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The International Patient Summary Standard and the Extensibility Requirement

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Abstract. The International Patient Summary Standard (EN 17269) normalizes the dataset within the European Guideline on cross-border exchange of a patient summary. This dataset has been widely appreciated and been taken as the basis for projects in both Europe and wider afield, e.g. U.S.A, Canada and more. The dataset is a relatively mature dataset and it is currently in its third iteration (i.e., 2013, 2016, 2020). Even so, to move from a policy-driven guideline to a formal standard was not straight forward. The paper describes how the 'minimal and non-exhaustive' dataset could be the basis for a reference standard; one that was intended to facilitate both an 'implementable' and 'sustainable' solution. In particular, the requirement of 'extensibility' for the standard dataset had to be addressed.

Keywords. IPS, Standard, Extensibility, COVID-19

Introduction

Terms such as 'ubiquitous', 'pervasive', 'mobile' are adjectives that are often applied to computation and computing artefacts. But not exclusively so. These same terms can also be applied to 'summarization' and to 'summary'. Professional summarization in the healthcare domain and the 'patient summary' in particular, are considered to be specializations of the more general concepts.

The International Patient Summary (IPS) Standard (EN 17269) [1] normalizes the dataset provided by the European Guideline on cross-border exchange of a patient summary. The dataset has its origins in the Europe-wide epSOS project [2] starting back in 2008, and has been refined and taken forward by the eHealth Network (eHN). The dataset's maturity and relevance, and the fact that it seemed relatively self-contained and straight-forward, made it an obvious candidate for standardization. A proposal was made by CEN/ TC 251 to the EC that the dataset should be normalized to support consistent use in Europe and to satisfy the evident growing requirement from the international community.

The eHealth Network (eHN) published "Guidelines on **Minimum/Non-exhaustive** Patient Summary Dataset for Electronic Exchange…". In this, they describe a Patient Summary as an identifiable "dataset of **essential** and **understandable** health information at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care". [3]

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The analysis of this description suggests that **"essential"** refers explicitly to the '**minimum'** criterion for the dataset in the eHN document. It is an interpretation that is consistent with the definitions of 'summary' and 'summarization', i.e., definition of a summary [4] is "a brief statement or account of the main points of something" and 'summarization' can be regarded as the skilled reduction of information to its most essential points, by retaining what is relevant and deliberately discarding the irrelevant for the purpose of effective communication [5].

The '**Non-exhaustive'** criterion suggests that there may be other 'important', and 'essential' data that at this point of time are either considered as 'irrelevant' for this specific purpose, or not yet part of the standard dataset (but it leaves open the option of further additions once consensus has been reached). The second criterion of the eHN dataset is the requirement that it be '**understandable'**. It requires that the intended reader(s), should be able to read the content of the summary easily and quickly in the specific communication situation. Both criteria, coupled with the urgency that might be inferred from the 'unscheduled care situation', suggest that the summary should be a condensed, reduced and concise artefact (e.g. document) to facilitate practical use.

The 'Non-exhaustive' property of the IPS Data Set "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" [6]. The extensibility of the IPS Data Set for current use and future requirements are addressed here.

1. The International Patient Summary Dataset

The IPS Data Set is defined as a "minimal, non-exhaustive set of data elements required for the international patient summary" [EN17269:19]. 'Minimal' reflects the ideas of a general 'summary' and the need to be concise. The 'understandability' criterion also alludes to the existence of a core set of data elements that all health care professionals can safely use. These considerations led to the identification of other underlying qualities of the IPS Data Set, i.e., that it be a specialty-agnostic and condition-independent dataset [7]. This does not imply that such data is unimportant or irrelevant. Rather it assumes that the core data is common, general knowledge and understandable to all intended readers, regardless of their specialty. Furthermore, this core data is applicable to all subjects of care, notwithstanding any particular known condition, which will, with high probability, require other data to complement the core for the subject of care's treatment.

The IPS Data Set is a proper subset of all healthcare data, and it is therefore necessary to consider how that subset can be extended. It does not imply that all the items in the IPS Data Set will be used in every summary instance. The IPS Document or IPS can, however, be extended with non-IPS standard condition-specific data.

1.1. The IPS, the EHR and Extract

The IPS standard uses the definition of a 'patient summary' from an early technical report,

> *"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]*

Over a decade old, it still expresses the current understanding of the IPS. It makes it clear that the Patient Summary is a "point-in-time" extract from the [digital] health record (EHRs). As such it is a temporal subset or snapshot of the longitudinal record. It should not be equated to an EHR, however, as it has a different purpose, one which seeks to condense and make the whole of an EHR (just the 'important parts') quickly usable with relevant information at the point of care.

The initial focus of use for the IPS was unscheduled care but the IPS can also be used within scheduled care scenarios. In such cases, attending clinicians may have access to the full EHR and have access to a more extensive set of data, which would also include the IPS Data Set elements. In this case, the IPS Data Set might serve as an executive summary that indexes the main body of information. However, even in scheduled care, the IPS can play an important role when the provider does not have access to the full EHR. In particular, in cross-jurisdiction situations there may be no other kinds of data available except for the IPS.

However, in some countries the IPS Data Set content may surpass what they have in their local or national EHR, so part or all of it may be used as a template for what they might introduce in the future. In Europe, the guideline is a recommendation for the Member States for the 'patient summary', but the eHN are aware of the different capacities and capabilities of Member States (MS). The EC are also in the process of launching an EHR Exchange format, that will consider the IPS to be an input but not the whole thing [8]. There should be no misunderstanding when the subject of 'extensibility' is raised in connection with the IPS. Be clear, there is absolutely no intention by the authors to extend the IPS (data or functionality) to a full-blown EHR or to confuse the two.

2. Extending the IPS Data Set

There are two broad, yet distinct ways of extending the use of the IPS:

- Refining, complementing and profiling the IPS Data Set for different health conditions and applications that relate to model derivation of IPS from the current standard, (e.g. Vaccination card, and COVID-19).
- Evolving the base or foundational IPS standard by consensus and that will require that the IPS standard be updated by new clinical and technical requirements from use (e.g. the vulnerable Subject of Care, and COVID-19).

2.1. The IPS and Sibling Specifications

Before examining these types of extension, it is necessary to position the IPS standard in relation to the other specifications that are associated with it (See Figure 1). The final output will require the buy-in from multiple stakeholders to make the IPS real. One key need is to be clear on the relationship of the abstract specification (i.e., EN 17269) to the other more concrete outputs from the SDO community and the required governance necessary to shape future, consistent and sustainable growth.

EN 17269 is currently being balloted as ISO 27269 in the fast-track process, which takes a CEN regional specification into the ISO domain, where it will be recognized as an international standard by the wider community. The intention is to socialize the

standard beyond the European and United States regions and make the international patient summary truly international.

A second specification, TS 17288:20 [9], was delivered by CEN as part of the EC contract. It is a guideline for implementing IPS within Europe and it describes jurisdictional factors that have to be considered to operationalize the IPS. TS 17288 utilizes the refined eHealth European Interoperability Framework [10] to structure its content in terms that are familiar to the MS and suggests ways in which to populate the cross-border IPS Section for European implementations. It is envisaged that other countries with specific concerns about adopting IPS for their own jurisdiction requirements, might use this standard as a model and produce similar documents for their own use. Both EN 17269 and TS 17288 are high level representations intended to describe the 'what' rather than the 'how' of the IPS. Consequently, they provide bridges from the policy guidelines to the implementations by refining and standardizing the eHN dataset.

From the EN 17269 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 HL7 CDA Implementation Guide [11], the HL7 FHIR IPS IG [12], and the IHE IPS profile [13]. EN 17269 is not bound by any terminology, although it does anticipate the use of the IDMP [14] standard for medication. The IGs and the eHDSI implementation have been offered use of the SNOMED Global Patient Set [15] that they can deploy, and the implementations may take advantage of the use of GS1 for some identifiers (e.g. devices) [16]. It is very important that there is only one CDA IG and one FHIR IG template and that all implementation specifications are harmonized.

To keep to the declared, shared vision of the IPS [17] for one standard solution, it is imperative that all the derived models will conform to the single reference data model of IPS that is now EN 17269 and will become ISO 27269 [18] in due course. Figure 1 offers an overview:

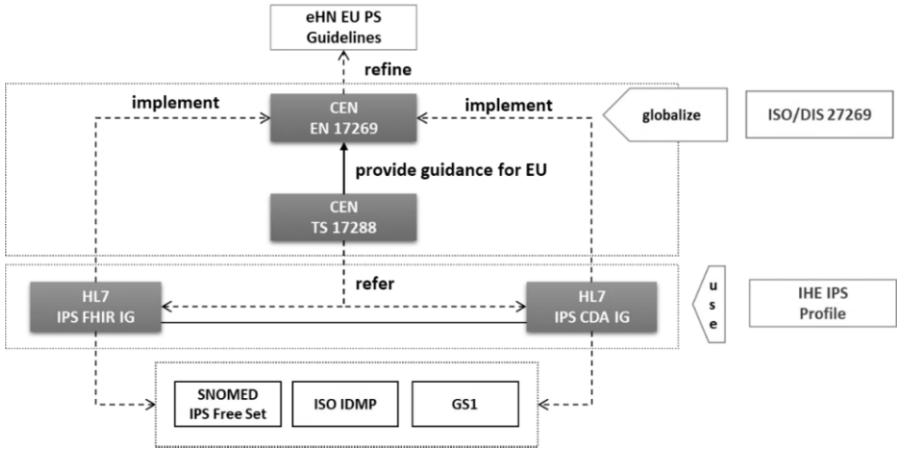

Figure 1. IPS Specifications associated with EN 17269

3. IPS Modelling and Profiling for Extensibility

It is 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 (e.g. the color of the inhaler for example) are specified by the core dataset in the IPS standard. So how does extensibility work with the standard to make the IPS support specific health conditions?

1. The IPS standard defines three fundamental levels of compliance, each having associated business rules and data definitions: 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 IPS Data Block model. A fully compliant model or a conformant implementation shall also:
   - 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.
   - Declare, if not self-evident, how the data patterns are realized.
   - Fulfil the conformance rules (from HL7), the descriptors being Mandatory (M: No exceptions); Required (R: exceptions allowed); Required if Known (RK); Conditional (C: has associated predicates); Optional (O).
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 (specifically IPS Sections of 'Provenance', Patient Identification, Problems, Allergies and intolerances, and Medication. Cross-border data is also mandatory if required for that particular scenario). 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.
3. The third level relates to the named IPS Data Blocks, the IPS Sections and IPS Attribute Collections, and also the smaller parts such as the Label Concepts (e.g. Vaccination). In theory, all these data blocks are reusable for other applications. The simple, hierarchical arrangement[2] described in the eHN guideline is retained, but the number of levels have been increased in the IPS Data Set from 3 to 8 to increase specificity of the representation. Note, level 8 is not a hard limit. The IPS Data Blocks are presented as data patterns within a tabular format within the standard; each element within the data block is represented within a row comprising: indentation to reflect the position within the hierarchy, an informative name, followed by a conformance descriptor, a data type description and a numbered link to further details, such as business rules or more detailed explanation of purpose. The hierarchy containing the element must be maintained but the ordering of the

[2] The IPS Standard uses tree data structures in this first iteration to keep it simple and to nurture adoption. However, the more complex graph data structure is a more faithful representation and may be explored for future models if there is a requirement.

elements in different hierarchies (i.e. those starting at the same indent) has no significance.

Models derived from the IPS standard, including implementable specifications, are allowed to further refine 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 concepts; and by adding non-IPS sections to the IPS (See Figure 2).

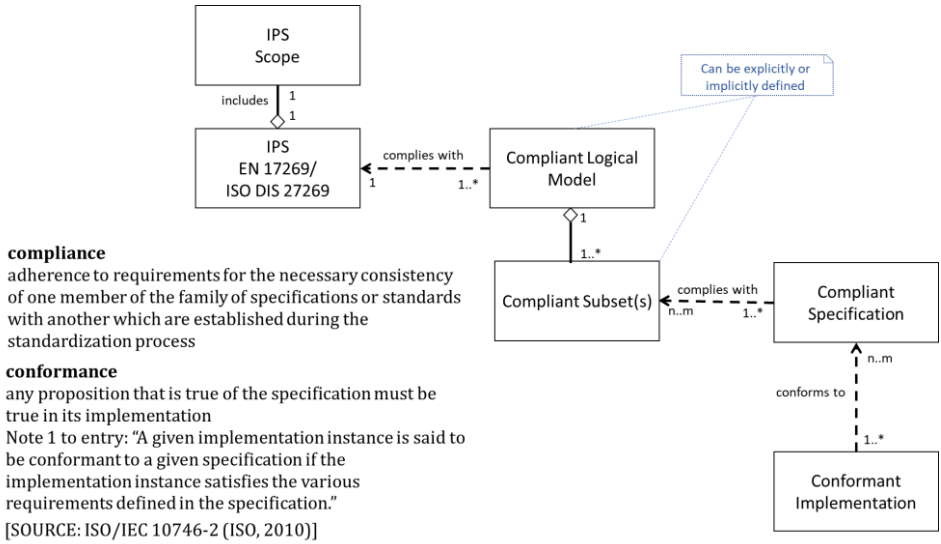

Figure 2. Different Models of IPS, from Abstract Reference to Concrete Implementation

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

> "Within the scope of the international patient summary the recipient can support safe care provisioning, even if it is not able to process semantics of the extensions. An extension shall therefore not change the meaning of the elements defined by this standard."

4. Examples of Extending the IPS

The inputs from multiple SDO's also needed to be aligned and extensibility needed to be addressed across the groups as separate documents emerge from the different SDOs. They have to be kept in sync and be harmonized if an interoperable solution is to be created and a difference made to the consumer. Systematic ways are needed to track SDO outputs and outcomes, the latter being the beneficial value of the IPS to the stakeholders e.g. [19].

In section 3 of this paper we highlighted two broad ways of extending the IPS. Here we give examples and Figure 3 shows the different compliance solutions with examples.

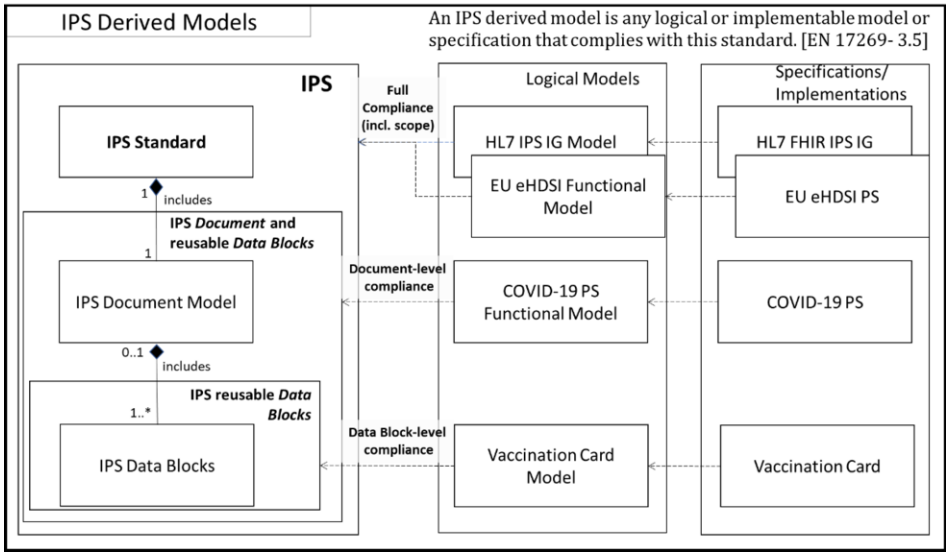

Figure 3. Different types of compliance related to the structures of the IPS Reference Model

4.1. Refining, Constraining, and Complementing the IPS Data Set

IHE profiling provides a way of supporting national specific extensions, perhaps further documented in a variant of TS 17288. More generally implementations may require things that are not in the IPS scope, for example header details that are in the HL7 CDA IG.

The IPS Reference model is very generic, but it maybe that there is a need to specialize to represent different constraints for lab results; imaging results; and vital signs. Another example is the Computable clinical guideline [20], which can leverage the IPS. Such guidelines are condition specific (or relate to multiple co-morbidities) and go way beyond the core data set in IPS. In due course, the refinements will be fed back for consideration of inclusion into the foundation IPS standard.

4.2. Evolving the Foundation IPS Standard

The eHN guidelines are considered to be an 'evolving document', one "that is further revised and updated on the basis of technical developments and feedback from users (Member States and other Stakeholders) and in response to other use cases". The same can be said of the IPS base standard.

One new use case that illustrates stakeholder demands, requiring a response and a set of new requirements for extending the IPS Data Set (in the ways introduced in Section 2) is the current pandemic, COVID-19. Stakeholders are looking for a kind of 'COVID-19 immune flag' to be highlighted in the IPS. Three associated facts necessary to record in the patient summary seem to be immediately available in the present IPS:

1. I have / had this disease… [IPS Sections: Problems / Past problems]
2. tests say that … [IPS Section: Results]
3. I've been vaccinated against … [IPS Section: Immunization (not applicable for COVID-19 yet)]

The 'flag' could be indirectly derived from the existing standard. This puts the onus on the user interface rather than the IPS Data Set. It also semantically overloads the already overloaded 'Problem' IPS Sections. The solution suggested for the time-being is to retain the scope of the Immunizations IPS Section to the vaccination-driven approach but allow for optional immunity data. Creating a new Public Health/ pandemic IPS Section is another option, although it may stretch the idea of the IPS being for an individual subject of care, but this could still relate to the Immunization Section. Depending on scope, such a section might reposition the current 'alerts and health risks' items from the existing, overloaded 'IPS Problem list'. This option is clean but may burden implementers and will not be an immediate solution.

Yet another option is to consider the attribute collection for Patients and to consider closer alignment with ISO 13940, 'System of concepts for continuity of care' [21]. In the current IPS specification, Attribute Collection serves a primarily administrative purpose. However, 'immunity' may well be considered to be an aspect of a person's health state, perceived or recorded as a health matter; conversely 'lack of immunity' could be recorded as a specialization of 'problem'. The change in where the details are recorded from one IPS instance to another reflects the fact that IPS is a snapshot, recording the relevant things about the patient's healthcare at a point in time. Changing the scope of the IPS Patient Attribute Collection to include health matters is feasible but will have to be tested to understand the impact on the healthcare provider' systems.

5. Conclusion

This paper has addressed the importance of designing in the extensibility requirement of the IPS reference standard. It explains the given ways permitted by the specification for extending the foundation standard and shows how the core IPS Data Set can play its part in both condition and specialty specific extensions for different care situations.

The paper shows how the foundation standard can evolve in response to stakeholder requirements and to new use cases such as the COVID-19 pandemic. In particular, the possible but different ways to express COVID-19 details is testimony to the flexibility of the IPS architecture. Which option is best? Each option has its pros and cons. Considering COVID-19 as just one of possibly many more pandemics to come, is it best to try a quick-fix or do we need to address the whole subject? How is it possible to provide a timely solution? There may not be a perfect solution.

However, the IPS has been exceptionally good at creating collaborations in which the SDOs learn from each other. Any extension will aim to retain the integrity of the IPS. Furthermore, it should be clear that any extension is part of a bigger extensibility process; the choice will be determined by consensus and governance processes with the explicit objective of providing a sustainable, implementable standard. In this instance, the upcoming Trial Use FHIR IG Publication, the current fast track process of EN 17269 to ISO 27269, and the Trial Implementation of the IHE IPS Profile all provide validation opportunities, allowing this current issue of immunity to be addressed by the community. Such extensibility tests should strengthen the standard's evolution by extending the present IPS in a coordinated and consensual fashion.

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