IPS Governance Framework: Current practices in Specification Use and Updates

Robert STEGWEE[a,b,1], Hans GILLE[b,] Catherine CHRONAKI[c]
[a] *CEN TC/251, Brussels Belgium*
[b] *CGI, The Netherlands*
[c] *HL7 Foundation, Brussels, Belgium*

Abstract. The *e*Standards methodology stressed the importance of trust and flow for health data as a key characteristic of well-functioning health systems. A digital health compass, leveraging perspectives of health systems, digital health markets, citizens, and workforce, drives a process of co-creation, governance and alignment in *e*Standards. A repository of best practices and common components further advances interoperability, as new projects add their experience. This paper proposes a governance framework for requirements management, intelligence gathering, specification use, and updates to promote sustainable governance for International Patient Summaries. It is based on interviews of 14 patient summary projects and initiatives in Europe and the United States.

Keywords. Standards Interoperability, Cross-border eHealth Services, Governance

1 Introduction

The International Patient Summary (IPS) was initially developed for unplanned cross-border care. However, soon it became clear that health care providers were not keen to invest in such an exchange of health information, if it was limited to this purpose. Thus, they extended the core notion of a patient summary (PS) to fit their business needs. In fulfilling a broader purpose, a governance framework for the standards used and the specifications developed to serve their local business case(s) is needed.

The Health Informatics Standards Life Cycle is intended to be generic for all eHealth Standards and not just specific to the IPS [1]. Viewed from a different perspective, the explicit standardisation activities are just one particular aspect of the real-world concept of a PS. A PS has its own life cycle and activities, much of which are not explicitly related to, or directly impacted by the formal standardisation processes. It is important to note that PS standardisation and implementation can take place at various levels.

At a global level, we have the Patient Summary Standards Set (PSSS) [2], a guidance document, published by the Joint Initiative Council on Global Health Informatics Standardisation, which catalogues several base standards from the participating standards developing organisations (SDOs). Meanwhile, CEN/HL7 collaboration led to the aligned CEN International Patient Summary Standards and the HL7 International Patient Summary, with implementation guides for HL7 CDA and

[1] Corresponding Author: Robert Stegwee, robert.stegwee@cgi.com

FHIR standard format. Together, the CEN and HL7 IPS standards take the notion of the informative guidance provided by the PSSS to a whole new level, providing a coordinated and fully specified set of standards and implementation guides for the PS. They build upon the C-CDA patient summary (US Meaningful Use Summary of Care) program in the US and a CDA patient summary using the eHealth Digital Service Infrastructure (eHDSI CDA Implementation Guide) building on the eHN guidelines in Europe [3]. Recently, SNOMED International made available a free set of SNOMED CT terms to use in the IPS leading to four linked standards (Fig. 1). If EU member states adopt PS in a way compatible/interoperable with global standards, that will drive sustainable cross-border exchange of PS data, giving rise to feedback and activities that influence standards and advance interoperability. Substantiated recommendations for governance of specifications in PS initiatives, connected to global standards, need consideration of PS governance at various levels of implementation.

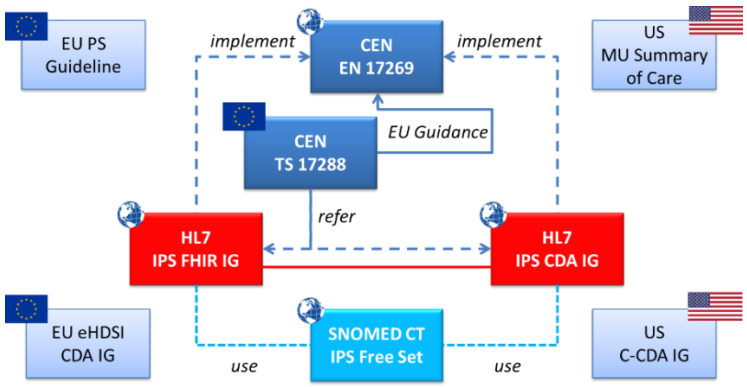

Figure 1: Four closely linked global IPS standards with EU Implementation Guidance

2 Methodology

In the context of this study**,** a PS initiative is defined as **any specification, implementation, or operational effort that uses the exchange of patient summary data as the basis for adding value to the identified care setting**. This includes the original focus on cross-border unplanned care for the international PS, as well as part of a targeted effort for specific patient groups (chronic diseases, rare diseases) or for general patient empowerment initiatives using personal health record exchange. The need for governance and the interlinked life cycle models of both generic standards and the IPS specifically guided the construction of an interview guide on the topic of IPS governance. An inventory of patient summary governance practices was taken using the following five steps:

1. Identify key Patient Summary initiatives;
2. Assess goals, objectives, and activities related to governance within the initiative;
3. Assess the initiative's current linkage with standards governance;
4. Make an inventory of the initiative's needs for standards updates and version management of the specifications in use;
5. Compare results, identify best practices and provide a summary.

We identified and conducted interviews with 14 PS initiatives in Europe and the United States. Twelve initiatives are PS at national or regional levels and two are standards developing initiatives. The questionnaire used in these structured interviews is available upon request. After processing the information collected, the findings were summarized in a report focusing on best practices and encountered problems [4].

3 Results: The IPS Governance Framework

Governance of PS specifications is focused on the Information layer of the Refined eHealth European Interoperability Framework [5] and is frequently isolated from the way PS is implemented in the Care Process and Application layers. The CEN/TS 17288 PS Guideline for European Implementation includes a section on governance that covers process and product aspects of governance, pointing to guidance on GDPR compliance considerations. The interviews confirmed the five main topics to be addressed by PS governance:

1. **Initiative:** aim of PS initiative and stakeholders directly involved in the exchange
   All interviews acknowledged a clear definition of scope and how stakeholders contribute to the stated objectives of the patient summary initiative.
2. **Specifications and Standards**: overview of specifications and standards;
   All initiatives confirmed the importance of standards. However, not all initiatives develop their own specifications; six of the twelve implementation and operation initiatives rely on specifications developed on a national scale or are conformant to the European Patient Summary specifications.
3. **Governance Scope and Objectives:** future scope, objectives, and sustainability considerations embedding the PS initiative in the broader governance structure;
   The majority of initiatives rely on governance by an independent party set up for health information exchange in general. This puts severe limitations on the influence key stakeholders in the use of the patient summary have.
4. **Stakeholder Involvement**: stakeholders not involved in actual PS exchange;
   It is striking that only a few of the initiatives explicitly mention the engagement of users and expert groups from different stakeholder communities.
5. **Update and Version Management**: provisions for updates to PS specification and alignment with maintenance of underlying standards;
   Only one of the fourteen initiatives employs a fixed cycle for publishing updates, most mention a dynamic process based on the needs expressed by the stakeholders.

4 Discussion

Interlinked governance processes of PS are complex and it is hard to establish an overarching governance for all aspects of the IPS. The governance framework developed can be employed by PS initiatives connecting related initiatives and SDOs. It provides pointers and functions for governance of individual PS initiatives:

1. Identifying change management processes for PS standards and specifications in the initiative engaging the user and stakeholder community;
2. Gathering experience and feedback for the governance processes focussing on best practices, sustainability and continuity of effort;

3. Refining governance structures over time in long and short-term, with flexible structures that facilitate alignment and feedback to standards organisations.

From the perspective of SDOs, it is recommended to establish a joint governance on IPS standards, as a single community or open governance framework for PS initiatives to turn to. SDOs should ensure a balance of interest and provide opportunities for broad participation. Simplicity is key. Community collaboration is favoured over rigid formal bodies to safeguard the relevance of IPS standards and specifications. Collaboration is also necessary at a national level, coordinated by National eHealth Competence Centres (NCCs). Via coordination with relevant sections and experts of the SDOs, NCCs ensure that standards and specifications are coordinated and that required changes are incorporated in the standards, the EU guidelines, and the eHDSI. The connection between local and global governance is crucial for sustainable standards-based innovation.

5 Conclusions

Promoting sustainable IPS governance takes the global collaboration of SDOs in the JIC on Global Health Informatics Standardization as a starting point. Interviewed initiatives provided best practices on engaging SDOs and initiatives in governance of specifications. Identification of shortcomings and coordination of change requests among initiatives, are crucial for effective governance. We recommend a community of experts from SDOs as the point of contact for questions about and suggested changes to the IPS standards. Similar communities can provide guidance at a national/regional scale, with an important role for NCCs. They drive adoption of IPS standards from the global community down to the local implementation in EHR systems. Consistent local implementation is crucial for the effective exchange of data, whether on a local level or a national or cross-border scenario, for improved data quality and ultimately patient safety and better care.

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