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SIST-TS CEN/TS 17288:2020

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Zdravstvena informatika - Mednarodni povzetek podatkov o pacientu - Smernica za evropsko implementacijo

Health informatics - The International Patient Summary - Guideline for European Implementation

Medizinische Informatik - Die internationale Patienten-Kurzakte: Leitfaden für die europäische Technische Spezifikation (TS) zur Umsetzung

Informatique de santé - Résumé international de dossier patient : Recommandations relatives aux spécifications techniques de mise en œuvre européenne

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Informatique de santé - Le résumé international des patients - Lignes directrices pour la mise en œuvre européenne

Medizinische Informatik - Die internationale Patienten-Kurzakte - Leitfaden für die europäische Technische Spezifikation (TS) zur Umsetzung

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European foreword

This document (CEN/TS 17288:2020) has been prepared by Technical Committee CEN/TC 251 “Health Informatics”, the secretariat of which is held by NEN.

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Introduction

This document provides a European implementation guideline for the International Patient Summary (EN 17269). The target audience is primarily software developers, and project implementation teams, but policy makers and SDOs have a role in assuring that the guideline is relevant to IPS.

European policy, directives, organisational and professional culture, and a diverse market place require implementation guidance that is technically relevant and contextually sensitive. This document describes these implementation aspects from the European perspective. The different ways that the International Patient Summary (IPS) and its content are communicated are the subject of this document. This document will reference and credit initiatives, such as the eHealth Networks' patient summary data set and the multiple European projects, that have contributed to the shared vision embodied in the joint CEN IPS and HL7 IPS Project.

The eHealth Network, the Cross border Directive, and the IPS Use Case

The requirements for the CEN IPS' deliverables come directly from the eHealth Network (eHN) and their support for the 'Specific Guidelines for Electronic Exchange of Health Data under the Cross border Directive 2011/24/EU'. "These guidelines, as adopted by the eHealth Network, are addressed to the Member States of the European Union and apply to the implementation of a patient dataset for cross border exchange." [1]

The objective of the EU policy is to support continuity and coordination of care for EU citizens across Member States (MS). In a cross border context, the eHN further asserts that "interoperability is essential to the provision of high-quality care. Member States shall therefore engage in taking appropriate measures to make their respective information systems interoperable, both technically and semantically, for this Use Case". [2]

The specific use case is more general, but the scenario from the eHN is to exchange a patient summary (PS) between countries, comprising an agreed minimal data set, for unscheduled care. Member State needs, however, require the IPS to also be useful for localized use, and to support scheduled care too. The required, core data elements in the eHN guideline are the basis around which meaningful patient summary (PS) implementations can be built. These data, their descriptions and definitions, have been formalized and refined in EN 17269 with the intention of making them usable, and reusable, for different communication purposes in the healthcare domain at a global level.

The relationship between the CEN IPS and other PS Initiatives

Patient Summaries are ubiquitous. The differences and diversity of existing implementations, however, make it currently difficult to safely communicate content. In what is an increasingly complex ecosystem there is a strong requirement to provide simple interoperable solutions for key applications. This has led to a drive to standardize patient summaries for widespread use. The EC chose to support this need for standardization by sponsoring a number of related projects, enabling international participation to consider how to deliver interoperability with respect to cross border exchange of the Patient Summary. The Health Informatics Committee of CEN (i.e. CEN/ TC 251) was commissioned to produce relevant IPS Standards based upon the eHN guideline. Figure 1 shows a map of key CEN IPS stakeholders.

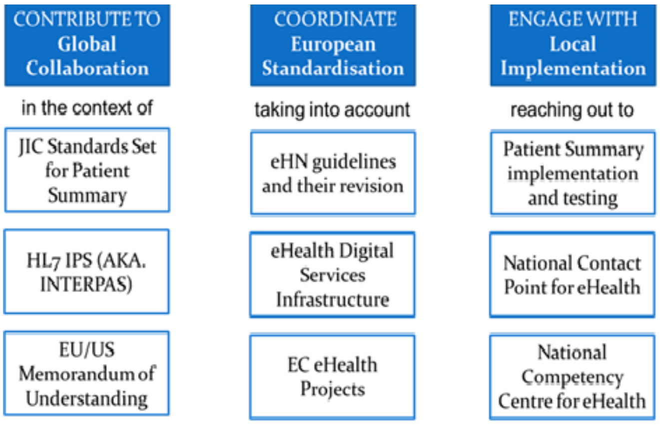

Figure 1 — CEN/TC 251's participative role in establishing the IPS Standards

The International Patient Summary Project comprises two concurrent standardization activities; one lead by CEN/TC 251 and the other by HL7 International. The standards developed by each of them are inter-related standard products, with informed coordination to realize coherent results.

The EC eHealth projects, aware of the EU/US MOU [3], have been supportive. The Trillium Bridge [4] and Trillium II [5] projects have taken as input the initial work from both CEN/TC 251 and HL7 IPS as the basis for its elaborations and analysis, thereby contributing to the new standardization approach, described by the eStandards [6] project, as "Co-creation, governance and alignment (CGA)". Concurrently, the eHDSI [7] under the CEF [8] project is realizing the cross border services for the Patient Summary based on the eHN PS guideline and using Patient Summary CDA specifications evolved from epSOS [9]. The lessons learnt by eHDSI (and its parent projects) have been taken into consideration for the development of the IPS Project. Figure 2 provides an illustration as to how the various products of these initiatives relate to each other.

The European Interoperability Framework

The Refined eHealth European Interoperability Framework (ReEIF) [10] is a "common refined framework for managing interoperability and standardisation challenges in the eHealth domain in Europe"; and it has been designed "for the communication and decision-making processes on projects and solutions for eHealth. ReEIF offers a framework of terms and methodologies for reaching a common language, a common starting point, for the analysis of problems and the description of eHealth solutions throughout Europe". To leverage that fact, ReEIF is used here to structure this document so as to provide relevant European guidance material for the International Patient Summary (IPS). The clause structure that maps to the Framework is presented in Table 1.

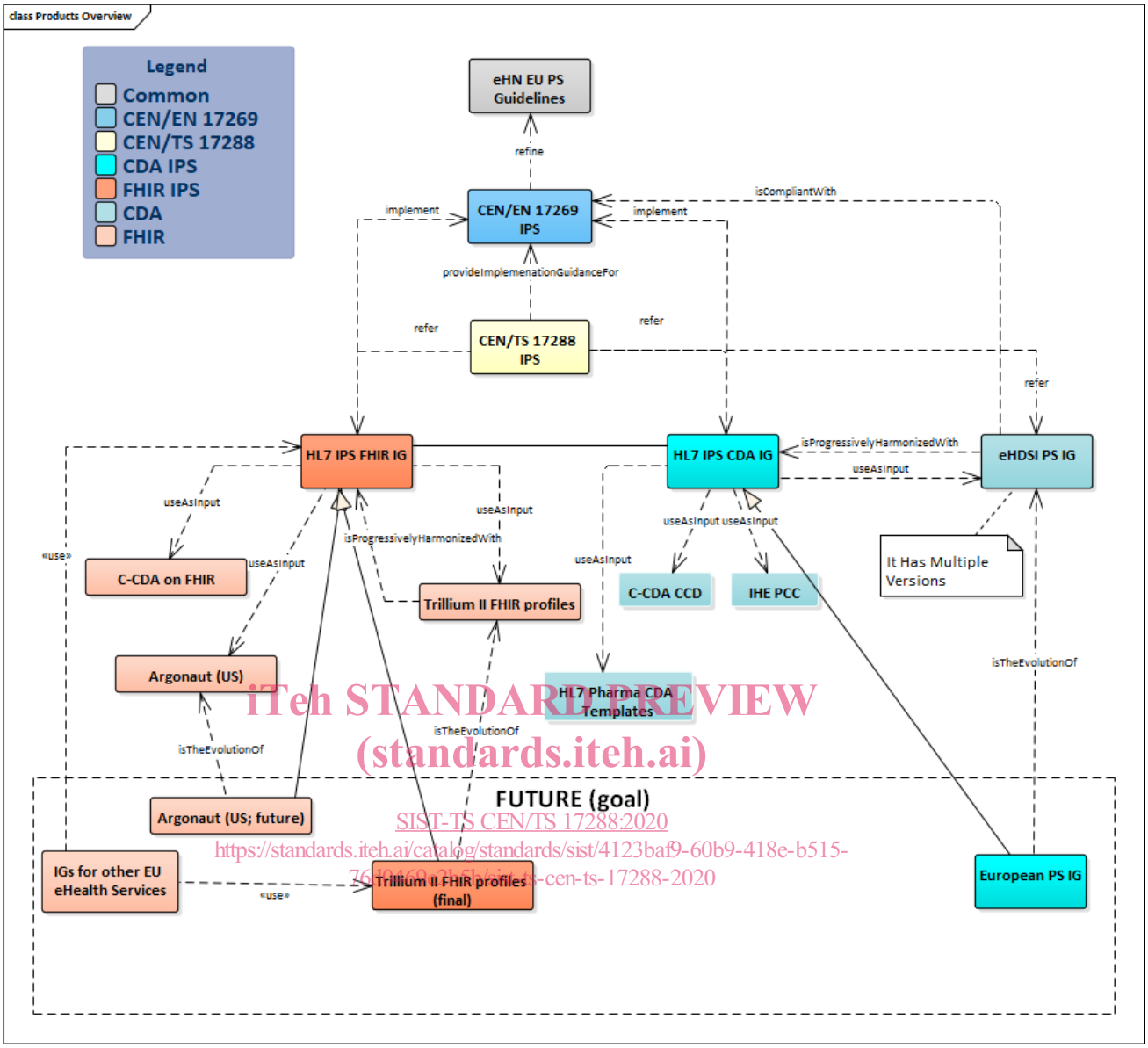

Figure 2 — An overview of the IPS Project

Table 1 — Description of the Clause mapping to ReEIF

Clause #	ReEIF's Consideration	Emphasis in this document
Clause 7	Governance	Information Governance
Clause 8	Security, Privacy and Confidentiality	Data Protection
Clause 9	Legal and Regulatory	Statutory requirements
Clause 10	Policy	European and organisational aspects
Clause 11	Care Process	Clinical Process and workflows

Clause #	ReEIF's Consideration	Emphasis in this document
Clause 12	Information	The Data sets, models and terminologies
Clause 13	Applications	Standardized Interchange formats
Clause 14	Infrastructure	IT and protocols of exchange
Clause 15	Standards and Profiles, Certification	Examples, Conformance Testing, deployment, and Evaluation

The single topic 'Security, Privacy and Governance' in ReEIF has been managed here as two separate clauses to highlight their importance to the IPS; the original format of the ReEIF is illustrated in Annex A. Frameworks and models are simplifications of the world they attempt to represent. Consequently, interpretation plays a part in how the ReEIF categorizes and differentiates between the different considerations. This document adapts the ReEIF to support this implementation guide.

The ReEIF provides a framework for the construction concepts, i.e. the identification and specifications concerning what is needed to deploy the solutions (here 'solution' is synonymous with the IPS). However, the operational aspects, including the project and deployment space, are not directly addressed by the ReEIF. This document considers these operational aspects in the latter part of Clause 15.

One example of ReEIF adoption and adaptation by Member States is given by Nictiz, the eHealth competency centre of the Netherlands. They make extensive use of the ReEIF in their national architectures (i.e. large, e.g. hospital network) and in local ones (i.e. small, e.g. GP office). The Centre deploys what are colloquially known as building blocks positioned at the Information layer of ReEIF, as a means of controlling communication which is "achieved by making agreements about the semantics, the meaning of the data and data structures as well as establishing these agreements in the form of health and care information models." [11].

Standardization initiatives relevant to the IPS

From the European context there are a number of formal activities that are of interest to the Standards Development Organisations (SDOs), which are mutually beneficial and compatible. They are:

- The Informative Joint Initiative Council (JIC) Patient Summary Standards Set (PSSS)

  o This activity is not intended to create a new standard; it is essentially an informative activity and its value is to inform the stakeholders about existing or developing standards in the PS space. The PSSS has a wider scope, providing a catalogue. Both CEN and HL7 are members of JIC.

- The normative CEN IPS and HL7 IPS initiatives (known as the IPS Project) focus on delivering a single consistent IPS information standard, guideline and implementation guides.

  o The HL7 IPS project succeeds the earlier INTERPAS project, whereas the CEN IPS project was intended to support standardization in Europe by formalizing the eHN Guideline through active participation in global SDO activities.

  o The IPS projects have been working together to produce a single compatible solution based on vision and agreements made at the Oslo workshop organized by Trillium Bridge back in 2016.

  o The IPS Project takes on board relevant detail from the JIC PSSS and will contribute to the PSSS content as their joint work proceeds to develop the formal standards required.

- The eHealth Digital Service Infrastructure (eHDSI) initiative for cross border health data exchange, which builds on the outputs of the epSOS pilot with a view of providing implementations for European Member States by 2019.

  o Whilst not strictly SDO related, it is a deployment activity, and considerable effort has been made by CEN and HL7, to harmonize their work to ensure European implementation is based upon a formal set of standards.

All these initiatives rely heavily on the eHN guideline for a PS data set, version 2 of which was published in November 2016.

NOTE 1 The JIC PSSS differs from the other initiatives in that it introduces extra items reflecting homecare requirements but these are outside of the IPS Project's current scope.

These eHN guideline has supported the harmonization efforts made by CEN/TC 251 and HL7. Policy considerations, stakeholders' interests, and technical changes provide the context for this document as illustrated by a simplified overview given in Figure 3, with the lighter arrows representing the historic influences and the darker arrows indicating specific inputs.

NOTE 2 There have been a number of projects and consortia that have been funded by EC initiatives that have also contributed in direct and indirect ways to the IPS Standards. Details of these may be found in the Bibliography of this document.

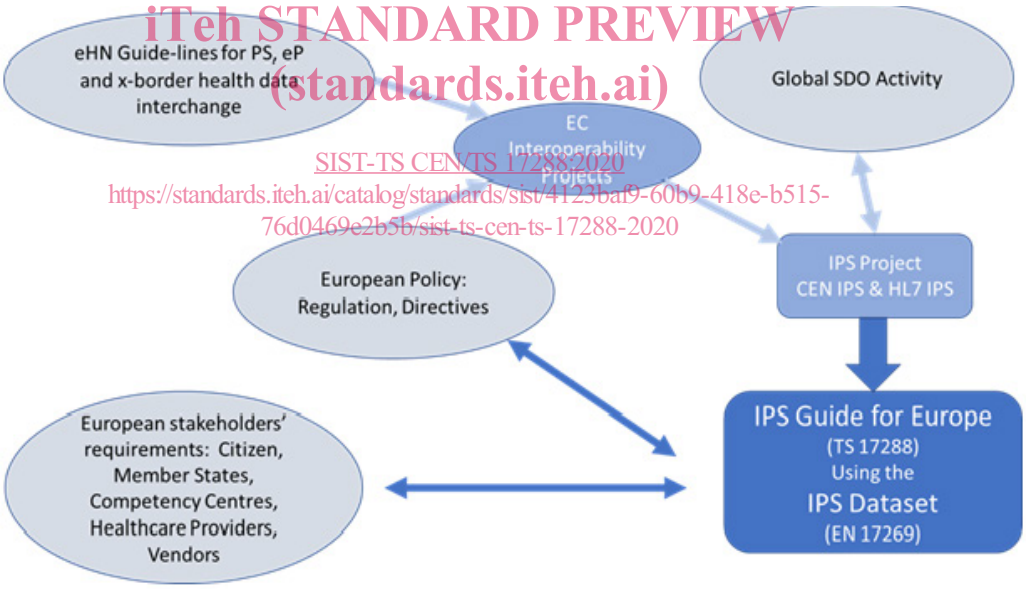

Figure 3 — Landscape affecting the IPS Guide for European Use

An amplified version of Figure 3, which explains the relationships between the CEN IPS and HL7 IPS deliverables and the context of the project work in more detail, is presented in Annex B (Informative).

1 Scope

This document is focussed on how the international patient summary (IPS) can be deployed within a European context. Specifically, this document provides guidance for the European implementation of EN 17269.

The guideline is also intended to be usable for more localized deployment, benefitting Member States that want to use the IPS within their own borders and, as an additional benefit, its components may be reused to improve the interoperability of EHRs through common exchange formats.

This document addresses:

— Jurisdictional requirements, such as EU directives and regulations, relevant to the usability of the International Patient Summary.

— Governance, privacy and data protection, so as to support the safe, legitimate and sustainable use of patient summary data. Continuity of care and coordination of care are considered with respect to cross border scenarios of care.

— Conformance, providing examples of conformant, derived models from EN 17269:2019 for both cross border and more localized use. Examples of transport formats for carrying patient summary data are given. Terminologies, deployment and migration guidance are also addressed.

Out of Scope:

This document will not recommend a particular delivery platform/service/template or terminology. The IPS is not a Personal Health Record (PHR), nor is it a comprehensive Electronic Health Record (EHR) both of which have different purposes.

2 Normative references

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

EN 17269:2019, *Health Informatics - The International Patient Summary for unscheduled cross border care*

3 Terms and definitions

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

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

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

3.1
condition independent IPS
set of data to help inform a person's treatment at the point of care, irrespective of the condition of the patient

[SOURCE: EN 17269:2019]

3.2
continuity of care
efficient, effective, ethical care delivered through interaction, integration, co-ordination and sharing of information between different healthcare actors over time

[SOURCE: EN-ISO 13940:2016]

3.3
cross border
passing, occurring, or performed across a border between two countries

NOTE 1 to entry: This scenario emphasizes the fact that countries will have different jurisdictions that might have legal, organisational and cultural implications for how personal data, and particularly health data are managed and shared.

NOTE 2 to entry: With respect to interoperability, cross border data interchange is the extreme case of the more general ones of organisational and professional boundaries found within a country's borders, and therefore the substantive part of the IPS standard is also applicable to national and local contexts.

3.4
extensible IPS Dataset
IPS content that can be extended for use in patient summary use case scenarios that complement the primary IPS Scenario

3.5
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: EN-ISO 13940:2016]

3.6
implementation independent IPS
IPS data model not bound to any implementation technology specification (e.g. XML, JSON) or implementable standard (e.g. HL7 FHIR; HL7 CDA) used to implement it.

NOTE 1 to entry: one or more implementation specific artefacts could be derived.

NOTE 2 to entry: it corresponds to the Conceptual and Logical Information Models, as defined by the HL7 SAIF Framework [18]; or to the Computational Independent and Platform Independent Models, as defined by the OMG Model-Driven Architecture approach [19].

3.7
IHE Profile
organization and leverage of the integration capabilities that can be achieved by coordinated implementation of communication standards, such as DICOM, HL7 W3C and security standards

Note 1 to entry: to entry: IHE Profiles provide precise definitions of how standards can be implemented to meet specific clinical needs.

3.8
HL7 FHIR (Resource) Profile
describes the general features that are supported by the system for each kind of FHIR resource. Typically, this is the superset of all the different use-cases implemented by the system. This is a resource-level perspective of a system's functionality

3.9
IPS
Synonym: IPS Document
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 '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 standard. The specific cross border scenario requires the Cross Border Data Block to be used, but this is not required for within border applications.

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 must have the same scope including the same purpose of summarizing the patient's healthcare history for continuity of care.

NOTE 5 to entry: IPS is also used as shorthand to denote the activity of the two SDO initiatives focused on delivering the IPS, i.e. CEN IPS and HL7 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.

[SOURCE: EN 17269: 2019]

3.10
IPS Consumer
healthcare provider or citizen who receives or accesses the IPS and manages its disposition

3.11
IPS Producer
healthcare provider, with possible patient as co-producer, who sources the IPS in response to an IPS request

3.12
IPS Request
healthcare information request where the requesting of the IPS can be made by any legitimate means of access

Note 1 to entry: There are many ways the IPS Request can be created and delivered; for example, it may be a message/document paradigm, or a legitimate query/view interaction, or a share between the healthcare provider and the patient or their proxy.

3.13
minimal IPS
IPS Dataset
core set of data items that all health care professionals can use

Note 1 to entry: The 'minimalist' concept reflects the ideas of 'summary' and the need to be concise at the point of care.

Note 2 to entry: It does not imply that all the items in the data set will be used in every *patient summary*

3.14
non-exhaustive IPS
recognition that the ideal dataset **is not closed**, and is likely to be **extended**, not just in terms of requirement evolution, but also pragmatically in instances of use

Note 1 to entry: However, such data are outside the scope of the IPS standards until revision.

3.15
open IPS Dataset
facilitation of extensions to allow for emerging solutions for unresolved issues or improvements

3.16
patient summary
health record extract comprising a standardized collection of clinical and contextual information (retrospective, concurrent, prospective) that provides a snapshot in time of a subject of care's health information and healthcare

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"; it can also be defined at a high level as: "the minimum set of information needed to assure health care coordination and the continuity of care". (eHN, article 2)

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

3.17
personal information
PI
any data that describes some attribute of, or that is uniquely associated with, a natural person

[SOURCE: OASIS PMRM TC, 2016]

3.18
personal identifiable information
PII
any (set of) data that can be used to uniquely identify a natural person

[SOURCE: OASIS PMRM TC, 2016]

3.19
specialty agnostic IPS
starter set of data to help inform a person's treatment at the point of care, irrespective of the specialist trying to manage the care