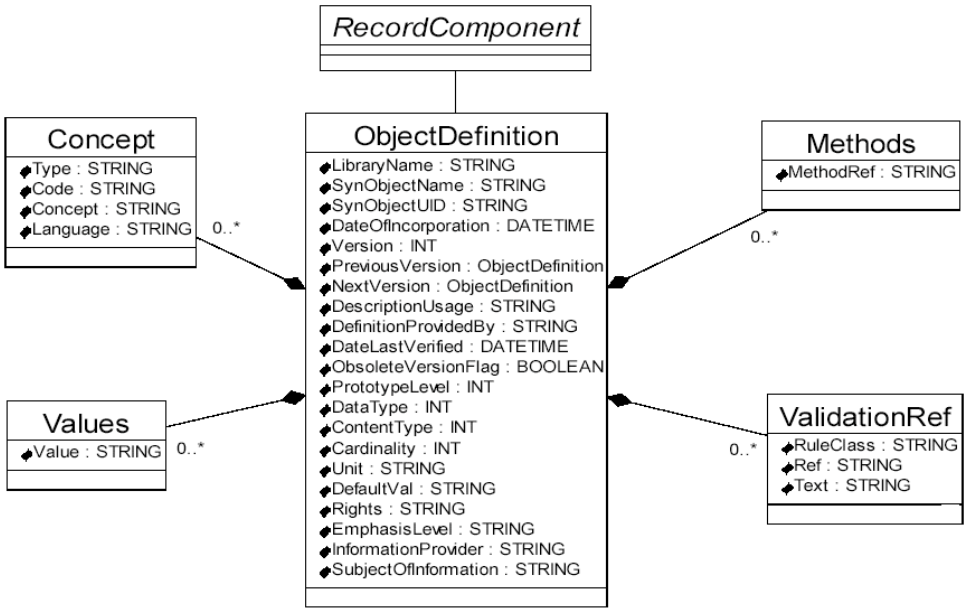


Figure 67: Information model of the Archetype Object Dictionary

ObjectDefinition Class

The ObjectDefinition class contains the attributes relevant to managing the library entries associated with each archetype. This includes the formal definition, author identification and version of any local or national standardised data sets within the Dictionary. In addition, some descriptive text (a definition or explanation) may be provided to clarify the intended clinical use of the object. It will also be necessary to store information about changes that occur to archetypes over time; this might mean recording if this particular object is the current definition, and the identification of its predecessors and/or successors. Each member of an archetype hierarchy has a unique identifier that is included in every FHR instance created according to that definition; this ensures that all entries in an FHR can be referenced to the archetype to which it corresponds and to any ancillary information held in the Archetype Object Dictionary that may facilitate its analysis. The individual attributes of ObjectDefinition are described below.

ObjectDefinition attribute	Mandatory Optional	Description of intended use	Type
LibraryName	Mandatory	Archetypes are authored within libraries to permit traceability and the managed distribution of these within multi-agency domains.	STRING
SynObjectName	Mandatory	This is the standard preferred name by which the archetype is known.	STRING
SynObjectUID	Mandatory	This UID is used to uniquely identify this archetype within Record Components.	STRING
DateOfIncorporation	Mandatory	When the archetype was authored in this Library.	DATE
Version	Mandatory	The version number.	INT
PreviousVersion	Optional	A reference to the previous version if this is a revision.	ObjectDefinition
NextVersion	Optional	A reference to the successor version if this archetype has been revised.	ObjectDefinition
DescriptionUsage	Optional	A textual description of how this archetype was intended to be used for record entries, intended as guidance for those mapping feeder systems or clinical applications.	STRING
DefinitionProvidedBy	Mandatory	The reference source guiding this archetype definition, such as a clinical guideline.	STRING
DateLastVerified	Mandatory	When the reference source was last checked to confirm this archetype is still valid.	DATETIME
ObsoleteVersionFlag	Optional	To permit archetypes to be marked as obsolete even if a revision has not been authored.	STRING

PrototypeLevel	Mandatory	This attribute permits selective sharing of parts of an archetype library to others. PERMITTED VALUES: {0-2} (2=PRIVATE, 1=PRIVATE_SHARABLE, 0=PUBLIC).	INT
DataType	Mandatory	The FHR-RM class to which this archetype applies. Permitted Values: {0-7} (0=Folder, 1=Com, 2=HeadedSection, 3=Compound, 4=Element, 5=Link, 6=View1, 7=View2).	INT
ContentType	Mandatory	Specifying the Data Value type for archetypes whose DataType is Element. Permitted Values: {0-5} (0=No_Content, 1=Text, 2=Numeric, 3=Date_Time, 4=Persons_Devices, 5=Bulky).	INT
Cardinality	Mandatory	Indicating the number of instances of this archetype that may be created within any one instance of its parent e.g. 1 to many.	STRING
Unit	Optional	Specifying the units to be used when recording archetypes whose DataType is Element.	STRING
DefaultVal	Optional	Providing a default value on instantiation for archetypes whose DataType is Element.	STRING
Rights	Optional	Permitted values for these Record Component attributes may be specified in the archetype definition, for example in the case of a Family History archetype to indicate that the SubjectOfInformation may not be the patient.	STRING
EmphasisLevel	Optional		STRING
InformationProvider	Optional		STRING
SubjectOfInformation	Optional		STRING

Values Class

This class permits the author of the archetype to specify a set of data values for corresponding instances of the Element class within the FHR.

Methods Class

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

Concept Class

This class enables a client application to reference an archetype through the use of a locally-defined label, an abbreviated name or a language translation of it. It will also enable an application to identify the set of available objects that correspond to a clinical subject heading. This class is a

place-holder for the methodology by which archetype definitions can be appropriately linked, for example, to GALEN ontology or terminology services.

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

ValidationRef Class

This class, which is still undergoing evaluation, is a place-holder for the expression of rules regarding the validation of instance values for element objects, or the interdependence of values on other components of an Item or Complex. These rules would be used primarily during data entry. 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 allows a set of rules to be defined that must be evaluated against any candidate value for an Element conforming to this archetype. A string text message can be returned to the clinical application if a condition is met. This provides a useful means of providing messages back to end users:

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

The three situations map to three sub-types of rule, reflected in three values for the RuleClass attribute: REJECT, CONFIRM, ACCEPT. If more than one rule has been defined for an archetype, the intention for the service implementing this class is to evaluate rules in the order:

1. REJECT
2. CONFIRM
3. ACCEPT

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

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

8.3. Design of the Archetype Object Dictionary Client

The above information model provides a methodology for specifying the hierarchical organisation of the headings, sub-headings and entries that are required within the EHR of any given clinical domain, for placing constraints on the values that entries may take, and for indicating a mapping of each element to tables and fields within one or more feeder systems. However in practice it is extremely difficult to author these hierarchy fragments without some graphical tool to depict the evolving schema and to capture the definitions of the archetypes from an author.

An archetype design tool was created for this purpose. It was originally intended for use by the author to define the archetypes required for use in the demonstrator, but has subsequently been used by other clinical and informatics colleagues in other demonstration settings. The Archetype Object Dictionary Client component (ODC):

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

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

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

Table 10: Core functions of the Archetype Object Dictionary Client

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 will also be incorporated, and their linkage to run-time protocol components is being explored.

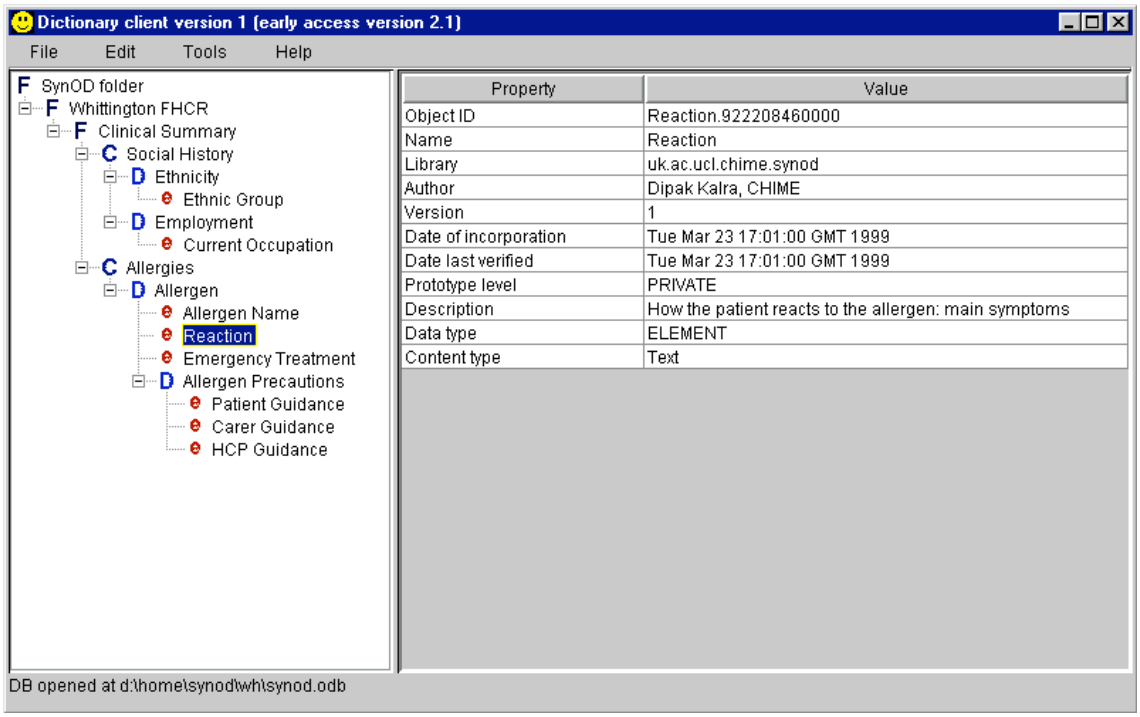


Figure 68: Example screen from the Archetype Object Dictionary Client

The Archetype Object Dictionary Client is described more fully in Appendix A. This tool can produce an XML representation of the library of archetypes held, and an import method can permit the inclusion of archetypes authored elsewhere. This XML DTD is included in that Appendix. The clinical archetypes authored for the north London demonstrator are presented in Chapter 10.

8.4. Archetype Libraries

In each enterprise or region there is a diversity of health information repositories on paper and in legacy feeder systems. These may give rise to a wide range of possible archetypes that could be required within a federation. The potential sources for such archetype definitions will include:

- the clinical data schemata (models) of existing feeder systems;
- the lay-out of computer screen forms used by these systems for data entry and for the display of analyses performed;
- data entry templates, pop-up lists and look-up tables used by these systems;
- standard data sets, messages and reports used locally and nationally;
- the structure of templates and guidelines used for the documentation of clinical consultations or summaries within paper records.

However, in order to optimise the benefits of such federation, enterprises ideally should progressively agree on common definitions that they could use to exchange clinical information. By conforming to the information model proposed earlier in this chapter the individual libraries of archetype definitions held in each Dictionary (however implemented) can be exchanged via XML in order to facilitate this progressive convergence across sites or regions. In the future the author hopes to establish a public domain library of archetype definitions that can be accessed via the Internet, and that will support a suitable standard exchange format by which individual definitions can be downloaded for local use.

In the longer term, it is anticipated that the involvement of national health services, academic departments and professional bodies in the development of such definitions will enable this approach to contribute to the pursuit of quality evidence-based clinical practice.

8.5. Feeder system signup

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

The work of associating such access methods with each archetype capable of execution as a run-time service is still in progress within the author’s research team. Stand alone pilots of this methodology have successfully been used. This aspect of the work is not specifically the subject of this Thesis but will be published later.

8.6. Interface to decision support systems

For one year the author worked closely with colleagues at the Advanced Computation Laboratory of the Imperial Cancer Research Fund to explore the interfaces that could helpfully exist between an FHR service and electronic guideline and decision support services. In order to achieve safe interoperability between these different services, it was recognised that there needs to be a common understanding of the names, data types and possible values of record entries. The archetype object dictionary was identified as the repository of such information that would ideally be held in common. A set of interrogation services was written by the author's engineering colleagues at UCL to permit an electronic guideline product (at the ICRF this is the proForma guideline authoring

tool) to retrieve a set of such archetype names for presentation to a human guideline author as a pick-list of available record entries to use within a guideline specification. Such a semantic coherence between an electronic guideline and an FHR service would permit a run-time guideline engine to issue precise requests to the FHR for record entries and for it to be returned precisely the values it requires for computation.

Ideally the ValidationRef class in the Archetype Model would be used to store data entry constraints according to a syntax that could be computed by an electronic guideline component, so that the guideline application interface could be used by clinicians to author new record entries of consistent data quality. This work could not be taken forward to a full evaluation during its short exploratory funding phase and both sides continue to look for a funding avenue to enable a full proof-of-concept demonstration of guideline-FHR interoperability.

8.7. Interface to terminology services

Informal investigations have been performed to consider how data entry validation constraints could be authored as part of an archetype definition (as values of the ValidationRef class) to restrict permitted values to sub-sections (chapters) of a terminology system. This is a highly desirable alternative to manually maintaining long picking lists whose values are, for example, a set of occupations or immunisations taken from a reference terminology.

There is no generic standard syntax for such a specification, but the author believes this is an important area of future work to ensure the consistent population of EHR entries whose values are to be drawn from specific sections of a terminology system.

Chapter 9. Access Control to FHR data

This chapter summarises an approach designed by the author for representing and managing access control within the FHR. It presents the third part of the ODP Information Viewpoint specification of the FHR information architecture. This work is still in progress.

9.1. The challenge of access control

The review of literature on ethical and legal issues (Sections 5.11 and 5.12) and the requirements listed in Section 6.4 all point strongly to the need to restrict access to FHR data in accordance with the wishes of the patient.

Ideally, each fine grained entry in a patient's record should be capable of being associated with an access control list of persons who have rights to view that information, which has been generated or at least approved by the patient and which reflects the dynamic nature of the set of persons with legitimate duty of care towards patients through their lifetime. The access control list will ideally include those persons who have rights to access the data for reasons other than a duty of care (such as health service management, epidemiology and public health, consented research) but exclude any information which they do not need to see or which the patient feels is too personal for them to access. On the opposite side, the labelling by patients or their representatives of information as personal or private should not hamper those who legitimately need to see the information in an emergency, nor give genuine health care providers such a filtered perspective that they are misled into managing the patient inappropriately. Patients' views on the inherent sensitivity of entries in their health record may evolve over time, as their personal health anxieties alter or as societal attitudes to health problems change. Patients might wish to offer some heterogeneous levels of access to family, friends, carers and members of their community as well as to those in health care professions. Families may wish to provide a means by which they are able to access parts of each others records (but not necessarily to equal extents) in order to monitor the progress of inherited conditions within a family tree.

Such a set of requirements is arguably more extensive than that required of the data controllers in most other industry sectors. It is in practice made extremely complex by:

- the numbers of health record entries made on a patient during the course of modern health care;
- the numbers of health care personnel, often rotating through posts, who might potentially come into contact with a patient at any one time;
- the numbers of enterprises with which a patient might come into contact during his lifetime;

- the difficulty (for a patient or for anyone else) of classifying in a standardised way how sensitive a record entry might be;
- the difficulty of determining how important a single health record entry might be to the future care of a patient, and to which classes of user;
- the logically indelible nature of the FHR and the need for revisions to access control to be rigorously managed in the same way as revisions to the FHR entries themselves;
- the need to determine appropriate access very rapidly, potentially in less than one second;
- the low level of concern the majority of patients have about these requirements;
- the high level of concern expressed by a growing minority of patients to have their consent for disclosure recorded and respected.

To provide a few examples of this problem:

- the Whittington Hospital, a medium sized suburban teaching hospital, has around 1200 personnel who might have legitimate need to see health record information;
- each anticoagulant clinic patient had on average 1,000 fine-grained record entries in the legacy feeder system that were transferred to the FHR server; this is a small departmental database and a complex patient could have thousands of times these data across multiple systems;
- a confirmed HIV positive diagnosis is arguably one of the most sensitive entries in a patient's EHR, and one they might most wish to restrict, but such an entry is also considered to be of greatest importance to know when treating this patient in an emergency;
- a termination of pregnancy carried out twenty years previously is of little importance to an orthopaedic surgeon treating a fractured femur, but the anaesthetic used for that termination might be relevant to the anaesthetist now managing the patient's sedation for a reduction of that fracture; how realistic is it for the present care team to have differential access to historic record information?

Over the past five years the UK NHS, like many other health services, has launched a number of pilot projects and legal investigations to explore the available options to address these concerns. The author has been involved in a few such projects and committees, each of which has produced a different (usually inconclusive) result but with a common theme: some compromise on the ideal is required. Many of the pilots documented in the literature have either been simplistic or have been exhaustive but are not scalable. Examples of good working practice do exist, for instance at the University Hospital of Geneva and the Beth Israel Hospital, and these have informed the author's own proposals outlined below.

The use of anonymised data for teaching, research or service management purposes, in compliance with data protection legislation, does not require measures of the kind described in this chapter that regulate access to identifiable patient information.

9.2. Access control information architecture

The approach proposed by the author is a kind of compromise on the access control ideals described above, which is compatible with the overall FHR approach and integrates several complementary features that are applied to different parts of the FHR service.

Sensitivity levels

There is a requirement to permit fine grained information to be labelled as sensitive by the patient, and thereby for limited disclosure. However, these labels need to be closely associated with individual entries and version controlled: this requires that they should need to be changed infrequently. These labels also need to be capable of interpretation longitudinally i.e. it should be possible to use the sensitivity levels that are stored within entries authored over several years in a consistent way when retrieving FHR information. These requirements point to the adoption of a limited number of sensitivity levels whose meaning can be applied across all patients consistently and are likely to be durable over the lifetime of a patient's record. They cannot be anchored on individual healthcare systems and organisational structures. From an evolution of thinking over several years the author has proposed the following five sensitivity levels.

1	**administrative data**: can be accessed by a wide range of clinical and non-clinical personnel at the discretion of a healthcare enterprise, but still to be disclosed with care. Examples are basic demographic details, which may be required by many ancillary and administrative staff in a hospital but should not be disclosed freely (patients are sometimes deliberately re-housed to escape an attacker or stalker).
2	**Audit, research or teaching**: entries for which consent has been given for the disclosure of identifiable patient information to audit management staff, or for general teaching (e.g. records that may be disclosed to students or staff undertaking examinations); this level would not normally be used for firm-based teaching or student clerkings, nor for internal audit performed by the clinical team.
3	**clinical**: the default level for routine entries intended primarily for access by all future clinical personnel providing care for the patient; it is anticipated that the vast majority of entries will have this level of sensitivity and that the amendment of this to more or less sensitive will be exceptional and by direct request of the patient or record author.
4	**core/emergency care team**: this level is intended to be accessed only by the small number of clinical members of the patient's immediate care team and not by the wider network of clinicians involved in a patient's care; persons accessing the record in an emergency would normally also have access to this level of sensitivity in the record; the definition of this core team is discussed below.
5	**personal clinicians**: this level is intended for information that can only be accessed by those persons classified by patients as their personal clinician(s).

Table 11: Sensitivity levels proposed for FHR entries

As stated in Table 11, the default sensitivity level envisaged for the vast majority of entries is 3, intended for most clinical care purposes. This is also intended to subsume basic private ongoing professional development and clinical audit performed by members of the clinical team. For

information that might be collected as part of a prospective audit or research data set, possibly involving additional personnel in its collection or collation, the entries should be marked as level 2 sensitivity (with the patient's consent). Level 1 data might be determined as part of institutional policy (core demographic details, patient's location in the hospital) but should still be so labelled with the patient's knowledge and ideally consent.

Patients will sometimes wish to provide information to an individual personal clinician, sometimes but not always their GP. It will be up to the discretion of that person if he or she is willing to accept authorship of information deliberately so restricted (he or she would not be able to regulate such a designation made by patients authoring their own entries, but would not be accountable for that information). This level (5) does not automatically grant access to the author of the entry: if the patient changes GP the former GP should not continue to have rights to access their previous entries and a new trusted GP might be the right person to acquire retrospective access to the most sensitive information in the patient's record.

Sensitivity level 4 is intended for information that is intended to be limited to those immediate members of a patient's care team (e.g. their GP practice or the staff of a ward the patient is currently on). The definition of who is in such a care team needs to be made by personnel departments classifying staff by department or ward, and by permission of the patient. This category exists because the extended clinical team of intersecting departments and professions dealing with a patient can be vast, and all such personnel should have level 3 access. It has been suggested to the author by colleagues within Europe that entries at this level of sensitivity should also specify which team is permitted to see them. In an indelible, distributed and longitudinal record this is problematic:

- there is no standardised classification of clinical teams to permit an unambiguous (and potentially international) interpretation of the name of a team;
- patients are not constantly under an individual care team: once that team has ceased to play a role in the patient's care their access should cease; however a new care team might require access to entries previously assigned to the former team; this is incompatible with an indelible FHR, although a mechanism for indicating team status is described later;
- the set of entries at sensitivity level 4 could easily become fragmented across several historic clinical teams, whilst it might be argued that a team with current core clinical responsibility for a patient should be able to see all of the entries at this sensitivity level.

It has been assumed that the patient is able to access entries at all five sensitivity levels. A mechanism for withholding information from patient access is described later in this section.

The FHR Reference Model includes an AccessAmendRights attribute with a data type of integer that has been used in the implementation for the representation of sensitivity levels. The attribute can have a value from 1-5, and the FHR service can filter retrieved record components on the sensitivity level presented for a user.

Role-based sensitivity mapping

Role-based access has gained considerable conceptual favour in recent years, as an alternative to access regulated at the level of individual persons. However, different papers and pilots have adopted varying numbers of different roles, some favouring:

- professional groups (GP, hospital doctor, nurse, physiotherapist, chiropodist etc.);
- specialities (diabetes, gynaecology, GP, mental health etc.);
- record activity (read, amend, write);
- care activity (patient care, audit, teaching, research etc.).

The author favours the last categorisation of roles, but recognises that for many years yet the number and nomenclature of roles will be variable geographically and over time. There is a need for patients to confirm consent to the adoption of each role within an FHR (possibly with the exception of *clinical care*, for which implied consent is being considered sufficient by some authorities). The author's proposal is that a specific consent record entry is made by the patient for each permitted role in their FHR, and that this entry links each role to a sensitivity level. This kind of entry should be relatively stable in each patient record but would be capable of revision over time. For example, if a patient's core care team changed, a new team could be defined and given "Level 4" access by a single instruction without the need to make changes to individual entries all through the patient's FHR.

Members of a particular research project (designated to a unique role for that project) might be given consent to access a patient's FHR to the patient's chosen level of sensitivity. The role *medical student teaching* might be granted Level 3 access instead of Level 2 by a willing patient.

The author has created a set of relevant archetypes for such consent entries in the FHR. These permit the patient to define any role (presently as free text) and to assign different sensitivity levels to that role for read, amend and create functions within their FHR. These mappings can be revised, and a full version history of such changes is maintained. The FHR service has been adapted to require a role to be specified with every interaction, and to look up and apply the role-based sensitivity level as a filter to any retrieved record components. In order to permit new patient records to function in the absence of any patient-defined role-based mappings, a limited set of default mappings is used if no mappings have been defined in the patient's FHR: these provide for the basic patient care roles that might be required as soon as a new record has been created.

This whole part of the overall access control framework proposal is still being tested and will be evaluated. 3 extensions to this role-based mapping are being considered for later implementation testing:

1) the ability to exclude access to certain archetypes for any given role;
2) the ability to exclude individual record component instances for any given role;
3) the ability to exclude named persons from assuming a given role in a patient's FHR.

By defining the role "Patient" in the same way as any other role, measure 2 above would deny a patient access to certain record entries of these were considered harmful to him or her. The complete archetype specification for the role-based access object will in the future be capable of being defined in a patient's record is shown in Figure 69 below. The Archetype Object Dictioanry Client uses an iconic letter to indicate the class in the FHR Reference Model that has been used for each archetype (except that **D** signifies the Headed Section class). The hierarchy view above does not show the data types associated with each Element class (those represented using the icon **e**).

Figure 69: Role based access control archetype

Interoperation with authentication and certificate services

In any real deployment scenario an FHR service will be deployed alongside a set of security components, and it is increasingly likely that these will include authentication mechanisms to verify the authenticity of the user and some PKI service that validates users, defines their access privileges and the roles they may assume. The FHR service has been adapted optionally to call such a PKI service before processing a user's request, in order to verify that a current certificate exists for that user and either to request a role or to confirm the validity of a role already offered. The approach taken by the author and the research team has been to facilitate the interoperation of the FHR service with such components rather than to duplicate any such functionality.

Grouping of patients into organisational units

In many situations the FHR service will be deployed to integrate the clinical data held in the systems of multiple institutions, for example within a district or regional healthcare network. The global set of patients within the federation might therefore be the superset of the individual lists of patients in several GP practices and in more than one hospital. The individual staff members of

each institution are unlikely to have legitimate access to all of these patients, or even to know of their existence.

The UCL persons dictionary service permits patients (and staff) to be represented within one or more directory sub-contexts to mirror the way in which patients or staff notionally belong to a general practice and/or hospital. Each person may appear in more than one context. The patient search functions associated with all of the demonstrator web applications require a directory sub-context to be specified, and all responses to that search are limited to the corresponding patient directory (or to a higher level if so specified).

In summary, this set of features, taken together, will provide the following access control measures:

- determine user profiles from available authentication and certification services;
- limit patient searching within organisational contexts;
- limit access to sub-categories of the record based on roles e.g. a department or speciality.
- map a user's role-based privilege to the sensitivity of individual record components;
- permit access to sub-categories of the record based on roles e.g. for research or teaching;
- exclude named persons from adopting certain roles for accessing individual patient records.

9.2.1. Use Case examples showing access control features

The following Use Case diagrams have been included to illustrate the way in which the access control features described above will come into play as a user logs in to the FHR service, searches for a patient, requests specific parts of the patient's FHR and the provides a new FHR entry (or a revised version of an original entry).

Confirm user identity and role

The user is assumed to be logging in to their clinical applications environment via a portal service, which interacts with an authentication service and a PKI service to authenticate the user and to confirm a valid role he or she may assume within that session. The FHR service relies upon these interactions taking place within the user's organisation or at a health service level. The user's home page may also contain many non-FHR related items, so no contact is made to the FHR service at this stage.

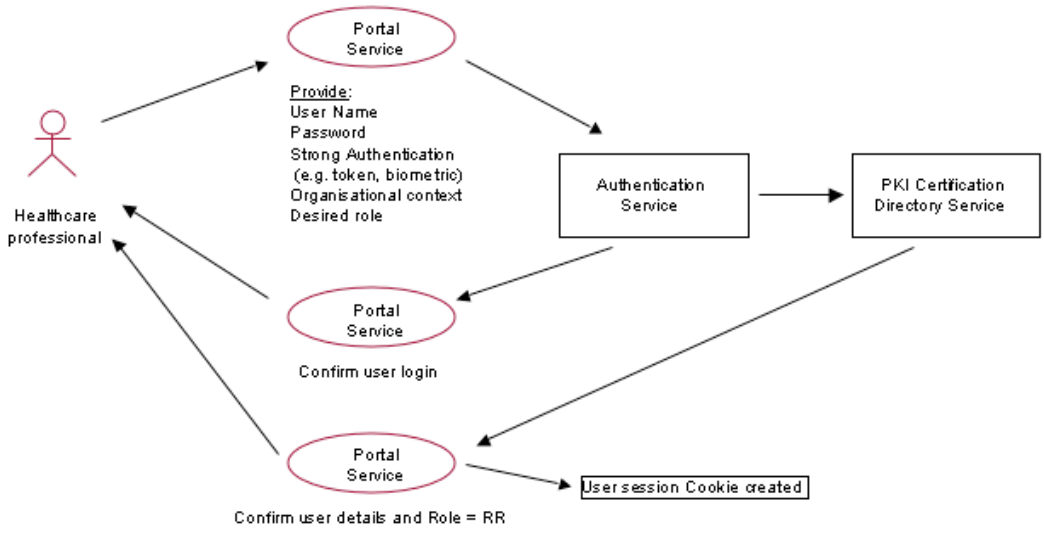


Figure 70: Access control Use Case - confirming user identity and role

Enter clinical application: patient search screen

By choosing to initiate a patient search, the user has indicated a wish to access patient records. The portal service now creates a user session object that contains the definitions of the author, the role he has assumed and the organisational context to be used for patient searches.

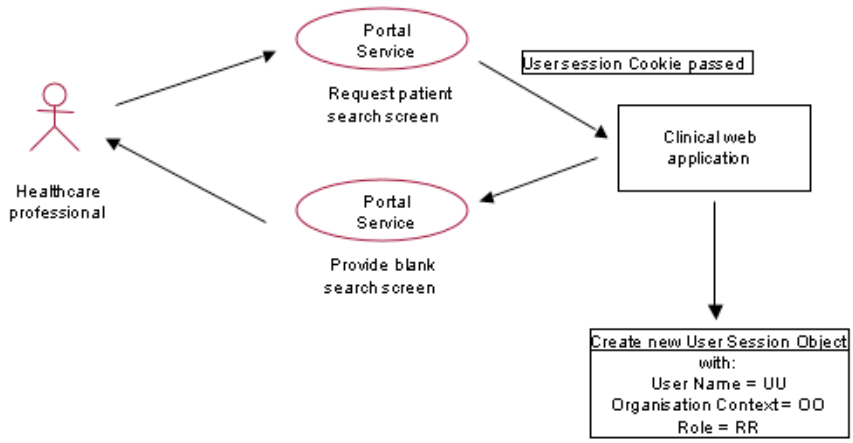


Figure 71: Access control Use Case - accessing the FHR service

Search for a patient

The patient search function of the FHR service uses the organisational context as a filter so that, for example, a search for patients with a surname of Smith only returns those patients in that organisational context.

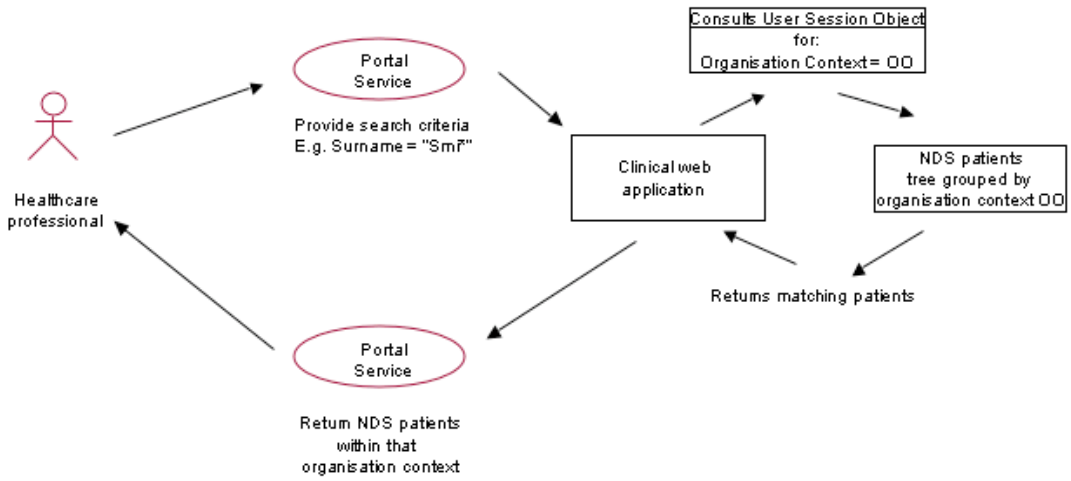


Figure 72: Access control Use Case - searching for a patient

Request specific patient's details

The patient consent object instances are first queried to retrieve one pertaining to that role. This object can be cached for that user/patient session and used to apply a sensitivity level filter to each request for patient record entries.

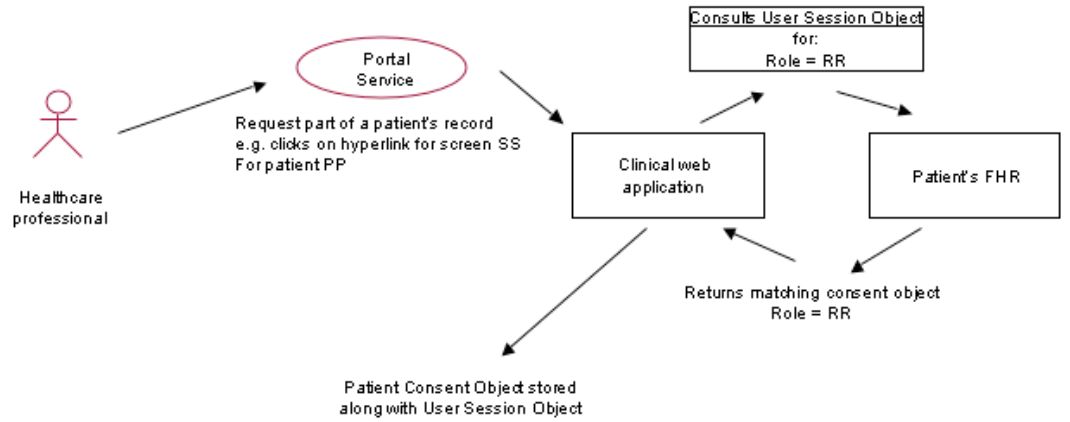


Figure 73: Access control Use Case - requesting patient record entries

Return specific patient's details

The record components returned by the FHR service have been filtered to remove any record components with a sensitivity level greater than that defined for that User's role in the patient's FHR.

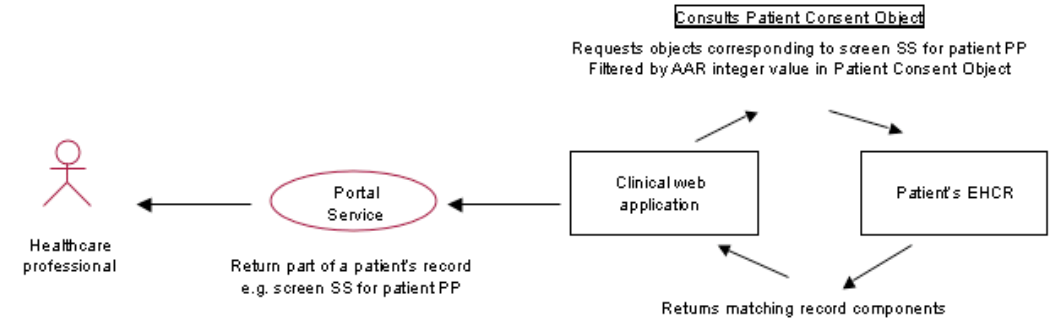


Figure 74: Access control Use Case - returning patient record entries

Add/revise patient records

New entries made by the end user are added with the default sensitivity level unless this is specified to be different by the clinical application.

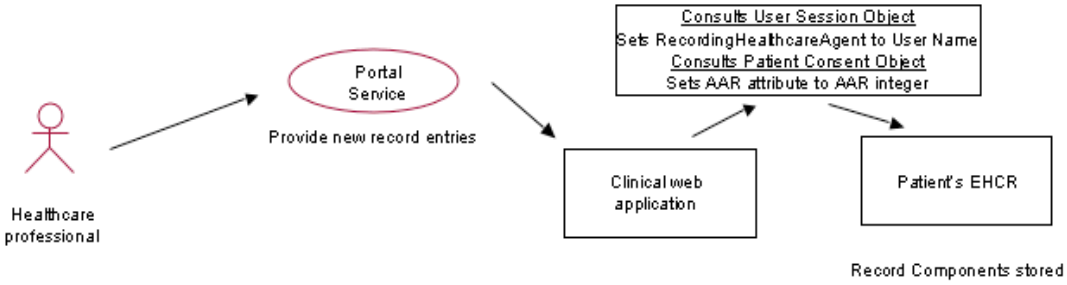


Figure 75: Access control Use Case - adding a new patient record entry

9.3. Audit trails within the FHR service

An audit trail should be seen as an essential component of the FHR service for medico-legal purposes. The most frequent information flows through the FHR will be when dealing with an extract obtained dynamically from a feeder system in response to a client request. A minimal audit trail for this process should comprise:

- information about the client, location and end-user making the request (including the role assumed);
- the date and time of the request;
- identifiers of the patient and of the requested object (archetype IDs and record component IDs);
- the feeder(s) on which method(s) were invoked, and the success of the response(s) including any error messages;

- the date and time of the feeder response(s).

The processing of new FHR entries would also require the recording of:

- information about the client application and end-user providing the data;
- the date and time that the new record entry was passed to the FHR service;
- the date, time and success of any attempts to store the record entry on the FHR cache database or other local database if implemented;
- the date, time and success of any attempts to offer the entry to an attached feeder system.

The UCL FHR service incorporates an audit trail comprising the above data components. It was felt by the author and his research team that an audit trail of FHR accesses is sufficiently pertinent to the overall accountability of the FHR service that it should be implemented as a core part of the service rather than assumed to be a local deployment issue.

Work is currently in progress on tools to permit the interrogation and display of the audit trail by date, time, role, archetype and patient. A patient view of his own audit trail, showing him who has seen which classes of information in their FHR, is also being developed.

Chapter 10. Defining the Archetypes

This chapter presents the first phase of evaluating the overall federation approach and the information models presented in the previous three chapters: applying the Reference Model and Archetype Object Dictionary to represent the schema of a legacy clinical database and the schemata required by new client applications as specified by the intended clinical users.

10.1. Background work undertaken during Synapses

Each of the main Synapses validation sites designed a clinical scenario to illustrate the way in which a Synapses Server could facilitate patient care in a particular department or unit. Each scenario had a detailed patient storyboard accompanied by an analysis of the healthcare record interactions that would occur during it. The scenario provided a focus for the identification of the main data sets used in the management of patients or in communications to support shared care. These provided the first candidates for Synapses clinical objects (archetypes) at each site. The author was responsible for defining this aspect of the project work-plan and for co-ordinating these investigations undertaken by the sites. A rigorous approach was encouraged to referencing the original source, version and structure of each of the clinical objects identified, together with any constraints or term sets associated with the instance values these objects could take.

Although no systematic tools were available during the project lifetime, the author collected and collated these site archetypes as they were defined and refined in order to gain a greater insight into the variations in the data sets used across domains and the varying ways in which these were modelled as archetypes. Given the high dependence of the Archetype Model on the Reference Model, it is not surprising that the evolutions of that Reference Model (the SynOM) during Synapses had an impact on the archetypes that had been proposed, and vice versa. Few of the archetypes authored by the sites were eventually implemented within those demonstrators (which were inevitably less extensive than originally envisaged). The author found the overall process very instructive and able to utilise this experience when defining the archetypes needed for the London demonstrator. The author's background in the design of a GP computer system and in medical audit also provided helpful experience in the construction of clinical data schemata.

10.2. Approach to defining the Archetypes used

The initial target domain for the FHR demonstrator in north London was the anticoagulation clinic run by the Department of Cardiovascular Medicine at the Whittington Hospital. The staff had been using a legacy clinical application for several years, and the goal for the author's research team was

to replace this stand-alone system with a record server and a new web-based application. The legacy application has accumulated nearly a decade of historic patient anticoagulation records that needed to be mapped to and transferred into the FHR record server as an example of decommissioning a feeder system.

The first phase of this work was to define the clinical data sets that were required to populate the new application, using archetypes. This was carried out by the author in partnership with the two lead clinicians working in that clinic: an anticoagulant nurse specialist and a pharmacist who had jointly run the clinic for the previous two years. The specification for the data sets was derived from:

- an analysis of the clinical workflow (and patient care pathway) through the clinic;
- a critique of the existing application, which the staff felt had a number of strengths and weaknesses;
- a review of the actual data within the database to see which fields were actually being used (and for what purposes);
- discussion with the head of the department about plans to extend the geographical locations of the anticoagulant service and the range of potential users of the application.

Ideally a set of mock screens would have been developed to further ratify the intended application design before proceeding with the archetype specification. However, the author's team needed to make progress on the final design and implementation of the FHR service, the internal cache repository and the mapping of the legacy data in parallel with the application development, and only a simple outline of each screen was produced before the formal implementation work was commenced.

The archetypes were defined using the Archetype Object Dictionary Client tool described in Section 8.3 above, and are shown using screenshots from the ODC in Section 10.3.1 below. The hierarchical display proved to be easily understood by the clinical staff, and the author was able to use the ODC interactively with them over several meetings to refine the archetypes before proceeding with the application design phase.

The XML output file from the ODC provides a source file which, with minor recasting, can be used to create and apply a specific filter class to the FHR repository effectively constraining it only to accept record components that comply with one or more of the specified archetypes. This filter provides both a means to quality-assure the content of the record server repository and to confirm the validity of those archetypes to the clinical data set requirements of the anticoagulant team.

10.3. Cardiovascular medicine Archetypes

10.3.1. Anticoagulation

The actual archetype hierarchy comprising the anticoagulant demonstrator is shown in Figure 76 below as a compiled screenshot fragment. The full Archetype Object Dictionary Client (ODC) screen cannot be included for space reasons but an example screen is shown in Section 8.3 above and a full set of screens are described in Appendix A; the whole hierarchy as shown below would in practice require the user to scroll down two or three times.

Figure 76: Anticoagulation Clinic Archetypes

Once the archetype design became stable it was possible for the author to produce a mapping of each field in each table of the legacy application to the element items (leaf nodes) within the archetype hierarchy. This then provided the blueprint for the author's engineering colleagues to write the code that would permit the actual transfer of legacy data to the record server, in this case as a batch process to reflect the one-off decommissioning of that legacy feeder that was envisaged.

It must be remembered that each archetype shown above corresponds to a concrete class in the Reference Model that has many contextual attributes in addition to the data value for each Element class. The mapping of the legacy database to this archetype schema therefore requires candidate values to be provided to several attributes at each level in a hierarchy. The author depicted this for use within the engineering team through an A2 sized coloured spreadsheet, a fragment of which is shown in Figure 77 below.

					Data Value Type	SynOM Attribute	TABLE	FIELD	TABLE	FIELD
Therapy Programme										
	Anticoagulation Plan									
		Anticoagulant Name			TEXT	Content	Rx Plans	Anticoagulant Drug ID		
		Date Commenced			DATE-TIME	Content	Rx Plans	Start Date		
		Planned Stop Date			DATE-TIME	Content	Rx Plans	PlannedStopDate		
		Actual Stop Date			DATE-TIME	Content	Rx Plans	ActualStopDate		
		Target INR Range			TEXT	Content	Rx Plans	Range&Target INR ID		
		Target INR			NUMERIC	Content	Rx Plans	Target INR		
		Anticoagulation Problems			TEXT	Content	Rx Plans	Dr Instructions	Rx Plans	Plan Reason
	Clinic Contact					RecordingDateTime	Events	DateRecorded	AC Controls	Start Date
	Clinic Contact					ResponsibleHealthcareAgent			AC Controls	Decided By
		Description of Present Health			TEXT	Content			AC Controls	Memo
		INR Test			NUMERIC	Content			AC Controls	Current INR
		Treatment Control Status			TEXT	Content			AC Controls	Controller
		Decision Support Recommendation								
			DS Dose		NUMERIC	Content			AC Controls	Rec Dose
			DS Interval		NUMERIC	Content (Units = "Days")			AC Controls	Rec Interval (Days)
		Planned Treatment								
			Accept DS Dose?		NUMERIC	Content			AC Controls	Rec Dose Accepted ?
			Accept DS Interval?		NUMERIC	Content			AC Controls	Rec Interval Accepted ?
			Therapy Over-ride Details			AuthorsComment			AC Controls	DoctorsAdvice
				Drug Strength	NUMERIC	Content			AC Controls	Next Dose
				Date Range	DATE-TIME	Content (Units = "Days")			AC Controls	Next Interval (Days)
			Next Appointment Date		DATE-TIME	Content			AC Controls	AppointmentTime
			Days of Anticoagulant Control		NUMERIC	Content			AC Controls	DaysOfAnticoagulantControl

Figure 77: Mapping of legacy database fields to the anticoagulation archetypes

In this example:

- the yellow cells indicate the hierarchically-organised archetypes;
- the pale blue cells the data types specified for each Element class;
- the pale green the Record Component attribute to be used for the legacy data item;
- the purple cells indicate the table name in the legacy database;
- the dark blue cells are the field names in that legacy table.

A similarly detailed mapping was required for each form object within the web application, which was defined by the author using mock screens composed of tables annotated by small extracts of the spreadsheet. Feedback from the legacy database import and during the design of the web application required several minor adaptations to the original archetype definitions, which were in turn communicated back to the clinical team through regular progress meetings.

10.3.2. Rapid Access Chest Pain Clinic

The success of the live deployment of the anticoagulant system (described later in Section 11.6) provided the stimulus for the development of web applications for a second cardiovascular care domain: the management of sub-acute chest pain by a specialist nurse running a new Rapid Access Chest Pain Clinic. This new development differed significantly from the anticoagulant clinic:

- there was no legacy application to provide a working exemplar of the clinical requirement; however a simple but very longstanding cardiac outpatient audit and outcomes database was required to be federated at the same time;
- this was a new clinic that was still developing a clear modus operandi and evolving in partnership with other members of the department and with local GPs;
- there is much published guideline information on good practice for managing patients with sub-acute chest pain, including a newly published National Service Framework;
- the Prestige project has developed a formal data set for cardiovascular care, although primarily for the use of decision support systems rather than an EHR;
- it was agreed early on to include the requirements of a newly-appointed heart failure nurse specialist in the hope that a common application could be developed for both nurses.

Having learnt from the anticoagulation clinic experience, the author decided this time to utilise the available evidence and the requirements of the clinical team to define the web application screens in detail, and then to use these to define the archetypes. The initial review of the cardiovascular literature and guidelines was performed jointly by the author and the Head of the Department of Cardiovascular Medicine. The draft web screens were presented to the nurse specialists as collections of tables on pages of a word-processed document accompanied by narrative functional descriptions. The document was reviewed and refined over several iterations. The staff were also able to review the anticoagulant application in order to acquire an understanding of the general look and feel envisaged and also to gain an understanding of the way in which web applications behave in contrast to conventional GUI applications.

The chest pain clinic archetypes were then defined and shared with the clinical team and with the lead web engineer within the author's research team. This has proved to be a relatively robust set of definitions, although during the screen design a process a couple of errors made by the author had to be corrected.

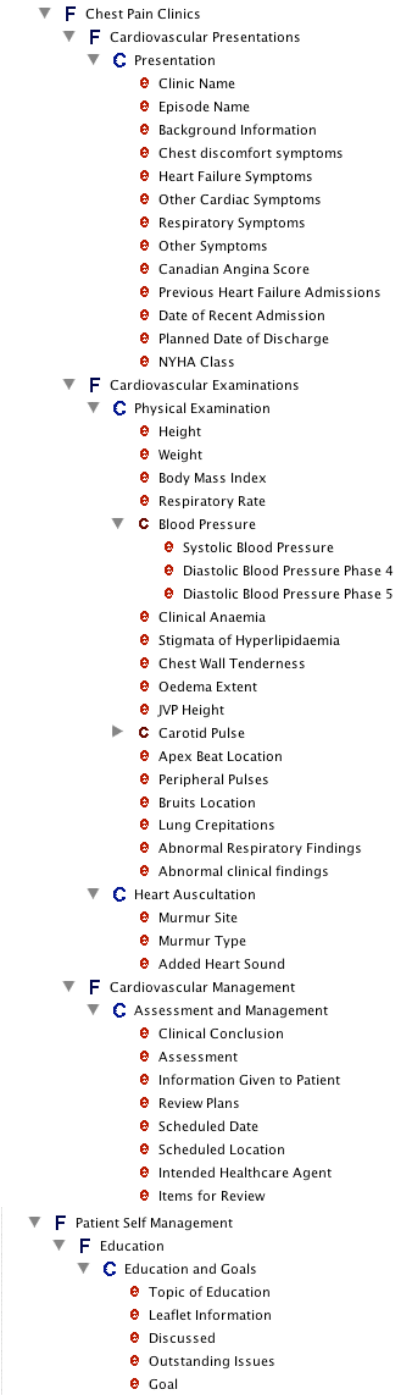


Figure 78: Rapid access chest pain clinic and heart failure archetypes

10.3.3. Medical summary

In parallel to the development of the chest pain clinic application it was agreed to develop a set of basic medical summary screens to manage a general medical summary that could be shared within the department. This summary was not intended to be particularly cardiovascular in nature, and the author drew primarily on previous work done in general practice and the east London Medical Audit Advisory Group on the design of medical summary templates.

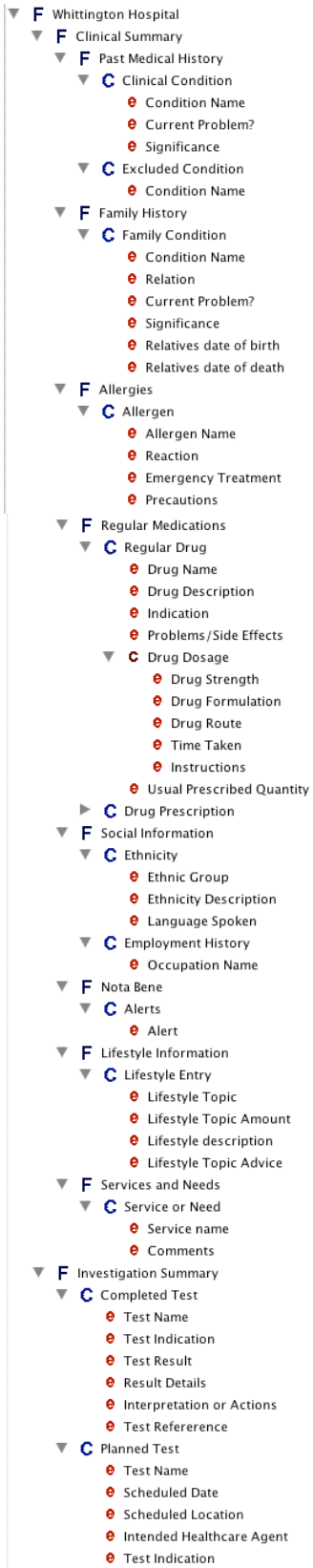


Figure 79: Basic medical summary archetypes

The medication section was envisaged as the potential future core of a prescribing system (either to be written in house or for the FHR to communicate with it) and this part of the archetype schema was defined to a fine level of detail. In contrast, the investigations part of the summary was kept fairly simple as it is intended next year to build an interface to a more sophisticated cardiac investigations application being developed by General Electric.

Two separate applications have been developed according to this archetype specification: a web-based version compatible with the cardiovascular applications described above and intended for deployment alongside the chest pain application; a WAP view-only application intended for emergency access to a patient's core medical summary. These applications are described in Chapter 11.

10.3.4. Future cardiovascular application areas

These three application areas described above, running live or about to go live at the time of writing this Thesis, are the starting points of a plan to grow a departmental cardiovascular EHR that can be accessed through a suite of web applications from a wide range of locations including wards, clinics and community settings where staff run outreach clinics. The archetype methodology, building on a comprehensive FHR Reference Model, has proved to be a highly manageable and adaptable way of designing this evolving cardiovascular record.

The Royal College of Physicians has developed an audit data set (MINAP) for the collection of data on the acute management of myocardial infarction. This is presently collected using a stand-alone application developed by the RCP, with an interface to allow its export for submission to a central data collection office. However, the application has limited functionality for the clinical department, and one possible future web application would be as a more functional replacement for this database. The author has designed the screens necessary for this, but the archetypes have yet to be defined.

As mentioned above, the Department of Cardiovascular Medicine is going ahead with the purchase of a General Electric application to provide an integrated view of the cardiovascular investigations performed using GE diagnostic equipment in the department. This application is a kind of private federation of their own equipment. It is intended in turn to federate this application repository to provide a direct link to the GE investigation from the patient's departmental cardiovascular record. This work is planned for completion during 2003.

10.4. Archetypes in other clinical domains

Asthma home monitoring

The Medicate project has been summarised in Section 5.2.9. A set of archetypes was defined in order to develop the asthma home monitoring record and web application for this.

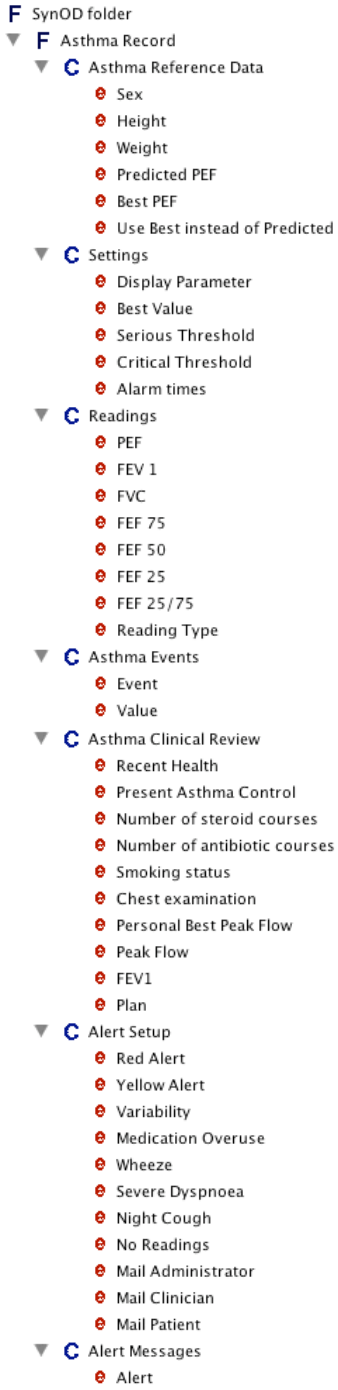


Figure 80: Medicate asthma home monitoring and disease management archetypes

These archetypes had firstly to map to the respiratory monitoring device whose internal data sets were to act as a live feeder to the FHR. Secondly, some archetypes were required to represent the

configuration of the alert settings that might be specified to be active in any individual patient by the respiratory clinician. Thirdly, some archetypes were required to maintain a permanent FHR record of any alert messages that were generated by the decision support middleware component, since this component was creating messages of medico-legal importance but had no independent persistent repository.

Diabetes shared care

Towards the end of the Synapses project (in 1999), and prior to the specification of the Archetype Object Dictionary Client, the author developed a set of archetypes to represent a patient's diabetes shared care record. This specification built on the author's activity within east and north London on steering groups to develop such data sets to support diabetes shared care in the two health districts. They drew on contemporary published work, locally developed clinical guidelines and the data structures of two successful diabetes management systems used in hospital and general practice. The archetypes were authored using a simple relational database using structures proposed by the author, which were then used to generate a set of web pages to illustrate how a future archetype library might look and function. These archetypes have not yet been taken forward in any implementation context, but the prototype web client informed the subsequent specification of the ODC.

General practice systems

The FHR service has been adopted as the EHR demonstrator for the South West Devon ERDIP project (outlined in Section 11.9). This has required a set of archetypes to be defined to represent the data extracted from GP systems. The methodology used to extract the data utilises a MIQUEST interface that is required to be present in all accredited GP systems, which specifies a generic file structure to which any GP system's clinical data can be mapped. Archetypes have been authored to match that file structure and the UCL FHR server has been updated to include these definitions.

The authoring of these archetypes has been performed largely by the local ERDIP team after some training from the author. They are not the direct work of the author, and so are not presented here. Nevertheless, it has been very reassuring to discover that the local team were quickly able to understand the archetype concept, to acquire skills at using the Archetype Object Dictionary Client as an authoring tool and to have successfully defined a set of GP system archetypes.

Chapter 11. Implementation

This chapter describes the approach that has been taken by the author and engineering colleagues to implement a federated health record service based on the information architecture described in Chapters 7-9. The FHR service has been deployed within the Department of Cardiovascular Medicine at the Whittington Hospital, which is described. An overview of a new demonstrator in progress in South West Devon as part of the NHS ERDIP programme is outlined. The same record service was used within the Medicate project for a demonstrator pilot of asthma home monitoring, which is also summarised.

11.1. FHR services, data flows and interfaces

This section outlines a set of services, data flows and interfaces that are required for communications to occur between the FHR service and the client applications and the feeder systems to which it is connected. These interfaces were originally designed in the Synapses project and have been adapted for the implementation deployed at the London demonstrator. In an ODP specification the content of this section would normally form part of the Computational Viewpoint.

Figure 81 depicts an overview of the FHR service:

- receiving requests for patient information in the form of a record from one or multiple applications; and
- responding in turn and issuing requests for patient information to information systems or EHR systems which are generally described here as 'feeder systems'.

This figure was produced by Grimson W. for the Synapses project (published in (Grimson and Groth 1996)) and has been reproduced here as it informed the early design of the FHR service. As the service needs to be managed, the concept of an administrator process is included in the figure.

The federation approach includes the concept that FHR servers can be connected to other FHR servers forming a network of servers with their own connected feeder systems. By this means local applications can gain access (under defined conditions) to foreign feeder systems that may hold relevant patient information.

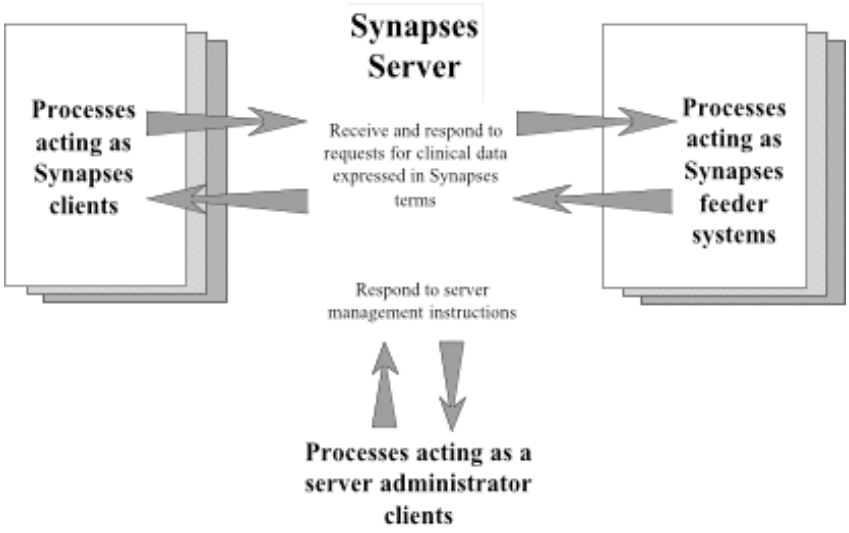


Figure 81: Concept diagram of the FHR service with connected applications and feeder systems From (Grimson and Groth 1996)

11.1.1. Data flows and interfaces

The services that need to be provided by the FHR middleware can be derived from the Use Case diagrams presented in Section 6.10.1. Figure 82 below shows the data flows that are required to satisfy those Use Cases. This diagram has been adapted from an original produced by Stephens G. and Berry D. (from Trinity College Dublin) for the Synapses project and published in (Grimson and Groth 1996).

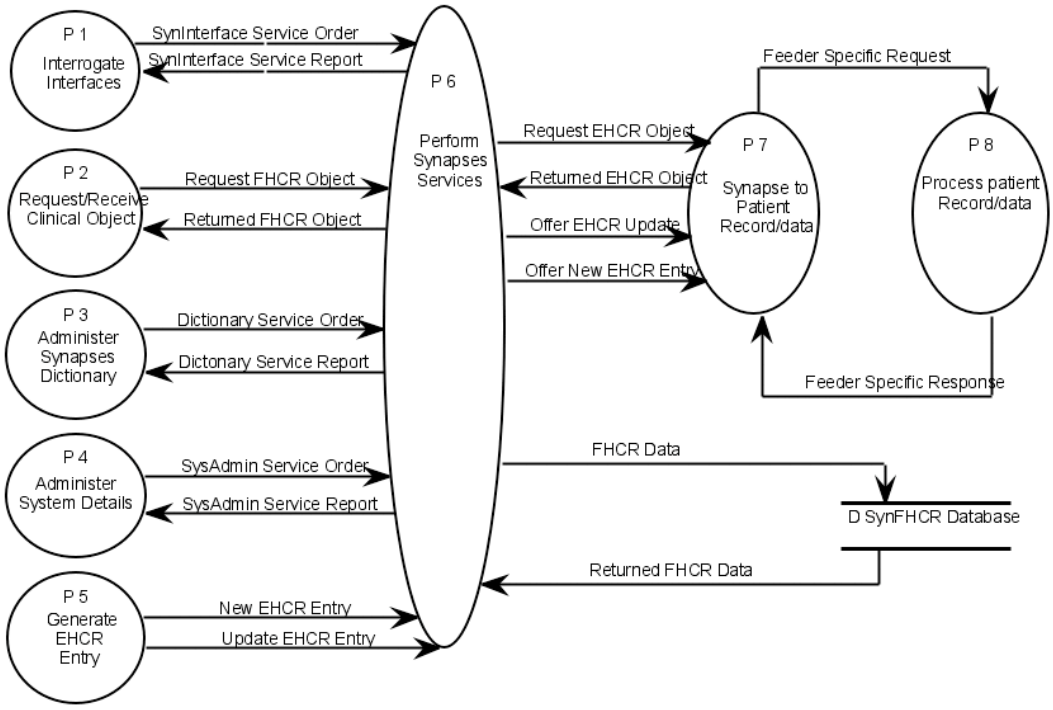


Figure 82: Data Flow Diagram showing the principal information flows to and from the FHR service From (Grimson and Groth 1996))

It is generally accepted that the definitions of client and feeder are usually "logical" rather than "physical", and that in practice these roles might be interchangeable from moment to moment depending on the specific data flows enacted. Table 12 below summarises the role of each numbered process in Figure 82.

Process Number	Process Name	Role
P1	Interrogate Interfaces	To enquire about the interfaces that are currently available from server processes
P2	Request/Receive Record Components	To request and receive record components corresponding to archetypes that have been defined in the Archetype Object Dictionary.
P3	Administer Archetype Object Dictionary	To insert, update or select archetype definitions or pointers to methods that are used to retrieve corresponding record components from feeder systems; the archetype management functions include: • add archetype • obsolete archetype • delete archetype • get archetypes • list archetype names • get archetype from synonym
P4	Administer System details	To administer access control management, naming services, audit trail specification and browsing etc.
P5	Generate FHR Entry	To update patient records or to create new entries in records.
P6	Perform FHR Services	To perform the functions internal to the service to deal with each of the other processes; i.e. to: • inform other processes of the interfaces it supports; • federate patient records; • manage archetypes; • issue requests and receive replies concerning information stored on feeder systems; • accept and process updates to patient records; • administer the above functionality in a secure and accountable fashion.
P7	Federate Patient Records/Data	To map the requested archetype to the specific notation for the relevant feeder system; to return the response data as a record components to P6.
P8	Process patient Records/Data	This process represents a feeder system.

Table 12: Principal processes within the FHR service

As this detail of definition corresponds to the ODP Computational Viewpoint each interface can be implemented either within an object oriented environment such as CORBA, Java or OLE, and/or within a standard messaging environment such as EDIFACT.

11.2. Engineering approach for the record server middleware

The following engineering approaches were adopted for implementing the UCL FHR service.

Open standards. These should enable users to share data, reduce integration costs, protect existing software investments, reduce maintenance costs, and have greater freedom in choosing their suppliers (Bryant 1995).

An object oriented approach. The anticipated advantage of treating the FHR as a set of objects is that this view corresponds closely to the actual way health record information is organised.

A middleware approach. Middleware is software that joins other software together to make them interoperable. The FHR service is ideally regarded as a middleware component as it interacts indirectly with end users through clinical applications and indirectly with databases through feeder systems. Its interfaces should equally permit interoperability with other middleware components such as decision support systems.

Java. Every major system supplier supports Java, it is internationalised, and there are API's for virtually every area of computing. The Java Virtual Machine (JVM) provides a universal layer on which Java applications can execute, which effectively makes Java applications operating system independent and thereby highly portable.

Jini. JINI, a new Java API from Sun, provides a mechanism by which any item of hardware or software service can automatically make itself available to other services on a network. Jini has been used to provide a self-managed and location independent wrapper to sub-components of the FHR service permitting, for example, the record server middleware to be run on a Linux computer whilst NDS and ObjectStore and Oracle are run on a different (Windows 2000) machine.

An object database. Since Java is capable of representing a hierarchical FHR as a Java object, it seemed plausible that an object-oriented database would offer the best performance for persistence. For functional and performance reasons, ObjectStore (from Object Design Inc.) was chosen as the core record database of the server environment.

A directory service. The directory service is now an industry standard approach to locating information about people and things through a central indexed repository. A directory service standard called Lightweight Directory Access Protocol (LDAP) has emerged to support

interoperable and cross-platform products. Sun's Java Naming and Directory Interface (JNDI) can access any directory service supporting LDAP. Novell Directory Service (NDS), being multi-platform and LDAP compliant, was chosen as the product and JNDI for the interfaces to the persons dictionary within the FHR service.

Web servlets. Java servlets enable the functionality of a 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.

XML. When the engineering work to implement the FHR service was begun in 1998 XML tools were relatively primitive and, for performance reasons, it was decided not to use XML as the internal representation of the FHR within the middleware service. The latest XML databases are now being promoted as an ideal storage choice for fine-grained hierarchical information and will be evaluated by the research team in the near future. An XML-based external interface to the FHR service was developed as part of the Medicate project.

11.3. FHR Middleware Services

The FHR comprises 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 (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.

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 are deployed on the Linux version.

11.3.1. Component engineering approach

FHR persistent cache repository

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 for optimal efficiency and performance. An Oracle version of the record server has also been developed and tested in a non-live setting in South West Devon (outlined in Section 11.9 below).

Such a cache can double as an audit trail of information processed by the FHR service, if all responses are copied to it. However, it is recognised that if the same patient record information exists in two different locations, version control problems may arise if only one of these sources is subsequently updated or amended. This problem is not unique to the FHR record database, and will arise within or between all institutions as a growing challenge as health records are shared electronically on a progressively wider scale. In the north London demonstrator use of the database has so far been exclusively as a repository by which to decommission feeder systems and legacy applications, so the problem of distributed version management has not yet arisen.

Clients

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.

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 information model for this service was described in Section 7.4.4.

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. This includes the addition of new attributes (e.g. for carer information, date of death). Figure 83 shows an example screen during the process of modifying the attributes in the schema. The relevant NDS classes (e.g. Organisational Person) were also amended to incorporate the additional attributes.

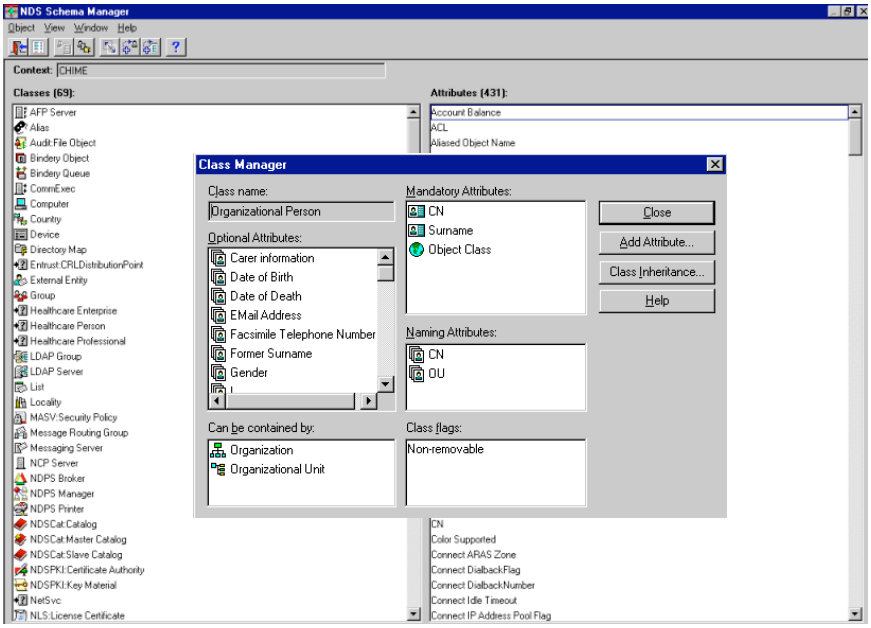


Figure 83: Modification of the Novell NDS schema

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 overall set of components and services operational at run-time within the live demonstrator are shown below in Figure 84.

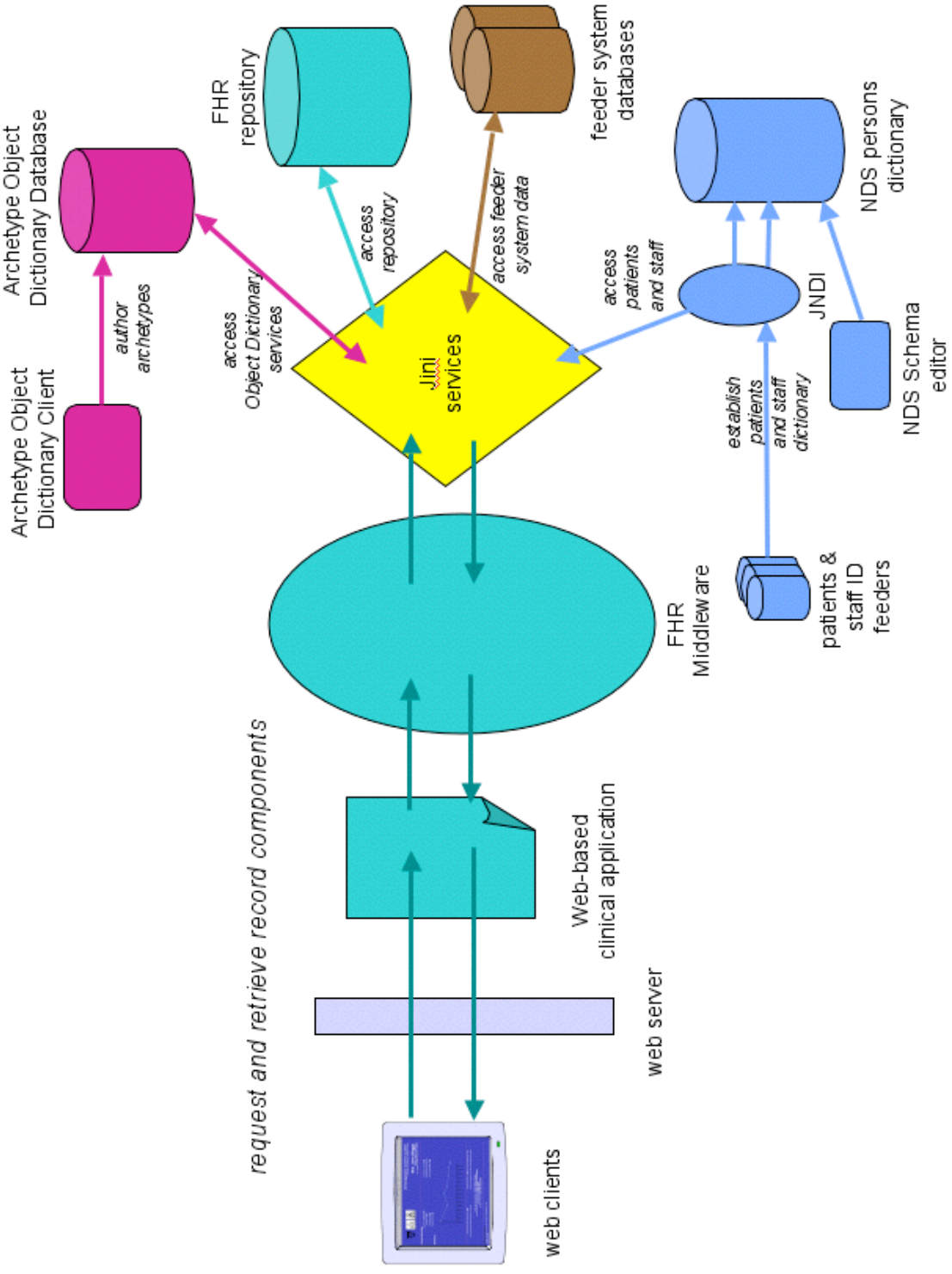


Figure 84: Core FHR components handling the run-time request for and retrieval of patient records

Automatic Updating of Legacy Servers

In situations where an end-user has generated an update or new entry and forwarded this to the FHR service, there may be occasions when an institution would wish to update another feeder system database with that new information. The automatic updating of legacy servers is considered to be particularly complex because of the need to:

- ensure that the new data complies with the data structure, content and data type requirements of the legacy databases;
- negotiate the data entry and access rights protections on the legacy server, possibly including the identification of authors not already known to its clinical systems;
- ensure patient identifiers, key fields and internal reference checks are maintained;
- manage potentially complex version control issues, including the need for transaction management and for commit and roll-back strategies in a distributed environment.

This case has so far been considered beyond the scope of the UCL implementation and deployment, although it is mentioned here for completeness and might be piloted in the future.

11.4. Overview of the north London demonstrator site

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

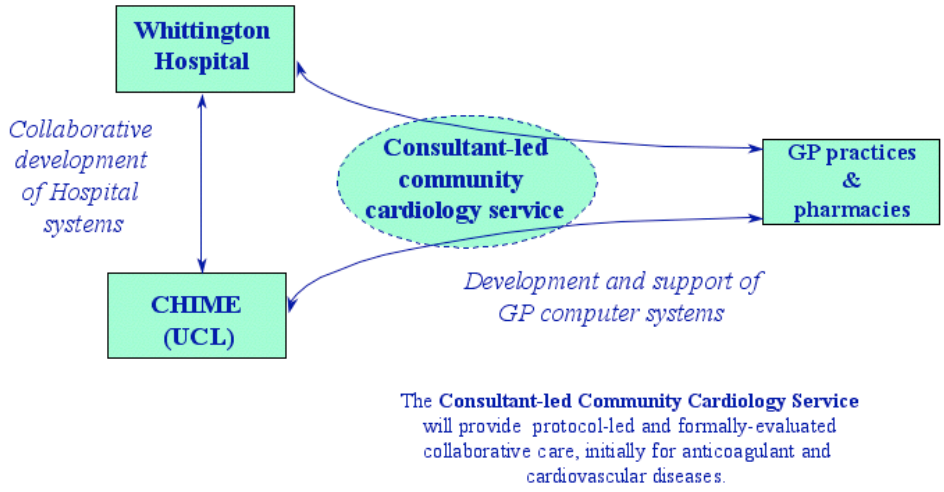


Figure 85: Partner sites in the London demonstrator

The plans for the clinical demonstrator are built on the shared use of the federated health record server. Individual clinical teams will progressively become involved as the range of web-based clinical applications is extended. It is also intended to involve several selected patients who have had training in self-monitoring and self-management of anticoagulation.

The partner sites are summarised briefly below focusing on the Whittington Hospital, which has been the principal user site to date.

The Whittington Hospital

The Whittington is a community based teaching hospital, once the largest in Europe, serving a busy and cosmopolitan part of the capital city. It has close ties with UCL and Middlesex University for undergraduate and postgraduate training, and for research. The consultants work closely with local GPs, and the hospital provides support for many GP educational activities.

The Department of Cardiovascular Medicine provides care for around 1,800 emergency inpatient admissions, almost 7,000 outpatients and co-ordinates around 20,000 cardiac investigations per annum. The department's close working relationship with The Heart Hospital (within the UCL Hospitals group) for tertiary referrals embraces cardiovascular medicine and cardiovascular surgery, and incorporates peripheral vascular as well as cerebrovascular disease. The Department has three consultants and seven junior medical staff supported by several cardiac technicians and specialist cardiac nurses trained in anticoagulation, chest pain and heart failure. A consultant in community cardiology is facilitating the development of a seamless cardiology service from the patient's home through primary care to secondary care and to tertiary care.

The FHR service needs progressively to federate many of the wide range of computer services and systems operating with in the cardiovascular medicine department, shown diagrammatically in Figure 86.

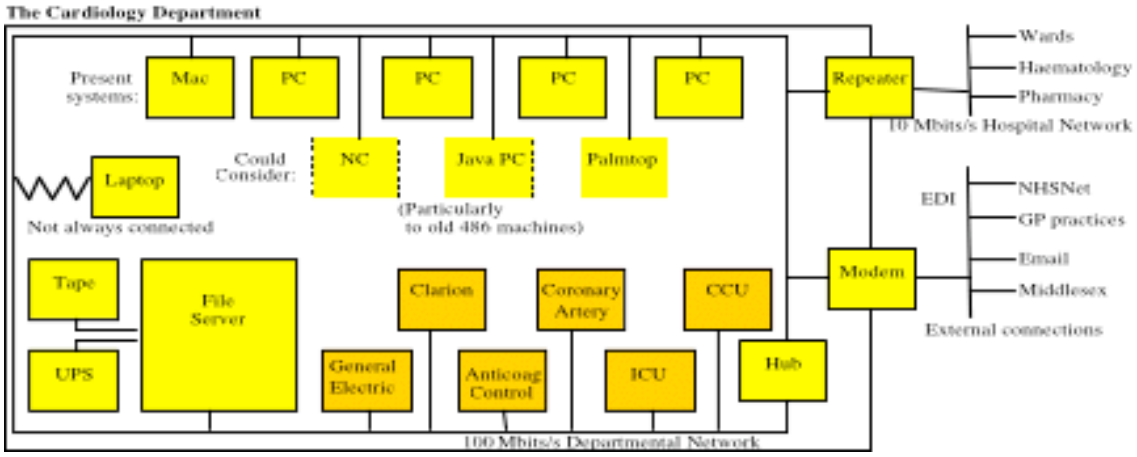


Figure 86: Overview of the present cardiology departmental IT Systems

Community Pharmacies

A selected group of north London pharmacy sites has begun to use the anticoagulant web application, running dedicated mini-clinics in the community in order to collaborate in the seamless but co-ordinated delivery of patient-centred care.

North London General Practices

Several GP practices will be recruited during the next 1-2 years to pilot Internet-based access to the web applications.

11.5. Clinical goals for the demonstrator

The north London demonstrator vision is to deliver the seamless shared care of patients with cardiovascular illness, in a managed care environment. Patients 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 will be subject to clinical and management audits, through interrogation of their federated health care records. The clinical focus of the demonstrator is in cardiology, and more specifically for outpatients (ambulatory care patients) requiring anticoagulation therapy or the investigation and management of sub-acute chest pain symptoms.

The Whittington Hospital Department of Cardiovascular Medicine already undertakes world-leading research in fields such as anticoagulation (Vadher, Patterson et al. 1997). The clinical effectiveness of anticoagulant and other drug dose advisory systems is well established (Chatellier, Colombet et al. 1998a), (Chatellier, Colombet et al. 1998b), (Walton, Dovey et al. 1999). Anticoagulant care is delivered by specialist nurses in a hospital clinic, until recently using a Microsoft Access Basic stand-alone anticoagulant advisory (decision support) application. This had been used successfully for several years and largely eliminated the need for clinic paper records to be kept except as printouts for the patient or GP. However, the legacy system was not available on-line to the wards (where anticoagulation therapy is often initiated) or outside the hospital to health professionals in the community (where patients can more conveniently be managed). The first phase of the demonstrator has been to facilitate on-line access to a new electronic advisory management system and to minimise the need for both manual and electronic entry. This system is described in Section 11.6 below; it went live in the Department and outreach clinics in June 2001, and the first community pharmacists began using it in north London in February 2002.

Chest pain clinic services are increasingly coming under National Health Service and public scrutiny, following the publication last year of a National Service Framework (NSF) for

cardiovascular health care. There is now a national challenge for hospital trusts and GP practices to collaborate in defining local care pathways and in collecting and sharing the appropriate data sets to reflect the NSF guidance. Heart disease (angina and myocardial infarction) care is presently based on the paper hospital record folder. A new web application for capturing the record of chest pain and heart failure management consultations is described in Section 11.6.

The Department has an electronic clinical database that includes referrals, diagnoses, management plans and outcomes of all patients treated for angina or myocardial infarction, accumulated over the past ten years. Experience has shown that this database is a valuable resource of background information when patients develop new cardiac symptoms, but access to it is limited to two physical settings inside the Whittington, and not at all in potential emergency community settings where it would most urgently be needed. This clinical database will shortly be federated and access to it provided by web applications.

Diagnostic investigations inside the hospital are largely performed using equipment from General Electric/Marquette. The GE MUSE system now has over 350,000 ECGs, 24-hour tapes and stress tests. A new integration database and web-based application has been developed by GE Medical Systems (Europe) and will be installed during the next year. The integration of this multimedia repository with the cardiovascular FHR server is a medium term goal for the demonstrator.

Patients requiring careful management of symptoms, physiology or function will need to communicate changes in self-monitored readings to their clinical team. In order to achieve this level of partnership, patients will require the access to a summary record, planning and reviewing of investigations, access to decision support advice and treatments given including medication. The latest generation of PDAs with a secure mobile link to the Whittington's (web-based) FHR services would in future allow the delivery of this kind of patient care.

11.5.1. The anticoagulant legacy application

The former anticoagulant application incorporated a Microsoft Access database with records for 2,500 patients accumulated over nearly ten years. The mapping of this database schema to archetypes has been described in Section 10.3.1. Specific feeder system import code was written to extract the demographic details of each patient to add to the persons directory and the clinical records of each patient to add to the ObjectStore persistence repository as his initial FHR. This latter mapping included the decoding of various look-up values in order to ensure that the health records created were comprehensible without reference to any external (locally developed) coding schemes.

Although the import took longer than expected because of the slow performance of the ObjectStore database, the process of importing the legacy data was successful in that all of the

required information was successfully brought into the FHR and after nearly one year no instances have yet been found of erroneous mapping or missing information.

This federation is an example of decommissioning a feeder system.

11.6. Cardiovascular web-based applications

The set of clinical applications presently or nearly operational within the north London demonstrator are:

- anticoagulant clinical management application;
- sub-acute chest pain and heart failure clinical management application;
- general medical summary application for use within the department;
- medical summary WAP application for emergency medical use, on hand-held computers (PDAs);
- medical summary and personal diary for patient use (PDA version similar to 4a above)

These have been developed as a set of web based or WAP applications running from a single web server, which also hosts a set of record services, directory services and some authentication and access control services (Kalra, Milan et al. 1998b). The medical summary WAP application will specifically be targeted for delivery to mobile users, such as GPs in patients' homes and patients themselves. The individual web applications are summarised below.

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 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 120 patients per day. It is also accessed from outside the hospital by two community pharmacists who have each begun to deliver anticoagulation services to a selected client group, and it is hoped to include other pharmacists, GPs and patients as users within the next 12 months. Only some of the FHR record component objects and attribute values are shown on the user screens, to meet the needs of the users who run the anticoagulation clinics at the Whittington.

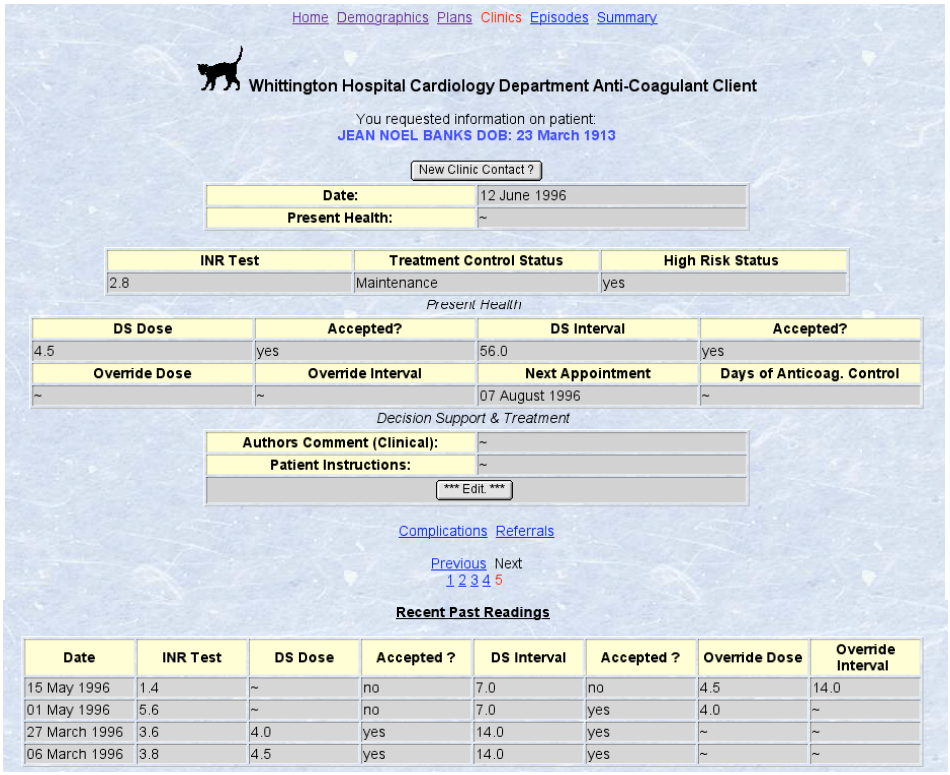


Figure 87: Anticoagulant client - viewing a clinic contact

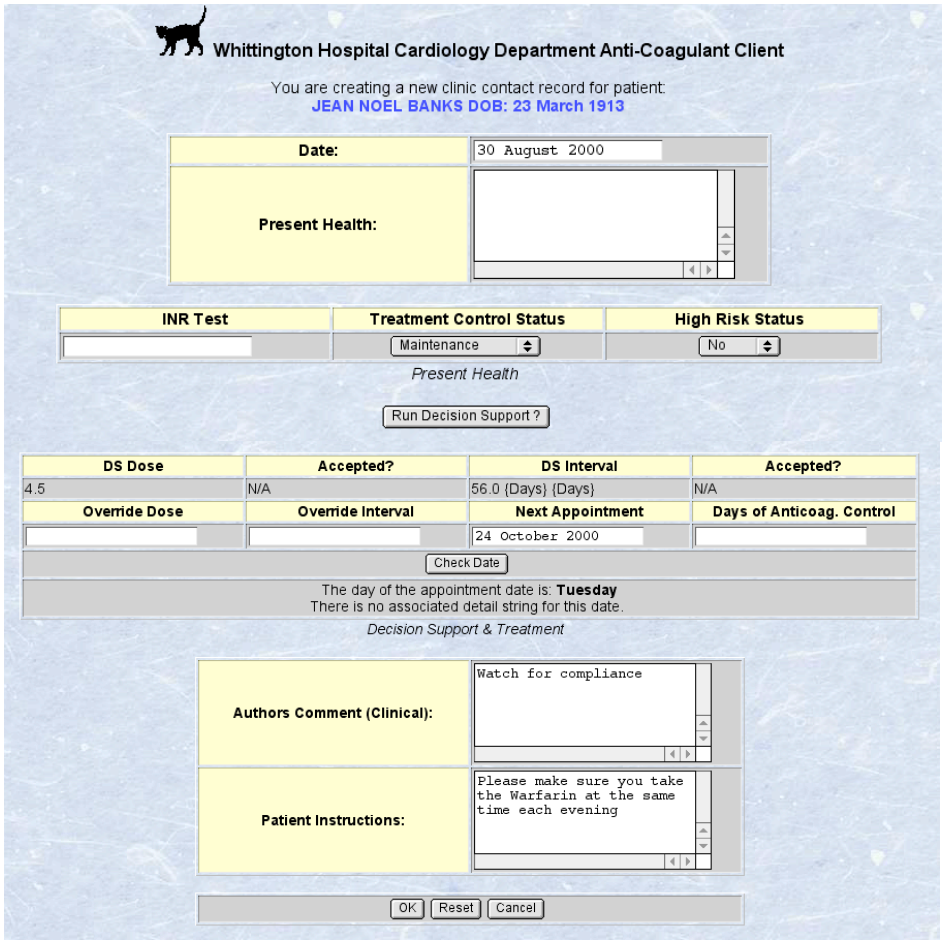
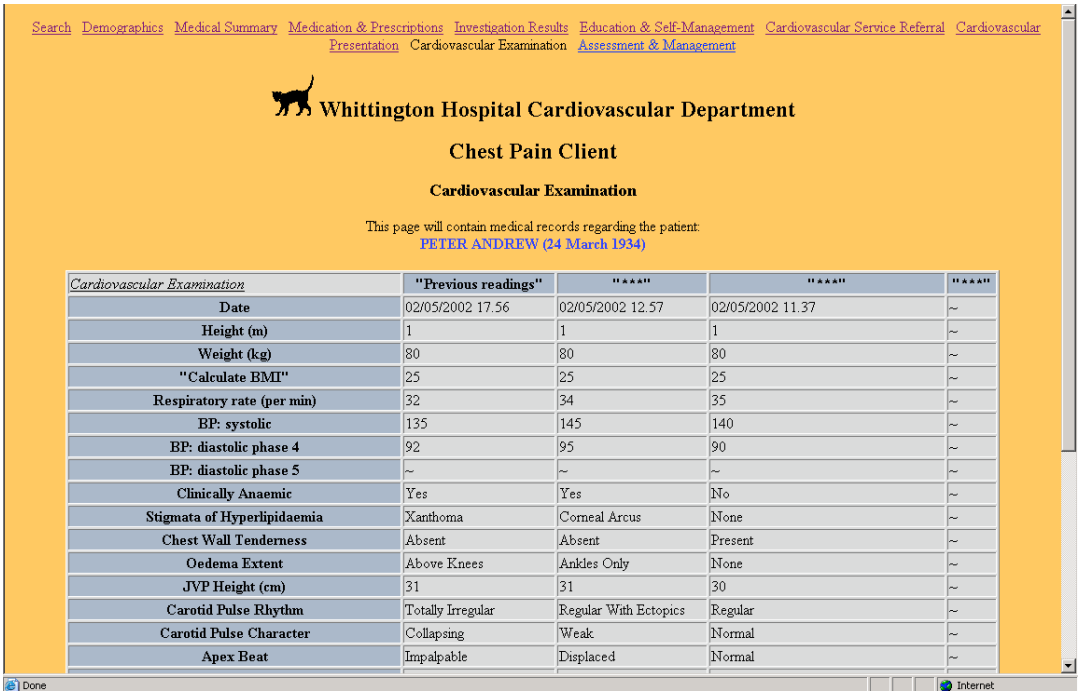


Figure 88: Anticoagulant client - entering a new clinic contact

A full screen-by-screen description of the anticoagulant application is given in Appendix B. Data from the new anticoagulant system has not yet been included in clinical outcomes evaluations but will be shortly.

Rapid Access Chest Pain Clinic (RACPC)

A new application has been written to provide clinicians inside and outside the hospital with access to the record of patients having non-acute or sub-acute chest pain (i.e. possible heart disease) symptoms. The primary clinical application has been hosted on the same FHR server as the anticoagulant system, and shares the same core middleware services. The application will shortly be going live and will initially be used by nurse specialists providing a Rapid Access Chest Pain Clinic service and a heart failure assessment service within the hospital and at patients' homes. The intention is for this application to be accessed in future from a wide range of workstations inside the Whittington Hospital and from selected GP practices. Figure 89 shows an example screen (populated with test data).



Cardiovascular Examination	"Previous readings"	"***"	"***"	"***"
Date	02/05/2002 17.56	02/05/2002 12.57	02/05/2002 11.37	~
Height (m)	1	1	1	~
Weight (kg)	80	80	80	~
"Calculate BMI"	25	25	25	~
Respiratory rate (per min)	32	34	35	~
BP: systolic	135	145	140	~
BP: diastolic phase 4	92	95	90	~
BP: diastolic phase 5	~	~	~	~
Clinically Anaemic	Yes	Yes	No	~
Stigmata of Hyperlipidaemia	Xanthoma	Corneal Arcus	None	~
Chest Wall Tenderness	Absent	Absent	Present	~
Oedema Extent	Above Knees	Ankles Only	None	~
JVP Height (cm)	31	31	30	~
Carotid Pulse Rhythm	Totally Irregular	Regular With Ectopics	Regular	~
Carotid Pulse Character	Collapsing	Weak	Normal	~
Apex Beat	Impalpable	Displaced	Normal	~

Figure 89: RACPC client – viewing cumulative physical examination data

Medical Summary

Several web screens have also been developed to provide an overview of a patient's basic medical history. These are intended for shared use by the various nurse specialists and by doctors running the cardiac outpatient clinics within the hospital. It is hoped that the experience gained in piloting this application will be a candidate approach for a hospital wide electronic medical summary in the future, to be shared with local GPs. Figure 90 shows an example screen with test data.

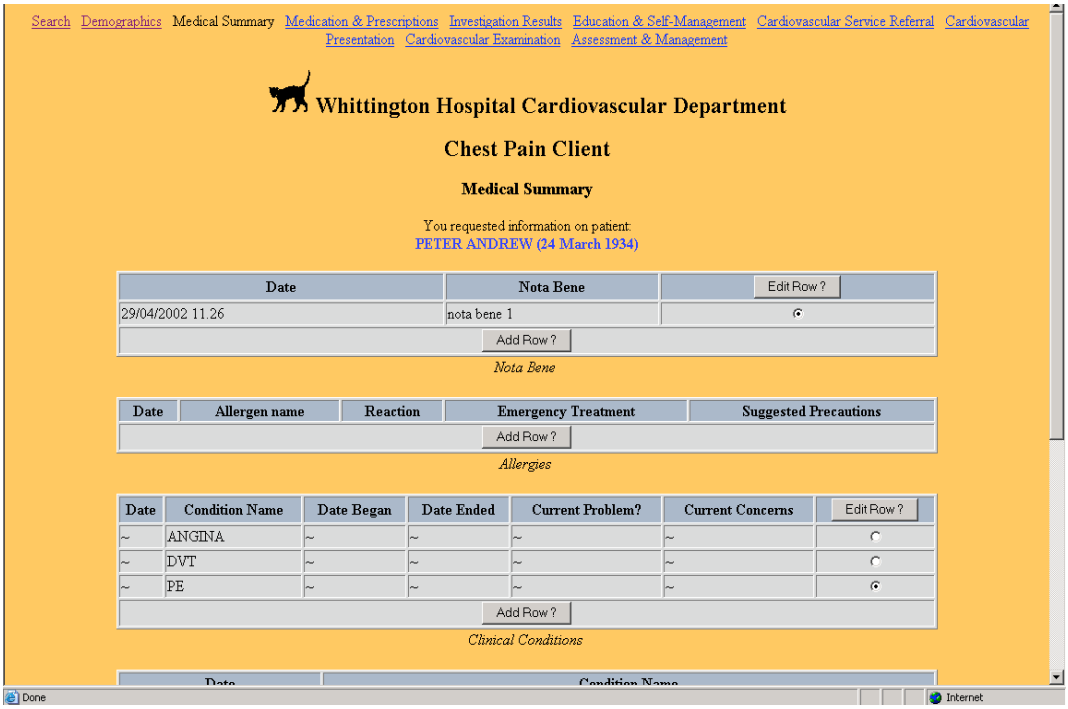


Figure 90: Medical summary web application – part screen showing allergies and principal conditions

Mobile views

Two WAP views of the medical summary record have been developed, one for emergency care (a summary) and one for patients who wish to view their own record. The emergency view is expected to be a helpful demonstration of secure mobile use of the IPv6 networks (see Section 11.7 below), and is a high-profile strategic goal of the UK Department of Health.

Figure 91: Medical summary WAP application – the main (root) page of a patient's record

The chest pain and medical summary applications are described more fully in Appendix D.

11.7. Demonstrating IPv6 and wireless access

The 6WINIT project has been described in Section 4.3.7. The UCL FHR demonstrator has been extended to exploit the opportunities presented by wireless Internet services and IPv6. The cardiovascular applications described in Section 11.6 above are being demonstrated within a set of clinical scenarios illustrating requirements for distributed and mobile access to the patients FHR, for example at the roadside scene of an accident.

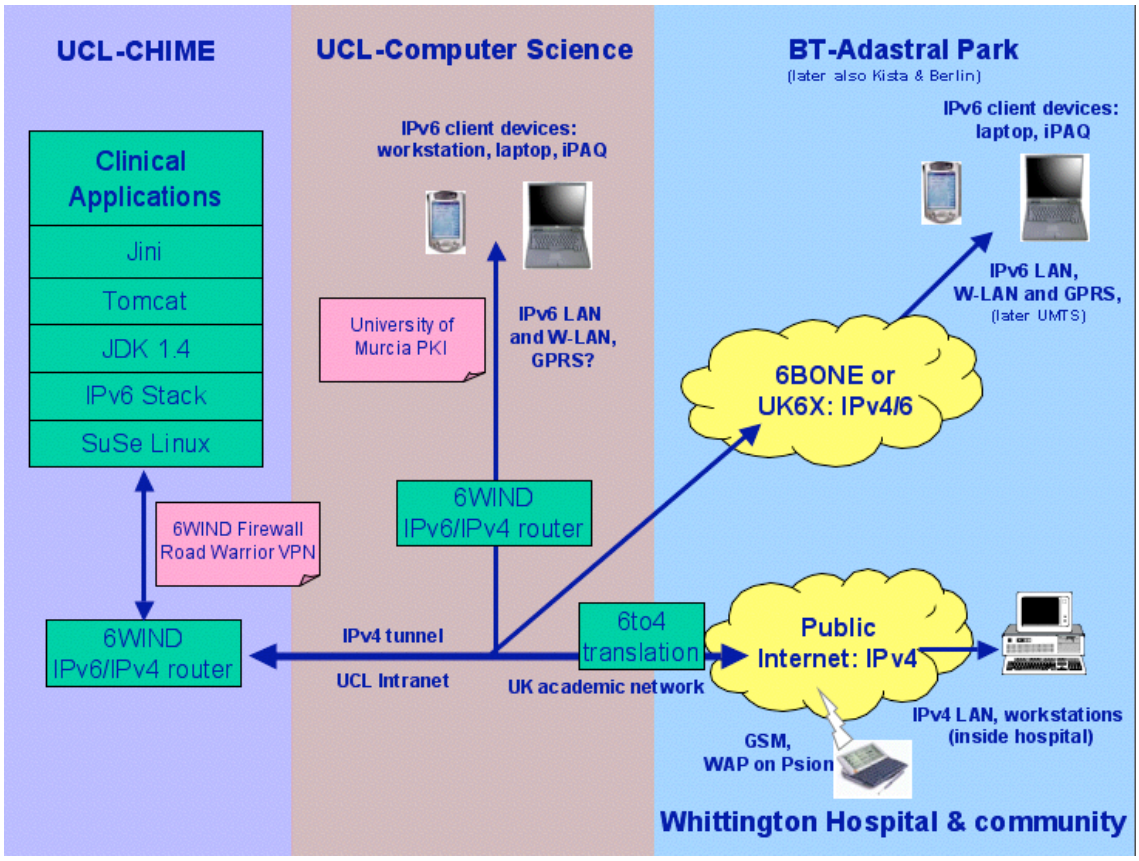


Figure 92: Network architecture of the London demonstrator site

Figure 92 above shows the principal clinical application (health record) services, located at CHIME, being delivered via an IPv6 stack infrastructure, communicated to UCL Computer Science and routed forward to the public Internet and to new IPv6 networks (6BONE and UK6X). The communications pathway involves the use of some IPv4 networks, such as the UCL Intranet connecting CHIME in north London to Computer Science in central London, and the public Internet. The technology description of the live demonstration given at the first 6WINIT technical review in Adastral Park, Ipswich, is shown diagrammatically in Figure 93.

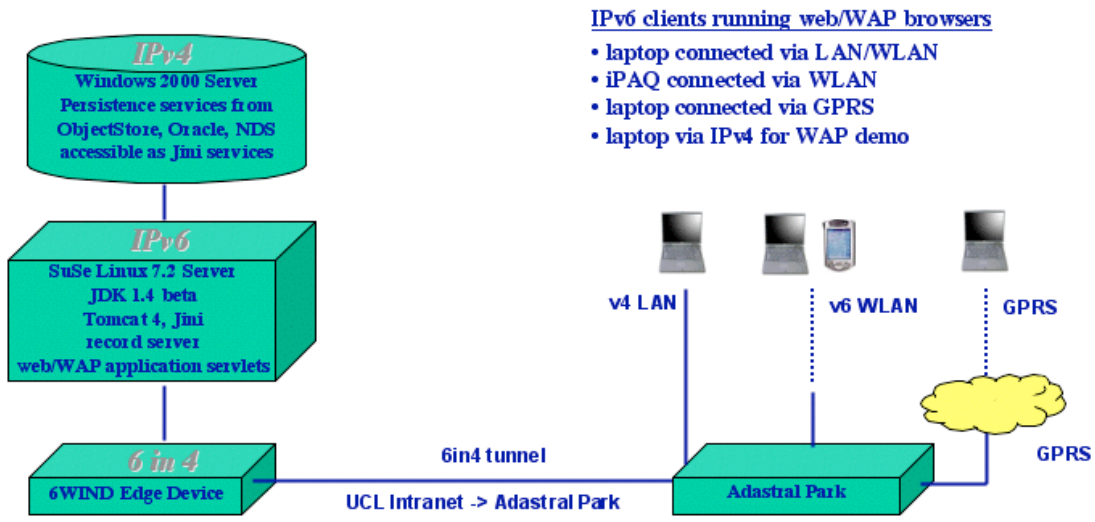


Figure 93: Network configuration of the demonstration given at the 6WINIT Technical Review

IPv6 transition mechanisms are an important component of this demonstrator, since the hospital staff working in the Whittington will require translation to enable IPv4 "legacy" access from existing their devices and networks.

Security requirements include the use of end-user authentication, certificate handling (using PKI) and encrypted data flows. In practice, it has been agreed that the demonstration will only use pseudonymised data to permit the gradual introduction of security measures independently of other aspects of the 6WINIT network architecture during 2002.

11.8. Asthma home monitoring

The Medicate project has been summarised in Section 5.2.9, and the archetypes defined by the author to represent the asthma home monitoring record in Section 10.4. The Medicate demonstrator included a Disease Management System that was developed by the author and colleagues as an asthma FHR system (utilising the same components as described earlier in this Chapter), two middleware components providing alerting services and e-mail alert generation, and a web application providing clinicians with a view of their patients' asthma management records. Figure 94 below shows the core components of the UCL asthma management system.

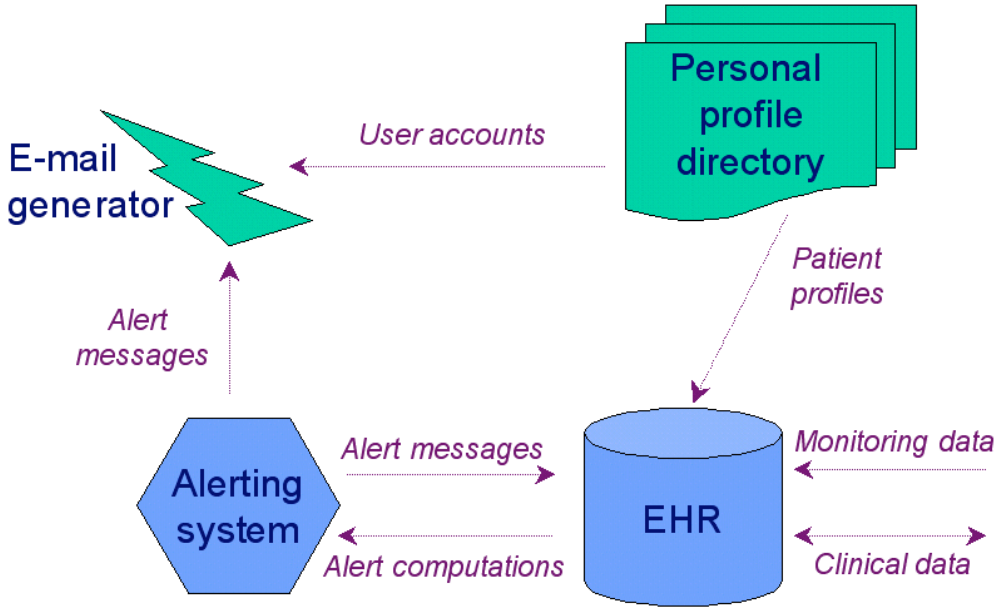


Figure 94: Core components of the Medicate asthma management system

The FHR service 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 component to send 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.

This demonstrator was installed at a secure server farm in Brentford on the premises of Cable and Wireless (the project co-ordinators). The project time-scale did not permit a full trial of the completed system; however, the demonstrator was technically completed and tested (see Figure 95 below).

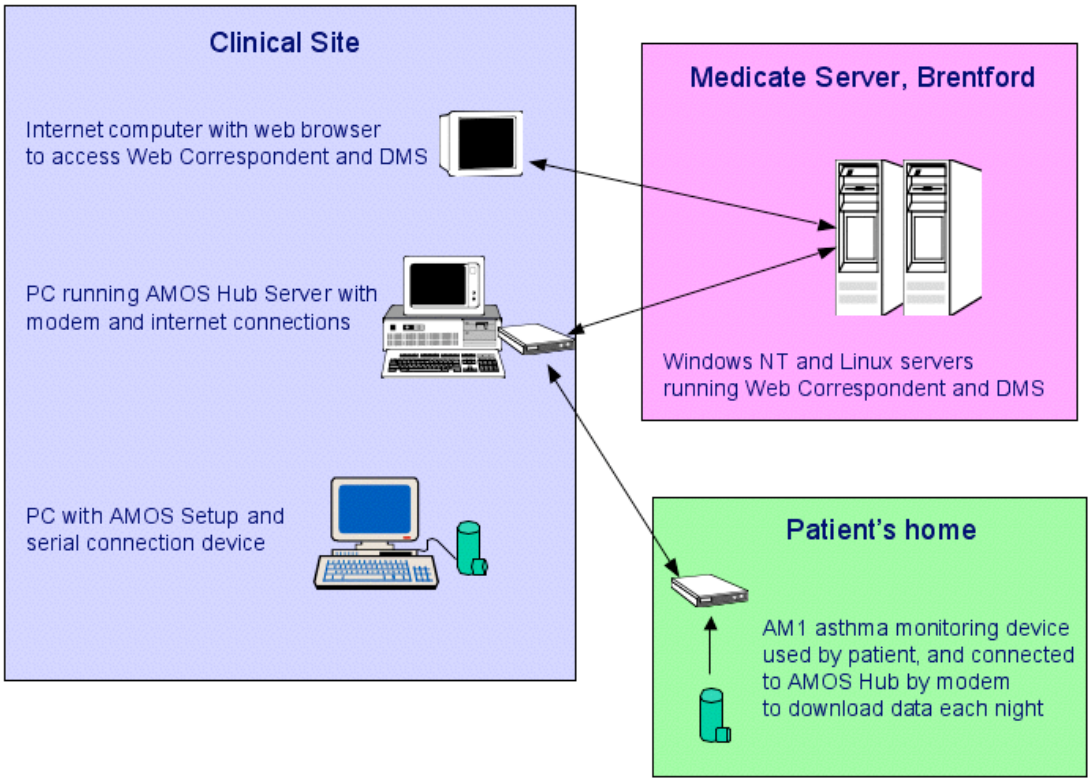


Figure 95: Overview of the configuration used for testing and demonstrating the Medicate system

This demonstrator, although not tested in a live clinical setting, has provided further proof-of-concept verification of the information architecture and of the potential exploitation opportunities for the FHR service. A fuller description of the Medicate system and web application is given in Appendix C.

11.9. South West Devon ERDIP

The UCL record server components form the EHR heart of the South West Devon ERDIP project. This demonstrator is developing a cardiovascular FHR to be connected to local feeder systems and delivered to end users through web applications. The feeder systems are a set of Devon GP practice systems and will include one or two clinical database systems (to be confirmed) at the Derriford Hospital in Plymouth. Because of the organisational problems associated with providing live clinical data in operational systems to users who already have existing clinical systems, the demonstrator is at this stage presenting anonymised patient records as a proof-of-concept. This will enable clinical users to interact with the cardiovascular FHR through the enactment of case scenarios.

In order to develop this demonstrator, the Devon ERDIP team have authored a set of archetypes to represent the data extracted from GP systems (as outlined in Section 10.4). A commercial

software development company has designed and implemented the web applications to present the general practice and cardiovascular health record. This has been a valuable first opportunity to communicate the details of the FHR service to a third party and to obtain their feedback on the overall approach and quality of the engineering work of the UCL team. The demonstrator is expected to being importing feeder data and for users to begin interacting with the web application during May 2002.

The FHR server infrastructure has been transferred to South West Devon, where an independent copy of the entire system is now running. This has also provided verification of the portability of the approach and of the engineering.

Chapter 12. Validation

12.1. Introduction

The proposals presented in this Thesis comprise primarily a set of requirements and information models for representing a patient's federated health record and for implementing an FHR service, as described in Chapters 6-9. These derive substantially from a ten year R&D journey undertaken by the author and colleagues, complemented by parallel work in this and related fields of health informatics as summarised as literature reviews in Chapters 3-5. The implementation and demonstration results are described in Chapters 10-11. This chapter discusses the validity of the requirements and information architecture in the light of the demonstration results, and their compatibility with other parallel work in this field.

As was discussed in (Section 2.6) the evaluation of a set of requirements statements and information models cannot readily be based on qualitative or quantitative assessments by the clinical end users of the demonstration systems. This is because the users' perceptions of "the system" would primarily be the visual appearance, functionality and performance of a set of web applications. These applications are in turn serviced by the software implementation of the FHR middleware components; these components are the real "users" of the information architecture specification. The experience of interacting with the Whittington Hospital clinical team, who are using the demonstrator to manage anticoagulant clinics inside the hospital and remotely in community settings, is that their primary concerns have been about overall system performance, and the need for additional customised reports and additional features within the web applications.

This evaluation problem is common to all middleware *specifications* (as opposed to middleware component implementations) and, as discussed in (Section 2.6), was explored in the Synapses project where a KAVAS cyclical evaluation methodology (O'Moore R., Doyle O. et al. 1995) was adopted with feedback loops from requirements and implementation phases to refine the middleware specifications. This approach has been adopted in the work presented in this Thesis through a succession of EU projects each of which has elicited requirements in a different way and implemented separate prototypes (through different vendors working at a range of sites across Europe). Each such cycle has helped to validate and refine the information models presented here.

For the specific results presented in the Thesis, the proposed criteria for successful validation are:

<u>for FHR requirements:</u>

- that they have been consistently confirmed across different professions and clinical domains (i.e. that they are *generic*);

- that they correlate with publications from other groups in this field;
- that they have been able to underpin the information architecture;

for the FHR information architecture:

- that this approach has influenced other published models, for example, CEN EHCR standards;
- that it has been possible to design archetypes that can map a range of legacy clinical databases and applications (i.e. that the approach is *generic*);
- that it has been possible to implement the FHR services in a practical demonstration setting.

The remainder of this chapter considers each of these criteria in turn.

12.2. FHR Requirements

Consistency

The requirements presented in Chapter 6 provide a functional specification of the FHR service and list the clinical, ethico-legal and technical requirements that such a service must meet. These requirements have been published as precursors through a succession of project deliverables and summarised in papers over several years. The collective inputs to the investigations of these have included a wide range of different healthcare professionals, health service managers, systems developers (at healthcare sites and vendors) and informaticians. The clinical inputs have spanned many different disciplines in primary, secondary and tertiary care, from a variety of settings across Europe.

Correlation with other work

There is collateral confirmation of their validity through similar statements of requirements in the publications of other projects, as summarised in Section 6.1. More recently, the UK Royal College of Physicians has published a draft set of requirements for secondary care EHR systems (Academy of Colleges Information Group 2002), and the NHS Information Authority has released a more extensive draft set of EHR requirements (ERDIP Team, NHS Information Authority 2002). The author has reviewed both of these, and although they each contain a mixture of requirements for EHR information, EHR systems, clinical applications, coding schemes etc. those statements that are applicable to EHR information *per se* are compatible with those listed in Chapter 6.

The present active work in ISO, which is now nearing a full Technical Specification, confirms that the goal of producing a generic set of EHR requirements is accepted internationally as both useful and achievable. The author has reviewed successive drafts of this, as well as feeding into it. Whilst recognising that any standardisation process has to include many compromises in the interests of harmonisation, it is the opinion of the author and colleagues who have reviewed both that the

requirements presented here have significant overlap with but are probably richer than the ISO specification.

Underpinning of the Information Architecture

Each class and attribute of the FHR Reference Model and Archetype Model has been included to meet one or more of the requirements statements listed in Chapter 6. It is difficult to reproduce here a complete mapping of the requirements statements (numbering over 400) with the features of the FHR Reference Model and Archetype Model (which include over 100 classes and attributes). The author has performed this task at various times during the different phases of the implementation, and whilst writing up this Thesis. As an example of the analysis undertaken, Table 13 in Section 12.3.1 below lists the key features of the FHR Reference Model classified by area of requirement, comparing the RM with two generations of CEN standard.

12.3. FHR Information Architecture

The model as described in Chapter 7 has been developed to comply with the requirements in Chapter 6, and is the fourth iteration of such an information model, building on the prior experiences of the GEHR, Synapses and EHCR-SupA projects. It has been informed by other publications such as the previous CEN pre-standard ENV 12265, and in turn informed the current pre-standard ENV 13606.

The ability to implement a working FHR service based on the model provides evidence of its technical rigour and contributes towards evidence of its completeness. However, several described features of the Reference Model have been implemented but not rigorously tested, because the demonstrator domains did not require or exploit those features, in particular:

- the use of the Link Item to establish linkage networks;
- the two View classes;
- the storage of bulky data such as photographs and images;
- a definitive set of access control features.

12.3.1. Comparison of the FHR-RM with CEN standards

Through the Synapses project, the 1995 CEN EHCR architecture pre-standard (ENV 12265, summarised in Section 7.2.2) was adapted to suit the comprehensive requirements identified for a federated health record architecture. During the course of the subsequent implementation at UCL an independent CEN Project Team published the current CEN pre-standard for EHCR Communication (ENV 13606, summarised in Sections 5.5.1 and 7.2.5). Although informed by the publications of EHCR-SupA and Synapses, the synthesis by that Project Team represents an

objective peer review of the key inputs to the FHR Reference Model. A comparison of this model with those published in ENV 12265 and in ENV 13606 therefore provides another form of evaluation. Table 13 below presents this comparison.

The complete list of requirements published in Chapter 6, although theoretically ideal, is too long to provide the basis for this comparison. The set of contexts described in Section 6.9 has been used as the framework for this table, supplemented by the main headings under which the requirements statements have been grouped within Sections 6.3 to 6.6.

A detailed analysis of each class and attribute in both models is similarly too detailed and would be difficult to assimilate. The table therefore presents a descriptive comparison of the architectural approach taken in the FHR-RM, ENV 12265 and ENV 13606 to each of the listed requirement contexts. Where specific constructs of each model are referenced the notation used in the table is **ClassName**.*AttributeName*.(data type).

Requirement context	FHR Reference Model	ENV 12265	ENV 13606
Composition context			
Medico-legal unit of contribution	**Composition**	Not distinguished	**Composition**
Both narrative and structured entries	Defined using archetypes	Not distinguished	**Text Data Item** for narrative entries
Record entry names	*Name*.(string) and reference to archetype name and definition	*Name*.(not typed)	*ComponentNameStructure* .(code) but no specified source of coded terms
Compounding hierarchies	**Compounds** containing **Compounds** and/or **Elements**	**Record Item Complexes** containing **Record Item Complexes** and/or **Record Items**	**Clusters** containing **Clusters** and/or **Data Items**
Grouping hierarchies (headings)	**Headed Section**, which may be nested	**Record Item Complex** not further specified	**Headed Section**, which may be nested
Derived views of original information	**View1** (executing a query) and **View2** (containing references)	**View sub-type1** (executing a query) and **View sub-type2** (containing references)	**Selected Component Complex** containing either a query or references
Data value context			
Text entries	Permitting either narrative or coded term entries	Value attributes not specified	Specific classes for narrative or for coded terms
Natural language	String attribute for any text entry	Not represented	Coded value (ISO code) for any class in the record hierarchy

Coded terms	Code and rubric and a concept code	Value attributes not specified	Code and rubric
Qualifiers	Additional code values	Not represented	*Additional related text* or a **Composite Code**
Term sets, versions, registering agencies	Fully specified as attributes	Not represented	ISO term set identifier
Quantities, ranges and ratios	**Quantity** for single values and ranges**,** and **Numeric** for ratios	Value attributes not specified	**Measurement, Measurement Range,** but ratios not represented
Accuracy and precision	Both represented	Not represented	Not represented
Units	**Unit**.(string) and exponent	Not represented	Units as a coded term
Reference ranges	Not represented	Not represented	upper and lower values
Date and time intervals	Both including imprecise dates	Not represented	Both including imprecise dates
Time series and other sequence data	Not represented	Not represented	Not represented
Graphical	Referenced	Value attributes not specified	Basic information
Multimedia	Classified by MIME type	Value attributes not specified	Basic information
Persons	Persons directory: simplified demographics	Value attributes not specified	**Healthcare Agent** and **Party** classes: comprehensive demographic and role attributes
Devices	Devices directory: simple register	Value attributes not specified	**Healthcare Device** class: simple register
Reasoning context			
Presence or absence	Boolean for any **Element** value	Not represented	Component annotation in Domain Termlist standard (value set)
Certainty	Boolean for any **Element** value	Not represented	Component annotation in Domain Termlist part-standard (value set)
Healthcare activity lifecycle	Value set for any **Element** value	Not represented	Component annotation in Domain Termlist part-standard (value set)
Clinical circumstances	String for any **Element** value	Not represented	Not represented

Emphasis or exceptional findings	Boolean for any class in the record hierarchy	Not represented	Not represented
Justification, clinical reasoning	String for any **Element** value	Not represented	Not represented
Supplementary author's comments	String for any class in the record hierarchy, restricted to use by the author of a new entry or a revision	*Comment* attribute for any class in the record hierarchy	Comment Item class may have separate authorship and date/time of recording from the entry being commented
evidence based care	String for any **Element** value, naming a protocol and/or step	Not represented	Not represented
external knowledge reference	String for any **Element** value	Not represented	Not represented
Ethico-legal context			
Subject of care	Specified for all classes in the record hierarchy (must be the patient)	Specified for all classes in the record hierarchy (must be the patient)	Specified for all classes in the record hierarchy (must be the patient)
Subject of information	Specified for all classes in the record hierarchy (value set)	Not represented	Component annotation in Domain Termlist standard (value set)
Information provider (person)	Optionally specified for all classes in the record hierarchy (string)	Not represented	Any number of related healthcare parties may be defined but their relationship is an unspecified string
Information provider (device)	Optionally specified for all classes in the record hierarchy (string)	Not represented	Any number of related healthcare parties may be defined but their relationship is an unspecified string
Author	Specified for all classes in the record hierarchy	Specified for all classes in the record hierarchy	Specified for all classes
Responsible clinician	Authorising and legally responsible clinician optionally specified for all classes	*Responsible Health Care agent*	Any number of related healthcare parties may be defined but their relationship is an unspecified string
Students and non-clinical authors	May be the recording agent	Not represented	Any number of related healthcare parties may be defined but their relationship is an unspecified string
Date and time of recording	Specified for all classes in the record hierarchy	Specified for all classes in the record hierarchy	Specified for all classes in the record hierarchy

Dates and times of health care events	Dates of the healthcare activity and of the observation, may each be an interval and may be imprecise	Not represented	Any number of related dates and times may be defined but their relationship is an unspecified string
Location of care	Locale attribute recorded for all classes in the record hierarchy, plus optional string attribute	Not represented	Optionally specified for all classes (string)
Data presentation	Not represented	**Presentation** attribute described but not specified	**Presentation** class with simple placeholder attributes
Revision management	Only certain internal identifiers may be directly modified; all other changes to any part of the record structure hierarchy constitute a new version, linked to the preceding version and subsequently to any succeeding version	*Revised version* attribute links a revision to the original version	**Revision Information** class contains a reference to preceding versions of any part of the record structure hierarchy
Authentication	Interface to an external authentication service	Not specified	**Attestation** class; digital signatures can be communicated within the EHR
Access control	Sensitivity level specified for all classes in the record hierarchy	Not specified	Special **Distribution Rule Reference** class relating to the Distribution Rule part-standard
Audit trails	records all accesses and modifications, including user and role	Not specified	Not specified
Care process context			
Problem links	**Link Item** can be used to establish a linkage network	Not specified	**Link Item** can be used to establish a linkage network
Episode grouping	**Folder** class (prospectively) or the **Link Item** (retrospectively)	**Record Item Complex** class could be used prospectively	**Folder** class (prospectively) or the **Link Item** (retrospectively
Links between entries	Direct links can be established between any pairs of classes, or through the **Link**	Not specified	**Link Item**

	Item		
Links between records	Not represented	Not represented	Not represented

Table 13: Comparison of the FHR-RM with CEN EHCR standards

A detailed discussion of this table is not possible here, but in summary the UCL FHR-RM corresponds closely with or is more complete than ENV 13606, both of which are significantly richer than the original foundation pre-standard ENV 12265. Given this, it is believed by the author and the research team that the UCL implementation could be classed as ENV 13606-conformant in that an extract conforming to that standard could be derived from the FHR. This implementation is, to the author's knowledge, the most complete clinically working implementation of ENV 13606 in Europe.

The appointment of the author to lead the Task Force to revise ENV 13606, drawing on work and experience gained in the field through the work reported here, is an external peer affirmation of the validity of the goal, of the approach that has been taken and of the results obtained.

12.4. The Archetype approach and model

The archetype approach described in Chapter 8 builds on:

- the recognition by the GEHR and I4C projects that a very generic information model for the EHR needs to be complemented by a formal method of communicating and sharing the named hierarchical structures within EHRs and the data types that values may take in order to ensure interoperability;
- the definition of metadata dictionaries for health record components pioneered by several US academic medical centres and by the Royal Marsden Hospital in the UK;
- the well-established computer science concept of an object dictionary to represent the database schema of a feeder process (system or application) contributing information within a federation;
- the empirical work of several Synapses validation sites developing and evaluating clinical object dictionaries.

The archetype methodology arose semi-independently in research work in Australia, resulting in a complementary model and archetype authoring tool. This work is now being integrated with the approach described here, drawing on the joint experience gained.

The validation of the archetype approach is partly through its parallels with other work in the field, and partly through its ability to apply its generic model to represent the specific clinical data schemata in a range of different existing systems.

There is no absolute number of different such schemata that could robustly prove that it is a generic approach. The FHR Archetype Model in Chapter 8 has been able to represent EHR requirements within cardiology, diabetes, general practice and asthma monitoring as presented in Chapter 10. These fields have included existing legacy databases and new web applications, both of which serve as examples of schemata corresponding to user requirements. The ability to import over 2,500 anticoagulant records from one schema and to successfully re-present these via a new web application conforming to an updated schema does evidence the soundness of the mapping that was performed. The Rapid Access Chest Pain Clinic schema was based upon the published National Service Framework, showing the ability to accommodate an evidence-based data set. The Australian archetype approach has been used to represent the schema of a laboratory data warehouse, a leading general practice system and to support diabetes shared care.

Whilst by no means an exhaustive set, these examples do reflect a range of different clinical settings. Ideally many more should be carried out before the approach could be confidently considered generic.

12.5. Implementation and demonstration of the FHR service

A number of lessons have been learned in the process of implementing the FHR service, mainly in relation to engineering choices made and some technical aspects of the interface to the database.

In general, the choice of Java, Jini and of a directory service to deliver a set of middleware sub-components has proved successful. Novell's directory service product is fast at searching but cumbersome to install and to configure. The research group were disappointed at the limited ability of the schema sufficiently to represent the desired model for persons, necessitating a number of compromises on the final structure chosen.

In the initial testing phase ObjectStore proved to be a little slow to add new objects to a patient record hierarchy (around 2 seconds to add a hierarchy of around 30-50 objects) but extremely fast at retrieving selected part of a patient's record (less than a second for most retrievals). However, the database is very much slower at searching across hierarchies (i.e. for a population search). A search for all instances of a particular Element archetype across the full database, containing ten years of legacy data, would typically take over an hour. This has required a variety of work-arounds including the implementation of a secondary cache to index the objects required in the commonest searches, such as the set of appointment dates held within the system. A major crisis unfolded when attempts were made to import several years of legacy data for the full list of 2,500 patients. The native object indexing mechanism of Object Store failed to cope with this volume of fine-grained entries, necessitating the re-engineering of the persistence service to utilise a different indexing approach. This has proved slower but with a greater overall capacity.

The Oracle persistence service is about three to five times slower than the ObjectStore equivalent within patient hierarchies, but because it is able to provide the same performance for population queries the overall application performance might prove comparable. This is the subject of current in vitro tests but no decision has yet been taken about migrating the live record server to Oracle. A third option, a native XML database, is being considered as these products are claimed to be well suited to large numbers of fine grained hierarchical objects.

The general robustness and scalability of the FHR service has otherwise been good, as evidenced by the feedback from the clinical staff (outlined below).

The results presented in this Thesis have primarily been validated through the implementation of an Archetype Object Dictionary and a working Federated Health Record service. These have been tested in the domain of cardiology through:

- the mapping of three cardiovascular sub-domains (anticoagulation, chest pain and heart failure management, and a general medical summary)
- the federation of one legacy feeder system;
- the development of three web-based applications to support clinical practice in those three areas;
- the implementation of a persons directory service to hold demographic information on healthcare professionals and patients;
- the live deployment for nearly a year of the anticoagulant application and the imminent deployment of the latter two in north London.

Some non-cardiology validation has also taken place:

- a smaller scale demonstration in the domain of asthma home monitoring, including the logical live federation of an asthma monitoring device;
- the federation of sample data from general practice feeder systems;
- the specification and implementation of an interoperable approach to access control and audit trails.

The experience gained in developing and deploying the demonstrator has been crucial in refining and establishing the clinical validity of the overall FHR approach and of the information architecture. The influence of this practical setting on the definition of archetypes, the design of the FHR service, the federation of feeder systems and the design of the web applications has been described in previous chapters. The more recent value of collaborating with an industrial software development organisation through the South West Devon ERDIP project has also been mentioned in the previous chapter. This company has recently completed a month of high volume interface

testing of the FHR service, and continues to use it for GP system data import and new application development.

Some examples of practical findings that have fed back to the design of the information architecture are listed below.

- The Folder class will almost certainly be used in a rather *ad hoc* way to reflect the local high level organisation of an enterprise, department, clinical domain or of the clinical applications and feeder systems.
- The main contextual attributes are within the Record Component class and are inherited by all of the principal classes of the Reference Model; this was deliberately done in order to cater for possible wide variations in feeder system schemata. The experience of developing applications and of mapping even a small number of feeder systems suggests that this is unhelpful and that a more prescriptive approach to the location of contextual attributes within the class hierarchy will improve consistency without impairing the faithfulness of feeder system mappings.
- The web applications need to commit new data to the record server per screen, which should ideally correspond to a new instance of a Com class from the Reference Model. However most clinicians would conceptually relate the Com class to a single clinical encounter, which might be reflected in two or three screens-worth of data. This inconsistency has no immediate solution, but in view of it the Reference Model now clearly proposes the Com class to be used for the cohort of data committed to the record server at any one instant rather than attempting to relate this precisely to a clinical session.
- Handling revision to existing entries is best managed at the level of the Composition from a medico-legal point of view, even if a revised version "re-uses" (references) many of the objects that were in the original version.
- The overall Reference Model is optimised for retrieval within a patient record hierarchy, not for population-based queries. A refinement to the persistence database schema has been piloted using the Oracle (relational) version of the record server to improve the ability to search for records across populations, and its performance is still being evaluated.

Conclusions

The general outcomes from the demonstrator have established that:

- the information requirements for the piloted cardiovascular domains can faithfully be defined as archetypes;
- feeder system data containing nearly a decade of anticoagulant management data on 2,500 patients have been successfully federated without misrepresentation or loss of original information;

- a web based application can use the FHR service and persons dictionary to identify patients, review their historic data and manage new anticoagulant care;
- the performance of the record server is sufficient to permit consultations to be completed within five minutes, including complete data entry, the running of a decision support system, the confirmation of a new appointment and the printing of a summary report for the patient to take home;
- multiple users, including some accessing the system from outside the hospital, can collectively deliver care for up to 120 patients per day;
- the same record server can be extended to include new cardiovascular sub-domains, thereby evolving towards a broader cardiovascular record and theoretically a multi-disciplinary record system.

Chapter 13. Discussion

13.1. The overall FHR approach

The FHR of any one patient is proposed as the longitudinal and multi-enterprise set of health and health care information acquired by health care professionals or contributed directly by patients or by their representatives. The primary objectives of this information are to support the future health care of the patient and to demonstrate the competence and quality of health care that has been provided. Secondary uses of health record information to manage services effectively and to support professional learning and research are embraced but with a recognition that these will best be served if the FHR is optimised towards the primary uses of the record.

The author proposes that such a record will in practice be best realised through the federation of the individual clinical applications, databases (and increasingly devices) that are each tailored to the needs of individual conditions, specialties or enterprises rather than by a single monolithic system that has to be used by all. Although individual projects and sites frequently do select a single vendor's system to provide an integrating framework the general trend of health service policies, as described in Chapter 3, has been to adopt strategies that are building towards a federation model at a community or national level.

13.2. FHR Requirements

The ability to define an information architecture based on multiprofessional and multidisciplinary requirements, which has led to a successful live clinical system, provides some confirmatory feedback on the requirements themselves. The modelling and implementation work has consistently referred back to these originating requirements, and most of the key conceptual and medico-legal requirements have been met. Those that could not be met in the time available for this implementation relate mainly to the representation of complex data:

- the representation of time-series data such as cardiac monitoring;
- the representation of spatially complex data such as n-dimensional tables and matrices;
- the representation of multimedia data (other than as simple bulky data) such as DICOM images;
- the incorporation of pre-coordinated or post-coordinated terms from next-generation terminology systems such as SNOMED-CT;
- normal ranges applicable to a particular measurement instance;

- the recording of a countersigning healthcare professional, as required for drug administration in hospitals;
- links between individual patient records, to establish family records or the selective sharing of information between family members.

Other novel areas of bio-scientific requirement will emerge, as is likely with genomics. It is probable that these will add to rather than negate the present set of requirements.

Across Europe, increasing importance is now being placed on the integration of health information with information required for or generated by social care teams. This may in the future include the police and other statutory authorities, as part of "joined up" e-Government. The ethical implications of this are significant, and any evolution in information systems to accommodate this (if it does indeed take place) will need to represent much more complex authorship, provenance and access control information than has been derived from the investigations of health-care focused requirements investigations reported here.

13.3. FHR Information Architecture

The value of the proposed FHR Information Architecture is that diverse health and health care information can be represented and communicated in a standardised way.

The need to preserve faithfully the set of contexts relating to a health record entry, to ensure the intended clinical meaning of the original author is preserved within the generic representation, has been discussed in Section 6.9. The proposed combination of the FHR Reference Model and the Archetype Model seeks to ensure this.

For example, if a user chooses to record a high blood pressure reading alongside (or linked to) an entry describing a recent bereavement, this associated information would not routinely be extracted when composing a table or graph of blood pressures over time. The bereavement might, however, have influenced a clinician not to respond to the raised blood pressure on that occasion. It is not possible to prevent users from requesting such graphs, nor is it possible to deny users the ability to compose links of the type described. However, the approach taken in defining the FHR architecture has been to ensure that users curious about an unusually high blood pressure on a graph would also have access to the consultation in which it was recorded and therefore the ability to uncover the clinical context in which it was taken. The Reference Model Com class, (corresponding to the GEHR Transaction and the ENV 13606 Composition) is intended to ensure that transfers of parts of a patient record between repositories comprise only whole Coms. Users should therefore never be in possession of part of a Com (although they might only routinely wish to view part of it).

The instantiation of archetypes as entries within an FHR is formally managed by the FHR service in accordance with the overall archetype schema. This has the advantage that, for example, health record entries containing a *Diagnosis* can be identified from within a range of groupings such as a *Summary*, an *Outpatient Consultation*, or a *Referral Letter*. However, the risk of extracting all entries containing a diagnosis from a record is that the result may also include entries under headings such as *Family History*, *Possible Diagnosis* or *Patient's Concerns*; none of these would establish that the patient actually had those conditions. This is why key attributes in the FHR Reference Model specifically record the subject of the information, degree of certainty and direct applicability of the information to the patent. This makes it possible safely to document independently of the heading used that the subject of the information is a relative, that a finding is uncertain, or that the patient is at risk of having a condition rather than actually having it. This approach for certain key "modifiers" reduces the risk of misinterpretation given that clinical practice does not have a consistent approach to the labels or headings used within health records.

The ability to reuse archetype fragments, provided as an easy-to-use copy and paste feature in the Archetype Object Dictionary Client, has permitted several record concepts to be shared between the web applications (such as a *drug prescription*). The inclusion of an archetype UID in all concrete classes of the Reference Model means that all entries in the FHR that have been instantiated according to the same archetype fragment can be retrieved collectively if so desired, even if they occur in different hierarchies. This could, for example, permit all entries for *weight* to be retrieved even if they have been recorded under different headings such as *physical examination* and *well-person check*. An implementation of the FHR service is able to retrieve individual record entries corresponding to an archetype either from within a specified hierarchy or throughout the patient's record. This would permit access to all of the weights recorded for a patient independently of where or why they were taken, or only to those relating to a particular defined clinical context such as, for example, to a patient's antenatal care.

The archetypes therefore need to be carefully defined to ensure that such reuse really does reflect the re-occurrence of an identical clinical concept and not the re-occurrence of a different concept that happens to be similarly named. Present paper health records, structured templates, computerised clinical applications and clinical audit data sets, developed by many different bodies over time, incorporate a wide range of headings, sub-headings and data structures with little consistency between them. The archetype approach does not in itself introduce coherence in this area, and there is still a risk that archetypes will be authored by different groups, using different heading hierarchies and different data structures to represent similar care processes. The value of the archetype approach is that, unlike at present, the structures used can be communicated in a consistent form, permitting different development teams to collaborate if they wish.

A potential strength of the FHR approach lies in its ability to enable the sharing and analysis of health record data even if the original records do not share a single common archetype structure. However, there is also an opportunity to use the perspective of a shared library of archetypes to encourage clinical convergence on the organisational structure of health records. It is the belief of the author that once clinical teams are able to share records and to benefit directly from a consistent FHR framework they will naturally and deliberately seek convergence. In the experience of the author through medical audit projects this bottom up approach to convergence is generally more successful, albeit slower, than a top down imposition of standardised data sets.

The future adoption of archetypes

Both Working Groups 1 (information models) and 2 (terminology) of CEN/TC 251 have welcomed the archetype approach as a valuable contribution to the representation and interoperability of EHRs. It has been specified in the CEN Work Item description as part of the intended scope of the new standard (due for publication in 2004) (Klein and Freriks 2001).

Further practical experience is needed to confirm that similar health record constructs that are used in very different clinical settings can be archetyped consistently to permit the sharing and combined analysis of their individual record entries. Other areas of future validation will include the interoperation of archetypes and of the record server with protocol authoring and run-time components, and with next-generation terminology servers.

The impact and influence of HL7

The proposed information architecture is one approach to the communication of clinical information between systems and teams. The main alternative has historically been the development of sets of messages, each message dealing with a specific communication requirement between parties. The latest innovation in this latter direction is the development of a Reference Information Model (RIM) for version 3 of HL7 (as described in Section 5.6.1).

Much effort has been made to develop the RIM as a model to support the systematic and consistent development of messages to succeed the highly successful version 2 message sets. HL7 has accumulated very extensive international experience with the specification of the messages that are required to support interoperability between components of a hospital information system and to support purchaser/provider communications for billing and service administration. The RIM is likely to provide a sound and rigorous basis for the future development of such messages.

However HL7 has yet to publish the requirements basis for the development of the RIM, and to indicate its capacity to meet the kinds of clinical and ethical requirements for EHRs that have been identified in Europe over many years. The RIM attempts to provide a generic foundation model for healthcare communication but, contrary to much published experience, embraces domain

knowledge, clinical process and workflow management paradigms in one "supermodel". It contains many arbitrary attributes that are highly specific to individual domains. Examples of this are the attributes to list the valuables taken from a patient on their admission (illustrated in Figure 31) and the two specific attributes for protein and carbohydrate in the Diet class. This approach is likely to result in a model that cannot scale to the wide range of health record entries across all clinical settings, nor cater for the future evolution of clinical practice and of medical knowledge.

The view of the author is that the EHR model is not in itself an extension of the model of a hospital information system and that the present RIM is not a sound basis for the communication of parts or whole EHRs between systems. However, the HL7 organisation is very large and well funded internationally; it may therefore prove a dominant influence on the next generation of clinical applications and their communications interfaces.

The higher-level classes of the RIM are relatively generic, and have been informed (and influenced) in part by the EHR work within Europe and Australia. These few classes *could* be adapted to meet the requirements of an EHR. This approach is presently being explored by the Structured Documents Technical Committee of HL7, which has responsibility for defining the Clinical Document Architecture (CDA), discussed in Section 5.6.1. The author and colleagues are presently collaborating with the co-chairs of that TC and the Chair-elect of HL7 itself in order to identify possible feeds into the CDA from the research work presented here, parallel work in Australia, and the process of revising ENV 13606 within CEN. A more harmonised approach is therefore possible for the future.

There is much valuable work occurring within HL7 that could usefully inform future refinements of the FHR Information Architecture. This includes strong links with the authors of DICOM-SR, and the new Integrating the Healthcare Enterprise (IHE) initiative which is also championing the incorporation of multi-media reports into clinical systems.

The dual Reference and Archetype Models published here are now contributing to the next iterative cycle of refinement in three ways:

1. the design of the *open*EHR Reference Model which combines the validated features of this model with parallel work carried out by GEHR Australia as summarised in Section 5.2.7;
2 as an input to the EHRcom Task Force charged with revising ENV 13606, and led by the author; it has been agreed that this will follow the dual-model approach;
3 as an input to the development of HL7 Clinical Document Architecture Level 3.

It is hoped that these three avenues will provide the opportunity to improve the present information architecture and extend its validation base.

13.4. Access control features

The importance of a sound approach to the documentation of and compliance with the disclosure wishes of patients has been stressed in Section 5.12 and in Chapter 10. A proposal has been made for representing the sensitivity of record entries, and for recording a patient's consent to role-based access within the record. This has now largely been implemented but only a limited testing of the functions has so far been carried out. It is nevertheless a strength of the overall information architecture that access control features meeting the requirements identified in Chapter 6 can be defined and implemented. The formal deployment and evaluation of the access control approach will be the subject of future research by the author and his research colleagues. This access control framework, implemented within the UCL FHR service, has now been connected to a PKI server running at UCL Computer Science Department, to permit role-based login and access management. Experience of populating this with suitable functional roles is at an early stage.

13.5. The need for further validation

It is the view of the author that a more rigorous evaluation of the FHR information architecture is now required, further to evaluate both the approach and the detailed models. The work reported in this Thesis, and its demonstrations at the Whittington Hospital and in other locations, provide limited proof-of-concept validations. Ideally more than one engineering group should implement the specifications in order to verify that they are technology independent (i.e. that they genuinely are Information Viewpoint specifications). Although precursors of this work have been implemented by multiple teams, the Information Architecture specified here has not. The absence of images, bio-signals and other complex data also limits the extent to which these results can be generalised. Extended validation should include a wider range of clinical domains (including some data intensive specialities such as intensive care), the interoperation of more feeder systems including live federation, interfaces to the applications of several independent third party developers, and evaluation by a wide range of clinical users and by patients.

However, it has proved difficult to advance this approach to the EHR beyond funded research projects, given the competing priorities of European health services in establishing national network infrastructures and the communication of prescribed clinical data sets for audit and service management. The industrial drivers for clinical systems in Europe have favoured rich functionality over interoperability, in an effort to entice clinicians to use any form of computerised system rather than one that permits them to share care effectively between teams and sites. The NHS ERDIP programme, outlined in Section 3.3.1, was an opportunity to take the EHR agenda forward that was not adequately funded or exploited.

Interest in the interoperability of clinical systems and in realising the person-centred EHR is now growing. The author therefore hopes that the new collaborations uniting EHR research and standards, in Europe and the US, will yield fresh opportunities to extend the evidence base of good quality EHR services.

Chapter 14. Conclusions and Future Work

14.1. Adopting a federated health record approach

The results presented in this Thesis offer a practical approach for the design of federated health record services as a means of realising the EHR within the distributed environment in which care is normally delivered. These results have been developed through iterative cycles of requirements analysis, information modelling, and practical implementation, and have been validated in clinical pilots in north London and Devon. However it is recognised that these are small-scale evaluations and that broader field trials of such an approach are needed before health services and industry can verify that this is a sound solution. The UCL results are being fed into the new CEN EHRcom Task Force, and it may be that a successor European standard drawing on these findings will stimulate larger scale demonstrators across Europe.

It will be important to show that federated access to health record information is feasible, scalable, and is of an acceptable quality to support clinical practice.

A prerequisite to the success of federated health records will be the ability faithfully to map the data held in disparate databases and acquired through a wide range of specialist applications and measurement devices. Reliable and fast access to a patient's federated record will be essential as will the efficient ability to identify relevant information for the correct patient, avoiding cumbersome navigation and information overload.

It will be important to end users, patients and to health services that user authentication and system security is demonstrably robust and conforms to data protection policies. A critical success factor will be the willingness of industry and of national health services to invest in a rigorous conceptual approach to the communication of EHRs between clinical systems.

14.2. New challenges

The FHR information architecture has been developed and validated on the basis of requirements arising from current clinical practice and primarily from the health care domain. There are many extensions to this view of health care that still need to be explored and integrated with the existing set of requirements, such as:

- sharing information with social services and other care agencies including the voluntary sector;
- shared care that includes complementary therapies;
- the active participation of patients and carers in managing their own health care;

- advances in the computation and application of patient-tailored medical knowledge, as in the field of genomics, with the potential to quantify a patient's lifetime disease risks and to provide statistically-based prognoses.

The delivery of high quality clinical care depends upon a well-recognised triad of information services: health records, medical knowledge and protocols of care (Figure 96).

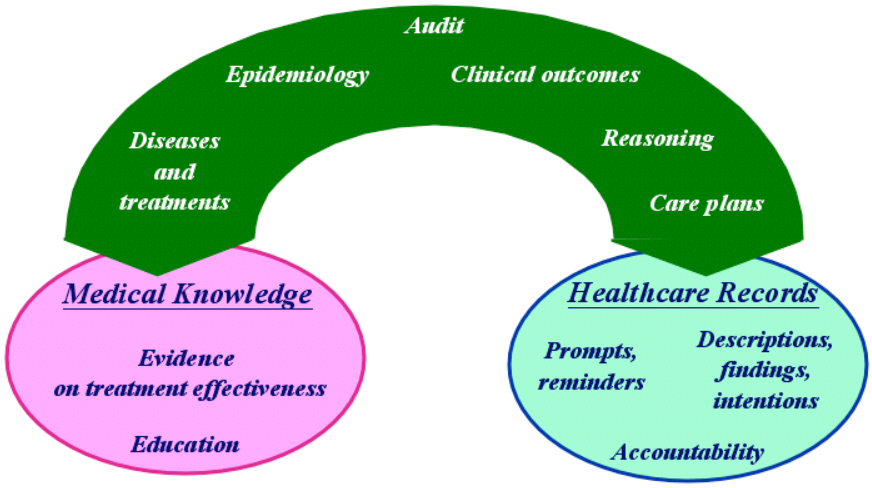


Figure 96: Clinical information services supporting patient care

It is likely that the next generation of health care systems will be designed as a set of collaborating middleware components in which this triad of clinical middleware itself interoperates with a range of other middleware services as illustrated in Figure 97 below.

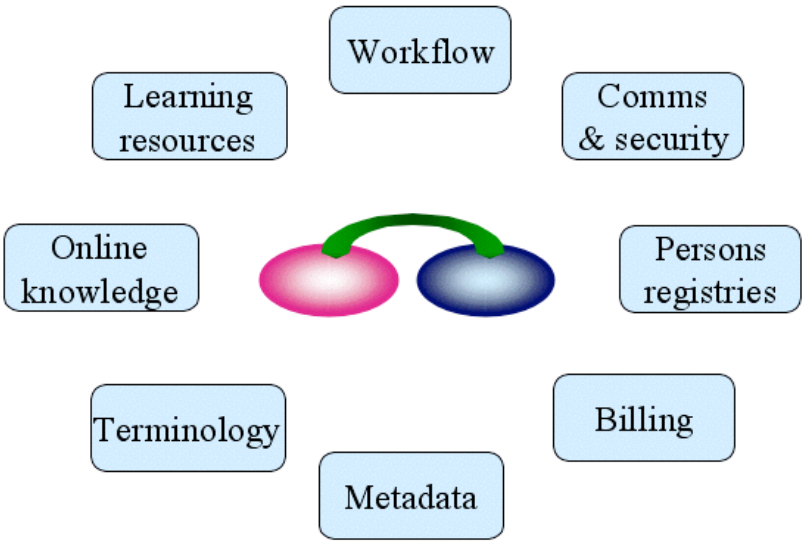


Figure 97: Other components and services supporting the clinical middleware

This kind of interoperability, particularly between vendor products, has yet to be embraced by industry. It is the view of many in the health informatics community that this interoperability between the core clinical middleware components will best be stimulated by the availability of good quality Open Source reference examples.

UCL is in the process of establishing an international Open Source foundation (*open*EHR, please see (Schloeffel, Lloyd et al. 2002)), co-ordinated by UCL and with specific collaborating centres in Australasia and the US. This will operate as a non-profit body to foster high quality electronic health records amongst the purchaser, vendor and user communities. The generic components of the UCL federated health record server will soon be offered as Open Source products through the *open*EHR Foundation.

Two other complementary Open Source foundations have been launched over the past 18 months (Figure 98) and the research necessary to develop seamless and clinically useful interoperability between these is within the scope of a new project within the MRC's UK e-science programme.

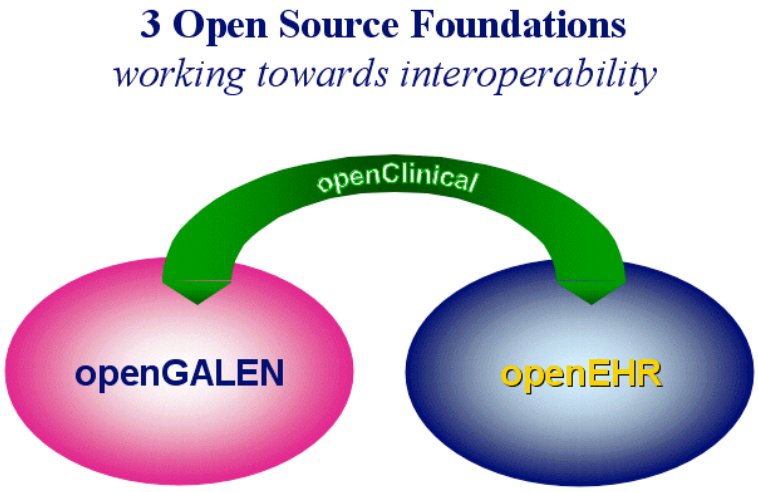


Figure 98: Clinical Open Source Foundations

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 Thesis is offered as a contribution towards realising that vision, hopefully with future opportunities to extend the knowledge so far gained and to embrace new challenges in health care and health informatics.

Medicine is an art as well as a science. If electronic information systems such as the FHR can provide the tools to enable clinicians to practise scientifically and efficiently, they should be better able to devote time and energy to the human dimension of their relationships with patients.

Chapter 15. Glossary of terms

2G	Second Generation Mobile Telecommunications (including GSM and GPRS)
3G	Third Generation Mobile Telecommunications (including UMTS technology)
6WINIT	IPv6 Wireless INternet IniTiative
Access control	A means of ensuring that the resources of a data processing system can be accessed only by authorized entities in authorized ways
ANSI	American National Standards Institute
API	Application Programming Interface
Archetype	An individual metadata class instance of the FHR Archetype Model, specifying the class name, clinical name and value constraints for one class of objects in an FHR
Archetype Object Dictionary	Persistent repository of archetype definitions, accessed by a client authoring tool or by a run-time component within the FHR service
ASTM	American Society for the Testing of Materials
Attestation	The process of certifying and recording legal responsibility for a particular unit of information
CBPR	Computer Based Patient Record
CEN	Comité Européen de Normalisation, responsible for European legislative standards
CEN TC/251	CEN Technical Committee 251 (develops standards within health informatics)
CHIME	Centre for Health Informatics and Multi-professional Education, the author's department within UCL
Client application	Any healthcare application which is behaving at that moment as a requester of health record data from the FHR
CORBA	Common Object Request Broker Architecture
CPR	Computer-based Patient Record
CPRI	Computer-based Patient Record Institute
DICOM	Digital Imaging and Communications in Medicine standard
Distributed processing	Information processing in which discrete components may be located in different places, or where communication between components may suffer delay or may fail
DTD	Document Type Definition (for XML documents)
ECG	Electrocardiogram/graphy
EHCR	Electronic Healthcare Record
EHR	Electronic Health Record
EKG	Electrocardiogram/graphy
EMR	Electronic Medical Record

EPR	Electronic Patient Record
ERDIP	Electronic Records Development and Implementation Programme of the NHS
EU	European Union
Federated Health Record	The virtual view of a patient's health record data which would be obtained from the global set of entries available about that patient.
Feeder system	A repository for health data that may be queried by the FHR service in order to obtain extracts of a patient's EHR
FHR Archetype Model	The information model of the metadata to represent the domain-specific characteristics of FHR entries, by specifying values or value constraints for classes and attributes in the FHR Reference Model
FHR information architecture	ODP Information Viewpoint specification of a federated health record
FHR Reference Model	The information model representing the generic characteristics of a patient's FHR satisfying clinical and ethico-legal requirements
Generic	This term has been used when describing requirements or information models that are applicable across healthcare professions, domains and countries
GLIF	GuideLine Interchange Format
GP	General Practitioner
GPRS	General Packet Radio Service
GSM	Global System for Mobile communications
HIS	Hospital Information System
HISA	Healthcare Information Systems Architecture
HISB	Health Informatics Standards Board (part of ANSI)
HL7	Health Level Seven
HTML	HyperText Mark-up Language
HTTP	HyperText Transfer Protocol
ICD	International Classification of Diseases
ICP	Integrated Care Pathway
ICPC	International Classification of Primary Care
ICU	Intensive Care Unit
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IETF	Internet Engineering Task Force
IP	Internet Protocol
IPSec	IP Security Protocol
IPv4	Internet Protocol Version 4
IPv6	Internet Protocol Version 6
ISDN	Integrated Services Digital Network

ISO	International Standardization Organization
ISP	Internet Service Provider
IST	Information Society Technologies programme of the European Union
JDBC	Java Database Connectivity
JNDI	Java Naming and Directory Interface
JVM	Java Virtual Machine
LAN	Local Area Network
LDAP	Lightweight Directory Access Protocol
Legacy data	Data that was collected and maintained using a "previous" system, but is now preserved on a "current" system
LOINC	Logical Observation Identifier Names and Codes
Metadata	"Data about data", a schema to define a data set or to provide knowledge about the contents of a data set
NDS	Novell Directory Service
NHS	National Health Service (United Kingdom)
ODP	ISO Open Distributed Processing specification, used for describing distributed systems
PDA	Personal Digital Assistant
Persistent data	Data which are stored on a permanent basis
PKI	Public Key Infrastructure
RMI	Remote Method Invocation
SGML	Standard Generalised Mark-up Language
SNOMED	Systematised Nomenclature for MEDicine
SNOMED-CT	SNOMED-Clinical Terms, a new terminology developed jointly by the American College of Pathologists and the UK NHS
SSL	Secure Socket Layer
Standard	A standard is a document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. (ISO 1992)
Standardised	A specification that is intended to be used consistently as if it were a standard
TCP	Transmission Control Protocol
UCL	University College London
UMLS	Unified Medical Language System, a project of the US National Library of Medicine
UMTS	Universal Mobile Telecommunications System
VPN	Virtual Private Network
W3C	World-Wide Web Consortium
WAN	Wide Area Network

WLAN	Wireless Local Area Network
WML	Wireless Mark-up Language
WWW	World-Wide Web
XML	Extensible Mark-up Language

Chapter 16. References

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Chapter 17. List of Appendices