Interoperability Standards enabling cross-border Patient Summary Exchange

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Abstract. In an increasingly mobile world, many citizens and professionals are frequent travellers. Access during unplanned care to their patient summary, their most essential health information, in a form physicians in another country can understand can impact not only their safety, but also the quality and effectiveness of healthcare. International health information technology (HIT) standards such as HL7 CDA have been developed to advance interoperability. Implementation guides (IG) and IHE profiles constrain standards and make them fit for the purpose of specific use cases. A joint effort between HL7, IHE, and HealthStory created Consolidated CDA (C-CDA), a set of harmonized CDA IGs for the US that is cited in the Meaning Use II (MU-II) regulation. In the EU, the Patient Summary (PS) Guideline recently adopted, cites the epSOS IG also based on HL7 CDA, to support cross-border care in the EU and inform national eHealth programs. The Trillium Bridge project supports international standards development by extending the EU PS Guideline to meet MU-II C-CDA in the transatlantic exchange of Electronic Health Records (EHRs). This paper presents preliminary findings from comparing patient summaries in the EU and US and reflects on the challenge of implementing interoperable eHealth systems in the cross-border or transatlantic setting.

Keywords. Patient summaries, eHealth interoperability, Meaningful Use, HL7 CDA

Introduction

Interoperability has been part of national eHealth strategies for many years. Initially, the focus was on technical interoperability and frequently limited to the in-hospital setting. Nowadays, semantic, organizational, legal interoperability are recognized as equally important as attention shifts toward patient empowerment and integrated care. Interoperability standards are technical specifications for the exchange, use, and shared understanding of health data from individuals or populations safely and at a lower cost. In 2010, the Memorandum of Understanding between the European Commission and the United States Department of Health recognized cooperation to advance eHealth/HIT as a driver for improved health and health care, economic growth, and innovation. The MoU highlighted HIT standards as a shared goal: *"Development of internationally recognized and utilized interoperability standards and interoperability implementation specifications for electronic health record systems that meet high standards for security*

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and privacy protection."[1]. The Meaningful use program that has revolutionised healthcare in the US cites standards, IGs, certification criteria for EHR technology and provides incentives for its use, cites HL7 CDA (see Table 1).

Table 1. HL7 CDA content exchange standards under Meaningful Use Stage II [2].

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.	
170.205(a)(3)	Consolidated CDA (C-CDA): Standardized representation of the Consult Note, Diagnostic Imaging Report, Discharge Summary, History and Physical, Operative Note, Procedure Note, Progress Note, and Continuity of Care Document (CCD).
170.205(h)	CDA Guide for Quality Reporting Document Architecture, Category I (QRDA-I): Standardized representation of quality data for an individual patient. Data in a QRDA-I report can be consumed by a calculation engine to determine if the patient met the numerator or denominator criteria for a given quality measure.
170.205(i)	CDA Guide for Reporting to Central Cancer Registries: Standardized cancer registry reporting format.
170.205(k)	CDA Guide for Quality Reporting Document Architecture, Category III (QRDA-III): Standardized representation of aggregate quality data (e.g. number of patients meeting the numerator criteria for a given quality measure).

On the 19th November 2013, the eHealth Network (eHN) established under article 14 of the EU Directive on patient's rights in cross-border care [3] approved the guidelines on minimum/non-exhaustive patient summary (PS) dataset [4]. The aim of these guidelines is primarily to support continuity of care and patient safety across borders focusing on emergency or unplanned care, but also to serve as a common baseline for patient summaries at national level. Patient summary is defined as the "*minimum set of information needed to assure healthcare coordination and continuity of care*" [4]. Emergency or unplanned care refers to "*the range of healthcare services available to people who need medical advice, diagnosis and/or treatment quickly and unexpectedly*" [4]. The guidelines present the *basic* dataset defined as the set of *essential* information from a clinical point of view that needs to be exchanged to deliver safe care to the patient, in the context of unplanned care. This information must be always available. In contrast, the *extended* dataset is defined as the set of *recommended* information that needs to be exchanged from a clinical point of view and should be completed whenever possible. Although the guidelines serve as non-binding recommendation to the EU Member States (MS), they provide for the first time the technical, semantic and organizational framework for cross-border care noting the implications and responsibilities of the MS. The epSOS project (www.epsos.eu) designed, built, and evaluated a service infrastructure that demonstrated cross-border interoperability between electronic health record systems and provided the background and practical experience for the PS guideline. Trillium Bridge (www.trilliumbridge.eu) carries out a feasibility study for the EU/US electronic exchange of patient summaries. Starting with the gap analysis, it compares the HL7 C-CDA Continuity of Care Document (CCD) specification cited in US MU-II [5] and the epSOS PS IG cited in the EU PS Guideline. Methodology and preliminary findings are presented below.

1. Methods

Trillium Bridge has adopted a four step strategy (shown in Figure 1) in its effort to establish an interoperability bridge for EHRs across the Atlantic. Its findings intend to inform international standardization efforts, promote high standards of quality and safety in cross-border care, and contribute to health system sustainability and economic growth:

- *Selecting the grounds*: Mobilize people and resources creating a forum of collaboration and knowledge sharing to select and analyse key use cases and to carry out gap analysis i.e. compare patient summary specifications and associated policies including eIdentification, authorisation, privacy & security.
- *Building the Bridge*: Assemble interoperability assets to align structure and terminology i.e. clinical document structures and semantic mappings for value sets published by the National Library of Medicine & epSOS.
- *Testing the Bridge*: Develop testing tools strategy and validate PS exchange.
- *Paving the way*: Contribute to policy alignment, standardization and future Sustainability by *informing* development of PS IGs and template libraries in liaison with Standards Development Organizations to reduce the cost of standards and by *delivering* policy briefs in seven feasibility areas identified for policy alignment: cross-vendor integration, incentives, standardization, innovative business models, education, clinical research, security & privacy.

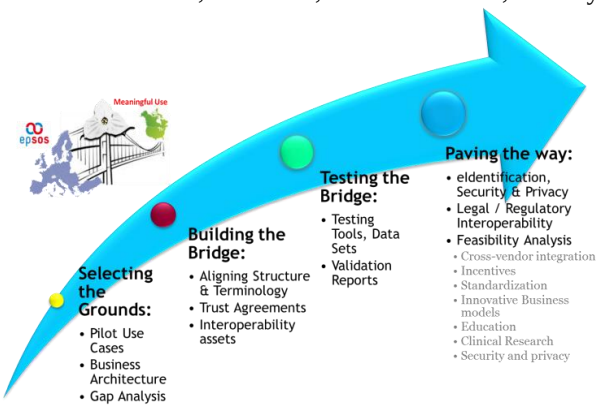

Figure 1: Trillium Bridge adopts a four step strategy in the feasibility analysis of transatlantic EHR exchange.

2. Results

In *Selecting the Grounds*, after establishing its community of knowledge, Trillium Bridge set out to collect user stories that reflect the need of patient summary exchange in the transatlantic setting: a woman that is a cancer survivor, a college student with known allergies, a retired businessman with hypertension and so on. All come down to a citizen crossing the Atlantic, who has access to his/her patient summary for unplanned care. Key questions are: "*Is it feasible to accurately communicate an EU patient summary or HL7 C-CDA/CCD to physicians on the other side of the Atlantic?"* and *"Is it feasible to receive a report from a healthcare encounter on the other side of the Atlantic in a format that can be understood and incorporated in the health system back home?*" The Digital Agenda for Europe sets 2015 as the milestone for giving patients online access to their medical data (Key action 13) and epSOS pilots the Patient Access (PAC) service [7]. In the US, the BlueButton+ drives citizen's access to their EHR data (http://bluebuttonplus.org). The EU PS Guideline cites the epSOS PS IG that uses HL7 CDA and has been designed as a dataset of "*essential and understandable health information"* that is made "*available at the point of care to deliver safe patient care."* On the other hand, HL7 C-CDA/CCD is a core data set of the most relevant

administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. Thus, HL7 C-CDA/CCD provides a means for one healthcare practitioner or system to aggregate all of the pertinent data about a patient and forward it to another practitioner or system to support continuity of care. Mindful of the slightly different purpose, we compared the two specifications and associated terminologies in the clinical context of unplanned care. Figure 2 presents the common patient summary sections as reflected in Europe (blue/PS) and the US (red/CCD). The coded sections shared in the two document specifications are: medications, allergies, immunizations (vaccinations), problems, medical devices and implants. Several elements are richer in content in CCD (social history observations, results, vital signs, surgical procedures, plan of care, and functional status. For instance, results in the EU PS include only blood group and vital signs only blood pressure. Assessing the epSOS patient summary and building on lessons learned, the eHN mandated in the EU PS guideline the following (previously optional) coded sections: surgeries past 6 months, treatment (plan of care), and autonomy (functional status). Moving towards an international patient summary IG, the blue (EU) and red (US) circles will converge further reducing the deployment costs of interoperability.

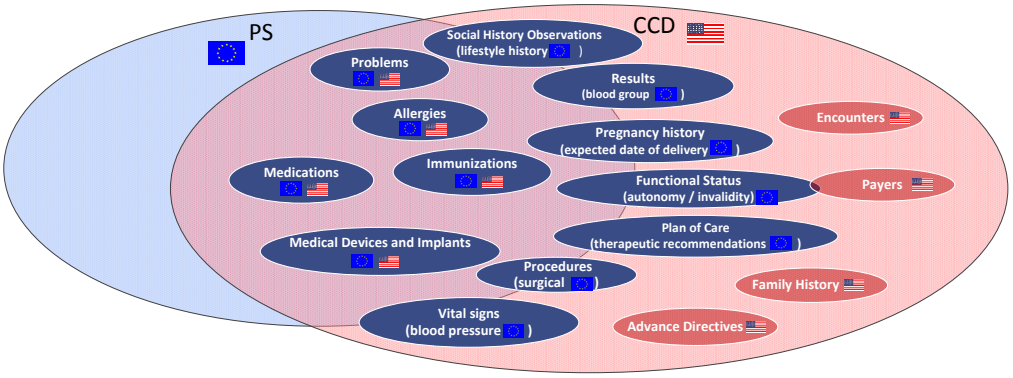

Figure 2: Intersection of coded sections between EU PS Guideline and US C-CDA/CCD (clinical view point).

A significant aspect of our comparison relates to the value sets used in each coded section. Table 1 presents a subset of the clinical equivalence mappings identified so far.

Table 1. Indicative equivalence mappings of value sets in selected coded sections.

Coded Section	C-CDA terminology		epSOS terminology
Allergies			
Allergy/Adverse Event Type	SNOMED CT	epSOSAdverseEventType/ epSOSReactionAllergy	SNOMED CT
Medication Clinical Drug Name Value Set	RxNORM	epSOSActiveIngredient	ATC
Immunizations/Vaccinations			
Vaccine Admin Value Set	CDC Vaccine Code (CVX)	epSOSVaccine	SNOMED CT
Problem			
Problem	SNOMED CT	epSOSIllnessesandDisorders	ICD-10
Medical Equipment			
N/A		epSOSMEdicalDevices	SNOMED CT
Medications			
Medication Route FDA	FDA RouteofAdministration	epSOSRouteofAdministration	EDQM
UnitsofMeasureCaseSensitive	UCUM	epSOSUnits	UCUM
Vital Signs			
Vital Sign Result	LOINC	epSOSBloodPressure	LOINC

3. Discussion

There has always been tension between general purpose and highly constrained standards or IGs in eHealth. The less constrained a standard is, the more susceptible it is to local extensions, and inconsistent implementation. The proliferation of various types of templates does not make things any easier and the need for implementation guidance and pre-production interoperability testing is only partly met by IHE profiles and connectathons. Our early experience with Trillium Bridge confirms that a lot of ground work is needed to lower cost of advancing interoperability in the widening space covered by eHealth. Only part of the effort to meet clinical needs and enable patient safety and high standards of care is technical. Work with professional societies is needed to develop a shared language of clinical attributes and educate the workforce. An infrastructure needs to be set up to facilitate service provision including translation, mapping and transcoding of terminologies, supported by a legal framework that acts as an enabler rather than inhibitor for cross-border care addressing security and privacy. According to the PS Guideline "*semantic mapping is a shared cross-border responsibility between respective Member States managed at the cross-border level and is part of its trust-building framework."* Last but not least, there are cultural differences to be addressed with education, training, awareness raising and patient empowerment.

For the next steps, Trillium Bridge aims to define interoperability assets that are well-understood and fit for the purpose of validating the key use cases of presented a PS in the patient's or the provider's device transformed and transcoded in the language and format of the country of treatment. Findings of the gap analysis, interoperability assets and the results of the validation exercise will provide practical input to the feasibility study of Trillium Bridge, which aims to lower standards development costs accelerating convergence towards global standards. If successful, Trillium Bridge will be pivotal in lowering costs/barriers of transatlantic business engagement, but more importantly in supporting the fundamental right of citizens to their health information.

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