Electronic Healthcare Records

Introduction

Modern clinical care requires healthcare professionals to manage increasingly detailed and complex information about their patients, and to selectively share this with colleagues in different disciplines within primary and secondary care. The individual patient healthcare record is the principal document in which this information is held and, despite the progressive introduction of computerised information systems across Europe, the majority of such records remain on paper [i].

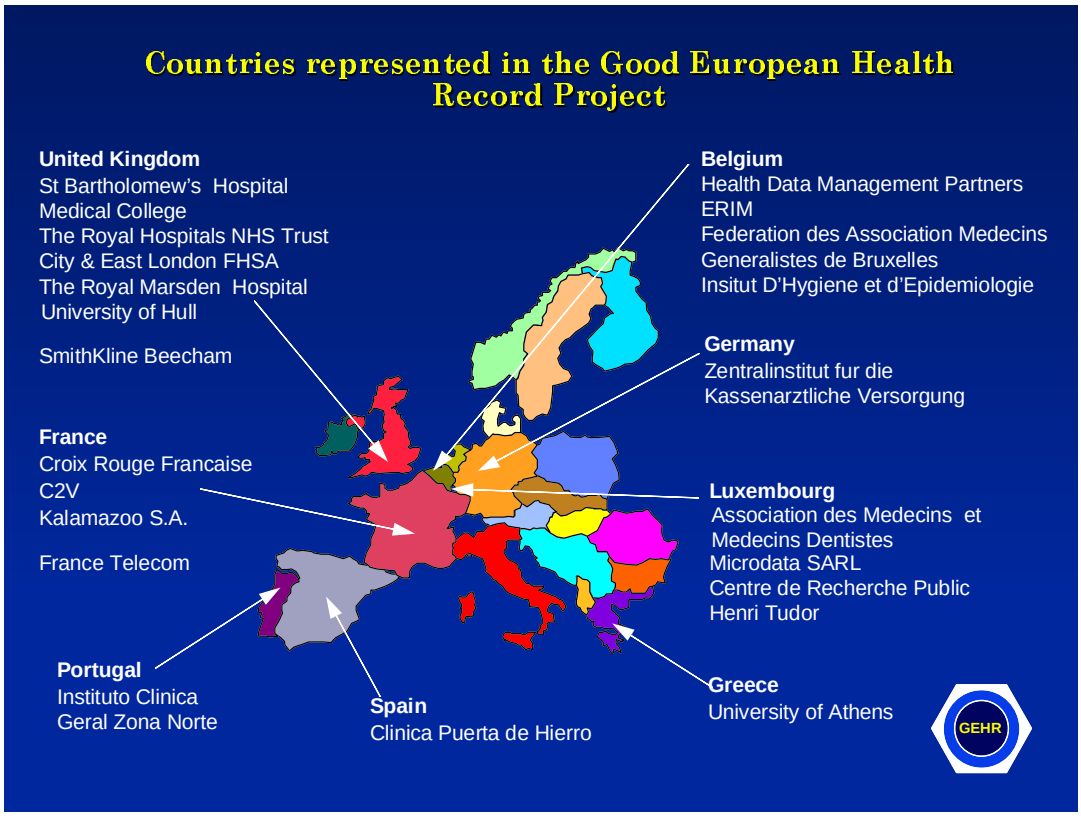
Computerised hospital information systems and computerised general practice patient administrative systems have been widely adopted to facilitate the overall management of each healthcare enterprise. There has similarly been a progressive increase in the adoption of departmental computer systems, particularly in pathology and radiology departments, and increasingly in high technology specialities such as intensive care. However the majority of doctors, nurses and other health professionals do not yet use computers as part of their daily practice except for an occasional administrative task. Since the late 1980's several EU Member States have adopted specific programmes to promote computerisation, either through systems development programmes or through financial incentives schemes, but these have been slow to penetrate the clinical computing market place.

The primary purpose of the record is to support patient care [ii], which subsumes many different functions including the documentation of a historical narrative account of the health care given and supporting the communications between healthcare professionals [iii].
The need for a clear organisational structure to health records, whether on paper or on a computer, has been discussed on many occasions [iv v vi vii], but it has proved difficult to encourage clinicians to abandon paper records in favour of a fully-computerised healthcare record system [viii ix x]. There are clear advantages to clinicians themselves of well-organised electronic healthcare records for improving the completeness of the information they elicit from the patient [xi], the scope for the subsequent analysis of that data [xii], for supporting shared care between clinicians [xiii xiv], and to demonstrate clinical competence [xv xvi]. Improving the ease with which EHCR applications can be learned and used [xvii] and developing more efficient means for clinical data entry [xviii] have both been suggested as solutions. However, the inherent diversity and complexity of medical data [xix] and the need to use rich and varied descriptive terms [xx xxi xxii] are held by many clinicians to be a fundamental obstacle to adopting more formal recording structures. The lack of an appropriate architecture for healthcare records has been identified as a major impediment to progress in this area [xxiii].

The Good European Health Record project

The Good European Health Record project has recently completed over three years of research within the European Health Telematics research programme (Advanced Informatics in Medicine). It has developed a comprehensive multi-media data architecture for using and sharing electronic healthcare records, meeting clinical, technical, educational and ethico-legal requirements.

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 architecture object model, exchange format, term sets and the specifications of access and integration tools have been placed in the public domain.



The GEHR architecture formalism was developed following an extensive investigation of clinical user requirements and their subsequent incorporation into a functional specification. Doctors, nurses and other allied professions from across Europe were involved in deriving a set of requirements in several key areas:

a the requirements for the comprehensive recording of consultations with patients for a wide range of disciplines in primary and secondary care, including the specific needs for a variety of multi-media data types, for the access to coded term-sets, and for the ability to annotate entries with free-text comments [xxiv];

b the requirements for the portability of healthcare records between different institutional systems independent of the hardware configurations, of the operating systems or of the applications at those sites, and independent of the original language and of the term-sets used [xxv];

c the requirements for the communication of healthcare records between clinicians involved in sharing the care of patients, whether via telecommunications networks or intermittently-connected devices such as smart cards [xxvi];

d the ethical, medico-legal and security issues which arise when using EHCRs as the sole medium for recording and storing patient-related information,

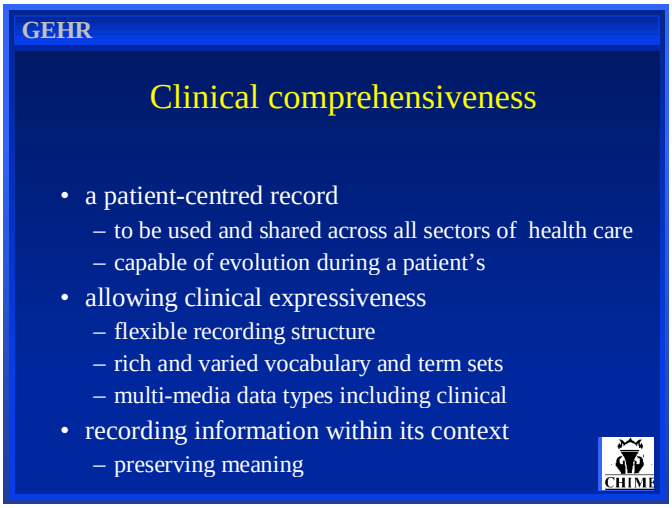
including both the features necessary within the architecture and the regulatory framework which must support their legitimate use [xxvii];

e the educational needs at an undergraduate and postgraduate level in order to enable the clinical workforce to utilise these new technologies and to accommodate the necessary changes in the way healthcare information is managed [xxviii].

The Requirements for Clinical Comprehensiveness

This Deliverable summarises the set of clinical requirements which must be met by a computerised healthcare record if it is to be comprehensive, communicating and portable whilst supportive of a high standard of clinical care. These rest on the results of the first-year workplan of the GEHR Project: the requirements for clinical comprehensiveness in primary and secondary care, across specialities and data types, and the testing of prototypes in these settings. Further requirements were identified from previously published work, liaison with other AIM projects and national initiatives in the field.

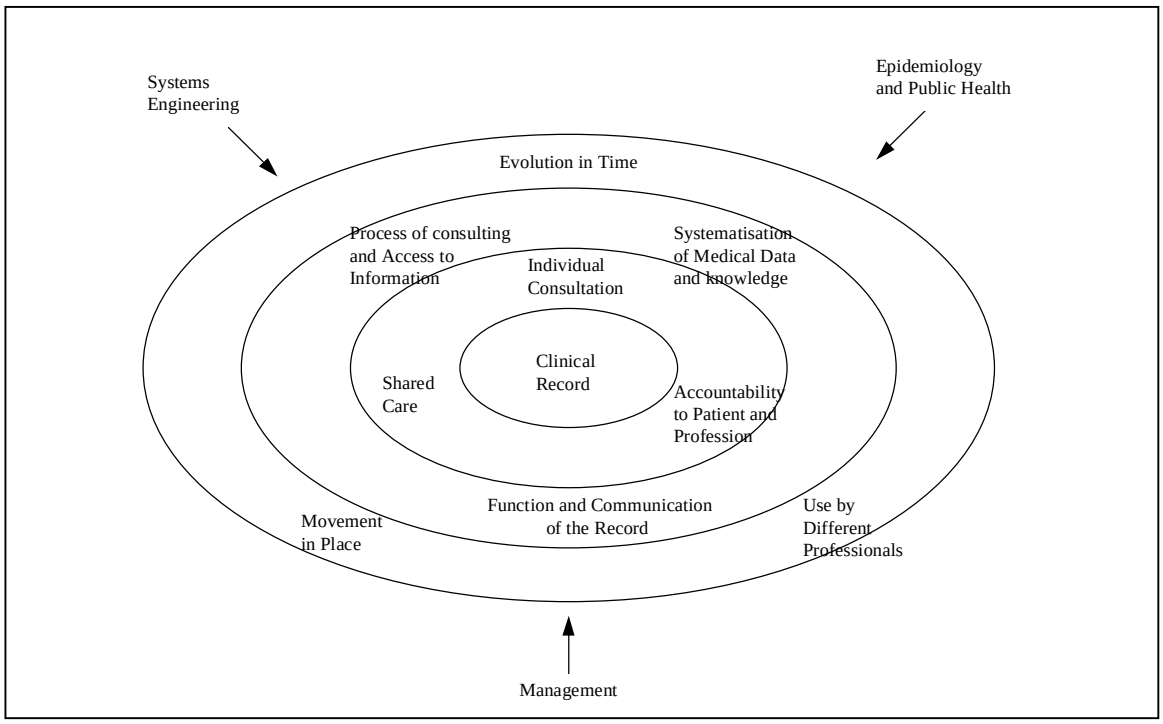
Clinicians value an opportunity for individual expression and creativity when recording within an EHCR; however this freedom may make it difficult to share healthcare record data. Even with the use of standard terms, classifications and languages, it cannot be assumed that others viewing the record will share the same understanding and that meanings will not be lost or changed. The requirement of expressiveness is seen as fundamental in some areas of medicine, especially in specialities where narrative style records are the norm, such as psychiatry. In such cases for the foreseeable future, meaning will probably be restricted to reading of a whole text entry by another clinician, and computability will be very limited. In other specialities a highly structured record is of greater benefit. The context may then be expressed explicitly, allowing grouping and relations to be recorded. An acceptance of these two styles in record-keeping is probably necessary.



Clinical drawings were identified as an important need through a multi-national questionnaire study; GEHR has produced a comprehensive library of anatomical drawings which has been placed in the public domain, together with the specification for a clinical drawings application.

It was considered important that the set of requirements embracing such a large field of reference be assigned relative priorities so that any compromises which proved necessary when specifying the architecture were consistent with the real world in which the record will be used. The priorities of the GEHR Project reflect the belief that

the healthcare record is most necessary, and should be most available, when a clinical member of staff is offering care or recording the care they have given in a consultation. Thus compromise should always be directed towards offering the most relevant information to an individual carer when attending a patient.



The Context of Healthcare Records

Ethical and Medico-legal Requirements

The ethical issues which are raised by the application of information technology to the electronic healthcare record are fundamentally important because there is a risk of serious harm to patients or clinicians which involves the EHCR and its processes. However the risk can be minimised without compromising the usefulness of the record, and regulation is both technically feasible and morally appropriate. Many of the ethical issues arise from the purposes of the EHCR: the definition below has been proposed by GEHR.

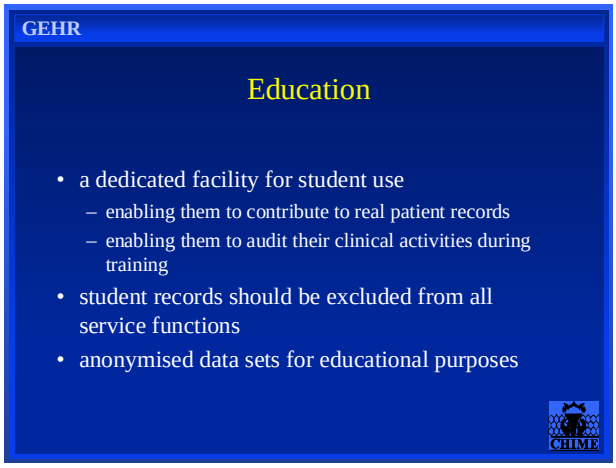
- The primary purpose of the EHCR is to benefit the patient by providing a record of care which supports present and future care by the same or other clinicians.
- The secondary purpose is to provide a medico-legal record of the care provided and hence support and demonstrate the competence of clinicians.
- Tertiary purposes must be legitimate (involve consent) and can never be allowed to compromise the primary or secondary purpose. Examples of tertiary purposes are the generation of data for health service management or public health programmes.

The foundations of the relationship between a clinician and a patient are the delivery of clinical care to the highest standard and the respect for patient autonomy. This inevitably means that the right to informed consent and the right to confidentiality are also moral principles of the highest importance behind a 'good' EHCR. Patients should exercise as much choice over the content and movement of their healthcare records as is consistent with good clinical care and with 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 the legitimate control of patients over them. The record must be secure yet accessible to patients.

The present situation across Europe is the result of uncoordinated and piecemeal legislation and there is a need to harmonise legislation if the Community-wide movement of healthcare records is to be sanctioned by clinicians and patients.

Educational Requirements

Modern healthcare is dominated by the need to integrate and process information. An episode of illness generates information from the patient, from investigations, and from different professionals. This information needs to be integrated with what has previously happened to the patient, and with relevant information about the disease and treatment. Most healthcare professionals feel apprehensive about their ability to assimilate and process the information they encounter daily.



Unfortunately students do not currently receive much training in the use of healthcare records, they are confused by variations in how notes are written, and the discrepancy in how they are taught to write notes. It is argued that electronic healthcare records could encourage students to develop a more positive interest in the process of recording patient data. If they learn to be systematic and code data, they will be able to use the EHCR to access clinical decision support systems and for bibliographic and knowledge links. This will enable them to become more independent in their learning.
In order to achieve a workable, ethically acceptable system GEHR has proposed three concepts: Shadow Notes, Dummy Systems and Logging Facilities.

Shadow Notes

Shadow Notes are a method to ensure students can experience using 'live' EHCR systems safely. Students are given access rights to an EHCR system. They are clearly

identified by the system as being students. They view the same record as a qualified professional and enter their observations as a qualified professional would. However, the system identifies these records as having 'student status'. This is done so that it is clearly visible to subsequent viewers of the record that the observations were recorded by a student. Student notes have different properties to other entries: they are excluded from analyses and are not transmitted to external institutions. It should be possible for a qualified professional 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.

Dummy Systems

To ensure that students realise the importance of accurate and conscientious data collection, they should have access to a database of anonymised cases which can be used for learning activities without disrupting the 'live' system. The dummy system would also provide a large database of cases so that students could practice manipulating aggregated data and learn from analysing large numbers of cases. Patients should give permission for their anonymised data to be used for teaching purposes.

Logging Facilities

It would be very helpful to be able to identify patients followed by particular students during their training. Each student could present a collection of such cases to a tutor to form the basis of a tutorial. Students could be provided with a report of what type of patients they had seen during their training (this would not identify patients). This would be useful for personal audit but could also be used for institutional audit to check students were gaining a wide enough experience.

Description of the GEHR Architecture

The Good European Health Record project has developed a generic architecture for electronic healthcare record (EHCR) data which meets the comprehensive requirements of clinicians across professional disciplines and specialities. This architecture has been formally and rigorously expressed as an object model and as a complementary exchange format. It has contributed strongly to the standardisation work of CEN PT1-011, and some of the GEHR contructs have been adopted by the PT in its first-part standard EHCR Architecture.

The GEHR architecture provides a framework which supports the full diversity of clinical data storage and communication requirements. It is formulated to encompass the different disciplines of primary and secondary healthcare, for doctors, nurses, and other professionals and in all European countries. The ready access to a wide range of data-types is of increasing clinical importance, and the work of the project included these multi-media aspects of the record architecture. Examples specifically addressed include x-ray and photographic images, biosignals, clinical drawings and most importantly textual information, for example clinical observations and laboratory data, in the form of coded terms and free text.

All information in a given EHCR implicitly relates to the care of one person, the patient. Within each patient record, the GEHR architecture preserves both the original structure of the data and how the entries in the record are grouped. Every effort has been made to propose an architecture which is as generic, flexible and non prescriptive as possible. However, where clinicians have identified the need to be prescriptive (for

example, in situations where medico-legal security must be maintained) the architecture incorporates features which may be utilised for this purpose.

Principal GEHR architectural components

- the **EHCR**

  provides the container for all data about a particular patient

- the **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

- the **Health Record Item (HRI)**

  provides the structure for recording the content values of EHCR entries

- the **HRI Collection**

  provides for aggregation of HRIs and other HRI Collections

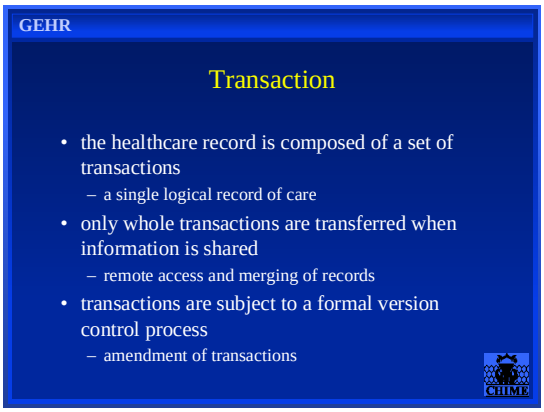
  provides the means of changing the scope (data subject) of the data

- the **Heading**

  provides annotation for groups of HRIs/Collections

Each of these constructs is further elaborated using Attributes which address aspects of identification, content and context. They are consistent with the structures apparent in existing records and fulfil the requirements identified by the project for the EHCR.

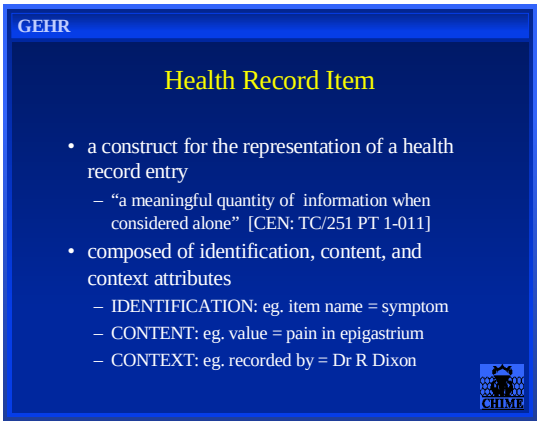
GEHR proposes that there should be a clear boundary to entries in an electronic healthcare record. This is formalised through the concept of *a Transaction.* The Transaction will commonly be recognised as a patient contact or a consultation, but may at times reflect an interaction with the record when the patient is not present, such as filing a test result or a letter. These Transactions are authored by clinicians who accept responsibility for the accuracy of the information added during a Transaction, and they encapsulate the cohort of information which has been entered as one 'interactive session' with the record. All clinical data within an electronic healthcare record should comprise only a set of such Transactions. All Transactions should be available for medico-legal scrutiny, even if they have been subsequently amended.

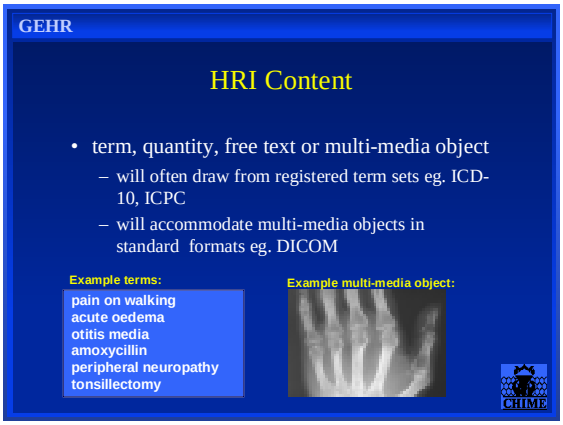


Medico-legally, it is essential that there can only be one recording of a particular patient consultation, by a particular clinician at any one moment, although this recording may be subsequently corrected or amended. By defining Transactions uniquely using these criteria, the logical integration of two record sources will always safely maintain each Transaction within its context in the combined record.

All of the healthcare information within an EHCR must be attributable to instances of Transactions, each uniquely identified by the time, the institution and the clinician responsible for its creation. 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.

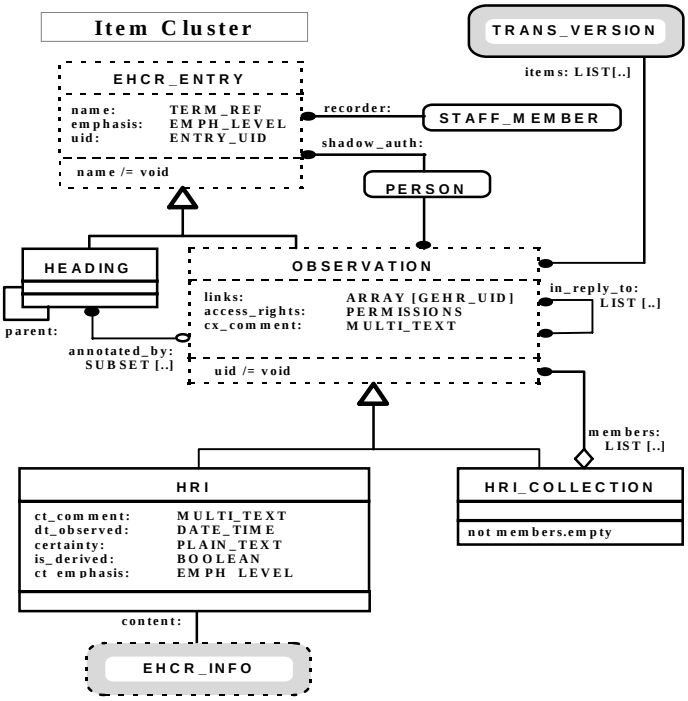
The fundamental GEHR architectural constructs, *Health Record Item (HRI)* and the *HRI Collection*, allow for the documentation of any chosen hierarchical arrangement of clinical concepts, and can accommodate any textual, quantity, coded or multi-media data type. The *Heading* provides an additional construct for the annotation within the EHCR of these concept hierarchies. All contemporaneous healthcare record entries are managed within a *Transaction* construct (of which there are several different types) to encapsulate the necessary medico-legal and language information relating to that set of entries.





The HRI, HRI Collection and Heading constructs enable individual and groups of clinical findings to be documented unambiguously through an object formalism in which every entry or aggregate has a name associated with the observed finding. The *HRI name*, *HRI Collection name* and *Heading name* provide the mechanism by which clinical entries can be appropriately identified for the purposes of searching and analysis within an EHCR system and for the exchange of information between systems.

The GEHR project has developed two formal definitions in support of the architecture: the GEHR Object Model and the GEHR Exchange Format. The diagram here is an extract of the object model, expressed in the Rumbaugh notation, derived from the definition of a Health Record Item expressed in the Eiffel language. The Exchange Format has been expressed in Abstract Syntax Notation (ASN.1).

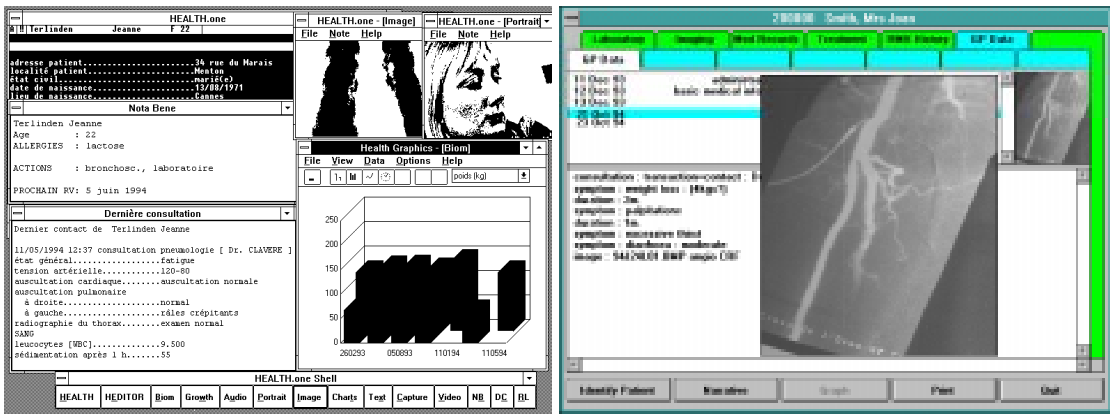


The Health Record Item Cluster

The interim specifications of the GEHR architecture have formed a major input for consideration by WG1 of CEN TC/251, in particular the work of PT1-011 on the standard for the Electronic Healthcare Record Architecture (EHCRA). The final work of GEHR will form an important input to new work within TC/251 on the development of an Extended Architecture (EHCREA).

To support the development of healthcare record systems incorporating the GEHR architecture, the project has also 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, and are accessible through an ftp server described below.

Several protoype healthcare record applications were developed within the GEHR consortium, some of which are now full commercial systems in clinical use.



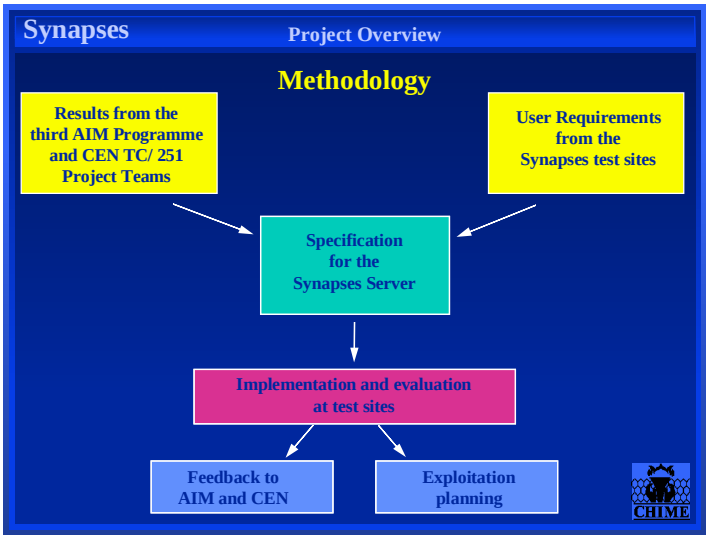
Health-One, by HDMP in Brussels HIS at the The Royal Marsden Hospital

GEHR Prototype Systems

The Synapses Project

The Synapses project, within the fourth European Health Telematics R&TD framework, has proposed to unite the main aspects of the GEHR architecture and the PT1-011 standard with the generic components of other specialised architectures to provide a *Federated Healthcare Record Architecture*.

This architecture will then be incorporated into an EHCR database for the storage of healthcare data within a computer network or for use as a buffer store between a client and other healthcare record servers (using different data architectures). Synapses servers will be built and prototyped in a variety of test sites across Europe, in order to test the applicability of a generic server specification to a range of different legacy healthcare record systems.



The Synapses project will develop a series of generic methods, hardware and software products to enable isolated computer systems to exchange healthcare data with each other whether on the same site or accessed by secure telecommunications links. An important part of this work will be to establish and formally define many of the compound clinical concepts which are in frequent use by the healthcare professionals participating in the project. This should enable individual clinicians working at their usual computer terminal to access healthcare information about their patients in a meaningful way from a wide range of computer systems to which their own institution is connected.

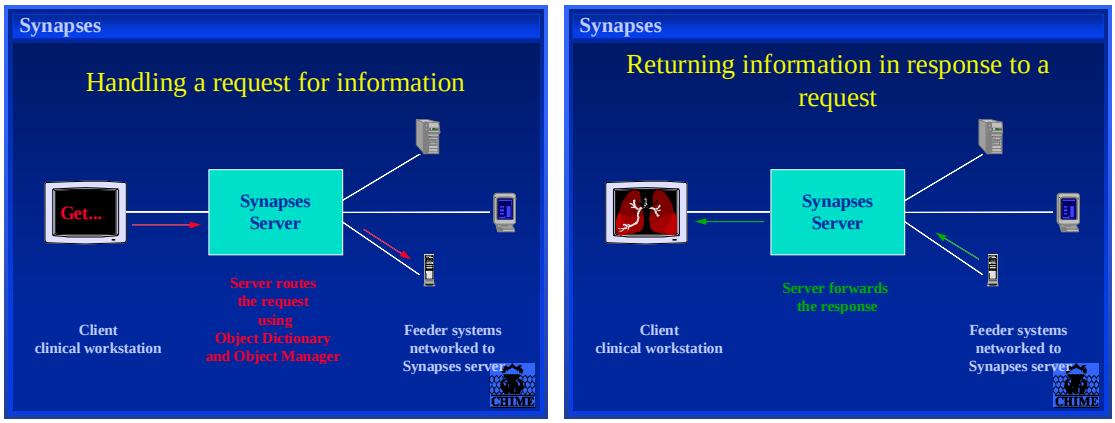


Illustration of the functions provided by a Synapses server

For further information about the work of GEHR or Synapses

Please contact:

Dr Dipak Kalra
Centre for Health Informatics and Multiprofessional Education (CHIME)
University College London
Whittington Hospital Campus
Archway Wing, 4th Floor
Highgate Hill
London N19 5NF
e-mail d.kalra@chime.ucl.ac.uk

The GEHR Deliverables, including the architecture description, object model, and term sets can all be obtained through the ftp site address:
ftp.chime.ucl.ac.uk

You will need to provide:
anonymous as the User ID
your email address as the password

Change to the directory /private/GEHR (please note the case to be used)

Please read the INDEX.TXT file which contains instructions.

You may also access the site via Netscape on the World Wide Web

Use Netscape or Spry Mosaic and the URL:

ftp://anonymous@ftp.chime.ucl.ac.uk/private/GEHR

You will be asked for your email address as a password.
(Note that you must get the upper/lower case right for the path part)

When connected, you can see all the files.
If SPRY, use View | Load to Disk Mode to down load selected files.
If Netscape, right click on the file or use Save As from the file menu.

References

[i] The Computer Based Medical Record. Dick R, Steen E, Eds. *Institute of Medicine, Committee on Improving the Patient Record.* National Academy Press, 1991.

[ii] Rector A, Nowlan W, Kay S. *Methods of Informatics in Medicine 1991;* **30**:179-186.

[iii] Shortliffe EH, Barnett GO. "Medical Informatics: Computer Applications in Health Care". *Addison Wesley Publishing, Reading, Massachusetts.* 1990.

[iv] Weed L. Medical Records, Medical Education and Patient Care: the Problem Oriented Record as a Basic Tool. *The Press of Case Western University Cleveland, Ohio.* 1971

[v] Roper N, Logan W, Tierney AJ. The Elements of Nursing, 2nd Edition. Churchill Livingstone, Edinburgh. 1985.

[vi] Dick R, Steen E, Eds. The Computer Based Medical Record. *National Academy Press, Washington.* 1991

[vii] Bishop CW. *MD Computing.* 1991;8:208-215

[viii] Campbell J, Ginver N, Seelig C, Greer A, Patil K, Wigton R, Tape T. *MD Computing.*1989; 6:282-287.

[ix] Fischer PJ et al. User Reaction to PROMIS: Issues Related to Acceptability of Medical Innovations. *Proceedings SCAMC.* 1980.

[x] Tang PC, Shortliffe EH, Detmer DE. *Annal. Int. Med.* 1991;115:979-981.

[xi] Lilford R, Kelly M, Baines A. Effect of using protocols on medical care: randomised trials of three methods of taking an antenatal history. *BMJ* 1992;305:1181-1183.

[xii] Spann SJ. *Journal of Family Practice.* 1990;30:457-464.

[xiii] Shortliffe EH, Barnett GO. Medical Data: Their Acquisition, Storage and Use. *Medical Informatics: Computer Applications in Health Care, Chapter 2.* Addison Wesley Publishing, Reading, Massachusetts. 1990.

[xiv]Pagano MP. Communicating Effectively in Medical Records. Sage Publications, London. 1991.

[xv] Proposals for New Performance Procedures: a Consultation Paper. General Medical Council, London. 1992.

[xvi] Southgate L, Berkson L, Fabb W et al. Towards Better Definitions of Competence: a Paper From the Cambridge Conference. *Office of the Regius Professor of Medicine.* Cambridge University. 1989.

[xvii] Skifjeld K, Harket G, Hurlen P, Piene J, Skjervold S. A Document Architecture for Health Care Records Integrating Structural and Semantic Aspects. *AIM Office.* 1992.

[xviii] Rodnick J. *Journal of Family Practice.* 1990;30:460-464.

[xix] Blois M. Information and Medicine: The Nature of Medical Descriptions. *Berkley and Los Angeles: University of California Press.* 1984.

[xx] Arnold R, Povar G, Howell J. The Humanities, Humanistic Behaviour, and the Humane Physician: a Cautionary Note. *Annal. Int. Med.* 1987;106:313-318.

[xxi] Bryant GD, Norman GR. *New England Journal of Medicine.* 1980;302:411.

[xxii] Hunter K. Doctors' Stories: The Narrative Structure of Medical Knowledge. *Princeton University Press, New Jersey.*

[xxiii] Rector A, Nowlan W, Kay S. *Methods of Informatics in Medicine.* 1991;30:179-186.

[xxiv] Ingram D, Southgate L, Kalra D, Griffith S, Heard S, et al. GEHR Requirements for Clinical Comprehensiveness. *The Good European Health Record Project, Deliverable No. 4. AIM Office 1992.*

[xxv] Ingram D, Hap B, Lloyd D, Grubb P et al. GEHR Requirements for Portability. *The Good European Health Record Project, Deliverable No. 5. AIM Office 1992.*

[xxvi] Ingram D, Lloyd D, Baille O, Grubb P et al. GEHR Requirements for Communication Capacity. *The Good European Health Record Project, Deliverable No. 6. AIM Office 1992.*

[xxvii] Ingram D, Southgate L, Heard S, Doyle L, Kalra D, et al. GEHR Requirements for Ethical and Legal Acceptability. *The Good European Health Record Project, Deliverable No. 8. AIM Office 1993.*

[xxviii] Ingram D, Murphy J, Griffith S, Machado H et al. GEHR Educational Requirements. *The Good European Health Record Project, Deliverable No. 9. AIM Office 1993.*