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Interoperability Assets for Patient Summary Components: A Gap Analysis

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Abstract. The International Patient Summary (IPS) standards aim to define the specifications for a minimal and non-exhaustive Patient Summary, which is specialty-agnostic and condition-independent, but still clinically relevant. Meanwhile, health systems are developing and implementing their own variation of a patient summary while, the eHealth Digital Services Infrastructure (eHDSI) initiative is deploying patient summary services across countries in the Europe. In the spirit of co-creation, flexible governance, and continuous alignment advocated by eStandards, the Trillum-II initiative promotes adoption of the patient summary by engaging standards organizations, and interoperability practitioners in a community of practice for digital health to share best practices, tools, data, specifications, and experiences. This paper compares operational aspects of patient summaries in 14 case studies in Europe, the United States, and across the world, focusing on how patient summary components are used in practice, to promote alignment and joint understanding that will improve quality of standards and lower costs of interoperability.

Keywords. International Patient Summary, Interoperability, eHealth, standards

1. Introduction

Patient summary is a standardized set of basic medical data that includes the most important clinical facts required to ensure safe and secure health care. Presented as a concise clinical document this information is applicable and relevant both in unexpected, as well as in expected healthcare contacts. Patient summaries piloted in large scale during epSOS (2008-2014), prepared the ground for the European Directive 2011/24 on patients' rights on cross border care [1]. The eHealth Network (eHN) of health ministry representatives established under article 14 that meets twice a year to discuss cooperation in cross-border Health services, adopted the patient summary guideline in 2013 and its revision in 2016[2]. Supported by the eHN, Patient Summary services are now entering production within the Connecting Europe Facility (CEF) eHDSI in 2018-2021[3]. This infrastructure is exploited by 23 European Countries to run in period 2017-21 and beyond, the Cross-Border eHealth Interoperability Services for Patient Summary (18 countries), and ePrescription (17 countries) services. CEF eHDSI is based on specifications of the

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF
[2] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf
[3] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co06_en.pdf

National Contact Point for eHealth, whose reference implementation is maintained by EC DG Santé, DG DIGIT and DG CONNECT. Meanwhile, different jurisdictions in Europe, the United States and around the globe, develop their own patient summary services to fit their specific needs and requirements in an inclusive multi-stakeholder approach, as health systems are transformed by digitization and citizens increasingly depend on apps and online resources for health decisions. Trillium Bridge, working under the auspices of the EU/US memorandum of understanding on cooperation in eHealth, recommended joining forces to support global standardization efforts. Trillium Bridge put forward 20 recommendations in seven areas, namely, future standardization, cross-vendor integration, innovative business models, clinical research, incentives, privacy and security and education[4]. A follow-up initiative, Trillium-II pursues the core recommendation of Trillium Bridge to "*advance an International Patient Summary (IPS) standard to enable people to access and share their health information for emergency or unplanned care anywhere and as needed. At minimum the IPS should include immunizations, allergies, medications, clinical problems, past medications, and implants*." The eStandards project (www.estandards-project.eu) developed a roadmap for eStandards adoption in Europe, to drive adoption of eHealth in a sustainable and cost-effective way. The eStandards roadmap recognizing the shift from documentation to sharing and productive use of data for better decisions, advocated renewed focus on open innovation and user experience. Building on a co-creation, governance, and alignment paradigm, the roadmap argues for eStandards driven by an iterative process that focuses on quality and stakeholder engagement, to build trust in the use of health data by individuals, health systems, and the industry. HL7 and CEN have joined forces to transfer the eHN patient summary guideline and associated best practices into consistent IPS Standards agreeing on the set of principles and approach shown in **Figure 1**.

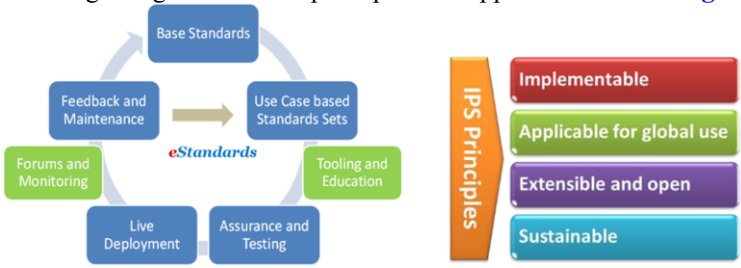

Figure 1: The eStandards lifecycle and IPS principles aim to broaden adoption and consistent implementation of patient summaries as a window to a patient's health information.

Given that patient summary information may be captured and held in multiple heterogeneous electronic health record systems, when extracted, data needs to be mapped to shared structures and value sets to support safe information sharing as part of the medical practice. Since there are presently several specifications, clinical model and terminology standards in use, it will help standards adoption if shared information structures are published with ready-made and quality assured mappings to commonly used, code systems or value sets. Interoperability assets ranging from specifications to software libraries implementing components, are the tools to support alignment and advance interoperability. However, these interoperability assets are embedded in diverse operational environments. Patient summaries pilots in different countries were analyzed in the JAseHN project focusing on the specifications and semantic infrastructure used in

[4]https://ec.europa.eu/digital-single-market/en/news/trillium-bridge-recommends-international-patient-summary-standard

different member states [1]. The IPS workshop hosted by the European commission explored the role of the patient summary in the health ecosystem of selected member states [2]. To our knowledge, this is the first study that considers the elements of the patient summary components or building blocks in detail. This paper results of our efforts to understand the variation in patient summary components across jurisdictions as the first step in a comprehensive gap analysis to assist creating a robust patient summary specification that is lean and cost-effective.

2. Methods

After reviewing various patient summary specifications available in Art Decor (www.art-decor.org) a survey was prepared and distributed to the Trillium-II community. The survey was accompanied by an introduction and instructions on how to complete the survey. The survey consisted of a questionnaire and a Topic Matrix. The questionnaire asked questions about the patient summary services related to organizational, legal aspects, as well as short and long-term desiderata. The Topic Matrix summarized the use of individual components or building blocks of the patient summary using HL7 FHIR resources as baseline. Following receipt of the completed surveys, personal interviews clarified responses and helped in quality assuring input to the Topic Matrix. Twenty-eight (28) initiatives were contacted via email with a request to participate in the survey and fourteen (14) responded. Despite the expected variations in concepts and practices from the eHDSI patient summary and IPS, capturing these differences in a structured way and developing tools to bridge gaps and promote best practices, is essential.

3. Results

Fourteen (14) of the twenty-eight (28) initiatives contacted, responded. Ten initiatives have national scope (Finland, Greece, France, Austria, Luxemburg, Portugal, Italy, Germany, Netherlands, Australia), one is regional (TicSalut Foundation, Catalonia), and one is health management organization (Kaiser Permanente, US). The EU Guideline implemented in the eHDSI and the current ballot of the IPS in HL7 were also analyzed.

3.1. Organizational aspects

Asked about the scope and purpose of the patient summary, ninety percent (90%) of respondents reported that the patient summary is for providers in cases of unplanned care and seventy percent (70%) also think that the patient summary is good for the patient.

Asked about the steps of use case definition, specification/balloting, implementation, and productive use (see eStandards lifecycle in **Figure 1**), while 90% have a patient summary in production, 75% completed a patient summary specification, but in only two cases a balloting process has been initiated. On the question "*how the patient summary is initialized/operationalized*", four options were provided: on demand; stored & regularly updated; manually/semi-automatically/automatically; other. The responses indicated that the creation of the patient summary is not well-regulated and varies. Other questions addressed how the content is determined and what are the sources of information. In most cases, rules derived from the specification are used to collect relevant parts and providers are the sources of information for the patient summary. In 70% of cases information from the patient is also included. Adoption varies and, in some

cases, a large percentage of the population with a patient summary was reported. Assurance of whether the patient summary is up-to-date is provided by the policy or governance model of the jurisdiction. Most of the member state generate automatically the Patient Summary upon request. In one case, biannual update was reported. Finally, to the question where the patient summary is accessed, the most frequent response was outpatient/ambulatory and inpatient/hospitals rather than emergency. Home care as a setting for the use of patient summaries was reported in US, Finland, and Luxemburg. Similar results were reported by CEF eHDSI: patient summaries are created automatically in Austria, Czechia, Switzerland, Ireland, Spain, Romania, and Croatia. In other countries, patient summary creation is semi-automatic followed by General Practitioner (GP) validation (Portugal and Malta). In Italy, France, and Luxemburg, patent summaries are created manually by GPs.

3.2. Legal Aspects

The question of ownership for patient summary data is quite prevalent, and some respondents indicated explicitly the patient as owner. Responses included also national social security agencies, or a dedicated custodianship agency. The quality and accuracy of the patient summary is attested by patients or professionals. However, in most cases, provenance was not captured in detail. Similarly, the legal aspects of deploying patient summaries at a scale are not clearly, uniformly, and unambiguously defined.

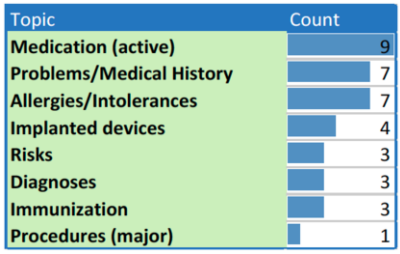

Figure 2: Most valuable topics in a patient summary, N=12 (left)

3.3. Topic Matrix

In situations of unplanned care there is a group of "Emergency Data" that informs a physician confronted with an emergency, referred as "SAMPLE": S – Signs/Symptoms; A-Allergies; M-Medications; P-Past Illnesses; L-Last meal; E-Events. Drawing an analogy to the building blocks of the patient summary, we asked what the most valuable topics in a patient summary are. The response appears in **Figure 2**. The question "*which are the components of the patient summary that have been implemented*" revealed that Allergy/intolerance and Condition in (93%), Procedure (86%), Medical History (82%), Medication (79%), Immunization (68%), encounter (57%), and Care Plan (54%). Substance and Device were used in 50% of the cases. Another somewhat surprising finding was that in most cases the richness of the content model of the component was not fully exploited. **Figure 3** and **Figure 4** show medication statement and allergies/intolerances. Maturity of the studies in terms of years in operation differs. Also, the level of coded information present also varies with most countries using custom subsets and versions of ICD10 for active problems, SNOMED-CT for immunizations and social history, ATC for medications, etc.

4. Conclusions

The practical use of patient summaries components was investigated using a questionnaire and interviews to develop a topic matrix. The results indicate the actual implementations are mostly in a pilot phase and do not operate under a clear administrative, operational, and legal framework. In fact, one of the goal of the eHDSI initiative is to harmonize the previously mentioned dimension in order to achieve not just interoperability but also mutual recognition, Moreover, in most cases the richness of the HL7 FHIR resources for the patient summary building blocks are not used, raising the question whether a constrained lean patient summary specification would accelerate adoption of patient summaries in the daily practice.

MedicationStatement

status	active | completed | entered-in-error | intended | stopped | on-hold	55%
category	Type of medication usage	25%
medication[x]	What medication was taken	82%
effective[x]	The date/time or interval when the medication was taken	90%
dateAsserted	When the statement was asserted?	11%
informationSource	Person or organization that provided the information about the taking of this medication	42%
taken	y | n | unk | na	11%
reasonNotTaken	True if asserting medication was not given	0%
reasonCode	Reason for why the medication is being/was taken	0%
reasonReference	Condition or observation that supports why the medication is being/was taken	0%
note	Further information about the statement	36%
dosage	Details of how medication is/was taken or should be taken	73%

Medication

code	Codes that identify this medication	92%
status	active | inactive | entered-in-error	33%
isBrand	True if a brand	27%
isOverTheCounter	True if medication does not require a prescription	9%
manufacturer	Manufacturer of the item	20%
form	powder | tablets | capsule +	67%
ingredient	Active or inactive ingredient	67%
package	Details about packaged medications	58%
image	Picture of the medication	0%

Substance

status	active | inactive | entered-in-error	0%
category	What class/type of substance this is	33%
code	What substance this is	56%
description	Textual description of the substance, comments	50%
instance	If this describes a specific package/container of the substance	13%
ingredient	Composition information about the substance	25%

Figure 3: Part of the HL7 FHIR medication statement (left) and medication & substance models (right) used.

clinicalStatus	active | inactive | resolved	36%
verificationStatus	unconfirmed | confirmed | refuted | entered-in-error	10%
type	allergy | intolerance - Underlying mechanism (if known)	50%
category	food | medication | environment | biologic	36%
criticality	low | high | unable-to-assess	45%
code	Code that identifies the allergy or intolerance	55%
onset[x]	When allergy or intolerance was identified	55%
assertedDate	Date record was believed accurate	36%
recorder	Who recorded the sensitivity	36%
asserter	Source of the information about the allergy	45%
lastOccurrence	Date(/time) of last known occurrence of a reaction	20%
note	Additional text not captured in other fields	40%
reaction	Adverse Reaction Events linked to exposure to substance	73%

Figure 4: A small part of the HL7 FHIR model for allergies/intolerances is in use in patient summaries.

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