Electronic Health Records

Dipak Kalra[1], David Ingram[1]

[1] Centre for Health Informatics and Multiprofessional Education, UCL, London, UK

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 multimedia entries. A longitudinal person-centred electronic health record (EHR) is a much-anticipated solution to this problem, but the challenge of providing clinicians of any profession or speciality with an integrated view of the complete health and healthcare 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.

From an academic vision in the late 1980s the EHR has evolved to become centre stage in the national health informatics strategies of most European countries, and internationally. Health services and vendors are now actively establishing national infrastructures to enable the communication of high volumes of clinical information, and incorporating the necessary security features to protect these data.

International research has highlighted the clinical, ethical and technical requirements that need to be met in order to effect this transition. There is a need for interoperability standards that can permit clinical computer systems to share health record data whilst preserving faithfully the clinical meaning of the individual authored contributions within it. Concerns about protecting the confidentiality of sensitive personal information must also be addressed if consumer confidence is to be maintained when EHRs are widely accessible.

There are many challenges and cultural changes facing the safe and effective delivery of contemporary healthcare services:

- the requirement to limit healthcare costs and to optimise resource utilization,
- 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 healthcare 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.

Smith suggests [62] that traditional models of healthcare services have been associated with inefficient and inequitable healthcare, favouring expensive specialised interventions over some more useful measures to provide support for patients and families at home. 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.

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 application of information technology to modernise health services has progressively 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" [14]. This promise has recently been translated at the Presidential level into a US national strategic plan [24].

The UK Government has made promises of NHS modernisation. Realising the EHR is a core target of, for example, the UK National Health Service IM&T strategy [11]. Health Secretary Alan Milburn has pledged that every adult will soon be able to access his or her own at-a-glance electronic healthcare record [21]. There is now a recognised urgency for a National Health Service longitudinal care record, for example to reduce the frequency of inappropriate and unsafe prescribing, to facilitate adherence to guidelines of best practice across enterprise boundaries and to increase consumer choice [16]. The National Programme for IT (NPfIT) has embarked on a ten-year plan, and currently committed £6.2 billion, to create a fully integrated electronic care record for the whole of England [15].

The NHS "big bang" approach, which is the largest current IT procurement programme on the planet, is in stark contrast to equivalent projects in, for example, Canada's Infoway [2] and Australia's HealthConnect [4] projects. In those countries the intention is to foster a network of regional projects, encouraged towards strategic alignment and interoperability through national co-ordinators and selected key infrastructure elements. In many countries there is also a recognition that a national solution will not in itself prove sufficient for our increasingly global society – international standards are needed to help ensure that patients and healthcare workers can experience a joined-up health service across national borders.

There is now an international momentum to establish the standards by which patient health record information can be shared between healthcare providers and follow patients as they move between them. Ilias Iakovidis, Project Officer for the European Commission's Health Telematics programme, identified that an important challenge for realising successful EHR implementations at a national or regional level includes "the storage, maintenance, communication and retrieval of multimedia information on heterogeneous and geographically distributed database systems" [32]. Rogers, 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 [54].

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 [65], [64], [66], [50], [22].

The delivery of safe and effective (i.e. evidence based) healthcare 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 [37]. 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 [3]. Surprisingly high rates of missing or erroneous information have been confirmed in a number of studies [68], [25], [71]. 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 [7], [72], [56].

Healthcare professionals need to share healthcare information with a growing range of professional colleagues, often on multiple sites. 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.

However, significant problems can arise in continuity of care if salient information is not communicated. Figure 0-1 shows the situations of high clinical risk regarded by east London GPs as requiring urgent communication from hospital [41]. 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 GPs indicated that the relevant hospital doctor should personally notify them by telephone rather than rely on fax or letter.

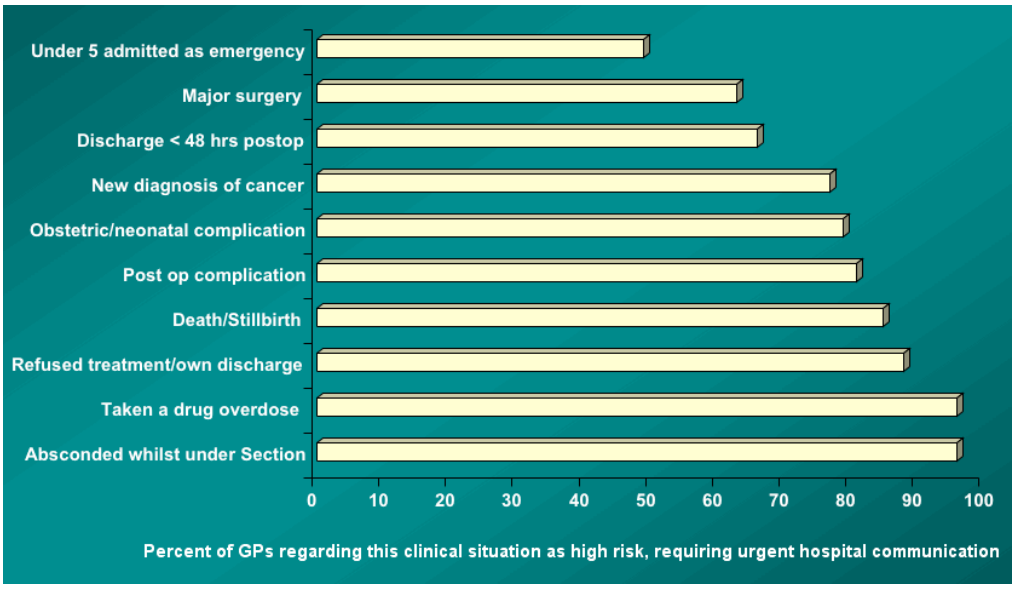

Figure 0-1 High-risk clinical situations requiring urgent communication from hospital to GPs.

The clinical requirements for which information technology solutions are needed are in the areas of [48]:

- 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.

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 healthcare, 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 healthcare 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 healthcare 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 healthcare 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 healthcare 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's Survey of EHR Trends and Usage [69] over 70% of respondents regarded the need to share patient record information between different healthcare 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.

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 healthcare 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.

In 1998 Shortliffe wrote [60]:

> "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…. 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."

His views remain pertinent today.

Visions of a Comprehensive 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) [17]. 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.

In [70] Waegemann defined five levels of Electronic Health Record, of which Level 5 extends the vision of the Electronic Medical Record of the CPRI.

> "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".

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 healthcare purchasers (health authorities or insurers) undertaking quality assurance,
- healthcare 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 [6], [36], [26], [49] and collated by Heard et al. [28].

Table 0-1 Roles for the electronic health record

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 healthcare
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 healthcare 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 healthcare
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

This list of roles 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 [36].

The EHR needs to represent responsibilities and intentions within the shared care process in order to support effective clinical workflow and 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 [1].

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 healthcare, provided that feedback on the acquired data is offered to them. 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. 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.

Computers offer tremendous opportunities to place patients in control of their own healthcare [61], and see them as informed partners in decisions about their own healthcare and in service priority setting [53], [10], [51]. Patients can acquire considerable expertise in managing their own health if they are given useful and appropriate material with which to educate themselves [12], [46], [38], [5]. A third of US home Internet users seek online health advice before calling their physicians [13].

Analyses of the utilisation of healthcare 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. EHR systems need to be able to identify relevant patient characteristics to inform commissioning decisions and to reduce inequalities in access to service. For public health surveillance purposes, these kinds of analyses across population health records are needed in real time.

Characteristics of a Good 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 healthcare 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. 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 0-2).

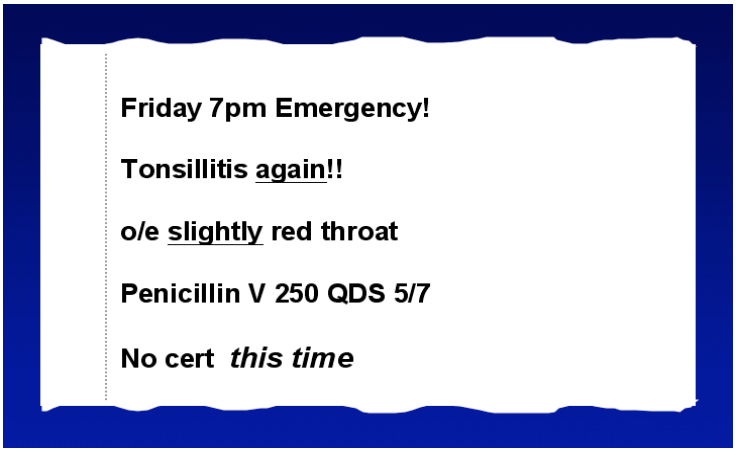

Figure 0-2 An example narrative record entry, showing the richness that can succinctly be expressed but is full of ambiguity.

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 are not supported by the clinical evidence. EHR adoption, if it is to meet future challenges, will require a greater clinical attention to data quality.

Whether using terminologies or free text, 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 [73]. Flexibility of data entry and support of narratives are major reasons for the retention of paper records by many clinicians [67]. 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.

Many contemporary systems lack both detail and uniformity to enable the consistent retrieval of good outcome data across providers [19]. Dolin 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."

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.

The medical record needs to be *faithful* [52], 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. 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 [47]. Their perspective will influence what is recorded and how it is expressed.

Berg 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 [9]. 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.

Research into Representing the Generic EHR

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 Euro of direct funding support to research projects whose budgets totalled 76 Million Euro [31].

Realising the electronic health record has been at the heart of the European Union's Third, Fourth and Fifth Health Telematics Framework Programmes. Considerable research has been undertaken over the past twelve years to explore the user requirements for adopting EHRs (for example, published by the Good European Health Record Project [36], [33], [34], [35], [27] and the EHCR Support Action [18]). These have formed the basis of architecture formalisms to represent and communicate personal health data comprehensively and in a manner which is medico-legally rigorous and preserves the clinical meaning intended by the original data author (e.g. the GEHR architecture [44], and the CEN standards ENV 12265 [30] and ENV 13606 [43]). These results have at their heart the recognition that personal health data is often very sensitive and always to be regarded as confidential.

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 [23]) and middleware architectures to integrate across R&D projects (SynEx [62]). EHR demonstrators have been established in many European countries, through these R&D projects and subsequently through national programmes, as the strategic importance of EHRs has grown. For example, University College London has been developing, evaluating and

refining an implementation of the EHR service architecture based on the results of these European projects and relevant CEN standards, with a principal demonstrator in cardiology [39].

In Australia a successor to the Good European Health Record, the Good Electronic Health Record project, has enabled various federal government-funded projects to establish demonstrators of an EHR server as an integrator of clinical information to support diabetes shared care and for laboratory test results [8] [58].

These research projects, standards and demonstrators have played a strong role internationally in defining the widely-accepted requirements for and information architecture characteristics of EHR systems, as reflected throughout this chapter, and in [42]. They have also provided the primary input for work internationally on EHR communication standards, and the *open*EHR Foundation, both described in later sections of this chapter.

Ongoing research continues to explore the optimal design of EHR system components, and tackle new informatics challenges such as clinical genomics and Grid computing and their consequent ethical issues [40].

Requirements for Representing the EHR

There is now a wealth of published clinical and ethico-legal requirements for the information architecture of an EHR if it is to be realised through the interconnection (federation) of diverse clinical systems. 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 many healthcare settings across Europe. 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.

These requirements have recently been consolidated on the international stage within an ISO draft Technical Specification, ISO TS 18308 [57].

Joining up diverse and sometimes discipline-specific and culturally specific kinds of clinical information to compose a whole-person EHR that can safely, legally and useably replace paper records is a complex challenge. Research 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. (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.) 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 0-3.

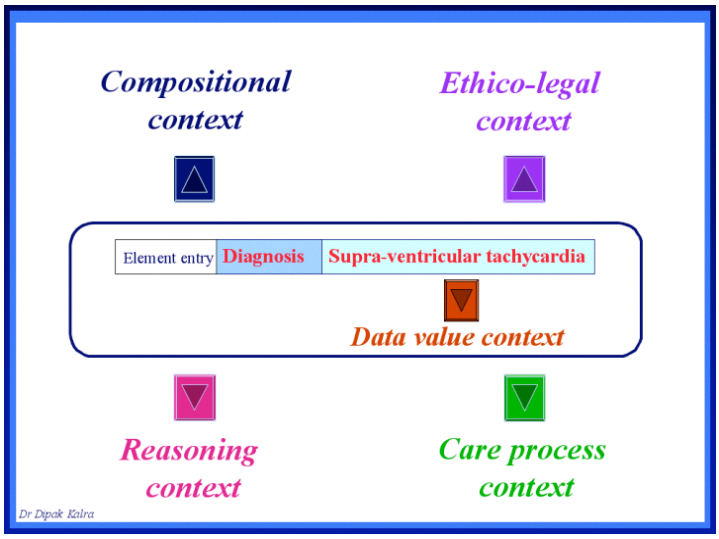

Figure 0-3 The kinds of context associated with a health record entry.

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.

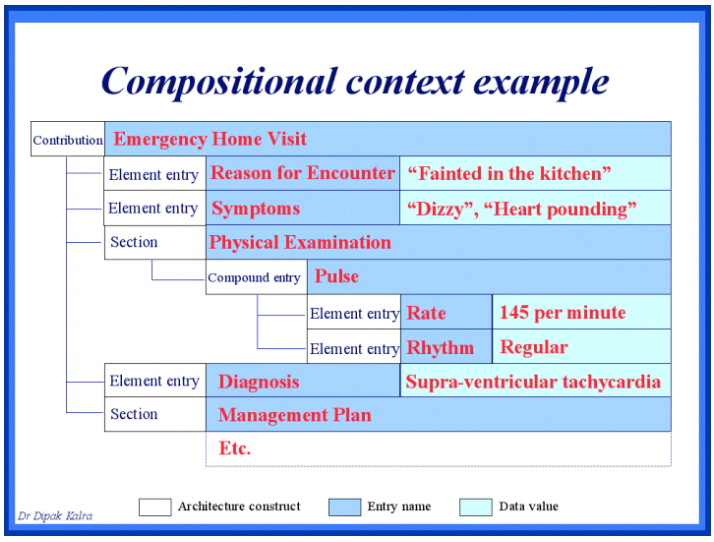

Figure 0-4 Illustration of the compositional context.

From the information in

Figure 0-4 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:
  1. an element e.g. for Weight,
  2. 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 EHRs 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.

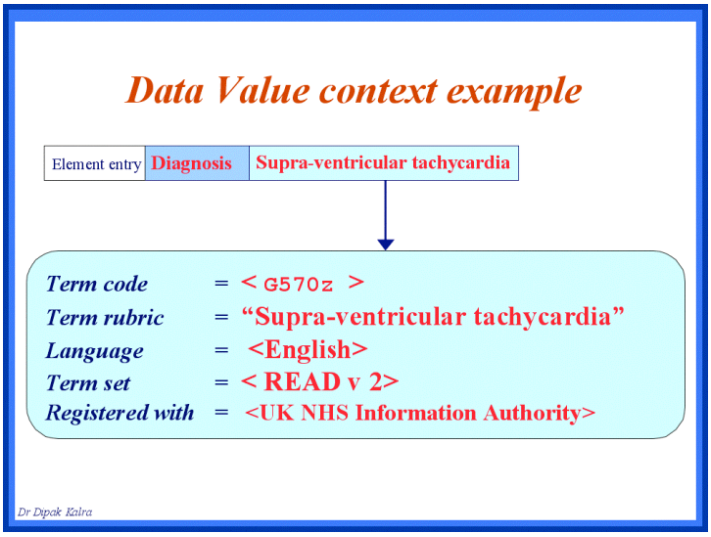

Figure 0-5 Illustration of the data value context.

The EHR clearly needs to be able faithfully to represent a comprehensive range of data types, including:

- text, quantities, time, persons, multimedia,
- 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 ethical and legal requirements of good clinical care emphasise the importance of documenting, for example, the authorship and dates and times associated with each record entry. The EHR must be able to represent these data faithfully.

Figure 0-6 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 kind of context may include:

- identifying authorship, authorising agents and those with legal responsibility for the documented healthcare,
- 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.

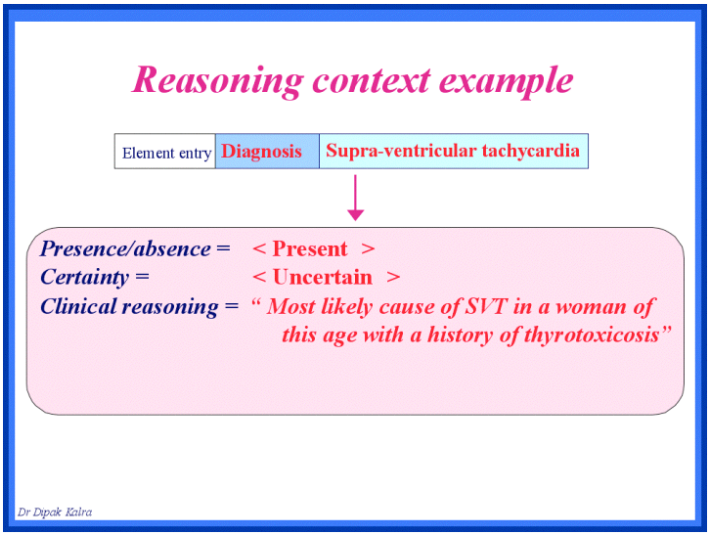

Figure 0-7 Illustration of the reasoning context.

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 0-8.

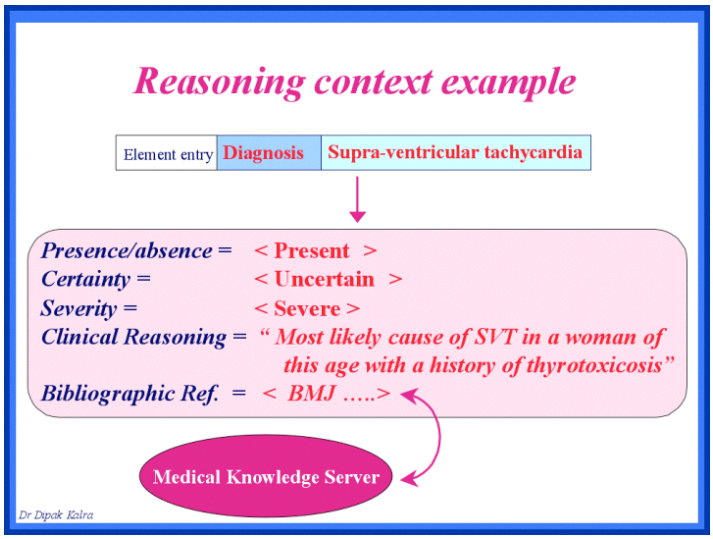

Figure 0-8 Illustration of a context link to a Medline reference.

The authors are 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.

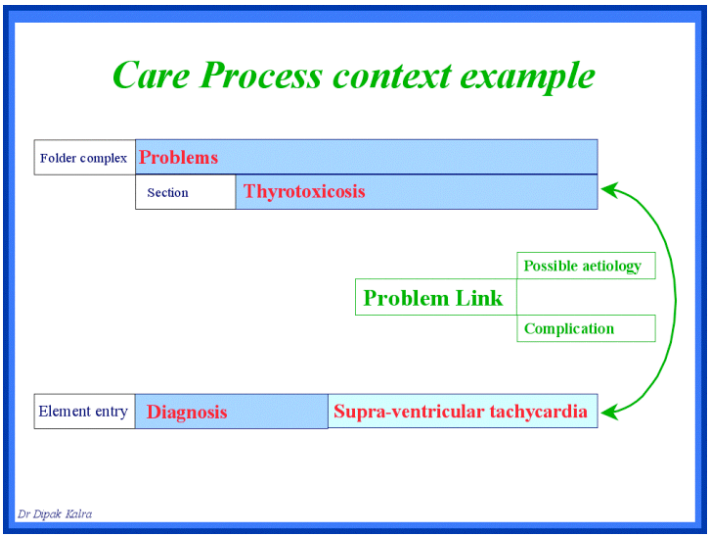

Figure 0-9 Illustration of the care process context.

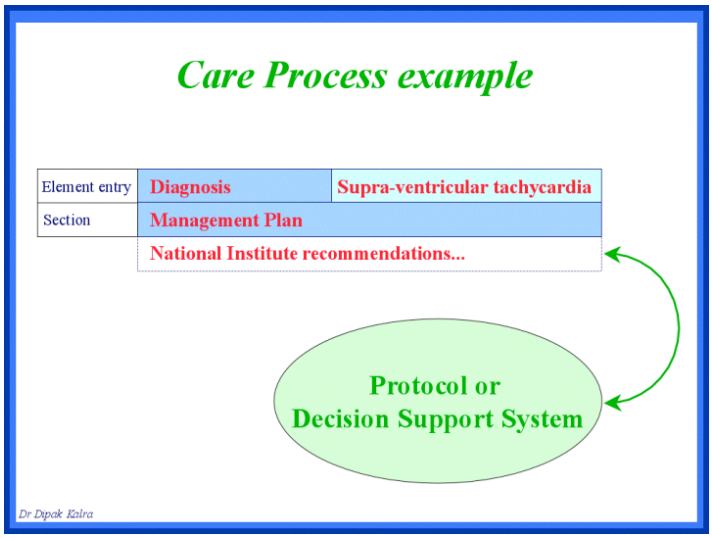

Figure 0-10 Illustration of a context link to a protocol.

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.

If the EHR is to be capable of representing a comprehensive lifetime record of a patient, and support interoperability, it needs to be able to retain all of these aspects of context in a consistent and rigorous way to ensure that any future requesting clinical system can interpret the individual observations safely. The research and standards work on EHR information architectures, described in the chapter, has precisely this goal.

Scope of the EHR

The principal set of software components that would be deployed in a health setting to deliver a functional EHR are drawn in Figure 0-11. The services that directly implement the core EHR are shown in green, middleware services that support the EHR are shown in yellow, and the end-user facing applications are shown in pink. When clinicians and purchasers conceptualise an EHR system, they commonly consider the pink zone and assume the existence of the other components. Health informatics research and standards on the generic EHR has concentrated upon the green zone. It is this core EHR that absolutely must be interoperable internationally in order to support a whole-person EHR. Applications developed in the pink zone will probably always exhibit diversity across health systems and specialities.

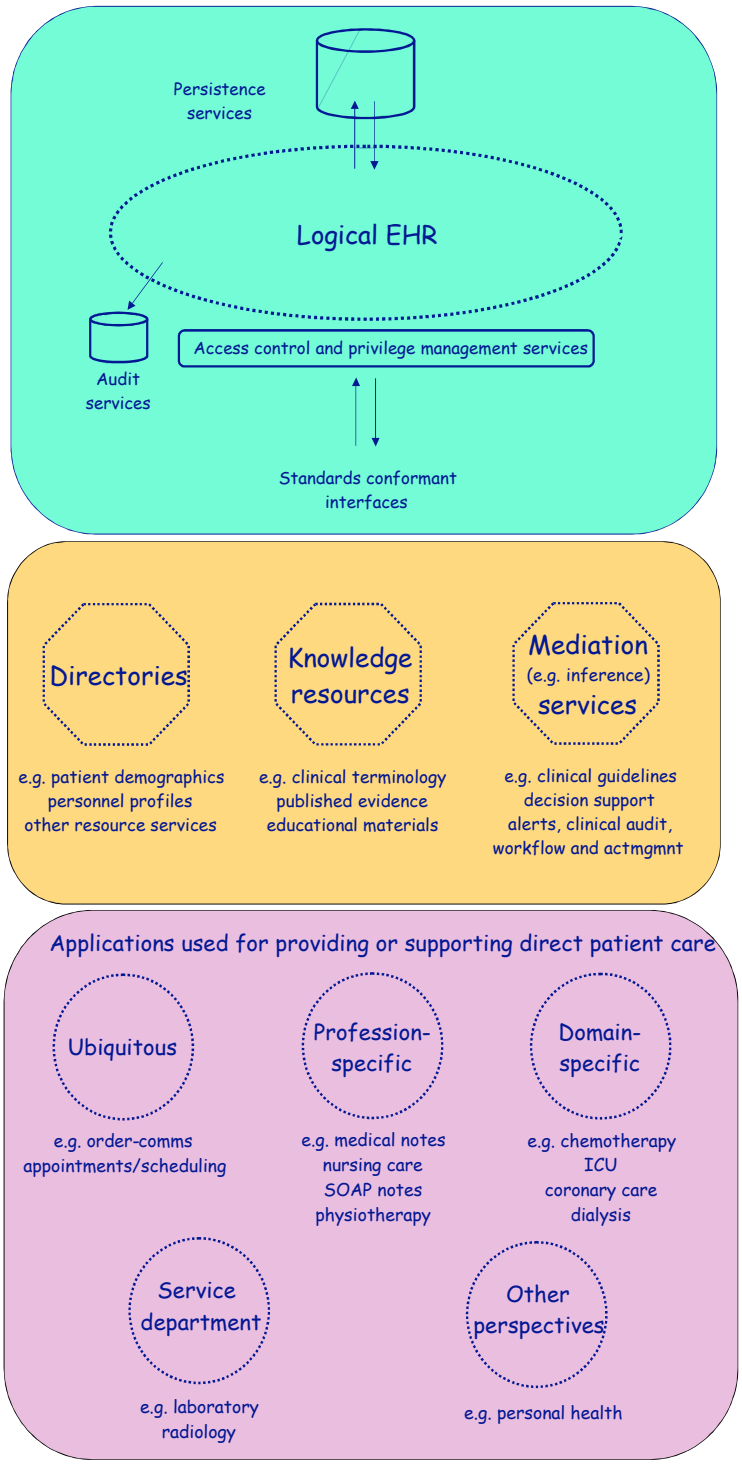

Figure 0-11 A layered view of the clinical system components interacting with the HER.

A vast number of requirements relate to the applications and systems that will capture EHR data from clinicians, carry out processing on that data including decision support, recalls and reminders, and deliver integrated or detailed views of EHR data back to clinicians. It is widely recognised that this vast field of clinical system design is broader than the EHR concept, which is limited in scope to the faithful and interoperable representation of EHR data itself. The full treatment of EHR clinical systems is therefore beyond the scope of this chapter.

Adopting an Architectural Approach to Representing the EHR

The Federation Approach

A comprehensive, multi-enterprise and longitudinal EHR will inevitably be realised through the joining up of the specific 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 question that remains open is whether this joining up takes place in real time, logically, or physically through the creation of a large dedicated EHR repository which these distributed clinical systems all feed on a frequent basis.

The federation approach, as demonstrated by the Synapses project (1996-8), is a validated mechanism for realising a distributed EHR service, which can be physical or logical. 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.

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.

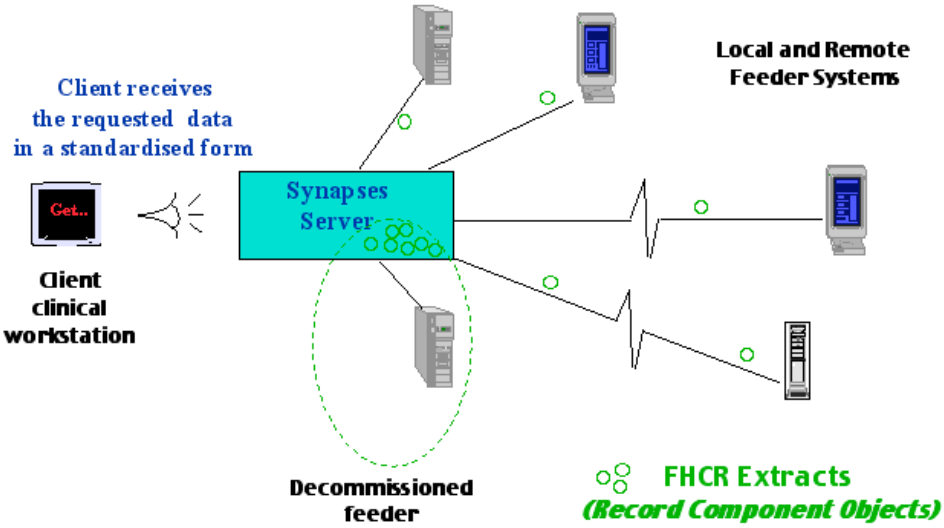

Figure 0-12 Distributed access to record components within a Synapses Federated Healthcare Record (FHCR) federation.

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 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 internationally on the EHR architecture 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 the nature of the clinical content have not been “agreed” in advance.

The Two-Level Modelling Approach

The challenge addressed by the two-level (dual-model) approach to the design of the EHR information architecture has been to devise a scalable model for representing any conceivable health record entry. 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. The two-level 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 represent the specific characteristics of the various kinds of clinical data that might need to be represented to meet the requirements of each particular profession, speciality or service.

The **Reference Model** represents the global characteristics of health record entries, 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.

Such 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, the data types and value ranges that actual record entries may take, and other constraints, in order to ensure interoperability, data consistency and data quality.

Archetypes each define (and effectively constrain) legal combinations of the building-block classes defined in the Reference Model for particular clinical domains or organisations by specifying particular record entry names, data-types and may constrain values to particular value ranges. 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 related to the Reference Model) and can be optimally expressed in archetype description language (ADL), developed by the *open*EHR Foundation (see later in this chapter). Although the ADL and Archetype Model are 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.

Archetype Repositories. In each enterprise or region there is a diversity of health information stored on paper and in legacy feeder systems. The range of archetypes required within a shared EHR community is presently unknown. The potential sources of knowledge for developing such archetype definitions will include:

- health information which is used for semantic processing within current systems;
- health information used in secondary data collections;
- the clinical data schemata (models) of existing systems;
- the layout 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;
- the pre-co-ordinated terms in terminology systems.

However, 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. By conforming to a common Reference Model and Archetype Model the individual libraries of archetype definitions held in each repository (however implemented) can be exchanged (e.g. via XML) in order to facilitate this progressive convergence across sites or regions.

In the longer term, it is anticipated that the involvement of national health services, academic organisations and professional bodies in the development of such definitions 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 healthcare 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 entry, to ensure the intended clinical meaning of the original author is preserved within the generic representation.

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 this nature. However, the EHR architecture ensures that users curious about an unusually high blood pressure on a graph would always 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 instantiation of record entries conforming to specific archetypes must be formally managed by the EHR service in accordance with the overall archetype schema. This ensures 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 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 yet have a consistent approach to the labels or headings used within health records.

A potential strength of the 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. Once clinical teams are able to share records and to benefit directly from a consistent federated record framework they will naturally and deliberately seek convergence. It is the experience of the author through medical audit projects that this bottom-up approach to convergence is generally more successful, albeit slower, than a top-down imposition of standardised data sets.

The two-level approach described here is being adopted in three areas of work:

- the design of the *open*EHR information architecture specifications,
- as an input to the EHRcom Task Force charged with revising ENV 13606, and led by one of the authors (DK),
- as an input to the development of HL7 Templates specification.

Each of these three activities is summarised in the rest of this chapter.

EHR Interoperability Standards

European (CEN) EHR Interoperability Standards

CEN is the principal legislative standardisation body for Europe; Technical Committee 251 has responsibility for health informatics (interoperability) standards. Since 1990 CEN TC/251 has regarded the Electronic Healthcare Record as one of the most important and most urgent areas for the establishment of European standards.

A pre-standard ENV 12265, outlining the key architectural features of an EHR, was first published in 1995 [30], and followed in 1999 by a more comprehensive four-part pre-standard ENV 13606. This defined the logical model of an EHR [43], and a message model derived from it [45], a set of access control measures that ought to be applied to the process of EHR sharing [29] and a set of vocabularies to support the overall EHR model [55].

These standards drew on the results of successive EU-funded research projects, summarised in Section 0 of this chapter). 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 has not been possible, unfortunately largely defeating the object of such a standard.

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 propose a revision that could be adopted by CEN as a formal standard (EN) during 2005. One of the authors (DK) 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.

The main provisions of this draft standard have already been widely reviewed within Europe, and internationally. The final draft is expected to be published in 2005. When published, it will be the most comprehensive standard specifically targeted at supporting electronic health record interoperability, and possibly the best-underpinned by research and implementation experience.

HL7 Standards Relevant to the EHR

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, and its practical experience base, has historically been the interface requirements of large healthcare enterprises. Version 2 is presently the most deployed health messaging standard internationally.

However, despite its wide uptake, 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. Message definitions are created via an incremental refinement process beginning with the RIM, and passing through various intermediate models, including Restricted Message Information Models (RMIMs) and Hierarchical Message Definitions (HMDs).

The **HL7 Clinical Document Architecture (CDA)** is a generic RIM-derived structure for the communication of clinical documents, and has sometimes been regarded as the HL7 equivalent of a record architecture, although it is designed as a single-document *transfer* mechanism. Level One of the CDA 1.0 is a formal American standard, and is primarily intended to represent narrative-style documents plus some basic header information in a structured form [20]. CDA Release Two is a draft specification, approaching final standardisation, for the structural organisation of fine-grained information inside a document. In this regard it is close in scope to that of the inner hierarchies of an EHR architecture, and work is ongoing between CEN and HL7 to enable best fit (and cross-mapping) between the EHRcom standard and the CDA, since both will undoubtedly be used to exchange clinical information in different settings.

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 *open*EHR archetype approach, and it is expected that some parts of the *open*EHR Archetype Definition Language will form part of this future HL7 standard.

The **HL7 EHR Technical Committee** has released 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.

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 healthcare. 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

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 [57] referred to earlier in this chapter, and is presently defining the overall scope of the EHR. It has provisionally approved a process of reviewing the CEN EHRcom draft standard (draft of EN 13606) with a hope of accepting it as a full international standard in due course.

Standards for Images

The Digital Imaging and Communications in Medicine (DICOM) standard arose out of a precursor standard for images (ACR-NEMA) that was first published in 1985 by the American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA). The DICOM standard is the most widely used common data representation internationally for the various medical images acquired and communicated. It has addressed many of the issues of vendor-independent data formats and data transfers for digital medical images. It is presently in version 3, with 14 chapters each relating to a different kind of image or signal data type or to a communication type. CEN and ANSI have adopted DICOM by reference in their imaging standards.

IHE

Integrating the Health Environment (IHE) is a recently-formed industry-sponsored organisation 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.

Other Standards and Specifications

It is not possible in this chapter to summarise all of the potentially relevant standards, industry standards and specifications that might pertain to parts of an EHR, such as particular data sets or data types. Examples of these include the Object Management

Group Health Domain Task Force (OMG-HDTF) and the American Society for the Testing of Materials (ASTM). For example, ASTM is developing a standard "Continuity of Care Record" which is a rich data set of clinical and administrative data items that ought to be considered for inclusion in a shared care clinical communication. This is not a replacement for a comprehensive EHR, but the work on generic EHR specifications reported above either has or is evolving links with these related standards bodies.

Figure 0-13 illustrates the roles within a distributed healthcare environment of several of the standards referred to in this section. Interoperability of specific clinical data sets is shown in purple and those supporting generic clinical information interoperability are shown in pink.

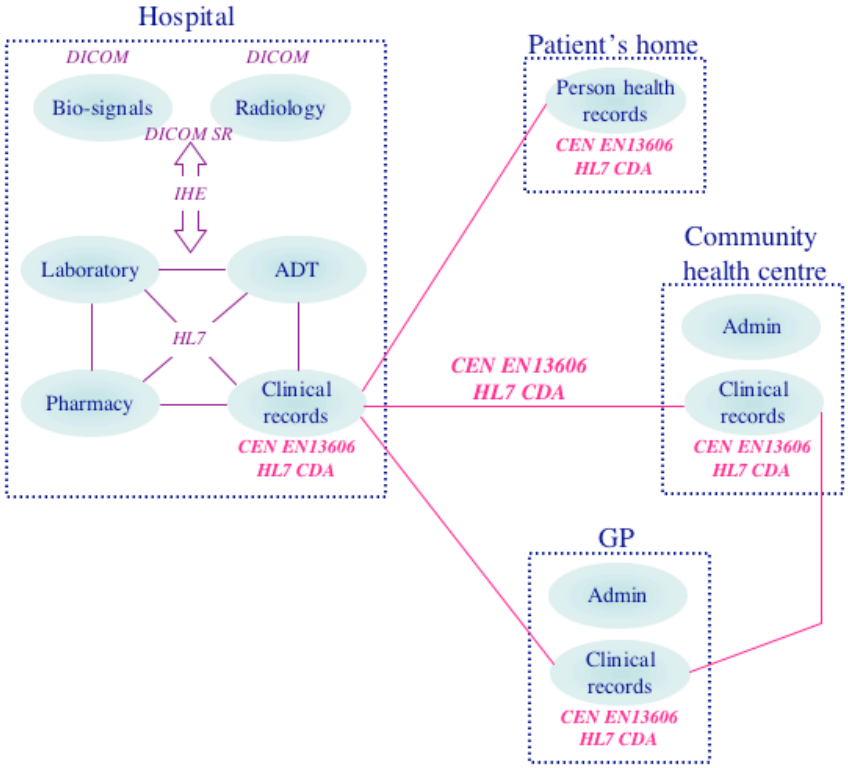

Figure 0-13 Domains of communication of health information covered by different industry and legislative standards.

Integrating 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,

- 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.

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.

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.

The *open*EHR Foundation

The *open*EHR Foundation is an independent, not-for-profit organisation and community, facilitating the creation and sharing of health records by consumers and clinicians via open-source, standards-based implementations [59]. 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."

The goal of *open*EHR is to exemplify good designs for interoperable EHR systems through open source components, and to validate and refine these through practical clinical demonstrators. The *open*EHR Foundation was formalised as a not-for-profit company in 2003. *open*EHR aims to:

- promote and publish the formal specification of requirements for representing and communicating EHR information, based on implementation experience, and evolving over time as healthcare 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, *open*EHR brings together many of the strong threads of R&D in the field of electronic and federated health record systems described in this chapter, underpinned by published requirements, and with the goal of evolving best practice in the design of the EHR information architectures through collaboration and the evaluation of implementations in live clinical settings. *open*EHR seeks to foster this collaborative approach through openly available specifications, open source components and hosting e-mail discussion fora to debate the issues and challenges that arise in working towards its mission. The process and deliverables of its activities are managed by a formal change control process.

The *open*EHR technical specifications define design principles, reference and archetype models and will in the future include other middleware service specifications. This work is becoming regarded internationally as the most complete and best-validated EHR information architecture.

The Challenge of Access Control

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 [27]. 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. 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. Around the globe these principles are progressively becoming enshrined in national data protection legislation.

In an ideal world, 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 healthcare 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 healthcare professions. Families may wish to provide a means by which they are able to access parts of each other's 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 healthcare,
- the numbers of healthcare 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 EHR and the need for revisions to access control to be rigorously managed in the same way as revisions to the EHR 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.

In order to support interoperable EHRs, and seamless communication of EHR data between providers of healthcare, the negotiation that is required to determine if a given requestor of EHR data should be permitted to receive the data needs to be capable of automation. If this were not possible, the delays and workload of managing human decisions for every or most record communications would obviate any value in striving for data interoperability: paper would probably be just as quick!

In practice, efforts are in progress to develop international standards for defining access control and privilege management systems that would be capable of computer-to-computer negotiation. However, this kind of work is predicated upon health services agreeing on a mutually consistent framework for defining the privileges they wish to assign to staff, and the spectrum of sensitivity they offer for patients to define within their EHRs.

The main principles of the approach to standards development in the area of EHR communications access control are to match the characteristics and parameters of a request to the EHR provider's policies, and with any access control or consent declarations within the specified EHR, to maintain appropriate evidence of the disclosure, and to make this capable of automated processing.

This requires consistency in the way the relevant information is expressed, to make this sensibly scalable at definition-time (when new EHR entries are being added), at run-time (when a whole EHR is being retrieved or queried), and durable over a patient's lifetime. It is also important to recognise that much diversity will exist across Europe on the specific approaches to securing EHR communications — including differing legislation — and that a highly prescriptive approach to standardisation is not presently possible.

The view taken by the authors, and reflected in work currently in progress within CEN (towards EN13606) is that a coarse-grained categorisation is needed for staff privilege, for record sensitivity and for their interrelationship. Such a framework needs to be underpinned by a sound set of defaults, in which the public have a high degree of confidence, since the vast majority of record accesses will occur in situations where patients do have trust in their clinical carers, and will wish to exercise few if any specific constraints, if those defaults are seen to be adequate.

This is a rapidly progressing aspect of health informatics standardisation, and the reader is encouraged to review the latest versions of publications from ISO TC/215 in this field.

Summary

Joining up diverse and sometimes discipline-specific and culturally specific kinds of clinical information to compose a whole-person EHR that can safely, legally and useably replace paper records is a complex challenge. There is currently 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. It is the hope of the authors that, for example, future standards arising from CEN and from HL7 can have a good degree of fit and be mutually compatible.

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 0-14).

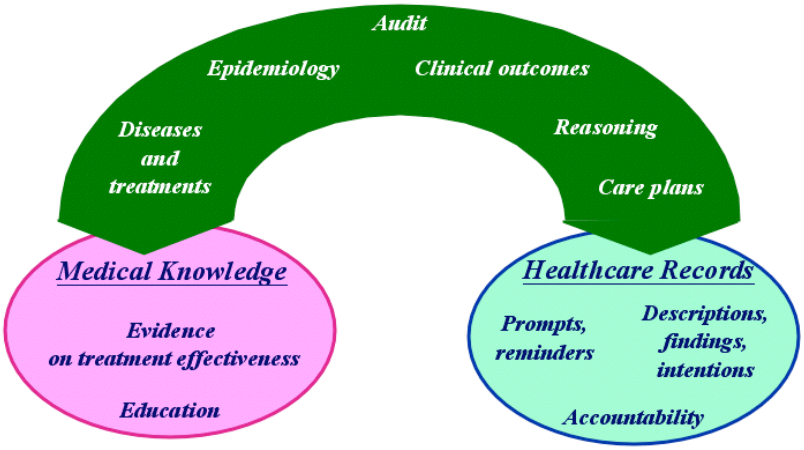

Figure 0-14 Clinical information services supporting patient care.

It is likely that the next generation of healthcare 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 0-15.

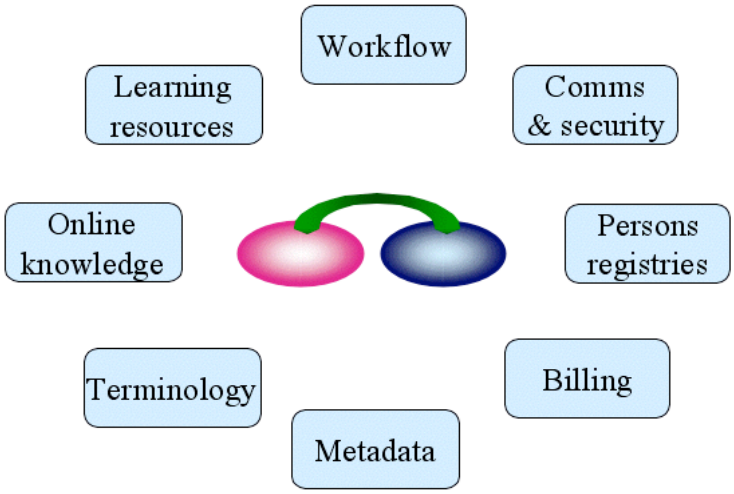

Figure 0-15 Other components and services supporting the clinical middleware.

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 *open*EHR.

It should be remembered that human and organisational factors play a significant role in the rate of acceptance of health informatics innovations. A key component of the EHR challenge will be to nurture the necessary skills within the clinical workforce to adopt the EHR as part of a modern and integrated health service. This will require an investment in training and, most importantly, the recognition that major change is often best implemented incrementally. Concerns about protecting the confidentiality of sensitive personal information must also be recognised and addressed if consumer confidence is to be maintained when EHRs are widely accessible.

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