

Electronic Health Records - Tutorial Handout

This tutorial handout has been produced by Dr Dipak Kalra, from CHIME, UCL, summarised from work published in a PhD Thesis (Kalra 2002).

Historical introduction

(Extract from Ingram D, Southgate L, Kalra D, Griffith S, and Heard S. The GEHR Requirements for Clinical Comprehensiveness. The Good European Health Record Project. 1992. European Commission.)

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 healthcare recording are papyri from ancient Egypt, which contain details of surgery and prescriptions.

Throughout this century, institutions have attempted to direct the data collected within their walls but there has always been resistance to standardisation on the grounds that the freedom of individual clinicians must be protected. 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)."

Had pro-forma been widely introduced in 1923 they might have hindered the development of new ideas in medicine by discouraging new observations and thoughts. 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 huge impact on medical practice and therefore on the content of medical notes which now tend to contain much information relevant to an individual's psychological well-being such as sources of stress, social interactions and perceptions of illness.

In 1971 Weed published "Medical records, medical education and patient care" which introduced a method of structuring a record, the Problem Orientated Medical Record (Weed 1971). This was a format for clinical recording consisting of a problem list, a database (that is, the history, physical examination and laboratory findings), and then, written out separately for each problem, a plan (diagnostic, therapeutic and educational) and a daily SOAP (subjective, objective, assessment and plan) progress note. However the POMR was not widely adopted exactly as Weed proposed because it proved to be too time consuming on paper and with early EHCR systems.

As both primary care and secondary care organisations have become more complex, instead of the notes just acting as an *aide memoire* for an individual clinician they have become important as a means of communication between clinicians. The involvement of different professionals in care and the recognition of the inter-relationship of physical, psychological and social factors has led to notes becoming vast repositories of data with little structure to facilitate the processing of these data (Gregson et al 1991).

As the process of human reasoning has become better understood, it has become apparent that logical thinking coexists with less well understood "intuitive" processes; both modes of thinking and reasoning are important in medical decision making (Dreyfuss et al 1986). This insight into cognitive processes has led to an apparent paradox between the need for more "structured data" which is used in a logical way to derive a conclusion and the need for "narrative data". This need to value and listen to the story as told by the patient is explored in "Doctors Stories" (Montgomery Hunter 1991). She suggests that when physicians have a working knowledge of life histories and a sense of medical narrative that can accommodate the experience of illness, they are better able to provide good medical care, especially for those they cannot quickly cure. This tension may only be an apparent paradox as both types of data are important and can coexist. A structured approach will ensure all the necessary information is acquired to arrive at the right decision. However within any structure there should always be the facility to record events as described by the patient (not in a processed form) and the ability to record data that does not immediately seem significant.

The challenge being addressed by a generic EHR

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. 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.

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. 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.

Integrated care pathways (ICPs) combine medical knowledge, workflow guidance and a multi-professional record within one convenient tool. 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 can therefore still fail to provide an integrated health record centred on the patient.

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. This, and much other research, would suggest that interoperability and faithful communication should be key requirements underpinning the specification of an EHR, in addition to data quality and clinical service governance.

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."

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.

The problem is complex because much of clinical meaning is derived not from individual data values themselves but from 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.

Role of the Health Record

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

<p><u>Supports communication</u></p> <p>Supports continuing, collaborative care and case management</p> <p>Accesses medical knowledge databases</p> <p>Allows automatic reports</p> <p>Supports email generation and electronic data interchange (EDI)</p> <p>Enables record transfer</p> <p>Enables record access when and where required</p> <p>Supports selective retrieval of information</p>
<p><u>Supports management and quality improvement</u></p> <p>Enhances the efficiency of health care professionals.</p> <p>Supports continuing professional assessment</p> <p>Facilitates management tasks and reduces routine reporting</p> <p>Demonstrates and improves cost-effective practice</p> <p>Accommodates future developments</p> <p>Provides a legal account of events</p> <p>Provides justification for actions and diagnoses</p>
<p><u>Supports population health care</u></p> <p>Supports policy development</p> <p>Provides evidence for development and evaluation of programs</p>
<p><u>Supports enquiry and learning</u></p> <p>Supports clinical research</p> <p>Assists with clinical audit</p> <p>Supports medical education</p>

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.

The health record is used by staff trained in different disciplines, working in different settings, on different sites, and in different languages. The recording of healthcare information is selective and will always involve a compromise, largely because of time and space constraints. We need to be aware of the danger that the growing enthusiasm for a better-organised and more statistically useful document may place additional burdens on those involved in creating it.

The electronic health record must however accommodate the current growth towards the systematisation of medical knowledge. This involves issues of terminology, classification and a fundamental understanding of the basic sciences of medicine and their clinical correlates. Given the use of the record in the individual clinician/patient consultation, it is clear that it should be ordered around a realistic support of the processes of clinical care and the requirements for access to information. It must take account of the wider needs for communication of the record which encompass all aspects of the health care services, and cross regional and national boundaries.

The health record must accept three areas of change: in time, place, and clinical perspective. A record evolves gradually over a person's lifetime, and family records over generations. We know that people's health care needs change and evolve in time, as does the practice of medicine and the economic and social framework within which medicine is practised.

It is recognised that a computerised health record will be developed within the context of current technology and systems. The record has to be responsive to public needs and priorities, which go beyond personal health care, and which need to be debated within an

epidemiological and public health context. The evolution of solutions will require work in all areas covered in the diagram (Figure 1).

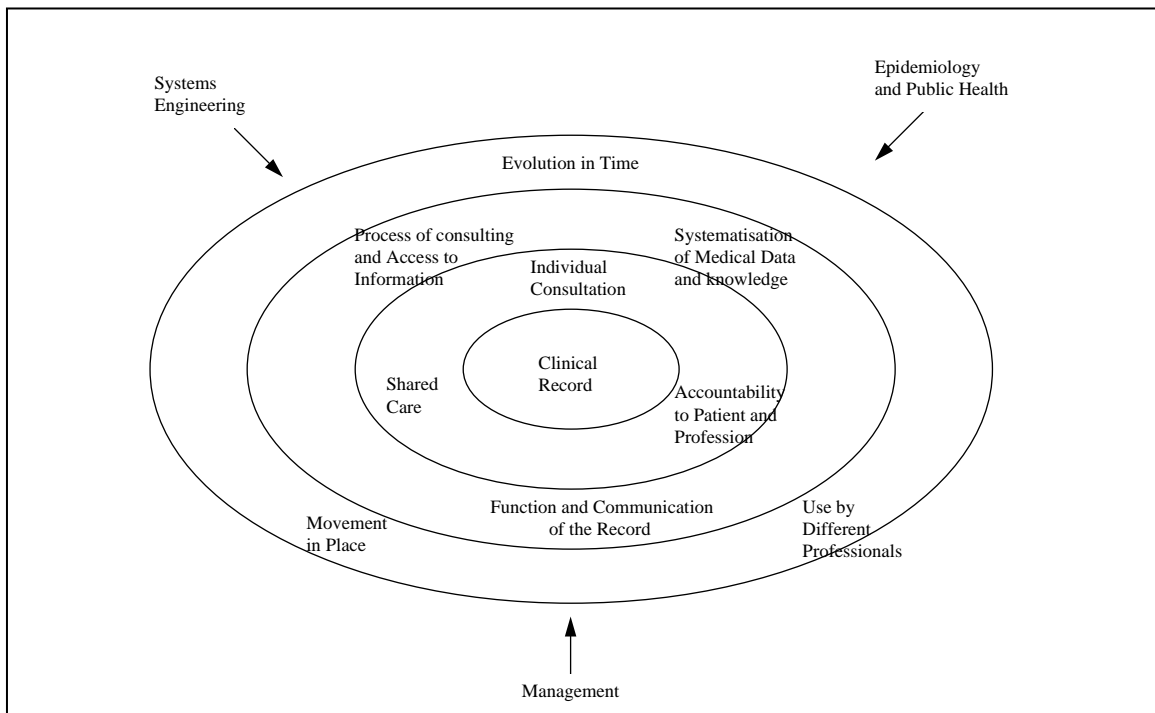


Figure 1: The Context of Healthcare Records

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 (Kalra, Ingram et al. 1999). 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.

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 structural organisation of the EHR needs to be appropriate to the needs of clinicians (Williams and Morgan 1995). (Tange 1999) suggests that the flexibility of data entry and support of narratives are major reasons for the retention of paper records by many clinicians. Achieving the optimum balance between structured, systematised record-keeping and holistic narrative is difficult, and the EHR must not be prescriptive about this: it needs to accommodate both.

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.

(Dolin 1997) suggests that many clinical 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, and 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.”

Clinicians of all disciplines and professions increasingly 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.

Information with considerable sociological and clinical complexity may need to be captured within a health record. Much international research has highlighted the importance of incorporating the context surrounding the authorship of individual EHR entries. (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.

(Berg 1998) 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.

Capturing User Requirements

The challenge being addressed by international research and standards on electronic health record architectures is to provide a formal representation of the generic characteristics applicable to all health record entries.

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

The most detailed review of this domain has been published by the GEHR project, and this set of requirements has informed the subsequent work of PrENV 12265 (Hurlen et al 1995) and the Synapses project (Grimson et al 1996). These reviews themselves incorporate findings from many other international efforts, and influenced the shape of the subsequent European standardisation (discussed later in this document).

Within the ODP Reference Model (ISO/IEC 1990), user requirements and any analysis of record entry contexts would form the basis of the enterprise viewpoint. The architectures developed from them, often expressed as object models, comprise the information viewpoint. Both of these levels of expression can support their implementation in a diversity of computational and engineering methodologies. By remaining at the information viewpoint level, the work on EHR architectures has remained independent of any particular implementation and has enabled the models to be re-expressed as relational schemata, pure object-oriented schemata, within messages and as document schemata (such as XML documents).

The Contexts of an EHR Entry

Although a number of different projects 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.

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 has usually identified a specific data set for context, and 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 EHR, while a few are more applicable to a medical knowledge service interfacing with a population of patient records. The table below summarises the overall set of contexts that need to be mapped to classes and attributes within an EHR architecture.

Table showing the range of contexts which may be associated with healthcare record entries

<p>Compositional Context</p> <ul style="list-style-type: none"> • Record entry names to provide a label for each content value • Compounding hierarchies of clinical concepts to express complex concepts • Grouping hierarchies for a sets of clinical concepts with common headings, to: • preserve the way in which entries were originally organised by the author • identify the way in which the clinical concepts relate to the health care activities and processes surrounding the patient
<p>Content Value Context</p> <ul style="list-style-type: none"> • Formal representations for all data types, including text, quantities, time, persons and multi-media • Names of term sets, versions and registering agencies • Natural language used in a recording • Accuracy, precision and units for quantities • Normal ranges
<p>Qualifier Context</p> <ul style="list-style-type: none"> • Presence / absence • Certainty • Severity • Site and laterality • Prevailing clinical circumstances (e.g. standing, fasting) • Justification, clinical reasoning • General comments • Knowledge reference (e.g. Medline)
<p>Ethical and Legal Context</p> <ul style="list-style-type: none"> • Authorship and duty of care responsibilities • Subject of care • Dates and times of healthcare actions and of their recording • Version control • Access rights • Emphasis • Preservation of meaning on transferring the record to another site
<p>Care Process Context</p> <p><u>Links and pointers:</u></p> <ul style="list-style-type: none"> • to other parts of the record, e.g. • cause and effect • request and result • process status • to a defined problem • to an episode of care • to a stage in a protocol • to a decision support system

R&D background to the EHR architectural approach

The architectural approach to representing the EHR has its origins in research undertaken through the EU Third, Fourth And Fifth 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. Between 1991 and 1998 the European Union provided 47 Million ECU of direct funding support to research projects whose budgets totalled 76 Million ECU (Iakovidis 1998).

Considerable research has been undertaken over the past fifteen years 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 standards ENV12265 and ENV13606). Other 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).

These projects 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. More recently parallel threads of research in Europe and Australia have been united through the *openEHR* Foundation.

The Federation approach

The federated electronic health record of any one patient is 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. 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.

The federation approach, as demonstrated by the Synapses project (1996-8), is a validated mechanism for realising a distributed EHR service. In database federation the 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.

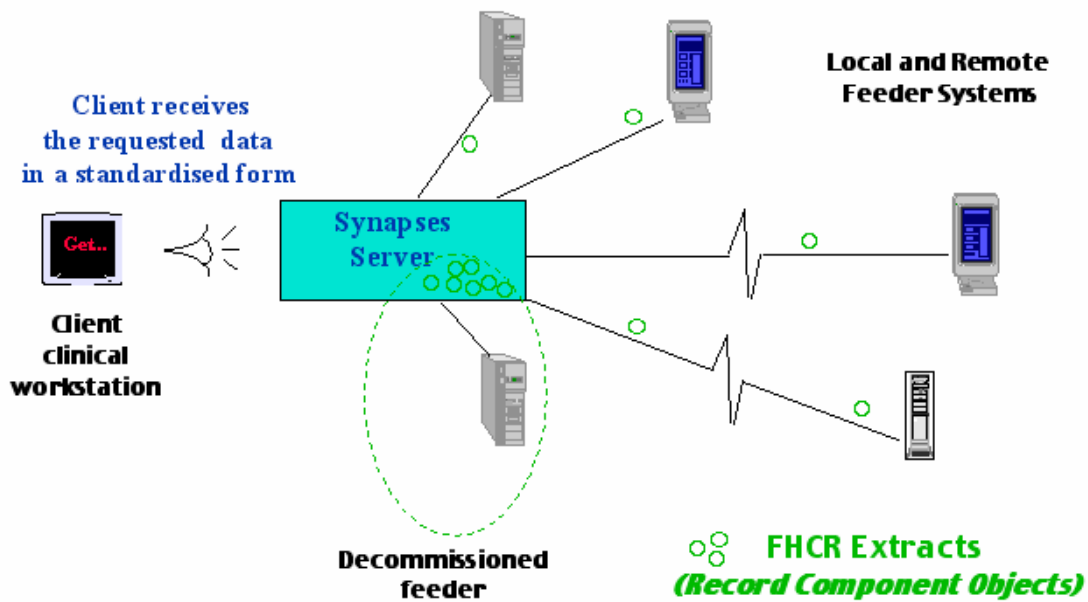


Figure 2: Distributed access to record components within a Synapses federation

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.

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.

This schema, in a health care context, is 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.

The strength of the approach taken in Europe and Australia on the EHR architecture (spanning GEHR, EHCR-SupA, Synapses, SynEx, GeHR and *openEHR*, 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 this core architecture is recognised by 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 the nature of the clinical content have not been "agreed" in advance.

The Dual Model approach

The wide-scale sharing of health records, and their meaningful analysis across distributed sites, requires that a consistent approach is used for the naming and organisation of EHR hierarchies,

so that requesting processes can precisely specify the desired parts of an EHR within a request, and anticipate the kinds of data structures that will be provided in response. The challenge for EHR interoperability is therefore to devise a generalised approach to representing every conceivable kind of health record data structure *in a consistent way*. This needs to cater for records arising from any profession, speciality or service, whilst recognising that the clinical data sets, value sets, templates etc. required by different health care domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance. This requirement is part of the widely acknowledged health informatics challenge of *semantic interoperability*.

The dual-model approach distinguishes a Reference Model, used to represent the generic properties of health record information, and Archetypes (conforming to an Archetype Model), which are meta-data used to define patterns for the specific characteristics of the clinical data that represents the requirements of each particular profession, speciality or service.

The Reference Model is specified as an ODP Information Viewpoint model, representing the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. This model defines the set of classes that form the generic building blocks of the EHR. It reflects the stable characteristics of an electronic health record, and would be embedded in a distributed (federated) EHR environment as specific messages or interfaces. This model corresponds conceptually to the EHCR architecture of GEHR (Lloyd, Kalra et al 1995), the Synapses SynOM (Kalra 1998), the information model of ENV 13606-1 and the *openEHR* Reference Model (www.openehr.org).

Such a generic information model for the EHR needs to be complemented in the knowledge domain by a formal method of communicating and sharing the organisational structure of predefined classes of EHR fragment corresponding to sets of record components made in particular clinical situations. These are effectively pre-coordinated combinations of named record component hierarchies that are agreed within a community in order to ensure interoperability, data consistency and data quality.

An Archetype is the formal definition of prescribed combinations of the building-block classes defined in the Reference Model for particular clinical domains or organisations. An archetype specifies (and effectively constrains) a particular hierarchy of record component sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity at any point in the hierarchy, the data types and value ranges that element (leaf node) data values may take, and may include other dependency constraints. Archetypes express the rules by which useful clinical templates can be constructed from the Reference Model in consistent and interoperable ways. Archetype instances themselves conform to a formal model, known as an Archetype Model (which is a constraint model, also specified as an ODP information viewpoint model). This model corresponds conceptually to the Synapses Object Dictionary (Kalra 1997), (Kalra 1998), the archetype concept of the Good Electronic Health Record project (Beale 2000), now consolidated as the archetype approach of *openEHR*. Although the Archetype Model is stable, individual archetype instances can be revised or succeeded by others as clinical practice evolves. Version control ensures that new revisions do not invalidate data created with previous revisions.

Archetypes may be used within EHR systems to govern the EHR data held within a repository. However, archetypes might be used as a means of ensuring a consistent mapping between EHR systems that themselves do not use archetypes internally.

If a set of EHR systems, enterprises or regions share a common set of archetypes, client services can reliably request specific parts of one or more EHRs, from one or more EHR systems, and ensure that the providing EHR systems will map the original clinical data to a consistent hierarchy of record components within an EHR extract.

Archetype Repositories The range of archetypes required within a shared EHR community will depend upon its range of clinical activities. The total set needed on a national basis is presently unknown, but there might eventually be several thousand archetypes internationally. The potential sources of knowledge for developing such archetype definitions will include:

- the data schemata (models) of existing clinical 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;
- shared-care data sets, messages and reports used locally and nationally;
- the structure of templates and forms used for the documentation of clinical consultations or summaries within paper records;
- health information used in secondary data collections;
- the pre-coordinated terms in terminology systems.

Any library of archetypes might be held in a repository for rapid access within a network of distributed EHR systems and other services that request or provide EHR data. Some large communities might have more than one interconnected repository. By conforming to a common Reference Model and Archetype Model the individual libraries of archetype definitions held in each repository can be exchanged in order to facilitate this progressive convergence across sites or regions.

In order to realise the full benefits of a local or national federation, enterprises ideally should progressively agree on common definitions that they could use to exchange clinical information. In the longer term, it is anticipated that the involvement of national health services, academic organisations and professional bodies in the development of archetypes will enable this approach to contribute to the pursuit of quality evidence-based clinical practice. In the future regional or national public domain libraries of archetype definitions might be accessed via the Internet, and downloaded for local use within EHR systems.

The value of the approach described here is that diverse health and health care information can be represented and communicated in a standardised way that is also scalable and maintainable. The combination of the Reference Model and the use of Archetypes (as the EHR information architecture) preserves faithfully the set of contexts relating to a health record fragment, to ensure the intended clinical meaning of the original author is preserved within the generic representation.

The dual Reference and Archetype Model approach described here is being adopted in three areas of work:

- the design of the *openEHR* Reference Model which combines the validated features of this model with parallel work carried out by GEHR Australia;
- as an input to the EHRcom Task Force charged with revising ENV 13606;
- as an input to the development of HL7 Templates.

Each of these three activities is summarised below, and the present harmonisation efforts between them is then discussed.

European (CEN) EHR interoperability standards

Task Force 13606: EHRcom. In December 2001 CEN TC/251 confirmed a new Task Force, known as “EHRcom”, to review and revise the 1999 four-part pre-standard ENV 13606 relating to Electronic Healthcare Record Communications. The intention of this work is to develop a new EHR communications standard that could be adopted by CEN as a formal standard (EN) by 2006. The author (Dipak Kalra) is leading this Task Force, which has set out to base the revision of ENV 13606 on the practical experience that has been gained through commercial systems and demonstrator pilots in the communication of whole or part of patients’ EHRs. Its overall mission 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.

There is wide international interest in this CEN work, and valuable experience from beyond Europe is contributing to the revision.

HL7 is engaged in a significant revision of its information architecture, with a partial overlap in purpose to this and other CEN activities.

A combination of good working relationships between CEN, *openEHR* and HL7 has led to an intention to harmonise the proposed new standard with both *openEHR* (reference model and archetype approach) and with HL7 (mainly the Clinical Document Architecture, discussed below).

EN 13606 will be a five-part standard.

Part 1: Reference Model, is a comprehensive, generic EHR model drawing on 12 years of R & D (and 2 previous CEN standards); it is mapped to the HL7 RIM and Clinical Document Architecture.

Part 2: Archetype Interchange Specification is an information model and exchange syntax for communicating archetypes; this specification is largely adopting the *openEHR* archetype approach, and will be compatible with the emerging HL7 Template specification.

Part 3: Reference Archetypes and Term Lists will contain a set of vocabularies and term lists to support the Reference Model, guidance on how to use the Reference Model classes and attributes, and how to design archetypes.

Part 4: Security defines measures to support access control, consent and auditability of EHR communications.

Part 5: Exchange Models defines messages and service interfaces to enable EHR and archetype communication.

Other relevant contemporary work in CEN

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. This standard is presently being updated.

CEN standard ENV12967 (Healthcare Information Systems Architecture) defines a generic model for health systems, including EHR systems. This standard is presently being revised and extended, and is being harmonised with EHRcom to ensure that EHR communications interfaces are also part of the next HISA standard.

Another potentially useful European interface to HL7 is the definition of General Purpose Information Components (GPICs), which are re-usable information model fragments (such as a demographic or address component), which are derived from the HL7 v3 RIM. These models will be used within future CEN standards to ensure a consistency between standards on certain

basic classes of information and also ensure that cross-mapping such standards to future HL7 v 3 messages will be easier. The clinical GPICs will be represented by EHRcom archetypes.

Health Level Seven (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.

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 v2 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.

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 information model 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 four major classes of information.

1. Entities, for example persons, organisations, places and devices;
2. Roles, for example that of patient or employee;
3. Participation relationships, for example that between a patient and a clinician;
4. Acts, for example the recording of patient encounters, observations, procedures;
5. Act relationships, for example between a request and a report or between a full blood count and its constituent measurements.

In addition, HL7 v3 specifies document structures, data types and control classes dealing with the message transaction process. 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 provides 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) 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 those formats in more widespread use.

Collaboration is now taking place between CEN and HL7 on the definition of CMETs and GPICs, which serve similar purposes.

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 sometimes seen, though, as an important competing alternative to the European EHR approach as proposed earlier in this document. This issue is discussed later.

The Clinical Document Architecture. The HL7 Clinical Document Architecture (CDA) is a generic structure for the communication of clinical documents, and is sometimes regarded as the HL7 equivalent of a record architecture (Dolin, Alschuler et al. 1999). Release One of CDA has is an XML-based standard that comprises a header with document authorship information, organisational origin and patient identifiers, and a body whose basic structure is defined at a high level (Dolin, Alschuler et al. 2000). Datatypes are taken from HL7 v3 RIM.

CDA Release Two, which has recently been passed as a standard, specifies the structural organisation of fine-grained information inside a document. In this regard it is now very close in scope to that of the inner hierarchies of an EHR architecture. A three-way collaboration now exists between the work on CDA Release 2, EHRcom and *openEHR*, discussed below.

CDA Release Three will probably utilise a template approach to constrain the permitted structure of clinical documents. A CDA Release Three document will therefore need to cite the valid HL7 Template definition to which it conforms. This work within HL7 has some deliberate overlap with the archetype approach of *openEHR*.

The **HL7 Template Special Interest Group** is actively developing a specification for constraints to be applied to RIM-derived message models. This work is drawing upon the *openEHR* archetype approach.

The **HL7 EHR Technical Committee** has published an EHR System Functional Model as a draft standard for trial use. This standard describes an inclusive set of functions that might be available in EHR systems in particular (profiled) settings – now and in the future. This set of functions provides a standardised way to describe EHR systems and their capability, as an aid to system comparison and procurement.

IHE

Integrating the Healthcare Environment (IHE) is a recently-formed industry sponsored organization seeking to promote interoperability between systems within specialist departments such as radiology, and the conventional hospital systems used to order such investigations and to receive imaging study reports. It is working closely with DICOM and HL7 in this area.

Its most recent specification, still in draft form, is for Cross-Document Sharing (XDS). It defines registry and repository services that can function as a centralised or distributed warehouse for clinical documents. Through specific collaborations between the parties involved, it will be capable of supporting HL7 CDA documents and EHRcom (13606) equivalent structures, but not a full EHR. It is a primarily a storage, indexing and distribution mechanism, and is a practical complement to these other standards.

International (ISO) EHR interoperability standards

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.

This ISO forum, bringing together a diverse international set of informatics and health service stakeholders, will progressively define standards for the EHR. Working Group 1 has published a set of requirements (Schloeffel 2002) that consolidates previously published research on EHR requirements, and is presently defining the overall scope of the EHR. It has approved a process of reviewing the CEN EHRcom draft standard (draft of EN 13606) with a intention of accepting it as a full international standard by 2007.

Other current ISO work includes the definition of standard datatypes that can be adopted by other future standards as an aid to their interoperability. This Project Team is seeking to also harmonise the data types with those specified in the HL7 v3 RIM (see below). This is being tackled by adapting a sub-set of these HL7 data types and refining them by incorporating features from other healthcare domain models such as the EHR specification of *openEHR*.

The *openEHR* Foundation

The *openEHR* Foundation is an independent, not-for-profit organisation and community, founded in 2000 by University College London and Ocean Informatics. Its aim is to facilitate the creation and sharing of health records by consumers and clinicians via open-source, standards-based implementations. Its mission statement is:

“To improve the clinical care process by fostering the development and implementation of open source, interoperable EHR components. These components should be based on internationally agreed requirements and address the need for privacy and security, while supporting the development of interoperable and evolving clinical applications.”

openEHR aims to:

- promote and publish the formal specification of requirements for representing and communicating electronic health record information, based on implementation experience, and evolving over time as health care and medical knowledge develop;
- promote and publish EHR information architectures, models and data dictionaries, tested in implementations, which meet these requirements;
- manage the sequential validation of the EHR architectures through comprehensive implementation and clinical evaluation;
- maintain open source "reference" implementations, available under licence, to enhance the pool of available tools to support clinical systems; and
- collaborate with other groups working towards high quality, requirements-based and interoperable health information systems, in related fields of health informatics.

Technically, *openEHR* is founded upon formal software engineering methods. It proceeds with domain and problem analysis, formulates requirements and design principles, then develops architectural specifications, and then initiates implementation projects that, through iterative refinement and testing, are used to validate and improve the architecture and requirements. The process and deliverables of these activities are all managed by a formal change control process and version management tools.

The *openEHR* technical specifications define design principles, reference and archetype models and will in future include other middleware service specifications. This work originated as the convergence of the European and Australian experience, but has matured considerably through contributions from many of its five hundred members. It is becoming regarded internationally as the most complete and best-validated EHR information architecture.

Discussion

There is considerable activity on the EHR front: specifying, standardising and implementing components to demonstrate comprehensiveness and interoperability. In practice, these different efforts are each tackling slightly different aspects of the interoperability challenge, and where overlap exists there is a good working relationship between the groups, including cross-membership, and harmonisation is actively sought.

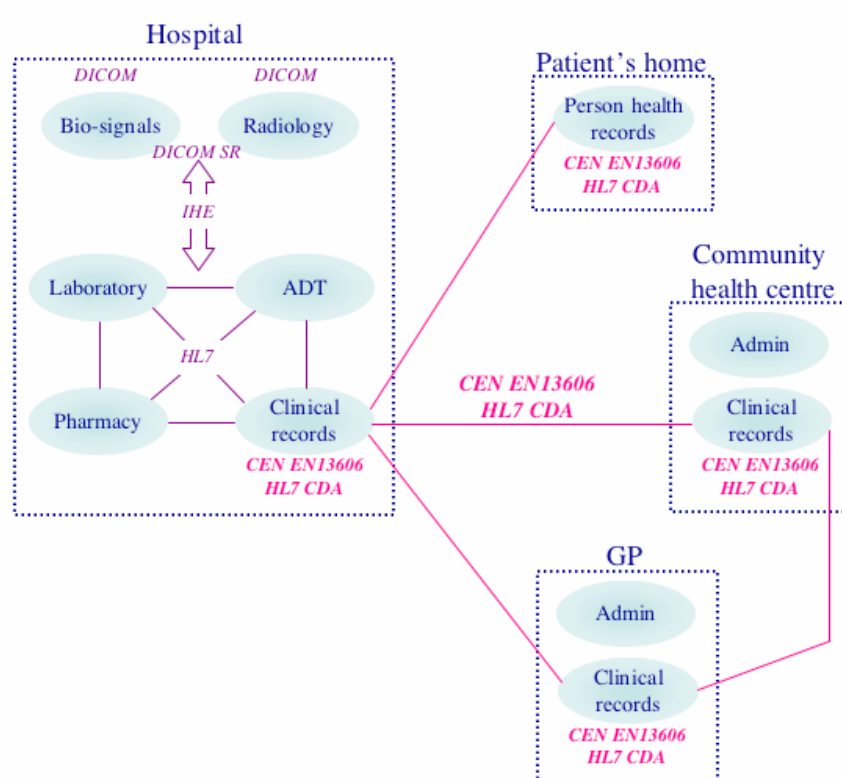


Figure 3: Domains of communication of health information covered by different industry and legislative standards

EHRcom and *openEHR* each have a long and overlapping pedigree in research into the requirements and information architectures for the EHR. There has also been considerable interest in *openEHR* and EHRcom within HL7, and some elements of the HL7 Clinical Document Architecture (CDA) and the Template draft specifications have drawn on *openEHR* concepts and documents, including the use of archetypes.

Reciprocally, there is much valuable work occurring within HL7 that could usefully inform future refinements of the *openEHR* 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 author (DK) and colleagues within CEN, *openEHR* and HL7 are presently collaborating towards harmonisation between these various approaches. The discussions that are taking place between members of these three organisations have positively impacted on all three evolving specifications, bringing some degree of convergence where this is felt appropriate. The three groups are now starting to identify the cross-mappings that would be needed to enable the exchange of EHR data between implementations of each approach.

Moving forward

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 4).

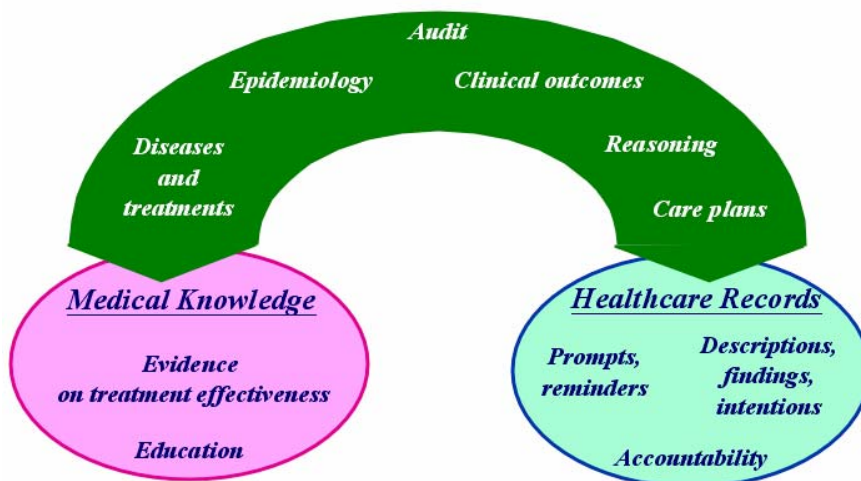


Figure 4: Clinical information services supporting patient care

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 5 below.

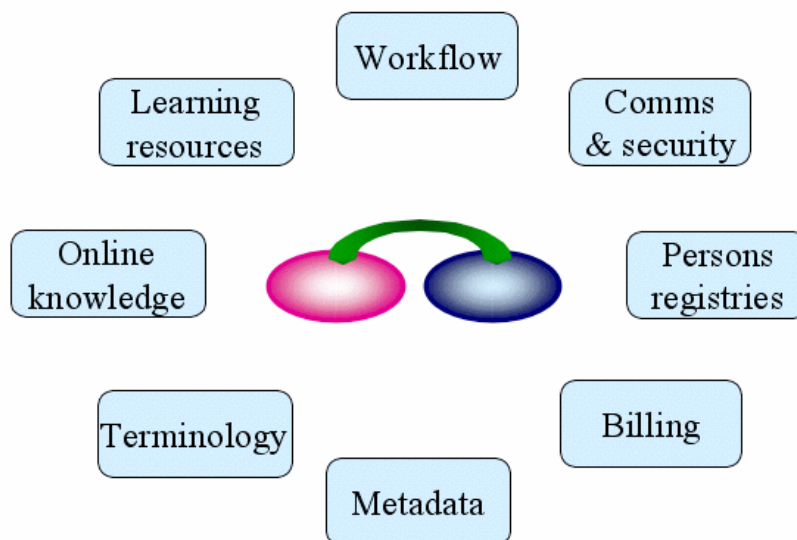


Figure 5: Other components and services supporting the clinical middleware

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, such as those presently being developed by *openEHR*.

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