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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).

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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.

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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.

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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/

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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]

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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]

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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.]

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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.

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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]]

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3.8.3.3
international patient summary data set
IPS Data Set
IPS Dataset
minimal, non-exhaustive set of data elements required for the international patient summary

Note 1 to entry: 'Minimal' and 'Non-exhaustive' criteria are derived 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 extract 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 EHR and provide a more extensive set of data but would also include the IPS Data Set elements.

3.8.3.4
international patient summary data set component
IPS Dataset component
IPS Data Set component
content found within the health record and defined within the IPS Data Set

3.8.3.5
international patient summary sub-component
IPS sub-component
general document and application information defined within the IPS Data Set

EXAMPLE provenance and cross border information

3.8.3.6
provenance
information on the place and time of origin, derivation or generation of a resource or a record or proof of authenticity or of past ownership

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[7].

[SOURCE: ISO/IEC 11179-7:2019, 3.1.10, modified — Addition of Note to entry.]

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 in compliance with the source if the transformation is considered "legal" by the source artefact's originator[6].

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.

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3.8.4.2
conformance
fulfilment of a product, process, or service of specified requirements

Note 1 to entry: According to Reference [6], 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.]

4 Abbreviations

CEN	European Committee for Standardization
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
SDO	Standard Development Organization
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
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 this document, 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:

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1. Patient Attributes ('Patient's name' from the Collection)
2. Allergies and Intolerances
3. Medication Sunmmary
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 includes IPS Data Blocks, which are required when known defined in this document.

These IPS data blocks are:

1. Healthcare Provider (Attribute Collection)
2. Patient's Address Book (Attribute Collection)
3. History of Procedures
4. Immunizations
5. Medical Devices
6. Results

A conformant IPS Document may contain optional IPS Data Blocks, which are also defined in this document. The optional IPS Data Blocks within the IPS Document are:

1. Advance Directives
2. Functional Status
3. History of Pregnancy
4. History of Past Problems
5. Plan of Care
6. Social History
7. Vital Signs

A conformant IPS Document may also include non-IPS components if required. However, the non-IPS components are outside of the scope of this document and are undefined in this document 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.

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5.2 IPS Conformance Detail

The IPS standard defines three fundamental levels of compliance, each having associated business rules and data definitions:

1. The first level represents full compliance. It comprises the IPS Scope and the complete IPS model, which represents both the IPS Document Model and the other IPS Data Blocks.

2. The second level is the 'IPS Document Model'. 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. This Document level defines a conformant IPS as a whole, detailing the purpose of the document and the mandatory, recommended and optional data blocks that can be part of the composition, as defined by the Standard. There is a limited number of mandatory data blocks; the standard 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. The IPS Document Model may be reused, but its purpose will be different.

3. The third level relates to the named IPS Data Blocks, i.e., the IPS Sections and IPS Attribute Collections, and also the smaller parts such as the Label Concepts (e.g. Vaccination). All these standardized data blocks are also reusable for other applications[21].

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®[4)] 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 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).

4) 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.

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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 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.
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').
RK	*Required, if known*	A "Required if known" element is one that should be provided. 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').

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Table 2 *(continued)*

Value	*Description*	*Comment*
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.
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.

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).

As mentioned above 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

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or results sections); while they can extend the IPS with additional non-IPS sections not covered by the existing sections.

6 Descriptors for the IPS Data Set

The informative description of the IPS Data Set provides the general layout of what follows. The purpose of this clause is to describe in detail the normative content, to identify and give meaning to the descriptors that are used to specify each component and sub component of the IPS data standard.

Each part of the IPS Data Set is described in the same way to provide a consistent and comprehensive expression of the requirement. The first part is a hierarchy represented within a tabular form naming and describing the data element and any constituent items. The table provides the naming and high-level conformance detail of the data elements. The second part comprises further details and includes a set of descriptors for the data element and 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 the IPS. Nevertheless, they will be explicitly included for each data element and their applicability status will be explicitly stated.so as to avoid any possible confusion by their absence.

Table 3 — Listing and meaning of IPS Data Element Descriptors

Descriptor	***Comment***
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	A predicate which defines or constrains some aspect of ***the IPS*** and always resolves to either true or false. More generally, 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 element within this document (consistent with the IPS Scenario)
Currency	Temporal recommendations for ensuring data are the most relevant for both 'planned' and 'unplanned' care.
Examples	Brief explanation regarding how a particular data element is used in practice
Notes	Further description related to the data elements, for example if 'optional or conditional' 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 Data Set is packaged within the IPS Document for the purpose of explanation within this document. 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 will be subject to the data protection rules implemented within a jurisdiction, or within a region, as in the case of a cross-jurisdictional regulation such as Regulation EU 2016/679 GDPR. This document uses this descriptor to highlight areas of concern but does not provide implementation detail. In this first iteration, the confidentiality requirement applies to the whole IPS by default; the exception being a further note attached to the 'Advance Directive' IPS Section. If IPS Data Blocks are reused for purposes other than for the IPS then appropriate safeguards will have to be taken to protect the patient.

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

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6.1 Patterns within the IPS Data Set

6.1.1 General

This document describes an abstract data model which is implementation independent.

The IPS Data Set is hierarchical and the nesting organizes the data elements. At the bottom of the hierarchical description in the IPS there are data elements that can be described in a generic fashion that are not use case dependent. Within the IPS Data Set it is easy to identify structures that have a similar pattern. These "patterns" may or may not correspond to "well-known" data types (for example coded elements; date-times; person names; addresses). Examples of these primitive value types that reoccur in the IPS Data Set are:

— Identifiers

— Entity Names (people, organizations, products, etc.)

— Date/time elements (or interval of date/time)

— Address details

— Telecom details

Where applicable, the ISO 21090 data types have been used as reference for describing their main characteristics. For example, when the name of a person is provided, that name should be provided as a list of parts such as given name or family name, prefix, suffix; when more than one part is given it should be allowed to distinguish among their usage (e.g. official name; maiden name); more representations should be recorded when the name is not alphabetic; and so on. All these properties are summarized indicating that the Person Name is related to the ISO EN.PN datatype without repeating all of these characteristics.

When an ISO 21090 data type is referred to, it is not assumed that implementations will have direct conformance (see ISO 21090:2011, 5.2) with them. However, derived models, including implementable specifications, should declare how the used patterns will be realized when not self-evident by the used standards (i.e. indirect conformance, see ISO 21090:2011, 5.3).

In order to better show how the patterns defined by this document may be realized by derived models (in this case by an implementable specification), a reference to the HL7 FHIR® datatypes has been also included. The reason of this choice is due to the presence – at the best of our knowledge – of only two standardization activities related to this IPS standard: one based on the CDA R2 standard and one on HL7 FHIR®. Since the CDA R2 standard uses a modified form of a previous version of the ISO data types it has not been considered useful to add this as reference. The mapping between the ISO datatypes and the HL7® V3 R1.1 is in fact straightforward: e.g. IVL(PQ) is IVL_PQ; ED is ED; and so on. Other reference implementations may be added in the future if new IPS standardization activities using different data types will be realized.

6.1.2 Label Concept

The term 'Label Concept' is used to describe data model elements that play the role of container and usually have complex structures, for instance they may contain clinical statements or details of participants. Label Concepts also facilitate recursive definitions. For example, the result of an assessment can be an assessment.

6.1.3 List

List structures are commonplace in clinical records. Virtually all of the IPS Sections comprise lists as part or perhaps all of their main content. It is therefore possible to represent parts of this specification with formal list structures to support business rules that assist with precision, conciseness and readability. However, the representation chosen to represent the lists in this document does not

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necessitate a particular implementation (e.g. it is not required that an IPS list element is realized by using a 'list' resource if HL7 FHIR® is used).

A list may be an empty list, a container awaiting content. The items in the list are of the same type and so their structure/content can be defined as a single template, rather than creating a separate template for each individual item to be placed in the list. For example, a list of Lifestyle factors, would have the same item structure (described generically once) for a factor, but the list would grow as new lifestyle data was required to be added, e.g. a smoking factor, an alcohol factor, drug dependency etc.

In the Patient Summary and similar clinical communication, it is necessary to determine why certain data are missing, and whether or not its absence is permissible. For example, the IPS Section PROBLEMS is mandatory in the IPS Document, and it comprises a list of problems; it maybe that the patient has never had any type of problem before this particular event and the problem list will be empty. In this example it would be necessary to explicitly state that there are NO problems in the patient's history. Often a predicate is evaluated, and the following material becomes conditional on the result.

6.1.4 Reference

A "reference" pattern is a means to provide a directional link from a source element to a target. References can be internal, i.e. they refer to information included in the patient summary; or external, i.e. they refer to objects found elsewhere.

Depending on the technology used and on the type of object referenced, different types of information may be requested, e.g. just an URL (literal reference); just an identifier (logical reference); a set of identifiers; a set of identifiers plus other information needed to access the object; and so on. An example is in the Advance Directive Section which may need a link to an external legal document.

6.1.5 Person Name

A name for a person constituted by a sequence of name parts, such as given name or family name, prefix, suffix. There is a need to be able to provide single-string and component-based representations of Person Name' in different scenarios reflecting jurisdiction and cultural practices.

Preferred use within borders in addition to permitting cross-border settings should be facilitated

References: ISO 21090:2011 EN.PN, ENXP datatypes for Person Name properties and parts; HL7 FHIR® HumanName.

Business Rules:

1. If not otherwise specified, it is allowed to provide more 'Person Name' elements for the same person.
2. Person Name SHOULD include the given and family components and at least one of the two SHALL be present.
3. In case of non-alphabetic representations of the names, at least one alphabetic representation SHALL be provided.

Variants such as 'preferred name' or 'alias' are implicit in the Person Name data type. For example, when the name of a person is provided, that name should be provided as a list of components such as given name or family name, prefix, suffix; when more than one component is given it should be allowed to distinguish among their usage (e.g. official name; maiden name); more representations should be recorded when the name is not alphabetic; and so on. All these properties are summarized indicating that the Person Name is related to the ISO EN.PN datatype without repeating all of these characteristics."

6.1.6 Coded Element

An element representing a single concept, usually supplied by providing a reference to external code systems, terminologies or ontologies. In exceptional cases, it might be allowed to define it by the provision of text.

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References: ISO 21090: 2011 CD, CS; HL7 FHIR® CodeableConcept code.

6.1.7 Date Time

A quantity specifying a point on the axis of natural time. It might be a complete or a partial date (e.g. just year or year + month). It may indicate the time zone.

References: HL7 FHIR® dateTime, Date

It is to be noted that partial dates and various formats of full dates are commonplace in clinical applications and are therefore present in the IPS Document and its many sections. It should be noted that date and time data can be critical data pertaining to patient safety and that the exchange format does not correspond to how that data are presented by an application. Furthermore, the degree of precision for a date will vary according to context, and the particular business rule in force will be stated in the IPS Component that is relevant.

Business Rules:

1. Dates SHALL be valid dates
2. If no additional constraints have been specified (e.g. day precision), at least a full year SHALL be specified
3. If the time is provided the time zone SHALL be indicated.

6.1.8 Identifier

An element that uniquely identifies a thing or an object.

References: ISO 21090:2011 II; HL7 FHIR® Identifier

6.1.9 Address

Mailing and home or office addresses.

For the IPS purposes the addresses are always sequences of address parts (e.g. street address line, country, ZIP code, city) even if postal address formats may vary depending on the country.

An address may or may not include a specific use code; if this attribute is not present it is assumed to be the default address useful for any purpose.

References: ISO 21090:2011 AD (for address), ADXP (for address parts); HL7 FHIR® Address

Business Rules:

1. If a known address is provided then it SHALL include at least one address part: addresses are never documented as a single string.

6.1.10 Telecom

This pattern provides detailed information about Telecommunication Addresses associated to a person or an organization. For example, a patient's contact telephone, email, etc.

References: ISO 21090:2011 TEL; HL7 FHIR® ContactPoint

Business Rules:

1. At least one telephone or mail address SHALL be provided; it is allowed to provide both

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6.1.11 Organization Name

A name for an organization.

References: ISO 21090:2011 EN.TN; HL7 FHIR® string.

Business Rules:

1. Organization Names SHALL be represented as a simple string.
2. In case of non-alphabetic representations of the names, at least one alphabetic representation SHALL be provided.

6.1.12 Text

This pattern provides a means to convey textual information about a thing. For example, an advance directive, a medication statement, a section narrative.

It is primarily intended for human interpretation. This includes unformatted or formatted language.

References: ISO 21090:2011 ED; ED.TEXT; SD.TEXT; HL7 FHIR® Narrative, string.

6.1.13 Any

Defines the basic properties of every data value. This is conceptually an abstract type, meaning that no proper value can be just a data value without belonging to any concrete type.

References: ISO 21090:2011 ANY

6.1.14 Range

A set of ordered Physical Quantities, that indicates that the value comes from a range of possible values.

In general, a range may be expressed in different ways: using a low and high value (e.g. from 3 mg to 5 mg); using a centre and a width (4 mg ± 1 mg); and so on.

This document imposes restrictions on the possible options allowed by the ISO 21090 data type, but derived models can further constrain the range representation.

Business Rules:

1. A range SHALL be represented specifying the low and high limits of the range (e.g. from 2 ml to 4 ml); No other options are allowed.
2. The units of the low or high limits SHALL match.
3. It is allowed to omit or value with exceptional values the low and the high limits. (e.g. to indicate <5 mg)

References: ISO 21090:2011 IVL(PQ); HL7 FHIR® Range

6.1.15 Quantity

A dimensioned quantity expressing the result of measuring

References: ISO 21090:2011 PQ; HL7 FHIR® Simple Quantity

Business Rules:

1. The choice of unit SHALL follow recommendations of ISO 80000-1:2009, in particular the International System of Units, SI, where possible

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2. For communication of units between systems UCUM expressions are recommended. UCUM unit expressions should not be used in screen, display or print interfaces intended for human reading.

In such interfaces the presentation shall follow the recommendations of ISO 80000-1:2009.

6.1.16 Period

A set of consecutive values of time-stamps.

In general, a period may be expressed in different ways: using start and end date times (e.g. from 2004 to 2005); using a start time and a width, a time quantity (e.g. from January 2nd 2019 for 3 weeks) and so on.

This document imposes restrictions on the possible options allowed by the ISO 21090 data type, but derived models can further constrain the period representation.

References: ISO 21090:2011 IVL(TS); HL7 FHIR® Period

Business Rules:

1. A period SHALL be represented either specifying the start and the end date times or specifying the start date time and the width. No other options are allowed.
2. A derived model can restrict the representation to a start and end date times.
3. It is allowed to omit or value with exceptional values the used components (start date time; end date time; width).

6.1.17 General Time Specification

An unordered set of distinct values that are time quantities. It is an abstract type and it is used to specifying the timing of events and actions and the cyclical validity-patterns that may exist for certain kinds of information: e.g. Twice a day from January 2017 to March 2017, excluding Saturday and Sunday.

A working GTS is specified as an expression tree built using a combination of operator and components (e.g. intervals, point in times, event related periodic interval, and so on).

References: ISO 21090:2011 QSET(TS)

Business Rules:

1. Any implementable specification SHALL describe how this abstract pattern is realized (e.g. combination of intervals and event related times).
2. No members of the GTS set SHALL be valued with null or exceptional values (e.g. nullFlavors).

6.1.18 String

The character string datatype stands for text data, primarily intended for machine processing (e.g. sorting, querying, indexing, etc.) or direct display. Used for names, symbols, presentation and formal expressions.

A String shall have at least one character or else have a nullFlavor.

References: ISO 21090:2011; ST; HL7 FHIR® string

6.1.19 Ratio

In this domain, ‘ratio’ is used in a very broad sense as in ISO 21090. A quantity constructed as the quotient of a numerator quantity divided by a denominator quantity.

“Ratios are different from rational numbers, i.e. in ratios common factors in the numerator and denominator never cancel out.

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