

# Electronic Health Record Standards

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## Summary

**Objectives:** This paper seeks to provide an overview of the initiatives that are proceeding internationally to develop standards for the exchange of electronic health record (EHR) information between EHR systems.

**Methods:** The paper reviews the clinical and ethico-legal requirements and research background on the representation and communication of EHR data, which primarily originates from Europe through a series of EU funded Health Telematics projects over the past thirteen years. The major concepts that underpin the information models and knowledge models are summarised. These provide the requirements and the best evidential basis from which HER communications standards should be developed.

**Results:** The main focus of EHR communications standardisation is presently occurring at a European level, through the Committee for European Normalisation (CEN). The major constructs of the CEN 13606 model are outlined. Complementary activity is taking place in ISO and in HL7, and some of these efforts are also summarised.

**Conclusion:** There is a strong prospect that a generic EHR interoperability standard can be agreed at a European (and hopefully international) level. Parts of the challenge of EHR interoperability cannot yet be standardised, because good solutions to the preservation of clinical meaning across heterogeneous systems remain to be explored. Further research and empirical projects are therefore also needed.

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## Keywords

Electronic health records, interoperability, standardisation, information model

## Introduction

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 and relevant 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.

From an academic vision in the late 1980's the Electronic Health Record (EHR) has evolved to become centre-stage in the national health informatics strategies of most European countries, and internationally [1-4]. International research over the past fifteen years 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 meeting these requirements 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.

This paper summarises the key EHR standards that are presently being developed to meet these requirements.

## The Need for Generic and Interoperable EHRs

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 [5]. 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 manage health care interventions (e.g. screening) 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. However, single-disease approaches are no longer rich enough to underpin good health care.

This recognition is not new. In a 1999 US Medical Records Institute survey of EHR Trends and Usage (reported in [6]) over 70% of respondents regarded the need to share patient record information between different health care sites as the major clinical driver for EHRs. In 1998 Shortliffe 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.”* [7]

## Requirements for Representing and Communicating EHRs

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 [8]. 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 [9]. Tange suggests that the flexibility of data entry and support of narratives are major reasons for the retention of paper records by many clinicians [10].

Extensive investigations of user and enterprise requirements have taken place over many years to capture the health record information needs across primary, secondary and tertiary care, between professions and across countries. These requirements have been distilled and analysed by expert groups, internationally, in order to identify the essential 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, whilst respecting the privacy wishes of individual patients.

The most detailed review of this domain has been published by the GEHR [11-15], EHCR Support Action [16] and Synapses projects [17], which informed the subsequent European EHR pre-standards [18,19] and ongoing EHR research. These requirements have now been consolidated by ISO as an International Technical Specification, which provides a single point of reference for the core EHR requirements [20].

The communication of EHR information 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 way in which individual clinical statements are hierarchically nested within a record confers an important context for their interpretation. 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 search for diabetic patients. Table 1 below summarises the kinds of clinical and medico-legal context that needs to be mapped to classes and attributes within an EHR architecture [21].

## 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 [22].

Considerable research has been undertaken over the past fifteen years to develop 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, such as GEHR [23] and the CEN standards ENV12265 [18] and ENV13606 [19]. Other research has identified the additional requirements to support the communication of EHRs within federated

**Table 1** The range of contexts which may be associated with healthcare record entries

<p><b>Compositional Context</b></p> <ul style="list-style-type: none"> <li>Record entry names to provide a label for each content value</li> <li>Compounding hierarchies of clinical concepts to express complex concepts</li> <li>Grouping hierarchies for a sets of clinical concepts with common headings, to:               <ul style="list-style-type: none"> <li>preserve the way in which entries were originally organised by the author</li> <li>identify the way in which the clinical concepts relate to the health care activities and processes surrounding the patient</li> </ul> </li> </ul>
<p><b>Content Value Context</b></p> <ul style="list-style-type: none"> <li>Formal representations for all data types, including text, quantities, time, persons and multi-media</li> <li>Names of term sets, versions and registering agencies</li> <li>Natural language used in a recording</li> <li>Accuracy, precision and units for quantities</li> <li>Normal ranges</li> </ul>
<p><b>Clinical Interpretation Context</b></p> <ul style="list-style-type: none"> <li>Presence / absence</li> <li>Certainty</li> <li>Severity</li> <li>Site and laterality</li> <li>Prevailing clinical circumstances (e.g. standing, fasting)</li> <li>Justification, clinical reasoning</li> <li>Additional explanatory comments by the author (e.g. of why things were done or not done)</li> <li>Knowledge reference (e.g. Medline)</li> </ul>
<p><b>Ethical and Legal Context</b></p> <ul style="list-style-type: none"> <li>Authorship and duty of care responsibilities</li> <li>Subject of care</li> <li>Dates and times of healthcare actions and of their recording</li> <li>Version control</li> <li>Access rights</li> <li>Emphasis</li> <li>Preservation of meaning on transferring the record to another site</li> </ul>
<p><b>Care Process Context</b></p> <p>Links and pointers to other parts of the record, e.g.</p> <ul style="list-style-type: none"> <li>cause and effect</li> <li>request and result</li> <li>process status</li> <li>to a defined problem</li> <li>to an episode of care</li> <li>to a stage in a protocol</li> <li>to a decision support system</li> </ul>

communities of healthcare enterprises to support shared patient care across sites [24] and middleware architectures to integrate across R&D projects [25].

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 (see below).

## 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 a requester can precisely specify the desired parts of an EHR within a request, and know 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 charac-

teristics of the clinical data that represents the requirements of each particular profession, speciality or service.

**The Reference Model** is specified as an information 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 needs to be partnered by a formal method of communicating and sharing the organisational structure of predefined classes of EHR fragment as they need to be organised for particular clinical settings. These are effectively pre-coordinated combinations of named record component hierarchies that are agreed within a clinical 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 (see Figure 2).

Archetype instances themselves conform to a formal model, known as an Archetype Model [26,27]. 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 versions.

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 then individual EHR or decision support systems can reliably request specific parts of one or more EHRs, from one or more EHR systems or a central repository, 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 number 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;
- 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. By conforming to a common Reference Model and Archetype Model the individual libraries of archetype definitions held in each repository can be exchanged. 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 dual Reference and Archetype Model approach, described here is being adopted in three areas of work:

- the design of the *openEHR* Information Architecture;
- 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 Communications Standard EN 13606 (EHRcom)

In December 2001 the Health Informatics Technical Committee of the European standards organisation CEN appointed a Task Force, known as *EHRcom*, to review and revise its 1999 four-part pre-standard ENV 13606 relating to EHR Communications, to produce a definitive European Standard (due for final vote in 2006) [28]. The author is leading this Task Force, whose 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.

EN 13606 will be a five-part standard.

Part 1: Reference Model, is a comprehensive, generic EHR model drawing on 14 years of R&D (and 2 previous CEN standards); it is mapped to the HL7 RIM and Clinical Document Architecture (see below).

Part 2: Archetype Interchange Specification is an information model and exchange syntax for communicating archetypes; this specification is an adoption of the *openEHR* archetype approach, and will also 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.

There is wide international interest in this CEN work, and Part 1 has also been adopted by the International Organisation for Standardisation (ISO) as a draft standard for consultation and subsequent voting. The intention is for Part 1 of CEN 13606 to also be an ISO standard by the end of 2006. ISO is presently reviewing the other draft parts of 13606 as they become available, to consider if these are also candidates for international standardisation.

## Overview of the EN13606 Reference Model

The CEN Reference Model for EHR Communication is a generic model capable of representing the structure and context of part

## Fetal heart rate: *OBSERVATION*

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Concept description:	Identification:	Information structure:
The rate the fetal heart is beating - either mechanically or electrically	<i>Id:</i> openEHR-EHR-OBSERVATION.heart_rate-fetal.v1 <i>Reference model:</i> EHR	<p>The diagram shows a central node connected to four other nodes: 'History' (green box), 'Protocol' (red box), 'Data' (yellow box), and 'State' (purple box). Lines connect the central node to each of these four nodes.</p>

### Data: LIST

Concept	Description	Type	Cardinality	Values
<b>Q</b> Rate	The rate of the heart	<i>Quantity</i>	mandatory 1..1	<i>Property</i> = FREQUENCY <i>Units:</i> /min, (>= 0)
<b>T</b> Rhythm	The rhythm of the heart beat	<i>Coded_text</i>	optional 0..1	Regular Irregular Irregularly irregular
<b>T</b> Description	The description of the rate and rhythm	<i>Text</i>	optional 0..1	<i>Free or coded text</i>

### State: LIST

Concept	Description	Type	Cardinality	Values
<i>Ordered</i>				
<b>T</b> Position	The position of the patient when the heart rate was measured	<i>Coded_text</i>	optional 0..1	Lying Sitting Reclining Standing

### Events: HISTORY

Events	Description	Constraints	Values
Any event	*	<b>PointInTime</b> 0..*	

Subject relationship restricted to foetus

### Protocol: LIST

Concept	Description	Type	Cardinality	Values
<i>Ordered</i>				
<b>T</b> Device	Device by which the heart rate was measured	<i>Coded_text</i>	optional 0..1	Stethoscope Doppler Electrical

Supported by the General Practice Computing Group of Australia through funding from the Commonwealth Department of Health and Ageing

Fig. 1 An example archetype for Fetal heart rate

or all of the electronic health record of one subject of care, to support interoperable communications between systems and services that might request or provide EHR data. It is not intended to specify the internal architecture or database design of such systems.

The standard considers the EHR to be the persistent longitudinal and potentially multi-enterprise or multi-national record of health and care provision relating to a single subject of care (the patient), created and stored in one or more physical systems in order to inform the subject's future health care and to provide a medico-legal record of care that has been provided. Whilst an EHR service or system will need to interact with many other services or systems providing terminology, medical knowledge, guidelines, workflow, security, persons registries, billing etc. this standard has only touched on those areas if some persistent trace of such interactions is required in the EHR itself. The standard may offer a useful contribution to the design of future EHR systems but will primarily be realised as a common set of external interfaces or messages built on otherwise heterogeneous clinical systems. It seems reasonable to assume that a multi-vendor "mixed economy" of specialist and general clinical systems will continue to evolve internationally in the coming years. The 13606 Reference Model defines a core hierarchy of building blocks to which any EHR can be mapped, as summarised in Figure 1. The terms used on the left to label each coloured level in the hierarchy are becoming increasingly shared within the health informatics community internationally, but are essentially unimportant. What is now widely accepted is that the descriptions given of each level on the right hand side of the figure do correspond well to the organisation and data structure of health records (whether on paper or electronic).

For each layer in this hierarchy the Reference Model defines a formal data structure (classes and attributes, expressed as a UML model). It includes at each level the ability

to include the relevant additional contextual information that will usually be saved along with the main data within clinical systems, and which needs to be communicated to any future recipients. This includes, for example, information about:

- persons: who committed the data, who composed (authored) the information, who was legally responsible for the care acts documented, to whom the clinical findings relate if not the patient (for example if to a family member);
- dates and times: when data were recorded, when the care events took place, when the life events happened to the patient, and if data is a projection into the future such as an intention for care, a goal or a prognosis;
- the clinical setting in which care or self-care was given;
- particular clinical circumstances relating to an observation (e.g. a standing or fasting measurement);
- the rationale behind clinical decisions, and links and pointers between parts of an EHR;
- certainty, negative findings, changes of opinion or links to join various descriptions of an evolving clinical picture;

- indications if data has been modified, and the kinds of person to whom it is (or is not) intended to be made available.

It is the hope and early feedback experience that the vendor of any good clinical system ought to be able to map the EHR data within its database to this model. Inevitably some vendors will find it easier than others to be able to import data that has come from another system, but the goal of this standard has been to avoid as much as possible any ambiguity in the way the EHR data is to be interpreted on import: a greater risk in sharing EHRs than a lack of data is that data is misrepresented when communicated, potentially misleading subsequent readers and harming patients.

## Other Relevant Contemporary Work in CEN

CEN standard ENV 13940 defines a set of concepts for health care parties, threads of

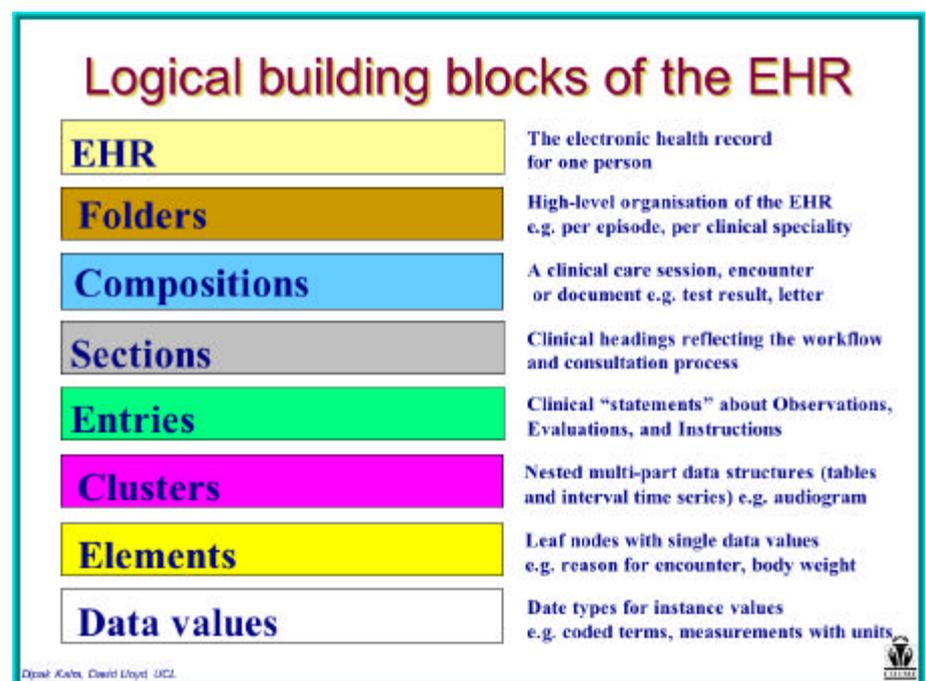


Fig. 2 Main hierarchy of classes of the EHR within the CEN 13606 (draft) standard

care, care plans and mandates (responsibilities) that are needed to ensure the complete documentation of on-going shared care [29]. This standard is presently being updated and harmonised with EHRcom.

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.

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 (see below). 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 v3 messages will be easier. EHRcom uses some of these for representing demographic information.

## Health Level Seven (HL7)

The Health Level Seven (HL7) organisation was formed in the United States in March 1987 [30]. 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 has historically been the interface requirements of large healthcare enterprises, but it is now engaging with healthcare systems at a higher (regional or national) level.

HL7 version 2 messages have been developed and refined over several years to reflect standardised reporting data sets for several

aspects of a patient's care in hospital, and are the most widely used internationally within a hospital information system.

Despite its wide uptake internationally, the problems of inconsistent implementations of Version 2 messages and the unsystematic growth of message segment definitions have limited the realisation of interoperability. A key feature of the new 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 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.

- Entities, for example persons, organisations, places and devices;
- Roles, for example that of patient or employee;
- Participation relationships, for example that between a patient and a clinician;
- Acts, for example the recording of appointments, patient encounters, observations, procedures.

The **HL7 Clinical Document Architecture (CDA)** is a generic message structure for the communication of a clinical document, derived as a message model from the HL7 RIM. 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 fairly high level [31]. 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 close in scope to that of the inner hierarchies of the CEN 13606 EHR architecture, and a cross-mapping has been developed between them.

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, and is expected to be used in a similar way.

The **HL7 EHR Technical Committee** has developed an EHR System Functional Model as a draft standard for trial use. This standard describes an inclusive set of functions that should be available in good 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. This work contrasts with other research and standards described in this paper, which focus on EHR communications and interoperability rather than the system functionality which might be experienced by an end-user. It is a vital contribution to future EHR quality.

## 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 standards organisations such as CEN and HL7.

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 primarily a storage, indexing and distribution mechanism, and is a practical complement to these other standards.

## International 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. Its activity in parallel to CEN 13606 has been described earlier in this paper. Other current ISO work relating to the EHR includes the definition of standard datatypes that can be adopted by other future standards as an aid to their interoperability.

It should be noted that other important international standardisation organisations exist for specific classes of information, such as DICOM for medical images, which are beyond the scope of this paper.

## The *open* EHR Foundation

The *openEHR* Foundation is an independent, not-for-profit organisation and community, founded in 2000 by University College London and Ocean Informatics [32]. Its aim is to facilitate the creation and sharing of health records by consumers and clinicians via open-source, standards-based implementations. *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 since 1991, but has matured considerably in recent years through contributions from many of its five hundred members. It is becoming regarded internationally as the most complete and best-validated EHR information architecture. *openEHR* works closely with the standards bodies described in this paper to ensure that its own designs conform to current standards, and to contribute its experience and designs to future standards. The contribution of the archetype approach into CEN and HL7 is one example of this.

## Conclusion

The need is now urgent for standards to enable EHR information to be shared. Many nations are procuring and building health infrastructures to permit clinical data to be communicated across regions and health services, although initially these are more likely to be summaries and subsets than complete electronic health records.

The pace of many of these national projects is pushing designers and suppliers to implement in haste. Near term objectives and budgets might make it seem attractive to attempt to solve the challenge of joining up clinical systems at a national level, by defining local standards or limiting choice to a small number of systems. However, health care and patient mobility is increasingly global, and eventually both costs and patient safety will be improved if we can reach global agreements on how to share and analyse EHRs.

Standards to support EHR communication are at an advanced stage of development. The value of the EHR architectural 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 (pioneered through *openEHR* and being standardised in CEN 13606) helps to ensure the clinical shared care can be delivered safely, underpinned by complete and unambiguous information.

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