SLOVENSKI STANDARD
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Zdravstvena informatika - Mednarodni povzetek podatkov o pacientu

Health informatics - The International Patient Summary

Medizinische Informatik - Die Patienten-Kurzakte für ungeplante, grenzüberschreitende medizinische Versorgung

Informatique de santé - Résumé international du dossier médical du patient

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35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN 17269:2019) has been prepared by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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Introduction

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

The scope of this standard is to achieve that goal by defining a minimal yet non-exhaustive data set and its associated business rules. This document is intended to be 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 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 International Patient Summary (IPS), with the initial focus upon unplanned care across national borders. Starting from this focus, the specification is intended to be used and be useful in local applications and also to be supportive of planned care. 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.

The data set described is intended for global use beginning with a shared vision[1] from a collaboration between CEN /TC 251 and HL7. CEN has produced a separate Technical Specification (CEN/TS 17288) that provides a European-specific guideline for IPS implementation. HL7 have produced CDA and HL7 FHIR[2] templates for realizing implementations of the IPS.

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 the ISO standard "System of concepts to support continuity of care" [3] and uses those concepts in the initial IPS scenario, which is fully described in Annex A.

This standard focuses upon the overall structure of the patient summary as well as the individual data elements that comprise it. The layout of this document 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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[1] CEN/TC 251 and HL7 have a shared vision for the patient summary, "to further the care for citizens across the globe by providing a single, common International patient summary (IPS) that is usable by all clinicians for the cross-border, unscheduled care of a person".

[2] HL7, Health Level Seven, CDA and FHIR are registered trademarks of Health Level Seven International. Reg. U.S. Pat & TM Off.

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, and IPS Metadata	Hierarchical description of data elements

The ordering of the IPS Data Blocks in this standard is alphabetic within three broad categories of Non-Clinical Data, Clinical Data and Metadata. This follows the eHDSI patient summary deployment project [4] and here is used purely to help presentation. However, in practice it is recognised 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 standard 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 any implementation. The name of the element is given in full, if the hierarchical arrangement in the description with the term is still open to ambiguous interpretation. This has been done 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.

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 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). The data set is minimal and non-exhaustive, providing a robust, well-defined core set of data items. This tight focus on the use case enables the IPS to also be used in planned care, and for both unplanned and planned care to 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 but takes into consideration other international efforts so as to provide an interoperable data set specification for global application.

This IPS standard 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 standard doesn't imply automatic technical interoperability; this result, enabled by this standard, can be reached with the conformity to standards indicated in the associated technical specification and implementation guides.

This international standard does not cover workflow processes of data entry, data collection, the summarization act itself, nor subsequent data presentation, nor assimilation, nor aggregation.

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., is specified in the associated Technical Specification (CEN/TS 17288).

In particular, representation by various coding schemes, additional structures and terminologies are not part of this standard. Terminology and its binding are addressed in the associated Technical Specification (CEN/TS 17288). The Identification of Medicinal Products standards (abbreviated to IDMP) are the recommended target for the Medication Summary related to this standard 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 may be necessary until IDMP becomes established as a norm.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies..

ISO 80000 (all parts), *Quantities and units*

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:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
compliance
adherence to requirements for the necessary consistency of one member of the family of specifications or standards with another which are established during the standardization process

[SOURCE: ISO/IEC 10746-2 (ISO, 2010)]

Note 1 to entry: In this context, compliance "refers to logical consistency and correspondence between a source artefact and a target artefact, with the target having undergone a transformation (usually a restriction). That is, given an existing source artefact such as a specification or standard, and a target artefact that resulted from applying a known transformation to the source, the target is in compliance with the source if the transformation is considered "legal" by the source artefact's originator [5].

Note 2 to entry: The target artefact is therefore compliant with the source artefact if and only if all conformant implementations of the target are also conformant with the source.

3.2
conformance
any proposition that is true of the specification must be true in its implementation

[SOURCE: ISO/IEC 10746-2 (ISO, 2010)]

Note 1 to entry: "A given implementation instance is said to be conformant to a given specification if the implementation instance satisfies the various requirements defined in the specification." [5].

3.3
continuity of care
efficient, effective, ethical care delivered through interaction, integration, co-ordination and sharing of information between different healthcare actors over time

[SOURCE: EN ISO 13940:2016]

3.4
core care plan
reusable content and structure for a potential care plan for a specified set of circumstances

[SOURCE: EN ISO 13940:2016]

3.5
derived model
any conceptual, logical or implementable information model that is obtained from applying a known transformation from a source information model

Note 1 to entry: example of derived models could be an EN 13606 archetype obtained from a conceptual model; or an HL7 FHIR profile derived from a HL7 FHIR Logical model; or a CDA template that specializes, or is adapted from, a parent CDA template. In this sense a CDA implementable specification can be considered a kind of derived model.

Note 2 to entry: An IPS derived model is any logical or implementable model or specification that complies with this standard.

3.6
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: EN ISO 13940:2016]

3.7
demand for initial contact
first demand for care concerning one or more specific health issues to be assessed by a healthcare provider

[SOURCE: EN ISO 13940:2016]

3.8
electronic patient summary
electronic health record extract containing essential healthcare information intended for specific uses

[SOURCE: EN ISO 13940:2016]

3.9
health condition
observed or potential observable aspects of the health state at a given time

[SOURCE: EN ISO 13940:2016]

3.10
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: EN ISO 13940:2016]

3.11
health record extract
EHR extract
health record extract consisting solely of electronic record components

[SOURCE: EN ISO 13940:2016]

3.12
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: EN ISO 13940:2016]

3.13
patient summary
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

[SOURCE: ISO/TR 12773-1:2009]

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".

3.14
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: EN ISO 13940:2016]

3.15
provenance
record that describes entities and processes involved in producing and delivering or otherwise influencing that resource

Note 1 to entry: Provenance provides a critical foundation for assessing authenticity, enabling trust, and allowing reproducibility. Provenance assertions are a form of contextual metadata and can themselves become important records with their own provenance. [6]

[SOURCE: W3C Provenance XG Final Report]

3.16
subject of care
Synonym: patient, client, citizen
healthcare actor with a person role, who seeks to receive, is receiving, or has received healthcare

[SOURCE: EN ISO 13940:2016]

4 Abbreviations

For the purposes of this document, the following abbreviations apply.

CEN	Comité Européen de Normalization (European Committee for Standardization, a federation of 34 national standards bodies that are also ISO member bodies)
CEN IPS	CEN International Patient Summary
CEN/TC 251	CEN Technical Committee 251 Health Informatics
eHDSI	eHealth Digital Services Infrastructure
EHR	Electronic Health Record
eHN	eHealth Network
EN	European Standard
epSOS	European Patients-Smart Open Services pilot project
EU	European Union
GP	General Practitioner
HL7	Health Level Seven
HL7 CDA	HL7 Clinical Document Architecture
HL7 FHIR	HL7 Fast Healthcare Interoperability Resources
HL7 IPS	HL7 International Patient Summary
IDMP	Identification of Medicinal Products standards
IHE	Integrating the Healthcare Enterprise
IPS	International Patient Summary

ISO	International Organization for Standardization
JIC	Joint Initiative Council
JIC PSSS	JIC Patient Summary Standards Set
PS	Patient Summary
TS	Technical Specification
UCUM	Unified Code for Units of Measure

5 Conformance

5.1 Introduction

To conform to the IPS standard, a patient summary shall be an IPS Document, comprising five mandatory IPS Data Blocks. One additional, required IPS Data Block, is conditional on the need for any cross-border application for the IPS. The six mandatory IPS Data Blocks within the IPS Document are:

1. Patient Attributes ('Patient's name' from the Collection)
2. Allergies and Intolerances
3. Medication Summary
4. Problems
5. Provenance ('Date of IPS Document Creation' from the Collection)
6. Cross Border (conditional)

An Attribute Collection Data Block is mandatory if an attribute within it is mandatory. The exception is the cross-border attribute collection; for cross-border applications only, a conformant IPS Document shall contain the IPS Cross Border data as the sixth required data element.

A conformant IPS Document may contain optional IPS Data Blocks, which are also defined in this standard.

A conformant IPS Document may also include non-IPS components if required. However, the non-IPS components are outside of the scope of this standard and are undefined in this standard and therefore no conformance for them from this document is possible.

Individual IPS Data Blocks can be used in non-IPS patient summaries providing a limited conformance to the IPS Data Set but for full conformance to this IPS standard, the IPS Document shall comprise at least the required IPS data elements specified in this clause and have the same purpose as a summary extracted from the patient's recorded history.

The IPS Document structure is essentially hierarchical. Whereas the hierarchical relationships between data elements are significant in terms of requirement, the order of sibling elements is arbitrary and has no requirement for any implementation.

5.2 IPS Conformance Detail

Table 2 shows the shorthand abbreviations for these 'requirement descriptors' and describes what they mean with respect to the different types of IPS data element. That having been said, the data element conformance information has been derived from HL7 and IHE semantics, which illustrate ways of representing data for transmission and receipt to ensure consistency.

A compliant model or a conformant implementation shall also:

1. Share the same scope of the IPS. Note, a Discharge Summary, although a type of continuity care document, does not have the same purpose as a patient summary and is not an IPS, although it can use the IPS Data Blocks as required.

2. Declare, if not self-evident, how the data patterns defined in section 6.3 are realized.

3. Fulfil the conformance rules, as described by the following table, for the IPS Data Blocks and elements specified in clause 7 Definition of the IPS Document or IPS.

Table 2 — Requirement Descriptors for IPS Document, Section types and IPS data

Value	***Description***	***Comment***
M	*Mandatory (exceptions not allowed)*	A mandatory element shall always be present and - where applicable - shall be valorised with valid values. No exceptions or empty/null values are allowed in this case. If it refers to a composite element (e.g. a section, a list; a label concept) the presence of the included elements is determined by the conformance rules of these sub-elements. Recipient shall understand mandatory elements. If a 'mandatory' element is missing then the document is no longer a conformant IPS. A derived model (that includes also implementable specifications) shall maintain an equivalent conformance strength.
R	*Required (exceptions allowed)*	A required element shall always be present and - where applicable - should be valorised with valid values. Exceptions or empty/null values are allowed in this case. If it refers to a composite element (e.g. a section, a list; a label concept a complex data type) the presence of the included elements is determined by the conformance rules of these sub-elements. Recipient shall understand required elements. If a 'required' element is missing then the document is no longer a conformant IPS. A derived model (that includes also implementable specifications) shall maintain an equivalent conformance strength; or may further constrain it (e.g. from 'R' to 'M').