Smart Open Services for European Patients - Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription

epSOS Response on Patient Summary Dataset

Date: 13 February 2013

1. Introduction

DG SANCO has asked for proposals for the content and format of the Patient Summary dataset to meet an EHealth Network commitment. This paper forms the response to DG SANCO and DG CNCT. It has been produced by the epSOS Policy and Strategy group (WP2.2), with input from members of KT1.4.10, Clinical and Semantic Expert Groups, and with additional comments and input from the epSOS Project Steering Board.

2. Background

In the letter to Mårten Kivi on 21 January, Tapani Piha from DG SANCO wrote:

I would be grateful if you could provide me in writing information on:

(i) The specifics of the standardized set of electronic health data of patients' summary, agreed by epSOS and the participating countries in the Patient Summary Pilot;

(ii) Information about the procedure used and considerations made to determine the above mentioned data set, including any outstanding issues for which ePSOS has not reached agreement;

(iii) Suggestions and recommendations for further reflection by the eHealth Network concerning the determination and development of usable patient's summaries for cross-border care.

3. Process of development of Patient Summary Dataset

The epSOS project started in 2008 with 12 participating nations that defined and agreed the initial functional design (Austria, Czech Republic, Denmark, France, Germany, Greece, Italy, the Netherlands, Spain, Slovakia, Sweden, and United Kingdom). Subsequently, 14 more countries (Belgium, Croatia, Estonia, Finland, Hungary, Latvia, Luxembourg, Malta, Norway, Poland, Portugal, Slovenia, Switzerland and Turkey) requested the opportunity to review and analyze the selected use cases and have shown specific interest to join the project and pilot, and have been accepted.

On two occasions the project performed a country analysis on the preconditions in the participating nations (PNs). This was achieved by sending a questionnaire to each participating nation and comparison of the data collected. The purpose of that comparison was to have an overview of the starting point that could help to understand the opportunities and constraints for common developments. The first outcome was released in May 2009 and included the initial countries[1] and the second one in February 2012 including also the new countries that were officially added at that point[2].

After the initial country analysis and a workshop by clinicians, a technical level working group which included clinical experts defined the functional service related to the Patient Summary. A Patient Summary, within the epSOS project, was defined as a "*dataset of essential and understandable health information*[3]" that is made available "*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]*";* it can also can be defined at high level as: *"the minimum set of information need to assure Health Care Coordination and the continuity of care*[3]".

Due to the unscheduled care scenario and the potential epSOS added value in emergency situations, the epSOS Patient Summary use case introduced the clinical concept of a maximum set of information that is allowed to be sent for the specific epSOS purpose. The intention was to highlight that there is a balance between the usefulness of having more clinical information and the practicality of having it summarised so the professional can quickly understand the relevant conditions. That means that the patient summary should give the professional a summary of the most relevant information that could be consulted "at first glance". Because of that, it was agreed that: fields not belonging to the Basic or to the Extended agreed epSOS LSP PS dataset would not be exchanged even if they are available in some countries[3].

Functional requirements and a common dataset were agreed within the group and afterwards in the epSOS decision project boards (Project Executive Board and Project Steering Board). Each field of the dataset have its definition and functional purpose. The group worked *"keeping in mind the medical perspective and the clinical purpose*[3]*"* but also the available information and the needs in the participating nations as the aim was to describe a real pilot. A new questionnaire, about specific Patient Summary information availability, was circulated among all countries and the information and initial constraints were taken into account as long as they didn't jeopardize the clinical purpose.

Because of the need to balance between the clinical purpose and the actual information available, the group defined divisions in the dataset. Those divisions are based on the "*degree of relevance of the information for the Patient Summary Service*[3]" and are as following:

"*Basic dataset: defined as a set of essential health information that is required from the clinical point of view to be sent to deliver safe care to the patient (focused in unscheduled care).'. Fields in the Basic dataset must be sent*[3]". Despite this,, the Patient Summary questionnaire showed that at this time important data (included in the basic dataset) was

[1] Deliverable 1.1.1 "Analysis and comparison of national plan/solution"
[2] Deliverable 1.4.2 "Country status outline and template specification"
http://www.epsos.eu/uploads/tx_epsosfileshare/D1.4.2_Country_status_outline_and_template_specification_v1.00.pdf
[3] Deliverable 3.2.2 "Final definition of functional service requirements- Patient Summary";
http://www.epsos.eu/uploads/tx_epsosfileshare/D3.2.2_Final_Definition_Functional_Service_Req_Patient_Summary.pdf

not yet available in some of the countries (not coded, not possible to be recovered, etc). The decision was that it was necessary to allow *"Null flavour values"* even if the section has to be added in the dataset to be exchange. The expectation is that the countries will focus on having that information ready to be exchanged.

"*Mandatory dataset':* *a subgroup of the Basic dataset, and this is the difference with the precedent fields, for which there must be a valid value. If the values are not valid, the PS will be rejected*[3]" Most of these fields are related with univocal identification.

"*Extended dataset':* *defined as the minimum desirable health information from the clinical point of view to be exchanged between the epSOS LSP participants. The fields are not compulsory (therefore, neither the fields nor the values are compulsory to be sent*[3,4].

To choose terminologies and bindings for the different fields of the agreed datasets, the semantic and technical groups followed the clinical one. Within those groups, agreements were defined that were also corroborated in the decision bodies of the project (PEB and PSB).

Following the clinical rationale that drove the definition of the datasets, the semantic group chose underpinning standards to enable the pilot:

- The document structure would be compliant to HL7 Common Document Architecture (CDA) Version 2, level 3;
- The terminology standards that are the most widely used among all the European countries, any which could be used freely for the purpose defined (e.g. with specific license arrangements for the purpose of the pilot).

The initial clinical definition of the epSOS Patient Summary and the technical implementation were also constrained by the fact that epSOS is expected to build on existing national infrastructures and policies. This has been a major contribution of epSOS, as it made it possible to define a service which could be piloted in the real world, while allowing for improvements from the clinical viewpoint as the systems gain maturity at all levels (local, regional, national, European and global)[5].

4. Impact of epSOS and PN policies and procedures on semantic interoperability

The semantic interoperability implemented by epSOS includes:

1. In the country of origin for the document:

[4] The whole dataset agreed in the clinical group is provided as Annex A to this document. The functional requirements and dataset agreements can be consulted in the public project document "Deliverable 3.2.2: Final definition of functional service requirements- Patient Summary" at http://www.epsos.eu/uploads/tx_epsosfileshare/D3.2.2_Final_Definition_Functional_Service_Req_Patient_Summary.pdf

[5] The whole dataset agreed in the semantic group and compliant with the standard HL7 CDA version 2, level 3 can be consulted in the public project document "Deliverable of WP 3.9 'Development of proof of concept system for pilot phase: appendix B1 (http://www.epsos.eu/uploads/tx_epsosfileshare/D3.9.1_Appendix_B1_Implementation.pdf); the terminologies management can be consulted in the public project document "Deliverable of WP 3.9 'Development of proof of concept system for pilot phase: appendix B1 B2 http://www.epsos.eu/uploads/tx_epsosfileshare/D3.9.1_Appendix_B2_MVC_MTC.pdf)
An overview of the main terminologies chosen is provided in Annex B to this document.

a. The transformation of a document generated in one Country into the epSOS CDA Pivot Document structure;

b. The mapping of the code system adopted in the country of origin into the epSOS coding system.

2. In the country receiving the document, the translation of the coded data into the country of destination language.

The management of code system mapping and coded data translation are handled by the eCRTS (epSOS Central Reference terminology Server) and distributed as Master Translation/Transcoding Catalogue (MTC).

Three major services are considered in the following analysis:

- PS: the Patient Summary generated in the Country of Affiliation is provided to a Health Professional in the Country of Treatment;
- HCER: a Health Care Encounter Report, generated in the Country of treatment, is returned to the Country of Affiliation;
- PAC: A patient may access his PS in the Country of Affiliation, translated into any language supported by epSOS.

The basic policies applied to semantic interoperability are:

- The country of origin of the document must:
    - apply transformation (1a) to the document
    - apply the mapping (1b) at least to the Basic Datasets
    - not include Datasets not included in the Extended Datasets
- The country of destination is requested
    - to translate all the Basic and Extended Datasets (2), to be ready to display any valid epSOS Document

The implications of this approach are that:

- The Country of Origin is not obliged to modify the national processes to comply with epSOS, unless the Basic Dataset is not fulfilled;
- Limiting the information transferred to the Extended Datasets, we ensure that no unexpected data is provided, keeping the responsibility on the generated document to the Country of Origin.

Despite the request to translate, we have observed two exceptions:

- The Country of Destination policies include the choice of presenting in the standard designation language (e.g. English) specific Code Systems;
- Some Standards Development Organisations (SDOs) have policies on translation or obligation for business agreements that do not allow the translations.

  In both cases it is permissible for countries not to translate, if the involved user is a health professional.

The quoted policies are applied to PS and HCER, where:

- PS: Country of Origin is the Country of Affiliation; the Country of Destination is the Country of treatment.
- HCER: Country of Origin is the Country of treatment; the Country of Destination is the Country of affiliation.

However, in the case of HCER, the exceptions on translation may have a direct impact to the Citizen, if it is foreseen that he can access his documents: it could be not acceptable that information is provided e.g. only in English directly to the patient.

In the case of PAC service, Country of Origin and Country of Destination:

- Coincide if the PS is made accessible to Citizens
- May be different if HCER access is provided as well.

In the first case, exceptions have no influence, because the document is compliant to Country of Affiliation rules.

In the second case, exceptions may have an impact on the document compliant to the foreign Country of Origin.

In order to provide the PAC service in the display language "XY", different from the Country of Affiliation, the Country "XY" must provide the MTC translation of all the Basic and Extended Datasets.

If exceptions exist in Country "XY", the Language "XY" is not eligible for PAC Service.

5. External validation

The epSOS functional service has been evaluated by external stakeholders in a number of ways:

1. By health professionals and patients through the two stakeholder workshops organised for the epSOS evaluation task responsible (service content evaluations; this gave some positive reports in the usefulness of the service).
2. By other European projects that have found the dataset and terminologies chosen as useful, for example the "Electronic Health Record for Clinical Research - EHR4CR (http://www.ehr4cr.eu/) and the Translational Research and Patient Safety in Europe – TRANSFoRm (http://www.transformproject.eu/)
3. By closer collaboration with other projects such as the Calliope thematic network (http://www.calliope-network.eu/) and STORK (https://www.eid-stork.eu/) that resulted in recommendations for the future and study of possible alignments and synergies.
4. By USA stakeholders in the EU-USA roadmap and MoU collaboration agreement.

6. Findings and Lessons Learned

During the process of agreeing the dataset, we recognized that a common semantic structure is not achievable within the epSOS time frame and with foreseeable resources. Some of the issues still to be resolved are:

1. An unambiguous identification of a foreign patient (patient outside his/her country of affiliation);

2. A common terminology, classification and data structure for laboratory and imaging examinations;
3. A common terminology and data structure for the functions or disabilities of the patient (as this was outside the scope of the pilot).

These items, especially the first two, significantly limit the implementation potential of the extended epSOS services of Health Care Event Report and Patient Access for data generated in a visiting country ("Country B")

The PS dataset created for epSOS is not a formal standard, although it has been built using a number of pre-existing standards. We would suggest further testing in a live context to provide assurance of its fitness for purpose before pursuing the standardization route.

The main lessons learned also provide pointers for the future:

- Agreement on the clinical requirement is the first step needed. Important constraints exist nowadays regarding information systems, but it is important to define the path towards quality information exchange by defining a common focus for improvement through national and regional strategies. The epSOS Patient Summary was developed primarily to support the unscheduled care use care; other purposes may have different requirements;
- The decision on having Basic Datasets and Extended Datasets depends on the clinical relevance of the information in the specific epSOS use case as defined in the introduction. It defined different levels of obligatory nature for the countries to send that information and it has been necessary for the current actual situation in the countries. It has relevant impact on clinical "correctness" and "usability" of the exchanged documents as well as on National Policies on defining the document contents and providing the translation. Strategies have to be defined, agreed and applied to avoid exceptions and national level and at SDO levels;
- The limitations on translation imposed by SDOs should be addressed at International Level, within the definition of Semantic Sustainability processes. There is a need for on-going maintenance of the Master Translation Catalogue; hopefully there will be developments with the Commission to enable this to happen.

ANNEX A – PATIENT SUMMARY: DATASET AGREED IN THE CLINICAL GROUP

PATIENT DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**DEFINITION AND COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
Identification [10]	National Health Care patient ID	National Health Care patient ID	Country ID, unique for the patient in that country. Example: ID for United Kingdom patient	Basic	Yes
Personal information	Full Name	Given name	The Name of the patient (Example: John). This field can contain more than one element	Basic	Yes
		Family name/Surname	This field can contain more than one element. Example: Español Smith	Basic	Yes
	Date of Birth	Date of Birth	This field may contain only the year[11] if day and month are not available. Eg: 01/01/2009	Basic	Yes
	Gender	Gender Code	It must contained a recognized valid value for this field	Basic	Pending decision by WP3.6 (in some countries 'gender' is needed for univocal identification of the patient)
Contact information	Address[12]	Street	Example: Oxford	Ext	No
		Number of Street	Example: 221	Ext	No
		City	Example: London	Ext	No
		Post Code	Example: W1W 8LG	Ext	No
		State or Province	Example: London	Ext	No
		Country	Example: UK	Ext	No
	Telephone No	Telephone No	Example: +45 20 7025 6161	Ext	No
	E-mail	E-mail	Example: jens@hotmail.com	Ext	No
	Preferred HCP/Legal organization to contact[13]	Name of the HCP/Legal organization	Name of the HCP/name of the legal organization. If it is a HCP, the structure of the name will be the same as described in 'Full name' (Given name, family name/surname)	Basic	No
		Telephone No	Example: +45 20 7025 6161	Basic	No
		E-mail	E mail of the HCP/legal organization	Basic	No

[10] Data set that enable the univocal identification of the patient. It will be defined in WP3.6 'Identity Management'. The variable 'Birth place' (Country of birth and place of birth) needs to be evaluated by WP3.6 as in some countries it is needed for univocal identification of the patient.
[11] To be aligned with prescription minimum dataset (in D3.1.2 'Final definition of functional service requirements-ePrescription')
[12] Will be adapted due to the variability of the countries.
[13] A foreign HCP may need a contact (HCP/legal organization) who knows the patient

	Contact Person/ legal guardian (if available)	Role of that person	Legal guardian or Contact person	Ext	NO
		Given name	The Name of the Contact Person/guardian (example: Peter. This field can contain more than one element)	Ext	No
		Family name/Surname	This field can contain more than one element. Example: Español Smith	Ext	No
		Telephone No	Example: +45 20 7025 6161	Ext	No
		E-mail		Ext	No
Insurance information	Insurance Number	Insurance Number	Example: QQ 12 34 56 A	Pending decision by WP3.6 of including it in Basic (in some countries 'Insurance Number' is needed for univocal identification of the patient).	Pending decision by WP3.6 of including it in Basic (in some countries 'Insurance Number' is needed for univocal identification of the patient).

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
Alerts	Allergy	Allergy description	Description of the clinical manifestation of the allergy reaction. Example: Anaphylactic shock, angioedema (the clinical manifestation also gives information about the the severity of the observed reaction)	Basic	No
		Allergy description id code	Normalized identifier	Basic	No
		Onset Date	Date of the observation of the reaction	Ext	No
		Agent	Describes the agent (drug, food, chemical agent, etc) that is responsible for the adverse reaction	Basic	No
		Agent id code	Normalized identifier	Basic	No
	Medical Alert Information (other alerts not included in allergies)	Health Care Alert description	Medical Alert Information: any other clinical information that is imperative to know so that the life or health of the patient does not come under threat. Example 1: intolerance to aspirin due to gastrointestinal bleeding. Example 2: intolerance to captopril because of cough (the patient is not allergic to captopril but can´t tolerate it because of persistent cough)	Basic	No
		Health Care Alert id code	Normalized identifier	Basic	No
History of past illness	Vaccinations	Vaccinations	Contains each disease against which immunization was given	Ext	No
		Brand name		Ext	No
		Vaccinations id code	Normalized identifier	Ext	No
		Vaccination Date	The date the immunization was received	Ext	No
	List of Resolved, Closed or Inactive problems	Problem Description	Problems or diagnosis not included under the definition of 'Current problems or diagnosis'. Example: hepatic cyst (the patient has been treated with an hepatic cystectomy that solved the problem and therefore it´s a closed problem)	Ext	No
		Problem Id (code)	Normalized identifier	Ext	No

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
		On set time	Date of problem onset	Ext	No
		End date	Problem resolution date	Ext	No
		Resolution Circumstances	Describes the reason by which the problem changed the status from current to inactive (e.g. surgical procedure, medical treatment, etc). This field includes 'free text' if the resolution circumstances are not already included in other fields. Example: It can happen that this field is already included in other like Surgical Procedure, medical device etc, eg: hepatic cystectomy (this wil be the 'Resolution Circumstances' for the problem 'hepatic cyst' and will be included in surgical procedures)	Ext	No
	Surgical Procedures prior to the past six months	Procedure description	Describes the type of procedure	Ext	No
		Procedure Id (code)	Normalized identifier	Ext	No
		Procedure date	Date when procedure was performed	Ext	No
Medical problems	List of Current Problems/Diagnosis.	Problem/diagnosis description	Problems/diagnosis that fit under these conditions: conditions that may have a chronic or relapsing course (eg: exacerbations of asthma, irritable bowel syndrome), conditions for which the patient receives repeat medications (eg: diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of medication (eg: dyspepsia, migraine and asthma)	Basic	No
		Problem Id (code)	Normalized identifier	Basic	No
		Onset time	Date of problem onset	Basic	No
	Medical Devices and implants	Device and implant Description	Describes the patient's implanted and external medical devices and equipment that their health status depends on. Includes devices as cardiac pacemakers, implantable defibrillator, prothesis, ferromagnetic bone implants etc that are important to know by the HCP	Basic	No

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
		Device Id code	Normalized identifier	Basic	No
		Implant date		Basic	No
	Major Surgical Procedures in the past 6 months[14]	Procedure description	Describes the type of procedure	Basic	No
		Procedure Id (code)	Normalized identifier	Basic	No
		Procedure date	Date when procedure was performed	Basic	No
	Treatment Recommendations	Recommendations Description	Therapeutic recommendations that do not include drugs (diet, physical exercise constraints, etc.)	Ext	No
		Recommendation Id (code)	Normalized identifier	Ext	No
	Autonomy/Invalidity	Description	Need of the patient to be continuously assisted by third parties. Invalidity status may influence decisions about how to administer treatments	Ext	No
		Invalidity Id code	Normalized invalidity ID (if any, otherwise free text)	Ext	No
Medication Summary	List of current medicines. (All prescribed medicine whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not.).	Active ingredient	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: Paracetamol	Basic	No
		Active ingredient id code	Code that identifies the Active ingredient	Basic	No
		Strength	The content of the active ingredient expressed quantitatively per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form. Example: 500 mg per tablet	Basic	No
		Pharmaceutical dose form	It is the form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablets, syrup)	Ext	No
		Number of units per intake[15]	The number of units per intake that the patient is taking. Example: 1 tablet	Basic	No
		Frequency of intakes[15]	Frequency of intakes (per hours/day/month/ week..). Example: each 24 hours	Basic	No

[14] As there is subjectivity in the term 'relevant', the date will be used as the limit to include procedures.
[15] Posology has been defined from the functional point of view as containing these three components: number of units per intake, frequency of intakes and duration of treatment (example: 1 unit/intake every 24 hours for a duration of 14 days

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
		Duration of treatment[15]	Example: during 14 days	Basic	No
		Date of onset of treatment	Date when patient needs to start taking the medicine prescribed	Basic	No
Social History	Social History Observations	Social History Observations related to: smoke, alcohol and diet.	Example: cigarette smoker, alcohol consumption...	Ext	No
		Reference date range	Example: from 1974 thru 2004	Ext	No
Pregnancy History	Expected date of delivery	Expected date of delivery	Date in which the woman is due to give birth. Year, day and month are required. Eg: 01/01/2010	Ext	No
Physical findings	Vital Signs Observations	Blood pressure	One value of blood pressure which includes: systolic Blood Pressure and Diastolic Blood pressure	Ext	No
		Date when blood pressure was measured	Date when blood pressure was measured	Ext	No
Diagnostic tests	Blood group	Result of blood group	Result from the blood group test made to the patient	Ext	No
		Date	Date in which the blood group test was done. This field may contain only the year if day and month are not available. Eg: 01/01/2009	Ext	No

PATIENT SUMMARY DATA (Information about the PS itself)					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
Country	Country	Country	Name of country A	Basic	Yes
Patient Summary	Date Created	Date Created	Data on which PS was generated	Basic	No
	Date of Last Update	Date of Last Update	Data on which PS was updated (data of last version)	Basic	Yes
Nature of the PS	Nature of the PS	Nature of the PS	Define the context in which it was generated. Distinguish among three methodological approaches to build the PS: direct human intervention of a HCP, automatically generated and mixed approach	Basic	No
Author organization	Author organization	Author organization	At least an author organization (HCPO) shall be listed. In case there is not HCPO identified at least a HCP shall be listed	Basic	No

ANNEX B – SUMMARY OF THE MAIN TERMINOLOGIES CHOSEN

FIELD	TERMINOLOGY CHOSEN
Field Labels	LOINC
Problem list	ICD 10 (3 digit code)
Medication list	ATC + EDQM + UCUM
Allergies	SNOMED
Surgical procedures	SNOMED
Medical devices	SNOMED
Country and languages	ISO
Professional role	ISCO