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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 27269

Health informatics — International patient summary

*Informatique de santé — Résumé international du dossier
médical du patient*

ICS: 35.240.80

ISO/TC 215

Secretariat: **ANSI**

Voting begins on:
2024-07-15

Voting terminates on:
2024-10-07

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

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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. [ANNEX B](#) 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).

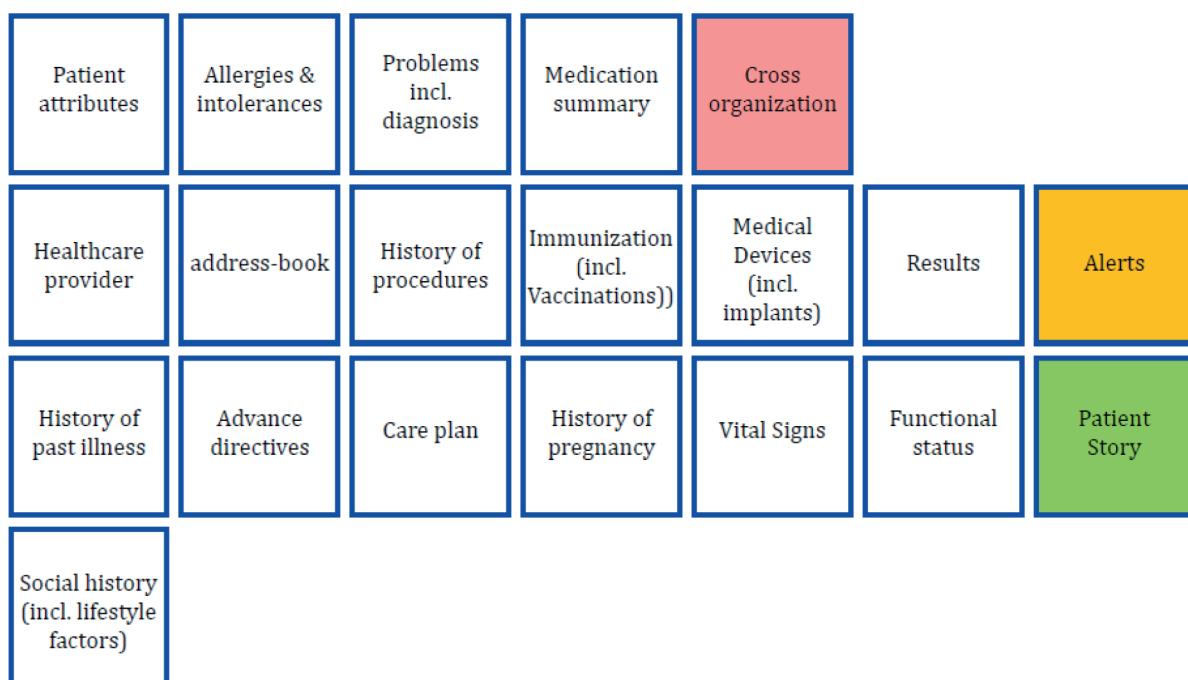


Figure 1 — The IPS Macro Datablocks, highlighting three substantive changes to this document.

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 [ANNEX E](#)), 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.

SNOMED²⁾ 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.^[5] This document used the eHN Guideline^[6] 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 [ANNEX E](#).

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 [ANNEX C](#)) provides a transparent means of documenting change. [ANNEX B](#) 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 [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-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	H0	H1	H2 – H7
IPS Mega Datablock	IPS Document	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.

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 foetus 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.

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/DIS 13940, 3.3.2, Modified as Note 2 omitted]

3.5 Healthcare planning

3.5.1

core care plan

care plan with reusable content addressing one or more specified health circumstances

Note 1 to entry: A core care plan is usually based upon knowledge in clinical guidelines (including protocols).

Note 2 to entry: Core care plans can be applied in care planning as a clinical process management method.

Note 3 to entry: A core care plan may include advanced formulated schemes for recommended care activities.

[SOURCE: ISO/DIS 13940, 3.7.7]

3.5.2

plan of care

care plan

dynamic, personalized plan including identified needed eligible social care activity, health objectives and care goals, relating to one or more specified social needs in a care 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.

Note 5 to entry: recommendations are not core care plans. If they are adopted and personalised for an individual, they are care plans.

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/DIS 13940, 3.7.1, modified to include 'healthcare' process]

3.6 Time

3.6.1

unscheduled care

unplanned care

healthcare service for an unexpected demand for care

Note 1 to entry: In this scenario, the assistance needed can be either 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

cross boundary

cross organization

communication across different types of organizations

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: Cross Organization is a more general case of communication between organizations of all types that includes organizational and professional boundaries found within, and across country's borders. This document is therefore applicable to interoperability across countries borders as well as national and local contexts.

3.7.2

demand for care

request for care

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/DIS 13940, 3.5.7 Modified to exclude examples]

3.8 Information Management

3.8.1 Concepts

3.8.1.1

patient summary

patient summary content

healthcare summary

summary content comprising a concise standardized collection of clinical and contextual information (retrospective, concurrent, prospective) that provides, minimally, a snapshot in time of a subject of care's relevant health information and healthcare

Note 1 to entry: The European Union eHN Guideline definition of a 'patient summary' in 2015 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".

Note 2 to entry: patient summary content is not limited to information in electronic format.

Note 3 to entry: patient summary content can be generated by a 'report', 'query', 'extract', or any other means, from one or more sources.

Note 4 to entry: The summary content may be generated by multiple authors.

Note 5 to entry: All patient summaries are snapshots (i.e., the content at a point of time), but not all snapshots are summaries (i.e., a snapshot can be just a data dump, and an extensive one at that, at a point in time which may be difficult for a recipient to manage). The purpose of the IPS is to be concise and clinically relevant as possible and any 'simple' snapshot will aim for brevity if it is to achieve those purposes. The IPS Dataset is minimal and can be used for snapshot and summary purposes. The goal is to deliver a true summary, however, the 'summarising act' and how the summary is created are outside of this document's scope.

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

3.8.1.2

electronic patient summary

digital medium representing patient summary content

[SOURCE: ISO/DIS 13940, 3.9.14]

3.8.1.3

International patient summary suite

IPS Suite

set of standard IPS Artefacts created by collaborating SDOs

3.8.1.4

International patient summary artefact

IPS Artefact

approved specification, standard and guidance materials for developing the IPS

3.8.1.5

medical device

instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
- investigation, replacement, modification, or support of the anatomy, or of a physiological process,
- supporting or sustaining life,
- control of conception,
- cleaning, disinfection or sterilization of medical devices,
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Note 1 to entry: This definition has been developed by the Global Harmonization Task Force (GHTF).

Note 2 to entry: Products which can be considered to be medical devices in some jurisdictions but not in others include:

- disinfection substances,
- aids for persons with disabilities,
- devices incorporating animal and/or human tissues,
- devices for in-vitro fertilization or assisted reproductive technologies.

Note 3 to entry: In certain regulatory jurisdictions, devices for cosmetic/aesthetic purposes are also considered medical devices.

Note 4 to entry: In certain regulatory jurisdictions, the commerce of devices incorporating human tissues is not allowed.

[SOURCE: ISO/IEC Guide 63:2019, 3.7]

3.8.2 Models

3.8.2.1

international patient summary model

IPS Model

purpose, concepts, and data structures to support an interoperable patient summary for international use

3.8.2.2

international patient summary document

IPS Document

IPS

electronic patient summary for use at the point of care comprising, as a minimum, the required IPS Data Blocks and, at a maximum, all IPS Data Blocks of the structured IPS Dataset

Note 1 to entry: The primary value of the IPS is to facilitate and support safe and appropriate clinical decision-making and patient care.

Note 2 to entry: The Use Case is to 'provide a patient summary for use at the point of care'; the following are IPS scenarios:

- 'Unscheduled, Cross organization care' is IPS scenario 1
- 'Scheduled, Cross organization care' is IPS Scenario 2

Note 3 to entry: International, national, and local applications of IPS are served by this document.

Note 4 to entry: IPS is applicable in any situation, irrespective of local/international and scheduled/unscheduled care situations.

Note 5 to entry: IPS Data Blocks may be used in other applications.

Note 6 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 7 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.

3.8.2.3

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 single element
 - e.g., 'name'
- Meso: a subset of IPS elements that can stand together, suitable for reuse.
 - e.g., Certain immunization data for a Vaccination Card, or a part of a discharge letter
- Macro: IPS Section and IPS Features are the two principal containers used for the meso and micro structures respectively
 - e.g., 'IPS Section 'Problems' and 'IPS Feature 'Cross organization' respectively
- Mega: IPS Data Set,
 - e.g., IPS Document, other specialized data summaries, the IPS Scope, two or more Macro IPS Data Blocks.

Note 2 to entry: IPS Features can be contained in an IPS Section, not vice versa.

Note 3 to entry: Reuse is possible for all data structures including the IPS Document.

3.8.2.3.1

international patient summary section

IPS Section

healthcare-specific content grouped with respect to clinical utility for inclusion in the IPS Document

Note 1 to entry: a section is a container of consistent data, acting as a structural component of the IPS document.

3.8.2.4.2

international patient summary feature

IPS Feature

a distinctive reusable grouping of data elements within the IPS Dataset

Note 1 to entry: An IPS Feature is a subset of data to be used within IPS Sections.

Note 2 to entry: An IPS Feature may be mandatory.

Note 3 to entry: The term 'IPS Attribute Collection' was used in the first edition of this document. 'IPS Feature' is the preferred term since its use by the ISO Maintenance Agency was established for ISO 27269.

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 [9]]

3.8.3.2

data element

basic unit of identifiable and definable data of interest

[SOURCE: Reference [9]]

3.8.3.3

international patient summary data set

IPS Data Set

IPS Dataset

minimal, non-exhaustive structured set of relevant data elements required for the IPS

Note 1 to entry: 'Minimal' and 'Non-exhaustive' criteria are taken from the eHN Guideline for the patient summary.

Note 2 to entry: 'Minimal' reflects the ideas of 'summary' and the need to be concise, but also alludes to the existence of a core set of data elements that all health care professionals can use; it is intended to be a speciality agnostic and condition independent set. It does not imply that all the items in the data set will be used in every *summary*. It is also possible to refine the data from a record such that the content of the summary is more relevant to a particular condition (e.g., asthma) but no asthma-specific elements will be specified in this document. The IPS Document or IPS can be extended by non-IPS standard condition-specific data.

Note 3 to entry: 'non-exhaustive' recognizes that the ideal data set is not closed, and is likely to be extended, not just in terms of requirement evolution, but also pragmatically in instances of use. However, such data are outside the scope of this current standard until review.

Note 4 to entry: The initial focus of use for IPS is unscheduled care but the IPS can also be used within scheduled care scenarios; scheduled care or planned care, would probably have access to the full patient record and provide a more extensive set of data but would also include the IPS Dataset elements.

3.8.4 Process

3.8.4.1 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

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 compliant with the source if the transformation is considered “legal” by the source artefact’s originator.

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.

Note 3 to entry: The family of specifications within the definition of this term alludes to the IPS Suite, which comprises its IPS Artefacts to be consistent.

3.8.4.2 conformance

fulfilment of a product, process, or service of specified requirements

Note 1 to entry: A given implementation instance is conformant to a given specification if the implementation instance satisfies the requirements defined in the specification.

[SOURCE: ISO/HL7 16527:2016, 3.2, modified — Addition of Note to entry.]

3.8.4.3 backward compatibility

compatible with the previous version of the standard or specification being used

4 Abbreviations

GDHP	Global Digital Health Partnership
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
PS	Patient Summary
SDO	Standard Development Organization
SNOMED	International Health Terminology Standards Development Organization
UCUM	Unified Code for Units of Measure

5 International patient summary data blocks

5.1 Introduction to the IPS Datablocks

[Figure 2](#) shows the data blocks that define the IPS in this document. The establishment of an IPS shall contain the following data blocks at a minimum:

1. Patient attributes *(Specifically, 'Patient's name' from the IPS Feature)*
2. Allergies and intolerances
3. Problems including diagnosis
4. Medication summary
5. Cross organization *(Specifically, 'Originating organization', 'Date of IPS document creation' from the IPS Feature)*

In [Figure 2](#), these five major IPS Datablocks are grouped and colour-coded in red. The amber blocks, shown in the second row, represent the IPS Data Blocks that are 'Required if Known', and the green coloured blocks shown represent the 'Optional' Datablocks for an IPS.

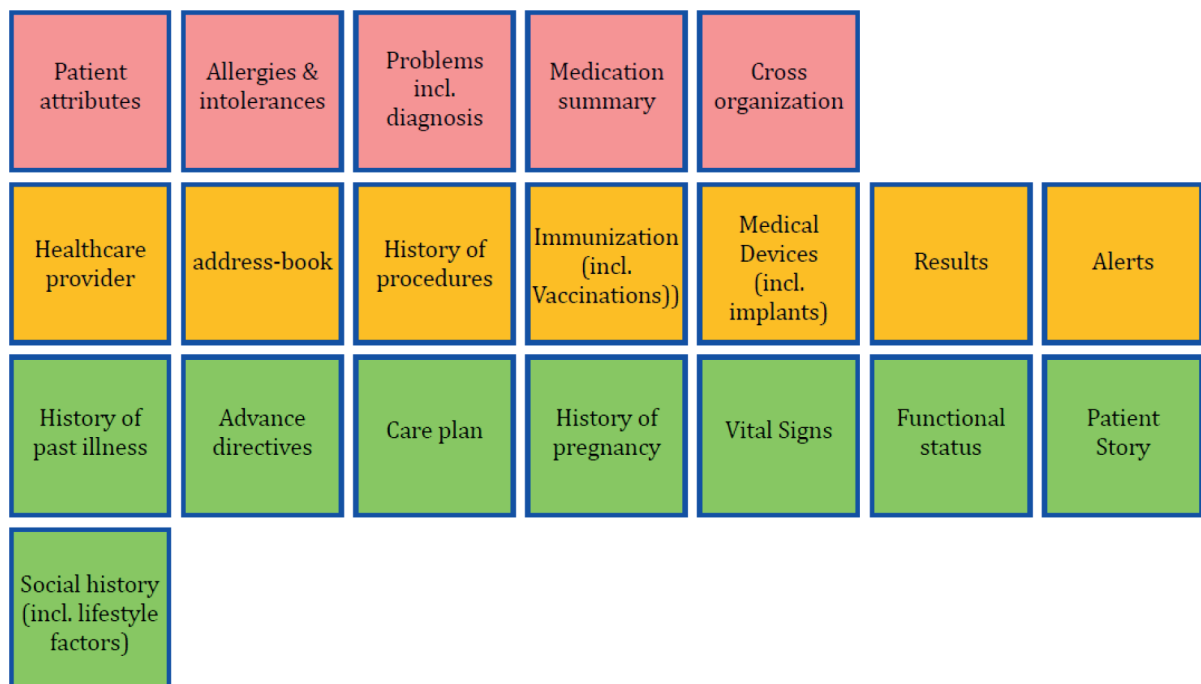


Figure 2 — The Major IPS Datablocks, colour-coded and grouped by strength of requirement.

Other data sets can be included in the establishment of the IPS based on organisational need etc. However, these are outside of the scope of this document and are undefined in this document. No conformance for them from this document is possible and examples are not included in [Figure 2](#).

5.2 Conformance Detail

The IPS is hierarchical. The top of the hierarchy is the IPS Document together with the 5 mandatory Datablocks and zero or more of the sibling Data Blocks identified in [Figure 2](#). Within every IPS Datablock the associated data SHALL be arranged in the same hierarchical style of presentation and uses a set of requirement descriptors to facilitate consistent data use within the IPS Model.

NOTE The order of sibling elements in both levels is arbitrary and has no requirement for any implementation.

This document defines three fundamental levels of compliance:

1. The first level represents full compliance with this document and the 'IPS Model'. Any derived model or implementation claiming full compliance SHALL conform to the IPS Model defined in this document, recognizing the scope, concepts, and data structures of the IPS Community to realise an interoperable IPS. Note, this document is not an implementation guide nor a complete solution which is beyond this document's scope. It is, however, intended to support these goals by providing a base for incremental improvement.
2. The second level is the 'IPS Document'. An IPS Document shall comprise the five mandatory Datablocks, and any recommended, and optional data blocks that can be part of the composition, as defined by this document. Note that the use of the 'document' metaphor does not restrict the IPS to a physical Document representation or to a CDA implementation that uses the same metaphor. The IPS high level structure SHALL be preserved, so, derived models are not allowed to break the existing sections into more specific ones.
3. The third level relates to the named IPS Data Blocks in [Figure 2](#), e.g., the IPS Sections and IPS Features, and also the smaller parts such as the Label Concepts (e.g., Vaccination). There is a limited number of mandatory data blocks; this document is intentionally permissive, making it easier to adopt, and easier to constrain later as required, rather than demand too much, too soon from would-be consumers with limited resource and capacity. As above with the IPS high level structure, these SHALL be preserved, so, derived models are not allowed to break the existing sections and features into more specific ones. All these standardized data blocks can be reusable for other applications.^[10] IPS Data Blocks can be used in non-IPS patient summaries too, providing a limited conformance to the IPS Dataset. [ANNEX A](#) gives an example of how the three 'levels' can be realised in relation to a use for a pandemic.

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.
2. Declare, if not self-evident, how the data patterns defined in [Clause 6](#) 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 (IPS).

[Table 2](#) shows the abbreviations for the 'requirement descriptors' and describes what they mean with respect to the different types of IPS data element. The data element conformance information has been derived from HL7® and IHE®³⁾ semantics, which illustrate ways of representing data for transmission and receipt to ensure consistency.

The value field of the Requirement Descriptors, (i.e., 'M', 'R', 'RK', 'O' and 'C') is used for all IPS Data Blocks. These descriptors are used in all the IPS Data Block Tables from [Clause 7](#), [Table 4](#), onwards.

3) IHE is a trademark of the Healthcare Information Management Systems Society in the United States and a trademark of IHE Europe in the European Community. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

Table 2 — Requirement Descriptors for IPS Document and IPS Datablocks

Value	Description	Comment
M	Mandatory (Exceptions not allowed)	A mandatory element SHALL always be present and - where applicable - SHALL be valorized 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. The way this "equivalence" is realized depends on the design patterns of the target model and by the mapping from this to the target model (not necessarily one-one).
R	Required (Exceptions allowed)	A required element SHALL always be present and - where applicable - should be valorized 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'). The way this "equivalence" is realized depends on the design patterns of the target model (e.g., using nullFlavored elements; using extensions or obligations); and by the mapping from this to the target model (not necessarily one-one).
RK	Required, if known	A "Required if known" element is one that should be provided. The "Required if known" is difficult to test and in some cases it might be ambiguous (as the Must Support in HL7 FHIR). But it is still useful from a business process perspective to distinguish what is truly optional (often not implemented at all) from what is strictly required. If there is information available, the element SHALL be present and - where applicable - valorized with valid values. If there is no information available, the element may be omitted, may be left empty, or may be valorized with exceptional or null values depending on the implementation. 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. A derived model (that includes also implementable specifications) SHALL maintain an equivalent conformance strength; or may further constrain it (e.g., from 'RK' to 'R'). The way this "equivalence" is realized depends on the design patterns of the target model and by the mapping from this to the target model (not necessarily one-one).

Table 2 (continued)

Value	Description	Comment
O	Optional	This data element can be omitted from a derived model, including from implementations. Recipient may ignore optional elements. 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 presence of this element and the conformance rules of its sub-elements. For example, no exception is raised if a required sub-element is missing, when the parent is omitted. The reason for specifying the optional data elements is to ensure that both sender and recipient use the appropriate semantic interpretation of these elements. No exception is raised if the data are missing.
C	Conditional (has associated condition predicates)	Depending on predicate conditions the element may assume different conformance strengths (e.g. O, R, RK) or not being present. A predicate can be simple (for example: «element A exists»; «attribute b = value1») or complex (for example: «element C exists» AND «the attribute x of element D = value2»). A conditional element may be evaluated on a single condition (if predicate A then 'Required' else 'Optional') or on multiple conditions (e.g. if predicate A then 'Required'; if predicate B then 'Optional'; else 'Not Present'). The resulting conformance strength (M, R, RK, O, ...) is determined by the conditions. 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 combination of the predicate conditions of this element and the conformance rules of its sub-elements. For example: 1. no exception is raised if a required sub-element is missing, when the parent is correctly omitted. 2. an exception is raised if a required sub-element is missing, when the parent is present. Derived models or implementable specifications shall maintain an equivalent conformance strength; but it is allowed to modify the conformance strength if the predicate condition permits. Recipient shall understand conditional elements, when required. For example, a conditional element that could be optional or not present could be omitted by a derived model and ignored by a recipient. Or, a condition for which a conditional element become required does not apply to a jurisdiction, in that case a jurisdictional specification could omit that element and recipient could ignore it. Depending on the conditions, exception is or is not raised if the data are missing.

A compliant model or a conformant implementation is not supposed to realize a 1 to 1 mapping with this document, excepting for the high level IPS structure. For example, the fact that “a mandatory element SHALL always be present” does not imply that an element with this name shall be included in the derived model, neither that it is realized by a distinct element. Derived models SHALL however represent that information following the rules specified by this document, and that the corresponding element shall be mandatory. The typical example is the textual description; often realized by a single “section level” narrative element. Moreover, entries can be specialized to better describe different kinds of entry (e.g. results can be specialized into lab, path, imaging and other results).

The IPS high level structure SHALL be preserved, so, derived models are not allowed to break the existing sections into more specific ones (e.g., introducing specialized advance directives or results sections).

6 Descriptors for the IPS Dataset

6.1 General

The purpose of [Clause 6](#) is to describe the layout of the IPS Data Blocks in tabular form, adding more detail to [Table 1](#). [Table 1](#) is in Clause 0.3, which introduces the hierarchical levels used in the structure of this document. Whilst the tables give a consistent presentation of the mega and macro data blocks, there are links and a set of descriptors, with associated narrative to provide a detailed description of the DataBlocks. The tabular form names the content and describes the hierarchy. The table provides details of conformance and a simple description. Further details are given by links to a set of descriptors for the data element and to further detailed information concerning the data elements.

The Descriptors used are introduced in [Table 3](#). Certain Descriptors may not be applicable for every part of each IPS Data Block. Nevertheless, they shall be explicitly included for each data element and their applicability status shall be explicitly stated so as to avoid any possible confusion by their absence.

Table 3 — Listing and meaning of IPS Data Element Descriptors

<i>Descriptor</i>	<i>Comment</i>
Purpose	The meaning and value of the data element
Definition	A formal description (this may not be necessary if common use is well known)
Business Rules	This descriptor is used to describe business logic.
Missing	The meaning of absent data and how it should be addressed
Format	How the data are to be represented if more information is required to clarify data type use.
Inclusion Criteria	The rationale for including the data block within this document This provides an assessment of an element's value to the IPS, resulting in a decision to 'include', 'defer' or 'exclude' a proposal for changing the document.
Currency	Temporal recommendations for ensuring data are the most relevant for both 'planned' and 'unplanned' care.
Examples	Brief explanation regarding how a particular data block is used in practice
Notes	Further description related to the data elements, for example if 'optional' requires more detailed explanation or some contextual information is required. For some coded elements examples of concepts used for valorising the element are provided; no vocabulary bindings are however defined by this document.

The IPS Dataset is packaged within the IPS Document for the purpose of explanation. It is a logical construct, and although a patient summary may be communicated by some form of document, this document does not imply that this is the only way for a patient summary application to be implemented.

Confidentiality: The IPS is an example of 'Personal Data' and may be subject to the data protection rules implemented within a jurisdiction, or within a region^[11].

This document uses this descriptor to highlight areas of concern but does not provide implementation detail. In this iteration, the confidentiality requirement applies to the whole IPS by default; the exception being a further note attached to the 'Advance Directives' IPS Section. If IPS Data Blocks are reused for purposes other than for the IPS then appropriate safeguards SHALL have to be taken to protect the patient.

NOTE IPS contains personal data which may be subject to local regulations.

The IPS Document will usually comprise several data elements taken exclusively from the IPS Dataset. The exception being the non-IPS section material which is not within the scope of this document but may supplement the IPS Dataset in particular circumstances (e.g., additional data for a specific condition or specialty).