INTERNATIONAL STANDARD

ISO 10781

Second edition
2015-08-01

Health Informatics — HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM)

Informatique de santé — Modèle fonctionnel d'un système de dossier de santé électronique, publication 2 (EHR FM)

Reference number
ISO 10781:2015(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/HL7 10781 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO/HL7 10781:2009), which has been technically revised.

Introduction

Information for readers

EHR System Functional Model Release 2.0 is based on a series of predecessors, starting in 2004 with the release of the first consensus Draft Standard, followed in 2007 by Release 1, then in 2009 with Release 1.1, jointly balloted with ISO/TC 215 and CEN/TC 251. Release 2.0 reflects many changes, including ballot comments that had been made on past ballots and where the HL7 EHR Work Group had committed to bringing consideration of requested changes forward. It also includes comments that were considered for future use from the ISO ballot of 2009 as well as considerations of the Comment Only ballot that was circulated in May 2011.

Other inclusions were made as a result of the multiple EHR System Functional Profiles that have been written on Functional Model Releases 1 and 1.1. There was great learning in those various domain as well as companion profiles. The EHR-S FM also incorporated two other Draft Standards for Trial Use: HL7 EHR Lifecycle Model and HL7 EHR Interoperability Model.

Changes from previous Release

The HL7 EHR-System Functional Model Release 2 had its first normative ballot in May 2012. The key changes as a result of the first normative ballot included the following.

- Moved the normative parts of the Glossary into the Conformance clause section as use of glossary consistently is key to ease in reading and understanding the model.
- Improved consistency in representation of Headers, Functions and Conformance Criteria throughout the model.
- Updated the conformance clause for ease of reading especially as it related to the different types of profiles: domain profiles and companion profiles.
- Provided clarity for functional description and related conformance criteria.
- Updated the content to be more current.

To see all of the comments and reconciliation of the Normative 1 ballot, please see the HL7 Ballot Website for the ballot cycle of May 2012.

Background

What are Electronic Health Record Systems?

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 US 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).

In developing this EHR-S Functional Model, HL7 relied on three well-accepted definitions: two provided by the US. Institute of Medicine and one developed by the European Committee for Standardization/ Comité Européen de Normalization (CEN). This Functional Model leverages these existing EHR-S definitions and does not attempt to create a redundant definition of an EHR-S.

Existing EHR System Definitions

The IOM's 1991 report, The Computer-Based Patient Record: An Essential Technology, and updated in 1997 (Dick, R.S, Steen, E.B., and Detmer, D.E. (Editors), National Academy Press: Washington, DC) defined an EHR System as follows.

- 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:
- 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.
- Immediate electronic access to person- and population-level information by authorized, and only authorized, users.
- Provision of knowledge and decision-support that enhance the quality, safety, and efficiency of patient care.
- Support of efficient processes for health care delivery.

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

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

How were the Functions Identified and Developed?

To achieve healthcare community consensus at the outset, the functions are described at a conceptual level, providing a robust foundation for a more detailed work. Functions were included if considered essential in at least one care setting. Written in user-oriented language, the document is intended for a broad readership.

Functional Granularity is a term used to describe the level of abstraction at which a function is represented. Functions that are commonly grouped together in practice or by major systems have been consolidated where appropriate; functions requiring extra or separate language or involving different workflows have been kept separate where appropriate. For example, decision support is maintained as a separate section, but mapped to other key sections, to indicate the "smart" function behind an action. All of the functions could be expanded into more granular elements but a balance between a usable document and an unwieldy list of functions has been agreed upon. The goal of determining an appropriate level of functional granularity at this time is to present functions that can be easily selected and used by readers of this standard, but that are not so abstract that readers would need to create a large number of additional functions within each function.

Although the determination of functional granularity is a relatively subjective task, systematic evaluation of each function by diverse groups of industry professionals has resulted in a level of granularity appropriate for this EHR-S Functional Model. Every attempt has been made to provide supporting information in the functional descriptions to illustrate the more granular aspects of functions that may have been consolidated for usability purposes.

Keeping with the intent of this EHR-S Functional Model to be independent with regard to technology or implementation strategy, no specific technology has been included in the functions, but may be used in the examples to illustrate the functions. Inclusion of specific technologies in the examples does not endorse or support the use of those technologies as implementation strategies.

Drafts of the EHR-S Functional Model and of specific functions have been widely reviewed by healthcare providers, vendors, and other stakeholders. This proposed standard reflects input from all these reviewers.

Health Informatics — HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM)

1 Scope

The HL7 EHR System Functional Model provides a reference list of functions that may be present in an Electronic Health Record System (EHR-S). The function list is described from a user perspective with the intent to enable consistent expression of system functionality. This EHR-S Functional Model, through the creation of Functional Profiles for care settings and realms, enables a standardized description and common understanding of functions sought or available in a given setting (e.g. intensive care, cardiology, office practice in one country or primary care in another country).

The HL7 EHR-S Functional Model defines a standardized model of the functions that may be present in EHR Systems. From the outset, a clear distinction between the EHR as a singular entity and systems that operate on the EHR, i.e. EHR Systems, is critical. Section 1.1.3 describes the basis and foundation for the HL7 definition of an EHR System. Notably, the EHR-S Functional Model does not address whether the EHR-S is a system-of-systems or a single system providing the functions required by the users. This International Standard makes no distinction regarding implementation; the EHR-S described in a Functional Profile may be a single system or a system of systems. Within the normative sections of the Functional Model, the term "system" is used generically to cover the continuum of implementation options. This includes "core" healthcare functionality, typically provided by healthcare-specific applications that manage electronic healthcare information. It also includes associated generic application-level capabilities that are typically provided by middleware or other infrastructure components. The latter includes interoperability and integration capabilities such as location discovery and such areas as cross application workflow. Interoperability is considered both from semantic (clear, consistent and persistent communication of meaning) and technical (format, syntax and physical connectivity) viewpoints. Further, the functions make no statement about which technology is used, or about the content of the electronic health record. The specifics of 'how' EHR systems are developed or implemented is not considered to be within the scope of this model now or in the future. This EHR-S Functional Model does not address or endorse implementations or technology, nor does it include the data content of the electronic health record.

Finally, the EHR-S Functional Model supports research needs by ensuring that the data available to researchers follow the required protocols for privacy, confidentiality, and security. The diversity of research needs precludes the specific listing of functions that are potentially useful for research.

This Functional Model is not:

— a messaging specification;

— an implementation specification;

— a conformance specification;

— an EHR specification;

— a conformance or conformance testing metric;

— an exercise in creating a definition for an EHR or EHR-S.

The EHR-S Functional Model is not sufficient to provide a longitudinal health record; however, it will contribute to its development. The information exchange enabled by the EHR-S supports the population of clinical documents, event summaries, minimum data sets, claims attachments, and in the future will enable a longitudinal health record.

Additionally, it is important to note that the EHR-S Function Model does not include a discussion of clinical processes or the interaction of the healthcare actors. However, ISO 13940 is an international standard that does outline key principles and processes in the provision of healthcare. Users of the EHR-S FM can refer to ISO 13940 for clinical processes that EHR systems support.

This EHR-S Functional Model package includes both Reference and Normative sections.

Table 1 — Normative Status Types

Status	Description
Reference	Content of the EHR-S Functional Model Package that contains information which clarifies concepts or otherwise provides additional information to aid understanding and comprehension. Reference material is not balloted as part of the standard.
Normative	Content that is part of the EHR-S Functional Model which HL7 committee members and interested industry participants have formally reviewed and balloted following the HL7 procedures for Balloting Normative Documents. This HL7 developed Functional Model document has been successfully balloted as a normative standard by the HL7 organization.

Each section within this document is clearly labelled "Normative" if it is normative. For example, in Clause 7, Conformance Clause, subclauses 7.2 and 7.4 are normative.

In the external Annex A, Function List, the Function ID, Function Name, Function Statement, and Conformance Criteria components are Normative in this Functional Model.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TR 12773-1:2009, *Business requirements for health summary records — Part 1: Requirements*

ISO/TS 13606-4:2009, *Health informatics — Electronic health record communication — Part 4: Security*

ISO/TS 17090-1:2002, *Health informatics — Public key infrastructure — Part 1: Framework and overview*

ISO 18308:2011, *Health informatics — Requirements for an electronic health record architecture*

ISO/IEC 2382-8:1998, *Information technology — Vocabulary — Part 8: Security*

ASTM E1769:1995, *Standard guide for properties of electronic health records and record systems*

3 Terms and definitions

3.1
access control
means of ensuring that the resources of a data processing system can be accessed only by authorized entities in authorized ways

3.2
base functional profile
existing domain or companion functional profile from which new functional profiles are created and/or derived

3.3
conformance
fulfilment of a product, process or service of specified requirements

3.4
conformance criteria
requirements indicating the behaviour, action and/or capability that constitutes implementation of the function

3.5
conformance clause
section of a specification that defines the requirements, criteria or conditions to be satisfied in order to claim conformance

3.6
conformance statement
description of the functions in an EHR system that have been implemented, reflecting the degree to which an EHR system has met the functional profile's requirements and which may include optional functions and information

3.7
derived functional profile
functional domain or companion profile that is created from a base functional profile (i.e. child functional domain profile to children's hospital domain profile)

3.8
extension
capability of an EHR-S to incorporate additional functionality beyond what is defined in the Functional Profile

3.9
functional profile
subset of the Functional Model, in which functions have been designated (sometimes in varying degrees) for certain EHR systems or healthcare delivery settings or narrow operation requirements

3.10
informative functional profile
registered functional profile that has successfully completed formal public scrutiny via the HL7 consensus process

3.11
inherited criterion
one of a set of conformance criteria listed in a parent function that is inherited by all its children functions

3.12
registered functional profile
functional profile that has successfully completed HL7 EHR Work Group registration process and review

3.13
situational criterion
criterion that is required if the circumstances given are applicable

EXAMPLE IF/Then or Dependent SHALL.

4 Overview and definition of the Functional Model (Normative)

The EHR-S Functional Model is composed of a list of functions, known as the Function List, which is divided into seven sections: Overarching, Care Provision, Care Provision Support, Population Health Support, Administrative Support, Record Infrastructure and Trust Infrastructure.

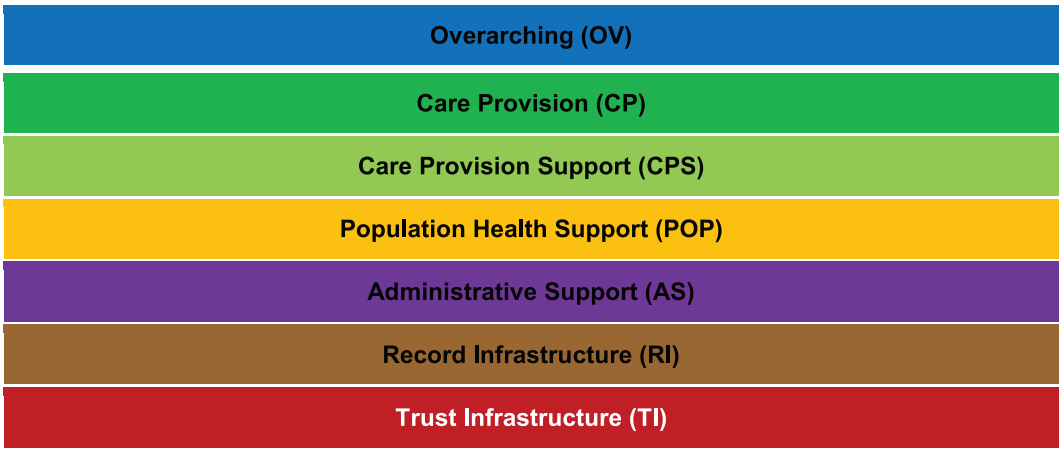

Figure 1 — Function List Sections

Within the seven Sections of the Functional List the functions are grouped under header functions which each have one or more sub-functions in a hierarchical structure.

4.1 Sections of the Function List

The seven sections of the function list reflect content of the Interoperability Model, now integrated in the Functional Model, and input from several profiles if the R1.1 version of the Functional Model. Below is a summary description of each of the seven sections:

- Overarching: The Overarching Section contains Conformance Criteria that apply to all EHR Systems and consequently must be included in all EHR-S FM compliant profiles.
- Care Provision: The Care Provision Section contains those functions and supporting Conformance Criteria that are required to provide direct care to a specific patient and enable hands-on delivery of healthcare. The functions are general and are not limited to a specific care setting and may be applied as part of an Electronic Health Record supporting healthcare offices, clinics, hospitals and speciality care centres.
- Care Provision Support: The Care Provision Support Section focuses on functions needed to enable the provision of care. This section is organized generally in alignment with Care Provision Section. For example, CP.4 (Manage Orders) is supported directly by CPS.4 (Support Orders).
- Population Health Support: The Population Health Support Section focuses on those functions required of the EHR to support the prevention and control of disease among a group of people (as opposed to the direct care of a single patient. This section includes functions to support input to systems that perform medical research, promote public health, and improve the quality of care at a multi-patient level.
- Administrative Support: The Administrative Support Section focuses on functions required in the EHR-S to enable the management of the clinical practice and to assist with the administrative and financial operations. This includes management of resources, workflow and communication with patients and providers as well as the management of non-clinical administrative information on patients and providers.
- Record Infrastructure: The Record Infrastructure Chapter consists of functions common to EHR System record management, particularly those functions foundational to managing record lifecycle (origination, attestation, amendment, access/use, translation, transmittal/disclosure, receipt, de-identification, archive…) and record lifespan (persistence, indelibility, continuity, audit, encryption). RI functions are core and foundational to all other functions of the Model (CP, CPS, POP, AS).

- Trust Infrastructure: The Trust Infrastructure Chapter consists of functions common to an EHR System infrastructure, particularly those functions foundational to system operations, security, efficiency and data integrity assurance, safeguards for privacy and confidentiality, and interoperability with other systems. TI functions are core and foundational to all other functions of the Model (CP, CPS, POP, AS and RI).

4.2 Functional Profiles

While the Functional Model should contain all reasonably anticipated EHR-S functions, it is not itself intended as a list of all functions to be found in a specific EHR-S. Functional Profiles should be used to constrain the functions to an intended use. This document defines the Functional Model and describes the general use of profiles and priorities (See 1.4 Anticipated Uses).

In the aggregate, the Functional Model is intended to include the superset of functions from which a subset can be generated by the user. This subset created by the user illustrates what is needed within an EHR-S. Only a subset of the superset of functions will apply to any particular EHR-S Profile.

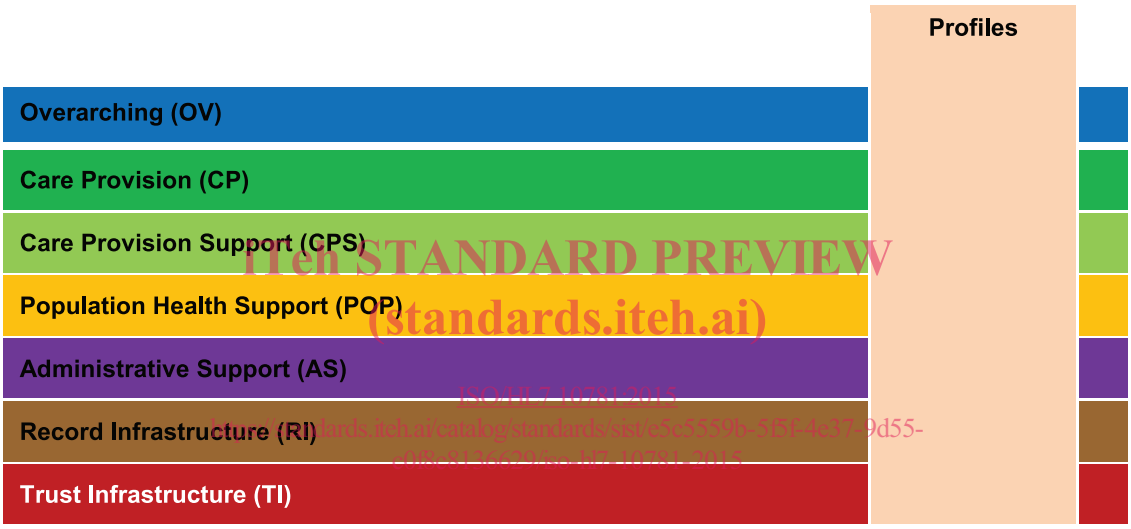

Figure 2 — Profiling from the EHR-S FM

Figure 2 shows that a profile would include all seven sections of the Functional Model, however it may not be necessary to include all the functions and criteria within each section. A profile may include additional functions and criteria to meet the requirements of the profile.

The Conformance Clause is a high-level description of what is required of profiles and implementations. It, in turn, refers to other parts of the standard for details. The Conformance Clause describes concepts critical to the understanding and implementation of the Functional Model, such as: '*What is a profile? What are Conformance Criteria? Or How do you know what is mandatory versus optional*? A Conformance Clause can also provide a communication between the implementers (vendors) and users (buyers) as to what is required, and gives meaning to the phrases, "conforming profile" and "conforming EHR system". Additionally, it serves as the basis for testing and certification activities which may be performed by organizations external to HL7.

Refer to the Conformance Clause, Clause 7, for additional information related to the rules for selecting and adding Conformance Criteria in the development of a Functional Profile.

4.3 EHR-S Function List Components

The EHR-S Function List is a list (superset) of functions organized into discrete sections. Functions describe the behaviour of a system in user-oriented language so as to be recognizable to the key stakeholders of an EHR-S.

EHR-S functions can be used to:

- Facilitate describing end user defined benefits such as patient safety, quality outcomes and cost efficiencies in terms of standard EHR-S functions.
- Promote a common understanding of EHR functions upon which developers, vendors, users and other interested parties can plan and evaluate EHR-S functions.
- Provide the necessary framework to drive the requirements and applications of next level standards, such as EHR content, coding, information models, constructs and interoperability for information portability between sub-systems of an EHR-S and across EHR-S'.
- Establish a standards-based method by which each realm (country) can apply these EHR functions to care settings, uses, and priorities.
- Inform those concerned with supporting subsequent use of data initially collected for the purpose of care (also known as "secondary use") on what functions can be expected in an EHR System.
- Inform those concerned with supporting realm-specific health information infrastructure on what functions can be expected in an EHR Systems.

Each function in the HL7 EHR-S Functional Model is identified and described using a set of elements or components as detailed below.

Table 2 — Function List Example

ID	Type	Name	Statement	Description	Conformance Criteria
CP.1	H	Manage Clinical History	Manage the patient's clinical history lists used to present summary or detailed information on patient health history.	Patient Clinical History lists are used to present succinct "snapshots" of critical health information including patient history; allergy intolerance and adverse reactions; medications; problems; strengths; immunizations; medical equipment/devices; and patient and family preferences.	
CP.1.4	F	Manage Problem List	Create and maintain patient- specific problem lists.	A problem list may include, but is not limited to chronic conditions, diagnoses, or symptoms, injury/poisoning (both intentional and unintentional), adverse effects of medical care (e.g. drugs, surgical), functional limitations, visit or stay-specific conditions, diagnoses, or symptoms…	
CP.1.4	C				1. The system SHALL provide the ability to manage, as discrete data, all active problems associated with a patient.
CP.1.4	C				2. The system SHALL capture and render a history of all problems associated with a patient.
CP.1.4	C				3. The system SHALL provide the ability to manage relevant dates including the onset date and resolution date of problem.

4.3.1 Function ID (Normative)

This is the unique identifier of a function in the Function List (e.g. CP.1.1) and should be used to uniquely identify the function when referencing functions. The Function ID also serves to identify the section within which the function exists (CP = Care Provision Section) and the hierarchy or relationship between functions (CP.1.1 is at the same level as CP.1.2, CP.1.1 is also a parent of CP.1.1.1 and child of CP.1; in many cases the parent is fully expressed by the children. For a detailed discussion and graphic of the parent and child relationship, see 6.6.1 Hierarchical Structure in Chapter 6, Conformance Clause.)

4.3.2 Function Type (Reference)

This is an indication of the line item as being a Header (H), Function (F) or Conformance Criteria (C). The Tag (T) is used to identify a new section in the spreadsheet and its related functions in the spreadsheet. A Tag has no directly associated Functions or Criteria.

4.3.3 Function Name (Normative)

This is the name of the Function and while expected to be unique within the Function List; it is not recommended to be used to identify the Function without being accompanied by the Function ID.

Example Manage Medication List.