TECHNICAL REPORT

ISO/TR 12773-1

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Business requirements for health summary records —

Part 1: Requirements

Exigences d'affaire pour les enregistrements de santé sommaires —

Partie 1: Exigences

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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.

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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 exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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/TR 12773-1 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

ISO/TR 12773 consists of the following parts, under the general title *Business requirements for health summary records*:

— *Part 1: Requirements*

— *Part 2: Environmental Scan*

Introduction

Consumer, clinician, industry and government demands for improved safety, quality, effectiveness and efficiency in healthcare are driving the need for more “connected” care, which in turn requires improved communication of clinical information between multiple providers and subjects of care. Internationally, various “summary” or “snapshot” health records have been developed to meet these communication needs. Many similarities are evident in these initiatives, but their conceptual foundations have not always been articulated with a set of business requirements as their starting point.

The purpose of ISO/TR 12773 is to identify the common business requirements these initiatives are seeking to address as well as the requirements for standards for health summary records (HSRs) that can guide future HSR development efforts.

Any future ISO initiative to create standards for a generic HSR specification or specifications for one or more types of HSR will leverage existing initiatives and adopt/adapt relevant standards utilized therein. Such HSR specifications are unlikely to require new standards, given that much of their content is deemed “common”, “core”, “essential” or “emergency” in nature and is therefore part of most EHR initiatives world-wide as evidenced in ISO/TR 12773-2.

Business requirements for health summary records —

Part 1: Requirements

1 Scope

This part of ISO/TR 12773 is based on a comprehensive review of a series of initiatives and implementations worldwide that for the purposes of this Technical Report are collectively called health summary records (HSRs). Project sponsors and/or authorities were contacted as needed to gather additional information and clarify questions or issues arising out of the review.

This part of ISO/TR 12773 defines and describes HSRs in general as well as specific instances of HSRs and their most common use cases. It summarises the business requirements driving HSR development and the content that is common across HSRs, as well as issues associated with them. Finally, it recommends some future ISO/TC 215 activities to support international standardization of HSRs.

It is important to note that this part of ISO/TR 12773 focuses primarily on requirements that are specific (unique) to HSRs. It does not attempt to articulate, other than at a high level, requirements that are generally applicable to all health records or all electronic health records.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
agent
see **healthcare agent** (2.19)

2.2
client
patient
individual who is a subject of care

[ISO/TR 20514:2005, definition 2.30]

NOTE The terms “client” and “patient” are synonymous but the usage of one or the other of these terms tends to differ between different groups of health professionals. Clinicians working in a hospital setting and medical practitioners in most clinical settings will use the term “patient” whereas allied health professionals may use the term “client”.

2.3
clinical data repository
CDR
data store that holds and manages clinical data collected from service encounters at point of service locations (e.g. hospitals, clinics)

[ISO/TR 20514:2005, definition 2.5]

NOTE Data from a CDR can be sent to the EHR for that subject of care; in that sense the CDR is recognised as a source system for a shared EHR or an integrated care EHR.

2.4
clinical data warehouse
CDW
grouping of data accessible by a single data management system, possibly of diverse sources, pertaining to a health system or sub-system and enabling secondary data analysis for questions relevant to understanding the functioning of that health system, and hence supporting proper maintenance and improvement of that health system

[ISO/TR 22221:2006, definition 2.2]

NOTE A CDW tends not to be used in real time; however, depending on the rapidity of transfer of data to the data warehouse, and data integrity, near real time applications are not excluded.

2.5
clinical information
information about a person, relevant to his or her health or healthcare

[ISO 13606-1:2008, definition 3.13]

2.6
clinician
health professional who delivers health services directly to a patient/client

[ISO/TR 20514:2005, definition 2.6]

2.7
consumer
individual who may become a subject of care

[ISO/TR 20514:2005, definition 2.9]

2.8
data object
collection of data which has a natural grouping and may be identified as a complete entity

2.9
electronic health record
EHR
⟨basic generic form⟩ repository of information regarding the health status of a subject of care, in computer processable form

[ISO/TR 20514:2005, definition 2.11]

2.10
electronic health record composition
EHR composition
the set of information committed to one EHR by one agent, as a result of a single clinical encounter or record documentation

EXAMPLES Progress note, radiology report, referral letter, clinic visit record, discharge summary, functional health assessment, diabetes review.

2.11
electronic health record extract
EHR extract
a) unit of communication of the EHR which is itself attestable and which consists of one or more EHR compositions

[ISO/TR 20514:2005, definition 2.13]

b) part or all of the electronic health record of a subject of care communicated between an EHR provider system and an EHR recipient

NOTE Adapted from ISO 13606-1:2008.

2.12
electronic health record (EHR) — integrated care (ICEHR)
repository of information regarding the health status of a subject of care, in computer processable form, stored and transmitted securely, and accessible by multiple authorized users and having a standardized or commonly agreed logical information model that is independent of EHR systems and whose primary purpose is the support of continuing, efficient and quality integrated healthcare and which contains information that is retrospective, concurrent, and prospective

NOTE 1 Adapted from ISO/TR 20514:2005.

NOTE 2 The definition of the EHR for integrated care should be considered the primary definition of an electronic health record. The definition of a basic-generic EHR is given only for completeness.

2.13
electronic health record repository
database in which electronic health record information is persisted

2.14
electronic health record — shareable
EHR — shareable
electronic health record with a standardized information model, which is independent of electronic health record systems and accessible by multiple authorized users

NOTE 1 The shareable EHR *per se* is an artefact between a basic-generic EHR and the integrated care EHR (ICEHR) which is a specialization of the shareable EHR. The shareable EHR is probably of little use without the additional clinical characteristics that are necessary for its effective use in an integrated care setting.

NOTE 2 Whilst the ICEHR is the target for interoperability of patient health information and optimal patient care, it should be noted that the large majority of EHRs in use at present are not even shareable let alone have the additional characteristics required to comply with the definition of an Integrated care EHR. A definition of a basic-generic EHR has therefore been included to acknowledge this current reality.

2.15
electronic health record system
EHR system
system for recording, retrieving, and manipulating information in electronic health records

[ISO 13606-1:2008, definition 3.26]

2.16
health
state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

[WHO:1948]

2.17
healthcare
activities, services, or supplies related to the health of an individual

[ISO 18308:—, definition 3.28]

2.18
healthcare activity
undertakings (assessments, interventions) that comprise a healthcare service

2.19
healthcare agent
person, device or software that performs a role in a healthcare activity

[ISO 13606-1:2008, definition 3.31]

2.20
healthcare organization
organization involved in the direct or indirect provision of healthcare services to an individual or to a population

[ISO 13606-1:2008, definition 3.33]

2.21
healthcare service
service provided with the intention of directly or indirectly improving the health of the person or populations to whom it is provided

[ISO 13606-1:2008, definition 3.35]

2.22
health condition
a) aspect of a person or group's health that requires some form of intervention

[Canada Health Infoway EHRS Blueprint v1.0: 2003]

NOTE These interventions could be anticipatory or prospective, such as enhancing wellness, wellness promotion or illness prevention (e.g. immunization).

b) symptoms, health problems (not yet diagnosed), diagnoses (known or provisional), e.g. diabetes, or physiological changes that affect the body as a whole or one or more of its parts, e.g. benign positional vertigo, and/or affect the person's well-being, e.g. psychosis, and/or affect the person's usual physiological state, e.g. pregnancy, lactation

[Canada Health Infoway, iEHR Clinical Standards Glossary 2007]

2.23
health information
see **clinical information** (2.5)

2.24
health problem
see **health condition** (2.22); see **problem** (2.39)

2.25
health professional
person who is authorized by a recognised body to directly provide certain healthcare services

NOTE Adapted from ISO/TR 20514:2005 and EN 13940-1:2007.

2.26
health record
repository of information regarding the health of a subject of care

[ISO/TR 20514:2005, definition 2.25]

2.27
health record extract
attestable unit of communication of all or part of a health record.

2.28
health summary record
health record extract comprising a standardized collection of clinical and contextual information (retrospective, concurrent, prospective) that provides a snapshot in time of a subject of care's health information and healthcare

2.29
HL7 Clinical Document Architecture
CDA
documentation that defines structure and semantics of medical documents for the purpose of exchange

NOTE CDA documents are encoded in Extensible Mark-up Language (XML). They derive their meaning from the HL7 Reference Information Model (RIM) and use the HL7 Version 3 Data Types, which are part of the HL7 RIM.

[HL7 International- HL7 CDA Release 2.0]

2.30
integrated care electronic health record (EHR) (ICEHR)
see **electronic health record (EHR) — integrated care (ICEHR)** (2.12)

2.31
metadata
a) information stored in a data dictionary that describes the content of a document

[ISO/TR 22221:2006, definition 2.10]

NOTE Metadata can include data structure, constraints, types, formats, authorizations, privileges, relationships, distinct values, value frequencies, keywords and users of the database sources loaded in the EHR repository and the EHR repository itself. Metadata facilitates information management for users, developers and administrators.

b) data that define object class and property for the information collected

[ISO 13606-1:2008, definition 3.37]

2.32
organization
unique framework of authority within which a person or persons act, or are designated to act towards some purpose

[ISO/IEC 6523-1:1998, definition 3.1]

2.33
persistent data
a) data which are stored on a permanent basis

[ISO 13606-1:2008, definition 3.40]

b) data in a final form intended as a permanent record, such that any subsequent modification is recorded together with the original data

[ISO/TR 22221:2006, definition 2.14]

2.34
personal health record
PHR
electronic, universally available, lifelong resource of health information needed by individuals to make health decisions

NOTE Individuals own and manage the information in the PHR, which comes from healthcare providers and the individual. The PHR is maintained in a secure and private environment, with the individual determining rights of access. The PHR is separate from and does not replace the legal record of any provider.

[AHIMA E-HIM PHR Work Group 2005]

2.35
personal health record system
system for recording, retrieving, and manipulating information in personal health records

2.36
physician
health professional who has successfully completed the prescribed course of studies in medicine in a recognised medical school and who has met the qualifications for licensure in the practice of medicine set by the state or country in which they are practicing

2.37
practice electronic health record (EHR) system
EHR system that a clinician or group of clinicians uses to document the care provided to a subject of care in their healthcare organization

NOTE In primary and ambulatory care settings, the practice EHR is usually referred to as an electronic medical record (EMR). In acute care settings such as hospitals, it is commonly referred to as an electronic patient record (EPR). In community care settings including home care settings, it may be referred to as an electronic client record (ECR) or an EPR.

2.38
primary care
overall management of a subject of care's health problems, including direct delivery of care as well as coordinating care to specialists and other providers in a gatekeeper system, i.e. a system where the primary care provider acts on behalf of their patients to manage and prioritize access to required healthcare services

NOTE Adapted from Canada Health Infoway iEHR Clinical Standards Glossary 2007.

2.39
problem
entity for which an assessment is made and a plan or intervention is initiated

[NZ EMR:1998]

NOTE The term "issue" is often used rather than "problem" by many allied health professions, especially in the more social/psychological disciplines. The term "condition" is also sometimes used to describe pregnancy and other non-disease health states which nevertheless usually involve interaction with a health system.

2.40
provider
person or organization involved in or associated with the delivery of healthcare to a subject of care, or caring for the wellbeing of a subject of care

2.41
records
information created, received and maintained as evidence and information by an organization or person, in pursuance of legal obligations or in the transaction of business

[ISO 15489-1:2001, definition 3.15]