



BSI Standards Publication

Health informatics — The International Patient Summary

National foreword

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Health informatics - The International Patient Summary

Informatique de santé - Résumé international du
dossier médical du patient

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

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European foreword

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

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of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 2020.

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

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

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

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

This document defines the International Patient Summary (IPS), with the initial focus upon unplanned care across national borders. Starting from this focus, the specification is intended to be used and be useful in local applications and also to be supportive of planned care. It emphasizes the data required and the associated business rules to support use and the necessary conformance of the use case for an international patient summary.

The data set described is intended for global use beginning with a shared vision¹ from a collaboration between CEN /TC 251 and HL7. CEN has produced a separate Technical Specification (CEN/TS 17288) that provides a European-specific guideline for IPS implementation. HL7 have produced CDA and HL7 FHIR² templates for realizing implementations of the IPS.

The 'International' element of the IPS emphasizes the need to provide generic solutions for global application moving beyond a particular region or country; consequently, wherever possible, reference is made to international standards, rather than local ones. However, different international contexts will offer a variety of requirements that need to be considered to ensure that patient safety is not compromised. The IPS is underpinned by the ISO standard "System of concepts to support continuity of care" [3] and uses those concepts in the initial IPS scenario, which is fully described in Annex A.

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

¹ CEN/TC 251 and HL7 have a shared vision for the patient summary, "to further the care for citizens across the globe by providing a single, common International patient summary (IPS) that is usable by all clinicians for the cross-border, unscheduled care of a person".

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

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

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

The ordering of the IPS Data Blocks in this standard is alphabetic within three broad categories of Non-Clinical Data, Clinical Data and Metadata. This follows the eHDSI patient summary deployment project [4] and here is used purely to help presentation. However, in practice it is recognised that individual attributes might appear in different categories depending on dynamic use rather than static classification.

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

1 Scope

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

It uses the European Guideline from the eHN as the initial source for the patient summary requirements but takes into consideration other international efforts so as to provide an interoperable data set specification for global application.

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

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

It is not an implementation guide that is concerned with the various technical layers beneath the application layer. Implementation guidance for specifically jurisdictional concerns, e.g. Directives, terminologies, formats etc., is specified in the associated Technical Specification (CEN/TS 17288).

In particular, representation by various coding schemes, additional structures and terminologies are not part of this standard. Terminology and its binding are addressed in the associated Technical Specification (CEN/TS 17288). The Identification of Medicinal Products standards (abbreviated to IDMP) are the recommended target for the Medication Summary related to this standard but, prior to IDMP's full implementation in practice, this IPS standard cannot insist in its use at this point in time and recognizes that interim schemes may be necessary until IDMP becomes established as a norm.

2 Normative references

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

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

3 Terms and definitions

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

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

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

3.1

compliance

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

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

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

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

3.2

conformance

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

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

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

3.3

continuity of care

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

[SOURCE: EN ISO 13940:2016]

3.4

core care plan

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

[SOURCE: EN ISO 13940:2016]

3.5

derived model

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

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

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

3.6

demand for care

demand for healthcare

demand for healthcare provider activities expressed by a healthcare actor

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

[SOURCE: EN ISO 13940:2016]

3.7

demand for initial contact

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

[SOURCE: EN ISO 13940:2016]

3.8

electronic patient summary

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

[SOURCE: EN ISO 13940:2016]

3.9

health condition

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

[SOURCE: EN ISO 13940:2016]

3.10

health record component

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

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

[SOURCE: EN ISO 13940:2016]

3.11

health record extract

EHR extract

health record extract consisting solely of electronic record components

[SOURCE: EN ISO 13940:2016]

3.12

healthcare information request

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

[SOURCE: EN ISO 13940:2016]

3.13

patient summary

Health record extract comprising a standardized collection of clinical and contextual information (retrospective, concurrent, prospective) that provides a snapshot in time of a subject of care's health information and healthcare

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

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

3.14**point of care**

location where direct healthcare activities are performed

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

[SOURCE: EN ISO 13940:2016]

3.15**provenance**

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

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

[SOURCE: W3C Provenance XG Final Report]

3.16**subject of care**

Synonym: patient, client, citizen

healthcare actor with a person role; who seeks to receive, is receiving, or has received healthcare

[SOURCE: EN ISO 13940:2016]

4 Abbreviations

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

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

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

5 Conformance

5.1 Introduction

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

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

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

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

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

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

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

5.2 IPS Conformance Detail

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

A compliant model or a conformant implementation shall also:

1. Share the same scope of the IPS. Note, a Discharge Summary, although a type of continuity care document, does not have the same purpose as a patient summary and is not an IPS, although it can use the IPS Data Blocks as required.
2. Declare, if not self-evident, how the data patterns defined in section 6.3 are realized.
3. Fulfil the conformance rules, as described by the following table, for the IPS Data Blocks and elements specified in clause 7 Definition of the IPS Document or IPS.

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

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

Value	Description	Comment
<i>RK</i>	<i>Required, if known</i>	A “Required if known” element is one that should be provided. If there is information available, the element must be present and - where applicable - valorised with valid values. If there is no information available, the element may be omitted, may be left empty, or may be valorised 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’).
<i>C</i>	<i>Conditional (has associated condition predicates)</i>	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 doesn’t 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.

<i>Value</i>	<i>Description</i>	<i>Comment</i>
<i>0</i>	<i>Optional</i>	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.

6 Definition and Descriptors for the IPS Data Set

6.1 International patient summary data set

Term: international patient summary data set

Abbreviation: IPS Data Set

Definition: minimal, non-exhaustive set of data elements required for the international patient summary

NOTE 1 'Minimal' and 'Non-exhaustive' criteria are derived from the eHN Guideline for the patient summary.

NOTE 2 '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 standard. The IPS Document or IPS can be extended by non-IPS standard condition-specific data.

NOTE 3 '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 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.

6.2 IPS Terms and Descriptors

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. Neither the less, 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 <i>the IPS</i> 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 standard (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.

The IPS Data Set is packaged within the IPS Document for the purpose of explanation within this standard. It is a logical construct, and although a patient summary may be communicated by some form of document, this standard 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 standard 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 standard but may supplement the IPS Data Set in particular circumstances (e.g. additional data for a specific condition or specialty).

Term: international patient summary data set component

Synonym: IPS Data Set component

Definition: content found within the health record and defined within the IPS Data Set

Term: international patient summary sub-component

Synonym: IPS sub-component

Definition: general document and application information defined within the IPS Data Set

EXAMPLES: provenance and cross border information

Term: international patient summary section

Synonym: IPS Section

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

Term: international patient summary attribute collection

Synonym: IPS Attribute Collection

Definition: 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.

Term: unscheduled care

Synonyms: unanticipated care; unplanned care

Definition: 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.

Term: cross border

Definition: passing, occurring, or performed across a border between two countries

NOTE 1 to entry: This scenario emphasises the fact that countries will have different jurisdictions that might have legal, organisational and cultural implications 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 organisational and professional boundaries found within a country's borders, and therefore the substantive part of this standard is also applicable to national and local contexts.

6.3 Patterns within the IPS Data Set**6.3.1 General**

This IPS standard 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, organisations, 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 conformance³ 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 conformance⁴).

In order to better show how the patterns defined by this standard 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.

6.3.2 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.

6.3.3 List

List structures are common place 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 standard does not necessitate a particular implementation.

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

³ See ISO 21090 section 5.2 direct conformance

⁴ See ISO 21090 section 5.3 indirect conformance.

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.

6.3.4 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.

6.3.5 Person Name

A name for a person constituted by a sequence of name parts, such as given name or family name, prefix, suffix.

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 SHALL include at least the given and family components and therefore names are never documented as a single string.
3. Exceptions are allowed for the given and family parts. Derived models can further constrain this rule requiring to have only valid family and given names.
4. 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 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.”

6.3.6 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.

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

6.3.7 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: ISO 21090:2011 TS; 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.

6.3.8 Identifier

An element that uniquely identifies a thing or an object.

References: ISO 21090:2011 II; HL7 FHIR Identifier

6.3.9 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.

6.3.10 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

6.3.11 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.

6.3.12 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 written language.

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

6.3.13 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

6.3.14 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 $\pm$ 1 mg); and so on.

This standard 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

6.3.15 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: 2009 'Quantities and Units standards series', in particular the International System of Units, SI, where possible
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: 2009 'Quantities and Units standards series'.

6.3.16 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 standard 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).

6.3.17 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).

6.3.18 Healthcare Provider

Synonyms: care provider, health provider, health service provider, healthcare service provider

Definition: healthcare actor that is able to be assigned one or more care period mandates

[Source: EN ISO 13940:2016]

Plural: healthcare providers;

NOTE 1 Healthcare Provider is described in the Patient's Address Book IPS Section.

NOTE 2 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 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.

References: ISO 13940:2015

6.3.19 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

6.3.20 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.

The Ratio datatype supports titre (e.g. "1:128") and other quantities produced by laboratories that truly represent ratios. Ratios are not simply "structured numerics", particularly blood pressure measurements (e.g. "120/60") are not ratios. See also note 1 RTO (ratio) description" [ISO 21090:2011]

A Ratio may be used for example for indicating medicine strengths (e.g. 100 mg / 100 ml) where, 100 mg is the numerator quantity and 100 ml is the denominator quantity. (not just a rational number).

References: ISO 21090:2011; RTO; HL7 FHIR Ratio

6.4 Model Extensibility

Model derived from this standard, including implementable specifications, are allowed to further constrain this model; this can be done by constraining the conformance strength of an element, where explicitly allowed; collecting narrative descriptions into a single section-level narrative block; including additional elements to the existing sections, lists and label concept; adding non-IPS sections to the International Patient Summary.

In case of inclusion of additional elements or sections not defined by this standard (hereafter called extensions), a derived model, including implementable specifications, is compliant to this standard if the model extensions fulfil the following basic principle:

- within the scope of the international patient summary the recipient can support safe care provisioning, even if it is not able to process semantics of the extensions.

An extension shall therefore not change the meaning of the elements defined by this standard.

7 Definition of the IPS Document or IPS

7.1 Overview Description: THE IPS DOCUMENT

Table 4 — The IPS Document

Conformant IPS comprising selected patient data and other IPS data				
Hierarchy: H0	H1	Conformance	Description	Further Details
IPS Document Synonyms: Acronyms: IPS		M	The IPS Document describes the totality of patient summary content to be interchanged as a conformant IPS	#1
	IPS Attribute Collection: Patient Attributes	M	Contains ' Patient's name ' attribute necessary for IPS conformance	
	IPS Section: Allergies and Intolerances	M	Section necessary for IPS conformance	
	IPS Section: Medication Summary	M	Section necessary for IPS conformance	
	IPS Section: Problems	M	Section Necessary for IPS conformance	
	IPS Attribute Collection: Provenance meta data Collection	M	Contains ' Date of IPS Document Creation ' attribute necessary for IPS conformance	
	IPS Attribute Collection: Cross border data	C	Data necessary for IPS cross border application conformance only	
	Other defined IPS Sections, and IPS Attribute Collection, 'Patient's Address Book'	RK	Remainder of IPS Data Set	#2
	IPS Sections that are optional	O		#3
	Non-IPS Sections	Undefined	Definition outside of this IPS version's scope.	#4