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Zdravstvena informatika - Mednarodni povzetek podatkov o pacientu (ISO/DIS 27269:2024)

Health informatics - International patient summary (ISO/DIS 27269:2024)

Medizinische Informatik - Internationale Patienten-Kurzakte (ISO/DIS 27269:2024)

Informatique de santé - Résumé international du dossier médical du patient (ISO/DIS 27269:2024)

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IT applications in health care

zdravstveni tehniki technology

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DRAFT International Standard

ISO/DIS 27269

Health informatics — International patient summary

Informatique de santé — Résumé international du dossier médical du patient

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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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 for the Technical Committee ISO/TC 215, *Health informatics*. This second edition cancels and replaces the first edition of this document, which has been technically revised.

The first publication of this document was as a European norm in 2019. A fast-track process made the regional standard to a fully international one; this document was published as ISO 27269:2021. The next step in 2022 was to ensure that there was only one single standard by acknowledging the succession of ISO 27269 within Europe and to begin work on this document.

Each step was balloted, and a good consensus was reached. However, each iteration also picked up a few change proposals that for several reasons could not be included in edition 1, but which needed to be addressed. This document has retained its original scope, and its content has remained stable throughout its revision. The process has strengthened this document and has resulted in a small number of significant additions. The SDO's, with a stake in the development of IPS, ensured that the changes requested to this document were managed in a consistent way within the IPS Suite. <u>ANNEX B</u> shows the development process, and the main changes to this document are as follows:

- Two new IPS Sections have been added on request:
 - Alerts
 - Patient Story
- 'Cross-Border' and 'Provenance' detail have been merged into one 'Cross-Organization' Section
- Increased alignment with ISO/DIS 13940: 2025 definitions.

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.

Introduction

The goal of this document is to present a single, common International Patient Summary (IPS), comprising core content in a concise form. [1] This document is an 'IPS Artefact', one that defines a minimal, structured IPS Dataset with associated business rules for a patient summary. The IPS Artefact is implementation independent by intention; it is designed to support conformant implementation by providing collaborating SDOs with definition and clear description of the IPS Dataset.

The primary value of a patient summary, normalized by the IPS, is to facilitate and support appropriate clinical decision-making for the patient at the point of care [2].

The purpose of the IPS is to enable a concise summary to be used and to be useful in cross organization applications, supporting both planned and unplanned care. The IPS is designed to provide relevant information to assist care across any organizational boundary, including country borders and their jurisdictional requirements (e.g., local, regional, state/provincial, national).

The IPS Dataset in this document is small, even so there is no expectation that the full data set must be realized for a conformant specification or conformant implementation to be produced. Such IPS Artefacts need not specify all the optional IPS elements.

The IPS Dataset is non-exhaustive. New IPS Datablocks are introduced to meet new patient summary requirements be they clinical, administrative, or technological in nature. Figure 1 shows the existing DataBlocks from edition 1, along with a reorganized Data Block 'Cross organization' (conformance: Mandatory), and the two new data blocks requested, i.e., 'Alerts' (conformance: Required if Known) and 'Patient Story' (conformance: Optional).

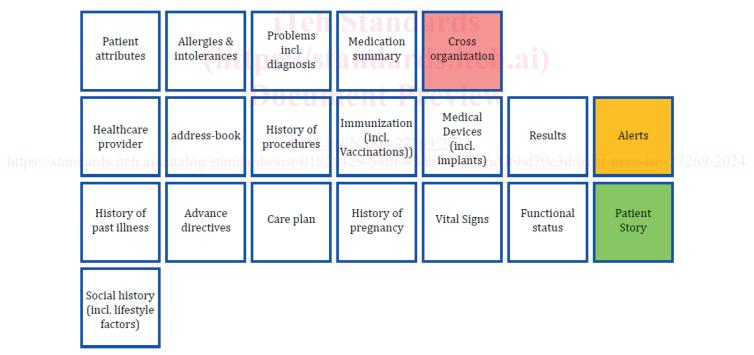


Figure 1 — The IPS Macro Datablocks, highlighting three substantive changes to this document.

0.1 The IPS Collaboration

The IPS facilitates a shared vision^[3] with collaborating SDOs (initially ISO/TC 215, CEN/TC 251, HL7 International, IHE International and SNOMED International), each contributing IPS Artefacts to an IPS Suite. From this document it is possible to derive compliant logical models that constrain it. Implementation-Guides are formalized in the HL7 CDA IG®²⁾ and HL7 FHIR¹⁾ IG®²⁾ and in the IHE IPS®²⁾ profile. The IPS Dataset

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.

is not bound by any terminology (see <u>ANNEX E</u>), although it does anticipate the use of the Identification of Medicinal Products standards (abbreviated to IDMP^[4]). IDMP is the recommended target for the Medication Summary related to this document but, prior to IDMP's full implementation in practice, this document cannot insist in its use now and recognizes that interim schemes might be necessary until IDMP becomes established as a norm.

SNOMED®²⁾ International has provided the SNOMED CT IPS Terminology set, which is directly maintained in response to global requirements for IPS.

The IPS emphasizes the need to provide generic solutions for global application and, where possible, reference is made to international standards rather than to local ones. However, different international contexts may 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, System of concepts to support continuity of care. This document used the eHN Guideline as the initial source for the patient summary requirement.

Representation by various coding schemes, additional structures and terminologies are not part of this document. Terminology and its binding are addressed in <u>ANNEX E</u>.

0.2 Maintenance of this document

To address the over-riding need for interoperability, the IPS stakeholder community requires this document be kept current and relevant. Revision of ISO 27269 needs to consider the capacity and capabilities of stakeholders requiring conformance to the IPS. Feedback from early implementers also needs to be addressed. To make these improvements achievable, an ISO Maintenance Agency (MA) has been created. The name and contact information of the MA can be found at.^[7] The MA allows new requests to be addressed in a timely fashion, to assess the clinical and technical impact, and to strive for backward compatibility for any agreed change. Updates are to be available online at.^[8] The inclusion criteria within this document (See <u>ANNEX C</u>) provides a transparent means of documenting change. <u>ANNEX B</u> documents the process used for this edition and is offered as a starting point for the MA.

The work undertaken in ISO to develop this document has attracted considerable interest from initiatives and organisations that would like to see extensions to its areas of clinical content coverage. Those items that would represent a minor adaptation to this version, and which have maturity and stability, have been added to the version in this document. There are other areas where further work is still needed to formalise the specification of the information.

The MA will keep track of proposals for potential extensions (e.g., continuing alignment with ISO IDMP suite of standards, and proposals for data items that are of primary relevance to children) and consider their maturity and relevance for inclusion in next version of this document.

0.3 Structure of this document

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 <u>Table 1</u>) 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-Hn describe the IPS Data Blocks in more detail; seven levels have been sufficient for this edition but that is not an upper limit and future editions may require more. Descriptors are used to better define the characteristics.

Table 1 — Description of IPS Dataset concepts and their hierarchical relationships

Hierarchy	Н0	H1	H2 – H7
IPS Mega Datablock		All relevant IPS Data Blocks are identified	Further detail is provided within the IPS Data Blocks' clauses
IPS Macro and Meso DataBlocks		Individual IPS Sections, and IPS Features	Hierarchical description for the Data Block

²⁾ SNOMED is the registered trademark of International Health Terminology Standards Development Organization. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

As the amount of information for each data block is variable, and can be extensive, this document presents the data as a set of tables with descriptors; each table provides an overview of the hierarchical structure with explicit links to more details using a consistent set of descriptors.

Rows in the table without further links to 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 Datablock is contextualized by the hierarchy to avoid any misunderstanding. For example, the term 'Device Type' is used rather than just "Type" albeit that it refers to a data element positioned within the Medical Device IPS Data Block.

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Health informatics — **International patient summary**

1 Scope

This document defines the core data set for a patient summary, which supports continuity of care for a person and assists with coordination of any healthcare experienced. The International Patient Summary (IPS) model supports the use case scenario for cross organization care.

The IPS is used in planned and unplanned care scenarios, and in local and international contexts.

This document provides an abstract definition of a patient summary from which derived models are implementable. Compliance with this document does not imply automatic technical interoperability. However, interoperability is enabled by this document through conformant IPS Artefacts such as implementation guides and profiles from within the IPS Suite.

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.

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 https://www.electropedia.org/

3.1 Healthcare

3.1.1

healthcare

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

[SOURCE: ISO 13940:2025, modified — healthcare rather than care is to the forefront in this document]

3.1.2

continuity of care

coherent and interconnected series of care events over time

[SOURCE: ISO 13940:2025, modified to concentrate on healthcare]

Note 1 to entry: the previous definition from ISO 13940:2015 emphasized the still relevant goals of 'continuity of care', i.e., efficient, effective, ethical care delivered through interaction, integration, co-ordination and sharing of information between different healthcare actors over time.

3.1.3

summary report

concise patient summary content, conveying specifically focused healthcare information in order to fulfil current information needs of the recipient

Note 1 to entry: The report may be compiled from more than one source, and the report itself may not be limited to a digital form.

[SOURCE: ISO 13940:2025, term modified from "clinical report" to "summary report"]

3.2 Terms related to actors

3.2.1

subject of care

patient

person seeking to receive, is receiving, or having received healthcare

Note 1 to entry: A fœtus may be considered as a subject of care when receiving care.

[SOURCE: ISO/DIS 13940, 3.3.8, modified by removing Examples]

3.2.2

organization

person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

Note 1 to entry: Groupings or subdivisions of organizations may also be considered as organizations where there is need to identify them in this way for purposes of information interchange.

Note 2 to entry: In this document, this definition applies to any kind of organizations, whatever their legal status.

[SOURCE: ISO 9000:2015, 3.2.1, modified notes replaced]

3.2.3

healthcare provider

care 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 IPS Feature '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: Organizations solely responsible for the funding, payment, or reimbursement of healthcare provision are not healthcare providers.

[SOURCE: ISO/DIS 13940, 3.3.10, modified Notes replaced]

3.3 Healthcare matter

3.3.1

health condition

aspects of the overall state of health of the subject of care at a given time

[SOURCE: ISO/DIS 13940, 3.2.4, modified by adding given time]

3.3.2

vital signs

common measurements that are considered important for tracking the patient state.