Irish Standard
I.S. EN 17269:2019

Health informatics - The International Patient Summary

I.S. EN 17269:2019

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 17269

November 2019

ICS 35.240.80

English Version

Health informatics - The International Patient Summary

Informatique de santé - Résumé international du dossier médical du patient

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

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

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

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of an identical text or by endorsement, at the latest by May 2020, and conflicting national standards shall be withdrawn at the latest by May 2020.

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

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

Introduction

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

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

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

The data set described is intended for global use beginning with a shared vision[1] from a collaboration between CEN /TC 251 and HL7. CEN has produced a separate Technical Specification (CEN/TS 17288) that provides a European-specific guideline for IPS implementation. HL7 have produced CDA and HL7 FHIR[2] templates for realizing implementations of the IPS.

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

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

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

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

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

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

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

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

1 Scope

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

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

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

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

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

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

2 Normative references

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

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

3 Terms and definitions

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

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

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

3.1
compliance
adherence to requirements for the necessary consistency of one member of the family of specifications or standards with another which are established during the standardization process

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