European Patient Summary Guideline and Continuity of Care Document: A Comparison

Ana Estelrich¹, Harold Solbrig², Giorgio Cangioli³, Marcello Melgara⁴, Catherine Chronaki³

¹Phast, Paris, France, ²Mayo Clinic, Rochester, MI, United States
³HL7 Foundation, Brussels, Belgium, ⁴LiSPA, Milan, Italy

Abstract

The European Union (EU) Patient Summary (PS) guidelines adopted in November 2013 by the eHealth Network established under Article 14 of the EU directive on patient rights to cross-border healthcare, specifies a minimal dataset of essential information for unplanned or emergency care based on the epSOS PS. The Blue Button+ initiative linked to Meaningful Use Stage 2 in the United States, grants patients access to their medical records with HL7 Consolidated CDA (C-CDA) Both the EU PS and Blue Button+ are based on the HL7 CDA R2 standard.

The Trillium Bridge project aims to deliver a feasibility study on the transatlantic exchange of patient summaries. After comparing the Implementation Guides (IGs) and patient summary samples, we identified similarities both in the syntax expressing key data elements and in the binding value sets. Semantic assets providing mappings can be part of a common interoperability framework raising awareness of barriers that persist. Findings in comparing concepts and value sets are placed in the context of efforts toward an international patient summary standard.

1. Introduction - background

The primary focus of the EU PS guidelines [1] is to support continuity of care and patient safety in emergency or unplanned care situation across EU member state borders [2]. The guidelines build on the experience of the large scale pilot epSOS (www.epSOS.eu) and adopt the relevant IG [3] with minor changes. The EU PS enhanced the functional specifications of the epSOS IG by requiring the optional sections past surgical procedures, treatment recommendations, and autonomy/invalidity, as well as mandating the use of four characters in the WHO ICD-10 (the epSOS IG requires codes up to third character).

Blue Button started in 2010 with the US Department of Veterans Affairs using the Blue Button logo on its portal to allow patients to download their medical records in text form. With physician and provider incentives [7] linked to MU more than half the eligible physicians and 80% of hospitals are able to provide patients with their clinical summary after a medical appointment [8]. Blue Button+ extends Blue Button to allow patients download their medical records in a standard format for human readability and machine processing. The Blue Button+ IG [5] defines additional functionality for trusted automated health data exchange. Blue Button+ is based on C-CDA as mandated by Meaningful Use Stage 2. The C-CDA IG for the US realm has harmonized templates from seven document types in IHE, Health Story and HL7. The Continuity of Care Document (CCD) is the C-CDA document type for Blue Button+.

![Figure 1. EU patient summary guideline use case.](image-url)

A bridge can be created across the Atlantic using the epSOS PS and C-CDA IGs. Fig. 1 shows the use case of the EU PS, highlighting national contact points and terminology services delivering a fit-for-purpose patient summary to a country where a different language may be spoken. Each EU member state has a contact point through which an authorized health professional may request the patient’s summary from their country of origin, subject to their consent. Contact points in Europe form a chain of trust that could be extended across the Atlantic with support from international agreements. However, if we extend the epSOS model across the Atlantic, transformation, i.e., syntactic conversion between CCD and EU PS section templates would be
required, since the IGs use different templates to convey the similar clinical information. A gateway that bridges differences in structure and semantics could mediate this interaction.

Attending physicians can request from a national contact point their patient’s EU PS to complete clinical data available locally, if any. The contact point relays the request to a contact point in the patient’s country of origin. The physician receives the patient summary as recorded in the country of origin along with a copy that is transformed, translated and transcoded to the language in the country of treatment. Transforming involves syntactically modifying a CCD to an EU PS (epSOS) patient summary and vice versa using an XSLT processor. Transcoding refers to providing the equivalent or corresponding concepts in the code system used in the country of treatment. Translation entails offering the same code in the language of the country of treatment.

In earlier work reported in [9], we presented a high level comparison of the clinical elements present in the EU PS and CCD, as shown in Table 1. This paper presents the results of the next step of detailed analysis of key sections that are mandatory in the EU PS Guideline and the associated value sets. These are allergies, medication, problem or diagnosis, surgical procedures, and medical devices. The next sections, methodology and results, present the methodological approach and findings in comparing sections and value sets for clinical equivalence. The discussion section places these findings in the frame of supporting the EU/US MoU on eHealth collaboration with efforts towards developing an international PS IG.

Table 1. Comparing patient summaries in EU and US [9].

<table>
<thead>
<tr>
<th>EU Patient Summary Guideline</th>
<th>BlueButton+ (CCD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergies</td>
<td>Allergies</td>
</tr>
<tr>
<td>List of current medicines</td>
<td>Medications</td>
</tr>
<tr>
<td>List of current problems / diagnoses</td>
<td>Problem</td>
</tr>
<tr>
<td>Surgical Procedures prior to 6 mos</td>
<td>Procedures (R inpatients)</td>
</tr>
<tr>
<td>Surgical Procedures past 6 mos</td>
<td>Procedures (R inpatients)</td>
</tr>
<tr>
<td>Medical Devices and implants</td>
<td>Medical Equipment</td>
</tr>
<tr>
<td>Vaccinations</td>
<td>Immunizations</td>
</tr>
<tr>
<td>List of resolved or inactive problems</td>
<td>Problem</td>
</tr>
<tr>
<td>Social History Observations</td>
<td>Social History</td>
</tr>
<tr>
<td>Pregnancy history (Expected date of delivery)</td>
<td>Social History (Pregnancy Observation)</td>
</tr>
<tr>
<td>Physical findings (Vital Signs Observations)</td>
<td>Vital Signs</td>
</tr>
<tr>
<td>Diagnostic tests (Blood group)</td>
<td>Results</td>
</tr>
<tr>
<td>Treatment Recommendations</td>
<td>Plan of Care</td>
</tr>
<tr>
<td>Autonomy / Invalidity</td>
<td>Functional Status</td>
</tr>
<tr>
<td>-</td>
<td>Advance directives</td>
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<tr>
<td>-</td>
<td>Family History</td>
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<tr>
<td>-</td>
<td>Payer</td>
</tr>
<tr>
<td>-</td>
<td>Encounters</td>
</tr>
</tbody>
</table>

3. Results

Our analysis showed that there are 12 distinct clinically equivalent sections in the EU PS that can be mapped onto CCD sections. For example, surgical procedures prior to six months can be distinguished from those in the last six months by the date, while “resolved problems” are simply “problems”, with status value of “resolved”. In the epSOS_MVC_1.9_ValueSets inventory there are 27 epSOS value sets, out of the whole collection of 46, which correspond to either a value set or an entire code system in CCD. There are 24 value sets out of 65 value sets present in the CCD IG, which are mapped to epSOS value sets. The CTS-2 service currently being validated offers the code system, value sets and the association maps. When available, official maps like the SNOMED CT to ICD-10 available from NLM was used [10]. The Trillium Bridge team worked on the remaining ones that are currently validated by subject matter experts. Transforming CCD to EU PS or vice versa can be as simple as changing only template ids, when structure and value sets are the same [11]. There are also cases where structure remains the same, but the value sets require mapping. The most frequent case is when both structure and value sets have to be transformed. Transforming an EU PS to CCD or vice versa may result in information lost. Thus, it is recommended that the original clinical summary should be sent with the transformed one.
**Header Data.** Looking at the common header data of EU PS and CCD, several common data elements appear: gender, country, entity name part qualifier, health professional roles, confidentiality code, language, contact relationship, address, and next of kin. The relevant value sets are based on code systems such as: HL7, ISO or for health professional roles from ISCO-08 and NUCC [11]. Even when the same code system is used, the value sets may not the same. Some of the data elements in the CCD header not present in the EU PS include ethnicity, marital status, religious affiliation, race, state, etc. some of which are not allowed to be displayed in EU countries.

**Allergies.** Corresponding elements appear in Fig. 2. Clinical information in EU PS can be presented in CCD, but there are elements in CCD not available in the EU PS, namely allergy status and severity. The expression of an allergy has different levels of granularity. EU PS has 9 allergy concepts, where CCD has 16443 concepts.

**Medication.** The medication section in the EU PS (Fig. 3) uses distinct fields for ingredient, dose, and form. Active ingredient is expressed in WHO’s ATC. CCD uses NLM’s RxNorm to designate medication brand name, clinical drug, and NDF-RD to indicate the drug class. Only 12971 out of 204035 RxNorm concepts have a corresponding ATC concept. Conversely, only 2828 out of 5592 ATC concepts are covered by the NLM RxNorm maps. 1366 out of the 52242 NDF-RT concepts have an ATC map, and only 604 concepts from ATC have correspondence in NDF-RT. The value set Clinical Drug Name of 31214 concepts and 4% coverage. The 13886 concepts of Medication Brand Name have 10% coverage and epSOSActiveIngredient has only 24%.

**Problems & Diagnoses.** The relevant value sets are based on SNOMED CT (SNOMED CT) and ICD-10 (epSOS) as shown in Fig. 4. The NLM provides the

![Figure 2: Clinically equivalent Allergy sections in CCD and in EU Patient Summary (epSOS).](image)

![Figure 3: Clinically equivalent Medication sections in CCD and in EU Patient Summary (epSOS).](image)

![Figure 4: Clinically equivalent problem sections in CCD and in EU Patient Summary (epSOS).](image)

![Figure 5: Clinically equivalent surgical procedure sections in CCD and in EU Patient Summary (epSOS).](image)

![Figure 6: Clinically equivalent device sections in HL7 CCD and the EU Patient Summary (epSOS).](image)

**Surgical Procedures.** Where the EU PS focuses only on surgical procedures, CCD lists the interventional, observational, and other procedures. CCD indicates that the codes may be selected from LOINC, CPT-4, ICD-9, ICD-10, or SNOMED CT, when the EU PS uses a value set from SNOMED CT. Beyond procedure identification, many elements in CCD have no equivalent in the EU PS.

**Medical Devices and Implants:** While the US template does not reference any coded value set, the EU PS references in a 64 term value set from SNOMED CT 2009. This value set is part of the MVC value set catalogue and translated to EU languages. Notably, the FDA Amendments act mandates use of UDI to identify medical devices by 2020. Similar regulation is underway in the EU.

4. **Discussion**
Although the US clinical and EU patient summaries are based on the same base standard, HL7 CDA, the actual IGs pose significant challenges to interoperability in the context of transatlantic exchange of EHRs. Differences arise from actual purpose of use, terminologies, and regulations. Even when limited to allergies, current medications, interventional procedures, as well as problems and diagnoses mapping an EU PS to CCD, the specification used in the US by Blue Button+, is not easy.

Optionality in the EU PS and CCD is probably the greatest barrier to achieving interoperability at low cost. CCD follows an open model, which means that any of the templates in HL7 C-CDA may be included in a valid clinical summary. Implementing interoperability means that information systems should anticipate any of these templates. Moreover, implementers have the freedom to be creative in expressing clinical concepts. Additional challenges stem from the use of different terminologies and value sets. Even when the terminologies are the same, the EU PS has adopted a static approach to terminologies and value sets, while CCD has adopted a dynamic one, automatically adopting new versions of recognized terminologies. Reference implementations may raise the cost of IGs but can help keep optionality in check, reducing the cost of implementation. FHIR (www.HL7.org/FHIR) taking a restful resource oriented approach to HL7, ties closely value sets to resources, cutting down implementation cost for systems supporting standards.

Moving forward towards an international patient summary standard, significant challenges need to be addressed. Even if the sections included in the international patient summary is limited to the EU PS, the topic of interoperability assets associated with templates and value sets needs to be addressed in robust way. This would mean that value sets are readily available and associated to specific templates. Another significant challenge is the lack of officially available maps aside from RxNorm and NDF-RT to ATC, and SNOMED CT to ICD10. By this we mean maps between UNII and SNOMED CT, CVX and SNOMED CT, EDQM Standard Terms and NCI Thesaurus, and ISCO and NUCC, to cite some of the “in-house” code system mappings done by the project team. Since a single approach to terminologies is practically infeasible due in part to intellectual property and license fees, the ontology-based approach of WHO and SNOMED CT on ICD-11, renews hope for interoperability.

5. Conclusions

Structural and terminology differences challenge the exchange of EHR among systems even when the same base standard is used. Strategies need to be developed that allow sharing of interoperability assets that are quality assured, can be combined and elaborated upon.

Acknowledgements

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Address for correspondence.
Catherine Chronaki  chronaki@gmail.com
38-40 Square de Meeûs, Brussels, 1000 Belgium