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Please Note:

The content within this white paper is not content which can be voted on. It is presented strictly as a reference document for those ballot readers that are interested in this additional information. There is some wording used in this White Paper that is normative in other places of the ballot package and able to be voted upon in the EHR System Functional Model Standard Overview document; however, identification of the normative content takes place in the Standard Overview and votes are then placed in the Ballot spreadsheet.

For the remainder of this document, the HL7 EHR System Functional Model and Standard will be referred to as the ‘EHR-S Model’ or ‘the proposed DSTU’.

1. Purpose

The purpose of this White Paper is to provide a comprehensive background for the HL7 EHR System Functional Model that is being balloted as a Draft Standard for Trial Use (DSTU). Much of the information found in the EHR System Functional Model and Standard - Standard Overview document is included in this White Paper, but there will also be a great deal of additional, background information in this document that is out of scope for the brief Standard Overview document. This White Paper will provide additional information about the use of profiles to select applicable functions for use, the context within which this ballot was created, and EHR System related standardization efforts around the world.

2. Overview of HL7 EHR System Functional Model

The HL7 EHR System Functional Model and Standard Draft Standard for Trial Use (DSTU) is intended to provide a summary understanding of functions that may be present in an Electronic Health Record System (EHR-S), from a user perspective, to enable consistent expression of system functionality. This EHR-S Model describes the behavior of a system from a functional perspective and provides a common basis upon which EHR-S functions are communicated. The DSTU can help vendors describe the functions their systems offer, and help those planning new purchases or upgrades to describe the functions they need.

For brevity, this draft standard will be referred to within this document as the “EHR-S Model” or the “proposed DSTU” where the meaning is not ambiguous. A DSTU is a draft standard that incorporates the input from industry prior to becoming a formal ANSI standard. (See Appendix D “What is a DSTU?”)

Notably, the EHR-S DSTU does not address whether the EHR-S is a system-of-systems or a single system providing the functions required by the users. The specifics of ‘how’ EHR-S’s are developed or implemented is also not considered to be within the scope of this DSTU now or in the future. It does not address or endorse implementations or technology; neither does it include the data content of the Electronic Health Record (EHR).
This DSTU is not:

- A messaging specification.
- An implementation specification.
- A conformance specification.
- An ANSI Standard.
- An EHR specification. (Note: Electronic Health Records and Electronic Health Record Systems are different entities.)
- A conformance or compliance metric.
- An exercise in creating a definition for an EHR or EHR-S. (ISO is currently addressing this task.)

3. Background

The effective use of information technology is a key focal point for improving healthcare in terms of patient safety, quality outcomes, and economic efficiency. A series of reports from the Institute of Medicine (IOM) identifies a crisis of “system” failure and calls for “system” transformation enabled by the use of information technology. Such a change is possible by “an infrastructure that permits fully interconnected, universal, secure network of systems that can deliver information for patient care anytime, anywhere.”(HHS Goals in Pursuing HL7 EHR Functional Standard” in Memorandum to HIMSS from C. Clancy and W. Raub co-chairs of HHS Council on the Application of Health Information Technology, dated November 12, 2003.) A critical foundational component for resolving these system and infrastructure issues is the Electronic Health Record System (EHR-S).

The U.S. Department of Health and Human Services, the Veterans Health Administration as well as the Health Information Management Systems Society and the Robert Wood Johnson Foundation, in a public-private partnership, approached HL7 to develop a consensus standard for defining the functions of an EHR-S. HL7, through its EHR Special Interest Group (EHR SIG), responded by developing an EHR-S Functional Model to be balloted as a Draft Standard for Trial Use (DSTU). Learning important lessons from its earlier DSTU, the HL7 EHR SIG now offers a clearer, more simplified functional outline, while delegating specification of care settings and priorities to individual realms.

HL7’s Electronic Health Records Special Interest Group (EHR SIG) was established in the spring of 2002 and in the spring of 2003 started to develop a standardized functional specification for Electronic Health Records Systems with the intention of promoting the uptake of Electronic Health Record implementation by standardizing the essential functions of a generic Electronic Health Record System.
4. Definitions

Until recently there was no generally agreed definition for an EHR. The first published international EHR technical specification “ISO/TS 18308: 2004 Health informatics-Requirements for an Electronic Health Record Architecture” [1] contains seven different definitions drawn from the United States, Australia, Europe and Canada. These definitions have more similarities than differences but reflect slightly different shades of meaning between different countries and organizations.

Many different names and definitions have been broadly used. These include:

- Electronic Medical Record (EMR)
- Electronic Patient Record (EPR)
- Computerized Patient Record or Computer-based Patient Record (CPR)
- Electronic Health Care Record (EHCR)
- Virtual EHR
- Personal Health Record (PHR)
- Digital Medical Record (DMR)

It is important to note that the DSTU does not attempt to establish another definition for EHR Systems, but chooses to utilize existing definitions that include the concept of EHR Systems as a system (at least one) or a system-of- systems that cooperatively meet the needs of the end user.

4.1 Electronic Health Record Systems (EHR-S) Definitions

In developing the DSTU, HL7 relied on three well-accepted definitions: two provided by the U.S. Institute of Medicine (IOM) and one developed by the European Committee for Standardization/ Comité Européen de Normalisation (CEN).

Existing EHR System Definitions

The Institute of Medicine’s 1991 report, Computerized Patient Record, defined the EHR System as:

“The set of components that form the mechanism by which patient records are created, used, stored, and retrieved. A patient record system is usually located within a health care provider setting. It includes people, data, rules and procedures, processing and storage devices (e.g., paper and pen, hardware and software), and communication and support facilities.”

The 2003 IOM Letter Report, Key Capabilities of an Electronic Health Record System, defined the EHR System as including:
“(1) longitudinal collection of electronic health information for and about persons, where health information is defined as information pertaining to the health of an individual or health care provided to an individual; (2) immediate electronic access to person- and population-level information by authorized, and only authorized, users; (3) provision of knowledge and decision-support that enhance the quality, safety, and efficiency of patient care; and (4) support of efficient processes for health care delivery.”

The 2003 ISO/TS 18308 references the IOM 1991 definition above as well as CEN 13606, 2000:

“A system for recording, retrieving and manipulating information in electronic health records.”

5. **HL7 EHR-S Functional Model**

5.1 **Phased development**

The HL7 EHR System Functional Model will be developed using a phased approach.

5.1.1 **Draft Standard for Trial Use**

The first step of the development will consist of a Draft Standard for Trial Use. This type of standard specification is intended by HL7 to be developed for the distinct purpose of enabling trial use of the specification prior to the balloting of a full-fledged ANSI standard. The DSTU period can last for up to two years and consists of receiving and incorporating industry and HL7 feedback while moving towards the goal of balloting parts or all of the DSTU as an ANSI standard.

The DSTU will consist primarily of a list of Function Names and Function Statements that have been identified through a global development and review process as essential in a care setting now or in the future. The list of functions is analogous to a dictionary, which is an excellent example of a superset (vs. a subset). In this dictionary, Function Names are defined and available for reference or for selection when composing a list of functions that are deemed necessary by the user. In other words, a user of the EHR-S DSTU may want to look up a function to gain an understanding of how that function is used, or, a user may want to select a number of functions to create a document to communicate functional needs to others. As with other dictionaries, the proposed DSTU is expected to evolve over time to reflect empirical needs and uses for EHR-S functions.

Note that the proposed DSTU is deliberately leaving out conformance criteria. Minimal conformance criteria are planned at the function level, (not the system level) and will state what is needed to determine whether a single function exists. Conformance criteria will be stated in user-oriented, system-behavior language, similar to a Function Name and Function Statement. This will not establish conformance criteria for comparing EHR Systems to the entire superset of functions. The development of the minimal conformance criteria will be performed with industry input and guidance.
5.1.2  Next Steps

During the DSTU period, as the standard is applied in healthcare informatics and feedback is being incorporated, the document will be continually refined. After the DSTU period, the lessons learned and good practices developed will be included in the next version of the EHR-S Functional Model which will be balloted as standard. The HL7 EHR SIG will determine both the time and the content when the proposed DSTU will be promoted to full ANSI standard status. The HL7 EHR SIG has seen its membership group expand by five fold during the DSTU development phase and is deeply grateful for the immense amount of outside knowledge and expertise that has been brought to this process. It is hoped that this larger group, and others, will continue to participate in the process of modifying the original DSTU into the future ANSI standard.

5.2  Functional Model Overview

The EHR-S Functional Model consists of a set of Functions and their associated Functional Descriptors. These functions are divided into three sections: Direct Care, Supportive, and Information Infrastructure.

These functions are intended to become the common language used by vendors, providers, regulators, policymakers, and other parties when describing the capabilities of their applications (vendors), their needs (providers) their quality requirements (regulators), or other purposes. Additionally, realm specific HL7 International Affiliates may endeavor to create their own country specific language. (See Functional Profiles below).

5.3  Future development of the Model: Functional Profiles

Profiles help to manage the master list of functions. A “Profile” is a selected set of functions that are applicable for a particular purpose, user, care setting, domain, etc. It is not anticipated that the full set of functions will apply to any single EHR-S implementation. Instead, the functions are profiled for particular care settings and for particular uses. Care
Setting Profiles relate priorities (Essential/Now, Essential/Future, Optional, Not Applicable) to specific functions. Ultimately, self-generated Profiles will express the capabilities of a real system (e.g., a vendor’s product or a set of applications) or the needs of a stakeholder (e.g., providers, national health organizations, or insurers).

The expression of Priorities (Essential/Now, Essential/Future, Optional, Not Applicable) allows users to better list what is currently desired for their needs and what is realistically achievable in the near future. (See definitions of Priorities below.)

### Functional Profile for Realm A

<table>
<thead>
<tr>
<th>ID</th>
<th>Function Name</th>
<th>Function Statement</th>
<th>Functional Description</th>
<th>See Also</th>
<th>Priorities</th>
</tr>
</thead>
<tbody>
<tr>
<td>31</td>
<td>Care Management</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31.1</td>
<td>Patient Identification</td>
<td>Patient identification and access by authorized personnel</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31.2</td>
<td>Secure Access</td>
<td>Secure access to patient information to ensure confidentiality and integrity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31.3</td>
<td>User Authentication</td>
<td>User authentication to ensure access to patient information is restricted to authorized personnel</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31.4</td>
<td>Electronic Prescriptions</td>
<td>Electronic prescribing service, including order entry, drug interactions, and refill management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>31.5</td>
<td>Pharmacy Services</td>
<td>Pharmacy services, including prescription fill, medication reconciliation, and priority medication management</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Direct Care Functions**

- Patient identification and access by authorized personnel
- Secure access to patient information to ensure confidentiality and integrity
- User authentication to ensure access to patient information is restricted to authorized personnel
- Electronic prescribing service, including order entry, drug interactions, and refill management
- Pharmacy services, including prescription fill, medication reconciliation, and priority medication management

**Supportive Functions**

- Secure access to patient information to ensure confidentiality and integrity
- User authentication to ensure access to patient information is restricted to authorized personnel

**Information Infrastructure Functions**

- Electronic prescribing service, including order entry, drug interactions, and refill management
- Pharmacy services, including prescription fill, medication reconciliation, and priority medication management
The possible priorities assigned to a function in a specific Healthcare Delivery Setting may be:

<table>
<thead>
<tr>
<th>Priority</th>
<th>Description</th>
</tr>
</thead>
</table>
| Essential Now             | The function must be feasible to implement now or within 18 months. That is, the function is readily available and the users can implement it. The function must also be critical or key to helping an EHR system address at least one of the following criteria [2]:
  - Support Delivery of Effective Healthcare
  - Improve Patient Safety
  - Facilitate management of chronic conditions
  - Improve efficiency
  - Facilitate self-health management |
| Essential Future          | The function should be feasible to implement by users and readily available in the future. The function must be also be critical or key to helping an EHR system address at least one of the following criteria [2]:
  - Support Delivery of Effective Healthcare
  - Improve Patient Safety
  - Facilitate management of chronic conditions
  - Improve efficiency
  - Facilitate self-health management |
| Optional                  | A level of significance applied to functions in relation to a functional profile. For the average users, the function is deemed an important/desirable but not a critical/key/essential component to an EHR system. It is recognized that for more complex healthcare provider settings, many items deemed optional may be viewed essential to them. |
| Not applicable/supported  | A level of significance applied to functions in relation to a functional profile. The function is deemed an unsuitable component for an EHR system, in relation to a specific functional profile. |

5.4  Functional Profile Overview

5.4.1  Realm-specific Profiles and Suggested Approach

The development of a Profile can be done by an individual, an organization, a vendor or a group of subject matter experts. The U.S. Realm reference portion of this ballot package has four examples of Profiles that were created by subject-matter experts from four care environments: Acute Inpatient, Care in the Community, Long-Term Care, and Ambulatory.
These four example documents can be found in the reference portion of the ballot package. The following methodology may be used for creating a Profile:

a) Identify participants for a workgroup that would create a Profile. The members may vary based on the type of profile, but generally should be subject-matter experts or stakeholders in the area/setting being profiled.

b) Define the area/setting to be profiled and establish the scope. For example, is the profile for a specific function which crosses multiple settings or is it for a single care setting?

c) Review the functional name, statements, descriptions and references in the existing EHR-S Functional Model. Consider these questions: Do the functions in the EHR-S Model apply to this Profile? Are certain functions required, but missing from the Model? (If functionality is missing, please notify HL7's EHR SIG for future revisions to the Model).

d) Review the existing functions in the model for the area/setting profiled to determine each function's priority. Determine whether each function is essential now, essential in the future, optional, or not applicable for the area/setting.

e) Create a use-case scenario or case study for the area/setting profiled. The case study would provide an example of how the functionality of the EHR-S Model would be applied to the area/setting. The use-case/case study would depict situations unique to the area/setting profiled and assist a reader in understanding how the EHR-S Functional Model would be applied in that unique situation or setting. When a function is described in the use-case scenario/case study, the function ID is referenced to tie the example back to the EHR-S Functional Model.

f) Complete the three profile documents (Definition of Area/Setting Profiled, Setting-Specific Model with Priorities, and Case Study) and submit the documents to the EHR SIG for review and comment. (Note: HL7 plans to maintain a library of the Profiles, but the process and procedure is currently not defined.)

5.5 Applications of the EHR System Functional Model

5.5.1 Vendor Perspective

Vendor – The HL7 EHR-S Functional Model & Standard judiciously stays away from implementation issues. The vendor generated innovation and applicable know-how is what will give life to the functions within the model. It is this innovation that is deemed irreplaceable and led the EHR SIG to remain away from the implementation ‘how’ issues. The use of the term ‘systems’ after EHR was purposely put in to indicate that vendors who have niche markets are just as important within the system as vendors who have large EHR products. The Functional Model will provide a communication tool by which a vendor niche product can communicate to a client that they meet all the functions and exceed by a large margin in the target area in which the client is focused.
5.5.2 **Provider Perspective**

Provider – The HL7 EHR-S Functional Model and Standard will give providers a common language to use when discussing functions that should be present within an EHR-S. By giving the provider a function name and definition that is standard throughout the industry, the provider has increased confidence in universal understanding when purchasing and using EHR-S functions.

5.5.3 **Patient Perspective**

Patient – The HL7 EHR-S Functional Model & Standard documents key functions that will enable patients to play an important role in their own healthcare. Systems that support these functions will provide decision support tools for self-health management, and make it feasible for patients to update their health records and better communicate with their providers.
Appendix A. Overview of related EHR standards

Purpose of EHR standards

The major purpose of EHR standards (and many other health technology standards) is to facilitate improvements in five main areas:

1. Interoperability
2. Safety/security
3. Quality/reliability
4. Efficiency/effectiveness
5. Communication (i.e. verbal and written communication to improve understandability)

These are clearly all important benefits and most standards will assist to a greater or lesser extent in achieving all five of these benefits. However, interoperability is arguably the single most important benefit of EHR standards since this is the area most lacking in health information management today. Furthermore, without interoperability, the ability to achieve the other three benefits is significantly limited.

Scope of EHR standards

In 2001, ISO/TC 215 established the EHR ad hoc Task Group to identify gaps and requirements for international standards for Electronic Health Records. The final report of this Group in 2002 [6] made 10 recommendations. The first three of these recommendations were:

1. ISO/TC 215 should develop a comprehensive consensus definition of the EHR.
2. ISO/TC 215 should define EHR standards as part of a family of standards based on a “system-of-systems” approach that collectively represents the major services in a distributed health-computing environment.
3. ISO/TC 215 should restrict the scope of EHR standards to a conception of the EHR that is concerned with a single subject of care, has as its primary purpose the support of present and future health care, and is principally concerned with clinical information.

The first of these recommendations is in its fourth (and potentially final) Draft Technical Report in the ISO 20514 project [2]. The second and third recommendations are interesting because they implicitly define the scope of EHR standards activity, at least for ISO. There are two quite distinct views on the scope of the EHR and of EHR systems. These have been called the “Core EHR” and “Extended EHR” [2] views. The Core EHR view is that the scope of the EHR (and therefore of EHR systems) is concerned principally with clinical information and the care of individual patients (as per Recommendation 3 above) and excludes other components of a comprehensive clinical information system (such as demographics, security, terminology, and decision support (as per recommendation 2 above)). The Extended EHR view is that the scope of the EHR and EHR systems includes not only the
related EHR “building block” services such as terminology and security, but also non-clinical functions such as patient administration, scheduling, billing, and resource allocation. The issue of EHR/EHR-S scope is discussed further in ISO 20514.

One very practical reason for adopting the more limited scope for the EHR/EHR-S is that it is difficult enough to create EHR standards for even the limited scope. Many would say that it is impossible to create EHR standards if the scope of the EHR/EHR-S is effectively extended to include all of health informatics (and beyond). Rather, “The best way to eat an elephant is in small pieces”.

Classification of EHR standards

There is no formally accepted classification of EHR standards. But one approach used in the ISO EHR ad hoc Group Report [6] is described below¹.

Core interoperability standards

There are at least six important types of standards that contribute to EHR interoperability, including unique identification of the subject of care and standardized EHR system functionality – but these will be discussed under other headings.

The ISO EHR ad hoc Group classification lists four key pre-requisites necessary to achieve semantic interoperability of EHR information, with the first two of these also being required for functional interoperability²:

1. A standardized EHR Reference Model (namely, the EHR information architecture) between the sender (or sharer) and receiver of the information.

2. Standardized service interface models to provide interoperability between the EHR service and other components such as demographics, terminology, access control and security services in a comprehensive clinical information system.

3. A standardized set of domain-specific concept models, namely, archetypes and templates for clinical, demographic, and other domain-specific concepts.

4. Standardized terminologies (which underpin the archetypes).

Content standards

Content standards is an important category of standards that can be further subdivided into “content standards for the ”HR” and “content standards for EHR systems”. EHR content is

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¹ The approach to standards classification described here is framed by the ISO RM/ODP methodology [7] and two-level modelling used by both HL7 V3 and the CEN/openEHR standards groups. An alternative classification based on the ISO Health Informatics Profiling Framework is also described in [6].

² The four points below are reproduced directly from ISO 20514. A further discussion on the key role of interoperability for EHRs can be found in section 4.2 of that document.
explicitly excluded from the DSTU, whereas the functional content for EHR systems is the purpose of the DSTU.

**Content standards for the EHR**

Content standards for the EHR includes standards for data elements comprising minimum data sets and disease registers such as emergency medicine, diabetes, cancer, and statutory reportable diseases. It may also include standards for the data element content of parts of an EHR (for example, a discharge summary or referral) or for EHRs with a specific focus (for example, the ASTM draft standard for a “Continuity of Care Record” (CCR)).

There may also be standards for transmission of standardized data sets. For example, a standardized HL7 message is being developed for a discharge summary. However, this is an example of a messaging standard and not an EHR standard. Note also that when transmission is required from one standards-based EHR system to another, service-based communication in the form of an EHR extract is more efficient than messaging for EHR content such as discharge summaries and referrals.

**Content standards for EHR systems**

Content standards for EHR systems refers to functional content of EHR systems (for example, the HL7 EHR System Functional Model DSTU).

**Standards for EHR-related services**

As mentioned earlier, standards for EHR-related services such as terminology, security, and decision support will normally be considered to be out of scope for EHR standards Technical Committees (TC) and Working Groups (WG) since they will be developed by TCs and WGs dedicated to these areas. There are, however, areas of overlap where it may be appropriate for an EHR TC/WG to work jointly with another specialist TC/WG. A good example is EHR access control and consent management standards. These standards typically contain both a policy element and a technical security element and are best developed jointly by an EHR TC/WG and a Security TC/WG with the former providing input on the policy issues and the latter on technical security matters.

One important EHR-related service which is often not covered by any specialist TC/WG within health informatics standards development organizations (SDOs) is demographics – particularly in regard to client (patient/subject-of-care) identification and provider (clinician) identification. Unique identification of all EHR parties is clearly essential for both medico-legal and interoperability purposes. Note that it is desirable to have a “Unique Identifier” (namely, a unique number) standard for EHR and other purposes, but a “Unique Identifier standard” is not essential for unique identification. ISO/TC 215 and several other health informatics SDOs have or are developing client and provider identification standards that use a combination of demographic attributes for identification, without requiring a unique identification number.
Standards for specific EHR technologies, sectors and stakeholders

The development of EHR standards for particular technologies, health sectors and/or stakeholders should be undertaken only where absolutely necessary to avoid the problem of incompatibility between “special purpose” and “generic” EHR standards. For example, there should be no reason to develop an EHR architecture standard for a Personal Health Record that differs from that of a generic EHR architecture standard.

The need for special interest EHR standards often arises because of the lack of a relevant generic standard. An example of this is the development of EHR architecture and content standards for Health Cards within CEN and ISO to meet the immediate needs of Health Card projects in Europe and elsewhere, before the equivalent generic EHR standards are available. Fortunately, there has been good liaison between the Health Card and EHR Working Groups in CEN and ISO to minimize the possibly of incompatibilities.

There are of course some legitimate examples of the need for special interest versions of generic EHR standards. The HL7 EHR-S DSTU is a good example of the combination of sector-specific specializations within an overarching generic EHR standard. The underlying functional model and function set is the same for all care settings, ensuring overall compatibility, while also allowing the function set to be customized to suit the needs of each particular care setting profile. This is being further extended to embrace the concept of realm-specific specializations so that an ambulatory care profile for the United States may be different from an ambulatory care profile for Canada.

EHR meta standards

This group of standards consists of high-level (Enterprise view in RM/ODP terms) standards such as the ISO Emergency Data Framework, Health Indicators Conceptual Framework, and Health Informatics Profiling Framework. An EHR Enterprise Architecture standard covering the scope, policies and high-level (conceptual/enterprise) architecture for the data management and knowledge management components of the EHR would be another example of an EHR meta standard.
Appendix B: Current International EHR Standards Activities

Overview

There are three main standards bodies currently active in international standards directly related to the EHR. These are ISO (International Standards Organization), CEN (Committee European Normalization - the European Standards Organization), and HL7 (Health Level 7) that is U.S.-based but with now over 20 international affiliates. Within the United States there are many other SDOs that are involved in the development of EHR-related standards, most notably ASTM [8] and the Object Management Group Health Domain Task Force (OMG HDTF) [9]. ASTM has been most active in the area of EHR content standards (e.g. the Continuity of Care Record standard) whilst the HDTF have made a significant contribution to the development of open service specifications such as COAS (Clinical Observation Access Service), PIDS (Person Identification Service), TQS/LQS (Terminology/Lexicon Query Service), and RAD (Resource Access Service). DICOM is the peak international SDO for image storage and communication in health.

ISO/TC 215

ISO/TC 215 [10] is the peak international standards body for EHR and other health informatics standards. However, it is a relative newcomer to health informatics standards, having been established only five years ago.

Some of the standards developed by TC 215 are produced “de novo” (e.g. ISO 18308 “Requirements for an EHR Reference Architecture”) within the TC 215 working groups, but many others use existing standards from other national and international standards organizations as at least a starting point for an ISO standard. Examples of such organizations are IEEE, CEN, HL7, DICOM, and Standards Australia. Some organizations such as IEEE, CEN, and HL7 have special agreements with ISO that enable their existing standards to be fast-tracked to become ISO standards. For example, HL7 V2.5 is undergoing fast-track adoption by ISO under a new ISO-HL7 Agreement and several CEN standards in the area of medical devices and health cards are being adopted under the ISO-CEN Vienna Agreement.

ISO/TC 215 currently has six working groups:

WG1: Health Records and Modeling Coordination

WG2: Messaging and Communication

WG3: Health Concept Representation

WG4: Security

WG5: Health Cards

WG6: e-Pharmacy
The Chair of TC 215 is currently held by South Korea and the Secretariat is held by the United States through HIMSS.

Some of the recent and current EHR-related standards on the TC 215 work program include:

- Requirements for an Electronic Health Record Architecture (WG1 - ISO 18308)
- Country Identifier Standards (WG1 - ISO 17120)
- Health Indicators Conceptual Framework (WG1 - ISO 21667)
- Health Informatics Profiling Framework (WG1 - ISO 17119)
- EHR Definition, Scope and Context (WG1 - ISO 20514)
- Identification of Subjects of Health Care (WG1 - ISO 17457)
- Framework for Emergency Data Sets (WG1)
- Health Indicators – Definitions, Attributes and Relationships (WG1)
- Architectural Requirements for EHR Systems (WG1)
- Data Types for use in Healthcare Data Interchange (WG2 - ISO 21090)
- Privilege Management and Access Control (WG4 - ISO 22600)
- Functional and Structural Roles (WG4)

CEN/TC 251

CEN is the peak European standards organization that transcends the national standards organizations of its member countries. It has a membership of 22 countries that comprise all of the 15 European Union states (this will become 25 countries in 2004) plus seven other member countries that are not currently part of the EU (Czech Republic, Hungary, Iceland, Malta, Norway, Slovakia, and Switzerland). CEN/TC 251 [11] is the health informatics Technical Committee of CEN.

At present there is only one comprehensive EHR interoperability standard in the world. This is the CEN ENV13606 standard that was published in 1999/2000. It built upon the first CEN EHR standard, ENV12265, published in 1995. It was based almost entirely on the Good European Health Record (the original GEHR) but was never implemented. ENV13606 has had limited uptake due mainly to difficulties with implementation inherent in its single-level modeling approach. In November 2001, a decision was taken by CEN to revise

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3 “ENV” denotes a “Pre-standard” (soon to be renamed a “Technical Specification” to comply with ISO terminology) whilst “EN” denotes a full de jure European standard. All CEN standards are ENVs for a period of three years which enables implementation experience and feedback before becoming a full standard. At the end of the three year period, a pre-standard can be converted without change to full EN status, or it can be revised to become an EN, or it can be scrapped.
ENV13606 and to adopt the openEHR\textsuperscript{4}/GEHR archetype methodology\textsuperscript{5}. An MOU was signed between CEN and the openEHR Foundation \cite{12} to enable the Australian members of openEHR to participate in the revision project.

The ENV13606 standard was in four parts but the revised EN13606 will consist of five parts:

- **Part 1: Reference Model** – a generic information model for communicating one or more EHR extracts (or the entire EHR) of any subject of care (patient/consumer).
- **Part 2: Archetype Interchange Specification** – a generic information model and language for representing and communicating the definition of individual instances of Archetypes.
- **Part 3: Reference Archetypes and Term Lists** – a range of Archetypes reflecting a diversity of clinical requirements and settings, as a "starter set" for adopters and to illustrate how other clinical domains might similarly be represented (for example by health professional groups).
- **Part 4: Security Features** – the information model concepts that need to be reflected within individual EHR instances to enable suitable interaction with the security components that are anticipated to be required in any future EHR deployment.
- **Part 5: Exchange Models** – a set of models that build on the above parts and can form the basis of message-based or service-based communication.

The revised CEN EN13606 will also include compliance with the HL7 CDA (Clinical Document Architecture) Release 2. This will form a very important harmonization bridge between Europe and the U.S.. A simple schematic diagram of this relationship between openEHR, CEN 13606, and HL7 CDA is:

\textsuperscript{4} The openEHR EHR model is common framework and open specification for structuring, storing and managing patient data so that it can be shared and exchanged between different healthcare providers in a safe and secure manner. openEHR is not in itself a standard but is a leading input into the development of CEN and other EHR standards.

\textsuperscript{5} A non-technical definition of an archetype is “a model of a clinical or other domain-specific concept which defines the structure and business rules of the concept.” Archetypes may define simple compound concepts such as ‘blood pressure’ or ‘address’, or more complex compound concepts such as ‘family history’ or ‘microbiology result’. They are not used to define atomic concepts such as anatomical terms.
The complete 5-part standard will be finished in 2004 and will become a full *de jure* standard in the 25 countries of the European Union at that time.

**Health Level Seven (HL7) Standards**

Health Level Seven (HL7) has traditionally been concerned mainly with interoperability standards. However, in 2000 its mission statement was modified to include the EHR. The first EHR-related HL7 standard development was for the Clinical Document Architecture (CDA). The CDA is not a full EHR specification but it forms an important sub-component of the EHR and is very compatible with the equivalent components in *open*EHR and CEN 13606⁶.

The CDA was not initiated as an EHR project but rather as a means of identifying and tracking the numerous clinical documents that are created and transmitted every day in the United States as part of the transcription process. The HL7 EHR-S DSTU project on the other hand, is HL7’s first conscious move into EHR standards development. There have been small projects in the past to develop standardized EHR functional specifications but nothing like the scale and potential international importance of the DSTU.

The work of the HL7 Templates, Vocabulary, and Decision Support TCs, whilst not primarily involved in the development of core EHR standards, is clearly also important in providing “building blocks” for the EHR.

**EHR-S Interoperability**

It is reasonable to assume that the EHR Systems of today and tomorrow will rely on interoperability standards to achieve seamless coordination and cooperation.

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⁶ A CDA Document is equivalent to a Composition in the CEN/openEHR EHR structure.
Conformance using Functional Profiles

Profiles are routinely used to specify unambiguously how a specific application or project conforms to an HL7 standard (Version 2, Version 3, etc.) or to other standards (e.g. DICOM).

The HL7 EHR-S Specification will use Functional Profiles to create specification based on this standard. These specifications may refer to an application by identifying which of the “standard” functions are implemented by an application.

Harmonization

The importance of harmonization of the standards development work being undertaken by the main SDOs cannot be overstated. ISO/TC 215 performs a very important function in promoting and undertaking harmonization at the international level but it is also important for harmonization to be occurring “at the coal face” between the two main regional players in EHR standardization. CEN and HL7 have signed an MOU to further cooperation between the two organizations, with a particular emphasis on harmonization. This effort received a considerable boost in 2002 when Mark Shafarman, the Chair Elect of HL7, joined the 13606 revision Taskforce and has become a regular attendee at CEN meetings. The CEN-HL7 Harmonization is occurring on several fronts:

- CEN/openEHR Reference Model with HL7 CDA – This has already been discussed in section 5.3.
- CEN/openEHR archetypes with HL7 templates – HL7 templates have many similarities to archetypes and the introduction of the new Archetype Definition Language (ADL) shows great promise for achieving harmonization.
- Data types – these are the lowest level artifacts for interoperability so harmonization of HL7, CEN, and openEHR data types is essential to ensure both EHR and messaging interoperability.
- HL7 RIM with CEN and openEHR – This is less urgent from an EHR viewpoint than the other harmonization tasks but it is highly desirable in the longer term to have good harmonization between HL7 V3 messaging standards and the EHR standards.
Appendix C: Future International Directions for EHR Standards

As the peak international SDO for health informatics standards, ISO/TC 215 is expected to be the “home” for all future EHR standards of international significance, even though many of these standards will initially be developed in national or regional SDOs. Two years ago there were very few such standards available or under development. Today, the outlook is much more optimistic. The likely source of the main international EHR standards necessary for interoperability and for the improvement of quality and safety in healthcare are discussed below.

EHR interoperability standards

Generic EHR interoperability standards

CEN/TC 251 has foreshadowed its intention to introduce the revised EN13606 standard into ISO/TC 215 under the Vienna Agreement when the project is completed in 2004. It would be possible under this Agreement to introduce 13606 into ISO as a Draft International Standard that could be balloted without modification. However, it is essential for the success of any 13606-based ISO standard that it has broad support beyond Europe and Australia before going to ballot. In particular, U.S. support is seen as essential given the size and importance of this market.

There are very encouraging signs that this will be achievable. European and other international EHR experts are actively participating in HL7’s EHR SIG and are working with the HL7 TCs on a range of harmonization activities as outlined above. HL7 experts are also working directly with CEN 13606 and other projects. CEN has also given its permission for the ISO EHR Working Group to participate in the 13606 revision project by receiving the draft CEN documents for review and comment back to the 13606 Taskforce. It is expected that the ISO EHR standard based on CEN EN13606 should be completed and become the international EHR interoperability standard within two years.

The ISO “Data Types for use in Healthcare Data Interchange”, based on harmonization of HL7 and CEN data types, will be another important standard for EHR interoperability.

Standardizing archetypes and templates

EN13606 fulfills the first of the four main requirements for EHR interoperability – i.e. a standardized EHR Reference Model. It also enables fulfillment of the third requirement – i.e. a standardized set of clinical and other domain-specific concept models (archetypes and templates). A production quality open source software tool for authoring archetypes and templates will be available in the near future. A number of clinical archetypes have already been built using a prototype Archetype Editor.

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7 The CEN EN 13606 drafts are already being used as the basis for the development of a set of Australian EHR interoperability standards.
The development of archetypes and templates is done by clinicians (physicians, nurses, allied health practitioners etc) and other domain experts rather than IT specialists. This is a major benefit in terms of empowerment and buy-in of EHR system users. It is estimated that around 300 archetypes will be required for each major health specialty/discipline and around 3,000 archetypes to cover all of health (due to significant overlap). It will be essential that the development of archetypes is done using a controlled process to avoid the problem of multiple incompatible versions of the same concept that has plagued the terminology field in the past.

It is preferable that archetype development should be done under the aegis of the health professional colleges (e.g. American College of Surgeons, American College of Nursing) in conjunction with an SDO such as HL7, CEN, or ISO. Templates (which are combinations of archetypes for data entry forms, views, etc) will be much more numerous and will mainly be used at a local level, thus requiring a lesser degree of agreement and control.

**EHR content standards**

There are many areas of need for international EHR content standards, but perhaps a strong candidate for the first of these will be the ASTM Continuity of Care standard as the basis for an ISO standard in this area.

The HL7 EHR-S DSTU is expected to form the basis for the international (ISO) standard for EHR system functionality. Its unique concept of “realm-specific” profiles within a single functional model and a consistent overall framework should find utility in the development of other health informatics standards. Australia has already foreshadowed the development of an Australian realm-specific version of the DSTU and several other countries have also expressed strong interest.

**EHR-related standards**

There are many important international standards that are required in the areas of security, terminology, and demographics to support comprehensive EHRs and EHR systems. Some of these are already under development or scheduled for commencement within ISO/TC 215, including identification of subjects of healthcare, provider identification, and EHR access control and consent management.

**Terminology standards**

Terminology is perhaps the most problematic piece of the EHR interoperability jigsaw. Most of the terminology standards produced by health informatics SDOs are meta-standards (i.e. standards about how to build quality terminologies) rather than standardizing the content of actual terminologies. There are exceptions such as the recent ISO standard nursing terminology. Most health terminologies have been developed or have grown from an original core in a rather haphazard way (hence the need for terminology meta-standards for the future development of better quality terminologies). Most large terminologies are “polluted” by a combinatorial explosion of pre-coordinated terms in addition to core atomic terms which makes them difficult to use and sometimes problematic when terms are post-coordinated in EHR systems for decision support and other applications.
Another significant problem with current terminologies, particularly large reference terminologies like SNOMED-CT, is that most are proprietary. To ensure at least de-facto standard status, it is necessary for such proprietary terminologies to be ubiquitously available to healthcare providers, usually through a national license.

Fortunately, the advent of archetypes and “micro vocabularies” means that significant interoperability of patient information can be achieved without having to wait for the “big terminology problem” to be solved. HL7 has already developed some 400 micro vocabularies to populate HL7 messages from its Clinical Terminology Service. openEHR/CEN is adopting the same strategy for naming nodes of archetypes and to populate list variables within archetypes. These micro-vocabularies enable a significant degree of interoperability without any reliance on the availability of external terminologies. However, they can be bound to any available external terminology such as SNOMED or ICD at runtime. Comprehensive reference terminologies will of course still be required for large groups of terms such as diagnoses, lab tests, and anatomical terms.

Service interface standards

Service interface standards are required to ensure that the various components of an integrated clinical information system (e.g. demographics, terminology, access control/security) can interoperate with the core EHR system. A number of open specifications for health service interfaces have been developed by the OMG [9] but some of these need revision and incorporation into a broader standards framework. HL7 is currently developing a Clinical Terminology Service (CTS) and may build other service specifications in the future. openEHR is also progressively developing service interface specifications (e.g. demographics) and CEN/TC 251 is currently revising its pre-standard ENV12967, “Health Informatics Service Architecture” (HISA).

More work needs to be done in this area of standardization, particularly in building and agreeing on a common set of service standards which can be moved into ISO for international agreement.

Where do messaging standards fit with the EHR?

Messaging standards such as HL7, DICOM, and UN/Edifact play a crucial role for interoperability between non-EHR systems (e.g. lab, radiology, and pharmacy systems) and EHR systems or between two non-standardized EHR systems (i.e. EHR systems that do not share the same information model. Messaging standards will therefore always be necessary for lab, imaging, and pharmacy orders and results since lab and similar systems do not contain/operate on patient-centered EHRs (since this is neither their primary purpose nor operationally efficient).

The Venn diagram below illustrates that health service messaging has a much larger domain than the EHR. Patient administration, billing and materials management are examples of areas within the scope of messaging but generally considered to be outside the scope of the EHR. Care plans, patient consultation notes and health summaries could possibly be
transmitted as messages but it is much more efficient to transfer EHR extracts directly between such systems using a lower level interoperability technology such as SOAP, RPC, CORBA etc. Of course this is only possible with standards-based EHRs and EHR systems (i.e. EHRs which comply to the same information model and are independent of the EHR systems architecture).

Figure 3  Relationship between messaging and the EHR

Lab tests, radiology and pharmacy are examples of areas where both messaging and the EHR play a role in communication. As stated above, messaging is necessary in these areas when placing orders and receiving results but the results could then be communicated to another standards-based EHR system more easily and efficiently using EHR extracts rather than messages.

It should be noted that archetypes and templates are also applicable to messaging and their use with HL7 V3 RIMs has already been demonstrated.

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8 “Messaging” in its broadest sense could be used to indicate any communication between two systems but the sense in which it is usually used in health informatics is more restricted to formal high-level messaging protocols such as HL7, DICOM, X12 etc.
Appendix D: What is a DSTU?

Definition from HL7 Policy and Procedure Manual:

*POL 14.00.01 Draft Standard for Trial Use*

In order to provide timely compliance with regulatory or other governmental mandate and/or timely response to industry or market demand, the Board of Directors is empowered to adopt and publish a Draft Standard for Trial Use (DSTU). The issuance of a DSTU shall be an extraordinary event and shall only proceed with the understanding that the draft standard will, following a suitable period for evaluation and comment, be expeditiously incorporated into a fully balloted and accredited version of the standard. Where the evaluation and comment period results in a need for substantive changes to the draft standard, the relevant accredited version of the standard may embody such changes or a revised DSTU may be published for further evaluation. In either case, given the need for substantive changes, the accredited version of the standard or the subsequent revised DSTU is not bound to maintain compatibility with the initial DSTU. Under such circumstances it is the obligation of the author(s), given that the intent of a draft standard is to improve the viability of the accredited standard, to select enhancement over compatibility. Conversely, recognizing the commitment and investment involved in implementing a DSTU for evaluation and comment, a DSTU implementation shall be accepted as viable for up to two years after its publication or for up to six months after the publication of a subsequent revised DSTU or the first accredited version of the standard that embodies the draft standard, whichever is longer.
References


