SLOVENSKI STANDARD
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Zdravstvena informatika - Povzetek podatkov o pacientu za nenačrtovano čezmejno zdravstveno oskrbo

Health informatics - The Patient Summary for Unscheduled, Cross-border Care

Medizinische Informatik - Die Patienten-Kurzakte für ungeplante, grenzüberschreitende Pflege

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Health informatics - The Patient Summary for Unscheduled, Cross-border Care

Informatique de santé - Résumé du dossier patient pour les soins transfrontaliers imprévus

Medizinische Informatik - Die Patienten-Kurzakte für ungeplante, grenzüberschreitende Pflege

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 251.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

This document (prEN 17269:2018) has been prepared by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by NEN.

This document is currently submitted to the CEN Enquiry.

Introduction

The goal of this standard is to deliver a single, common International Patient Summary (IPS), comprising core content suitable for the scenario of cross-border, unplanned care of a person with a health need.

The scope of this standard is to achieve that goal by defining a minimal yet non-exhaustive data set and its associated business rules. The resulting standard should be implementation independent yet supportive of any implementation by providing formal definition and clear description of the data set and its use. The primary input to the data set is the second revision of the European eHealth Network's data set (eHN: 2016), which, in turn, builds upon significant clinical input from the European Patients-Smart Open Services pilot project (epSOS: 2011).

This particular standard defines the domain model for an International Patient Summary (IPS) focused upon unplanned care across national borders. Notwithstanding 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.

The data set is global in scope beginning with a shared vision[1] of the IPS standard from a collaboration between CEN /TC 251 and HL7. CEN will produce a separate Technical Specification that will accompany this international standard to provide European-specific guidance profiling its implementation by the Member States. HL7 will produce CDA and FHIR templates for realizing implementations of the IPS.

Patient summaries are not new. Indeed, they are part of the very fabric of healthcare delivery, probably being the first examples of practical reuse of clinical data. They are in common and frequent use, throughout the healthcare domain, used to support continuity of care and the coordination of that care; consequently, patient summaries take many forms and have variable content. There is no doubt about their importance and place in today's healthcare provision, but their value to the individual and to the healthcare providers suffers from the current lack of formality and precision. Paradoxically the variability stemming from the pervasive, common-sense use of summaries makes them difficult to share in digital form across boundaries and restricts interoperability between heterogeneous systems.

The absence of a patient summary, or the presence of a summary that is restrictive, irrelevant or open to wrongful interpretation at the point of care, devalues its use, increases risk, and potentially compromises patient safety. Whilst the focus of this standard is upon the person with the health need, it should also be apparent that the potential problems have serious and adverse side effects (e.g. cost, liability) for the healthcare providers that have to treat that person at the point of care.

The 'International' element of the IPS emphasizes the need to provide generic solutions for global application beyond a particular region or country. This means that, where-ever possible, reference is made to international standards, rather than local ones, to avoid wasteful re-invention. However, different international contexts will offer a variety of requirements that need to be considered and disambiguated if possible to ensure that patient safety is not compromised. The IPS is underpinned by the ISO standard 13940:2016 "System of concepts to support continuity of care" and uses those concepts throughout for the derivation of a logical model for interoperability.

The fact that patient summaries play an extensive and integral part in operational healthcare activities argues against an intrusive standardization approach that attempts to formalize everything in one go. Such a scattergun approach would be hit and miss, as well as highly disruptive; it would require a large and inevitably error-prone specification with layers of optionality and flexibility to cope with the wide diversity of practice that exists today. Not only would the design of the specification be over-complicated,

[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".

its translation to construction would mean that it would be very difficult to implement whilst simultaneously increasing the likelihood of missing any designated target.

The argument for 'focus' goes beyond the difficulty of matching the complexity of the healthcare ecosystem with an overly complicated specification, and is not just the problem for the standards development organisations (SDOs) and the vendors. The greater issues lie with the area of 'agreement' and the respective positions of professional, organisational and legal perspectives. The more extensive the scope of any patient summary, the more difficult it becomes to gain consensus between the various parties over what it should and should not include.

Furthermore, the international aspiration of this standard magnifies the consensus issues and, in addition, has to consider the different capabilities, capacities and competencies of different countries to conform and manage an international norm. The adoption of an international standard in an important and pervasive area of healthcare will inevitably impact those countries (e.g. in terms of cost and clinical behaviours) that either do not currently collect the required data, or collect it in a way that differs from the IPS standard. For all, the consequences of adoption of this data set will have sustainability, management and governance issues going forward and this standard is tasked to ease that burden.

An IPS designed to be, and constructed as, the lowest common denominator would not satisfy the majority of stakeholders and consequently it would be ignored. The IPS standard is a key to unlock other health data and therefore has to balance the various known requirements and provide an incremental approach, a viable opportunity to improve the availability of relevant person-based information at the point of care. This balance has implications for the technical domain actors, i.e. the SDOs and vendors who are tasked with specifying and implementing usable and useful solutions for the IPS.

Stating the intended use of any patient summary qualifies and adds meaning to its scope and application. Importantly, the intended use provides a focus that differentiates this initiative from the multitude of summary documents that purport to do the same job.

The naming of this standard as the International Patient Summary (IPS) uniquely distinguishes its purpose; at the very least it should satisfy the given scenario of providing core content for 'unscheduled, cross-border care'. A secondary aim is to do so without compromising a wider, more general application. A given scenario of unscheduled, cross-border care is taken to provide a basis for the standardization activity that also extends its use to local and planned care. The IPS scenario is fully described in Annex A.

The layout uses a hierarchy of 6 levels (H0-H5) 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-H5 describe the IPS components 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 (e.g. IPS Sections and IPS Attribute Collections) are then presented in detail.

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

Descriptive hierarchy	H0	H1	H2	H3	H4	H5
IPS Data set	IPS Document concept	IPS Data set Components and IPS attributes	IPS content	IPS Content definitions and description refinements. H5 provides links to more detailed descriptors.		
	IPS Document	IPS Sections, IPS Attribute collections, and IPS Metadata	IPS attributes	IPS Attributes described with distinct and common elements described with IPS descriptors and examples		

The ordering of the IPS Data set Components in this standard is alphabetic within three broad categories of **Non-Clinical Data, Clinical Data** and **Metadata.**

This standard focuses upon the overall structure of the patient summary as well as the individual data elements that comprise it. The IPS Structure is represented as a document with sections and groupings of attributes plus metadata which describes some of the semantics for the document's components.

The eHN Guidelines allude to existing CDA implementations, and whilst this does not determine how this present standard will be implemented it does simplify the way in which the data elements can be described, and the levels of granularity that might be expected in any conformant implementation.

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 set Component; 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 generic view of how data elements are structured within sections within a document has been adopted for this standard. 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 "Type' albeit positioned within the Medical Device component.

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 '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 paradoxically enables the specified data items 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 Guidelines (eHN version 2, November 2016) 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 specifications.

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 associated Technical Specifications.

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 Specifications and comprise part of the Guidance for IPS implementation. The Identification of Medicinal Products standards (abbreviated to IDMP) are the recommended target for the Medication Summary related to this standard but, prior to IDMPs' 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 the 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:

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

3.1
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]

3.2
core care plan
reusable content and structure for a potential care plan for a specified set of circumstances

[SOURCE: EN ISO 13940:2016]

3.3
demand for care
demand for healthcare

demand for healthcare provider activities expressed by a healthcare actor

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

[SOURCE: EN ISO 13940:2016]

3.4
demand for initial contact
first demand for care concerning one or more specific health issues to be assessed by a healthcare provider

[SOURCE: EN ISO 13940:2016]

3.5
electronic patient summary
electronic health record extract containing essential healthcare information intended for specific uses

[SOURCE: EN ISO 13940:2016]

3.6
health condition
observed or potential observable aspects of the health state at a given time

[SOURCE: EN ISO 13940:2016]

3.7
health record component
part of a *health record* that is identifiable for the purposes of referencing and revision

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

[SOURCE: EN ISO 13940:2016]

3.8
health record extract
EHR extract
health record extract consisting solely of electronic record components

[SOURCE: EN ISO 13940:2016]

3.9
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]

3.10
patient summary
Health record extract comprising a standardized collection of clinical and contextual information (retrospective, concurrent, prospective) that provides a snapshot in time of a subject of care's health information and healthcare

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

Note 1 to entry: 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".

[SOURCE: eHN, article 2]

3.11
point of care
location where direct healthcare activities are performed

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

[SOURCE: EN ISO 13940:2016]

3.12
provenance
to evidence and attributes describing the origin of health information as it is captured in a health system

[SOURCE: HL7]

3.13
subject of care
Synonym: patient, client, citizen

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

Note 1 to entry: to entry: 'Patient' will be used as the term in common use with the 'Patient Summary'.

[SOURCE: EN ISO 13940:2016]