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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

This document provides guidance on how four complementary international standards can be used in combination by developers of health ICT systems and infrastructures.

The goal of these four standards is to bring consistency and to maximize the smooth use of ICT by healthcare actors in the creation, representation, analysis and interoperable communication of health information, so that the use made of these main standards that represent health information is as best aligned as possible. It is therefore likely that implementers will elect to use more than one of the standards together and will benefit from guidance in how best to achieve this.

Three international standards have been published by ISO (two of which are parts of a five-part series), and one by HL7. The scope of each is summarized below. These standards environments are probably the most important to align in order to allow accelerated development and adoption of sophisticated clinical information systems and of better interoperability between them.

0.2 ISO 13940:2015

ISO 13940:2015 defines a comprehensive concept model that applies to all aspects of clinical and patient workflows, and it can therefore be considered the overarching domain model for the development of clinical information models. It specifies a concept model for continuity of care provided to any subject of care by any health system. It defines concepts representing the health status of a subject, the permissions and contractual relationships between healthcare provider organizations, plans of care and undertaken to deliver health and care. It defines the relations between these concepts, and some important areas of semantics for the values that can be provided for different properties.

0.3 ISO 13606-1:2019and ISO 13606-3:2019

The ISO 13606 series is a five-part standard series defining a high-level interoperability framework for the communication of electronic health record information. This includes a logical reference model, in ISO 13606-1, for the representation of health information within electronic health record (EHR) systems that can be communicated between heterogeneous EHR systems and with eHealth infrastructures. ISO 13606-2 formalizes the archetype concept, which is a dominant formalism for representing clinical information models. ISO 13606-3 includes an intersection of the two standards ISO 13606 and ISO 13940, by defining a set of clinical reference models as “reference archetypes” derived from ISO 13940, which are the clinical information models corresponding to the most frequently used clinical concept models that can be represented within persisted clinical information. This document makes particular use of ISO 13606-1 and ISO 13606-3. (Although not specifically included in this document, the Archetype Interchange Specification defined in ISO 13606-2 is also relevant.)

0.4 HL7 Fast Health Interoperability Resources (FHIR) Release 4

FHIR is an interoperability standard to facilitate the exchange of healthcare information between healthcare providers, patients, caregivers, payers, researchers and other actors in the healthcare ecosystem. HL7 FHIR defines generic and use case specific exchange models to communicate particular sets of health information for general support of the healthcare process. HL7 FHIR is an increasingly adopted interoperability interface specification for the communication of health information, including clinical information. It incorporates a profiling mechanism, termed FHIR Resources, that allow for the equivalent representation to clinical information models, as interface specifications suitable for specified business purposes. This document utilises FHIR Release 4, which was the most recent normative edition of this standard at the time of developing the guide. HL7 handles a wide range of healthcare exchange use cases, only some of which are relevant to the same scope as the other two standards, dealing with EHR data. This subset was used when developing this document.

0.5 The content of this document

This document focuses on three use cases for the combined use of the standards:

— the representation of continuity of care concepts conforming to ISO 13940:2015 within FHIR, and vice versa;

— the representation of EHR extracts conforming to ISO 13606-1:2019 within FHIR, and vice versa;

— the correspondence between reference archetypes conforming to ISO 13606-3:2019 and FHIR resources.

Clause 4 summarizes the mapping from ISO 13490:2015 to HL7 FHIR, including the mapping method, findings and mapping issues that adopters can be mindful of, where the representation capability of the standards differs. Clause 5 presents the detailed mapping tables to use whenever developers of information systems that manage continuity of care, including EHR systems and healthcare provider information systems, need to generate HL7 FHIR messages to communicate certain aspects of continuity of care that are represented in the source system using ISO 13940, to another system. The mapping tables include mapping notes to indicate if the target representation covers a broader, or narrower, scope than the source representation, or to indicate that no corresponding representation exists in the target and that some of the information will not be capable of being communicated or imported. Other guidance notes are sometimes included in the tables. Clause 6 summarizes the mapping from HL7 FHIR to ISO 13490, similarly to Clause 4. Clause 7 presents the detailed mapping tables and mapping notes in that direction, to be used when developers of information systems dealing with managing the continuity of care to individuals need to ingest information from HL7 FHIR messages in order to determine the aspects of continuity of care that are included with each message.

Clause 8 summarizes the mapping in both directions between the reference model of ISO 13606-1:2019 and HL7 FHIR. Clause 9 presents the detailed mapping tables from ISO 13606-1:2019 to HL7 FHIR, using the same table structure as Clauses 5 and 7. These mapping tables can enable the developer of an EHR system to communicate parts of the health information about one or more subjects of care in a way that conforms to ISO 13606-1:2019 and manifests as HL7 FHIR messages. Clause 9 presents the detailed mapping tables from HL7 FHIR to ISO 13606-1, to enable EHR information to be imported from clinical HL7 FHIR messages and represented using the ISO 13606 standard series, to then be persisted or processed by the EHR system or other receiving system in its usual way. As with the previous clause, the mapping tables indicate through comments the level of precision of the mapping and if there are areas of information content that the other standard cannot represent. Clause 9 also includes mapping tables for relevant term lists from ISO 13606-3.

Clause 10 provides guidance that explains how the reference archetypes defined in ISO 13606-3 correspond with HL7 FHIR resources, and the potential benefit of using the reference archetypes (many of which are information patterns for the continuity of care concepts that are defined in ISO 13940:2015) as the basis for defining FHIR resources and profiles. Clause 10 documents how to create FHIR resources that represent the clinical information structures within the Reference Archetypes in ISO 13606-3 that correspond to ISO 13940:2015 concepts. This is a relatively complex process, and Clause 10 provides methodological guidance on how reference archetypes can be transformed into FHIR resources, with an example FHIR profile for Health Condition is given. Clause 11 provides detailed tables guiding the representation of several example Reference Archetypes as FHIR resources.

Many of the tables in the above-mentioned clauses contain extracts of text quoted from the source standards. These have been reproduced in order to make these tables meaningful to read, and to avoid the need to frequently cross-check each row of a table with two or more source documents. Hyperlinks are provided in some rows of the tables to specific information properties of HL7 FHIR, since this document is published as an online resource. These links are being maintained permanently by HL7 and point specifically to the relevant parts of the normative version of FHIR that has been used when creating this document.

An additional standards mapping relating to archetypes and FHIR is provided in Annex A, which adds a description of the correspondence of these standards to ISO 13972. ISO 13972 is scoped on clinical information models in general, of which archetypes and some FHIR resources are examples.

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1 Scope

This document provides guidance on how four complementary international standards can be used in combination by developers of health ICT systems and infrastructures. These standards, three published by CEN and ISO and one by HL7, are

— ISO 13940:2015,

— ISO 13606-1:2019,

— ISO 13606-3:2019, and

— HL7 Fast Health Interoperability Resources (FHIR) Release 4.

This document defines mappings between these standards: between ISO 13940 and HL7 FHIR in both directions, between ISO 13606 and HL7 FHIR in both directions, it proposes the content of an HL7 FHIR profile corresponding to the ISO 13606-1:2019 "COMPOSITION" class. It also provides guidance and worked examples of the mapping between ISO 13606-3 Reference Archetypes corresponding to ISO 13940 and HL7 FHIR.

This document also summarizes the extent to which the source concept is broader than or narrower than the best fit target concept. It also highlights mapping issues that adopters will need to be mindful of, where the representation capability of the standards differs.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13940:2015, *Health informatics — System of concepts to support continuity of care*

ISO 13606-1:2019, *Health informatics — Electronic health record communication — Part 1: Reference model*

ISO 13606-3:2019, *Health informatics — Electronic health record communication — Part 3: Reference archetypes and term lists*

HL7 FHIR, *Glossary*[1)]

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13940:2015, ISO 13606-1:2019, ISO 13606-3:2019 and in the HL7 FHIR Glossary apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

1) http://hl7.org/fhir/help.html

— IEC Electropedia: available at https://www.electropedia.org/

4 Summary of the ISO 13940:2015 to FHIR R4 map

4.1 Goals

This mapping exercise has three main goals:

— to map ISO 13940:2015 concepts to FHIR R4 resource or attribute;

— to identify ISO 13940:2015 concepts that do not have a matching FHIR R4 resource, and vice versa.

4.2 Approach

The approach taken for this mapping exercise is as follows:

— The versions used for mapping are ISO 13940:2015 and FHIR R4.

— Each ISO 13940:2015 concept is mapped to an FHIR resource or attribute.

— When an ISO 13940:2015 concept does not have an exact match to an FHIR R4 based on their descriptions, a brief description of the mapping issue is provided.

4.3 Findings

The key findings from this mapping exercise include:

— Several ISO 13940:2015 resources are identified as not supported in FHIR. Many of these are ISO 13940:2015 concepts that are deemed not expected to be instantiated in FHIR (e.g. Healthcare actor, Healthcare provider), a few are beyond the scope of FHIR (e.g. Health record, Professional health record), while others might in the future be supported in FHIR (e.g. Subject of care proxy, Healthcare activity delay).

— Several FHIR resources with corresponding map to ISO 13940:2015 concepts are identified as having gaps including needing an FHIR resource with narrower scope (e.g. List) to support an ISO 13490:2015 concept (e.g. Health problem list), or an FHIR resource with a broader scope (e.g. RiskAssessment, ClinicalImpression) to support an ISO 13940:2015 concept (e.g. Healthcare assessment).

4.4 Mapping issues

A number of mapping issues are identified and indicated in the right-hand column of each of the tables in Clause 5. These reflect differences in the representation capability of the mapped standards and can therefore prove to be limitations in the ability for adopters of these standards to map certain data content between them. These issues can be resolved in future versions of the standards, and adopters therefore can be mindful that these issues can change in the future.

5 Mapping of concepts from 13940:2015 to FHIR R4

5.1 Mapping of concepts related to healthcare actors

Table 1 maps concepts related to healthcare actors.

Table 1 — Mapping of concepts related to healthcare actors

Concept name and corresponding subclause in ISO 13940:2015	ISO 13940:2015 concept quoted description	FHIR resource or attribute name	FHIR resource or attribute quoted description	Mapping issues
5.2 Healthcare actor	Organization or person participating in healthcare	Not supported	Not supported	Not supported, and not expected to be instantiated as an FHIR resource
5.2.1 Subject of care	Healthcare actor with a person role; who seeks to receive, is receiving, or has received Healthcare. EXAMPLES: A treated patient, a client of a physiotherapist, each particular member of a target population for screening, each particular member of a group of diabetic people attending a session of medical education, a person seeking health advice.	Patient N	Demographics and other administrative information about an individual or animal receiving care or other health-related services.	FHIR Patient includes animal whereas ISO 13940:2015 Subject of Care is limited to a person.
5.2.2 Next of kin	Person role being either the closest living relative of the subject of care or identified as the one he has a close relationship with	1. Patient.contact Where Patient.contact.relationship = N (Next-of-kin) 2. RelatedPerson 2 Where RelatedPerson.relationship = N (Next-of-kin)	1. A contact party (e.g. guardian, partner, friend) for the patient. 2. Information about a person that is involved in the care for a patient, but who is not the target of healthcare, nor has a formal responsibility in the care process.	None identified
5.2.3 Healthcare provider	Healthcare actor that is able to be assigned one or more care period mandates	Not supported. Note: FHIR (e.g. Practitioner 3) supports specialization of ISO Healthcare provider (e.g. Healthcare professional)	Not supported. Note: FHIR (e.g. Practitioner 3) supports specialization of ISO Healthcare provider (e.g. Healthcare professional)	None identified, and not expected to be instantiated as an FHIR resource
5.2.3.1 Healthcare organization	Healthcare provider having an organization role EXAMPLES: A care team, a group practice, a hospital, a hospital department, a hospital care unit, self-employed GP	1. CareTeam 2 2. Organization 3 Where Organization.type = ‘prov’ or ‘dept’, etc.	1. The Care Team includes all the people and organizations who plan to participate in the coordination and delivery of care for a patient. 2. A formally or informally recognized grouping of people or organizations formed for the purpose of achieving some form of collective action. Includes companies, institutions, corporations, departments, community groups, healthcare practice groups, payer/insurer, etc.	None identified

Table 1 *(continued)*

Concept name and corresponding subclause in ISO 13940:2015	ISO 13940:2015 concept quoted description	FHIR resource or attribute name	FHIR resource or attribute quoted description	Mapping issues
5.2.3.2 Healthcare employment	Contractual framework between a healthcare personnel and a healthcare organization describing the roles and responsibilities assigned to that healthcare personnel	PractionerRole	PractitionerRole covers the recording of the location and types of services that Practitioners are able to provide for an organization.	The ISO 13940:2015 concept name is currently specific to employment, whereas contractual relationship does not necessarily imply employment.
5.2.3.3 Healthcare personnel	Individual healthcare actor having a person role in a healthcare organization EXAMPLES: GP, medical consultant, therapist, dentist, nurse, social worker, radiographer, nurse's assistant, children's nurse, nursing officer, head of department, social worker, medical consultant, etc.	Practitioner 3 PractitionerRole 2	A person who is directly or indirectly involved in the provisioning of healthcare. EXAMPLES: physicians, dentists, pharmacists, physician assistants, nurses, scribes, midwives, dietitians, therapists, optometrists, paramedics, receptionists handling patient registration, IT personnel merging or unmerging patient records… A specific set of roles/locations/specialties/services that a practitioner may perform at an organization for a period of time.	While the ISO 13940:2015 Healthcare personnel supports roles such as receptionist, IT personnel, etc., the examples do not currently include non-healthcare professional such receptionist and IT personnel.
5.2.3.3.1 Healthcare professional	Healthcare personnel having a healthcare professional entitlement recognized in a given jurisdiction EXAMPLES: GP, medical consultant, therapist, dentist, nurse, radiographer, etc.	1. Practitioner 3 2. PractitionerRole 2 Note: Would also require an FHIR Practitioner to instantiate an ISO Healthcare personnel and Healthcare professional	1. A person who is directly or indirectly involved in the provisioning of healthcare. EXAMPLES: physicians, dentists, pharmacists, physician assistants, nurses, scribes, midwives, dietitians, therapists, optometrists, paramedics, receptionists handling patient registration, IT personnel merging or unmerging patient records… 2. A specific set of roles/locations/specialties/services that a practitioner may perform at an organization for a period of time.	None identified
5.2.3.3.2 Healthcare professional entitlement	Registered authorization given to a person in order to allow the person to have or perform specific roles in healthcare EXAMPLES: Diploma, professional registration (e.g. registered nurse).	Practitioner. qualification	The official certifications, training, and licenses that authorize or otherwise pertain to the provision of care by the practitioner. For example, a medical license issued by a medical board authorizing the practitioner to practice medicine within a certain locality.	None identified
5.2.4 Healthcare third party	Healthcare actor other than a healthcare provider or the subject of care	Not supported. Note: FHIR supports examples of ISO Healthcare third party (e.g. Organization 3, RelatedPerson 2)	Not supported. Note: FHIR supports examples of ISO Healthcare third party (e.g. Organization 3, RelatedPerson 2)	None identified

Table 1 *(continued)*

Concept name and corresponding subclause in ISO 13940:2015	ISO 13940:2015 concept quoted description	FHIR resource or attribute name	FHIR resource or attribute quoted description	Mapping issues
5.2.4.1 Other carer	Healthcare third party having person role EXAMPLES: A relative (family member), a neighbour.	RelatedPerson 2 Where RelatedPerson.relationship <> N (Next-of-kin)	Information about a person that is involved in the care for a patient, but who is not the target of healthcare, nor has a formal responsibility in the care process. EXAMPLES: A patient's wife or husband, a patient's relatives or friends, a neighbor bringing a patient to the hospital, the owner or trainer of a horse, a patient's attorney or guardian, a guide dog	None identified
5.2.4.2 Healthcare supporting organization	Healthcare third party having organizational role EXAMPLES: Voluntary aid organization, a homecare service organization, a health insurance fund, the operator of a telemedicine system, family.	Organization 3 Note: Organization.type must be valued with appropriate code to indicate healthcare supporting organization	A formally or informally recognized grouping of people or organizations formed for the purpose of achieving some form of collective action. EXAMPLES: Companies, institutions, corporations, departments, community groups, healthcare practice groups, payer/insurer, etc.	None identified
5.2.4.3 Subject of care proxy	Healthcare third party having person role with the right to take decisions on behalf of the subject of care	Not supported	Not supported	FHIR does not currently support a RelatedPerson.relationship of type subject of care proxy or legitimate representative (other terms are substitute decision maker). It is currently valid to have ONESELF as a RelatedPerson relationship.

5.2 Mapping of concepts related to healthcare matters

Table 2 maps concepts related to healthcare matters.