TECHNICAL SPECIFICATION

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Health informatics — Document registry framework

Informatique de santé — Cadre d'enregistrement de document

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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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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/TS 27790 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

Development and implementation of electronic health records (EHR) are rapidly progressing around the world. An appropriate deployment of EHR will enhance various aspects of healthcare delivery in the future. EHR are thought to enable the provision of essential care information to providers at point-of-care through information and telecommunications technologies. This includes a broad spectrum of capabilities including acquisition, storage, presentation, and management of patient information (represented in different digital forms such as video, audio or data) and communication of this information between care facilities with the use of communications links.

Recent development of health information exchange where the patients' EHR are accessed securely whenever necessary (sharing EHR information at point-of-care and by the consumer citizen) requires that electronic health records of an individual, although they originate from various health-related subjects distributed over space and time, remain accessible irrespective of their centralized or distributed storage. The use of centralized registry systems pointing to such records can greatly facilitate the discovery of their locations to allow effective access to the appropriate and secured EHR.

This Technical Specification describes the principles and specification of interoperability needed to support a registry system for locating and accessing records grouped into documents. The supported documents may contain any type of person-centric health information, structured or not, depending on the standard used for their content. The clinical document architecture (CDA) is one such standard that is a likely companion to this Technical Specification. This Technical Specification does not address the security and privacy considerations in detail but refers to related work in this critical area. The specification is not intended to be prescriptive either from a methodological or a technological perspective but rather to provide a coherent inclusive description of principles and practices that could facilitate the formulation of policies and governance practices locally or nationally.

Health informatics — Document registry framework

1 Scope

This Technical Specification specifies a general-purpose document registry framework for transmitting, storing and utilizing documents in clinical and personalized health environments. It is quite broad in its applicability to realise the goal of sharing health-related documents spanning a broad spectrum of health domains such as healthcare specialities covering laboratory, cardiology, eye care, etc. and the many areas of personalized health.

This web services-based registry framework includes a document registry and associated repository to allow the sharing of any form of health documents including HL7 CDA (clinical document architecture). It specializes in health, W3C Web Services Standards, ISO 15000 (ebXML registry standards) and OASIS ebXML Registry Information Model 3.0 through the use of the IHE Cross-Enterprise Document Sharing (XDS) from the Integrating the Healthcare Enterprise (IHE) Information Technology Infrastructure (ITI) technical framework, quoting from the Cross-Enterprise Document Sharing (XDS) Profile:

“The Cross-Enterprise Document Sharing IHE Integration Profile facilitates the registration, distribution and access across health enterprises of patient and citizen electronic health records. Cross-Enterprise Document Sharing (XDS) is focused on providing a standards-based specification for managing the sharing of documents between all health enterprises, ranging from private physician offices to clinics to acute care in-patient facilities to personal heath record systems. The XDS IHE Integration Profile assumes that these enterprises belong to one or more affinity domains. An affinity domain is a group of healthcare enterprises that have agreed to work together using a common set of policies and that share a common registry infrastructure.”

This Technical Specification also supports document registration and retrieval via the federation of documents’ registries (see IHE Cross-Community Access) in terms of individual users to reduce health information extrusion possibilities.

This Technical Specification supports the sharing of documents of any standardized content in the context of healthcare and well-being. It describes the means of locating and accessing documents among a diverse set of health organizations. It is designed for leverage of existing health informatics for structuring and semantically rich health information, if so desired. It does not require the development of new health informatics standards.

This Technical Specification also references a number of companion standards-based specifications that offer optional extensions to enhance the basic capabilities offered by IHE XDS, as listed below.

1) An XDS extension supporting the fragmentation of the content of the documents into two parts: a header fragment and a body fragment. This separation scheme enhances confidentiality because the gathering of both header and body and their relational information involves cracking into multiple repository servers. This has been developed as an IHE Korean Extension on the IHE XDS Profile.

NOTE 1 The incremental effectiveness achieved by header/body separation will have to be re-evaluated once the effectiveness of the security solutions to protect data at rest (e.g. encryption) has been finalized.

2) A series of security- and privacy-related IHE profiles, such as Patient Identification Cross-Referencing (PIX), Patient Demographics Query (PDQ), Basic Patient Privacy Consent (BPPC), and Cross-Enterprise User Assertion (XUA).

NOTE 2 The use of IHE Audit trail and Node Authentication (ATNA) as well as Consistent Time (CT) is required as part of IHE XDS. These Profiles are therefore not listed above.

2 Normative references

The following referenced documents are indispensable for the application 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.

OASIS Standards/ISO/TS 15000 (all parts), *Electronic business eXtensible Markup Language (ebXML)*

ebXML RIM V 3.0, OASIS ebXML Registry Information Model

ebXML RS V 3.0, OASIS ebXML Registry Service Specification

IHE IT Infrastructure Framework

IHE ITI-TF-1 IHE IT Infrastructure Technical Framework V5.0:

— Cross-enterprise Document Sharing (XDS.b) Integration profile

— Audit Trail and Node Authentication (ATNA) Integration profile

— Consistent Time (CT) Integration profile

Extensible Markup Language (XML) 1.0 W3C Recommendation, http://www.w3c.org/TR/REC-xml

SOAP Version 1.2 specification, http://www.w3.org/TR/soap12-part1/, March 2004

SOAP Message Transmission Optimization Mechanism http://www.w3.org/TR/soap12-mtom/

WSDL 1.1 Note http://www.w3.org/TR/wsdl

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. Only key terms and definitions are provided in this clause.

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
accountability
property that ensures that the actions of an entity may be traced uniquely to that entity

3.3
actor
user of the system-of-interest interacting with the system in a particular usage context (role)

3.4
agent
device that provides data in a manager/agent communicating system

3.5
architecture
that set of design artefacts or descriptive representations that are relevant for describing an object such that it can be produced to requirements (quality) as well as maintained over the period of its useful life (change)

3.6
archival
relating to the storage of data over a prolonged period

3.7
attestation
process of certifying and recording legal responsibility for a particular unit of information

3.8
authentication
act of verifying the claimed identity of an entity

3.9
authorization
granting of rights, including the granting of access based on access rights

3.10
availability
〈in computer science〉 property of data or of resources being accessible and usable on demand by an authorized entity

3.11
class
description of a set of objects that share the same attributes, methods and associations

3.12
clinical process
steps that are involved in the delivery of healthcare services to a patient/consumer

3.13
clinician
healthcare professional who delivers healthcare services directly to a patient/consumer

3.14
confidentiality
property that information is not made available or disclosed to unauthorized individuals, entities or processes

3.15
consumer
person requiring, scheduled to receive, receiving or having received a healthcare service

3.16
controller
natural or legal person, public authority, agency or any other body that, alone or jointly with others, determines the purposes and means of the processing of personal data

3.17
data aggregation
process by which information is collected, manipulated and expressed in summary form

NOTE Data aggregation is primarily performed for reporting purposes, policy development, health service management, research, statistical analysis and population health studies.

3.18
data format
arrangement of data in a file or stream

3.19
data integrity
property that data have not been altered or destroyed in an unauthorized manner

[ISO 7498-2:1989, definition 3.3.21]

3.20
data object
collection of data that have a natural grouping and may be identified as a complete entity

3.21
data structure
manner in which application entities construct the data set information resulting from the use of an information object

3.22
data subject's consent
any freely given specific and informed indication of his wishes by which the data subject signifies his agreement to personal data relating to him being processed

3.23
data validation
process used to determine if data are accurate, complete or meet specified criteria

3.24
Electronic health record
EHR
repository of information regarding the health status of a subject of care, in computer processable form

[ISO/TR 20514:2005, definition 2.11]

3.24.1 electronic longitudinal collection of personal health information, usually based on the individual, entered or accepted by healthcare providers, which can be distributed over a number of sites or aggregated at a particular source

NOTE The information is organized primarily to support continuing, efficient and quality health care. The record is under the control of the consumer and is stored and transmitted securely [NEHRT:2000].

3.24.2 longitudinal collection of personal health information of a single individual, entered or accepted by healthcare providers, and stored electronically

NOTE The record may be made available at any time to providers, who have been authorized by the individual, as a tool in the provision of health care services. The individual has access to the record and can request changes to its contents. The transmission and storage of the record is under strict security [OHIH:2001].

3.24.3 collection of data and information gathered or generated to record clinical care rendered to an individual

[ASTM E1769:1995]

3.24.4 comprehensive, structured set of clinical, demographic, environmental, social, and financial data and information in electronic form, documenting the health care given to a single individual

[ASTM E1769:1995]

3.24.5 healthcare record in computer-readable format

NOTE Definitions 3.21 to 3.26 of ISO 13606-1:2008 provide further information.

3.24.6 electronic patient record that resides in a system designed to support users through availability of complete and accurate data, practitioner reminders and alerts, clinical decision support systems, links to bodies of medical knowledge, and other aids

[IOM:1991]

3.24.7 virtual compilation of non-redundant health data about a person across a lifetime, including facts, observations, interpretations, plans, actions and outcomes

NOTE Health data include information on allergies, history of illness and injury, functional status, diagnostic studies, assessments, orders, consultation reports, treatment records, etc. Health data also include well-being data such as immunization history, behavioural data, environmental information, demographics, health insurance, administrative data for care delivery processes and legal data such as consents.

3.25
encounter
patient contact
contact between a clinician and patient

3.26
event
change in device status that is communicated by a notification reporting service

3.27
framework
logical structure for classifying and organizing complex information

3.28
generalization
taxonomic relationship between a more general element and a more specific element

3.29
healthcare professional
person who is authorized by a nationally recognized body to be qualified to perform certain health duties

3.30
host system
term used as an abstraction of a medical system to which measurement devices are attached

3.31
identifiable person
one who can be identified, directly or indirectly, in particular by reference to an identification number or one or more factors specific to his physical, physiological, mental, economic, cultural or social identity

3.32
information model
structured specification of the information requirements of a project

3.33
information object
provision of an abstract data model applicable to the communication of vital signs information and related patient data

NOTE The attributes of an information object definition describe its properties. Each information object definition does not represent a specific instance of real-world data, but rather a class of data that share the same properties.

3.34
inheritance
mechanism by which more specific elements incorporate structure and behaviour of more general elements

3.35
instance
realization of an abstract concept or specification

EXAMPLES Object instance, application instance, information service element instance, VMD instance, class instance, operating instance.

3.36
integrity
property of data whose accuracy and consistency are preserved regardless of changes made

3.37
interaction
combination of the specific elements that are needed to support the functional requirements defined within the use case model

3.38
interchange format
representation of the data elements and the structure of the message containing those data elements while in transfer between systems

NOTE The interchange format consists of a data set of construction elements and a syntax. The representation is technology-specific.

3.39
interoperability
ability of two or more systems or components to exchange information and to use the information that has been exchanged

[IEEE Standard Computer Dictionary]

3.40
latency
⟨communications⟩ time delay between the sending of a signal from one device and its reception by another device

3.41
manager
device that receives data in a manager/agent communicating system

3.42
medical device
device, apparatus or system used for patient monitoring, patient treatment or therapy, which does not normally enter metabolic pathways

NOTE For the purposes of this document, the scope of medical devices is further limited to those patient-connected medical devices which provide support for electronic communications.

3.43
message element
unit of structure within a message type

3.44
message type
organization of message elements that is specified in a hierarchical message definition

3.45
model
abstraction used to express the relevant concepts and interdependencies of a project