

The relationship between CEN 13606, HL7, and *openEHR*

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ABSTRACT

With the recent release of the NEHTA report on standards for Shared EHRs, there has been much interest and some confusion over the report's discussion and recommendations for standards. This paper gives an overview of the roles of the main interoperability standards and specifications discussed in the NEHTA report. It begins with a brief section on the practical importance of interoperability for clinicians and consumers in the increasingly common shared-care environment. It then discusses the relationship between the openEHR specifications and the formal consensus standards recommended by NEHTA for Shared EHR systems in Australia – CEN 13606, HL7 CDA, and HL7v2.x. Finally the need for an Australian Standard for a Shared-EHR architecture is canvassed and openEHR is proposed as the basis for this standard.

Keywords:

CEN 13606, HL7, CDA, *openEHR*, semantic interoperability, standards, EHR, shared EHR

THE IMPORTANCE OF INTEROPERABILITY

The recent NEHTA (National E-Health Transition Authority) review and recommendations on interoperability standards for Shared Electronic Health Records (EHRs) [1] has created much interest and some confusion both in Australia and overseas. Why are these standards important?

The development and adoption of national and international standards for EHR interoperability is essential for:

- sharing patient health information between health professionals in a multi-disciplinary shared-care environment.
- interoperability between organisations within an enterprise, a regional or national health system, or in future, across national borders.
- supporting interoperability between software from different vendors

***openEHR* ELECTRONIC HEALTH RECORD ARCHITECTURE**

openEHR and standards

openEHR [2] is an open, detailed, and tested specification for a comprehensive interoperable health information computing platform for the EHR and other major services such as terminology. It is based on 15 years research, focussed engineering design and real-world implementation experience, rather than being created as a formal consensus standard. However, over the past five years it has had a significant influence on the development of EHR standards by the three main international e-health standards development organisations, CEN (European Committee for Standardization), HL7 (Health Level 7), and ISO (International Organization for Standardization). In fact, CEN EN13606 [3] is a subset of the full *openEHR* specification.

openEHR and interoperability

The *openEHR* model and specifications [4] provide both functional interoperability (humans can read transmitted health information) and the far more demanding semantic interoperability (computers can understand and automatically process transmitted health information). Semantic interoperability is essential to enable local processing of the shared data; this is a pre-requisite for intelligent decision support and care planning which are arguably the most important added-value applications of the EHR.

CEN 13606 ELECTRONIC HEALTH RECORD COMMUNICATION STANDARD

The CEN ENV13606 pre-standard

The first version of the 13606 four-part pre-standard was published in 1999-2000 [5]. Attempts to implement this pre-standard in software proved to be difficult and those implementations which were undertaken suffered from the “HL7 v2 problem” of too much optionality. This makes achieving semantic interoperability impossible without the sender and receiver agreeing how each communication will be implemented.

The CEN 13606 revision project

In 2002 CEN made a decision to revise the 13606 pre-standard and upgrade it to a full normative European standard. The most important aspect of the revision project was a decision to adopt the *openEHR* two-level modelling approach, known as the ‘archetype methodology’, and also to incorporate some of the *openEHR* Reference Model into the revised CEN standard. Dr Dipak Kalra, from University College London, the co-founder of *openEHR* with Ocean Informatics, was elected Project Leader and an MOU was signed between CEN and *openEHR* to enable the principals of Ocean Informatics in Australia to actively participate in the project. The Standards Australia IT-14-9-2 EHR Working Group has also played an important role in the project and it is intended that the five parts of EN13606 will be adopted as Australian Standards as they are completed in Europe over the next year.

The scope of CEN 13606

It is important to note that CEN 13606 is a specification for exchange of EHR Extracts, not for a full EHR system. There are many more requirements for an EHR system, including version management, workflow management, interfaces to other systems etc. Some of these requirements impact upon the Extract. For example, because the CEN EN13606 Extract does not yet cater properly for version information, it cannot be used between *openEHR* systems, or any other systems wanting to preserve versioning information. Also, the specification is somewhat of a “lowest common denominator”, which in a sense all standards are. 13606 is not the place to expect to see all the requirements one has for EHR systems, only those relating to moving pieces of the EHR from one system to another. *openEHR* not only provides a specification for the communication of EHR Extracts of various levels of complexity but also a full specification for the creation, storage, maintenance, and querying of EHRs. Neither CEN 13606 nor the HL7 RIM define a reference model for an EHR. Also, the *openEHR* development process has moved on with the recent publication of release 1.0, and now includes some features that are very important for implementation but not included in CEN 13606.

HEALTH LEVEL 7 (HL7)

HL7 Clinical Document Architecture (CDA)

The HL7 Clinical Document Architecture (CDA) [6] is HL7’s current main strategy for EHR interoperability, and is defined as a single XML schema. The “clinical statement” is a similar initiative for use with HL7v3 messages. Neither of these are an EHR specification however, both correspond to an important component of the EHR. At present neither support archetypes, although

there is now an international effort to overcome this. HL7 CDA is approximately a subset of the 13606 EHR Extract, limited to one version of one composition, with some minor differences.

HL7 Version 2

HL7v2 [7] (in its various subversions, usually represented generically as HL7v2.x) has widespread acceptance and is now widely used within the Australian health system and internationally for messaging applications. HL7 version 2 is not based on any underlying reference model and is therefore not suitable for an EHR architecture. However, it is appropriate for transmitting clinical and necessary demographic/administrative information from source clinical information systems (e.g. in GP practices or hospitals) to a Shared-EHR system¹. HL7v2.x messages have been recommended for this purpose in the NEHTA report [1], at least in the short-to-medium term. In the longer term, NEHTA has recommended that HL7v2.x and other similar messaging protocols should be replaced by XML web services-based messaging [8].

HL7 Version 3

Whilst HL7v3 [9] is based on a reference model (the RIM) it is designed primarily for the messaging environment and does not currently have a specification for an EHR architecture. It was not recommended in the NEHTA Shared EHR standards report because it "...would be more complex, costly and take considerably longer than the recommended approach." [1].

CONCLUSION

The relationship between openEHR, CEN 13606, and HL7 CDA is shown diagrammatically in Figure 1 below:

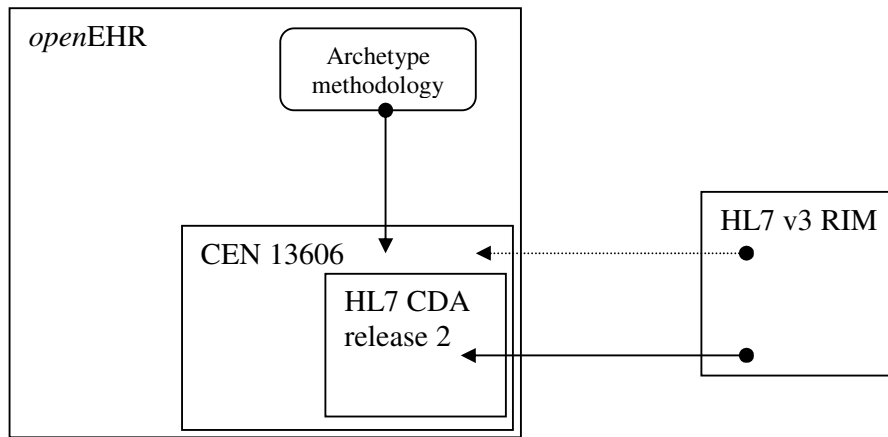


Figure 1 Schematic relationship between *openEHR*, CEN 13606, and HL7 CDA

HL7v2.x messaging is an appropriate standard, at least for the short to medium term, for transmission of information from source clinical information systems to a Shared-EHR system. HL7 CDA may also be suitable for this purpose at some later stage. CEN EN13606 is an appropriate standard for the exchange of Shared EHR Extracts between different nodes of a multi-node Shared-EHR system (e.g. the original national HealthConnect concept) or between different Shared-EHR systems.

¹ It should be noted that the contents of incoming traditional HL7v2 messages will need to be transformed to an appropriate format (e.g. *openEHR*) before they can be stored in a Shared EHR. However, work is currently being done within Standards Australia to specify a modified form of HL7v2 messages which would carry content already in *openEHR* or CEN 13606 format (as archetypes). This would make the process of both HL7 message creation and subsequent storage into the Shared EHR much simpler.

However, there is currently no standard available in Australia or elsewhere for a Shared-EHR system which supports the creation, storage, maintenance, and querying of Shared EHRs. *openEHR* is the only open specification currently available which is a candidate for this purpose. It has been suggested that CEN EN13606 could be extended to achieve this purpose but whilst this may be possible, there is currently no plan within CEN to do this. Accordingly, a proposal has recently been made to the Standards Australia IT-14 Health Informatics Technical Committee to develop an Australian Standard for a Shared-EHR system architecture based on *openEHR*.

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