TECHNICAL REPORT

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Health informatics — IHE global standards adoption —

Part 3: Deployment

Informatique de santé — Adoption des normes globales IHE —

Partie 3: Déploiement

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Foreword

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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. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215, *Health Informatics*, WG 2, *Systems and Device Interoperability*.

ISO 28380 consists of the following parts, under the general title *Health Informatics – IHE Global Standards Adoption:*

— *Part 1: Process*

— *Part 2: Integration and Content Profiles*

— *Part 3: Deployment*

Part 1 and 2 have been approved by the TC 215 and have been published.

This technical report will complement and support the general requirements for the adoption of global standards towards increasing the efficiency of deploying interoperability in health.

Introduction

The purpose of this Technical Report is to structure and facilitate adoption and deployment of health interoperability standards in a broad range of eHealth projects, including regional and national programs.

A solid standards adoption process is a critical element that complements standards development and ensures that timely and effective implementation of standards is realized for health information exchange.

This technical report is intended to help and guide eHealth projects in the way to specify their use of interoperability standards in health information exchange by reusing IHE Profiles to support specific business use cases chosen by the project.

This technical report is the third part of a multi-part Technical Report on IHE Global Standards Adoption. It builds upon:

— TR 28380-1, *Health Informatics — IHE Global Standards Adoption — Part 1: Process*

— TR 28380-2, *Health Informatics — IHE Global Standards Adoption — Part 2: Integration and Content Profiles*.

This Technical Report uses the term Profile as defined by TR 28380. A Profile is intended to guide implementers in a detailed manner and to ensure that implementations may be tested for compliance. For each use case, a Profile selects from a number of interoperability standards specific to healthcare (ISO TC215, HL7, DICOM, CEN, etc.) as well as general IT standards from ISO, or Internet related standards bodies (e.g. W3C, IETF, OASIS).

Such Profiles are intended to guide implementers in a detailed manner and ensure that implementation may be tested for compliance and interoperability among implementations of like profiles achieved.

For each standard it profiles, i.e. defines a specific and proper subset of each selected standard; IHE leverages implementation guides produced by the source standard development organizations (SDO), if they exist, and specifies the integration of these standards. This coordinated process has been developed by Integrating the Healthcare Enterprise (IHE) and has been in effective use since 1998 to address a rapidly increasing number of healthcare interoperability problems for citizens as consumers of health services and for health professionals in the care of their patients.

Integrating the information systems and devices within healthcare institutions, across a variety of care settings, and personal health management services will empower patients and healthcare professionals with a more efficient access to accurate information. IHE has a formal Type-A Liaison relationship with ISO TC215. It is sponsored by a large number of healthcare user organizations world-wide and has engaged over 300 vendors in healthcare IT (www.ihe.net). 16 countries are directly engaged in IHE at the time of writing this Technical Report.

The information exchange among IT systems, applications and devices in healthcare is a complex challenge. In particular, it needs to account for the wide range of medical specialities, for the rapid evolution of knowledge and for the use of technology in the delivery services, among the broad range of stakeholders that need to cooperate ranging from democratic institutions, governmental entities, insurers and employers, to care providers organized in a variety of entities of all sizes (single doctors' practice to large hospital networks).

Interoperability standards have proven quite complex to develop and are driven by a wide range of standard development organizations (SDO) each effective at engaging a subset of these many stakeholders. In such a complex environment, standards have to incorporate much flexibility and optionality to account for a variety of environments in which they could be used. Removing the need for flexibility and optionality in these standards would only result in further fragmentation. An agreed upon process to rationalize and constrain the implementation of combined sets of these standards is required in order to address some of the most common cases of information exchange in a definite manner that can be tested.

This Technical Report is based on the valuable work done by the IHE initiatives in which several of the ISO/TC 215 member countries are engaged. This Technical Report is intended to provide all ISO members with an understanding of the practical experience gained as well as access to the results achieved.

IHE is both a process and a forum that rationalizes at a multi-national level the adoption of interoperability standards that can be profiled and combined to meet healthcare needs. IHE draws on established healthcare specific standards such as those developed by ISO/TC 215 and HL7, as well as general purpose IT standards, in order to define a technical framework for the implementation of information exchange to address specific health improvement or clinical goals. It includes a rigorous interoperability testing process for the implementation of this technical framework.

IHE also organizes educational sessions and exhibits at major meetings of health professionals to demonstrate the benefits of this framework and encourage its adoption by the healthcare industry, the technology industry, and other stakeholders worldwide. These elements are further discussed in Part 1 of this technical report.

The intended audience of this ISO Technical Report is:

— IT departments of healthcare institutions;

— Technical and marketing staff in the healthcare technology industry;

— Experts involved in standards development;

— Health Professionals interested in integrating healthcare information systems and workflows;

— National and regional healthcare information exchange projects leadership.

Health informatics — IHE global standards adoption —

Part 3: Deployment

1 Scope

This part of this Technical Report describes the general methodology to analyse interoperability requirements in support of a use case to produce the selection and combination of the relevant Profiles specified in TR 28380-2. It is illustrated by applying this methodology to a small number of examples. It also identifies and proposes a high-level quantification of the benefits gained by the use of a profile based specification of interoperability. Finally this technical report will discuss the approach to effectively test interoperability from the specific of the standards and profiles, up to the level of business use cases.

ISO/TR 28380-1 is a companion to this part of this Technical Report. ISO/TR 28380-1 describes how the IHE process identifies technical use cases for interoperability and specifies profiles of selected standards to support these carefully defined healthcare tasks that depend on electronic information exchange. The reader is encouraged to be familiar with this process followed by IHE in developing its Profiles.

A wide portfolio of such profiles for Integration, Security, and Semantic Content is now available across various domains of healthcare clinical specialities and technologies, as described in ISO/TR 28380-2.

The reader of this part of this Technical Report is encouraged to be familiar with this process followed by IHE in developing its Profiles as it builds upon ISO/TR 28380-1 and ISO/TR 28380-2 by addressing a number of key issues to support eHealth projects across all sectors of health to more effectively deploy standards-based interoperability between software applications and devices, including within healthcare organizations and across healthcare and home settings.

2 Normative References

ISO/TR 28380-1, *Health informatics — IHE global standards adoption — Part 1: Process*

ISO/TR 28380-2, *Health informatics — IHE global standards adoption — Part 2: Integration and content profiles*

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the terms and definitions of ISO/TR 28380-1 and the following apply.

3.1
actors
actors are information systems or components of information systems that produce, transmit or act on health information exchanged to support operational activities

3.2
eHealth
refers to the combined use of electronic communication and information technology in the health sector to enable better health and healthcare

[SOURCE: WHO]

3.3.1
electronic health record
EHR
information relevant to the wellness, health and healthcare of an individual, in computer-processable form and represented according to a standardized information model

[SOURCE: ISO 18308:2011, 3.20]

3.3.2
electronic health record
EHR
longitudinal electronic record of an individual that contains or virtually interlinks to data in multiple EMRs and EPRs, which is to be shared and/or interoperable across healthcare settings and is patient-centric

Note 1 to entry: Adapted from the European 2011 eHealth Strategies Final Report, January 2011.

3.4
health
state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

[SOURCE: WHO 1948]

3.5
health information
information about a person relevant to his or her health

[SOURCE: ISO 18308:2011, 3.28]

3.6
healthcare
activities, services, or supplies related to the health of an individual

[SOURCE: EN 13940-1:2007]

3.7
healthcare activity
activity performed for a subject of care with the intention of directly or indirectly improving or maintaining the health of that subject of care

[SOURCE: EN 13940-1:2007]

3.8
healthcare professional
person authorized to be involved in the direct provision of certain healthcare provider activities in a jurisdiction according to a mechanism recognized in that jurisdiction

Note 1 to entry: Adapted from EN 13940–1:2007.

3.9
healthcare provider
healthcare organization or healthcare professional involved in the direct provision of healthcare

[SOURCE: EN 13940-1:2007]

3.10
patient
individual who is a subject of care

[SOURCE: ISO/TR 20514:2005, 2.30]

3.11
policy
set of rules such as legal, political or organizational which can be expressed as obligations, permissions or prohibitions

Note 1 to entry: Adapted from ISO/TS 22600-1:2006, 2.13.

3.12
privacy
freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of data about that individual

[SOURCE: ISO/IEC 2382-8:1998, 08.01.23]

3.13
registry
server capable of holding data for the systematic and continuous follow-up of information objects maintained in accordance with specific rules

[SOURCE: ISO/TR 21089:2004]

3.14
semantic interoperability
ability for data shared by systems to be understood at the level of fully defined domain concepts

[SOURCE: ISO 18308:2011, 3.45]

3.15
syntactic interoperability
capability of two or more systems to communicate and exchange data through specified data formats and communication protocols

[SOURCE: ISO 18308:2011, 3.48]

3.16
use case
methodology used in system analysis to identify, clarify, and organize system requirements

Note 1 to entry: The use case is made up of a set of possible sequences of interactions between systems and users in a particular environment and related to a particular goal. In the context of this Technical Report, a use case provides a depiction of the actors and services that addresses information exchange in the context of a set of specific tasks performed by different systems or devices

3.17
vocabulary
terminological dictionary which contains designations and definitions from one or more specific subject fields

[SOURCE: ISO 1087-1:2000]

4 Abbreviations

ATNA	Audit Trail and Node Authentication
BPPC	Basic Patient Privacy Consent
CEN	European Standardization Committee
CDA	Clinical Document Architecture
DICOM	Digital Imaging and Communications in Medicine
EHR	Electronic Health Record
HL7	Health Level Seven
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standards Development Organization
ISO	International Organization for Standardization
ISO/TC 215	ISO Technical Committee 215 (Health Informatics)
IT	Information Technology
LOINC	Logical Observation Identifiers Names and Codes
MoH	Ministry of Health
OASIS	Advancing Open Standards for the Information Society
PDQ	Patient Demographics Query
PHR	Personal Health Record
SDO	Standards Development Organization
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
W3C	World-Wide Web Consortium
XCA	Cross-Community Access
XDS	Cross-enterprise Document Sharing
XUA	Cross-Enterprise User Assertion

5 General approach to analyse the interoperability requirements in support of an interoperability use case

5.1 Concept of an Interoperability Use Case

A Use Case is a concept that is widely used but often called with different terms (requirement, business scenario, etc.). In this Technical Report, we focus the use case content on interoperability defined as: “A depiction of the actors and services that address information exchange in the context of a set of specific tasks performed by different systems or devices in support of its users”.

Use Cases can be defined at various levels. An Interoperability Use Case is at a level that Part 1 of this report describes as:

"This encompasses health system objectives such as "chronic disease management" or "sharing patient summaries with a medication history." There are many ways of identifying and structuring use cases at the business level, which contributes to the challenge of accepting a certain fuzziness and flexibility. Interoperability level use cases are most successful, when they select a small – and therefore achievable and implementable scope, thus providing value while remaining achievable. This is what a number of regional and national projects around the world are often using to shape their objectives in the area of interoperability. However, as the number of use cases providing incremental interoperability requirements increases, it becomes apparent that they overlap, each potentially reusing a subset of another Interoperability Use Case (e.g. in our example above "sharing patient summaries and "patient empowerment with a medication history" have likely some overlap). This needs to be recognized, and factoring will happen at the lower levels of requirements."

An Interoperability Use Case can be summarized in one sentence and described in a few pages of text that any stakeholder in health, including non IT professionals would understand along with the necessary underlying exchange of health information.

An Interoperability Use Case is described by a flow of health information between Actors, where Actors are a representation of health information systems supporting users such as healthcare professionals in specific roles as well as the patients, but also extend to include the organizations they support and benefit from the real world information interchange defined by an Interoperability Use Case.

Examples of Interoperability Use cases:

— Patient summaries for regional/national information sharing;

— Prescriptions for regional/national information sharing;

— Request and results distribution for radiology enterprise workflow (e.g. within a hospital);

— Flow of device measurements from mobile and/or home-based monitoring devices to care management services.

These examples of Interoperability Use case cover a diverse range of information exchange environments: cross-border, national/regional, intra-hospital; and citizens on the move or at home. They come from the European eHealth Interoperability Framework (http://ec.europa.eu/digital-agenda/en/news/ehealth-interoperability-framework-study) and the eHealth Interoperability Standards Mandate (www.ehealth-interop.eu).

5.2 Decomposition of an Interoperability Use Case into Technical Use Cases

A set of Technical Use Cases may be derived from an Interoperability Use Case by taking the requirements at a service/content/semantic level, where the flows of health information are more specific and described between specific software entities, or Technical Actors that support the Actors engaged into the Interoperability Use Case. This results in a decomposition of an Interoperability Use Case into Technical Use Cases of different types, such as:

a) Specific flows of health information between Technical Actors abstracting the part of software applications, which are engaged in one or more specific transactions or services to support a specific aspect of a real world health information interchange.

b) Specific health information content and semantics associated with each flow between the Technical Actors identified in 1) above.

c) Specific security and privacy requirements attached to the above specific flows identified in 1) above.

The isolation of these Technical Use Cases is important because it modularizes the specification process around Profiles, or a reusable communication service which is defined in Part 1 of this technical report as:

"A communication service defining a number of related means and constraints to exchange specific types of health information for the purpose of communicating this information from one or more systems to