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Health informatics — International patient summary

Informatique de santé — Résumé international du dossier médical du patient

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

This document was prepared by European Committee for Standardization (CEN) (as EN 17269:2019) and was adopted, with the following modifications by Technical Committee ISO/TC 215, *Health informatics*.

— changed "this European Standard" to "this document";

— changed any "EN ISO xxxx" references to "ISO xxxx" references;

— changed "section" to "Clause", if appropriate;

— definitions of IPS terms in body of text were moved to Clause 3;

— Clause 3 was reorganized based upon existing ContSys hierarchy;

— more description on conformance, data blocks, more examples in concept values and updated definition citations given in response.

— on implementation evidence from HL7 FHIR ®[1)], the requirement to require/enable the expression of the name data element as a single string as well as the structured representation to permit the natural way of expression in some eastern countries and facilitate cross-border use;

— 'Healthcare Provider' became an Attribute Collection data block, defined and positioned in Clause 3 rather than be treated as a data type.

— complete editorial revision.

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

1) HL7 FHIR is the registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

Introduction

The goal of this document is to deliver a single, common International Patient Summary (IPS), comprising core content.

This document achieves that goal by defining a minimal yet non-exhaustive data set and its associated business rules. This document is implementation independent yet still supportive of any implementation by providing formal definition and clear description of a small data set. The primary input to the data set is the second revision of the European eHealth Network's (eHN) data set[1], which, in turn, builds upon significant clinical input from the European Patients-Smart Open Services (epSOS) pilot project[2].

This document defines the IPS, with the initial focus upon unplanned care across national borders. Starting from this focus, and building upon it, the specification is intended to be used and be useful in national and local applications and also to be supportive of both planned and unplanned care. The IPS is designed to provide clinical information to assist care across any jurisdictional border (e.g. local, regional, state/provincial, national). It emphasizes the data required and the associated business rules to support use and the necessary conformance of the use case for an international patient summary. Even though the data set is relatively small, there is no expectation that the full data set has to be realized for a conformant implementation or conformant specification to be produced. Such artefacts need not specify all the optional IPS elements, given that they should assure the openness and extensibility of the derived model.

The data set described is intended for global use beginning with a shared vision[1] from a collaboration between CEN /TC 251 and HL7®[2)], but now involving five Standard Development Organizations each contributing artefacts to support the single solution IPS going forward. From the IPS reference model it is possible to derive a number of compliant logical models that constrain it, and these lead to implementable specifications, such as the IPS CDA and FHIR Implementation Guides. These guides are formalized in the HL7 CDA IG®[2)] and HL7 IG®[2)] and in the IHE IPS®[2)] profile. The IPS Dataset is not bound by any terminology, although it does anticipate the use of the IDMP standard for medication. SNOMED®[3)] International has provided a Global Patient Set for the IPS implementations. CEN has produced a separate Technical Specification[3], that provides a European-specific guideline for IPS implementation, which can also be used as an example for other jurisdictions.

The 'International' element of the IPS emphasizes the need to provide generic solutions for global application moving beyond a particular region or country; consequently, wherever possible, reference is made to international standards, rather than local ones. However, different international contexts will offer a variety of requirements that need to be considered to ensure that patient safety is not compromised. The IPS is underpinned by ISO 13940, which is a system of concepts to support continuity of care[4] and uses those concepts in the initial IPS scenario, which is fully described in Annex A.

This document focuses upon the overall structure of the patient summary as well as the individual data elements that comprise it. The layout of this document (see Table 1) uses a hierarchy of levels (H0 to H7) to facilitate more detailed description with the purpose of supporting consistent implementation of the data set. The level 'H0' describes the IPS Document as a whole, whilst levels H1-H7 describe the IPS Data Blocks with attributes. Descriptors are added to each data element to better define the characteristics. The 'H0' level document structure and constraints will be described first, the components start with H1 (e.g. IPS Sections, IPS Attribute Collections).

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Table 1 — Description of IPS Data Set concepts and their hierarchical relationships

Descriptive hierarchy	H0	H1	H2 – H7
IPS Data Transfer Object	IPS Document	All possible IPS and the Non-IPS components are identified	Further detail is provided within the IPS Data Blocks' clauses
IPS Data Blocks	-	Individual IPS Sections, IPS Attribute Collections	Hierarchical description of data elements

The ordering of the IPS Data Blocks in this document is within three broad categories of Non-Clinical Data, Clinical Data and Metadata. This follows the eHDSI patient summary deployment project[5] and here is used purely to help presentation. However, in practice it is recognized that individual attributes might appear in different categories depending on dynamic use rather than static classification.

As the amount of information for each data element is variable, and can be extensive, this document presents the information using a table with descriptors for each IPS Data Block; the table provides an overview of the hierarchical structure and its requirement with explicit links to more details using a consistent set of descriptors. Those attributes in the table that do not have a link to further detail are either self-explanatory or explained by the hierarchical context. Note, the order of sibling attributes is arbitrary and has no implication for implementations of this document. The name of the element is contextualized by the hierarchy so as to avoid any misunderstanding. For example, the term 'Device Type' will be used rather than just "Type" albeit that it refers to a data element positioned within the Medical Device IPS Data Block.

Health informatics — International patient summary

1 Scope

This document defines the core data set for a patient summary document that supports continuity of care for a person and coordination of their healthcare. It is specifically aimed at supporting the use case' scenario for 'unplanned, cross border care' and is intended to be an international patient summary (IPS). Whilst the data set is minimal and non-exhaustive, it provides a robust, well-defined core set of data items. The tight focus on this use case also enables the IPS to be used in planned care. This means that both unplanned and planned care can be supported by this data set within local and national contexts, thereby increasing its utility and value.

It uses the European Guideline from the eHN as the initial source for the patient summary requirements, then takes into consideration other international patient summary projects to provide an interoperable data set specification that has global application.

This document provides an abstract definition of a Patient Summary from which derived models are implementable. Due to its nature therefore, readers should be aware that the compliance with this document does not imply automatic technical interoperability; this result, enabled by this document, can be reached with the conformity to standards indicated in the associated technical specification and implementation guides.

This document does not cover the workflow processes of data entry, data collection, data summarization, subsequent data presentation, assimilation, or aggregation. Furthermore, this document does not cover the summarization act itself, i.e. the intelligence/skill/competence that results in the data summarization workflow.

It is not an implementation guide that is concerned with the various technical layers beneath the application layer. Implementation guidance for specifically jurisdictional concerns, e.g. Directives, terminologies, formats, etc., an example is specified in the associated Technical Specification[3].

In particular, representation by various coding schemes, additional structures and terminologies are not part of this document. Terminology and its binding are addressed in Reference [3]. The Identification of Medicinal Products standards (abbreviated to IDMP) are the recommended target for the Medication Summary related to this document but, prior to IDMP's full implementation in practice, this IPS standard cannot insist in its use at this point in time and recognizes that interim schemes might be necessary until IDMP becomes established as a norm.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

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

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

3.1 Healthcare

3.1.1
healthcare
care, services, or supplies related to the health of an individual

Note 1 to entry: It includes any:

a) preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, counselling, service, or procedure with respect to the physical or mental condition, or functional status, of a patient or affecting the structure or function of the body;

b) sale or dispensing of a drug, device, equipment, or other item pursuant to a prescription; or

c) procurement or banking of blood, sperm, organs, or any other tissue for administration to patients.

Note 2 to entry: Healthcare may also include the management of clinical knowledge.

[SOURCE: HIPAA, modified — Note 2 to entry was added.]

3.1.2
continuity of care
efficient, effective, ethical care delivered through interaction, integration, co-ordination and sharing of information between different healthcare actors over time

[SOURCE: ISO 13940:2015, 3.1.2, modified — Note to entry removed.]

3.2 Healthcare actor

3.2.1
subject of care
patient
citizen
client
healthcare actor with a person role; who seeks to receive, is receiving, or has received healthcare

[SOURCE: ISO 13940:2015, 5.2.1]

3.2.2
healthcare provider
care provider
health provider
health service provider
healthcare service provider
healthcare actor that is able to be assigned one or more care period mandates

Note 1 to entry: Healthcare Provider is described in the Attribute Collection HEALTHCARE PROVIDER

Note 2 to entry: The personnel of a healthcare organization that is a healthcare provider may include both healthcare professionals and others which participate in the provision of healthcare.

Note 3 to entry: According to the definition in ISO 13940:2015, organizations solely responsible for the funding, payment, or reimbursement of healthcare provision are not healthcare providers; for the purpose of this International Standard they are considered as healthcare third parties.

[SOURCE: ISO 13940:2015, 5.2.3]

3.3 Healthcare matter

3.3.1
health condition
observed or potential observable aspects of the health state at a given time

[SOURCE: ISO 13940:2015, 6.4]

3.4 Healthcare activity

3.4.1
point of care
location where direct healthcare activities are performed

Note 1 to entry: Location refers to the geographical location of the subject of care; not the body area of the subject of care that the treatment is applied to.

[SOURCE: ISO 13940:2015, 7.2.9.1]

3.5 Healthcare planning

3.5.1
core care plan
reusable content and structure for a potential care plan for a specified set of circumstances

[SOURCE: ISO 13940:2015, 9.2.3]

3.5.2
plan of care
care plan
plan of treatment
healthcare plan
dynamic, personalized plan including identified *needed healthcare activities, health objectives* and *healthcare goals*, relating to one or more specified *health issues* in *a healthcare process*

Note 1 to entry: A care plan may be recorded in one or more health records.

Note 2 to entry: A care plan could be subdivided from different perspectives by different constraints. One example is uniprofessional care plan, for example, a nursing care plan with the constraint of only one specific healthcare professional involved. Other examples of specific constraints for a care plan are: care plan to address one health issue, one health condition, one contact, one clinical process, healthcare activities to be performed by one healthcare provider, etc.

Note 3 to entry: Care plans are reviewed repeatedly during a healthcare process, each review based on a new healthcare needs assessment.

Note 4 to entry: The healthcare activities in a care plan follow a life cycle. Examples of statuses of such a life cycle are: 'planned', 'performed', 'cancelled', etc.; all of these statuses are included in the care plan

EXAMPLE A care plan for retinopathy in diabetics by video-retinoscopy, which involves the GP and an ophthalmologist and implies specific mobile equipment (video-retinoscope) with a camera.

[SOURCE: ISO 13940:2015, 9.2.3]

3.6 Time

3.6.1
unscheduled care
unplanned care
unanticipated care
healthcare service for an unexpected demand for care

Note 1 to entry: In this scenario, the assistance needed can be emergency or non-emergency.

Note 2 to entry: The International Patient Summary is presumed to be the information needed to quickly help advise, diagnose, and/or treat the person requiring assistance.

3.7 Responsibility

3.7.1
cross border
passing, occurring, or performed across a border between two jurisdictions

Note 1 to entry: This scenario emphasises the fact that countries, states, provinces, regions and the like will have different jurisdictions that might have legal, organizational and cultural implications and responsibilities for how personal data, and particularly health data are managed and shared.

Note 2 to entry: with respect to interoperability, cross border data interchange is the extreme case of the more general ones of organizational and professional boundaries found within a country's borders, and therefore the substantive part of this document is also applicable to national and local contexts.

3.7.2
demand for care
demand for healthcare
demand for healthcare provider activities expressed by a healthcare actor

Note 1 to entry: A demand for care may be expressed either by the subject of care or on their behalf.

[SOURCE: ISO 13940:2015, 11.3]

3.7.3
demand for initial contact
first demand for care concerning one or more specific health issues to be assessed by a healthcare provider

[SOURCE: ISO 13940:2015, 11.3.1]

3.8 Information Management

3.8.1 Concepts

3.8.1.1
patient summary
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

Note 1 to entry: The eHN Guideline definition is: A Patient Summary is an identifiable "dataset of essential and understandable health information" [that is made available] "at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care"; [defined at a high level as:] "the minimum set of information needed to assure Health Care Coordination and the continuity of care".

[SOURCE: ISO/TR 12773-1:2009, 2.28, modified — "patient summary" added as preferred term, note to entry added.]

3.8.1.2
electronic patient summary
electronic health record extract containing essential healthcare information intended for specific uses

[SOURCE: ISO 13940:2015, 12.5.2]

3.8.1.3
health record component
part of a health record that is identifiable for the purposes of referencing and revision

Note 1 to entry: The content of a health record is not limited to information in electronic format, the content of health record components may be in formats other than electronic.

[SOURCE: ISO 13940:2015, 12.2.3]

3.8.1.4
electronic health record extract
EHR extract
health record extract consisting solely of electronic record components

[SOURCE: ISO 13940:2015, 12.5.1]

3.8.1.5
healthcare information request
request sent out by a healthcare actor to another healthcare actor for specific healthcare information needed for the provision of healthcare to a subject of care

[SOURCE: ISO 13940:2015, 12.5.5]

3.8.2 Models

3.8.2.1
international patient summary document
IPS Document
IPS

electronic patient summary for use at the point of care comprising, as a minimum, the required elements of the IPS Data Set.

Note 1 to entry: The Use Case is 'provide a patient summary for use at the point of care'; the following are IPS scenarios:

— 'Unscheduled, Cross Border care' is the initial IPS scenario 1;

— 'Scheduled, Cross Border care' is IPS Scenario 2;

— 'Unscheduled, Local care' is IPS Scenario 3;

— 'Scheduled, Local care' is IPS Scenario 4.

Note 2 to entry: National and local applications of IPS are served by this document. The specific cross border scenario requires the Cross-Border Data to be used, but is also usable for other related scenarios, i.e., scheduled care and national or local use

Note 3 to entry: IPS is applicable in any situation, irrespective of local/international and scheduled/unscheduled care situations.

Note 4 to entry: IPS Data Blocks may be readily used in other applications, but to be an IPS the application shall have the same scope including the same purpose of summarising the patient's healthcare history for continuity of care.

Note 5 to entry: The 'Document' vocabulary in this document was deliberately chosen as a metaphor to be a familiar concept. The IPS Document can be implemented in quite different ways from a physical document-centric representation, freeing the IPS and its IPS Data Blocks to be reused to give additional value.

Note 6 to entry: IPS is also used as shorthand to denote the activity of the SDO initiatives focused on delivering the IPS. The context in which the term is used determines the specific meaning, e.g. when it is associated with the SDO name it refers explicitly to the initiative rather than to the IPS content.

3.8.2.2
international patient summary data block
IPS Data Block
IPS Datablock
scalable IPS data structure that can be reused

Note 1 to entry: A terminology of scale is suggested:

— Micro: IPS Element is a basic IPS unit or data element

  — e.g. 'name'

— Meso: IPS Feature is a subset of IPS elements that can stand together, suitable for reuse.

  — e.g. Certain immunization data for a Vaccination Card, or structure for part of a discharge letter

— Macro: IPS Section and Attribute Collection are the principal containers for the micro and meso structures

  — e.g. 'IPS Section Problems' and 'IPS Attribute Collection Provenance' respectively

— Mega: IPS Document,

  — e.g. IPS, and other specialized data summaries, perhaps for specific conditions or specialties.

Note 2 to entry: reuse is possible for all data structures including the IPS Document. However, the IPS dataset, like all datasets, is specified for a specific purpose (i.e. a summary of the patient's longitudinal record for continuity of care), and therefore caution should be exercised when implementing and reusing IPS Data Blocks to ensure that any original intention for IPS data retains its meaning in a different context.

3.8.2.3
international patient summary section
IPS Section
healthcare-specific content grouped with respect to clinical utility for inclusion in the IPS Document

3.8.2.4
international patient summary attribute collection
IPS Attribute Collection
healthcare-related content within the IPS Data Set and grouped with respect to identification and administrative purposes for inclusion in the IPS Document

Note 1 to entry: Attributes in IPS Attribute Collections are used in IPS Sections.

3.8.3 Data

3.8.3.1
dataset
set of data that is collected for a specific purpose

Note 1 to entry: A minimum data set is the name given to a selective core set of data that have been identified by users and stakeholders as the minimum for collection for a specific purpose.

Note 2 to entry: Data that are suitable for some purposes may have limited use for other purposes.

[SOURCE: Reference [20]]

3.8.3.2
data element
basic unit of identifiable and definable data of interest

[SOURCE: Reference [20]]

