
**Business requirements for health
summary records —**

**Part 1:
Requirements**

*Exigences d'affaire pour les enregistrements de santé sommaires —
Partie 1: Exigences*

STANDARDSISO.COM : Click to view the full PDF of ISO/TR 12773-1:2009



PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

STANDARDSISO.COM : Click to view the full PDF of ISO/TR 12773-1:2009



COPYRIGHT PROTECTED DOCUMENT

© ISO 2009

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Terms and definitions.....	1
3 Examples of health summary records.....	8
4 Nature and definition of health summary records	10
4.1 General.....	10
4.2 Health record extracts.....	10
4.3 Standardized health record extracts.....	11
4.4 Integrated care EHRs (ICEHRs).....	12
4.5 Dynamic creation of a health summary record — List clinical summary/profile.....	13
4.6 Defining health summary records.....	13
5 Purposes of health summary records	14
6 Common use cases for health summary records	16
6.1 Overview	16
6.2 Use case 1: Creating a health summary record.....	17
6.3 Use case 2: Querying, viewing, replacing (superseding) the HSR.....	17
6.4 Use Case 3: Provider-to-provider referrals.....	18
6.5 Use case 4: Acute care discharge to home or other ambulatory care environment.....	19
6.6 Use case 5: Acute care discharge to a sub-acute care nursing facility (SNF).....	19
6.7 Use case 6: Initiate HSR transfer	20
6.8 Secondary use cases	20
7 Business requirements for health summary records	21
8 Data and information management requirements for health summary records.....	22
8.1 General requirements.....	22
8.2 Clinical content priorities for health summary records.....	22
8.3 Health summary record data development.....	24
9 Standardization of health summary records	25
10 Recommendations.....	25
Acronym Index.....	27
Bibliography	28

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 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.

STANDARDSISO.COM : Click to view the full PDF of ISO/TR 12773-1:2009

STANDARDSISO.COM : Click to view the full PDF of ISO/TR 12773-1:2009

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]

2.42**referral**

practice of a provider sending a subject of care to receive healthcare services or a clinical opinion from another provider when the sending provider is not qualified or prepared to offer such services or opinion

NOTE 1 Adapted from Canada Health Infoway iEHR Standards Glossary 2007.

NOTE 2 A referral letter is a clinical document that accompanies the referral request. It contains the reason for the referral and includes details of the subject's health condition(s) and other additional health information relevant to the referral, as well as a date and the authentication of the referring provider.

2.43**secondary data use**

use of data for additional purposes than the primary reason for their collection, adding value to this data

[ISO/TR 22221:2006, definition 2.16]

2.44**secondary use**

⟨of a healthcare record⟩ any legitimate use of a healthcare record other than for the purpose of supporting the direct delivery of healthcare services to the subject of care

EXAMPLES medico-legal, quality management, clinical research, epidemiology, population health, health administration, financial, educational or health service planning purposes

2.45**security**

combination of confidentiality, integrity and availability

2.46**service**

number of processes involving an organization in the provision of specific objectives

[ISO 12967-1:—, definition 3.4.7]

2.47**shareable EHR**

see **electronic health record — shareable** (2.14)

2.48**shared EHR**

see **electronic health record — shareable** (2.14)

2.49**specialist**

⟨physician⟩ whose practice is limited to a particular area of medicine in which the physician is usually certified by a recognized board or college of physicians

2.50**standard**

document, established by consensus and approved by a recognised body that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at achievement of the optimum degree of order in a given context

[ISO/IEC Guide 2:2004, definition 3.2]

2.51**subject of care**

one or more persons scheduled to receive, receiving, or having received healthcare

NOTE 1 Adapted from ISO 13606-1:2008.

NOTE 2 The terms “patient” and “client” are synonymous with subject of care in a health record context and are commonly used instead of the more formal term “subject of care”.

NOTE 3 The term “consumer” is also often used as a synonym in this context. However, it should be noted that a consumer may not necessarily be a subject of care since it can be argued that it is possible for a consumer to have a health record without ever having received a healthcare service.

3 Examples of health summary records

There are many initiatives in which “summary” or “snapshot” data are extracted or compiled from source systems and represented in standardized ways. Various definitions have been developed, often tied to specific business needs. Terms, definitions and contextual descriptions of initiatives identified through the environmental scan are briefly described in this clause, listed alphabetically, not by country.

For the purposes of this part of ISO/TR 12773, all such records are referred to as health summary records (HSRs). ISO/TR 12773-2, Clause 6 gives details of these initiatives.

— Care record summary: a summary of care document that contains a patient’s relevant health history for some time period. It is intended for communication between healthcare providers and often accompanies the transfer of care of a patient from one provider/organization to another.

HL7 CDA Care Record Summary, U.S. Realm Implementation Guides Level 1 & Level 2, 3rd Informative Ballot, Nov 2005^[10]

NOTE Internationally, a care record summary is the most common first area of application for the HL7 clinical document architecture (CDA).

— Continuity of care document (CCD): describes how to implement the continuity of care record dataset with the standard architecture for clinical records developed by HL7 — the clinical document architecture (CDA). The standard can be used to send electronic health information among providers without loss of meaning. Clinical information that can be exchanged includes patient demographic data, medication and allergy information.

ASTM and HL7 International^[5]

— Continuity of care record (CCR): a patient health summary standard that provides a snapshot in time of a core dataset of the most relevant and timely facts about a patient’s health information and healthcare (current and historical). The CCR is organized and transportable and prepared by a practitioner at the conclusion of a healthcare encounter to enable the next practitioner to readily access such information electronically or via a paper copy. Data can be sourced from many clinical documents, including a patient’s personal health record.

ASTM International E31 Committee on Health Informatics and E31.28 Sub-committee on EHR — CCR Workgroup^[4]

— Core dataset: a standardized dataset that can be used to enable the export and import of all administrative and clinical information needed to provide continuity of patient care when primary care physicians switch from one EMR vendor system to a different EMR vendor system.

OntarioMD Clinical Management System (EMR system) specification 2007^[17]

— Emergency care summary: provides a GP summary dataset for use by other clinicians in unscheduled care settings.

NHS UK – Scotland^[15]

- Electronic medical summary: a standardized core dataset of key health information that can be communicated electronically and is available at the point of care to provide a snapshot of relevant patient information. The intention is to support shareable care in the contexts of patient referrals, on-call care and emergency care.

Canada: British Columbia Ministry of Health electronic Medical Summary Project, 2005^[6]

- Health profile: a summary of essential demographic and clinical information, e.g. current and relevant past medical conditions, allergies and medications, which will inform healthcare providers and facilitate care. It should contain, at a minimum, some key types of data. Jurisdictions should have the ability to add more data types (extensions) to this basic structure.

Canada Health Infoway — EHRS Blueprint v1.0^[7]

- Individual health record: provides an extract of all coded data from GP systems except sensitive data such as sex changes or sexually transmitted infections, to support out-of-hours and emergency care.

NHS UK – Wales^[16]

- Limited clinical data object: data intended to aid the delivery of emergency care and include a limited emergency dataset, a blood grouping and transfusion record dataset and an immunizations received dataset. The data by themselves are neither intended, nor fit for purpose for the total information needed for the delivery of emergency care.

ISO 21549-3^[30]

- Medical Summaries: a class of clinical documents that contain the most relevant portions of information about the patient, intended for a specific provider or a broad range of potential providers in different care settings.

IHE XDS Medical Summary Integration Profile from the Trial Implementation Version of the Patient Care Coordination Technical Framework, Revision 1.0, balloted summer 2005^[11]

- Medical summary for transfer of patient data: a dataset that will include the necessary and sufficient patient information, in the absence of the entire medical record, that can be transferred from one physician office system to another to support informed medical care. The intention is to provide a medical summary to support the business needs of physicians in providing informed medical care that is independent of the technology used to perform the transfer.

Alberta Health Information Standards Committee of Alberta, Physician Office System Program Medical Summary for Transfer of Patient Data, Version 0, July 2005^[3]

- National discharge summary: encompasses standard specifications for the content and structure of a typical discharge summary, and can be used in a range of clinical settings (e.g. an emergency department visit or an admission encounter) where relevant clinical information might be captured, stored, exchanged or displayed.

National E-Health Transition Authority, Discharge Summary Content Specifications, Release Notes, 21 December 2006^[13]

- Personal health record (PHR) minimum common data elements: patient-supplied minimum common dataset that must be included in a PHR in order to ensure its interoperability among different care settings and different providers. Suggested categories include personal demographics, general medical information, allergies and drug sensitivities, conditions, hospitalizations, surgeries, medications, immunizations, clinical tests and pregnancy history.

AHIMA E-HIM PHR Work Group, 2005^[1]

- Summary care record: a record which holds essential elements of a person's electronic record, extracted from general practice notes and essential elements relating to that person from other organizations where they receive care.

NHS UK – England^[14]

Noteworthy about these terms and definitions is the focus on relevance and timeliness of the data, and communication of information between healthcare providers for purposes of shared care in various contexts (transfers, emergency, etc.). The definitions also speak to one or both business contexts for use — point-to-point provider communication and the shared EHR in support of continuity of care. Many of the definitions do not imply that the source or recipient of the data is a user with an EHR system, nor do they imply that the transmission of the health summary is electronic.

NOTE The terms 'patient' and 'subject of care' are used as synonyms in this part of ISO/TR 12773.

4 Nature and definition of health summary records

4.1 General

A record is defined under 2.41. See Reference [21].

A health record is defined under 2.26. See Reference [24].

Health summary records (HSRs) as articulated in this part of ISO/TR 12773 form a subset of health records. They comprise standardized extracts from an EHR system or from an EHR repository or multiple EHR repositories of information regarding the health of subjects of care. HSRs summarize (constitute a summary of, or abstract into one place) the most important pieces of health information relevant to the purposes at hand.

HSRs such as those identified in this clause typically contain information regarding a subject of care's key health history — current health conditions, ongoing health conditions, significant past medical/surgical history, medication, allergies and adverse reactions, alerts and special needs, etc. — as well as identifying demographic and contextual information. They may exist in either paper or electronic formats, and both free-text and structured data are typically included, although there is increasingly a preference for structured, computer processable content.

The primary use of HSRs is the communication of targeted clinical information between and amongst healthcare providers and providers and subjects of care in support of ongoing care or delivering unscheduled/unplanned care and/or enabling appropriate self-care. The primary beneficiaries are subjects of care and their providers.

4.2 Health record extracts

An electronic health record (EHR) extract is defined in ISO/TR 20514^[24] as "the unit of communication of the EHR which is itself attestable and which consists of one or more EHR compositions". ISO 13606-1^[28] defines an EHR extract as part or all of the EHR of a subject of care communicated between an EHR provider system and an EHR recipient (the latter might be another EHR system, a clinical data repository, a client application or a middleware service such as an electronic guideline component (from ISO 13606-1:2008, Table 1).

Therefore health record extracts more generally (i.e. including non-electronic extracts) may be described as 'units' of communication between authorized and interested parties to a healthcare transaction or transactions.

Such extracts may be either ad hoc in terms of their content, format and/or representation — e.g. a clinician selects specific content from a health record either "on the fly" or in an idiosyncratic manner and transmits it to another clinician or to the subject of care — or the extracts may be standardized in terms of content, format and representation. In the latter case, the most relevant content for a community of providers and/or subjects of care for a defined set of purposes is likely to have been pre-determined by, or on behalf of that community, along with the formatting and representation of the selected content.

HSRs are part of the latter subset, which is depicted in Figure 1.

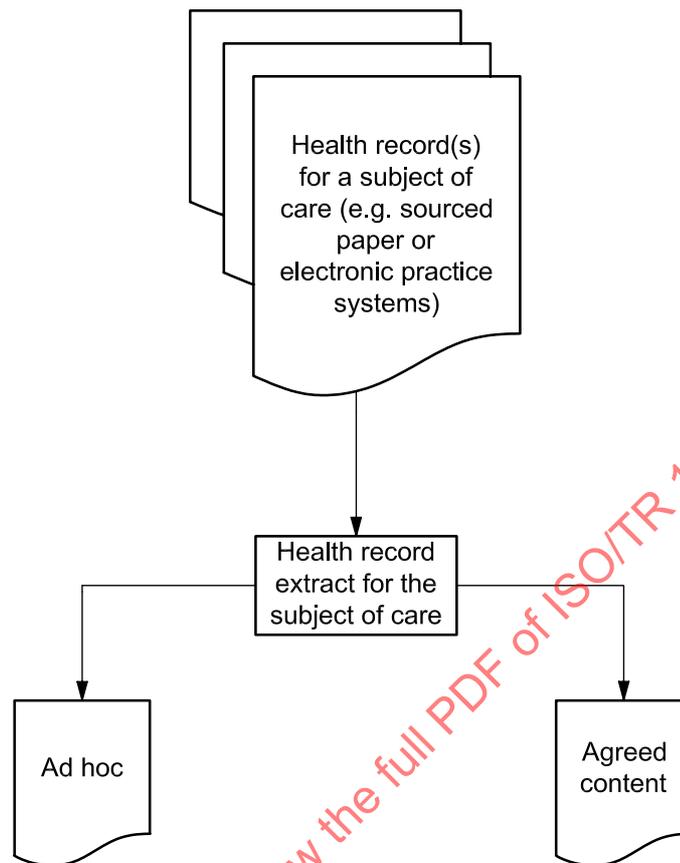


Figure 1 — A binary classification of health record extracts

It should be noted that:

- an instance of a health record extract may be drawn from either a single or multiple instances of health records for a specific subject of care;
- health record extracts in this generic sense are agnostic of standardized data structures; e.g., they may conform to ISO 13606-1 or HL7 V3 RIM semantics, or they may not (e.g. in the case of paper-based health record extracts).

4.3 Standardized health record extracts

Health record extracts that are standardized in terms of pre-agreed content may range from very generic in nature — e.g. a record of a general health assessment forming an initial entry in an EHR — to the very specialized summary records intended to capture detailed or sentinel summary data (disease indicator data) on specific types of health conditions or for specific purposes, e.g. cancer registries or notifications of infectious diseases. Figure 2 depicts this continuum.

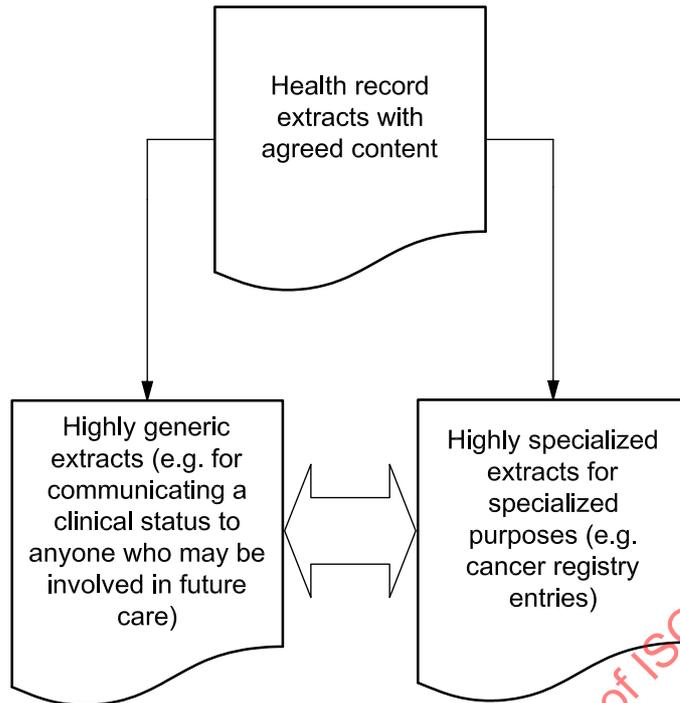


Figure 2 — A continuum of health summary records

The ISO definition of a standard is a “document, established by consensus and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at achievement of the optimum degree of order in a given context”^[32].

Accordingly, discussion of the need for standards must consider both the nature of the “order” required and the given context.

The primary domain of interest for this part of ISO/TR 12773 is towards the left hand side of the continuum depicted in Figure 2 — i.e. health record extracts that are standardized, the primary purpose of which is for a healthcare provider to pass on to other providers or to the subject of care, a set of information that has been agreed to be relevant and important to the subject’s ongoing care. Other forms of health record extracts to which much of the content of this part of ISO/TR 12773 may apply but which are outside its scope include:

- reports extracted from the health record(s) of a subject of care for purposes of notification of specific (e.g. infectious) conditions, as input to registries of health conditions (e.g. cancer registries) or primarily for administrative or billing purposes;
- data collection forms coded from the health record(s) of a subject of care for the purpose of aggregation of statistical information (e.g. hospital morbidity data collections) for secondary usage of data rather than support of ongoing care.

4.4 Integrated care EHRs (ICEHRs)

ISO/TR 20514^[24] defines the ICEHR as a 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. It has a standardized or commonly agreed logical information model which is independent of EHR systems. Its primary purpose is the support of continuing efficient and quality integrated healthcare and it contains information which is retrospective, concurrent and prospective.

There is a close relationship between health summary records (HSRs) and ICEHRs, not the least of which is a commonality of purpose.

Key differences, however, include:

- HSRs may not be electronic;
- ICEHRs may contain all available data pertaining to a subject of care, whereas HSRs contain selective subsets;
- although ICEHRs may have a logical information model, this may only extend to the method of organizing data content (e.g. sections, folders, compositions), and the data itself may not be standardized, whereas HSRs (of the type under discussion in this part of ISO/TR 12773) would have pre-agreed, standardized content.

It should be noted that considerable dialogue concerning the existing terms and definitions for various kinds of EHRs and EHR systems (i.e. those already specified in existing ISO documents) occurred during the compilation of this part of ISO/TR 12773. This dialogue provided the basis for the report's recommendation that all such related/similar terms and definitions be systematically reviewed by ISO TC 215.

4.5 Dynamic creation of a health summary record — List clinical summary/profile

Within the context of an ICEHR, Canada Health Infoway developed (2006) an HL7 v3 transaction — List Clinical Profile — which will return the “summary” versions of all demographics, medications, allergies, health conditions, lab tests, observations, procedures, encounters, referrals and other clinical data stored in one or more ICEHRs. The HL7 CDA model was adapted to develop this transaction. Because of its cross-domain nature and uniqueness to Canada's EHR architecture, this is a Canadian-specific HL7 v3 transaction, i.e. international balloting is not planned.

For this type of transaction, the default would be to filter for a “standard” view showing the most commonly needed summary data, based on consensus achieved via the governing authority for a particular ICEHR or ICEHRs. The transaction would be executed by invoking “summary” queries for each clinical area. The response would be composed of response messages defined for each clinical area. A parameter can be added to allow certain types of data to be retrieved as CDA “blobs” e.g. for local systems that are unable to handle discrete data. The ICEHR can render the blobs for these systems. Conformance needs to allow for support of different “pieces” of this transaction, with “blob” support as a minimum.

Templates as defined by a particular ICEHR authority can be used to filter which types of data come back, e.g. a “diabetic summary”. Additional filtering can occur at the practice EHR system level, e.g. family physician's office EHR system.

4.6 Defining health summary records

4.6.1 Health record extract

An attestable unit of communication of all or part of a healthcare record.

4.6.2 Health summary record (HSR)

A 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.

Noteworthy elements of these definitions include:

- The definition of a health record extract is a generalization of existing ISO definitions for electronic health record (EHR) extracts, such as those found in ISO/TR 20514; ISO 13606-1.

- An HSR is a form of health record extract.
- The focus of standardization of HSRs is their data content. Other standards (e.g. security, archiving and data structures) may or may not be applied to HSRs, but the context for their application is that they are subsets of records, healthcare records and health record extracts and these other standards apply at those levels. The only unique need for standardization associated with HSRs is associated with their informational content. This is discussed further in Clause 10.
- The information comprising a HSR is either clinical or contextual (i.e. providing essential context for the interpretation of the clinical information, such as data identifying the subject of care and/or healthcare service provider, clinically significant demographic information, etc.).
- The information comprising an HSR may be retrospective (historical), concurrent (where the extraction of information occurs at the point of care) or prospective (e.g. providing a protocol for future care).
- An HSR is a snapshot — it provides health information for a subject of care, which is relevant at a point in time.
- The sources of HSR information may include, but are not limited to, various types of EHRs, demographic registries for clients, providers and location of care and non-electronic sources, e.g. entered by the clinician.
- An HSR is viewable by the originating clinician and receiving clinician(s), such as in a final form document reader (e.g. PDF) or in a browser.
- None, some or all of the HSR may be processable by the recipient's EHR system.
- An HSR may be communicated electronically or by other means, e.g. fax; mail; portable media (CD, USB stick).
- An HSR may be persisted as a unit.
- As a form of health record extract, an HSR is attestable, and is a unit of communication.

5 Purposes of health summary records

The need for standardized HSRs to facilitate care and clinical decision-making is increasingly being recognised at the jurisdictional, national and international levels.

It is evident from a review of HSR initiatives planned or underway, that the primary impetus for creating an HSR originates with physicians, particularly primary care physicians, who have a need for timely communication of relevant patient information to other primary care physicians, specialists and others to whom they routinely refer or transfer their patients for healthcare services. Of equal importance is the primary care physician's need to access similar information when their patients move out of a care setting and back to the primary care physician or into another care setting, e.g. discharge from a hospital inpatient admission, outpatient specialist assessments, admissions to long term care facilities, etc.

The increasing interest in sharing health information is being driven by new models of primary care such as multidisciplinary teams who are recognized as improving continuity of care and subsequently, patient outcomes.

The need for sharing (communicating, transferring, accessing) health information exists at every level of patient-provider interaction — internal to the healthcare organization, across multiple organizations and across local, regional and national EHR systems and repositories.

Another important, but less often cited requirement is the transfer of a patient's health records from one provider to another provider where such transfers are legally permitted, e.g. provider retires and the patient's original records are permanently transferred to a new provider; patient moves or changes providers and copies of their records are made available to the new provider. Today, the records often do not follow the patient or if they do, the record is largely paper and of little utility unless a summary of the health information is

provided along with the full set of records. Communication with the CIO of a large HMO in the United States (as part of the environmental scan for this part of ISO/TR 12773) indicated that clinical users, in moving their patients' records from one large EHR system to a different EHR system, identified that 80 % of the information stored in the original EHR system was rarely accessed to support care decisions.

Other information-sharing needs identified in specific HSR projects relate to the utility and value of an HSR in tracking and managing chronic diseases, managing complex patients, e.g. the elderly, and supporting health maintenance, health education and healthy lifestyles.

As interest in HSRs has grown, many other health sectors and healthcare organizations have identified similar information sharing needs.

Consumers as well are driving the need for quick access to a summary of their health information, through their increasing interest in personal health records. These records are usually maintained by the person who created the record. They may incorporate information from HSRs created by their healthcare providers, plus information that they contribute themselves, e.g. over-the-counter medication, alternative medication, alternative therapies, etc., as well as sensitive health information that the person wishes to restrict from providers other than those to whom they grant access privileges.

Consumer requirements around personal health records include access to their health records when and where needed and the ability to have greater involvement in, and control over their own health and healthcare including empowerment to engage in intelligent self-care.

Specific examples of health summary information sharing are outlined below, in order of priorities identified by providers, patients and consumers:

- transfers of care to/from one provider to another: referrals; discharge summaries; admissions to hospital, admissions to long-term care;
- first point of contact care;
- unscheduled care, e.g. ER, after/off hours clinic, walk-in clinic visits; on-call visits; temporary residents/visitors, where the patient's entire health record (primary care record; hospital record, other) is not available, not required or in a format that is not amenable to supporting effective, efficient clinical decision-making at the point of unscheduled care;
- initial care, e.g. new patient — an HSR is created to initialize the patient's EHR;
- transfers of patient records between providers, e.g. physician moves, dies or retires; physician changes EHR system vendors, patient moves or changes physicians;
- less complex care, i.e. the HSR in conjunction with history of the current problem and physical exam, may be all that the provider needs in order to deliver safe care;
- care monitoring and enhancement, e.g. chronic disease management; complex comprehensive care, e.g. multi-system problems in the elderly;
 - for quick look-up of the patient's health history and current health status and to help determine whether access to the patient's complete health record is required;
 - may require sector, speciality, domain or organization — specific HSRs or HSR dataset extensions to meet these requirements, with a generic HSR specification as their foundation;
 - care maintenance — annual health exams; recommended health screening tests, e.g. mammography; risk factor reduction, behaviour modification, health promotion, health education activities;
 - again, HSR dataset extensions may be required to support these requirements;

- creation and maintenance of personal health records (PHRs); transfer of PHR data between providers and patients;
- export/import of health record extracts between EHR systems and between EHR systems and PHR systems.

In summary, HSRs are intended to facilitate/support:

- care, e.g. intermittent care (scheduled and unscheduled), ongoing/continuous care such as chronic disease management; preventive care; self-care;
- transfers of patients and/or records between providers;
- encapsulation of key information held in detailed EHR source system records;
- creation of personal health records.

A series of use cases for HSRs is presented below.

Although their primary purpose is to support and facilitate the provision of care, HSRs may be utilized for secondary purposes. A distinction is worth reiterating though, for the purposes of this part of ISO/TR 12773, a summary compiled primarily for a 'secondary use' (e.g. input to a cancer registry) would be an instance of a health record extract but not an HSR.

Secondary uses for HSRs include:

- medico-legal, e.g. was the HSR accessed during an ER visit and used appropriately to support care decisions — a reflection of provider competency;
- quality management, e.g. the HSR as a standard of practice that requires a provider to review it as part of their patient assessment and to support treatment decisions where appropriate; practice audits to monitor the use of the HSR;
- data aggregation to support clinical research and health surveillance activities, e.g. creation of population health profiles of prescription drug use or provider/patient compliance with immunization guidelines, etc.;
- other, e.g. targeting/planning preventive health interventions and public education programmes; planning healthcare services.

6 Common use cases for health summary records

6.1 Overview

The primary use of HSRs is communication and sharing of health information to support care, including continuity of care and clinical decision-making for authorized clinicians in any healthcare setting. Given this context, examples of four common use cases are included below:

- creating an HSR;
- querying, viewing, updating an HSR;
- creating an HSR to facilitate transfer of care, e.g. provider to provider referrals; discharges from acute to primary care; discharges from acute to sub-acute/chronic care;
- health record handling, e.g. record transfers, removal of records from an EHR system, archiving of records.

NOTE The shared EHR referenced in all use cases is assumed to be an integrated care EHR (ICEHR).

Use cases were developed by the author of ISO/TR 12773-2 (a physician) based on clinical experience and on the results of the environmental scan. Clinicians in Canada also provided input to draft versions of ISO/TR 12773-2.

Examples of secondary use cases and other types of use cases are included for completeness.

6.2 Use case 1: Creating a health summary record

This use case involves a patient visiting a primary care provider (PCP) for the first time.

Pre-conditions: the PCP sees the patient in her office. The patient has no records from her previous PCP. The previous PCP did not have an EHR system and the patient has no other electronic records that she is aware of. The PCP obtains a history of the presenting problem and relevant past health history, performs a physical examination and enters the relevant information into her practice EHR system.

Assumptions: the new PCP has a practice EHR system with capability to write free text notes and manage data elements. Explicit consent to create a shareable HSR is obtained if required by applicable legislation. The patient's identification and demographic information is obtained and confirmed. The PCP also uses this information to confirm that no shared EHR exists for the patient in the shared EHR repository with which the practice EHR system interoperates.

Use case: the specific data elements managed by the PCP's EHR system are used to create the HSR, based on information provided by the patient and in accordance with a standard HSR data specification.

An instance of the HSR is persisted in the practice EHR system. This instance is also sent to the shared EHR repository to initiate the patient's shared EHR.

Post-conditions: the patient has an HSR in the PCP's practice EHR system and in the shared EHR repository. The patient receives a paper copy of her HSR upon request, or a digital copy (e.g. USB mass storage device or CD).

Variation:

- The patient's initial HSR is created in a shared EHR repository at the time of registration for state/provincial health insurance, and populated with demographic data only (from the state/provincial client registry). At the time of the patient's first visit to the new PCP, the PCP accesses the patient's HSR in the shared EHR repository and adds relevant clinical information to create a new instance of the HSR which replaces (supersedes) the initial instance. The PCP imports the new instance of the HSR into her practice EHR system.

Comments: if the patient's original PCP implemented a practice EHR system, that PCP would not be able to access the new HSR unless that PCP remains within the patient's circle of care, i.e. is actively involved on a regular or ongoing basis with the patient's care, or if that PCP is otherwise allowed to access the HSR, e.g. the original PCP is part of an after-hours on-call group for the new PCP's practice. Even if the original PCP can access the HSR, they will not be able to update the HSR unless multiple providers are permitted to maintain the HSR. This may not be supported in many jurisdictions. Access and updating privileges will largely be determined by the policies, regulations and practice standards in effect in the jurisdiction where the original PCP, the new PCP, the patient and the shared EHR repository are located/managed.

6.3 Use case 2: Querying, viewing, replacing (superseding) the HSR

This use case involves a patient visit to an after-hours clinic for an exacerbation of a chronic disease.

Pre-conditions: the patient has not visited the clinic previously, but tells the clinic nurse that he has an electronic record that holds all of his important health information, at which she and the physician can look. The patient's identification and demographic information is confirmed. This information is used to confirm the existence of a shared EHR for the patient in the shared EHR repository with which the practice EHR system interoperates. Consent is obtained to access the patient's shared EHR. The physician takes a history and examines the subject.

Assumptions: the clinic has a practice EHR system with capability to write free text notes and manage data elements. The practice EHR system interoperates with a shared EHR repository.

Use case: the physician determines that the patient is a poor historian: he does not recall the details of his previous lab tests, hospital admissions, medication, etc. To clarify this information, the physician uses the clinic's practice EHR system to query and read the patient's shared EHR. The shared EHR holds a recent HSR that appears to be clinically valid. (Clinical validity is determined by the provider viewing the HSR, based on the provider's knowledge of the patient and/or their assessment and understanding of the data in the HSR.) The HSR provides results of tests, regular and current medications, ongoing and recent health problems, etc. in a standardized form from a variety of clinicians. Because the HSR data specifications are standardized, the physician can unambiguously interpret the information presented, and can import data such as blood pressure measurements into the practice EHR system and chart them. Based on this information and the findings from the physical examination, the physician makes a diagnosis and treats the patient accordingly, completes the patient's clinical record for the visit and creates a new instance of the patient's HSR in the practice EHR system and sends a new instance of the HSR to the shared EHR repository where it will replace (supersede) the current instance.

Post-conditions: there is a record of the patient's visit in the clinic's practice EHR system and an instance of an HSR. A new instance of an HSR exists in the patient's shared EHR. All historical versions of the HSR will be maintained in the shared EHR repository. The patient is provided with a paper copy of the new instance of his HSR or a copy on portable media, e.g. CD, because he informed the physician that he is travelling out of town in the next week and may require further care in settings that may not have access to his shared EHR.

NOTE Portable media devices might not be usable/readable, depending on where the patient is travelling. The onus is on the patient in collaboration with their provider to assess this situation prior to travel. If relevant information is not available, or the patient does not wish to be responsible for a portable media device, a paper copy of the HSR can be provided.

6.4 Use Case 3: Provider-to-provider referrals

This use case involves the referral (transfer of care) of a patient from a PCP to a specialist.

Pre-conditions: a PCP has seen a patient in his office. The PCP has talked to the patient and performed an examination, and has decided to refer the patient to a specialist.

Assumptions: the PCP and the specialist have practice EHR systems with capability to write free text notes and manage data elements. The practice EHR system interoperates with a shared EHR repository. The patient already has an HSR stored in the practice EHR system, the shared EHR repository or both.

Use case: the PCP accesses his practice EHR system and, where applicable, a shared EHR repository. He reviews the existing HSRs and creates a new instance of the HSR as required. A referral note is created and sent along with the new instance of the HSR, e.g. via point-to-point transmission or the note is posted to the shared EHR repository and includes a link to the HSR in the patient's shared EHR.

Assumptions: an appropriate level of collaboration/communication between the sending and referral physicians occurs prior to the actual transfer of clinical information.

Out-of-scope: steps to identify the specialist, and obtain insurance preauthorization.

Post conditions: the targeted referral note is posted to the shared EHR repository and then 'pushed' to the specialist's practice EHR system via the EHR repository. Alternatively, the specialist receives an electronic notification of the referral in his practice EHR system via the EHR repository or secure e-mail and retrieves (pulls) the referral note documents (via direct query to the EHR repository or via a document registry which includes pointers to the HSR and other relevant data in the EHR repository). The specialist views the documents and optionally imports data into his practice EHR system. Import is based on the assumption that the specialist's practice EHR system has the capability to manage those discrete data elements.

Variation:

- PCP referral to a hospital ER — Usually, minimal history is communicated between the PCP and the ER physician on duty prior to the patient's arrival. The HSR would be accessible to the ER physician by accessing the shared EHR repository or, where no shared EHR exists, the local hospital IS or emergency department information system. In the latter case, the HSR is derived only from hospital data, or from a few additional sources, e.g. from the PCP's practice EHR system via an interface with the hospital EHR system. The PCP may also provide transport media to the patient (copy of the HSR downloaded from the PCP's EHR system to a CD or USB storage device or a paper copy).

PCP referral to pre-hospital emergency medical services personnel for transport: similar to the ER transfer use case, the ambulance personnel should be able to use their pre-hospital EHR system to access an existing HSR in a shared EHR repository, or where no shared EHR exists, obtain a copy of the HSR from the PCP prior to transport, e.g. CD; USB port; paper copy.

6.5 Use case 4: Acute care discharge to home or other ambulatory care environment

This use case involves a patient discharge from a hospital to home or other ambulatory care environment. The attending physician (a specialist) in the hospital creates a standard discharge summary for inclusion in the hospital record, sharing with the patient's PCP, the specialist's own office and other providers involved in follow-up care.

Pre-conditions: a patient has been admitted to hospital under the care of a specialist for an acute problem. The specialist is ready to discharge the patient. The patient will see the specialist in her office for follow-up, as well as his own PCP.

Assumptions: the patient has an HSR in the hospital EHR system, the shared EHR repository or both. The specialist uses the HSR(s) to electronically populate a standard discharge summary. He calls up the HSR and other relevant data elements in the hospital/shared EHRs (e.g. the list of current medication) for inclusion in the discharge summary.

Use case: the events of this use case involve creation of the discharge summary (HSR) and its transmission to the shared EHR repository, with notifications sent via the repository to the PCP's practice EHR system, the specialist's practice EHR system and the practice EHR systems of other providers who will be involved in the patient's follow-up care. Where no shared EHR repository exists, the discharge summary can be communicated direct via hospital to PCP, specialist and other provider EHR systems (if one or more of these systems are integrated and interoperable) or via other means e.g. secure e-mail; fax; mail.

Post-conditions: include electronic receipt of the discharge summary into the PCP's practice EHR system or alternatively, notification of the PCP's practice EHR system that the summary is available in the shared EHR repository; viewing of the discharge summary by the PCP, the specialist and other providers (as applicable) via their practice EHR systems and where applicable, optional import into these systems from the shared EHR repository.

6.6 Use case 5: Acute care discharge to a sub-acute care nursing facility (SNF)

EXAMPLE Nursing home; complex continuing care hospital; rehab hospital.

This use case involves the discharge of an elderly patient from an acute care hospital post hip fracture and total hip replacement to a sub-acute care nursing facility (SNF).

Pre-conditions: the patient is ready for discharge from the surgical service but suffers from dementia. He is assessed by a hospital discharge planner/case manager for determination of the level of sub-acute care required and type of facility. The discharging physician has not yet created a discharge summary.

Assumptions: a recent instance of an HSR exists on the patient at the local level (hospital EHR system) and where applicable, in a shared EHR repository. Variability in EHR implementations and usage may result in variability in the content of the summary.

Use case: the hospital discharge planner/case manager queries the hospital EHR system and the shared EHR repository and imports relevant data to populate forms generated in the acute care setting for pre-acceptance to the selected SNF, e.g. mental status; functional abilities status; activities of daily living status; appliances/equipment. A new instance of the patient's HSR is created in the hospital EHR system and sent to the shared EHR repository. The completed forms are also sent to the shared EHR repository, with notifications sent via the repository to the intake/social work receiving staff at the SNF, the patient's PCP and other providers who may be involved in the patient's ongoing care in the SNF. Where no shared EHR repository exists, a copy of the new HSR and the forms are communicated via direct point-to-point electronic communication (hospital EHR system to SNF EHR system) or via other means e.g., secure e-mail; fax; paper.

Post-conditions: include the receipt of the HSR and the completed forms or notification regarding the availability of the HSR and the forms in the shared EHR repository, and viewing of the HSR and forms by authorized staff of the SNF, the patient's PCP and other providers, with optional import into these practice EHR systems. The SNF intake/social work staff review the HSR and the forms to determine if the patient is suitable for the selected SNF facility. The patient is accepted in transfer. The forms are updated as required by an authorized collaborative team of SNF clinicians. SNF staff now has up-to-date health information about the patient. Continuity of care is maintained.

NOTE The availability of an HSR in conjunction with other shared EHR data will greatly facilitate appropriate and timely transfers to SNFs, as well as continuity of care and ongoing care for these patients. The prevalent manual workflow process is plagued with duplication and inefficiencies. Requisite assessments and related forms for SNF placement are very lengthy and detailed. Problem areas are communications between institutions, communications between departments in hospitals, redundancy of paper work, incomplete paperwork, and the need for additional staff to manage the transcribing, compilation, copying and transferring by fax or mail of many pages of information.

6.7 Use case 6: Initiate HSR transfer

This use case allows a PCP to transfer one or multiple patients' HSRs to another PCP as a means of initializing the new PCP's practice EHR records for these patients.

Pre-conditions: multiple patient HSRs are being transferred to a new PCP because the current PCP has moved to a geographic area distant from his current practice location or the PCP has retired or died. The new PCP has agreed to the HSR transfers. Both the current and the new PCPs have practice EHR systems that are capable of transferring and storing a standard HSR. Optionally, the practice EHR systems interoperate with a shared EHR repository.

Assumptions: the necessary patient consents have been obtained for the HSR transfers. Permanent transfer of patient health records from one provider to another is permitted in the jurisdiction.

Use case: the current PCP selects the patients in his practice EHR system whose HSRs will be transferred to the new PCP. He reviews the existing HSRs for these patients and creates new instances of HSRs where required, e.g. where health information is not current, and where applicable, sends a copy of the new instances to a shared EHR repository. The HSRs are transferred individually or in bulk (if there are multiple records) e.g., via direct electronic transfer if the practice EHR systems interoperate or via the shared EHR repository with which the practice EHRs interoperate or via loading on to portable media.

Post-conditions: confirmation of HSR transfers is sent to the current PCP from the new PCP, e.g. electronically system to system, or via the shared EHR repository or via secure e-mail. The HSRs are stored in the new PCP's practice EHR system.

6.8 Secondary use cases

Capability already exists for collecting personal health information for secondary use. However, processes are inefficient and generally result in collection of data from multiple source systems, often with duplication. Shared EHR repositories offer opportunities to reduce duplication of data collection, i.e. collect once; use for primary and secondary purposes.

Public health, research institutes, health policy institutes, health data warehousing and outcomes analysis institutes could establish agreements with the custodians of shared EHR repositories allowing data to be sent to both the shared EHR repository to support direct care and clinical decision-making as well as to a clinical data warehouse where it is anonymized/pseudonymized for approved secondary uses.

Examples of potential secondary uses for HSRs include, but are not limited to the following.

- Transmission of public health surveillance information; this use case assumes that this type of information (e.g. communicable disease history) is routinely captured in an HSR, which may not be the case given that the disease history for many types of communicable diseases is not regarded as significant enough for a provider to persist in an HSR. Capture of reportable communicable diseases in an HSR should be supported as a public health surveillance requirement.
- A health research organization requests access to HSR data in an anonymized format from data held in a shared EHR repository as part of an outcomes assessment, e.g. all subjects of care who have undergone open heart surgery and valve replacement over a given time period.
- A clinician's office participating in a pharmaceutical research trial uses the HSR data stored in their practice EHR system to populate the research forms. This use case assumes that the office's study coordinator has created the relevant research forms in the clinician's practice EHR system and, where required according to laws applicable to secondary use of data for research, has de-identified the data.

7 Business requirements for health summary records

Clause 4 of ISO/TR 12773-2 presents the key findings of the environmental scan that were used to compile the business requirements listed in this clause. The details of the best known HSR initiatives are included in Clause 5 of ISO/TR 12773-2. These provide additional clarity with respect to how the requirements were derived. An in-depth analysis and comparison of each initiative's requirements was not performed for the purposes of this part of ISO/TR 12773.

The following business requirements have been inferred from contemporary HSR initiatives.

- HSRs are data-centric, i.e. accumulators of persistent data that are structured/organized and easily computable to enable rapid assimilation and communication of health information for a subject of care.
- HSRs are subject of care (consumer-centric), i.e. each instance of an HSR and the health and contextual information it contains should pertain to a subject of care.
- HSRs are dynamic and content must reflect the most current health information available on the subject of care.
- In the shared EHR context, the HSR content must be maintained. Maintaining HSRs manually in this context where a master editor is not likely to be assigned will be difficult. Automatic/semi-automatic generic business rules for information decay and filtering may need to be implemented but this solution requires considerable more research (including patient safety evaluations). Once there is a good evidence base, such business rules might be "owned" and endorsed for use in future by professional bodies and health systems;
 - in this context, users will need to be alerted to the dynamic nature of the HSR, e.g. via on-screen warnings, disclaimers and alerts that appear automatically after authorized users obtain access to the shared EHR repository; screen alerts should indicate that only a part of the subject of care's health information is being displayed via the HSR.
- HSR content may be extracted from one or more health records pertaining to the subject of care held by/sourced from one or more healthcare service providers.
- HSRs should be attestable by the healthcare service providers who create them or authorize their creation.
- HSRs should enable reliable and unambiguous interpretation of their content.
- HSRs may exist in both paper and electronic formats, and be independent of technology platforms.

- HSRs may be “stand alone” — i.e. used for point-to-point communication between providers, or part of a shared EHR to which many providers may have authorized access.
- HSRs should be extensible, in that additional (local) data for specific purposes may be added to the core (standardized) dataset.
- HSRs may include links to data that the subject of care has stored in other systems, e.g. shared EHR repositories; document registries; local systems.
- HSRs should be designed for easy export and import between record systems, and easy portability via transportable media (e.g. health smartcard; USB mass storage device).
- HSRs should be timely, reliable, relevant to the care context, and accurate.
- HSRs should be designed to enable data aggregation for research and administrative purposes, especially HSRs intended for use in a shared EHR.

8 Data and information management requirements for health summary records

8.1 General requirements

The following data and information management requirements have been inferred from contemporary HSR initiatives. Clauses 5 and 6 of ISO/TR 12773-2 provide further information.

- An HSR should support the capture and transfer of both free-text and coded data. However, it is preferable that free text be as highly structured as possible (e.g. via the use of headings), and that codes used, as far as possible, be based on international, national and local standards, in that order.
- Metadata for HSRs and its retention period should be defined. ISO/TC 215 has made considerable progress on requirements for an EHR reference architecture (ISO 18308^[23]) and EHR models (ISO 13606-1^[28]) that support the capture of a fair amount of context metadata, much of which is likely applicable to the HSR. However, at this juncture, there is no consensus on metadata for HSRs or its retention period. This part of ISO/TR 12773 recommends a future ISO work item to develop a standard HSR specification, e.g. a Technical Specification or an International Standard.
- A high level of data integrity and data quality is important for any health record, but even more so for data that may be accessed outside the context of its creation. HSR data should be subject to specified levels of data quality and the creation of HSRs should be guided by good health information management practices.

Requirements and responsibilities for review and maintenance of HSR data quality will vary with the use context and the agreements reached regarding overall management of the HSR within those contexts. With respect to the shared EHR context, to date, few, if any, health programmes implementing an HSR have published any kind of data quality criteria or have even acknowledged that such criteria are needed.

8.2 Clinical content priorities for health summary records

The scope and granularity of the clinical and contextual data in an HSR will usually be dictated by the use context and provider roles and the agreements that are reached by or on behalf of the community of providers operating within that context and those roles. Content is that which is commonly agreed by the provider community to be relevant to supporting ongoing care and continuity of care.

The determination of “relevance” of content will be significantly influenced by the clinical utility needs that the HSR is intended to address (see Clauses 5 and 6).

What is relevant for a particular clinical purpose might require different data to be collected by different provider groups. So a consensus on what is relevant, even for a single purpose, might not be unanimous.