INTERNATIONAL STANDARD

ISO 27269

First edition
2021-04

Health informatics — International patient summary

Informatique de santé — Résumé international du dossier médical du patient

Reference number
ISO 27269:2021(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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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.

1) HL7 FHIR is the registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

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).

2) HL7, HL7 CDA IG, HL7 IG and HL7 IPS are the registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the products named.

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

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.

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/

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]

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]

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.]

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.

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]]

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.

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:

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.

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.

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').

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

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).

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

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.

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

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

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.

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

6.2 Model Extensibility

Model derived from this document, 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 document (hereafter called extensions), a derived model, including implementable specifications, is compliant to this document 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 document[21].

7 Definition of the IPS Document (IPS)

7.1 Overview Description: THE IPS DOCUMENT (Table 4)

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: IPS 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 Collections.	RK	Remainder of IPS Data Set	#2
	IPS Sections that are optional	O		#3
	Non-IPS Sections	Undefined	Definition outside of this IPS iteration's scope.	#4

7.2 Detailed Description: THE IPS DOCUMENT

Purpose: provides the logical structure required to convey patient summary content, i.e. documentation concerning the IPS itself and patient-related information, in order to provide continuity of care and to coordinate further healthcare activity. The concept of 'document' is well understood throughout this domain and has therefore been used in this first iteration. The fact that this document uses this concept to describe a patient summary, however, does not restrict any implementation to adopt that form.

The International Patient Summary (IPS) is synonymous with the IPS Document and is described as being a "minimal and non-exhaustive Patient Summary, specialty-agnostic, condition-independent, readily usable by all clinicians for the care of a patient."

Definition:

For the formal definition of the IPS Document, see (3.8.2.1).

Business Rules: No rules are given as to how the IPS is generated or consumed within this document. However, principles to permit the document to be extended by data not described in this document are necessary and are presented in 7.2 #4.

Missing: For the purposes of this document, 'missing' refers to absence/presence of IPS data elements within the IPS Document and the associated meaning or interpretation of that state. This descriptor is not applicable to the document as a whole.

Format: The IPS is a data transfer object. The format of the IPS content is taken from this document, it is specified in the pertinent clause related to the data elements of the IPS Data Set. Whereas the domain model includes complex and primitive data types, the IPS Document will be resolved to all primitive types (e.g. character, string) so as to be in serializable form for transfer. The transform processes from the Domain to the serializable form and the converse transformation are not addressed here.

Inclusion Criteria: The IPS is required for the use case scenario of unplanned or unscheduled cross-border care but is also usable for other related scenarios, i.e., scheduled care and national or local use.

Currency: A patient summary for unplanned, cross border care is a snapshot of what is known about the patient and their health state at the time of the healthcare event. Although the situation is not necessarily an emergency, it is likely that there is some urgency and therefore it is desirable that the patient summary for the attending healthcare provider is concise and relevant. The IPS Data Set is meant to be core data set and therefore applicable and understood for most situations; additional data, say for a chronic condition, may be necessary to complement the core. This descriptor describes details regarding 'planned' and 'unplanned' care in the IPS Scenarios.

Examples: A conformant IPS might contain:

(1) IPS {Required data elements only ('M' and 'R')}

(2) IPS {Required data elements ('M' and 'R') and Conditional 'C' cross-border data} for cross-border

(3) IPS {Required data elements ('M' and 'R') 'C' metadata and one or more available 'RK' data elements}

(4) IPS {Required and conditional data elements ('M', 'R', 'C'); none, some or all RK; and some or all optional 'O' data elements)

Notes: The IPS shall contain the mandatory data elements from the IPS Data Set to be conformant. The IPS Data Set comprises material from the eHN data set given in the Guideline (version 2) and, in addition, can comprise other materials from other sources deemed to be important for international use.

#2 IPS Sections Required if known

An IPS comprises IPS Sections and IPS Attribute Collections, drawn from the IPS Data Set. Only a subset of these is required to claim full conformance with this document, but the remainder may still be required and useful for a range of care events.

In this document there are just three (clinical data) IPS Sections considered to be mandatory (i.e. Allergies and Intolerances, Medication Summary, and Problems). If there is no information available, the included data element SHALL contain a value indicating the reason for omission of the data. As these three IPS Sections are mandatory, the 'absence of data' status may be the only data content exchanged.

In addition to the three clinical IPS Sections that are mandatory, the Patient Attributes and Provenance meta data are also mandatory.

There are a number of other IPS Sections that are 'required if known'. These are deemed important for inclusion in a patient summary but it is accepted that data may not be collected in the same form or at all in different countries and within countries, with the consequence that data are not universally available for interchange at this point in time. It maybe that the data are not available at source **or** perhaps not collected. These are pragmatic considerations and an acknowledgement of the burden that comes with the collection of these extended items.

'Required if known' requires a reason to be given if the data are not available for the care event. It maybe that the data are not available at source and perhaps not collected. Another reason might be the author's intent. For example, the author might not send data because of its confidential nature or because of its

volume may defeat the purpose of keeping the IPS as concise as possible. The IPS components with designation 'RK' are:

— Healthcare Provider (Attribute Collection)

— Patient's Address Book (Attribute Collection)

— History of Procedures

— Immunizations

— Medical Devices

— Results

#3 IPS Sections that are Optional

Some IPS sections may be absent without any concern being raised. The optional IPS Sections are:

— Advance Directives

— Functional Status

— History of Pregnancy

— History of Past Problems

— Plan of Care

— Social History

— Vital Signs

#4 Non-IPS Sections

The IPS Data Set is intended to be minimal and non-exhaustive. The fact that the data set is non-exhaustive means only that there will inevitably be other data that a requestor wishes to include in a patient summary that has not been defined here. For example, data relating to different specialities or to a patient's chronic condition. In these circumstances, it may be necessary for the IPS to be complemented by other clinical data that is not a part of the IPS Data Set. It is recognized that data outside of this 'core' may indeed be valuable, but, at this time that data are not defined in this version of the standard. The IPS is intended to be speciality agnostic, and condition-independent. It is permissible to optionally transmit Non-IPS data within the IPS Document but that content cannot be tested for conformance. The minimal IPS Data Set, however, might suffice in some circumstances and therefore it is valid if there are no Non-IPS Sections within the IPS; no error or exception would be raised by a receiving system. A different type of Summary, e.g. a Hospital Discharge Summary might use the IPS descriptions in this document but it is created for a different purpose and has a different role to play; for these reasons it should not be considered to be an IPS.

Examples: Non-IPS Sections might provide more specific data for a chronic condition e.g. COPD, or for a different speciality such as Social Care that are beyond the scope of the present IPS.

8 Definition for IPS Attribute Collection: PATIENT ATTRIBUTES

8.1 Overview Description: PATIENT ATTRIBUTES (Table 5)

Table 5 — Patient Attributes Overview

Patient non-clinical data							
Hierarchy: H1	H2	H3	H4	H5	Conformance	Description	Further Details
IPS Attribute Collection Patient Attributes Synonyms: None; Acronyms: None					M	Every PS conformant to IPS SHALL contain 'Patient's Name' from this IPS Attribute Collection.	#1
	Patient's name				M	Person Name	#2
	Patient's address and telecom				RK	Label Concept	#3
		Address			C	Address	
		Telecoms			C	Telecom	
	Administrative gender				RK	Coded Element	#4
	Date of birth				R	Date Time	
	Patient's preferred language				O	Coded Element	
	Healthcare related identifiers				RK	List	#5
		Patient identifier			RK	Identifier	#6
	Insurance information				O	Label Concept	#7
		Insurance identifier			RK	Identifier	

8.2 Detailed Description: PATIENT ATTRIBUTES

#1 IPS Attribute Collection PATIENT ATTRIBUTES

Purpose: An IPS Attribute Collection will provide various data that may be used individually or collectively to identify, or to ensure the identity of a person and/or patient to an attending clinician at the point of care, to inform of any preferences or insurance and to introduce a new patient to an attending clinician.

Definition: Non-exhaustive, collection of data used for administration, identification, assurance of identity and preferences and introductions within a patient summary.

Business Rules:

1. The Patient's postal and telecom addresses SHALL be required if known.
2. Insurance Information, and specifically the insurance number, SHALL be used as an identifier if and only if required by the Country of Affiliation.

Missing: This IPS data are required for identification purposes (for administrative and/or clinical use) and will likely be present in any IPS, although it does not imply that every attribute within it will necessarily be present or complete. 'Insurance number' is conditional and will be dependent upon a country's jurisdiction.

Format: Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion Criteria: While this data may also fulfil an administrative role in planned care or in the follow up after unplanned care, the defined use case of unscheduled care for the IPS suggests that the immediate use of this data may be used for identification and communication purposes.

Currency: This IPS Attribute Collection shall always have current information, e.g. current names and numbers rather than historic associations.

Examples: Attending clinician asks for address details to confirm the person's identity.

Notes: In the eHN Guideline the data in this component was broadly categorized as being 'Administrative', however, the critical role that 'identification' plays in all processes mean that the emphasis was changed in this document.

Whilst all the Attributes are collected under the same IPS component for convenience, it is not necessary for any implementation to relate to them in the same way.

#2 Patient's name

The name of a person is a familiar, cross-sector idea, independent of a particular use case. It is explained in the Primitive Values clause. (See Patterns, 6.1). This is mandatory for conformance.

#3 Patient's address and telecom

This Label Concept positions the nested attributes. However, it is useful to note that the patient's address is administrative but can also be used in the clinical process to assist with the verification of the patient's identification.

#4 Administrative gender

Some countries require 'gender' as part of their identification of the patient. It SHALL not be used to record a person's sex.

Notes: This item should not be used to record the 'sex' of a person. 'Sex' is a clinical term but not always provided or collected at source. It may be included as an optional attribute in the next iteration of this document.

#5 Healthcare related identifiers

A list of patient identifiers.

Notes: Arguably a national health number would be of more use locally than for cross-border purposes. It is also possible, even probable, that a person will have several numbers, each one related to one or more healthcare providers. In an international context, a national healthcare identifier may be useful. However not all countries have such a registration scheme in place.

#6 Patient identifier

Note, Patient Number is often used as a synonym, albeit that the identifier is not necessarily numeric; some jurisdictions use the Social Security Number as a healthcare identifier.

#7 Insurance information

Insurance information is not always required in a patient summary. However, in some jurisdictions, the insurance number is also used as the patient identifier. It is necessary not just for identification but also forms access to funding for care. In those countries that require such information, it shall be present.

9 Definition for IPS Attribute Collection: HEALTHCARE PROVIDER

9.1 Overview Description for HEALTHCARE PROVIDER (Table 6)

Table 6 — HEALTHCARE PROVIDER Overview

Patient non-clinical data						
HierarchyH1	H2	H3	H4	Conformance	Description	Further Details
IPS Attribute Collection: HEALTHCARE PROVIDER Synonyms: None Acronyms: None				RK	healthcare actor that is able to be assigned one or more care mandates.	#1
	Healthcare provider (person)			C	Label Concept	
		Name		R	Person Name	
		Role		O	Coded Element	
		Telecoms		RK	Telecom	
	Healthcare provider (organization)			C	Label Concept	
		Name		R	Organization Name	
		Telecoms		RK	Telecom	

9.2 Detailed Description for HEALTHCARE PROVIDER

#1 IPS Attribute Collection HEALTHCARE PROVIDER

Purpose: This IPS Attribute Collection provides contact details for healthcare people and organizations relevant to the patient with respect to the IPS.

Definitions: See Healthcare provider (3.2.2).

10 Definition for IPS Attribute Collection: PATIENT'S ADDRESS BOOK

10.1 Overview Description for PATIENT'S ADDRESS BOOK (Table 7)

Table 7 — Patient's Address Book Overview

Patient non-clinical data						
HierarchyH1	H2	H3	H4	Conformance	Description	Further Details
IPS Attribute Collection: PATIENT'S ADDRESS BOOK Synonyms: None Acronyms: None				RK	People and organizations' address details relevant for the patient's healthcare.	#1
	Preferred healthcare providers			RK	List	#2
		Preferred healthcare provider		R	Healthcare Provider	
	Other's address details			O	List	#3
		Addressee		R	Label Concept	
			Role	RK	Coded Element	
			Name	R	Person Name	
			Address	O	Address	
			Telecoms	RK	Telecom	

10.2 Detailed Description for PATIENT'S ADDRESS BOOK

#1 IPS Attribute Collection PATIENT'S ADDRESS BOOK

Purpose: This IPS Attribute Collection provides an Address Book resource detailing the address details for people and organizations relevant to the patient with respect to the IPS.

Definitions: Considered to be generic to the English language and not specific to this document.

Business Rules:

1. The Preferred Healthcare Provider (either Person or Organization, or both) SHALL be required if known.

Missing: The preferred healthcare provider (i.e. healthcare professional and/or the responsible organization who are to be contacted for this care event; this is what 'Preferred' means) will always be required; other people/organizations that might be contacted may not be present within the address book, but if they are then they shall have a specific role recorded. Whilst all the attributes are collected under the same IPS component for convenience, it is not necessary for any implementation to treat them in the same way.

Format: Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion Criteria: The eHN Guideline refers to this data as 'contact information'. Given that 'contact' in this domain has several meanings, this document uses the familiar concept of 'address book' to collect together the attributes identified by the Guideline. Some of the data within the Address book can have several purposes, for example: The patient address can be used to verify a person's identity and also their country of origin and residence; the preferred healthcare provider is necessary for cross-border data and provenance meta data requirements, and the people with specific roles may play a part in relation to the IPS Advance Directives Section.

Currency: All the details reflect the current state; no historic data are to be included, e.g. past addresses. For 'unplanned care', 'preferred' data are the most minimal and concise contact details to be exchanged.

Examples: Carer, Primary Care doctor, Cardiologist, Rheumatologist, Gynaecologist, etc.

Notes: A list relating to people or organizations details who might need to be contacted for this care event; it is not to do with previous care events involving this patient. These entities can be considered as providers (person or organization) who are wholly or partially responsible for the safety and well-being of the subject of care.

#2 Preferred healthcare providers (Persons and Organizations)

If known, this information shall be provided. Note it is not necessarily the case that Preferred Healthcare Provider is the same party as the source of the patient summary; the latter is given by the Provenance meta data. 'Preferred' indicates the most relevant entity to be contacted for use in this patient summary.

#3 Other's address details

The urgency of the scenario suggests that the contact details will be minimized to the most likely means of getting in touch. The role distinguishes between individuals (and organizations) by means of their function with respect to the patient's care to enable the relevant person to be contacted by the healthcare provider at the point of care. The role can be both functional (e.g. doctor) and a specialization (e.g. specialist).

Examples: Legal guardian, Next of kin, Decision maker with respect to advance directives, clinical specialist.

11 Definition for IPS Section: ADVANCE DIRECTIVES

11.1 Overview Description for ADVANCE DIRECTIVES (Table 8)

Table 8 — Advance Directives Overview

Patient clinical data							
Hierarchy: H1	H2	H3	H4	H5	Conformance	Description	Further Details
IPS Section: ADVANCE DIRECTIVES Synonyms: Living will, Personal directive Acronyms: None					O	A conformant IPS document MAY include this section. Healthcare directives concerning life or after life wishes of the patient	#1
	Advance directives				R	List	#2
		Advance directive			R	Label Concept	
			Person authorizing directive		RK	Label Concept	#3
				Name	RK	Person Name	
				Role	RK	Coded Element	
				Telecoms	RK	Telecom	
			Directive category		O	Coded Element	#4
			Directive description		C	Text	#5
			Reference to legal document		C	Reference	#6

11.2 Detailed Description for ADVANCE DIRECTIVES

#1 IPS Section ADVANCE DIRECTIVES

Purpose: Deemed to be of value in unplanned care if a life-threatening event or fatality occurs and the patient or a legitimate decision maker has stipulated what should happen with respect to the patient who is too ill or too hurt to express their wishes.

Definition: provision for healthcare decisions in the event that, in the future, a person is unable to make those decisions.

Business Rules:

1. The reference or the description of the Advance Directive SHALL be provided; it is allowed to provide both.
2. The address information concerning the decision maker SHOULD be within the Patient's Address Book IPS Section.
3. Legal and interpretation issues concerning registering and acting on advance directives are out of scope for this specification, but they SHOULD be addressed in any IPS implementation.

Missing: If this IPS Section is present then there will be information about the Advance Directives in the IPS.

Format: Contains structured information related to the identity and address details of the decision maker and a description of all known patient's advance directives; this may reference a legal document. As there may be multiple directives it may be that the content is organized as a list. Furthermore, there may just be a reference to a document (sometimes known as a Living Will) rather than simple text. This reference may be an URL but is not restricted to just that form of reference.

Inclusion criteria: Although not explicitly identified in the eHN Guideline it could be argued that it is a valid interpretation or extension for the 'Treatment Recommendations' (Variable 2)'. It also appears in other recommendations from HL7® and JIC. It is of particular relevance to unplanned (and emergency) care of the IPS Scenario.

Confidentiality note: This component may carry sensitive data beyond healthcare data. In particular if this IPS Section refers to a legal document, then additional considerations may be required.

Currency: It is assumed that the advance directives stated or referred to are the most current. Even so, the clinician at the point of care will often feel obliged to check the veracity of the data before accepting it.

Examples: 'Objection to transfusion'; 'No attempts to be made to resuscitate patient'; 'permission to donate body parts on fatality'.

Notes: This IPS Section on Advance Directives is within the defined scope of the IPS but is a relatively new concept which explains the diverse ways that are currently used in formatting the necessary information. Even if it is recognized that several kinds of directives may exists, it is not expected that specialized Advance Directives sections will be created by the derived models. This IPS Section is increasingly important but varies from jurisdiction to jurisdiction.

#2 Advance directives

A list comprising one or more advance directives

Note: Although not in this version of the standard, future versions of the Advance Directives IPS Section might also include definitions and descriptions regarding 'CONSENT practices' as directives and mandates from particular jurisdictions.

#3 Person authorizing directive

The source of each directive if known; the decision maker is usually the patient and/or a delegated person such as a Legal Guardian. There is an opportunity to be more specific about 'role' if known. If the authority is not the patient, then it will be someone to contact for further information and clarification of the patient's wishes. The postal address elements are not included reflecting the urgency for the contact; however, full details should be consistent and available from the Patient's Address Book.

#4 Directive category

There are Directives related to decisions prior and after death. For example, directives prior to death might relate to:

- Intubation
- Tube Feedings
- Life Support
- Cardiopulmonary resuscitation
- Antibiotics
- Resuscitation
- Artificial respiration
- Administration of medication
- Transfusion
- Transfer of care to hospital
- Dialysis procedure
- Intravenous infusion

#5 Directive description

Textual description of the directive.

Derived models may choose to use distinct elements for each narrative directive or to collect them into a single section level narrative block.

#6 Reference

The Directives may take the form of a reference to a legal document (e.g. Living Will) or an external textual description.

12 Definition for IPS Section: ALLERGIES and INTOLERANCES

12.1 Overview Description for ALLERGIES and INTOLERANCES (Table 9)

Table 9 — Allergies and Intolerances Overview

Patient clinical data							
Hierarchy: H1	H2	H3	H4	H5	Conformance	Description	Further Details
IPS Section: ALLERGIES and INTOLERANCES Synonyms: None Acronyms: None					M	Every PS conformant to IPS SHALL contain this IPS section.	#1
	Allergies/Intolerances content status				C	Coded Element	#2
	Allergies and Intolerances				C	List	#3
		Allergy/Intolerance			M	Label Concept	
			Allergy/Intolerance description		R	Text	#4
			Clinical status		R	Coded Element	#5
			Onset date		RK	Date Time	#6
			End date		C	Date Time	#7
			Criticality		O	Coded Element	#8
			Certainty		O	Coded Element	#9
			Type of propensity		RK	Coded Element	#10
			Diagnosis		O	Coded Element	#11
			Reaction		RK	Label Concept	#12
				Manifestation of the reaction	RK	Coded Element	#13
				Severity	RK	Coded Element	#14
			Agent		R	Label Concept	
				Agent code	R	Coded Element	#15
				Category	O	Coded Element	#16

12.2 Detailed Description for ALLERGIES and INTOLERANCES

#1 IPS Section ALLERGIES and INTOLERANCES

Purpose: To inform the treatment and care provisioning of an attending clinician to identify problem or to avoid adverse events arising from action taken. At a minimum, it should list currently active and any relevant historical allergies and adverse reactions.

Definition: relevant allergies and/or intolerance conditions for subject of care.

At a minimum, it should list currently active and any relevant historical allergies and adverse reactions.

NOTE 'Alerts' was used to describe this Section in the eHN guidance -lines, but 'Alerts' are far more general and are not regarded here as a synonym. 'Alerts' more generally are recorded under 'Problems' in this iteration.

Business Rules:

1. This is a required IPS Section and shall be in the document. Unknown and known absence should be stated explicitly.

2. If 'there is content' then Allergies and Intolerances list SHALL be non-empty AND the content status SHALL be omitted. (i.e. it is not Required).

3. If content status records absence then Allergies and Intolerances list SHALL be omitted.

4. End Date SHOULD be given if Clinical Status indicates 'resolved'.

Missing: This is a required IPS Section for conformance and SHALL NOT be empty; at the least, some statement is given explaining the missing data.

Format: Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion Criteria: This is a required IPS Section. Useful for both planned and unplanned care in the IPS Scenario.

Currency: All current and past conditions that are relevant for the scope of the IPS.

Examples: Anaphylactic Reaction to Peanuts - (Mild, Moderate, Severe) Eye swelling reaction to cat dander - (Mild, Moderate, Severe) Tongue swelling reaction to Bactrim, Angioedema. Intolerance to aspirin due to gastrointestinal bleeding. Intolerance to Captopril because of cough (the patient is not allergic but cannot tolerate it because of persistent cough). For care provision, this information may inform food given during an hospital stay.

Notes: None.

#2 Allergies/Intolerances content status

As this IPS Section is mandatory for conformance, information about "known absence of allergies" or no information about allergies is required to be stated. Known Content will be accompanied by the conditional list of Allergies and intolerances.

#3 **Allergies and Intolerances**

If allergies present then they shall be listed else give explicit reasons for why none are recorded. An ordered list comprising the name, code, a description of the Allergy/intolerance and Agent details for each Allergy/intolerance.

#4 Allergy/Intolerance description

Textual description of the allergy or intolerance.

Derived models may choose to use distinct elements for each narrative statement or to collect them into a single section level narrative block.

#5 Clinical status of the condition

Provides the current status of the allergy or intolerance, for example, whether it is active, in remission, resolved, and so on. Adopted value sets should include concepts such as:

— active

— inactive

— resolved

#6 Onset date

It shall be provided with the highest known precision, at least year.

#7 End date

If Clinical Status is non-active, then an exception can be raised to indicate inconsistency.

It shall be provided with the highest known precision, at least year.

#8 Criticality

This attribute represents the gravity of the potential risk for future life-threatening adverse reactions when exposed to a substance known to cause an adverse reaction in that individual. When the 'worst case' result is assessed to have a life-threatening or organ system threatening potential, it is considered to be of high criticality.

Notes: In some contexts, the **severity** is used as a synonym of the **criticality,** but the IPS standards treat them as distinct concepts.

Adopted value sets should include concepts such as:

— High Risk

— Low Risk

— Exception: Unable to assess risk

#9 Certainty

Assertion about certainty associated with the propensity, or potential risk, of a reaction to the identified substance.

Adopted value sets should include concepts such as:

— Unconfirmed (There is not sufficient diagnostic and/or clinical evidence to treat this as a confirmed condition.)

  — Provisional (This is a tentative diagnosis - still a candidate that is under consideration.)

  — Differential (One of a set of potential (and typically mutually exclusive) diagnoses asserted to further guide the diagnostic process and preliminary treatment.)

— Confirmed (A high level of certainty about the propensity for a reaction to the identified substance, which may include clinical evidence by testing or re-challenge).

— Refuted (A propensity for a reaction to the identified substance has been disproven with a high level of clinical certainty, which may include testing or re-challenge, and is refuted.)

#10 Type of propensity

Type of allergy or intolerance.

Format: Coded information:

Adopted value sets should include concepts such as:

— Allergy

— Intolerance

— propensity to adverse reaction

#11 Diagnosis

A code indicating the type of reaction and the agent; an alternative option for describing an allergy to the agent. Described with Textual information if coded data are unavailable.

Example: lactose intolerance.

#12 Reaction

A Label Concept recognizing that other data concerning the reaction may be made available in later versions of this document.

#13 Manifestation of the reaction

Description of the clinical manifestation of the allergic reaction. Example: anaphylactic shock, angioedema (the clinical manifestation also gives information about the severity of the observed reaction).

Textual information if coded/quantified data are not available. This is typically a more complex structure than simple text.

Example: "intestinal discomfort" is the manifestation of the reaction.

#14 Severity

Coded element that described the subjective assessment of the severity of the condition as evaluated by the clinician, in the case of an allergy it is used as attribute of a manifestation of a reaction. For example, a person may have a severe rash as reaction, that it is not however critical.

Adopted value sets should include concepts such as:

— Severe

— Moderate

— Mild

#15 Agent Code

A specific allergen or other agent/substance to which the patient has an adverse reaction propensity. This will be taken from a list of agents and the associated code from an adopted value set.

#16 Category

Allergy substance category.

Adopted value sets should include concepts such as:

— Food

— Medication

— Environment

— Biologic

13 Definition for IPS Section: FUNCTIONAL STATUS

13.1 Overview Description for FUNCTIONAL STATUS (Table 10)

Table 10 — Functional Status Overview

Patient clinical data						
Hierarchy: H1	H2	H3	H4	Conformance	Description	Further Details
IPS Section: FUNCTIONAL STATUS Synonyms: None Acronyms: None				O	A conformant IPS document MAY include this section. It provides information about patient disabilities and their functional assessment(s).	#1
	Disabilities			C	List	#2
		Disability		R	Label Concept	
			Disability description	R	Text	#3
			Disability code	O	Coded Element	#4
			Onset date	O	Date Time	
	Functional assessments			C	List	#5
		Functional assessment		R	Label Concept	#6
			Functional assessment description	R	Text	#7
			Date of assessment	RK	Date Time	
			Functional assessment type	RK	Coded Element	
			Functional assessment result	C	Any	
			Functional assessment	C	Label Concept	#8

13.2 Detailed Description for FUNCTIONAL STATUS

#1 IPS Section FUNCTIONAL STATUS

Purpose: The need of the patient to be continuously assessed by third parties, invalidity status may influence decisions about how to administer treatments.

Definition: An individual's ability to perform normal daily activities required to meet basic needs, fulfil usual roles and maintain health and well-being[24].

Business Rules:

1. For the Functional Status a Functional Assessment or a Disability list SHALL be provided (or both).
2. Each functional assessment entry SHALL include a result OR a subordinated functional assessment entry (not both). The subordinated functional assessment SHALL include a result.

Missing: Refers to a subset of people and therefore may be missing without being justified or creating any exception.

Format: Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion Criteria: Whilst this does refer to a subset of people, it is subset that is potentially at higher risk with the possibility that a patient summary will be required for an unscheduled care event.

Currency: Not applicable.

Examples: None.

Notes: The eHN Guideline only mentioned the two data elements given here under Medical problems for a grouped "Autonomy/Invalidity" concept. In this version this concept has been split in two parts: (a) disabilities, related to the invalidity term used in the Guideline; (b) Functional assessments that generalize the autonomy determination. With a general increase in aged communities, it is expected that more structured attributes will be required for later versions of this document. Capacity and Competency are part of the functional assessment.

#2 Disabilities

Disabilities is an umbrella term, covering impairments, activity limitations, and participation restrictions. An impairment is a problem in body function or structure; an activity limitation is a difficulty encountered by an individual in executing a task or action; while a participation restriction is a problem experienced by an individual in involvement in life situations.

For more information see Reference [8].

#3 Disability description

A narrative description of the nature of the invalidity.

Derived models may choose to use distinct elements for each narrative statement or to collect them into a single section level narrative block.

#4 Disability code

Code Identifying the disability of the subject of care.

#5 Functional assessments

It lists the results of reviews of an individual's mobility, transfer skills, and activities of daily living, etcetera, to determine also his/her autonomy.

#6 Functional assessment

This label concept describes a single or a group of assessments performed on this subject of care.

For each of the assessments or group of assessments, a date; a coded description of the type of assessment(s) should be provided if known.

In case this element refers to a group of assessments the contained functional assessment(s) should be provided if known. In case it refers to a single assessment its result should be provided if known; the result may be a physical quantity, a string, a coded descriptor; or other types of data depending on the kind of assessment performed.

#7 Functional assessment description

Textual description of the functional assessment.

Derived models may choose to use distinct elements for each narrative statement or to collect them into a single section level narrative block.

#8 Functional assessment

This Concept Label refers to the same concept as in #6. It is recursive permitting an assessment to be part of the group of assessments.

14 Definition for IPS Section: HISTORY OF PAST PROBLEMS

14.1 Overview Description for HISTORY OF PAST PROBLEMS (Table 11)

Table 11 — History of Past PROBLEMS Overview

Patient clinical data						
Hierarchy: H1	H2	H3	H4	Conformance	Description	Further Details
IPS Section: HISTORY OF PAST PROBLEMS Synonyms: History of past Illness Acronyms: None				O	A conformant IPS document MAY include this section. Past problems that the patient has experienced, providing background for the current situation.	#1
	Past problems			R	List	#2
		Past problem		R	Label Concept	#3
			Problem type	RK	Coded Element	#4
			Problem description	R	Text	#5
			Diagnosis	R	Coded Element	
			Severity	O	Coded Element	#6
			Onset date	RK	Date Time	
			Problem status	O	Coded Element	#7
			Date resolved	RK	Date Time	#8
			Specialist contact	O	Healthcare Provider	#9

14.2 Detailed Description for HISTORY OF PAST PROBLEMS

#1 IPS Section HISTORY OF PAST PROBLEMS

Purpose: to describe historic record of problems, including illnesses; provides a historical context from which to view the current state of the patient.

Definition: list of problems that the patient suffered in the past, and which have been closed or resolved and are not considered to be active or on-going and are therefore not currently monitored.

Business Rules: None.

Missing: The section is Optional. A patient may have no previous history, or the past problems are no longer being tracked/monitored.

Format: A list containing narrative and structured codes. Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion criteria: It is optionally included here to provide contextual material to the current planned or unplanned healthcare event.

Currency: The list, if not empty, will contain only those problems that have been resolved, closed or considered to be inactive.

Examples: diseases, disorders, injuries.

Notes: This IPS Section is very similar to the IPS Section on Problems. Indeed, it is common for implementations of Problem lists to contain all problems irrespective of historicity.

As this is history and it could be very extensive, it may be constrained by the sender or filtered by the recipient either by a time constraint (e.g. the last year) or by a size constraint (e.g. 10 most recent) to keep the spirit of the IPS as a concise document. Such constraint/filters are not part of this document.

#2 Past problems

The past problems are described as a list.

#3 Problem

Container of elements describing a problem.

#4 Problem type

An agreed means of categorizing the problem.

#5 Description

Textual description of the problem, including possible resolution circumstances.

Derived models may choose to use distinct elements for each narrative statement or to collect them into a single section level narrative block.

#6 Severity

A qualifier of the problem.

Note: Indications of extreme severity may have bearing on the current health need. The Severity attribute is also present in the IPS Section Problems.

#7 Problem status

The status of the problem may be, at least, active or inactive.

The eHN Guideline refers to a resolution textual field describing how the problem has been resolved if "not already included in other fields such as surgical procedure, medical device, etc.," In this document this information is realized by the description field (#5 above).

#8 Date resolved

Date, if known, that the problem was 'resolved'.

#9 Specialist contact

An optional healthcare provider who may have expertise related to a particular health condition or problem of interest at the healthcare event but is not necessarily the author of the IPS.

The specialist contact may provide an additional resource relevant to the treatment at the point of care. The detail may be found in the Patient's Address Book and may be defined with a specific role.

15 Definition for IPS Section: HISTORY OF PREGNANCY

15.1 Overview Description for HISTORY OF PREGNANCY (Table 12)

Table 12 — History of Pregnancy Overview

Patient clinical data							
Hierarchy: H1	H2	H3	H4	H5	Conformance	Description	Further Details
IPS Section: HISTORY OF PREGNANCY Synonyms: None Acronyms: None					O	A conformant IPS document MAY include this section. The main emphasis is on the current state, but optionally carries previous pregnancies.	#1
	Current pregnancy status				R	Label Concept	
		Pregnancy description			C	Text	#2
		Pregnancy details			C	Label Concept	
			Date of observation		R	Date Time	#3
			Pregnancy state		R	Coded Element	#4
			Expected delivery date		RK	Date Time	#5
		Specialist contact			O	Healthcare Provider	#6
	Previous history of pregnancies				O	Label Concept	
		Previous pregnancies status			C	Coded Element	#7
		Previous pregnancies description			C	Text	#8
		Previous pregnancies			C	List	
			Previous pregnancy details		R	Label Concept	
				Outcome date	RK	Date Time	#9
				Outcome	R	Text	#10
				Specialist contact	O	Healthcare Provider	#11
		Summary metric			C	Label Concept	#12

15.2 Detailed Description for HISTORY OF PREGNANCY

#1 IPS Section HISTORY OF PREGNANCY

Purpose: to present the current health state of the woman with respect to pregnancy and to provide chronological and outcome information about past pregnancies.

Definition: Considered to be generic to the English language and not specific to this document.

Business Rules:

1. If pregnancy state is given then the expected delivery date SHOULD be given.
2. The description of the current Pregnancy SHALL be in Text or in a structured form, or both.
3. If this IPS Section is included in the IPS Summary then it SHALL provide data concerning the current pregnancy status and optionally any information about previous pregnancies if known.

4. If previous pregnancies are included then four possible ways of representing such information are given, i.e. Status, Text or List of date and outcome pairs or a Summary metric. One way SHALL be given but this does not exclude other descriptions being exchanged in the summary.

Missing: This IPS Section is optional and should only be present for women patients.

Format: Current pregnancy state (and if so the associated expected delivery date) is given first. Previous pregnancy information may be given and, if so, would follow with associated outcomes. This may be given as narrative but structured data if available would be preferable. Details about the attribute's format are either given when the attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion criteria: The eHN Guideline uses the category 'Pregnancy History' but only give the example of the current state, but also allude to 'actual date'. History, without qualification, suggests a comprehensive data set and 'past pregnancy' information is included as an optional set of data.

Currency: The most current pregnancy state is top of any presentation of the history.

Examples: None.

Notes: current pregnancy details are available as coded concepts in some implementations, but stakeholder's capabilities and capacities to record such data in this way vary. It is expected that this area will receive further attention in the next iteration of IPS.

#2 Pregnancy description

The detail of the current Pregnancy is either given as text or in a structured form, but not in both.

#3 Date of observation

Provides information about when the observation of the pregnancy state was made.

#4 Pregnancy state

Purpose: To give the women's current state at the date the observation made.

Adopted value sets should include concepts such as:

— Pregnant

— Not Pregnant

— Unknown

#5 Expected date of delivery

If pregnant, this attribute provides delivery information, an approximation usually month/year but no day element.

#6 Specialist contact

An optional healthcare provider who may have expertise related to the pregnancy, but is not necessarily the author of the IPS Document.

The specialist contact may provide an additional resource relevant to the treatment at the point of care. The detail may be found in the Patient's address book, and may be defined with a specific role.

#7 Previous pregnancies status

This is optional but possible information would include:

— Yes, previous pregnancies

— No, previous pregnancies

— Unknown

#8 Previous pregnancies description

Note, this may represent a narrative description describing the outcome of any previous pregnancies. More formally, the information may be structured as a non-empty list comprising pairs of date and outcomes. Note, past pregnancies and associated outcomes may require special consideration around privacy and confidentiality measures. If there have been recorded pregnancies then the amount of information may be extensive. The following attributes should be considered to be a minimum part of the information conveyed, but is not intended to be exhaustive.

#9 Outcome date

Expected to be a full date. This is sometimes called the 'actual date' but given the possibility of an adverse event, the more neutral Outcome date is suggested. A single date may be repeated in the list in the case of multiple births.

#10 Outcome

Adopted value sets should include concepts such as:

— Safe delivery

— Termination

— Stillborn

#11 Specialist contact

Serves the same purpose and role as Specialist contact for the current pregnancy but in this case, it refers to any previous pregnancy. It is optional for both.

Notes: There may be a different Specialist contact attached for each pregnancy and also the current and the past specialists may also be different. The need for two attributes is consistent with the past and present 'problems' that are represented by two IPS Sections in this document rather than having both in the same IPS Section as in this case.

#12 Summary metric

This may be an alternative way of recording previous history of pregnancy or a way of providing complementary detail to the narrative and/or list of outcomes. They are based around concepts of Gravidity (defined as the number of times a woman has been pregnant regardless of the outcome) and Parity (Parity – X = (any live or stillbirth after 24 weeks) | Y = (number lost before 24 weeks)).

These concepts are notated by a variety of schemes with acronyms such as GP, GPA or TPAL and combinations such as GTPAL, GTPALM and GTPAL. These schemes provide numeric counts for different outcomes… if these were to be used in the IPS, the actual scheme would be required to be specified so as to disambiguate the metric's score.

16 Definition for IPS Section: HISTORY OF PROCEDURES

16.1 Overview Description for HISTORY OF PROCEDURES (Table 13)

Table 13 — History of Procedures Overview

Patient clinical data						
Hierarchy: H1	H2	H3	H4	Conformance	Description	Further Details
IPS Section: HISTORY OF PROCEDURES Synonyms: None Acronyms: None				RK	Required if information about History of Procedures is known. Any type of procedure known to have been performed on the patient.	#1
	Procedures content status			C	Coded Element	#2
	Procedures			C	List	#3
		Procedure		R	Label Concept	#4
			Procedure code	R	Coded Element	
			Procedure description	RK	Text	#5
			Body site	O	Coded Element	#6
			Procedure date	R	Period or Date Time	

16.2 Detailed Description for HISTORY OF PROCEDURES

#1 IPS Section HISTORY OF PROCEDURES

Purpose: a list of the procedures, and their descriptions, performed on the patient (procedure is generic and not just surgical).

Definition: Considered to be generic to the English language and not specific to this document.

Business Rules:

1. If content status positive then list of the procedures SHALL be non-empty AND the content status SHALL be omitted.

2. If content status records absence then list of the procedures SHALL be omitted.

Missing Required if available, if not then a reason shall be given.

Format: List of all types of procedures identified, time stamped and narrative description. Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion criteria: It is an aggregation of the required "Major surgical procedures prior to the past six months", under Medical History, and the "Surgical procedures in the past six months", under Medical Problems, in the eHN Guideline. In that it covers a less-restrictive set of procedures (i.e. not just surgical), it can be seen as an extension to the eHN Guideline.

Currency: All known procedures should be required if known.

Examples: Invasive Diagnostic procedure (the results of these procedures are documented in the results section); Therapeutic procedure: e.g. dialysis; Surgical procedure: e.g. appendectomy.

Notes: None.

#2 Procedures content status

History of procedures informing whether there is no information about procedures or no known procedure.

#3 Procedures

A list of procedures performed on the subject of care.

#4 Procedure

Each member of the list describes the type of procedure and identifies the actual procedure performed and when it happened.

#5 Description

Textual description of the procedure.

Derived models may choose to use distinct elements for each narrative statement or to collect them into a single section level narrative block.

#6 Body site

Details of where the procedure was performed. In some cases, it might be needed to consider the laterality as qualifier of the body site. For example, body site = ‘left hand’ or body site = ‘hand’; laterality = ‘left’.

17 Definition for IPS Section: IMMUNIZATIONS

17.1 Overview Description for IMMUNIZATIONS (Table 14)

Table 14 — Immunizations Overview

Patient clinical data							
Hierarchy: H1	H2	H3	H4	H5	Conformance	Description	Further Details
IPS Section: IMMUNIZATIONS Synonyms: VACCINATIONS Acronyms: None					RK	Required if information about Immunizations is known. Immunization (or vaccination) record for patient	#1
	Immunizations content status				C	Coded Element	#2
	Immunizations				C	List	#3
		Immunization			R	Label Concept	#4
			Vaccine for type of disease		R	Coded Element	#5
			Target diseases		O	List	#6
				Target disease	R	Coded Element	
			Date of immunization		R	Date Time	
			Product administered		O	Label Concept	#7
				Brand name	RK	Text	
			Product administration process		O	Label Concept	
				Performer	O	Healthcare Provider	#8
				Route of administration	O	Coded Element	#9

17.2 Detailed Description for IMMUNIZATIONS

#1 IPS Section IMMUNIZATIONS

Purpose: To list immunizations given to the patient and their status at the point of care. The primary purpose is to enable communication of a patient's immunization status. The section should include current immunization status, and may contain the entire immunization history that is relevant to the period of time being summarized. Adverse reactions against vaccines should be documented in the allergy section.

Definition: patient's current immunization status and pertinent immunization history that is relevant to the period of time being summarized.

It may include a complete vaccination history.

Business Rules:

1. If content status positive then immunization list SHALL be non-empty AND the content status SHALL be omitted.

2. If content status records absence then immunization List SHALL be omitted.

Missing: These two situations should be explicitly documented in the IPS section:

— Known absence of vaccinations

— No information available about vaccinations

Format: The list holds structured data and coded entries. Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion Criteria: Given that part of the use case would include the international traveller, immunizations will be of increasing importance.

Currency: All known vaccines shall be included, giving a complete history if possible.

Examples: None.

Notes: None.

#2 Immunization content status

Element informing whether there is no information about vaccinations or no known vaccination.

A predicate that tests if any immunizations have been performed.

#3 Immunizations

A non-empty list of immunizations is conditional on content existing.

#4 Immunization

A container for information related to information of the vaccine and its administration.

#5 Vaccine for type of disease

The type of vaccine for particular disease or diseases against which the patient has been immunized.

#6 Target diseases

Optionally, a list of specific diseases may be given to add precision.

#7 Product administered

Medicinal product administered; this may include Local product code; lot number; etc.

At least the brand name should be provided if nothing else is available.

Composite object identifying and describing the product that has been administered.

#8 Performer

Healthcare provider (person, organization) who administered or supplied the vaccine. At least name and possible identification and contact details.

#9 Route of administration

To record how the patient received the vaccine.

Definition: path by which the pharmaceutical product is taken into or makes contact with the body [ISO 11239:2012].

18 Definition for IPS Section: MEDICAL DEVICES

18.1 Overview Description for MEDICAL DEVICES (Table 15)

Table 15 — Medical Devices Overview

Patient clinical data						
Hierarchy: H1	H2	H3	H4	Conformance	Description	Further Details
IPS Section: MEDICAL DEVICES Synonyms: None Acronyms: None				RK	Required if information about Medical Devices is known. 'Implants' are considered to be a type of device.	#1
	Device content status			C	Coded Element	#2
	Devices			C	List	#3
		Device		R	Label Concept	#4
			Device type	R	Coded Element	#5
			Device identifier	RK	Identifier	#6
			Use start date	R	Date Time	#7
			Use end date	O	Date Time	#8

18.2 Detailed Description for MEDICAL DEVICES

#1 IPS Section MEDICAL DEVICES

Purpose: To inform the reader that the patient has internal and/or external devices, and these may need to be taken into account in any planned treatment or intervention.

Definition: devices that are implanted in the patient and external medical devices and equipment that the health status depends on.

Business Rules:

1. If there is recorded content then Device list SHALL be non-empty AND the Device content status SHALL be omitted.

2. If there is no recorded content then Device List SHALL be omitted.

Missing: if missing then the reason should be declared.

Format: Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion criteria: Increasingly important, as the formal device definitions broaden their scope.

Currency: Useful data for both planned and unplanned care IPS Scenario.

Examples: pacemakers, implantable defibrillator, prostheses, ferromagnetic bone implants etc. a device that is important to communicate to the healthcare provider who takes care of the patient.

Notes: Described under Medical problems in the eHN Guideline but given its own section here and, although required in the epSOS pilot project, other schemes such as HL7 IPS® do not mandate it.

#2 Device content status

Records whether there is reportable information about devices or no known devices.

#3 Devices

A conditional list of devices.

#4 Device

Each member (Device) of the list should have the same structure (i.e. type, identifier and use date).

#5 Device type

Category of the device.

#6 Device identifier

NOTE This was not part of the eHN data set; the device identifier (e.g. UDI) has been added in the HL7 IPS® as optional data.

Unique and normalized identifier of the device.

#7 Use start date

Date when the device was implantable to the patient or the external device was first in use. This field may contain only the year if the day and month are not available (example: 01/01/2017).

#8 Use end date

Date when the device was explanted from the patient or the external device was no more in use. This field may contain only the year if the day and month are not available (example: 01/01/2017).

19 Definition for IPS Section: MEDICATION SUMMARY

19.1 Overview Description for MEDICATION SUMMARY (Tables 16 and 17)

Table 16 — Medication Summary Overview (Part1)

Patient clinical data					
Hierarchy: H1	H2	H3	Conformance	Description	Further Details
IPS Section: MEDICATION SUMMARY (PART 1) Synonyms: None Acronyms: None			M	Every PS conformant to IPS SHALL contain this IPS section.	#1
	Medication summary content status		C	Coded Element	#2
	Medications		C	List	#3
		Medication	M	Label Concept	#4

19.2 The IPS Medication Summary and IDMP

NOTE 1 Medication Summary has had extensive attention lavished upon it, primarily because of the ISO IDMP Standards, but also because of European eHealth projects. Consequently, it has a rich depth of specification and the hierarchy of 5 levels used throughout this document is exceeded by several levels. Rather than extend every template to seven levels that would make the presentation difficult to read, an exception has been made for Medication Summary, using a two-part table.

NOTE 2 The IDMP standards are the recognized and good direction of travel for this IPS (i.e. ISO 11238, ISO 11239, ISO 11240 and ISO 11615). However, currently the IDMP standards are not yet fully implemented in practice and so the concept descriptions in the IPS Medication Summary Section are intended to be at a high level of abstraction, permitting the current ways of implementing the concepts to exist but with the expectation that they will evolve to the IDMP notation and specification in due course. This IPS standard restricts the term 'Medicinal Product', defined in ISO 11615:2017, to 'human use' and to clinical care settings for which the patient summary use case scenario applies. The worldwide unique Product Identifier is not yet a reality and consequently the more general 'Product Code' is used if required.

Table 17 — Medication Summary (Part 2)

Patient clinical data							
Hierarchy: H3	H4	H5	H6	H7	Conformance	Description	Further Details
IPS Section: MEDICATION SUMMARY (PART 2 beginning with H3 level) Medication					M	Part 2 comprises a paired list of Medicine and Administration. Labelled Concept	#4
	Reason				O	Label Concept	#5
	Medicinal product				R	Label Concept	#6
		Product code			O	Coded Element	#7
		Product common name (and strength)			RK	String	#8
		Pharmaceutical dose form			R	Coded Element	#9
		Brand name			O	String	#10
		Active ingredients			R	List	#11
			Active ingredient		R	Label Concept	
				Substance code	R	Coded Element	#12
				Strength	R	Ratio	#13
	Administration instruction				R	Label Concept	#14
		Instruction			O	Text	#15
		Period of medication use			R	Period	#16
		Route of administration			O	Coded Element	
		Dose instruction			R	Label Concept	
			No. of units per intake		R	Range or Quantity	#17
			Frequency of intake		R	General Time Specification	#18

19.3 Detailed Description for MEDICATION SUMMARY

#1 IPS Section MEDICATION SUMMARY (Table Parts 1 and 2)

Purpose: List of medications relevant for this patient summary.

Definition: All medications that are relevant for the scope of the Patient Summary. Typically, medications whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not. [derived from eHN Guideline].

The eHN restricted the medication summary to 'prescribed medicines'; here the scope is broadened to all known medicines taken, or to be taken, by the patient. It may be known that non-prescribed medication is being taken and this may be included.

NOTE Compliance to any medication is not certain.

Business Rules:

1. If content status positive then Medication list SHALL be non-empty AND the content status SHALL be omitted.

2. If content status records absence then Medication List SHALL be omitted.

Missing: Required for IPS conformance, shall be present. If missing, the reason SHALL be explicitly stated.

Format: Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion criteria: This IPS Section is required for conformance, and is an integral part of the IPS use case.

Currency: None.

Examples: None.

Notes: Medication identification etc. is changing and it is expected that the ISO IDMP standards will be used for the IPS. Currently, IPS will use existing schemes for the interim but indicate optionality where appropriate.

#2 Medication summary content status

As this IPS Section is mandatory this attribute records whether there is no information about a medication history or whether there is no medication in the patient's history; the reason for no medication data has to be stated.

#3 Medications

If Medication information is present then the list cannot be empty. It will contain details of pairs of medicine and the associated administration instruction for the particular patient.

#4 Medication

A complex structure that comprises a list of paired concepts, Medicinal Product and associated Administration Instruction.

NOTE The Medication attribute is the link between the two parts of the Medication Summary Tables.

#5 Reason

This is the reason why the medication is being prescribed or used. It provides a link to the Past or current health conditions or problems that the patient has had or has.

#6 Medicinal product

Any substance or combination of substances, which may be administered to human beings … for treating or preventing disease, with the view to making diagnosis or to restore, correct or modify physiological functions.

Whilst the term and definition of Medicinal Product serves here, it should not be assumed that the IDMP standard as a whole is usable for the IPS Standard at this point in time. The term 'Medicine' may satisfy the need to more general.

In certain jurisdictions, a medicinal product may also be defined as any substance or combination of substances which may be used to make a medical diagnosis. (ISO 11615:2017)

#7 Product code

Product code is a more general term for identifying a product without the rigour of a full identifier. Product Code permits current usage rather than the unique identifiers (PhPIDs, MPID, PCID) allocated to a medicinal product for medicinal products worldwide [ISO 11615:2017], which have not yet been realized.

#8 Product common name (and strength)

Non-proprietary name of the pharmaceutical product possibly including the strength of each ingredient.
This name is associated with the PhPID_L2 IDMP identifier if it exists.

Notes: International non-proprietary name recommended by the World Health Organization (WHO), or, if one does not exist, a non-proprietary name recommended by the jurisdiction within which the name is used.

Example:

with optional strength included in the string

"Irbesartan/Hydrochlorothiazide 300mg/12,5mg".

#9 Pharmaceutical dose form

Physical manifestation of a Medicinal Product that contains the active ingredient(s) and/or inactive ingredient(s) that are intended to be delivered to the patient [ISO 11615 (IDMP)].

Notes:

1. Dose form, dosage form and pharmaceutical dose form are synonymous.
2. "Pharmaceutical dose form" can refer to the administered dose form or the manufactured dose form.

#10 Brand name

Brand name is required if a biological medicinal product or when justified by the healthcare professional.

#11 Active ingredients

A list of Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product.

#12 Substance code

Eventually will be normalized with IDMP.

Example: paracetamol.

#13 Strength

Content of the substance(s) or specified substance(s), expressed quantitatively per dosage unit, unit of presentation, per unit of volume or mass, according to the dose form.

Example: 500 mg per tablet

#14 Administration instruction

Medication is the first part of a pair and Administration Instruction is the associated second part of the same pair that describes the members of the medication Summary list.

#15 Instruction

Textual description of the Rationale.

Derived models may choose to use distinct elements for describing this element or to include it into a single section level narrative block.

#16 Period of medication use

This information may be expressed using start and end date times OR indicating the duration. The first is used to indicate a specified interval (e.g. from March 15th, 2017); the latter for indicating a 'floating' period (e.g. 2 weeks). In case of unbounded period (continuous therapy) the end element will be valued with an exceptional value.

#17 Number of units per intake

The number of units per intake that the patient is taking.

Examples: 1 tablet.

#18 Frequency of intakes

Purpose: Frequency of intakes per hour/day/week/month.

Examples: each 24 h.

20 Definition for IPS Section: PLAN OF CARE

20.1 Overview Description for PLAN OF CARE (Table 18)

Table 18 — Plan of Care Overview

Patient clinical data								
Hierarchy: H1	H2	H3	H4	H5	H6	Conformance	Description	Further Details
IPS Section: PLAN OF CARE Synonyms: care plan, plan of treatment, healthcare plan; Acronyms: None						O	A conformant IPS document MAY include this section. Multiple plans may co-exist	#1
Plans						R	List	
Plan						R	Label Concept	
Plan type						O	Coded Element	#2
Plan date						RK	Date Time	
Plan description						C	Text	#3
Recommendations (Core Care Plan)						C	List	#4
Recommendation						R	Label Concept	#5
Recommendation for treatment						R	Text	#6
Given recommendation date						RK	Date Time	#7
Applicable date						RK	General Time Specification	#8
Extensive Plan						C	Reference	#9

20.2 Detailed Description for PLAN OF CARE

#1 IPS Section PLAN OF CARE

Purpose: The Plan of Care IPS section is the first steps towards providing a care plan for the Subject of care. It should also complement a narrative of the expectations for care including proposals, goals, and order requests for monitoring, tracking, or improving the condition of the patient. The Plan of Care will contain Therapeutic recommendations that do not include drugs (diet, physical exercise constraints, etc).

Definition:

For formal definition see (3.5.2)

Business Rules:

1. The Plan SHALL be described as Text or in a structured form that permits the possibilities of listing multiple plans rather than a single consolidated plan.

2. A Plan SHALL either contain core Recommendations, Reference to an Extensive plan or both.

Missing: It may not be available.

Format: Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion criteria: The elements included in the eHN Guideline may be considered as a minimum, starting point for a more well-defined care plan IPS Section.

Currency: Care plan can be prospective as well as in operation. Past care plans would not be expected in the IPS.

Examples: Treatment recommendations on discharge from a hospital.

Notes: A care plan is a complex document in its own right as the definition makes clear. The HL7® definition[8] extends the purpose given above, by adding "the [lifetime] condition of the patient with goals of educating the patient on how to reduce the modifiable risks of the patient's genetic, behavioural, and environmental pre-conditions and otherwise optimizing lifetime outcomes."

This level of detail seems to go beyond what a Patient Summary for unplanned care could be expected to deliver, but the requirement is also to serve planned care. The eHN Guideline limits plan activities to recommendations. That having been said, there is clear merit for incorporating such information if requested. This document follows the same convention used in the Advance Directives IPS Section and provides the opportunity of referencing an existing external document, treating the Recommendations as the core of a reusable care plan.

#2 Plan type

The plan may be uni-professional or multi-professional in its construction. The plan type may include:

— planned observation

— planned procedure

— planned encounter

— planned immunization

#3 Plan description

Narrative representation of the care plan(s). Plan descriptions may be collected into a single narrative block or represented as separate narratives describing each plan.

#4 Recommendations (Core Care Plan)

The Core Care Plan is reusable content and structure for a potential care plan for a specified set of circumstances; the Recommendation list is that core content and structure for exchange.

#5 Recommendation

Each recommendation should contain a triple comprising two dates and a recommended treatment. Both dates should be given if the information is available; the recommended treatment is required.

#6 Recommendations for treatment

A recommendation for treatment is given.

#7 Given recommendation date

Each recommendation is given a separate given date in the table; however, it may be that the plan is given on a single date with multiple recommendations in the same plan.

#8 Applicable date

The date which applies to the recommended treatment. Plans are unique in the IPS, which like full EHRs are primarily retrospective and historical. Plans are prospective and dates may be in the future.

#9 Extensive plan

This is conditional and may be an alternative to the treatment recommendations or it may be given in addition to the data given in the 'core care plan' recommendations for treatment.

The extensive plan comprises a reference to a care plan document, separate from the IPS.

21 Definition for IPS Section: PROBLEMS

21.1 Overview Description for PROBLEMS (Table 19)

Table 19 — Problems Overview

Patient clinical data						
Hierarchy: H1	H2	H3	H4	Conformance	Description	Further Details
IPS Section: PROBLEMS Synonyms: health problems; Acronyms: None				M	Every PS conformant to IPS SHALL contain this IPS section. A list of problematic health conditions	#1
	Problems content status			C	Coded Element	#2
	Problems			C	List	#3
		Problem		M	Label Concept	#4
			Problem type	RK	Coded Element	#5
			Problem description	R	Text	#6
			Diagnosis	R	Coded Element	#7
			Severity	RK	Coded Element	#8
			Onset date	RK	Date Time	
			Problem status	O	Coded Element	#9
			Specialist contact	O	Healthcare Provider	#10

21.2 Detailed Description for PROBLEMS

#1 IPS Section PROBLEMS

Purpose: To provide a concise overview of health conditions affecting the patient. Medical alerts and clinical risks identified, e.g. problematic intubation, person with brittle diabetes, immuno-compromised/risk of infection etc. can also be described here.

Definition: health condition considered by a healthcare actor to be a problem; a list of current, active problems that have not been resolved or are existing concerns that are still being monitored.

Business Rules:

1. If a problem is reported in the IPS, then the Problems list SHALL be non-empty and the Problem content status SHALL be omitted.

2. If no current problems are reported then a statement SHALL be given to that effect within the Problem content status.

Missing: This is a required IPS Section for conformance and shall not be empty; at the least, some statement shall be given explaining the missing data.

Format: The problem list is given as a structured list. The Problem type will be taken from a value set (coded), and narrative description or alternatively a diagnosis, as label; together these will constitute a list member. Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion criteria: Only active or current problems will be listed. This is an important data element, and is a recognizable component in most patient summaries.

Currency: All the 'problems' in the IPS Section are deemed to be active, current or not resolved. Furthermore, resolved problems that are still of concern and are being monitored are also included.

Examples: Problems or diagnoses that are current/active include "a chronic or relapsing course (e.g. irritable bowel syndrome, otitis media), conditions for which the patient receives repeat medications (e.g. diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of medication (e.g. dyspepsia, migraine and asthma)".

Notes: None.

#2 Problems content status

The patient has no problems to be reported or the problem information is unavailable.

#3 Problems

The problem list comprises members that are current, either because they are active, unresolved or of concern and being monitored.

#4 Problem

One or more problems are listed; each comprising the same structure describing the nature of the problem and its date of onset.

#5 Problem type

A means of categorizing the different types of problem, to distinguish for example a diagnosis, from a clinical risk or a medical alert. Note 'Medical Alerts', i.e., one type of alert, are represented as a problem in this first iteration of this document.

#6 Problem description

Narrative represented in a textual form of the nature of the problem. It may be given even if a diagnosis is given and shall be given if the diagnosis is not given.

Derived models may choose to use distinct elements for each description or to collect them into a single section level narrative block.

#7 Diagnosis

Label used to describe a problem; usually coded.

#8 Severity

A qualifier of the Problem giving an indication of importance.

#9 Problem Status

The status of the problem may be, at least, active or inactive.

#10 Specialist contact

An optional healthcare provider who may have expertise related to a particular health condition or problem of interest at the healthcare event, but is not necessarily the author of the IPS Document.

The specialist contact may provide an additional resource relevant to the treatment at the point of care. The detail may be found in the Patient's Address Book, and may be defined with a specific role.

22 Definition for IPS Section: RESULTS

22.1 Overview Description for RESULTS (Table 20)

Table 20 — Results Overview

Patient clinical data						
Hierarchy: H1	H2	H3	H4	Conformance	Description	Further Details
IPS Section: RESULTS Synonyms: Observed condition Acronyms: None				RK	Required if information about Results is known.	#1
	Observation results			R	List	#2
		Observation result		R	Label Concept	
			Date of observation	R	Date Time or Period	
			Observation type	R	Coded Element	#3
			Result description	RK	Text	#4
			Result value	C	Any	#5
			Observation result	C	Label Concept	#6
			Performer	O	Healthcare Provider	#7
			Observer	RK	Healthcare Provider	#8

22.2 Detailed Description for RESULTS

#1 IPS Section RESULTS

Purpose: This section assembles relevant observation results obtained on the patient. These may be measurements, laboratory results, anatomic pathology results, radiology results or other imaging or clinical results. It may be necessary to convey the provenance and authoring for results that have been collected from authors other than the IPS author.

Definition: Considered to be generic to the English language and not specific to this document.

Business Rules:

1. Each observation result entry SHALL include a value OR a subordinated observation result (not both). The subordinated observation result SHALL include a value.

Missing: The implication is that no findings or results have been observed that are relevant to the present summary.

Format: A list of result types, with descriptions, dates and measurements of, and related to the observed condition. Each of the result types should have provenance data. Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion criteria: Results from types of observed condition are extremely important, particularly if they relate to a previous case of the same health condition (e.g. a chronic condition flare up).

Currency: Most recent results, relevance determined by the author.

Examples: A haemoglobin value.

Provenance data should be recorded for each result to provide trust in the attending healthcare provider.

Notes: Derived models may choose to specialize the Observation Result label concept to better capture the characteristics of the different kinds of results (e.g. lab, path, imaging).

#2 Observation Results

A list of all observation results pertaining to the subject of care's health condition.

#3 Observation type

The list contains members representing the types of results.

#4 **Result description**

A description of the Observed condition.

Derived models may choose to use distinct elements for each description or to collect them into a single section level narrative block.

#5 Result Value

The measurement value.

#6 Observation Result

This Concept Label refers to the same concept that is listed in #2. It is recursive permitting an Observation Result to be part of the group of Observation Results.

#7 Performer

Identifies who/what is performing the observation. e.g. in case of an imaging study it could be the actor who performed the imaging series. For some types of results the performer and observer roles may coincide.

#8 Observer

Identifies who/what was the author of the observation, e.g. in case of imaging study it could be the actor who made the interpretation of the images. It should not be confused with the individual who made the observation statement (i.e. the asserter).

23 Definition for IPS Section: SOCIAL HISTORY

23.1 Overview Description for SOCIAL HISTORY (Table 21)

Table 21 — Social History Overview

Patient clinical data						
Hierarchy: H1	H2	H3	H4	Conformance	Description	Further Details
IPS Section: SOCIAL HISTORY Synonyms: None Acronyms: None				O	A conformant IPS document MAY include this section. Health related "life-style factors" or "life-style observations" (e.g. smoking habits; alcohol consumption; diets etc.)	#1
	Life style factors			R	List	#2
		Life style factor		R	Label Concept	#3
			Life style factor description	R	Text	#4
			Life style factor details	O	Label Concept	#5
			Reference date range	RK	Period	#6

23.2 Detailed Description for SOCIAL HISTORY

#1 IPS Section SOCIAL HISTORY

Purpose: To present observations on social factors such as alcohol consumption or smoking. From the healthcare perspective, life-style factors relate to well-being but can also provide a source of risk factors.

Definition: Considered to be generic to the English language and not specific to this document.

Business rules: None.

Missing: Required if information is available but no exception raised if missing.

Format: Structured and coded entries. Within a list. It would be possible to provide a specific template for each factor or simply to code the factor and use a generic template. Here the latter is chosen because of the commonality of information and to allow for simple expansion over time; no particular way is prescribed here for the form of implementation that should be taken.

Inclusion criteria: See Notes.

Currency: Current and past observations relevant for the scope of the IPS.

Examples: None.

Notes: 'Social History' is a term which covers a multitude of concerns, alcohol consumption and smoking constitute the minimum set of factors considered for this version of the IPS. Other factors as diet, living conditions, employment, environmental concerns, and exercise, to mention just a few, may be documented by the derived models, even though they are not required to do so.

#2 Life style factors:

An open-ended list that describes the past and current habits of the patient with respect to a particular life style observation.

If this IPS Section is present then the list shall be non-empty.

#3 Life style factor:

The purpose is to identify the particular factor of interest. Among the several multitudes of concerns at the minimum it should cover alcohol consumption and smoking. Other kinds of lifestyle factors such as diet, living conditions, employment, environmental concerns and exercise, to mention just a few, may be documented as well. Drug dependencies are not in the eHN Guideline; in some countries, Life Style factors are type of sensitive information that requires special confidentiality rules.

A life style factor shall be described at least by a descriptive text (Life style factor description #4) and optionally by structured information (Life style factor details #5).

#4 Life style factor description

Derived models may choose to use distinct elements for each description or to collect them into a single section level narrative block.

#5 Life style factor details

Life style factor is typically described by narrative, but structured, coded and quantified information may also be given if possible (this Label Concept).

A Life style factor detail is often represented by a simple code-value couple; with a codeable concept describing the type of Life style factor (e.g. alcohol consumption) and a value providing this will include the type of measurements applicable to the factor; for example, alcohol units consumed; for smoking, the number of packs smoked, the coded occupation of the person, the organization where the person is employed, etc.

#6 Reference date range

Life Style factors observations often span a considerable length of time. This attribute records the Interval of time the “lifestyle factors” described is referring to.

Dates should have at least year precision.

Example: From 1974 through 2004.

24 Definition for IPS Section: VITAL SIGNS

24.1 Overview Description for VITAL SIGNS (Table 22)

Table 22 — Vital Signs Overview

Patient clinical data						
Hierarchy: H1	H2	H3	H4	Conformance	Description	Further Details
IPS Section: VITAL SIGNS Synonyms: Physical findings Acronyms: None				O	A conformant IPS document MAY include this section. These may primary vital signs (e.g. blood pressure) plus additional measurements such as height, weight and BMI.	#1
	Vital signs			R	List	#2
		Vital sign		R	Label Concept	
			Date of observation	R	Date Time or Period	
			Observation type	R	Coded Element	#3
			Result description	RK	Text	#4
			Value	C	Quantity	#5
			Vital sign	C	Label Concept	#6

24.2 Detailed Description for VITAL SIGNS

#1 IPS Section VITAL SIGNS

Purpose: This section assembles relevant observation results to record the vital signs associated with a patient that include the primary vital signs plus additional measurements such as height, weight and BMI.

It may be necessary to convey the provenance and authoring for results that have been collected from authors other than the IPS author.

Definition: Considered to be generic to the English language and not specific to this document.

Business Rules:

1. Each Vital sign entry SHALL include a value OR a subordinated Vital sign (not both). The subordinated Vital sign SHALL include a value.

Missing: The implication is that no vital signs have been observed that are relevant to the present summary.

Format: A list of result types, with descriptions, dates and measurements of, and related to the observed condition. Each of the result types should have provenance data. Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion criteria: Vital signs from types of observed condition may be important, particularly if they relate to a previous case of the same health condition (e.g. a chronic condition flare up).

Currency: Most recent results, relevance determined by the author.

Examples: A blood pressure, body weight.

Provenance data should be recorded for each result to provide trust in the attending healthcare provider.

#2 Vital Signs

A list of all vital signs pertaining to the subject of care's health condition.

Vital Sign is a specialization of the Results' Observation result.

#3 Observation type

The list contains members representing the types of vital signs.

Typical vital signs types are:

— Body Temperature

— BP Diastolic

— BP Systolic

— Head Circumference

— Heart Rate

— Height

— Height (Lying)

— O2 % BldC Oximetry

— Respiratory Rate

— Weight Measured

— BMI (Body Mass Index)

— BSA (Body Surface Area)

#4 Result description

A description of the recorded Vital Signs.

Derived models may choose to use distinct elements for each description or to collect them into a single section level narrative block.

#5 Results value

A measurement value.

#6 Vital sign

This Concept Label refers to the same concept that is listed in #2. It is recursive permitting a Vital sign to be part of the group of Vital signs.

25 Definition for IPS Attribute Collection: Cross Border

25.1 Overview Description for CROSS BORDER (Table 23)

Table 23 — Cross Border Overview

Cross border data				
Hierarchy: H1	H2	Conformance	Description	Further Details
IPS Attribute Collection: Cross Border Synonyms: None Acronyms: None		C	Every cross-border PS application conformant to IPS SHALL contain this IPS data. Country of Affiliation, and a place holder for data related to jurisdiction	#1
	Country of affiliation	M	Label Concept	#2
	Country specific requirements	RK	Label Concept	#3

25.2 Detailed Description for CROSS BORDER

#1 IPS Attribute Collection: CROSS BORDER

Purpose: These data are the provenance detail necessary for cross border transactions.

Definition: Considered to be generic to the English language and not specific to this document.

Business rules: None.

Missing: Conformant requirement for cross-border IPS but Conditional for other applications. These details are only supplied and are mandated for cross-border application. Otherwise they can be missing.

Format: Coded data for country codes, Label Concept for other parts.

Inclusion criteria: Cross border is an integral part of the use case and scope of this document.

Currency: None.

Examples: None.

Notes: Data required for cross border application. At this moment, these data are scant and is specific to the EU and the official Country Contact points. It is Conditional in the IPS Document depending solely on the intent to use the IPS cross border. Local and National applications do not need this data.

Note too, that the cross-border data uses the provenance data related to the preferred healthcare provider.

#2 Country of affiliation

Country of affiliation is the designated source country where the patient and their healthcare information are based. This may be provided through a coded element or as a string if the adopted datatype does not support coded country information; as, for example, the country address part used by the HL7 CDA® standard.

#3 Country specific requirements

A placeholder; used to describe unique facts, cultural, legal details and jurisdictional matters of the realm that need stating as part of the agreement to interchange. It may include Confidentiality/consent

rules for sharing data, details of languages and translations but some of these can be considered with respect to the individual needs as well as the country or national characteristics.

26 Definition for IPS Attribute Collection: Provenance Metadata

26.1 Overview Description for PROVENANCE (Table 24)

Table 24 — Provenance Overview

Metadata					
Hierarchy: H1	H2	H3	Conformance	Description	Further Details
IPS Attribute Collection: Provenance Metadata Synonyms: None Acronyms: None			M	Every PS conformant to IPS SHALL contain at least the 'Date of IPS Creation' from this IPS collection. Attributes that describe dates, sources, nature and legitimacy of the patient summary	#1
	Asserter (source of information)		RK	Label Concept	#2
	Date of IPS Document creation		M	Date Time	#3
	Language of document		O	Coded Element	
	Date of last update of IPS content		R	Date Time	#4
	Generation of IPS content		R	Label Concept	#5
		Nature of the IPS	R	Label Concept	#6
	Healthcare providers		R	List	
		Authoring healthcare provider	R	Healthcare Provider	#7
	Legitimacy		RK	Label Concept	
		Legal authenticator	RK	Healthcare Provider	#8

26.2 Detailed Description for PROVENANCE

#1 IPS Attribute Collection: PROVENANCE Metadata

Purpose: This provides the source and context of the information supplied. Data to afford trust in the communication and the data being interchanged. Provenance data may be at the document level, the section level and even at the attribute level. It is a sub-component of the IPS Data Set.

Definition: Considered to be generic to the English language and not specific to this document.

Business rules: None.

Missing: This metadata can be applicable to the entire IPS and also refer to its various components as the IPS can be an eclectic composition. The source and the context of the whole IPS is probably supplied from the system from which the IPS was extracted and will always be present.

Format: Details about the attribute's format are either given when the Attribute is described or explained in the Primitive Values clause. (See Patterns, 6.1).

Inclusion criteria: Provenance data at the document level is required to know from whom the summary is given, and again to promote trust of results.

Currency: Provenance metadata should be up to date.

Examples: Reported by the patient, Extracted by the patient vaccination record in their EHR.

Notes: it provides a measure of trust and transparency, and permits the recipient to clarify what has been given by the authoring healthcare provider.

#2 Asserter

The source of information, usually the patient.

#3 Date of IPS Document creation

The IPS document can only be created once.

#4 Date of last update to IPS content

The content of the IPS may have variable dates of update or change.

#5 Generation of IPS content

This is the actual container of IPS provenance data: how it has been assembled from which sources, etc.

#6 Nature of the IPS

Defines the context in which the IPS was generated. 'Nature of the IPS considers two cases; Human created and automatically assembled.

NOTE Three methodological approaches to build the summary were suggested by the eHN Guideline: direct human intervention by a healthcare actor, automatically generated and a mixed approach. HL7 IPS® have suggested that these can be resolved into two cases: Human curated and automatically assembled. The cases in which an automatically generated PS is edited by a human being (i.e. the mixed approach) is considered to be human curated. If a human verifies the content of an automatically generated IPS, the IPS is still an automatic generated PS with a human verifier.

#7 Authoring healthcare provider

A means of verifying origin and providing some measure of confidence /trust. At least an author organization shall be listed. In case there is no healthcare professional, at least a healthcare organization shall be listed.

8 Legal authenticator

The responsible author / healthcare provider. Attesting or signing the patient summary or parts of it may be required, dependent on jurisdiction.

Annex A
(informative)

The first IPS Scenario focussed on 'unscheduled, cross-border care'

A.1 Introduction

The original focus for the International Patient Summary was the use case scenario of 'unscheduled, cross-border care'. The System of Concepts for Continuity of Care (ISO 13940[4]), or to use its abbreviation, ContSys, was used to underpin this document. Concepts used from ContSys are presented in **bold** and are defined in ISO 13940 rather than repeated here.

The IPS scenario is just the first of four scenarios considered in the IPS use case. Here the purpose of the IPS Scenario is to illustrate and set the scene of the present scope of the IPS standard. Furthermore, the IPS scenario highlights grey areas around the edges of the initial scope that needed addressing and thereby aims to provide more clarification about what the IPS can and cannot do within the current scope.

This IPS scenario is simply the starting point. It identifies the activities and contexts that require a core but minimal data set, which can front-end more specialized data as and when required. The use case modelling nor the scenario itself defines in detail all of the specific data contents required.

Figure A.1 illustrates the IPS scenario by means of a mind map; the numbered soft-boxes (SB) are referenced in the following commentary.

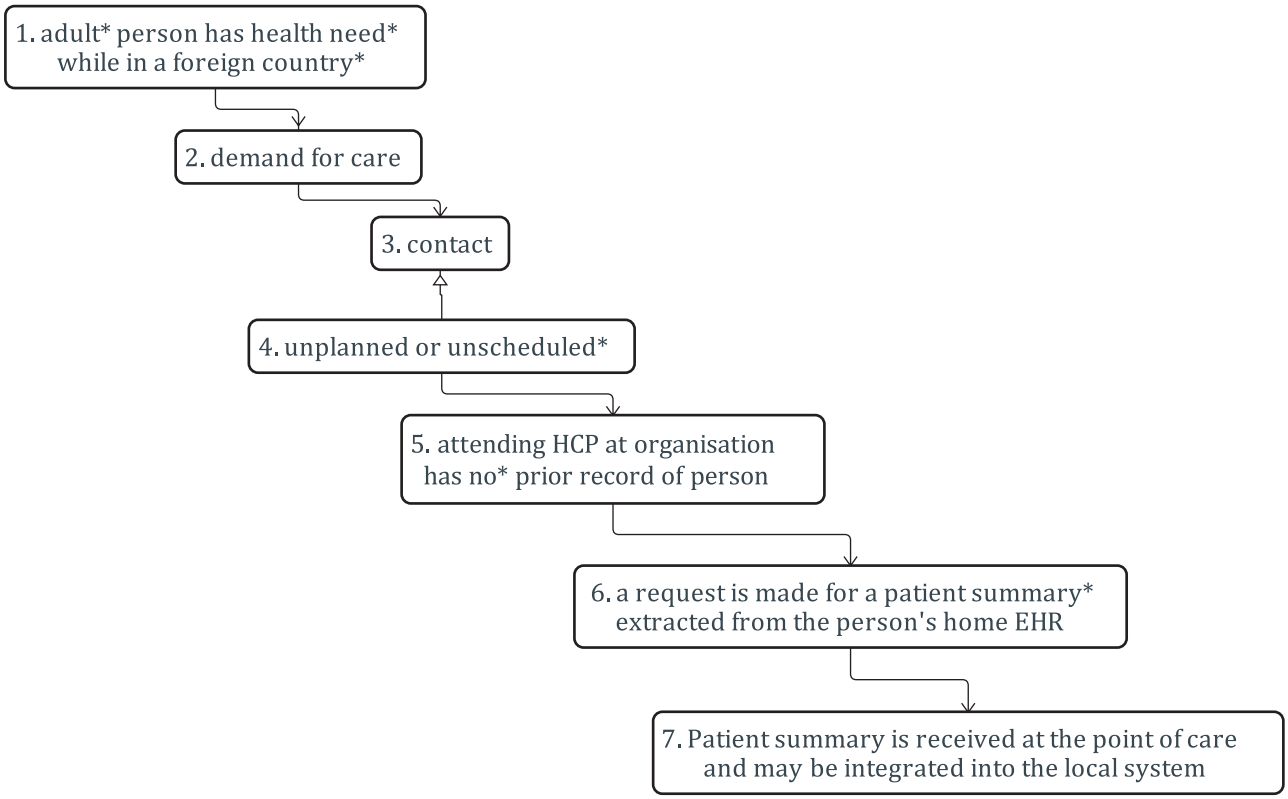

Figure A.1 — The first IPS Scenario

A.2 Commentary on the first IPS Scenario

An explicit, initial requirement for developing the IPS was to enable citizens of one country to receive relevant treatment for their unplanned health need in another country.

Soft-box 1 (SB1) stars 'adult', '**health need**' and 'foreign country' for the reader's attention. First, 'adult' is highlighted because the starting data set assumes that the '**subject of care**' in question is an adult staying in a foreign country either for business or leisure; if the citizen is a child, it maybe that additional data might be required in a patient summary (for example, legal guardian details and the person's date of birth are already in the eHN data set but data related to development and growth are not). In general, the IPS Data Set, which provides a core of data that is specialty agnostic, is applicable for all ages. However, the IPS was designed to support incremental development which allows new specialized, optional Data Blocks to be added when a requirement has been established. The next iteration of IPS should be applicable to all ages.

Second, the '**health need**' is, as yet, unspecified; it may or may not relate to a chronic **health condition**, but again the IPS data set is intended to be "minimal and non-exhaustive" implying that the data elements are valid as a core set applicable to any health condition, perhaps with the expectation that other data could be added as required. The fact that it is a 'health need' should not prevent a summary from expressing social, mental and spiritual conditions (the 1948 WHO definition of health is very inclusive); that having been said, the data elements comprising the current IPS Data Set major on the healthcare aspects of well-being and would have to be substantively extended and revised to provide adequate coverage for the core parts of a more inclusive summary.

Third, 'foreign country' is starred, because although 'cross border' was the impetus for establishing the eHN data set, the experience of the epSOS project showed that the value of the patient summary is much greater at a national and local level if volume of transactions is considered. Indeed, a cross border application is probably non-viable without the buy-in of more localized benefits (see Reference [9]). The cross border concept then is best considered as a specialized case, perhaps a more difficult one, of cross-boundary problems, as it includes jurisdictional matters as well as professional and organizational boundaries. The IPS shall deliver value to national and local healthcare parties as well as regional and international ones.

Soft-box 2 (SB2) '**demand for care**' is specialized by '**demand for initial contact**' (not shown[5)]), which results in a '**contac**t' (SB3) that is 'unplanned' (SB4). The eHN Guideline indicates that 'unplanned care' is likely to offer the most value/benefit for having the patient summary available at the **point of care**.

Soft-box 4 (SB4) an unexpected health need, does not limit the contact to an emergency. Indeed, emergency care is a speciality in its own right, often with its own data set requirements, and the time-frame and context of an emergency may actually negate realistic access to the IPS unless it is held by the patient or their **legal guardian** and is directly available at the point of care. Note too that the IPS Data Set is intended to be useful for 'planned contacts' too, but it is a different scenario in the same use case.

The 2nd revision of the eHN Guideline uses the term 'unscheduled', rather than 'unplanned', which has more of an organizational connotation. Even so, it is the unexpected and urgent nature of the health need event that finds the healthcare provider unprepared, often with no prior record of the person to be treated.

Soft-box 5 (SB5): the starred SB5 assumes that this 'unplanned contact' is the first of its kind and so no previous record exists in the local site; it is, however, conceivable that the person is a returning patient and the subsequent request in SB6 is to provide a more recent patient summary. The '**Healthcare Provider**', either the Healthcare Professional (**HCP**) or the organization require an '**electronic patient summary'** at the very least to offer the appropriate response.

Soft-box 6 (SB6): the person's summary is the result from a '**health information request**. Patient summary is starred in SB6 for two reasons. The first reason is the IPS scenario makes no explicit reference to technical implementation matters, such as federation where multiple fragments or entire

5) 'Demand for initial contact' and 'initial contact' concepts are important but represent only a part of the IPS Scope, which includes the possibilities of 'further' contacts.

patient summaries exist on different systems across different organizations brought together as one document in response to the request. The IPS scenario assumes a patient summary will be available without saying how. The IPS Scope explicitly excludes the processes of generation of the patient summary, although the Provenance Data Block provides an attribute to record how the IPS was generated. The second reason highlights the fact that the request made is explicitly for an extract of the EHR rather than the whole record. The implication is that a patient summary is easier to share, manage and assimilate than a more complex and comprehensive EHR, given that (a) time is at a premium, (b) a degree of urgency exists, and (c) a hoped-for possibility that only the most relevant parts of the person's history comprise the '**health record extract'** when a summary is required; one that is both concise and understandable.

Soft-box 7 (SB7) assumes that this could be a first contact. In which case, the IPS has to be available at the '**point of care'**. The received IPS may form a new, minimal EHR within the local system. Conversely a 'planned' contact or a repeated contact may require the new summary to be integrated (possibly updating the previous one if existing and legitimately/legally allowed) rather than just stored within the local system. The import process of IPS data are not a part of this document.

A more formal mind map of the IPS scenario (in Figure A.1) enables a more abstract view to be taken of the scenario, making the current IPS scope more general than just taking the first scenario rather than the richer use case.

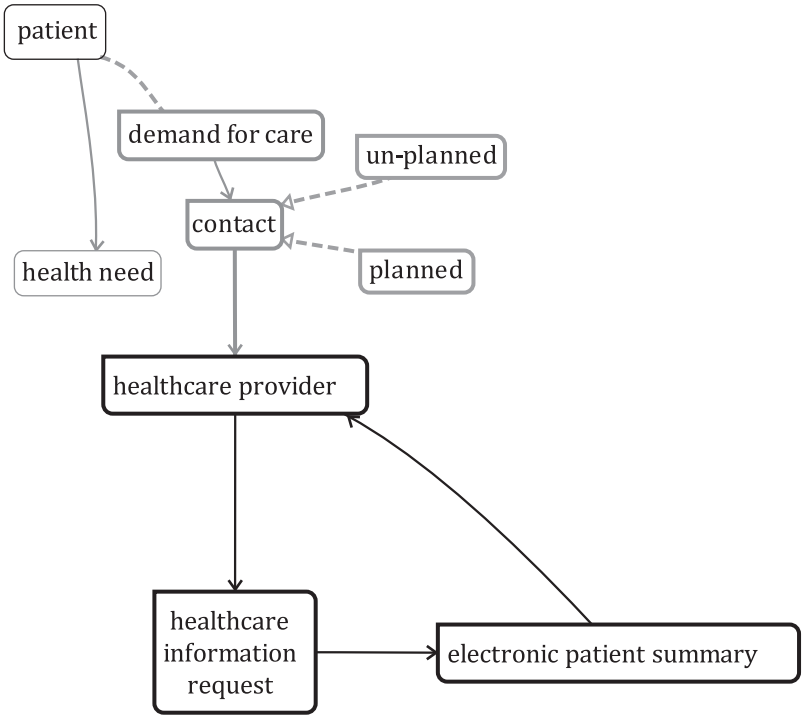

Figure A.2 — Abstract version of the IPS Scenario

A.3 Governance of the IPS Data Set

A.3.1 General

The IPS scenario (as illustrated by Figures A.1 and A.2) does not define a detailed IPS Data Set; more generally it indicates how the IPS Data Set might be used as a whole. It does not describe how the IPS Data Set should be controlled; in particular it does not describe the composition of the IPS Data Set or the process in which data elements are chosen or selected to be a part of it.

NOTE The CEN/TS 17288 considers the IPS and Governance as part of the context for implementation of the IPS within Europe.

A.3.2 Clinical and Information Governance

Figure A.3 distinguishes between the concepts which are under the exclusive control of clinical governance and the digital representations that are under the remit of information governance. The **health record** and any **health record extract** are comprised of **health record components** and their meaning and purpose are governed primarily by the healthcare professions; the digital representations of these artefacts, i.e. **'electronic health record extract'** and '**electronic record component'** are sub-types with multiple stake-holders with an interest and responsibility with respect to their governance. The data does have associated business rules that support the standard's use and the conformance for derived implementations.

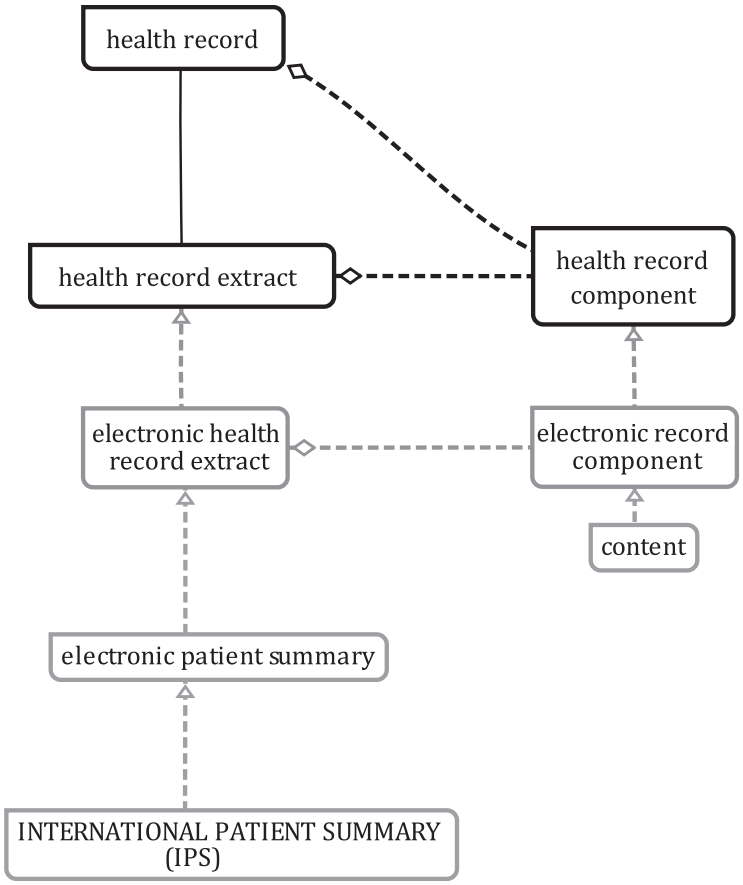

Figure A.3 — The IPS relationship with Non-digital and Digital artefacts

This document, in contrast to the IPS scenario, does describe the detailed composition of the IPS Data Set. Its justification for doing so is, in the main part, taken directly from the requirements of the patient summary Guideline accepted and endorsed by the member states and countries represented by the eHN (eHN:2016). However, the data set will be influenced by other international initiatives so as to be fit for global use rather than just regional. Decisions for inclusion of additional data elements for this current version of the data set are based upon clinical acceptance of items from other initiatives and the evidence for this is required to be transparent and verifiable (see Annex B). Two important areas, attestation ("evidence showing that something is true") and audit trail data are not explicitly included in this version of the IPS Data Set; rather they are considered to be part of the whole EHR architectures and systems, rather than something specific to an extract.

Whereas most of the IPS content is directly clinical, however, there are also other data which serve a different function. This data can be related to identification of the '**patient'** and to administrative and organizational data such as that which refers the address details of all the relevant actors implied by the IPS scenario. Other data, described more generally as **metadata**, relates to provenance i.e. the source of the data within the IPS. This latter data might provide the identity and address details of the healthcare providers who created the received summary, allowing the attending clinician to follow

up some detail as required. In terms of the cross-border aspects of the scenario, such data might also identify the country of residence and the origin of the source document (see Figure A.4). This figure also recognizes the potential contribution of the **'personal health record'** to the health record, which is mainly constituted as a **'professional health record'** and to any extract of that source record, although how these entities interact relates to the implementation and is not considered in this document.

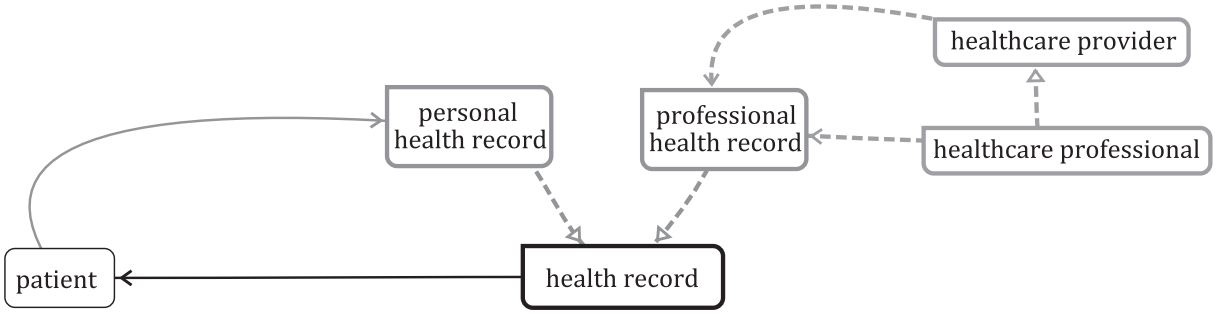

Figure A.4 — Source of data for the IPS

It is anticipated that time, practice, feedback and innovation will naturally spawn change requests and updates to the current version of the IPS Data Set. An international clinician-based body is required to undertake a systematic review of the clinical elements of the IPS standard and should oversee later clinical additions or changes to the content of this document. In association with this, the SDOs should conduct their own systematic review of the information and technical data specifications to complement any update. Information governance will need to distinguish between the need of new sections and the need of additional information in the existing sections and to show how the data set can be extended in an orderly and consistent way.

A.4 IPS Independence and Dependence

The success or failure of the IPS standard is ultimately dependent upon the acceptability of the data set for clinical use. This document defines and describes all the data within the IPS, but not how it is implemented nor how it is used in practice. Such considerations are an integral part to the implementation guidance associated with this document. However, some aspects of use, such as provenance, do require data elements to be included within the IPS to support an implementation. (Arguably, 'Provenance' is required for all health data exchange, and the IPS should use a general, standardized data block rather than define it in this document. At present, however, no such standard exists.)

Given that the clinical acceptance of the data set is paramount, there are still other factors that need to be taken into consideration if the IPS is to succeed at both international and local levels, and all the levels in between.

Implementation Independence

This document has to be implementation independent; this document is all about the IPS data and its logical definition. For example, Figure A.5 shows the conceptual differentiation from the IPS Data Set concepts and the use of the term 'IPS Section' in the IPS and non-IPS sections (the latter is intentionally out of scope). The term 'section' has been chosen to define IPS grouped, data elements that are closest to typical implementation structures; 'IPS Attribute Collections' comprise data that may be used in one or more defined IPS sections. The term 'section' is used both in the ISO 13606 Architecture and the HL7 CDA® forms for documents, but the usage here is compatible with both and therefore the intent succeeds in being implementation independent and is a term that is generally understood with respect to documents. The IPS is a composition of Sections, Attribute Collections and metadata and whereas the origin of the Section and Attribute Collections is from the IPS Data Set content from the health record, the metadata are non-clinical, representing necessary documentation.

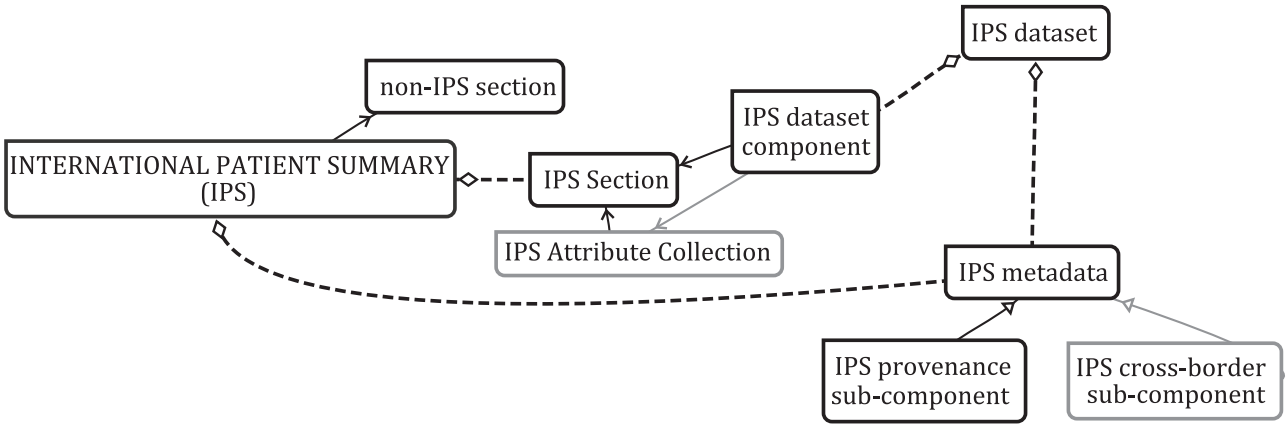

Figure A.5 — The IPS concepts defined in the IPS Data Model

The different standards, architectures and data representations have their champions (and detractors!) but this document tries to be completely unbiased about how the data are used within such schemes; taking a detailed and at the same time, a high level of description so as to permit the widest possible use within existing and future systems. This is important as many implementations of patient summaries already exist in different countries and within different organizations and attempts to dictate one way of doing it will be resisted. Even so the current data set in this document, and any future changes to this IPS Data Set, will inevitably have implications (e.g. financial, professional, legal) for data use, data capture and the associated changes in workflow. A particular requirement satisfied by this approach is to make the IPS standard flexible enough to accommodate change and to permit it to evolve in response to clinical knowledge and technical knowhow by avoiding silos. It does not require a particular EHR/PHR to be used for the extract or its receipt.

Speciality and Condition Independence

At a minimum, the IPS is a structure and a set of data elements selected from the IPS Data Set, which is itself declared to be a minimum and non-exhaustive data set. It is therefore intended to be a starter set or a core set of data to help inform a person's treatment at the point of care, irrespective of the condition of the patient or of the specialist trying to manage the care. It can be argued that the core set is not enough (either for the specialist or for the chronically ill patient) or, in some cases, even too much. However, the goal of the standard is to provide a robust set of well-defined, clinically agreed data for the purposes of unplanned care; it has no aspirations to be comprehensive or to contain fine-grained specifics, but neither does it restrict such data being added to the IPS to complement its function and serve a more specific use.

Use case dependence

The IPS Use case is, in essence, the provision of patient summary data at the point of need. The IPS project has considered four scenarios associated with the use case starting with 'unplanned, cross-border' care. However, some data description within the IPS can be used in many different use cases and so can be described as being use case independent. This applies to primitive values, for example specification of names, addresses and dates, but also to the larger data elements, the IPS Sections, such as 'Medication Summary' and 'Allergies and Intolerances'.

The IPS as a whole, however, **is** use case dependent and the term and its purpose, i.e. as a patient summary, is intended to differentiate it from other documentation in the healthcare domain. It is a truism that there are myriads of patient summaries within the healthcare domain and the fact that they are non-standard poses a potential hazard to both meaning and safe use and hinders sharing. This document required that the IPS be focussed, situated and positioned to avoid such problems. In particular, IPS uses an agreed system of concepts that were developed to support interoperability in general and uses the specific use case of a patient summary being used at the point of care. Figure A.6 shows the final mind map that combines the Figures A2 to A5 into a single map that utilizes ContSys and complements it with IPS-specific concepts and terms.

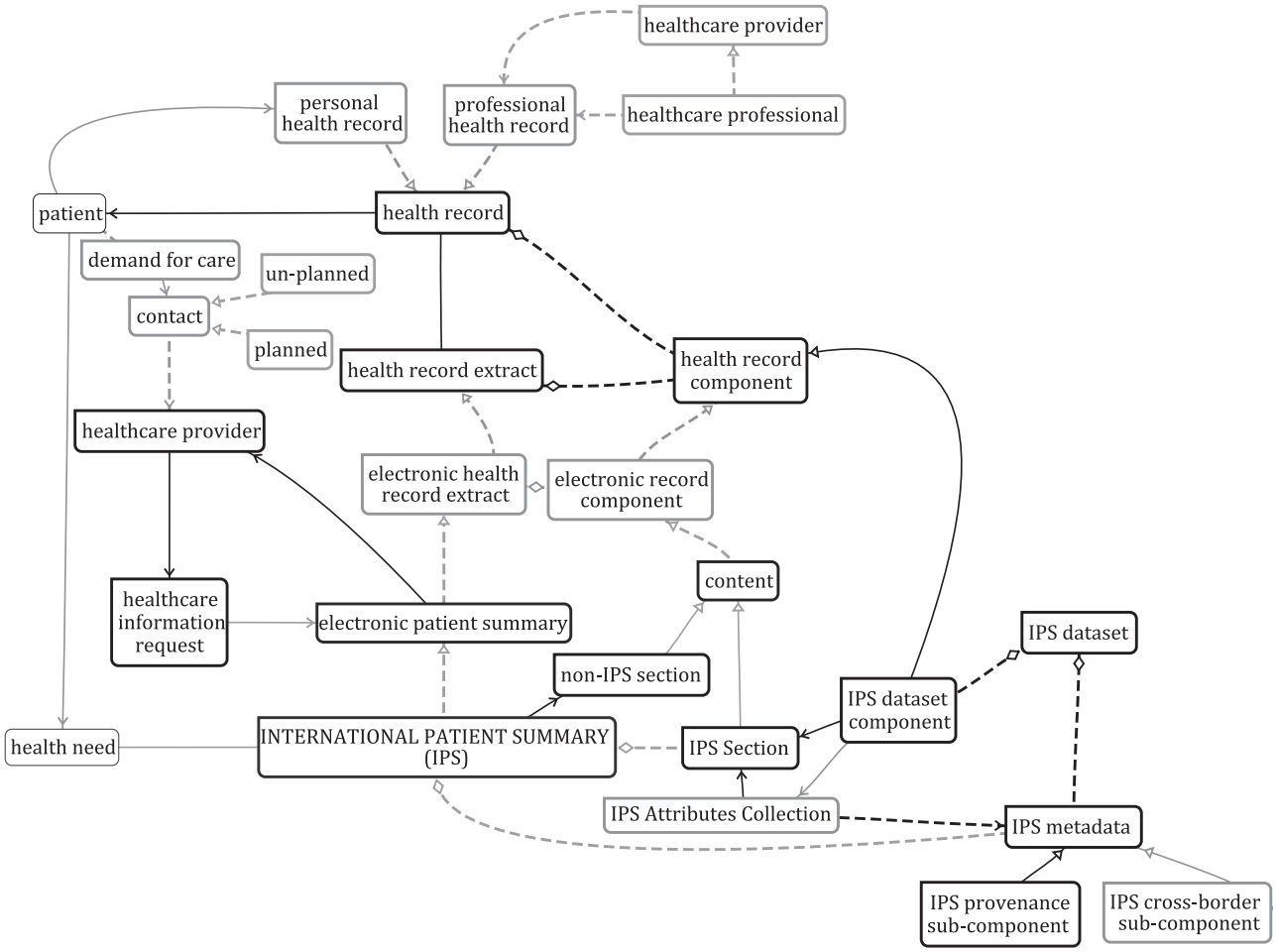

Figure A.6 — The IPS standard within a System of Concepts

Annex B
(informative)

Explicit Trace between eHN Guideline Version 2

B.1 General

Grant Agreement (SA/CEN/GROW/000.2016) for this work focussed upon the eHN Guideline for Patient Summary. The CEN PT's explicit task in the agreement was to take the eHN Guideline and to turn it into a formal, international standard. The 'international' aspiration for the IPS standard was supported in the grant by encouraging participation between CEN/TC 251 and HL7®.

This annex explains the relationship between the eHN as the primary input and the final standard presented here and provides transparency and traceability for the differences by explaining what has been explicitly covered and what has been added, and the rationale for what has been done.

B.2 The eHN Guideline and this document

The eHN Guideline provided the groundwork and foundation for this document. Annex C provides further information about related efforts in the patient summary space. The standard has built on the guideline by being more formal in specifying the requirement so as to provide a sustainable product, suitable for regulation if required.

The eHN Guideline provided a hierarchy with nested variables. This document has used the same hierarchical concept but has strengthened the semantics to facilitate derived models for conformant implementations. The eHN Guideline (as described in versions 1 and 2 of the eHN document) present the patient summary data set in tabular form by using a hierarchy of 3 nested variables. The nesting of the variables was intended to correspond with the granularity of the defined data elements. In this document, 8 levels were used to provide greater precision. The full eHN PS data set has been covered by this document.

The eHN Guideline provides an overall sketch, comprising broad brush strokes serving as an outline with other parts of the sketch showing more detailed work. For example, Diagnostic tests are mentioned as a heading, with 'Blood Group' and a further two attributes nested beneath, whereas 'Address' is given much more detailed attention. This is in part because the 'Address' element is a simpler concept (albeit complicated) but also because it is a much more common-use, cross-sector data element so is more well-known and easier to define.

The eHN Guideline describes its data set as 'minimal'; the clear implication is that these particular data elements have been chosen or selected as being the desired content for any patient summary. In the first version of the Guideline there were the concepts of 'Basic' and 'Extended' requirements; this distinction disappeared in the second, later version of the Guideline but the idea of essentially the same elements constituting the 'minimal' data set remains. As noted, the granularity, even of these chosen elements is variable, which poses challenges for a standard which has to be more formal and more prescriptive in its specification to have value.

This document is implementation-independent. It is situated in a conceptual framework in order to support feasible interoperability and provides sufficient precision, by definition and by description, to make conformance and continual improvement possible for a sustainable solution.

Furthermore, the participation and collaboration aspects made it necessary to align the data model in this new standard with existing work. This was achieved both by harmonizing the naming conventions used for various components of the IPS and by rationalising structures to present the consumer of the

standard with a smoother transition from the conceptual level, through to concrete representations of a Patient Summary. The following shows how the eHN variables are positioned in this document.

Table B.1 — Naming of eHN Guideline and its Correspondence with the present IPS Standard

Category	Guideline Name	Guideline Level	IPS Sections, and Attribute Collections
Non-clinical Data	Identification	Healthcare ID	Patient's Attribute Collection
	Personal Information	Name, DOB, Gender and address	
	Insurance Information	Insurance Number	
	Contact Information	*Address Book*	Patient's Address Book
Clinical data	N/A	–	Advance Directives
	Alerts	Allergy	Allergies and Intolerances {Note, Alerts are not a separate part of this iteration of IPS. Medical Alerts and Clinical Risks are currently subsumed by 'Problems'.}
		Medical Alert	
	Medical History	Vaccinations	Immunizations
		Resolved, closed, inactive problems	History of Past Problems
		Surgical procedures (prior to 6 months)	History of Procedures
	Medical Problems	Surgical procedures (in the past 6 months)	
		Current problems	Problems
		Medical devices and implants	Medical Devices
		Treatment Recommendations	Plan of Care
		Autonomy/invalidity	Functional Status
	Medication Summary		Medication Summary
	Social History		Social History
	Pregnancy History	Expected Delivery date	History of Pregnancy
	Physical Findings	Blood pressure	Vital Signs
	Diagnostic Tests	Blood group	Results
Metadata	Name of Country Affiliation		Cross-border data
	PS Creation date		Provenance metadata
	PS Update date		
	PS Nature	Contextual data	
	Author		

The eHDSI work uses NON-CLINICAL, CLINICAL, and METADATA for its main categories, which were similar to the eHN usage with the minor exception that NON-CLINICAL replaced the 'Administrative' naming in the guideline. Similarly, the IPS Section names were viewed with respect to the HL7 CDA® implementation, and the latter were selected as the preferred names if the meaning was clear. IPS is the required prefix to Section (Note, IPS Data Block is a general term for IPS Section and other data structures in IPS) to maintain the distinction between the Standards Concepts and any derived model for implementation. Table B.1 shows how the eHDSI categories and the eHN Guideline's higher-level headings are used in the IPS Naming.

B.3 The Rationale for the IPS Naming

This document's aim was to facilitate the transition from a data set guideline to a formal robust standard which an implementation could conform to. To smooth this process, the concepts named in the standard were selected to be as close as possible to those within the target implementation. The re-naming principle is complemented by two others; one related to the use case and the other related to the efficiency of any implementation.

The first of these principles is to ensure that any renaming or restructuring keeps faith with the use case scenarios scope of unplanned, cross border care. The second principle looks upon any restructure as an opportunity to make the implementation fit for purpose and sustainable. The eHN Guideline uses variables but only partially describe different levels of detail. For implementation it is desirable that the data are described consistently and in detail. The Guideline heading and the associated guide line levels presented some challenges for the more formal structure required of the standard.

The non-clinical data in the first three rows has been subsumed under a single IPS Section called Patient Attribute Collection. One purpose of the 'personal information' in the scenario of unplanned care is primarily for identification purposes. The address detail is to help with the identification and perhaps to verify that the person is who he/she claims to be rather than just an administration requirement. Gender, sometimes called Administration Gender, is also used in some countries as part of the identification process. Similarly, the eHN data set reduces the insurance information to an insurance number, which again in some countries is used to identify the person.

In a healthcare setting, 'Contact' is a term used for the meeting between a subject of care and the healthcare provider, as well as the term used to address organizations and people relevant to the subject of care. A heading such as 'contact information' is therefore ambiguous and Patient's Address Book is used to reduce ambiguity and includes all addresses in one IPS Section that might be required for a particular instance of an IPS.

In the clinical data, a new section (the only one) has been added that is not within the original eHN Guideline. ADVANCE DIRECTIVES is present in the HL7® work, the Trillium Bridge project work and in the JIC Standards Set, and in terms of providing a data set that is an international one, the decision has been made to include this as an optional IPS Section. Although not quite the same thing, 'Treatment Recommendations' within the eHN Guideline could have accommodated such directives but it seemed more appropriate to separate and clarify a section that may be important in an unplanned care event such as an emergency or fatality.

ALLERGIES and INTOLERANCES is more important than the 'Alerts' heading in the Guide-line would suggest; Allergies and Intolerances are a required IPS Section in the first iteration of the IPS Standard. The Allergy and Intolerance description is not specified in detail within the eHN Guideline but the attributes included in this document relate well to those used in existing implementations. Medical alerts and clinical risks can be recorded under PROBLEMS in the first iteration of the standard. ALERTS, of all types are to be considered for the next IPS iteration.

The eHN Medical History was broken down into three separate IPS Sections, i.e. IMMUNIZATIONS, HISTORY of PAST PROBLEMS, and HISTORY of PROCEDURES. The first, IMMUNIZATION, is a synonym for 'Vaccination' and broadly carries the same information, although in more detail than expressed in the eHN Guideline. HISTORY OF PAST PROBLEMS includes all the past, inactive problems (i.e. resolved, closed and inactive). HISTORY OF PROCEDURES is here more extensive, covering all types of procedure whether 'surgical' or not. Furthermore, this section deals with all procedures that had been undertaken on the patient, both current and past. This IPS Section has also rationalized the 'procedures' data under the one heading rather than have it spread across the Medical History and Medical Problems headings in the eHN Guideline.

Medical Problems has also been deconstructed. It has been split into 5 separate sections. HISTORY OF PROCEDURES has been explained above; in addition, PROBLEMS, MEDICAL DEVICES, PLAN OF CARE and FUNTIONAL STATUS appropriate its data.

The most obvious Section to be mapped to Medical problems is PROBLEMS. The PROBLEMS section highlights the current, active problems and separates that data from the HISTORY OF PAST PROBLEMS

section which contains resolved and inactive problems or ones that are no longer monitored. ALERTS may be recorded under PROBLEMS. Again, this is felt to fit well with the need for concise and significant data required for an unplanned care event. MEDICAL DEVICES are seen as an important set of data and currently is split off into a separate section. The more generic term subsumes the 'implants' mentioned in the eHN. 'Treatment Recommendation's and 'Autonomy/invalidity' have been elevated to their own sections too (respectively, PLAN OF CARE and FUNCTIONAL STATUS). In the eHN, the variables are stand-alone items, however, both have significant bearing on the use case and it is expected that more related fields will be required. The rationale for having a different section in the IPS highlights the importance of these areas and suggests an implementation pathway for a more substantive structure.

'Medication Summary',' Social History' and 'Pregnancy History' map directly to the IPS Sections of similar name. The only significant difference is that more detail is provided in the IPS Sections to make the data more comprehensive and usable. History of Pregnancy is inclusive and includes previous pregnancies as well as the current status, and is an optional section.

'Physical Findings' in the eHN Guideline is now under the VITAL SIGNS IPS Section.

'Diagnostic Tests' have been subsumed under a more generic RESULTS IPS Section.

The Metadata variables are described by two IPS sub-components that provide source information for specifically cross border applications and for more general provenance and contextual data that describes the who, where, how, and when data has been generated or updated. The IPS refers to the Cross-Border Attribute Collection rather than to 'metadata'.

NOTE There have been requests to consider how patient mediation/mobility impacts the IPS Content. The Patient's story as narrative, either as told by the clinician and/or told by the patient themselves in their own words would offer different perspectives, but have yet to be described in a sufficiently rigorous manner to achieve consensus. Although this is a distance from the current eHN Guideline, and therefore not included here, further consideration of this and the enhancement of the subject of care is suggested for the next iteration of this data model standard.

B.4 Identifiers in eHN Guideline

In the eHN Guideline identifiers are usually described but not explained as 'Normalized identifiers'. The eHN Guideline is sometimes unclear as to whether an actual 'identifier' or a simple code is required. It is assumed that the 'normalization' would refer to and be represented in the Master Value Sets Catalogue (MVC), which is an EU specific construct related to terminology. The MVC is considered in Reference [3] that provides a guideline that explains the context related to European implementation of this document.

Annex C
(informative)

The eHN Guideline, the JIC PS Standards Set, and IPS

The JIC Patient Summary Standards Set (PSSS)[11] offers informative guidance about what standards and standard's artefacts exist in regard to a Patient Summary. The beneficiaries and the purpose of Patient Summaries are also well covered in their introduction. The PSSS landscape is broad, covering multiple types of standards in brief, whereas this document focuses solely on what they term 'data related standards' but in depth. The other fundamental difference regarding this document and PSSS is that the PSSS is entirely informative, whereas the CEN and HL7 IPS® are normative; PSSS intentionally does not create a new standard, rather its main purpose is to inform the market about existing work. In contrast, the IPS project are developing standards concurrently and so the PSSS points to these developments rather than represents them in any detail. PSSS will help inform current and future work as it evolves. The PSSS and the IPS projects are complementary initiatives from JIC, which includes the CEN and HL7® SDOs.

The PSSS use-case is very similar to this document, albeit their data set emphasizes chronic (e.g. COPD) and home care situations. The data elements are primarily the same as in this document, but PSSS uses an older version of the eHN Guideline and the INTERPAS project (now the HL7 IPS®), reflecting the PSSS activity timeline. The more recent, formal data definitions and their associated conformance within the CEN and HL7 IPS® project are not within the published PSSS version. As a live document it is expected that the differences will be resolved in due course. The list of data elements in JIC PSSS is identical to those in the eHN Guideline, but with minor adjustments. Different elements suggested by PSSS and the action taken here, are:

1. Attribute: **Allergy substance category**, with category types including food, medication, etc.
    a. Action: This attribute has been included in the Allergies and Intolerances IPS Section.
2. Attribute: **DNR alert**
    a. Action: None; this was already included as an example in the Advance Directives IPS Section
3. Attributes: **Patient Access Alert** and a **Last Review Date**:
    a. Action: None taken at this time; it will be reviewed in future versions of IPS
4. Attributes: **Home care alert** and the **home care monitoring**
    a. Action: None. It does not fit the primary IPS use case of 'person receiving treatment abroad'.
5. Attributes: **Preferred Language of Patient** and **Language Code for document** …
    a. Action: The former is included in the Patient Attributes collection and the latter in the Provenance collection.
6. Attributes: **Title of document** for different types of Summary
    a. Action: None. Focus here is on the IPS scope.

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ICS 35.240.80

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