Smart Open Services for European Patients

Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription

D3.2.2 Final definition of functional service requirements- Patient Summary

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ABSTRACT
D3.2.2 Final definition of functional service requirements- Patient Summary **This document describes the use cases to be found on the epSOS LSP regarding the PS Services, identifying the needed requirements, the dataset of information to be exchanged and possible issues from the users' point of view.**

Change History					
Version	**Date**	**Status Changes**	**From**	**Details**	**Review**
V0.1	2009-08-28	First draft	ESNA	Based on final version of D3.2.1 with addition of storyboards, the agreed PS dataset and Supervision Services	WP3.2
V0.2	2009-09-30	Second draft	ESNA	To incorporate the changes as a result of the comments made by WP3.2 to version 0.1 and the changes agreed in the Rome meeting on the 17th of September of 2009	WP3.2
V0.3	2009-10-13	Third draft	ESNA	To incorporate the changes as a result of the comments to version 0.2	WP3.2
V0.4	2009-12-11	Final version	ESNA	It includes the changes after Quality Review	
V0.5	2010-02-23	Inputs from the technical WPs	ESNA	To incorporate the PEB decision (January 14th Brussels) to leave the requirement “sharing the medication summary as a separate document” for a further step.	WP 3.2
V0.6	2010-05-13	Inputs form semantic WP 3.5	ESNA	Agreements for alignment with WP 3.5, slight changes in the dataset need it. TPM/technical WPleader: request to add to the document the possibility to share the PS through a PDF format	WP 3.2

TABLE OF CONTENTS

1 FOREWORD

epSOS LSP project operates within a complex policy background and focuses on electronic patient record systems, with its initial focus on two cross border services, i.e., Patient Summary and e-Prescribing/e-Dispensing. The aim of the pilot is to demonstrate that it is feasible for any Member State (MS) that already provides these ehealth services to its residents, to create the conditions that will allow to also offer these services to them when they travel abroad to other Member States taking part in the epSOS LSP.

A relationship of trust between the epSOS LSP MSs must exist as it is established in Annex I. This means that all the countries are integrated on one system of trust, not only functional and technical but also with respect to quality and reliability of the information exchanged between countries. The framework must ensure that Health Care professionals can rely upon the authenticity of the clinical data on which they will base decisions.

It is important to note that the epSOS LSP services involving Patient Summaries and e-Prescribing/e-dispensing will be offered on a pilot basis and the intention is to gather data and learn from this pilot operation to accelerate deployment of these services. The pilots will test the feasibility and acceptance of the overall functional, technical and legal interoperability of the proposed solutions.

It is also important to clarify that it is a basic principle of epSOS LSP that the solutions proposed will build interoperability on current national solutions. This means that the exchange of information (Patient Summary) between different epSOS LSP Member States must take into account the existing and under construction solutions and must respect the laws and regulations of these MSs regarding Patient Summary. In the same way, it is not the objective in epSOS LSP to propose new or amendments to existing legislation but rather to create interoperability between existing legal and regulatory frameworks.

Concepts paper epSOS LSP

2 EXECUTIVE SUMMARY

Based on the principles stated in the Foreword, once the common understanding of the Patient Summary service within the epSOS LSP framework has been agreed on and the use cases identified, the goal of this deliverable is to identify the requirements necessary to implement a feasible service adopting the point of view of the Health Care professional and considering the level of maturity of the solutions within the Member States. In consequence, the aim is to focus on strictly necessary requirements in order to achieve a minimum but safe and secure service.

The discussion and the content regarding this deliverable start from some concepts, ideas and recommendations from WP1.1 'Analysis and Comparison of national plans/solutions' where the solutions of the different countries are analysed, and is based on the outputs of the previous deliverable, D3.2.1 'Draft definition of functional service requirements – Patient Summary', WT5.2.1 'Initial Scope', 'Concepts paper epSOS LSP' and WP2.1 'Analysis and comparison of legal and regulatory issues'. The scope of the document has been defined with the intention of simplifying the services, avoiding already existing complex matters (from the functional and legal perspective) in the different MSs.

The driving concept followed in WP3.2 has been to keep the medical perspective and clinical purpose while the technical issues are to be managed in other WPs. The methodology carried out in this WP to produce this deliverable has been described in a separated document placed in PP (internal work document, epSOS_WPInitiationDocument_WP3.2_v0.2.doc)

The primary application of electronic Patient Summary is to provide the Health Care professional with a dataset of essential and understandable health information at the point of care to deliver safe patient care during unscheduled care and planned care with its maximal impact in the unscheduled care. Any access to the Patient Summary information is in the context of a resident of one Member State (country A) visiting another MS (country B) and seeking for Health Care. The PS made available to the Health Care professional of country B should contain updated and reliable information.

At European level, it has to be assumed that the patient may have more than one electronic PS, in one or many countries, made available abroad in a structured way compliant with epSOS LSP PS specification. It has been agreed that only one common structured epSOS LSP PS per country visible from outside will be provided. A single (unique) stored European PS is out of the scope of epSOS LSP.
It is out of scope of this deliverable to analyze the methodology that each Member State envisions to produce a valid PS. Also medical processes in each Member States are not analysed.

Cross-border care in epSOS LSP has been conceived around two use cases and foresees both scheduled and unscheduled encounters. Use case 1 refers to an occasional visitor in country B and use case 2 to a regular visitor or long term visitor to country B. In this deliverable both use cases have been analysed together as there are no differences between them in terms of the services and the information requirements by the final user.

A list of possible cases in which access to the Patient Summary would support better treatment of cross border patients is presented in section 9 (examples of use cases: storyboards).

The functional requirements identified to fulfil the use cases are related to:

- assure the security of the service (like for example identification, authentication or patient consent)
- access the information from/to another country
- the correct interpretation of the information
- meet the information needs of the physician
- the minimum information needed to fulfil all steps of the PS service.

In addition to the functional requirements, non functional requirements have been identified as they are needed to fulfil the functional ones and are directly related to the HCP experience and to the security of the process from the functional point of view.

This is the list of the identified requirements:

Functional Requirements	
FR01	HCP Identification and authentication
FR02	Trust between countries
FR03	Patient identification
FR04	Patient consent to access data
FR05	Structured Information

FR06	Equivalent Information
FR07	Information Understandable
FR19	Patient summary of country A available
FR20	Information Traceability
Non Functional Requirements	
NFR01	Service availability
NFR02	Communications
NFR03	Response time
NFR04	Confidentiality
NFR05	Access control
NFR06	Audit Trail
NFR07	Integrity
NFR08	Non repudiation
NFR09	Trust between countries
NFR10	Guaranteed delivery
NFR12	Supervision services

It is important to note that description of Use Cases and Functional Requirements have been done with the approach: 'Only the PS of country A (which is the MS of affiliation) will be shown to HCP of country B'. This decision was agreed within the WP in order to reduce complexity and facilitate the viability of the pilots in the epSOS LSP scenario. Nevertheless, the approach ´'Multiple PSs' (meaning this that the Health Care professional gets access to the list of existing PSs for that patient and selects and asks for any of them) is presented in Annex A of this deliverable for information purposes in preparation of a possible future epSOS LSP scope extension.

It is also an objective of this WP to agree on the Patient Summary dataset to be exchanged (epSOS LSP PS) not only on the minimum data set but also in the maximum dataset. It has been agreed that the Patient Summary dataset has to be defined from the medical standpoint. This common and agreed structure of the fields in the PS (epSOS LSP PS) will be represented in each national application as decided by country B. A classification of the different datasets of information identified has been developed based on their degree of relevance in the PS service:

- 'Minimum dataset´ of the PS: is defined as the agreed set of essential health information ('Basic dataset') that is required from the clinical point of view to be sent to deliver safe care to the patient focused in unscheduled care. It may be sent with a value 'null flavor' if the source system of the country does not track that information.
- 'Mandatory dataset': it is a subgroup of the 'Minimum dataset' and all the fields included in it must have a valid value. If the values are not valid, the PS will be rejected.

- ‘Maximum dataset’: is an agreed ‘Extended dataset’ or desirable health information from the clinical point of view to be exchanged between the epSOS LSP countries. The fields are not compulsory to be sent.

The common dataset to be exchanged has been agreed among WP3.2 in a face to face meeting in Paris on July 22nd 2009 and is presented in section 6 (Common structure of Patient Summary).

During the whole process, a set of issues and recommendations for other WPs have been identified. One of the most important recommendation is addressed to the Semantic WP: coding of the PS information with currently available classification systems is strongly suggested to support semantic interoperability services foreseen within the scope of epSOS LSP.

During the work carried out by WP3.2, it has been also analysed the possible inclusion of a new Use case (Use Case 3): access of the patient to his PSs located in a country different from country A without the intermediation of a HCP. It was agreed that this UC is out of scope of epSOS LSP. This analysis is included in Annex A of this deliverable only for information purposes in preparation of a possible future epSOS LSP scope extension.

3 INTRODUCTION

The aim of this document is to identify and describe the service requirements necessary to achieve the general and specific objectives defined in Grant Agreement for Pilot Type A - Annex I in relation with the Patient Summary Services.

This deliverable is not a self-contained document, which means that it is part of the work of the epSOS Large Scale Pilot (LSP) project and is based on the outputs of Annex I, 'Initial Scope' produced by WP5.2, 'Concepts paper epSOS LSP', WP2.1 'Analysis and comparison of legal and regulatory issues' and final version of D.3.2.1 (Draft definition of functional service requirements-PS) that are used as starting point for the development of the deliverable.

All the activities carried out within WP3.2 to achieve WP3.2 goals and to produce this deliverable (face to face meetings, specific workshops, conference calls etc), are described in a separated document 'Work methodology' (internal working document, not to be published). The following beneficiaries have contributed to the development and production of this deliverable: ESNA (Spanish Ministry of Health and Social Politics, Spain), LOMBARDY (Regione Lombardia, Italy), ELGA (Task Force ELGA and Austrian Ministry of Health , Austria), ANDA (Regional Service of Andalucia, Spain), CLM (Regional Health Care Service of Castilla la Mancha, Spain), GIPDMP (Group d'intérêt Public-Dossier Médical personnel, France), INDUSTRY (Industry team), NICTIZ (National IT Institute for Health Care, The Netherlands), NHS (NHS connecting for Health, United Kingdom), ZI (Central Research Institute of Ambulatory Health Care in the Federal Republic of Germany), FHGISST (Fraunhofer Gesellschaft, Germany), MEDCOM (Medcom and Danish National Board of Health, Denmark), IZIP, (IZIP-Internet Access to Patient Electronic Health Record , Czech Republic), SALAR (Swedish Associations of Local Authorities and Regions, Sweden), NHIC (National Health Information Centre, Slovakia),CATA (Fundacio Privada Centre Tic i Salut, Spain), DENA (Federal Ministry of Health, Germany), Gematik (Germany) and FRNA (French Ministry of Health, France).

3.1 Goal of WP3.2 as stated in Annex I

A definition of the functional service requirements for the epSOS LSP System is to be drawn up. The definition is to be based on use cases and to describe system outputs, not processes. Additional requirements and necessary constraints may be incorporated into the specification as appropriate (e.g. data protection requirements). This approach is to be scaled down to PS Services as delimited in the initial scope. Variants/alternatives are documented in Initial Scope of the deliverable, submitted for board decision and the decision implemented in the final version 2 of the deliverable.

4 CONTEXT

The proposals in this section have as main antecedents the use cases defined in the Initial Scope, the recommendations made by WP1.1 (D1.1.1), the legal and regulatory requirements and constrains identified in WP2.1 and in the concepts addressed in the epSOS LSP Initial Scope and 'Concepts paper epSOS LSP'.

The starting point, as stated in WP1.1, 'Analysis and comparison of national plans/solutions' is that all countries have mayor differences regarding the language, the level of deployment of the Patient Summary services and the eHealth processes, concepts and legislation. The challenge for this WP is to define a common service, as less intrusive as possible, with unified and common understandable concepts and within the current legislations (European and national) in order to provide a safe and added value for the patient if he needs Health Care when travelling abroad.

4.1 Definition of the Patient Summary

Patient Summary is understood to be a reduced set of patient's data which would provide a health professional with essential information needed in case of unexpected or unscheduled care (emergency, accident..) and in case of planned care (citizen movement, cross-organisational care path..) being its main purpose the unscheduled care.

The content of the Patient Summary is defined at a high level as the minimum data set of information needed for Health Care coordination and the continuity of care. As stated in epSOS LSP Initial Scope and to be meaningful, the Patient Summary might contain data such as: (defined in detail in chapter 6):

1. Patient's general information (mandatory)
2. Medical summary (mandatory)
3. Medication summary (mandatory)

As stated in Initial scope: the Patient Summary does not hold detailed medical history or details of clinical condition or the full set of the prescriptions and medicines dispensed. Detailed and complete data are usually contained in the Electronic Health Record.

The Patient Summary dataset to be exchanged can be divided as follows, based on their degree of relevance in the PS service:

- ‘Basic dataset: it is 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). This is the so called ‘Minimum dataset’ in the Grant Agreement for Pilot Type A - Annex I. Fields in the Basic dataset must be sent but not necessarily its content. “Null flavor” values are allowed. For example: if the source system of a country does not track the field.
    - ‘Mandatory dataset’: it is a subgroup of the Basic dataset. However, and this is the difference with the precedent fields, they must have a valid value. If the values are not valid, the PS will be rejected. In section 6.1 it is explained which are the valid values for the fields agreed as mandatory (eg: for ‘given name’ a valid value must be a valid name).
- ‘Extended’: it is defined as the desirable health information from the clinical point of view to be exchanged between the epSOS LSP participants. The fields are not compulsory to be sent (therefore, neither the fields, nor the values are compulsory to be sent). This is the so called ‘Maximum dataset’ in the Grant Agreement for Pilot Type A - Annex I

The fields not belonging to the Minimum or to the Maximum agreed epSOS LSP PS dataset will not be exchanged even if they are available in some countries.

The Patient Summary dataset to be exchanged (epSOS LSP PS) has been defined from the medical standpoint and has been agreed between epSOS LSP member states not only on the basic dataset but also in the extended dataset (see section 6)[1].

The Medication Summary, which is part of the PS, is defined as the list of the current medicines, this is, all prescribed medicines whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not. Therefore, it is not necessarily related to the prescription/dispensation process defined in D3.1.2[2]

[1] Although the clinical point of view was the driving force behind the agreement on the epSOS LSP PS dataset, it is also understood that, in order to make the pilot viable, the basic dataset should be available in all or most of countries that are planning to be a pilot site.

[2] There was a requirement coming from WP3.1 (Definition of functional service requirements-e-Prescription) regarding the possibility for the pharmacist of consulting the Medication Summary, if in that country is permitted, in order to safely dispense the medicine. This means that the Medication Summary should be accessible independently from the rest of the Patient Summary as the pharmacist is not allowed to access the whole PS in all MSs. However, the feedback from the technical WPs was that it was not possible to implement, within the piloting timeframe, the access to the medication summary as a separate document so at the PEB on Brussels January 14th a decision was taken to leave that requirement for a further step. The 3.1 remaining requirement (mandatory) is the pharmacist’s access to CURRENT PRESCRIPTIONS, independently of the data source defined by country A. It was also decided to let the countries that showed interest (Sweden, Denmark, Austria but not from the beginning, and maybe Spain) to share a medication summary within the epSOS project. Those countries committed to give their feed-back to the project.

The Patient Summary must be presented in a structured way, this is, in structured modular data groups or sections (sorted under the correct nesting headers) each of them containing related items of information. The main aim of this way of presentation is to facilitate the comprehension of the content of the PS for the HCP and to make it possible for each subset of information to be managed individually when applying semantic services or when applying any kind of translation into the native language of the person requesting the PS consultation.

The common and agreed structure of the fields in the PS (epSOS LSP PS) will be represented in each national application as decided by country B although, in order to ease the process for the HCP, it is recommended that the information is presented as it is normally done in country B.

4.2 Background and basic concepts around the patient summary

In this section a definition of the antecedents and the real scope, specifying what is in and out of WP3.2 within the epSOS LSP Project is stated. A clear differentiation of this deliverable from other deliverables in the project is also specified (e.g. functional requirements are identified, no architectural modelling done; only information necessary for Patient Summary is identified, no data modelling) plus the requirements and assumptions, on which the analysis in this document is based.

4.2.1 Scope

The objective of WP3.2 is to define the functional service requirements for the Patient Summary Services as delimited in the Initial Scope. The definition is to be based on the Use Cases described in Initial Scope document and to describe system outputs, not processes.

Cross-border care in epSOS LSP has been conceived around two use cases and foresees both scheduled and unscheduled encounters. Use case 1 applies when the person is an occasional visitor in country B, for example someone on holiday or attending a business meeting, and use case 2 when the person is a regular visitor to country B, for example migrant workers. These two use cases are analysed in Section 5.2 and 5.3.

The epSOS LSP Initial Scope also makes reference to the following situations: “The situation that needs to be considered is that a conscious or unconscious person visits an HCP and this one wants to make use of the patient summary of the patient which is abroad. This situation can arise in an emergency or be planned”. It is important to notice that the maximum impact of epSOS LSP project will be in the unscheduled scenario.

Having analysed the use cases defined above, WP3.2 assumed that from the functional point of view the variable “frequency of visit” (occasional and regular) in UC1 and UC2 does not make different use cases in terms of the services and the information requirements by the final user because in both cases the UC starts when the HCP needs access to essential patient information which is in a different country from the country where the patient seeks for care. The Patient Summary dataset to be exchanged is to be applied to all the UCs described in epSOS LSP, this means that the dataset to be exchanged will not be different for each UC defined. For this reason both UCs (UC1 and UC2) will be analysed together in the document as a single use case.

Following the general approach of Grant Agreement for: Pilot Type A - Annex I, where it is recommended that this project should avoid interfering in the functioning and organization of each country available internally, every MS is responsible for the content of the PS generated in it. This means that it is left to the responsibility of each country when and how the Patient Summary is built as well as other processes bound to the normal development of PS in each country.

4.2.2 Out of the scope

This section precisely describes all the issues that are not addressed in this document as they are considered to be beyond the defined scope in the epSOS LSP project.

- It is out of scope of epSOS LSP to transfer clinical information from country B (country in which information about a patient is needed in case that the patient needs Health Care) to country A (country where the patient can be unequivocally identified and his data may be accessed) (in ‘Concepts paper epSOS LSP‘). Therefore it is out of scope that country B sends a record of the Health Care encounter to country A (epSOS LSP project is about making available to HCP-B the PS of the patient but no other electronic health documents like patient health encounters, electronic health records etc).

- It is out of scope to provide the HCP with all the health information related to that patient (eg: complete electronic patient record, all health encounters, all laboratory tests, all X-rays exams etc). It is also out of scope in epSOS LSP other potential uses of the PS information (e.g: public health, epidemiology, health management, etc.).
- It is out of scope to analyse in this deliverable the individual medical processes within each Member State, e.g. the way the HCP perform their work, the way a HCP is identified and authorized etc. Besides, a relationship of trust between the epSOS LSP MSs must exist (e.g. validity of the identity of a professional in other MS) as it is established in Grant Agreement for: Pilot Type A - Annex I. This means that all the countries are integrated on one system of trust (functional and technical) and also with respect to quality and reliability of the information exchanged between countries.
- It is out of scope to analyze the methodology that each Member State envisions to produce a valid PS and to analyze the consequences of the different methodological approaches (automated extraction of the PS, direct human intervention of a HCP etc) or their possible impact on the reliability of the information.
- A unique European PS stored is out of the scope (option removed by the Legal team after Legal meeting in Vienna on April 21st 2009).
- Technical issues are out of scope of WP3.2. They have to be managed in other WP (agreed in WP3.2 Vienna meeting on April 22nd 2009).

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347 The following tables summarises what is in the scope (Table 1) and out of scope (Table 2) of
348 WP3.2.

349

IN SCOPE
Service definitions and requirements based on agreed Use Cases
Identification and description of functional requirements including the requirements about the data presentation
Identification and description of additional requirements
Functional definitions and the human understandable description of the data model
Definition of a common structure of PS (minimum and maximum common datasets)
Definition of similarities and differences between PS and eP in the content structure and the requirements
Outline constraints
Outline alternatives (with clarifications and comparison between them)
Recommendations that other WPs must take into account

350 **Table 1. Scope of WP3.2**

OUT OF SCOPE
Considering the option ‘a unique stored European PS’
Description of the Patient Summary processes in every Member State and the methodologies to produce the PS in each Member State
Description of the legal value of PS in each country
Providing the HCP with all the related health information of the patient
Management of the authentication process of the HCP in his/her system
Description of the individual medical processes within each MS
Management of the identification/authentication/authorisation process of the patient
Architectural and data modelling (will be handled by working group 3.3)
Semantic interoperability (e.g. solve semantic differences such as medication names and clinical terminologies)
Transfer of clinical information from country B to country A
Technical issues related to PS

Table 2. Out of the scope for WP3.2

4.2.3 Principles

The basic principles and framework in the definition of the PS services within the epSOS LSP project are the following:

- The primary purpose of electronic Patient Summary in epSOS LSP is to provide the Health Care Professional (HCP) with a dataset of key health information at the point of care to deliver safe patient care during unscheduled care and planned care having its maximal impact in the unscheduled care. We will not go into what is relevant to each medical specialist (as it could differ depending on the type of physician), but on what is necessary for the unscheduled care. Therefore, the content of the PS is not the entire medical record but the essential patient information to provide the assistance. The electronic patient record, health encounters, discharge letter of a hospital etc they are not, by themselves a PS, because they do not satisfy the criteria of ‘essential information’ from the clinical point of view inherent to the PS definition. In this sense, the purpose of the PS information is to support the coordination and continuity of Health Care in a pan-European mobility of citizens.

- Any access to the Patient Summary information is in the context of a resident of one MS visiting another MS (country B) and seeking for Health Care; the HCP-B may need access to the PS that the patient has in country A in order to deliver safe Health Care.
- The driving concept in the development of this deliverable has been the medical perspective and clinical purpose.
- Patient can have Patient Summaries in different countries (agreed in WP3.2 Vienna meeting on April 22nd 2009), therefore one citizen could have one PS in each European country. The safekeeping of country X Patient Summary remains to country X. It is also important to state that there is no central European database within epSOS LSP where any patient related data is held.
- Only one common structured epSOS LSP PS per country visible from outside will be provided. This option was agreed in WP3.2 Vienna meeting on April 22nd 2009 in order to reduce the number of PSs belonging to one single patient as, in some MSs one patient can have more than one PS (eg: one PS per region). This is because it was perceived that it is not possible to define a set of rules to decide the prevalence of the clinical information in the process of its integration: integrating information from many different Summary documents can therefore produce a less useful document with a lot of complementary, redundant or similar information regarding the same issue (eg: allergy to betalactamics, allergy to antibiotics, allergy to penicillin, rash due to penicillin ..etc) .
- Use cases and functional requirements are described in this deliverable with the approach that the HCP of country B accesses only to the PS of country A. The approach 'multiple PSs' (access to the existing PSs in the MSs) is described in Annex A only for information purposes but not included in the technical implementation of the epSOS LSP realm.
- Independently from the procedure that each country applies to produce a valid PS, it is considered that the information contained in the PS made available to country B is consistent (eg: if the patient is allergic to penicillin, his Medication Summary must not contain Penicillin).
- Independently from the procedure that each country applies to update the information in their PS, it is considered that the PS made available to country B contains updated and reliable information. In any case, knowledge of the date of last update is critical for the best assessment of the information from the PS query.

- If the patient has decided to hide any information from his PS in country A, it will not be included in the epSOS LSP PS, therefore such information will not be made available to HCP of country B. Health Care professionals participating in the epSOS LSP pilot should be informed (through the appropriate documents to be addressed by the Legal group) that there can be hidden information about the patient when using the epSOS LSP PS service.
- Country B will maintain information collected on care episodes for a patient of country A for legal and reimbursement purposes but there is no obligation to maintain health records of any kind beyond any nationally required record keeping for audit purposes. As it was stated before, it is left to country B decision whether to create or not a PS for a patient of country A who seeks for Health Care in country B.
- Any access from an authorised health professional to the PS will generally take place with a citizen's explicit consent by the means and methodology that the Legal group (WP2.1 'Analysis of legal and regulatory issues') and WP3.6 ('Identity Management') will establish. This issue needs to be analysed by the WP2.1 to address the situations when a patient is unable to give his consent (unconscious, handicapped) and there is a risk for the patient's health.

4.2.4 Requirements

- A basic requirement to achieve the purpose of PS in epSOS LSP is that the information exchanged must be understandable in both countries involved in the interaction.
- A basic requirement to achieve the purpose as expressed in the PS in epSOS LSP is to ensure the comprehensibility of the information by the one who receives it. This understandability must be minimally assured by two key elements: concept understanding and text understanding and must take priority over the completeness/exhaustiveness of the provided information. Thus, very special care should be given to the receivers side of the PS, in terms of informing him/her about the meaning of the elements in the patient summary.
- As from the analysis from D1.1.1, since substantial parts of the content of PSs in the MSs are in free text form, in the local country languages, a solution has to be found to overcome this huge interoperability challenge. The most future-oriented solution could be to find a way of making a patient summary 100% coded, on the epSOS LSP level, enabling translations to and from the local environments.

- One-to-one and unmistakable identification of the patient must be assured.
- The protection of personal data, privacy and confidentiality must be assured.

4.2.5 Interdependencies with other Groups

These are some of the identified interdependencies between WP3.2 and other WPs within the project:

Interdependencies between 3.2 and 3.1 'Definition of functional service requirements- ePrescription'

The structure of the data contained in the Medication Summary (within the PS) is consistent across both WPs, to show coherent information. The definition and content of the medication summary is in the scope of WP3.2.

Interdependencies between 3.2 and 3.3 'System architecture'

Data modelling must be done in WP3.3 but the functional definitions and the human understandable description of the data model must be made in WP3.2.

Interdependencies between 3.2 and 3.5 'Semantic Services'

In this deliverable, the fields that the PS must contain will be defined. Also the definitions or meanings of these fields but not the possible contents (e.g. the field "active ingredient" will be described in the Medication Summary but the different value sets or library as amoxicillin, acetylcysteine etc will not be identified).

Interdependencies between 3.2 and 3.6 'Identity Management'

WP3.6 is in charge to deliver Identification, Authentication and Authorization for patients and HCP/HCPO whereas WP3.2 describes the need for identification which is necessary for UC1&2.

The following figure depicts the flow of inputs and outputs required from and to other WPs:

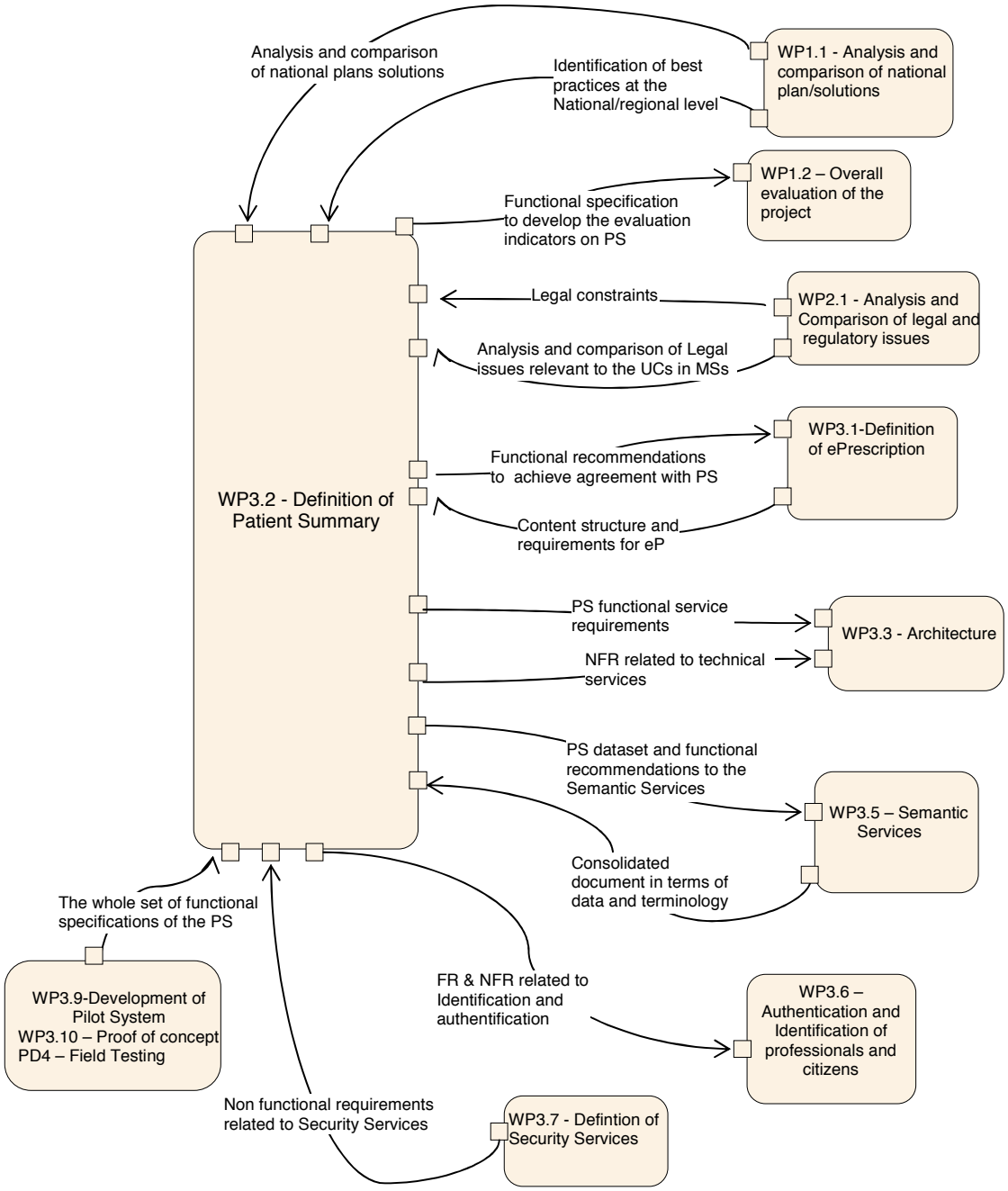

Figure 1. Inputs and outputs required from WP3.2 and to other WPs:

5 REQUIREMENTS IDENTIFICATION

In this chapter the objective is to describe the agreed Use Cases, to identify the functional requirements and to summarize the responsibilities and actions that are needed per each actor (technical and human) in the epSOS LSP project.

5.1 Summary actors' description

This section deals with the actors involved in the Patient Summary service. Basically, these actors may be categorized as:

Human actors (individuals):

- Patient: individual from country A requesting Health Care in country B: This person could need emergency or non emergency care.
- HCP: It is the health professional who provide the Health Care. The HCP must be registered with at least one HCPO or to a Health Authority belonging to the country that could unequivocal identify him or her. Each country must have a system to check the attributes (right for accessing to the information) of the end user who requests the PS information.

Institutional actors

- Health Care Service Providers Organization. They are organizations/Institutions to which the HCP is registered with.. These organizations provide the HCPs a status, identification, an authentication, from which the HCP trust is derived.
- Health Authorities Institutions: They are generally public institutions which provide the governance of health services within a given territory (province / region / MS level), that assigns and assure the status, the function, and sometime the authentication of HCP. This happens because it has been always assumed the HCPO or the institution has to identify the doctor although some exceptions are possible in some countries, where freedom of medical practice is guaranteed. Even in those cases, a Health Authority Institution should guarantee a proper authentication.

System actors (information system or provider such as those used to convey information across borders):

- National Contact Point or NCP: as already set out in the Initial Scope, takes care of external and internal national communication in the epSOS LSP project and the semantic mapping between information on either side. The NCPs will be furthermore responsible towards all MS partners in epSOS LSP for securing that the needed

processes are properly implemented at their own networks which will be typically points where care is delivered. Regarding the PS services:

- The NCP will deal with the identification of patients and identification and authentication of HCPs.
- The information is made exchangeable by means of the National Contact Points in the both countries.
- Country B will handle the PS received from country A.

- The Semantic Services to make understandable the PS originated in country A to an HCP in country B.

5.2 Agreement on the scope of the use cases

After analysing the proposed Use Cases, two main uses cases are identified. The two UCs must be understood as an access to the PS.

-USE CASE 1: an occasional visitor in country B, for example someone on holiday or attending a business meeting. The distinguishing characteristic is that this type of visit is irregular, infrequent, and may not be repeated. This is a type of incidental encounter where the Health Care professional may have no previous record of the person seeking care.

-USE CASE 2: the person is a regular visitor to country B, for example someone who lives in one country but works in another country. The distinguishing characteristic is that this type of visit is regular, frequent, and the person seeking care may be accustomed to using services in the country where he or she works as a matter of personal convenience. This is a type of occasional situation where the Health Care professional may have some information available from previous encounters, therefore the patient could have a medical record locally stored in country B, and maybe a PS in country B plus in country A. If this is the case, both PSs should be available for the HCP to be consulted.

5.3 Description of the Requirements and the Use cases

The objective of this section is to describe the set of functional and not functional requirements necessary for the implementation of the use cases. This includes required knowledge (not data) and requirements about how to access and get information.

Description of Use Cases and Functional Requirements have been done with the approach that HCP of country B accesses only to the PS of country A. This decision was agreed in the face to face meeting in Athens on July 1st 2009 in order to reduce complexity and facilitate the viability of the pilots in the epSOS LSP scenario. Nevertheless, the approach ´'Multiple

PSs' (meaning that the Health Care professional gets access to the list of existing PSs for that patient and selects and asks for any of them) was also analysed by WP3.2 and this analysis is included in Annex A of this deliverable for information purposes in preparation of a possible future epSOS LSP scope extension.

Technical and syntactical interoperability, as well as semantic services will be needed as a baseline and will be described in other WPs.

5.3.1 Requirements description

The identified requirements are presented in Table 3 . The numbering of the requirements is not always consecutive in order to have a unique number for the same requirement across D3.1.2 and D3.2.2 and to avoid duplication of requirement numbering. Those requirements which are common to D3.1.2 and D3.2.2 may have different actors and different information to be accessed as in the former document the information to be exchanged is related to the ePrescription and in the latter to the Patient Summary.

The goal of these requirements has been to assure the security of the service, the accessibility of the information from/to another country, the right interpretation of the information and the information needed to fulfil the service.

Functional Requirements	
FR01	HCP Identification and authentication
FR02	Trust between countries
FR03	Patient identification
FR04	Patient consent to access data
FR05	Structured Information
FR06	Equivalent Information
FR07	Information Understandable
FR19	Patient summary of country A available
FR20	Information Traceability
Non Functional Requirements	
NFR01	Service availability
NFR02	Communications
NFR03	Response time
NFR04	Confidentiality
NFR05	Access control
NFR06	Audit Trail
NFR07	Integrity
NFR08	Non repudiation
NFR09	Trust between countries
NFR10	Guaranteed delivery
NFR12	Supervision services

Table 3. Requirements identification for PS Services

5.3.2 Functional Requirements

Functional Requirement 01: HCP Identification & authentication

Requirement FR01	HCP Identification & authentication
Description	The HCP must be unequivocally identified and authenticated in his local system and must be identified according to his/her role/profile.
Associated Goals	• To provide security to the process. • To ensure that the HCP is legally allowed to perform the functionalities described in this document. • Prevention of disclosure to unauthorized persons.
Actors	• HCP-B • NCP-B

Functional Requirement 02: Trust between countries

Requirement FR02	Trust between countries
Description	All the countries involved in the project are integrated into one system of trust (functional). It is necessary to have an agreed framework for creating trust, by establishing policies for critical data protection, privacy and confidentiality issues as well as mechanisms for their audit.
Associated Goals	• To enable the exchange of information between countries. • To avoid having to identify all professionals and institutions from a foreign country in the country of origin. On the one hand, each HCP will be unequivocally identified and authenticated in his local system and must be identified based on his/her role/profile. On the other hand, Health Care Provider Organisation provides HCP a status, a function, an authentication from which the HCP trust is derived. Furthermore, Health Authorities Institutions assign and assure the status, the role, and sometimes the authentication of HCP.
Actors	• HCP-B with rights for accessing PS • NCP-A • NCP-B

Functional Requirement 03 - Patient identification

Requirement FR03	Patient identification
Description	The patient needs to be univocally identified in a reliable way (unique and unequivocal ID) to allow the HCP to consult his information[3] (after his explicit consent or authorisation). For functional and security purposes in the information usage, the univocally identification of the patient is highly relevant. One-to-one and unmistakable identification of the patient must be assured. Patient authentication will be guaranteed at national level based on the concept of mutual trust. Special attention needs to be paid to people under protection and children as they might not own an identification. The process of identification (positive or negative) must be recorded.
Associated Goals	• To have certainty of the identity of the patient.
Actors	• HCP-B with rights for accessing PS • NCP-A • NCP-B

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Functional Requirement 04: Patient consent to access data

Requirement FR04	Patient consent to access data
Description	This requirement is subject to legal aspects defined in WP2.1 'Analysis of legal and regulatory issues' and the different solutions to handle it are described in WP3.6 'Identity Management'. Consent must be given by the patient in country B per request and informed, specific and freely given. It must furthermore enforce the consent by deciding on whether a certain request for data is legitimated by the consent or not (country A can not disclose any information until patient consent has been given in country B). The lifecycle of the consent must be logged in a way that the legitimacy of each request can be reconstructed in retrospect.
Associated Goals	• Manifesting the legal foundation for a lawful data processing. • Granting the patient his specific rights according to data protection regulations. • Deciding on whether a certain request for data is legitimated by the consent or not.
Actors	• HCP-B • NCP-A • NCP-B

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[3] The necessary datasets for the HCP in UC1&2 (PS dataset is described in section 6)

Functional Requirement 05- Structured Information

Requirement FR05	Structured Information
Description	The information sent to another country must be structured this is, in structured modular data groups (sorted under the correct nesting headlines) each of them containing related items of information with a unified meaning of fields (e.g. field 'Current Problems/Diagnosis' is properly identified in country A and translated to country B). The information should be presented in his system as decided by country B . However, in order to ease the process for the HCP, it is recommended that the information is presented as it is normally done in country B.
Associated Goals	• Safety reason. • HCP understands the meaning of all the fields that are going to be shown to him. • To provide the HCP with the necessary information to deliver safe care to the patient. • To guarantee the safety of the patient through a proper understanding of the received information. • To ensure safety delivery of care to patients thanks to the faithful exchange of meanings between systems and between systems and people. • To reduce time in searching necessary information to provide Health Care to the patient. • To facilitate the later treatment of the information to assure its comprehension through semantic tools, systems of codification or of translation according to how it will be established later in the epSOS LSP project.
Actors	• HCP-B • NCP-A • NCP-B

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Functional Requirement 06- Equivalent Information

Requirement FR06	Equivalent Information
Description	The information sent to another country must be equivalent in the Meaning, i.e. a unified meaning of the information must be coherent with that system (e.g. the field 'active ingredient' means the same in both countries).
Associated Goals	• Safety reasons. • HCP understands the meaning of all the fields that are going to be shown to him. • To provide the HCP with the necessary information to deliver safe care to the patient. • To guarantee the safety of the patient through a proper understanding of the received information. • To ensure safety delivery of care to patients thanks to the faithful exchange of meanings between systems and between systems and people. • To reduce time in searching necessary information to provide Health Care to the patient. • To facilitate the later treatment of the information to assure its comprehension through semantic tools, systems of codification or of translation according to how it will be established later in the epSOS LSP project.
Actors	• HCP-B • NCP-A • NCP-B

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Functional Requirement 07: Information Understandable

Requirement FR07	Information understandable
Description	The information sent to another country must be Understandable (language) by the human actors that will make use of it.
Associated Goals	• Safety reasons. • HCP understands the meaning of all the fields that are going to be shown to him. • To provide the HCP with the necessary information to deliver safe care to the patient. • To guarantee the safety of the patient through a proper understanding of the received information. • To ensure safety delivery of care to patients thanks to the faithful exchange of meanings between systems and between systems and people.
Actors	• HCP-B with rights for accessing PS • NCP-A • NCP-B

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Functional Requirement 19: Patient Summary of country A available

Requirement FR19	Patient summary of country A available
Description	The HCP-B needs to access the Patient Summary of the patient available in country A.
Associated Goals	• PS of country A must be available to be requested by HCP of any other country. After the identification of the patient who requests Health Care in country B, HCP-B requests the visualization of the PS the patient has in country A.
Actors	• HCP-B with rights for accessing PS • NCP-A • NCP-B

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Functional Requirement 20: Information Traceability

Requirement FR20	Information Traceability
Description	The information describing the process and the data involved in the process must be able to be traced and recovered. This includes all the information that has been considered as basic and extended data in the PS. It also includes such information as the location and the identification of the requester, time of consulting and the rest of the information contained within the PS effectively accessed and transferred to the HCP-B.
Associated Goals	• Security reasons. • Legal reasons.
Actors	• HCP-B with rights for accessing PS • NCP-A • NCP-B

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5.3.3 Non Functional Requirements.

Non Functional Requirement 01: Service availability

Requirement NFR01	Service availability
Description	Availability is the property of being accessible and usable upon demand by an authorised entity (ISO 7498-2:1989). There are different causes for technical unavailability (of communications, NCPs, local systems…) of the epSOS LSP service as o failure o unplanned stop (bug, random error) o partial planned stop (non optimal running) o planned stop (maintenance, update) Each unpredictable service interruption will be detected as soon as possible. The origin of the failure (HCP system, NCP system, ...) will be explained. It will be notified which systems or types of information cannot be reached at the present time due to circumstances or technical failures. The procedure to follow will be specified in order to come back to a normal mode. Instead of completely unavailability, the service can be degraded. This state needs to be defined and when this happens, the suitable alerts and the procedures to follow will need to be defined.
Associated Goals	• The epSOS LSP service will be continuously available.

Non Functional Requirement 02: Communications

Requirement NFR02	Communications
Description	Information has to travel from one country to another. The epSOS LSP service requires secure communications between different local systems, situated in several countries. The information exchanged between countries must be protected from random errors as well as snooping or hacking attacks. This means: • That the parties participating to the communication must be properly identified in both countries • The information exchanged must be protected. • The integrity of all information exchanged during the performance of any of the use cases must be guaranteed. • The session and the information exchanged must be associated with secured data allowing afterward verification.
Associated Goals	• To have secure communication means between National Contact Points.

Non Functional Requirement 03: Response time

Requirement NFR03	Response time
Description	As the information has to travel from one country to another it has to be accessible and available with reasonable response times. Of course, all the countries are integrated on one system of trust. The purpose is to deliver timely requested information to the HCP but always guaranteeing Health Care. An acceptable response time not only applies to the receipt of the information, but also to the identification and authentication of HCP and patient. The system should provide an end to end response time (as experienced by the country B HCP) within a few seconds, possibly no more than 10 seconds[4].
Associated Goals	• Information has to travel from one country to another. The response time could vary depending on the chosen architecture; that is, whether it's centralized or distributed and whether there are several PS or just one per citizen. • The system should provide an acceptable end-to-end response time, not degrading or delaying the already existing services because the patient is waiting while the system accesses and shows the required information. • The access times should be tested continually by the system to give the user some idea of what to expect.

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[4] The technical groups will have to evaluate the feasibility of this response time. It has to be understood that the 10 seconds limit is not a service level agreement but a proposal of threshold.

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Non Functional Requirement 04: Confidentiality

Requirement NFR04	Confidentiality
Description	Whenever identifiable medical data is communicated, stored, or processed, the confidentiality of the data must be enforced and safeguarded by the epSOS LSP services (by all actors involved). All communication of identifiable data between the epSOS LSP partners must be performed in a way that prohibits any unwanted disclosure of medical data to any third party. Furthermore, the epSOS LSP services must enforce that any data access is only possible over safeguarded, well-defined interfaces. An unwanted or unlawful disclosure to an unauthorised party must also be prohibited at all times.
Associated Goals	• Manifesting the legal foundation for a lawful data processing. • Protecting and safe-guarding the patients medical information. • Ensuring the involved HPC to be fully compliant with their professional code.

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Non Functional Requirement 05: Access control

Requirement NFR05	Access Control
Description	Each system must assure that only authorized persons and systems are able to access protected data. As authorisations may involve the existence of a treatment context inside a HCPO, these treatment relationships must be justifiable on demand. The communication partners (origin, destination, and potential facilitators) need to be known to each other with prior positive verification that all involved partners are authentic: security features to be provided by the means of an identity (subjects, actors, objects) and access management.
Associated Goals	• For traceability reasons. • For security reasons. • To assure confidentiality. • For confidentiality and integrity of medical data reasons. • To align to the European Data Protection Regulations[5].

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[5] From DIRECTIVE 95/46/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

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Non Functional Requirement 06: /Audit Trail

Requirement NFR06	/Audit Trail
Description	Any data access or attempt to access medical data through the epSOS LSP services, must be fully transparent and traceable and reproducible e.g. by logging of “who” accessed “which” medical data from “where” at “what” time under “whose” authority. When all audit data is available, a supervision authority must be able to fully recover and reconstruct an access attempt and access path in order to verify its regulatory compliance. The collected data must be available and suitable for scheduled and unscheduled security audits. Extraordinary and/or emergency accesses must be specially marked in order to facilitate the local management of those. All data gathered by the audit services may contain identifiable personal data and must be protected accordingly. Furthermore, since the audit trail may be considered as evidence/proof in potential investigations, all protocols must be fully safeguarded in integrity and confidentiality. Access to the audit trail must be restricted and only be granted to authorised persons with concrete access necessities within epSOS LSP. The audit services of the epSOS LSP services should collect a pre-defined set of operational data in order to provide an adequate quality- and capacity-assessment. These protocols must only be used for continuous service delivery and/or service improvement and must not leave the epSOS LSP context.
Associated Goals	• Enabling a transparent and reconstructable system operation. • Documenting compliance and legitimacy of data accesses. • Making the epSOS LSP services auditable.

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Non Functional Requirement 07: Integrity

Requirement NFR07	Integrity
Description	The integrity of the transmitted information must be guaranteed. This requirement guarantees that all transmitted data for a patient arrives at the assessing HCP in country B without any alteration from the NCP in country A. It must be identified that the transmitted data has not been damaged, reduced or altered. Any loss of integrity of the transmitted data must be recognizable by the recipient.
Associated Goals	• For safety reasons. • To transmit the patient summary unaltered (integer). • To enable detection of any damage, reduction or alteration of the patient summary.

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Non Functional Requirement 08: Non repudiation

Requirement NFR08	Non-repudiation
Description	The issuer of the transmitted information must be held accountable for this. This requirement guarantees that medical data from a patient at the assessing HCP in country B is supported by the necessary assurance about the issuer of the information. It must remove the possibility that the issuer of information denies that the sending has taken place covering also the content.
Associated Goals	• To guarantee that the issuer of the information agreed in this deliverable to be exchanged, cannot refuse that the issuance has taken place.

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Non Functional Requirement 09: Trust between countries

Requirement NFR09	Trust between countries
Description	All the countries involved in the project are integrated into one system of trust (technical). It is necessary to have an agreed framework for creating trust, by establishing processes and procedures for critical data protection, privacy and confidentiality issues as well as mechanisms for their audit. Such issues include, but are not limited to: • Identification, authentication and authorisation mechanisms. • Security and trust mechanisms. • Recording and exchanging patient consent.
Associated Goals	• To enable the exchange of information between countries. • To avoid having to identify all professionals and institutions from a foreign country in the country of origin. On the one hand, each HCP will be unequivocally identified and authenticated in his local system and must be identified based on his/her role/profile. On the other hand, Health Care Provider Organisation provides HCP a status, a function, an authentication from which the HCP trust is derived. Furthermore, Health Authorities Institutions assign and assure the status, the role, and sometimes the authentication of HCP.

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Non functional Requirement 10: Guaranteed delivery

Requirement NFR10	Guaranteed delivery
Description	When information is sent from one country to another, it must be assured that the information has been properly received by the end user (HCP of country B).
Associated goals	• For security reasons. • To check that the Patient Summary service has been properly completed.

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Non functional Requirement 12: Supervision services

Requirement NFR12	Supervision services
Description	A service must be put in place to detect all the technical exceptions and to check and monitor the performance of the service (time response, communications…) and to alert so that appropriate measures can be perfomed to solve these exceptions. This requirement will be further described by the technical WPs.
Associated goals	• To assure that the system is technically working properly. • To assure the availability and to avoid degradation of the service.

Further to those requirements the technical work packages leaders plus the TPM (technical project management) agreed in having the possibility of sharing the information through a PDF format on request and in the country A language. That requirement is not mandatory.

The PDF content should be constraint for what is defined as the dataset of the patient summary in 3.2 in order to be able to maintain a common understanding of what a patient summary is. From a clinical point of view the aim of the group is not to share as much information as possible but to define what a patient summary has to contain and what should be avoided in order to keep its main use: a summary containing all the important information but being easy and quick to be read by a professional in a short time frame.

However, at first, some countries that use one single document as a source of information are not able to separate the fields to create the PDF with only the information of the dataset defined. Consequently sometimes at this first step of the project the information will be more than the dataset defined because it will have to be what that entire single coded document contains.

In any case the PDF document will have medical and legal validity and one HCP (in the case of a PS generated and signed by an HCP) or one HCPO (in the case of a PS constructed through different sources of clinical information) will be liable of the data provided.

5.3.4 Relationship between use cases and requirements

Three major actions are identified for the description of the use cases (UC1&2):

UC 1&2 Action list
A: Check Patient ID
B: Verify patient consent
C: Consult Patient Summary of country A

The two UCs are analysed in the following sequence diagram and table description

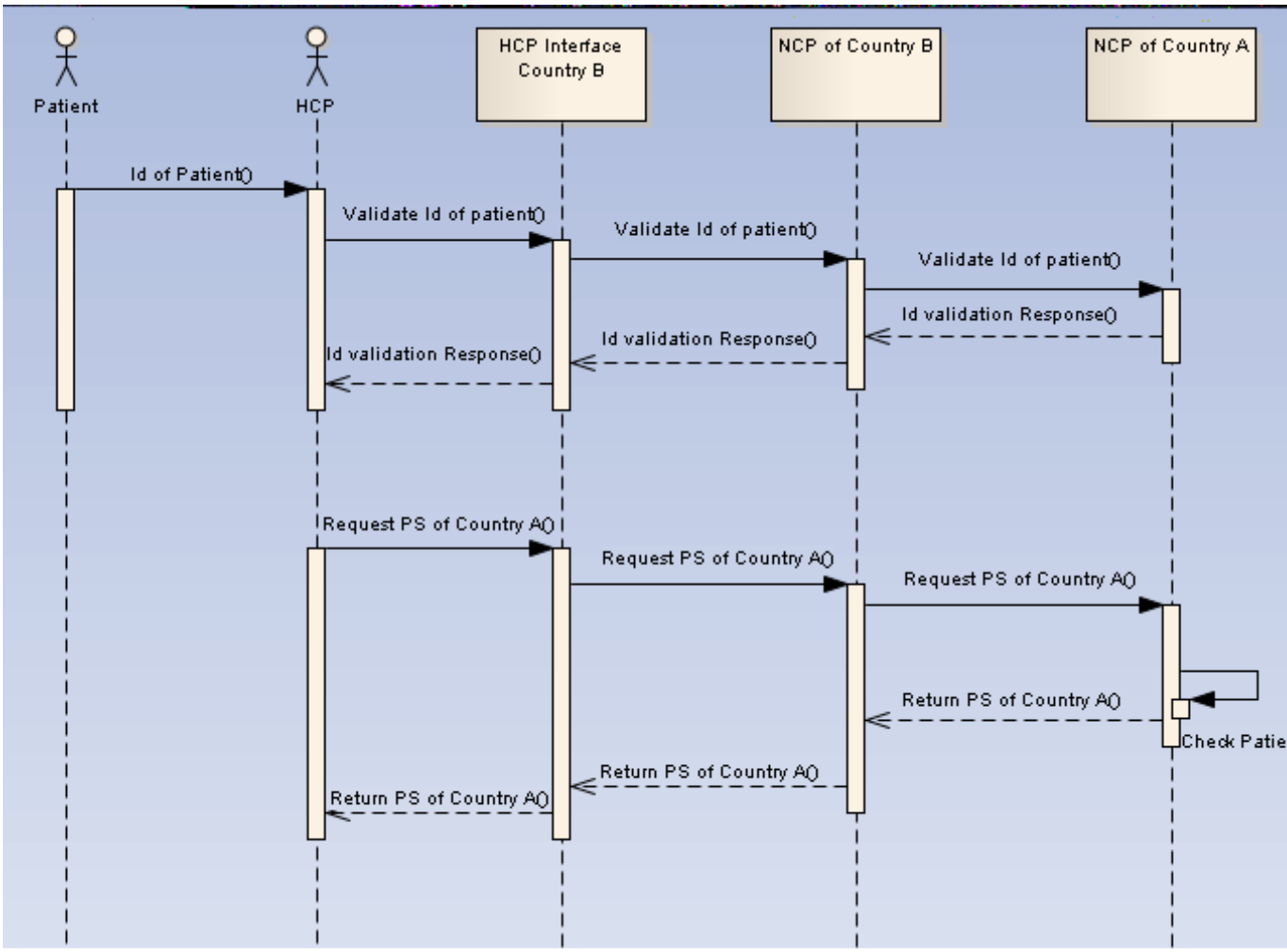

Figure 2. Sequence diagram Use Case 1&2: Patient summary occasional and regular visit

<table>
<tr><td>UC 1&2</td><td colspan="2">Patient summary occasional and regular visit</td></tr>
<tr><td>Goal</td><td colspan="2">The goal of UC 1&2 is to allow the HCP of country B to consult the Patient Summary of country A of the patient seeking for Health Care either in occasional or in regular visit</td></tr>
<tr><td>Functional Requirements to be fulfilled by country A</td><td colspan="2">FR02: Trust between countries
FR03- Patient identification
FR04: Patient consent to access data
FR05: Structured Information
FR06: Equivalent Information
FR19: Patient summary of country A available
FR20: Information Traceability</td></tr>
<tr><td>Functional Requirements to be fulfilled by country B</td><td colspan="2">FR01: HCP Identification & authentication
FR02: Trust between countries
FR03- Patient identification
FR04: Patient consent to access data
FR05: Structured Information
FR06: Equivalent Information
FR07: Information Understandable
FR20: Information Traceability</td></tr>
<tr><td rowspan="2">Actors</td><td>Human and institutional actors</td><td>Technical actors</td></tr>
<tr><td>• Patient
• HCP
• HCPO</td><td>• NCP B
• NCP A</td></tr>
<tr><td>Preconditions or requirements</td><td colspan="2">1. Patient request for medical assistance in country B to a HCP
2. PS in country A
3. The HCP is a person legally authorised in country B to provide Health Care and is identified and authenticated in country B[6] (FR01)
4. A mechanism to validate the identity of the patient and to handle patient consent against country A has to be available at the Point of Care
5. HCP of country B knows the identity of country A
6. The Health Care Professional must be related to at least one HCPO or to a Health Authority.
7. Country B must provide, maintain and support a NCP supporting communication of information with country A and viceversa (FR20)
8. There is a chain of trust between system actors in this process (FR02)
9. The HCP must be able to access the “communication layout” that handles the PS in the European Countries
10. All technical actors involved in the process must be able to retrieve all the information describing the process and the data involved in it (such as the identification of the HCP, the identification of the patient, the information contained in the PS…), all this information must be able to be traced and recovered (FR20)</td></tr>
<tr><td>Post conditions</td><td colspan="2">The HCP-B gets access to the PS (of country A) of the patient at the point of care

The information exchanged must be understandable in both countries involved resolving semantic differences such as medication names and clinical terminologies. Syntactical interoperability and record of the access must be done.</td></tr>
</table>

[6] It is important to emphasize that there might be different definitions of roles/attributes of the end user in each Country (e.g.: patient, physician, pharmacist) which is based on national law. This means that the rights for accessing the information based on the profile of the HCP could be different in each Country

Normal sequence		
Step	**Actions (or description)**	
	A: Check Patient ID	**FRs fulfilled: FR 03**
1.	A patient from country A visits a HCP in country B seeking for Health Care assistance	
2.	Patient is identified	
3.	The HCP requests the validation of the identity of the patient through the HCP interface	
4.	The HCP interface conveys this request to the NCP of country B	
5.	The NCP of country B conveys this request to the NCP of country A	
6.	The NCP of country A checks ID and provides to the NCP of country B the (positive or negative) patient's identification confirmation.	
7.	The NCP of country B provides the patient's identity confirmation to the HCP interface	
	B: Patient consent (per request)	**FRs fulfilled: FR 04**
8.	Once the identity of the patient is validated, the patient consent is verified[7]	
	C: Consult PS of country A	**FRs fulfilled: FR 05, 06, 07, 19,**
9.	Once the identity of the patient is validated, the HCP of country B requests, with the consent of the patient (FR04), the PS of country A that can be visualized by HCP interface	
10.	The HCP interface requests the PS of country A to the NCP of country B	
11.	The NCP of country B requests PS of country A to the NCP of country A	
12.	The NCP of country A, after checking if patient consent has been provided, gets and provides to the NCP of country B the PS of country A on the epSOS LSP format.	
13.	The NCP of country B conveys the PS of country A to HCP interface	
14.	The HCP-B accesses to the Patient Summary of country A	
15.	The use case is terminated	
Exceptions[8]		
The identity of the patient cannot be properly validated in country A		
6	The NCP of country A informs the NCP of country B of the identification failure	
7	The NCP of country B informs the HCP interface of the identification failure	
8	The HCP informs of this failure to the patient. The validation of the identification might be requested again many times[9] and if not possible the use case is terminated. Should the validation be successful, the use case is resumed at step 6	
Denial of Patient Consent		
8	If patient consent is not given by the patient or it can not be recorded in country B, the use case is terminated.	
Patient consent can not be checked		
12	If country A can not check that patient consent has been given, a notification is sent to country B and the PS of country A is not provided. The use case is terminated	

[7] This point is subject to Legal aspects defined in WP2.1 and the different solutions to handle it are described in WP3.6. The Legal group will have to address the situations when the patient is a child, a person under guardianship or is unable to give his consent (eg: unconscious) and there is a risk for the patient´s health.
[8] The numbers under "Exceptions" refer to the 'steps' numbers in the 'Normal sequence' section of this table.
[9] This issue is to be addressed by the technical groups (eg: WP3.7 'Security Services')

Patient Summary does not exist in country A	
11	The HCP informs of this situation to the patient.. The use case is terminated.
Patient Summary can't be retrieved from NCP A	
11	The HCP informs of this failure to the patient. The solicitation to the PS might be requested again many times[9] and if not possible the use case is terminated. Should the validation be successful, the use case is resumed at step 12
The communication is broken somewhere during the process (steps A,B,C)	
	The HCP needs to be informed of the issue and the probable cause.
	The HCP informs of this issue to the patient. The process can be repeated again many times[9] and if not possible the use case is terminated. This issue has to be logged and reported

658 **Table 4. Use case 1&2 description: Patient summary occasional and regular visit**

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6 COMMON STRUCTURE OF PATIENT SUMMARY

This section contains the proposal agreed by WP3.2 on the epSOS LSP Patient Summary dataset. It has been defined according to the clinical point of view keeping in mind the medical perspective of the final user (expectations of the HCP) and the framework described in section 4 ('Context') of this deliverable.

Based on their degree of relevance in the PS service, the different dataset of information identified have been classified into two categories: 'Basic dataset' and 'Extended dataset' The agreed definition of the Basic dataset (or the 'Minimum dataset') and the 'Extended dataset' (or the Maximum dataset') has been described in section 4.1 of this document.

The data items should enable an unambiguous interpretation of their contents. All these fields are required to be filled using standards as much as possible. It has to be clearly stated that full codification structure of the PS must be accepted as a Project overall goal to be mandatory reached for a correct full functioning of the whole epSOS LSP system, but that an intermediate phase still relying on some free text will probably be unavoidable.

During the work carried out within WP3.2. a PS questionnaire was circulated among all countries. The objective was to find out the data items used in the different Member States within the PS. It focused on availability of the data item in that Member State and the 'mandatory' attribute of each data item, understanding by mandatory that this data field was needed by law or that was considered as minimum by that Member State. All the responses delivered by the Member States are kept in a separated document (internal working document, WP3_2_Questionnaire_Structure_PS_Results_v0_1.doc).

6.1 Minimum common structure of Patient Summary (Basic dataset)

The agreed basic dataset is a very fundamental dataset understood as a set of essential information required by the HCP to provide safe care to a patient in an unscheduled scenario. The agreed fields must be sent even if there is no content available, that is 'null flavor' is allowed (this concept will be explained in detail in WP 3.5).

The 'mandatory dataset' is a subgroup of the basic dataset which fields must be sent with a valid value, therefore the value must not be left as 'Null'. It is important to notice that for the 'mandatory dataset, .a value of 'Not specified' or a value of 'Not known' can be used only if

they are recognized as valid values for that field. (e.g: for 'gender' a value of 'Not Specified' may be used as a valid value by some systems, for example in the United Kingdom system). The following, is the agreed mandatory dataset (also depicted in Table 5):

- Identification: ID univocal. "Not specified" value is not allowed
- Given Name: "Not specified" value is not allowed
- Family name/surname: "Not specified" value is not allowed
- Date of birth: must be expressed as a date or just a year. The date must be a valid date. A code should be found for "not known" date (example: 9/9/9999 or 1/1/1900).
- Country: "Not specified" value is not allowed
- Date of Last Update of PS: It refers to the last version of the PS. It should be a valid date. "Not specified" value is not allowed. It was agreed that it will not be accepted a code for 'not known' date.
- Other fields will be or not included as mandatory pending decision by WP3.6 (Identity management) because in some countries these fields are needed for identification issues

6.2 Maximum common structure of Patient Summary (Extended dataset)

It is also an objective of WP3.2 to identify and agree on the maximum epSOS LSP PS dataset although, the exchange of this sets of information has a lower priority for the pilot that will be developed in epSOS LSP. Therefore, neither the fields, nor the values are compulsory to be sent.

In the following table, the structure of epSOS LSP PS is presented (Table 5) with the items that has been agreed by WP3.2 to be included in the Basic, the Mandatory and the Extended dataset according to the definitions provided above. The data elements are presented in structured data groups, each of them containing related items of information. They are shown taking into account that they are a defined set of key data without any architectural or data modelling consideration which is out of the scope of this document and will be handled by WP3.3. To understand the defined dataset,a column named 'comments' with the functional definition and examples of the items to be shared, has been included (to provide a human understandable description of the data model).

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).

728

729

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	Allergies and intolerancess	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
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
		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:	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**
			hepatic cystectomy (this wil be the 'Resolution Circumstances' for the problem 'hepatic cyst' and will be included in surgical procedures)		
	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
		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~~	~~Normalized identifier~~	~~Ext~~	~~No~~

[14] As there is subjectivity in the term 'relevant', the date will be used as the limit to include procedures.

PATIENT CLINICAL DATA					
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**COMMENTS**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**MANDATORY Yes/No**
		(code)			
	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
		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.	Ext	No

[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**
			Eg: 01/01/2010		
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
Author/Nature of the patient summary	Author of the patient summary	Author oof the patient summary	To highlight if the data is collected manually by an HCP or is collected automatically form different sources (eg: hospital doctor repository, GPs…etc) through predetermine clinical rules.	Basic	No
Legal entity	Responsible of the PS data	Responsible of the PS data	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

Table 5. epSOS LSP Patient Summary data set

The field “alerts” was originally defined to include all the important and objective medical information that should be highlighted (such as allergies, thrombosis risk, immune deficit …etc). When defining the content only allergies and intolerance to drugs appear to be the common understanding and the easiest to be transferred.

A lot of surveys are being made in different countries (not only in Europe) to make a more evidence-based definition of what should be inside and what shouldn’t in the concept “alerts” so, for at that first step, not enough information could be provided to take a further decision. On the other hand some people proposed that it could be considered more a way to present the information than a different field.

The final decision was to keep allergies and intolerance as the content of that field in that first step and to get the subject retaken in epSOS2 for a more complete solution if possible. The feeling was that the concept of alerts is a positive one to be defined in a PS but that no further content could be describe at this moment.

7 FUNCTIONAL RELATIONSHIP WITH E-PRESCRIPTION

During the work carried out in WP3.2 'Definition of functional requirements –Patient Summary' and WP3.1 'Definition of functional requirements –ePrescription', there has been a constant process of harmonisation between the ePrescription and the Patient Summary services to build a coherent and consistent service (the whole service, Patient Summary and ePrescription). This harmonisation has been performed from different perspectives:

- The requirements identified. Some requirements are common to both services (with the exception of the actors involved and the exchanged information), for example the security requirements, and some others are different as the specific objectives of the services are also different.

- The information shared and who access to it in the different scenarios.
    - The dependencies between the information exchanged in both services is analysed in the following table:

	Medication Summary data	**ePrescription data**	**Dispense medicine data**
Fields included			
Active ingredient	Yes	Yes	Yes
Active ingredient id code	Yes	No	No
Posology			
Number of units per intake,	Yes	Yes	No
Frequency of intakes	Yes	Yes	No
Duration of treatment	Yes	Yes	No
Strength	Yes	Yes	Yes
Date of onset of treatment	Yes	Yes (maximum)	No

Date of end of treatment	No	Yes (maximum)	No
Medicinal product package	No	Yes	Yes
Pharmaceutical dose form	No	Yes	Yes
Brand name	No	Yes (maximum)	Yes
Route of administration	No	Yes (maximum)	Yes (maximum)
Number of packages	No	Yes	Yes
Date of issue of the prescription	No	Yes	No
Instructions to patient	No	Yes (maximum)	No
Advise to the dispender	No	Yes (maximum)	No
Date of the dispense medicine event	No	No	Yes
Substitution	No	No	Yes (maximum)

Table 6. Dependencies between information exchanged

It is important to understand that the Medication Summary is not used for dispensing and it does not contain, as defined in chapter 6, the dispensed medicine information. The Medication Summary is not updated with the dispensed medicine information but with the finalisation of the treatment.

Who access to what information depends on the role of the health professional and on the country legislation. In some countries, the prescriber can access to all the fields contained in the Patient Summary. However in this same country, the information that the dispenser is allowed to access could be only the information contained in the Medication Summary. Access to other data in the PS is forbidden to the dispenser.

- The concepts. A common understanding of the terminology used and of the definition of concepts and the data elements to be exchanged has been achieved to assure the congruence of the whole service.

Concerning the tranfer of information from country B to country A, in the case of a HCP-B consulting the Patient Summary of country A, there is no return of information to country A as it is shown in Figure 2 (sequence diagram use case 1&2). But in the case of the ePrescription services and, in order to guarantee the security of the patient, there is a return of information to country A when dispensing medication in country B (country B must assure that country A has successfully received the information about the medicine(s) dispensed in country B before requesting again the 'available' prescriptions of that patient to country A). When this happens, the Medication Summary is not updated because the dispensed medication is not included in the Medication Summary.

8 ISSUES AND FUNCTIONAL RECOMMENDATIONS

As result of work carried out in this WP, a set of recommendations based on the functional requirements specification are delivered to other WP.

8.1 WP1.2, WP3.3, WP3.9, WP3.10 and PD4

Recommendations:

- Exceptions to the process, either functional (e.g. the HCP can´t retrieve the PS) or technical (e.g. communication problems with retrieving information from a country), have to be measured during the pilot phase and a procedure needs to be put in place in order to evaluate and solve these exceptions.

  In order to deal with the possible exceptions to the use cases, a structure (human and technical) to control the failures is needed. An information procedure regarding functioning of the service, duties, rights etc, is also needed directed to the potential patients and all the actors involved on the process. WP1.2 'Overall evaluation of the project', WP3.3 'System architecture', WP3.9 'Development of proof of concept system for pilot phase'. WP3.10 'Proof of concept testing' and PD4 'Field testing' should collaborate in this task.

8.1.1 Assistance services

The objective of the assistance services is to provide guidelines to epSOS LSP end users (HCPs) in case they need assistance or something goes wrong in the pilot phase during the use of the PS service. Possible errors may be:

- Wrong identification of a patient
- Errors in the display of the information

These assistance services should provide a way to facilitate the use of the services as well as to report possible problems that may appear during their use. In addition, these assistance services should provide recommendations to warn the HCP in case any technical problem appears.

The following assistance services are recommended:

1. Help Desk:
    - Contact Telephone to provide on-line support to HCPs.
    - Email address. An email address within the HCPO should be available to report errors, suggestions and complaints of the HCPs about the epSOS LSP services.

2. Frequently Asked Questions list (FAQ list):
   A FAQ list should be easily reachable within the HCPO that is providing the services locally and should include answers to possible misuse, known problems or limitations of the application/services. The following are some examples:
    - What countries can I access to use the epSOS LSP services?
    - Which services and where are available?
    - What is in the scope of the project?
    - What is out of the scope of the project?
    - How do I identify a patient?
    - Why information of a patient is not available? (to have into account possible restrictions because of legal issues or epSOS LSP requirements).

3. Warnings to the user.
   Information about possible problems should be provided to the user during the use of the application. These are some of those problems that could be automatically detected:
    - Communication problems
      A message should appear saying that information cannot be shown due to communication problems and that it should be tried later.
    - Technical problems (e.g. server not working)

A message should appear saying that information cannot be shown due to technical problems and that it should be tried later.

- Problems in the documents received.

  There might be problems in the information received because this is incomplete, doesn't fulfil the epSOS LSP requirements, etc (e.g. the information received is incomplete or doesn't fulfil the epSOS LSP requirements)

  A warning should be displayed saying that the 'information received is not complete'

8.2 WP2.1 'Analysis and comparison of legal and Regulatory Issues'

Issues

1. Patient consent: Grant Agreement for Pilot Type A - Annex I establishes unequivocally the need for patient consent as key regulating access by third parties. WP2.1 states that Patient Consent may be requested for access to health data by any trusted entity, anywhere, anytime within the epSOS LSP pilots trusted domains. But if this applies, which guarantees would have country A that the consent has been given by the patient in country B in order to allow access of PS to HCP of country B? The verification of the patient consent has to be defined from WP3.6 together with WP2.1. Another issue to be analysed by the Legal group is to address the situations when the patient is a child, a person under guardianship or is unable to give his consent (unconscious, handicapped) and there is a risk for the patient's health.
2. The 'Concepts paper epSOS LSP' states that the national regulations in the country of delivery (country B) apply to the episode of care. But, what happens when there is different legislation in the different countries about what information can be seen? If the national regulations in the country of care delivery apply to the episode of care, it can be in conflict with legal rights in some countries where for example a pharmacist can not access the PS of the patient. If this patient is in country B and the pharmacist is allowed to access the PS this will be against the acquired patient legal rights in country A.
3. The 'Concepts paper epSOS LSP' states that the patient´s right to hide information contained in his PS depends on country A legislation. Therefore, if the patient has decided to hide information of his PS in country A, such information will not be made available to HCP of country B. But, can this right be overruled in country B in emergency situations when there is a risk for the patient's life?
4. It has to be evaluated if it is legally correct that the PS of a patient, generated and kept safe by country A, can be directly imported in the Clinical Record of the ICT

system of country B. If the answer is 'yes' it has to be evaluated who holds the data ownership and the responsibility.

Recommendations:

- WP2.1 will need to make sure that countries are aware of all the possible legal situations identified in this deliverable to be faced during the piloting when signing the Framework Agreement.
- Establish a European framework to include and solve all these legal issues.
- When a patient is unable to give his consent (unconscious, handicapped) and there is a risk for the patient's health, patient consent should be overridden. Tracebility of accesses has to be assured.
- Health Care professionals participating in the epSOS LSP pilot should be informed (through the appropriate documents within the Framework agreement) about the PS service to be provided in the cross border scenario during the pilot phase of the project. This will include information such as there can be hidden information about the patient when using the epSOS LSP PS service.
- We recommend that the ability to hide information should be available to the patient from the point when the information is created and it should be exercised by the patient at any stage.

8.3 WP3.5 'Semantic Services'

Recommendations:

- Coding of information with currently available classification systems is strongly suggested to support semantic interoperability foreseen within the scope of epSOS LSP. Also, it is desirable, if the codification system allows it, to have the grading/staging of the diagnosis contained in the the field problems/diagnosis' (current problems and solved problems)
- The implementation of the whole Patient Summary system will have to address the need to code for each attribute included in the sections of the PS.
- The fields that are free text should be presented in the original language to avoid possible misunderstanding with automatic translations.

8.4 WP3.9 'Development of proof of concept system for pilot phase' and WP3.10 'Proof of concept testing'

Recommendations:

- WP3.2 recommends presenting the most important information of the PS preferably in the first screen and an appropriate level of nested screens should allow to easily reach for other less important information. The purpose is to deliver timely and secure Health Care.

9 EXAMPLE OF USE CASES: STORYBOARDS

This section illustrates by examples the use of the Patient Summary and how accessing to the Patient Summary would improve the Health Care assistance for cross border patients. It is a rather broad selection of medical topics trying to integrate the general scenarios of unplanned (unpredictable emergency, pre-existing disease, deterioration of known disease) and planned care (including commercial “cosmetic” care). Some of the storyboards include unconscious, uncooperative, minor, disabled, lying and deranged patients.

9.1 Classification of mobility

The Storyboards refers to different types of patients around Europe, who can be classified according to the following mobility categories:

1. Incidental (short) stay in a foreign country

This category includes people who are on the move for a vacation or on business trip (e.g: employees of multinational companies and international organizations such as the EC). The main characteristic of this type is that there is no medical information available in the local Health Care environment of country B..

2. People frequently crossing borders.

The reason for moving could be business (e.g.: migrant workers) or citizen mobility within border regions (e.g. in the Maas-Rhine Euregio between Belgium, the Netherlands and Germany). Contacts with Health Care Systems tend however to be limited to two or three Countries (e.g.: the one of residence and the one where the person works). Previous or historic medical data could be present in country B in this case. The possibility of a structural parallel build up of medical data could exist for this type of mobility.

3. Longer periods of stay in a foreign country

In this category, people move abroad for long periods of time. These are people that migrate for the season, e.g. wintering at the Mediterranean sea. One important characteristic is that these people return to country A, e.g. after 3 months. In this situation previous or historic medical data could also be present in country B. The medical data is built up in a serial way with the medical data build up in country A.

In all of these identified categories, it could also happen that the patient seeks Health Care in an emergency situation context.

The scenarios described above can be applied to the use cases defined in epSOS LSP (section 5.2):

-Use case 1: when the person is an occasional visitor in country B. For example someone on holiday (category 1) or attending a business meeting (category 1).

-Use case 2: when the person is a regular visitor to country B. For example migrant workers (category 2) or migrants for the season (category 3).

9.2 Examples of storyboards

In this section a list of storyboards is presented. The design of all cases follow the trail that something relevant can be retrieved from accessing the PS of the patient in country A.

The Storyboards are classified in one of the 3 categories stated in the precedent section.

9.2.1 Incidental (short) stay in a foreign country

Storyboard n°1

A 10 year old Italian girl falls of bicycle in Vienna and suffers some minor injury with bruises on both legs. It is in question whether tetanus protection is present. Her tutor is not sure about this.

Possible answer from PS: vaccination has been recent, no re-immunisation required.

Storyboard n°2

A 19 year old female from Scotland has an epileptic seizure in Barcelona and suffers from an apparent nose fracture. She is disoriented at admission into hospital. Routine exploration before X-ray of the skull reveals an early pregnancy. Being disoriented thereafter she cannot be questioned about this. In her pocket nurses discover a paper prescription for an antiepileptic drug (Valproat). Blood level of the drug is above the recommended therapeutic range. When recovering she reports about a recent change in medication, however cannot recall names and doses. Her pregnancy is a surprise to her, causing massive excitation.

Possible answer from PS: patient summary shows current medication, gradual replacement to new drug better suitable for pregnancy is started.

Storyboard n°3

A 72 year old male from Prague suffers from a large hemorrhagic stroke during a river Thames city cruise in London. He is accompanied by his wife, who reports about hypertension and heart disease with valve replacement about 5 year ago. Treatment with blood diluting agent (Warfarin) is reported by her, though her husband apparently has omitted recent laboratory controls. Though she is requesting maximum treatment neurosurgeons and anaesthetists are uncertain about a lung infiltration visible on X-ray and thorax- Computed Tomography. They suspect a lung cancer and are reluctant to operate.

Possible answer from PS: pulmonary infiltrate has already been reported for several years leading to assumption of older inactive tuberculosis.

Storyboard n°4

A 44 year old Sweden woman develops a urinary tract infection during her holidays in Greece. Though being uncomplicated she reports about an allergy against an antibiotic without recalling the name.

Possible answer from PS: a specific antibiotic (Sulphonamide) is not given.

Storyboard n°5

G.M is a 18 year old Italian boy. During a vacation in France he suffers from sore throat. When consulting a local GP he refers about intolerance to “some drugs” but cannot be more explicit since he left home his own Health Care documentation.

The local GP diagnoses an “acute bacterial tonsillitis”.

Possible answer from PS: consultation of PS shows that G.M. is affected by a “prolonged QT”, a rare congenital disease which contraindicates a list of drugs with potential negative effects on cardiac rhythm. Appropriate antibiotic is prescribed.

Storyboard n°6

F.L, a 72 year old Spanish man visiting England reports to the London Brompton Hospital’s emergency room with his wife. He tells a story about repeated fainting episodes. Unfortunately the couple, which appears to be very worried, shows only limited knowledge of English language and is able only to tell about cardiac problems with no further detail.

The emergency room doctors apply therefore to F.L. Patient Summary.

Possible answer from PS: F.L. Patient Summary reports a health history of hypertension and severe cardiac disrythmia which required a pacemaker implantation a few months before. A routine ECG made in the London Brompton Hospital´s emergency room shows

pacemaker malfunction. Happily enough the implanted pacemaker is similar to the ones used locally. Reprogramming of the pacemaker is subsequently performed. After a short observation period, the patient is discharged and advised to contact his own treating cardiologist as soon as back home.

Storyboard n°7

HPR, a German 66 year old retiree, is a known Insulin-Dependent Diabetes Mellitus patient. While on vacation in Italy a pickpocket stoles the purse in which HPR carries his antidiabetic medication.

HPR reports to a nearby hospital to seek for a new insulin prescription.

Possible answer from PS: the emergency room doctor looks in HPR's Patient Summary to get the appropriate insulin type and dosage and issues a prescription for the corresponding brand names available on the italian market.

Storyboard n°8

D.R. a 62 year old archaeology academic from Amsterdam is found disoriented and sweating in his hotel room in Paris where he was scheduled to deliver a lecture.

D.R. is admitted to a nearby hospital's emergency room.

Possible answer from PS: the consultation of DR's Patient Summary excludes previous major health problems. Blood glucose level is highly abnormal (530 mg/ml). Insulin treatment is started. After stabilization, D.R. is discharged from hospital and advised to report to his own GP as soon as back in Amsterdam for appropriate follow up.

9.2.2 People frequently crossing borders

Storyboard n°9

A 52 year old obese man from Germany suffers from severe immobilizing pain in the hip after trying to get up from the stairs in front of the Hofburg in Vienna. At hospital X-ray reveals a hip fracture (caput femoris). The physicians consider this to be an inadequate trauma, searching for potential reasons such as osteoporosis and bone metastasis. lumbar X-ray shows sign of osteoporosis and an older vertebral compression fracture. Exploration reveals nothing but an asthma bronchial controlled by inhalers.

Possible answer from PS: several episodes of prolonged corticoid treatment lead to diagnosis of corticoid induced osteoporosis.

Storyboard n°10

A 49 year old male is picked up by Danish police while walking without orientation on a rail track in Copenhagen. He is partly disoriented and cannot give conclusive answers how he got there. He provides working credentials of a company in Denmark and a living address in Hamburg (Germany). Examination and laboratory results reveal progressed liver disease and haematological disorder. He reports about a recent hospital treatment in Germany, but cannot give the name or address of the hospital in Hamburg.

Possible answer from PS: patient is a known alcoholic, receives Thiamine infusion rapidly.

9.2.3 Longer periods of stay in a foreign country

Storyboard n°11

A 55 year old chronic dialysis patient from Germany travels to Paris every year for a trimester. He would require several planned dialysis sessions during the 3 months stay. The details of the condition have been clarified with the receiving dialysis unit in Paris by the German physician prior to the travel. Due to an unexpected train strike in France the journey is however delayed in Lyon. Here his overall condition deteriorates, probably due to some dehydration and travel stress, and hospital treatment becomes necessary.

Possible answer from PS: yet uninformed physicians in Lyon receive information on condition and medication.

9.3 Conclusions

The precedent section illustrates the use of the Patient Summary as being an important document to support treatment of previously unknown patients in an unscheduled scenario. In most of the cases, it would be recommended that the patient would contact his HCP in country A in order to update its Patient Summary when finishing his stay abroad. This consideration leaves rooms to seek, in a future extension of present epSOS LSP Project, for methods to fulfil this task, somehow “closing the information loop” from country B to country A by IT means.

10 TERMINOLOGY

This section summarises the common terminology adopted in the epSOS LSP Project. The WP5.2.1 definitions have been used as a starting point. This section also includes terminology adopted within the WP3.2 in order to understand the description of the Use cases. That last line of each item represents the source from where the definition was derived.

10.1 Project name

Smart Open Services for European Patients-Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription. Project acronym: epSOS LSP

10.2 Medical terms.

Active Ingredient	Is defined as a substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. NOTE FOR GUIDANCE ON DATA ELEMENTS AND STANDARDS FOR DRUG DICTIONARIES (EMEA/CHMP/ICH/168535/2005)
Current problems/Diagnosis	Problems/diagnosis that fit under these conditions: conditions that may have a chronic or relapsing course, conditions for which the patient receives repeat medications and conditions that are persistent and serious contraindications for classes of medication epSOS LSP D3.2.2
Adverse Reaction	A response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function epSOS LSP D3.2.2
Alerts	Meaning any allergies, adverse reactions and alerts as part of the medical history of a patient epSOS LSP D3.2.2
Allergy agent	Agent (medicinal product, food, chemical agent etc) that is responsible for an adverse reaction epSOS LSP D3.2.2
Brand name	The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorisation holder. DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human
Closed Problems/diagnosis	Problems or diagnosis not included under the definition of 'Current problems or diagnosis. It's a synonymous of inactive

	problems/resolved problems epSOS LSP D3.2.2
Continuity of care	Component of patient care quality consisting of the degree to which the care needed by a patient is coordinated among practitioners and across organizations and time http://www.astm.org/Standards/E2369.htm
Current prescriptions	Any prescribed medication which period of time indicated for the treatment has not yet expired, whether they have been dispensed or not .This does not mean that is a valid prescription as the time to withdraw the medicine can have expired but the treatment is still on. epSOS LSP D3.1.2 and epSOS LSP D3.2.2
Dose form	Is defined as the physical manifestation [“entity”] that contains the active and/or inactive ingredients that deliver a dose of the medicinal product. The key defining characteristics of the Dose Form can be the state of matter, delivery method, release characteristics, and the administration site or route for which the product is formulated NOTE FOR GUIDANCE ON DATA ELEMENTS AND STANDARDS FOR DRUG DICTIONARIES (EMEA/CHMP/ICH/168535/2005)
Episode of care	An interval of care by a HCP for a specific medical problem or condition. It may be continuous or it may consist of a series of intervals marked by one or more brief separations from care, and can also identify the sequence of care (e.g., emergency, inpatient, outpatient), thus serving as one measure of Health Care provided. http://www.mondofacto.com/dictionary/medical.html
ePrescription	Means a prescription for medicines or treatments, provided in electronic format. [Term from D5.2.1, adapted]. epSOS LSP D.2.1.1
General practitioner	A general practitioner (GP) is a physician who provides primary care. A general practitioner treats acute and chronic illnesses and provides preventive care and health education for all ages and both sexes. http://www.medical-solutions.co.za/General_Practitioners.php
Health Care Professional	A doctor of medicine or a nurse responsible for general care or a dental practitioner or a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications or another professional exercising activities in the Health Care sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC epSOS LSP D5.2.1
Health Care Service Providers Organization.	An institution, authorized to provide Health Care services, unequivocally identified in the set of the Health Care Institutions epSOS LSP D3.2.2
Mandatory PS dataset	It is a subgroup of the ‘Minimum PS dataset’ in which the fields must have a valid value. If the values are not valid, the PS will be rejected. epSOS LSP D3.2.2
Maximum PS dataset	Desirable health information from the clinical point of view to be exchanged between the epSOS LSP countries. The fields contained within the maximum dataset are not compulsory to be sent. It is also

	called ‘Extended dataset’ epSOS LSP D3.2.2
Medical device	Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings. Devices are to be used for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease. alleviation of or compensation for an injury or handicap, investigation, replacement or modification of the anatomy or of a physiological process and for control of conception Directive 2007/47/EC
Medical Record:	Is a systematic documentation of a patient's medical history and care. The term 'Medical record' is used both for the physical folder for each individual patient and for the body of information which comprises the total of each patient's health history. Medical records are intensely personal documents and there are many ethical and legal issues surrounding them such as the degree of third-party access and appropriate storage and disposal. Although medical records are traditionally compiled and stored by Health Care providers (HCP) personal health records maintained by individual patients have become more popular in recent years. epSOS LSP D.2.1.1
Medication Summary	All prescribed medicine which period of time indicated for the treatment has not yet expired, whether they have been dispensed or not . It’s a synonymous of current medication. It contains the following information of each one: active ingredient, strength, posology (number of units per intake, frequency of intakes (per day/month or week) and duration of treatment) and onset date of treatment. epSOS LSP D3.2.2
Medicinal Product	(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.’ DIRECTIVE 2004/27/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human
Minimum PS dataset	It is defined as the agreed set of essential health information that is required from the clinical point of view to be sent to deliver safe care to the patient in country B. It may be sent with a value ‘null flavor’ if the source system of the country does not track that information. It is also called ‘Basic PS dataset’ epSOS LSP D3.2.2
Patient Summary	Should be understood to be a reduced set of patient’s data which would provide a health professional with essential information needed in case of unexpected or unscheduled care (e.g. emergency) and in case of planned care (e.g. citizen movement)

	epSOS LSP ANNEXI, D2.1.1 and D5.2.1
Pharmaceutical dose form	A Pharmaceutical Dose Form is the form in which a pharmaceutical product is presented in the medicinal product package as supplied by the marketing authorization holder/manufacturer/distributor (e.g. tablets, syrup) NOTE FOR GUIDANCE ON DATA ELEMENTS AND STANDARDS FOR DRUG DICTIONARIES (EMEA/CHMP/ICH/168535/2005)
Posology	Instruction on number of units per intake, frequency of intakes (per day/month or week) and duration of treatment Real Decreto 1910/84
Surgical procedure	A medical procedure involving an incision with instruments performed to repair damage or a disease in a living body www.wordreference.com/definition
Route of administration	Indicates the part of the body through or into which, or the way in which, the medicinal product is intended to be introduced. In some cases a medicinal product can be intended for more than one route and/or method of administration. NOTE FOR GUIDANCE ON DATA ELEMENTS AND STANDARDS FOR DRUG DICTIONARIES (EMEA/CHMP/ICH/168535/2005)
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. DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 6 NOVEMBER 2001 ON THE COMMUNITY CODE RELATING TO MEDICINAL PRODUCTS FOR HUMAN USE
Substance	Any matter irrespective of origin which may be: human, e.g. human blood and human blood products; animal, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products; vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts; chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis. DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 6 NOVEMBER 2001 ON THE COMMUNITY CODE RELATING TO MEDICINAL PRODUCTS FOR HUMAN USE

10.3 Technical and other Terms

Access	The ability to obtain certain services (Health Care, electronic services: patient summary, electronic prescription), as determined by factors such as the availability and affordability of goods and services. epSOS LSP D3.2.2
Attribute based	An attributable role-based access that controls and limits the user access

access	to the defined services based on his/her role/profile. epSOS LSP D3.2.2
Authentication	Process to verify the claimed identity before authorising a particular action to be performed.
Authorization	Process by which entitlement of a requester, to access or use a given service, is determined. epSOS LSP ANNEXI
Comprehensible	Attribute of a variable that makes it understandable to the user
Country A	Is the Member State of affiliation i.e., the state where the mobile patient is insured. This is the country where the patient can be unequivocally identified and his data may be accessed. To each patient one country is attributed as "country A [Term from D5.2.1, adapted]. epSOS LSP D.2.1.1
Country B	Is the Member State of treatment i.e., where cross-border Health Care is actually provided when the patient is seeking care abroad. This is a country, different from country A, in which information about a patient is needed in case the patient needs Health Care [Term from D5.2.1, adapted]. epSOS LSP D.2.1.1
Cross border service	Services provided in a country different from country A (e.g. Health Care services) epSOS LSP ANNEXI
Demographics	Sufficient data to characterize a person like for example: name, date of birth, gender.. epSOS LSP D3.2.2
Electronic Health Record	A comprehensive, structured set of clinical, demographic, environmental and social data information in electronic form, documenting the Health Care given to a single individual. http://www.astm.org/
European Patients – Smart Open Services	Smart Open Services for European Patients - Open eHealth initiative for a European large scale pilot of patient summary and electronic prescription epSOS LSP D5.2.1
Functional Requirement	Defines a function of a software system or its component. A function is described as a set of inputs, the behavior, and outputs http://en.wikipedia.org/wiki/Functional_requirements
Identification	Assignment of a unique number or string to an entity within a registration procedure which unambiguously identifies the entity. This number or string serves thereafter as an identifier uniquely attached to this entity. i2-Health_D3.1_1.0
National Contact Point (definition needs to be revised in technical WPs)	Single node where a set of functionalities and services is provided at national level for the proper working of the epSOS LSP platform D3.2.1

Non functional Requirement	Requirement that specify criteria that can be used to judge the operation of a system, rather than specific behaviours. http://en.wikipedia.org/wiki/Non-functional_requirement
Point of Care	is any natural or legal person or any other subject having legal capacity that relies on the usage of personal health related data in order to fulfill tasks or business purposes notwithstanding whether those tasks have been delegated by law or not. epSOS LSP D.2.1.1
Project place	Electronic space for the editorial and management of epSOS LSP project
Reliability	Ability to provide security on the veracity of the information provided. http://thesaurus.reference.com
Use Case	Is a methodology used in systems analysis to identify, organize and describe system requirements involved in Health Care scenarios. Contains all system activities that has significance to the user. www.businessanalysisbooks.com

11 GLOSSARY

D1.1.1	Report on Opportunities and constraints of Participating MS architectures
D3.2.1	Draft definition of functional service requirements- Patient Summary
D3.2.2	Final definition of functional service requirements- Patient Summary
D3.1.1	Draft definition of functional service requirements- ePrescription
D3.1.2	Final definition of functional service requirements- ePrescription
EC	European Commission: http://ec.europa.eu/index.htm
her	Electronic Health Record
eP	Electronic Prescription
epSOS LSP	European Patients – Smart Open Services
EU	European Union (Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark,, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom)
F.A.Q	Frequently Asked Questions
FR	Functional Requirement
GP	General practitioner
HCP	Health Care Professional
HCPO	Health Care Professional Organization
HCP-A	Health Care Professional of country A
HCP-B	Health Care Professional of country B
ICT	Information and Communication Technologies
ID	Identity
IHE	Integrating the Health Care Enterprise - Europe
IT	Information Technologies
L&R	Legal and regulatory
LSP	Large Scale Pilot
MS	(EU) Member State
NCP	National Contact Point
NCP-A	National Contact Point of country A
NCP-B	National Contact Point of country B
NFR	Non functional requirement
No	Number
PC	Project coordinator
PD3	Project Domain 3
PD4	Project Domain 4
PEB	Project Executive Board

PM	Person month
PoC	Point of Care
PP	Project Place
PS	Patient Summary
PSB	Project Steering Board
TelCon	Conference call
ToC	Table of contents
UC	Use case
WG	Working group
WP	Work package
WPL	Work package leader
WT	Work task
XML	Extended Mark-up Language

12 LIST OF FIGURES

13 LIST OF TABLES

14 Annex A: Analysis beyond the current epSOS LSP scope

In order to prepare effectively for a possible epSOS LSP next phase, this section describes further functionalities beyond the current spSOS scope that were analysed within WP3.2 with the purpose of a future scalability of the epSOS LSP solution. The aim is to profit from existing favourable cross border regional environments and present, with information purposes, possible enhancements to allow beneficiaries to implement additional functionalities on a voluntary basis and among their MSs in order to learn and prepare effectively for a possible epSOS LSP future extension.

These are the two additional functionalities described: the approach 'Multiple Patient Summaries' and a new use case: access of the patient to his Patient Summaries located in some countries different from country A .

14.1 Approach 'Multiple Patient Summaries'

As stated in section 4.2, use cases and functional requirements in this deliverable has been described considering that the HCP-B accesses only to PS of country A in order to obtain the needed medical information to deliver safe care to a patient seeking for Health Care in country B in an unscheduled situation. This means that, if the patient has a PS in any other country different from country A, the HCP-B will not have access to it, therefore losing potentially medical information that could be important to know and maybe not included in the PS of country A (it cannot be assured that PS of country A contains the most updated information for that patient). Moreover, as it is out of scope of epSOS LSP to transfer clinical information from country B to country A, the medical information generated for that patient in any Country different from country A cannot be consulted in the epSOS LSP scenario.

The approach 'Multiple Patient Summaries' implies that the HCP-B get access to the existing Patient Summaries for that patient in the different MSs. The HCP-B can then select and ask for any of them that will be presented to him with the common structure epSOS LSP PS. With this option of Multiple PSs, the user interfaces have to handle the possibility of the existence of multiple PS and the presentation of the information about these PSs. This list should be presented to the HCP-B with the necessary information to select the required PS (e.g. country of origin of the PS, HCPO, date of the last update). Nevertheless the existence of a large number of PSs for the same patient should be the exception.

14.1.1 Additional Functional Requirements required

The implementation of the UCs with the approach 'Multiple Patient Summaries' requires the following additional Functional Requirements (besides the requirements describes in section 5.3)

Functional Requirement A01: Patient Summaries available

Requirement FR-A01	Patient Summaries available
Description	The HCP-B needs to access the list of the existing Patient Summaries of the patient.
Associated Goals	• PS must be available to be requested by HCP of any other country. After the identification of the patient who request Health Care, in country B, HCP of country B requests through a simple action (just a click) the visualization of the complete list of existing PSs for this patient. • HCP to be able to identify the last updated PS. The HCP must be aware when a new PS about a patient has been generated. • NCP-B asks NCP-A for the list of available PSs, and this list is sent and presented to the requesting HCP including, for each PS, the date of last update.
Actors	• HCP-B • NCP-A • NCP- B

Functional Requirement A02: Data presentation

Requirement FR-A02	Data presentation
Description	The HCP should be able to see at a glance the different PSs that patient has and the necessary information to select the required PS. One of the possible ways of presenting the list of the existing PSs is in a table format where each row corresponds to a PS in a country for the identified patient. Therefore, there will be as many rows as existing PSs for that patient. The information that the HCP visualizes and utilizes for selecting the appropriate PS must be: country of origin of the PS, HCPO and date of the last update.
Associated Goals	• To provide the HCP/patient with sufficient and key information that enables them to select, among the existing PSs for that patient, the required PS in a simple and comprehensible way and with the minimum actions.
Actors	• HCP-B • NCP-A • NCP- B

Functional Requirement A03: Updated Information notification sent to country A

Requirement FR-A03	Updated Information notification sent to country A
Description	Country B will just send to country A a notification that a new generation/update of PS has been done in country B (but will not send medical information). It is left to country A what to do with that information.
Associated Goals	• To assure that the HCP who did the consultation is aware of all the PSs available and last updates.
Actors	• NCP-A • NCP-B

1169

1170 ### 14.1.2 Relationship between use cases and requirements

1171 Four major actions are identified for the description of the use cases:
1172

UC 1&2 Action list
A: Check Patient ID
B: Verify patient consent
C: Consult 'available' Patient Summaries
D: Updated Information notification

1173
1174 The two UCs are analysed with the approach 'Multiple Patient Summaries' in the
1175 following sequence diagram and table description.
1176

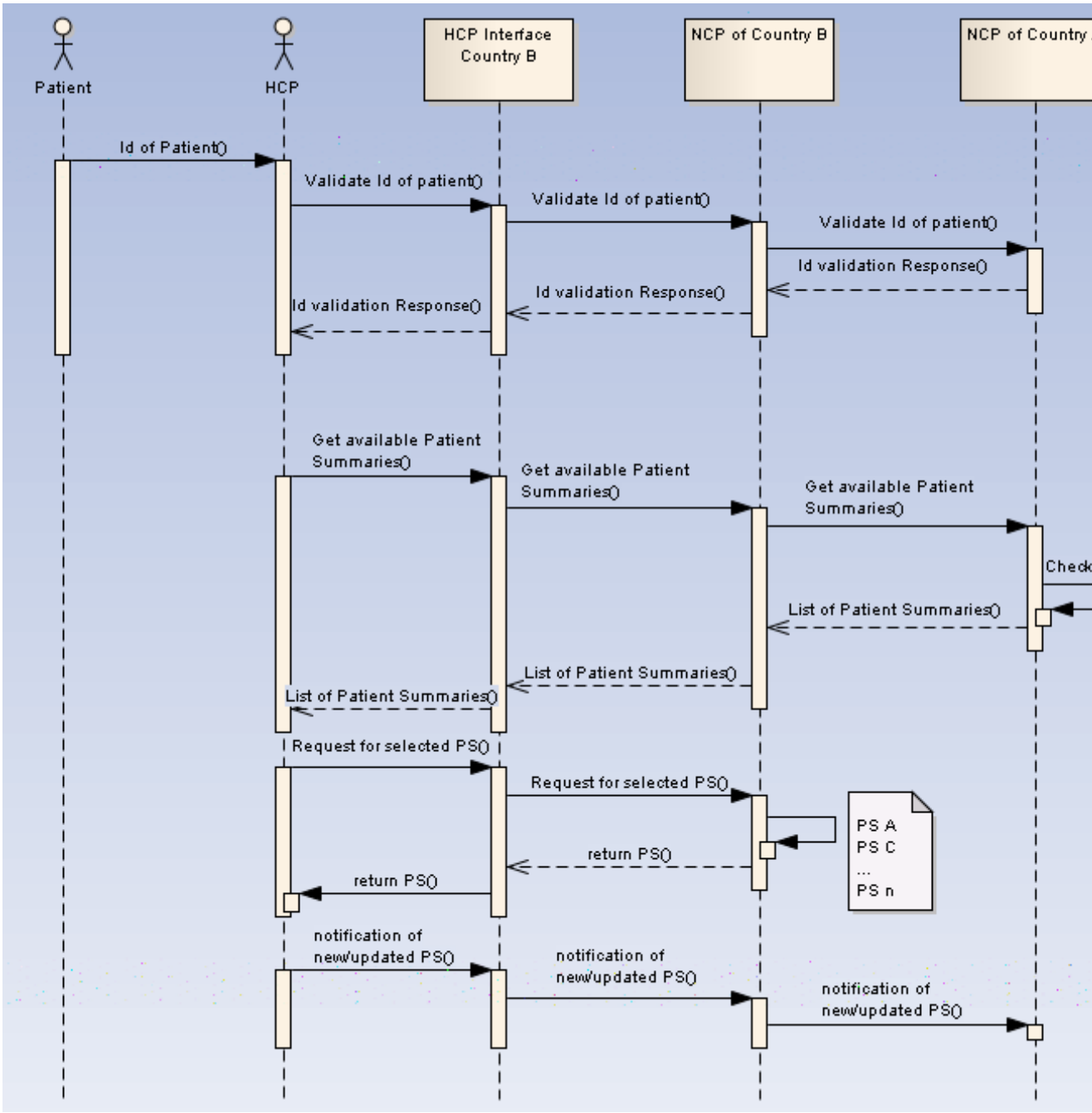

Figure A1. Sequence diagram Use Case 1&2 with the ´Multiple PSs' approach

UC 1&2	**Patient summary occasional and regular visit**
Goal	The goal of UC 1&2 is to allow the HCP of country B to consult the Patient Summary/Patient Summaries of country A of the patient seeking for Health Care either in occasional or in regular visit
Functional Requirements to be fulfilled by country A	FR02: Trust between countries FR03: Patient identification FR04: Patient consent to access data FR05: Structured Information FR06: Equivalent information FR19: Patient summary of country A available

	FR20: Information Traceability FRA01: Patient Summaries available FRA02: Data presentation	
Functional Requirements to be fulfilled by country B	FR01: HCP Identification & authentication FR02: Trust between countries FR03- Patient identification FR04: Patient consent to access data FR05: Structured Information FR06: Equivalent information FR07: Information Understandable FR20: Information Traceability FRA03: Updated Information notification sent to country A	
Actors	**Human and institutional actors**	**Technical actors**
	• Patient • HCP • HCPO	• NCP B • NCP A
Preconditions or requirements	1. Patient request for medical assistance in country B to a HCP 2. PS in a Country different from country B 3. The HCP is a person legally authorised in country B to provide Health Care and is identified and authenticated in country B[16] (FR01) 4. A mechanism to validate the identity of the patient and to handle patient consent against country A has to be available at the Point of Care 5. HCP of country B knows the identity of country A 6. The Health Care Professional must be related to at least one HCPO or to a Health Authority. 7. Country B must provide, maintain and support a NCP supporting communication of information with country A and viceversa (FR20) 8. There is a chain of trust between system actors in this process (FR02) 9. The HCP must be able to access the “communication layout” that handles the PS in the European Countries 10. All technical actors involved in the process must be able to retrieve all the information describing the process and the data involved in it (such as the identification of the HCP, the identification of the patient, the information contained in the PS…), all this information must be able to be traced and recovered (FR20)	
Post conditions	The HCP-B gets access to the PSs of the patient at the point of care The information exchanged must be understandable in both countries involved resolving semantic differences such as medication names and clinical terminologies. Syntactical interoperability and record of the access must be done.	

Normal sequence

Step	**Actions (or description)**	
	A: Check Patient ID	**FRs fulfilled: FR 03**
1.	A patient from country A visits a HCP in country B seeking for Health Care assistance	
2.	Patient is identified	
3.	The HCP requests the validation of the identity of the patient through the HCP interface	

[16] It is important to emphasize that there might be different definitions of roles/attributes of the end user in each Country (e.g.: patient, physician, pharmacist) which is based on national law. This means that the rights for accessing the information based on the profile of the HCP could be different in each Country

4.	The HCP interface conveys this request to the NCP of country B	
5.	The NCP of country B conveys this request to the NCP of country A	
6.	The NCP of country A checks ID and provides to the NCP of country B the (positive or negative) patient's identification confirmation.	
7.	The NCP of country B provides the patient's identity confirmation to the HCP interface	
	B: Patient consent (per request)	**FRs fulfilled: FR 04**
8.	Once the identity of the patient is validated, the patient consent is verified[17]	
	C: Consult 'Available' PSs	**FRs fulfilled: FR 05, 06, 07, 19, A01, A02**
9.	Once the identity of the patient is validated, the HCP of country B requests, with the consent of the patient (FR04), the list of available PSs (for that patient) that can be visualized by HCP interface	
10.	The HCP interface requests the list of available PSs to the NCP of country B	
11.	The NCP of country B requests the list of available PSs to the NCP of country A	
12.	The NCP of country A, after checking if patient consent has been provided, gets and provides to the NCP of country B the list of available PSs on the epSOS LSP format.	
13.	The NCP of country B conveys the the list of available PSs to HCP interface	
14.	The HCP selects a PS from the provided list. The HCP asks to the NCP of country B for the selected PS (a PS either from country A or from a Country different than country A)	
15.	The NCP of country B requests for the selected PS.	
16.	The NCP of country B conveys the selected PS to HCP interface	
17.	The HCP accesses to the Patient Summary he has selected. Afterwards, if he needs to consult any other PS of the available PSs, the process restarts at step 10	
18.	**D: Updated Information notification**	**FRs fulfilled: FR A03**
19.	If a PS is created and/or updated in country B (it is left to the country decision to do so), the NCP of country B conveys the notification of this information to the NCP of country A	
20.	The use case is terminated	
Exceptions[18]		
The identity of the patient cannot be properly validated in country A		
6	The NCP of country A informs the NCP of country B of the identification failure	
7	The NCP of country B informs the HCP interface of the identification failure	
8	The HCP informs of this failure to the patient. The validation of the identification might be requested again many times[19] and if not possible, the use case is terminated. Should the validation be successful, the use case is resumed at step 6	
Denial of Patient consent		
8	If patient consent is not given by the patient or it can not be recorded in country B, the use case is terminated	
Patient consent can not be checked		

[17] This point is subject to Legal aspects defined in WP2.1 and the different solutions to handle it are described in WP3.6. The Legal group will have to address the situations when the patient is a child, a person under guardianship or is unable to give his consent (eg: unconscious) and there is a risk for the patient´s health.
[18] The numbers under "Exceptions" refer to the 'steps' numbers in the 'Normal sequence' section of this table.
[19] This issue is to be addressed by the technical groups (eg: WP3.7 'Security Services')

	If country A can not check that patient consent has been given, a notification is sent to country B and the list of available PSs is not provided. The use case is terminated
Patient Summaries do not exist	
11	The HCP informs of this situation to the patient. The use case is terminated.
Patient Summaries can not be retrieved from NCP	
11	The HCP informs of this failure to the patient. The solicitation to the PS might be requested again many times[19] and, if not possible, the use case is terminated. Should the validation be successful, the use case is resumed at step 12
The communication is broken somewhere during the process (steps A,B,C,D)	
	The HCP needs to be informed of the issue and the probable cause.
	The HCP informs of this issue to the patient. The process can be repeated again many times[19] and if not possible, the use case is terminated. This issue has to be logged and reported

Table A1. Use case 1&2 description with the ´Multiple PSs' approach

14.1.3 Pros and cons

The pros and cons of the approach 'Multiple Patient Summaries' are analysed in Table A2 and Table A3.

Pros of 'Multiple PSs' approach
HCP-B get access to consult the information contained in all the existing PSs for that patient
HCP-B get access to the most updated and relevant information as he has access to all the existing PSs for that patient

Table A2. 'Multiple PSs' approach pros

Cons of 'Multiple PSs' approach
HCP-B needs more time to access the proper information for each encounter turn into a collection of PS from different countries (list of existing PSs)
Complex legal situations, negotiating the laws of the different countries during the access to the PS.

Table A3. 'Multiple PSs' approach cons

14.2 Use case 3: access of the patient to his existing Patient Summaries

The Use Case 3 deals with the possibility given to a patient to access to his PS/PSs generated and kept in other Countries (different from country A) without the presence of a HCP. This UC must be understood as an access for the patient to visualize his PSs being

out of scope of this UC that the patient records data and any other transaction except the record of all the accesses done to his PSs.

The reasons for the inclusion of this UC in a possible future expansion of epSOS LSP are based on these antecedents:

- This UC was not included in Grant Agreement for Pilot Type A - Annex I but it states that the overarching goal of this project is focused in the needs and wishes of citizens.
- The epSOS LSP Initial Scope document left open the possibility of introducing this UC
- From the results in D1.1.1 ('Report on Opportunities and constraints of Participating MS architectures v1.0.pdf') all Member States but one include this service for its citizens within its Countries. The MS not including it does not allow by law the patient direct access to his PS information.
- The experts WP3.2 meeting held in Prague on February 17th 2009 supported the inclusion of this UC in epSOS LSP

14.2.1 Additional Functional Requirements required

For the implementation of this UC, an additional Functional Requirements is needed: Patient authentication/authorization.

Functional Requirement A04: Patient Authentication/Authorization

Requirement FR-A04	Patient Authentication/Authorization
Description	The patient must be unequivocally authenticated to allow the access to his/her available Patient Summaries in every country
Associated Goals	• To provide security to the process • To ensure that the patient is allowed to see in every country the information about his/her Patient Summaries • Prevention of disclosure to unauthorized persons
Actors	• Patient • NCP-A • NCP-B

14.2.2 Functional steps of Use Case 3

The functional steps of UC3 are depicted in the following figure:

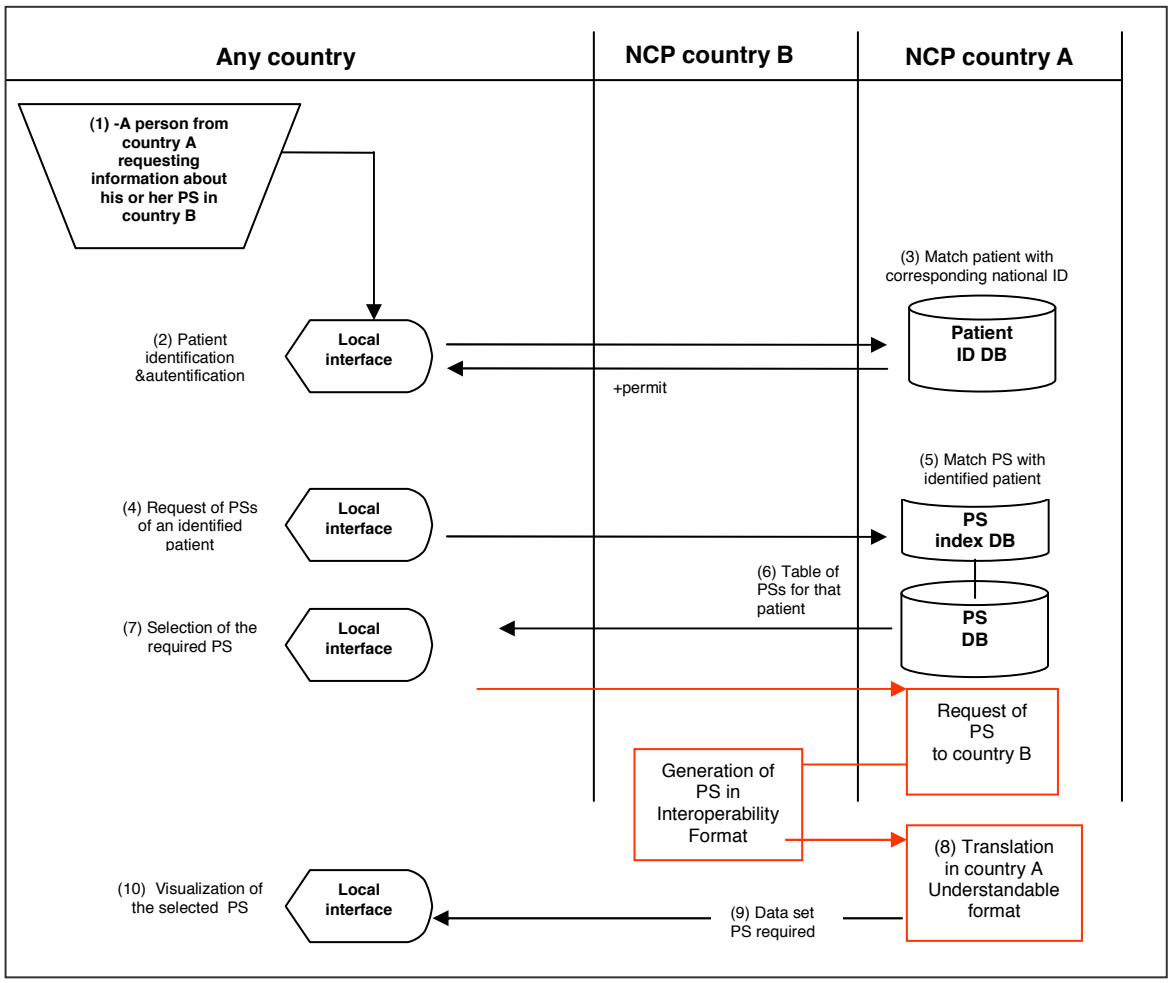

Figure A2. Functional steps of Use Case 3

The steps reported in Figure A2 are as follows:

1. Through a secure web service via NCP of country A, an European citizen (from country A) requests information about his or her PSs in country B
2. The patient asks to be identified and authenticated in country A
3. The patient is identified and authenticated by a national identification service in country A
4. The patient requests the list of his/her available PSs
5. NCP of country A retrieves the existing PSs for the identified patient.
6. The NCP from country A presents to the identified patient the list of his/her PSs.
7. The patient selects the PS to consult through the NCP from country A
8. Translation of the select PS in country A understandable format
9. The NCP A requests the data set of the PS to the NCP of the country that holds the selected PS
10. The patient visualizes through the NCP of country A, the data of the selected PS

14.2.3 Pros and cons

1241 The pros and cons of this UC are analysed in Table A4 and Table A5 The main limitation
1242 of UC 3 is that it implies difficulties from the technical and from the legal point of view
1243 (see table A5).

1244

Pros of Use case 3
The main “pro” for this use case is the empowerment of the patient who is in control of access to his medical information.
Although the added value from the Quality of Care point of view is much higher in UC1&2, it is a right of the patient in most of the MSs to direct access to his medical information.
It is considered as a good practice recommended by different organizations
epSOS LSP cross-border Interoperability services are used

1245 **Table A4. Use Case 3: pros**

1246

Cons of Use case 3
Data protection: how can we determine that the patient is who he says he is (authentication)?
Does patient’s Authentication provides the same level of trust and security of HCP’s Authentication?
How can we ensure the security of the application?
How can we ensure that the patient is able to interpret correctly the information held on their summary?
Country A law authorise a direct access of the patient to his clinical data. According to D1.1.1, only one MS does not allow by law the patient direct access to his PS info
Legal issue: NCP-B should reply to a request coming from a patient. What about if country B does not allow by law patients’ direct access?. The situation could be solved with the Contract.
Legal issue: it might happen that country A does not allow direct access to PS and country A citizen, while in B, requests and gets a country A PS. The situation could be solved with the Contract.
The translation of the PS from another country to the language of the patient has to be managed.

1247 **Table A5. Use Case 3: cons**

1248

1249 # 15 Annex B: Referring documents

Date	Type	Description	Version	Origin	Document
2008-06-30	Final	This document is a contractual agreement between	June 24th 2008	EMP/S.O.S. LSP-eHealth team. Grant	Annex I – “Description of Work”

		the different participants in the project.		Agreement for Pilot Type A - Annex I	
2009-01-28	Final	Document defining the scope of the epSOS LSP at a high level	1.0	epSOS LSP WP5.1	epSOS LSP_ Initial Scope definition
2009-06-01	Final	Report on Opportunities and constraints of Participating MS architectures	1.0	WP1.1: Analysis and comparison of national plans/solutions	D1.1.1 Report on Opportunities and constraints of Participating MS architectures
2009-06-11	Draft	This document is a 'life' document which describes the already approved concepts in epSOS LSP and is to be approved by PEB	0.11	Concepts paper epSOS LSP	The epSOS LSP Trusted Domain(s): CONSOLIDATION OF CONCEPTS
2009-08-20	Final	Final version of D3.2.1 after Quality Review	0.71	epSOS LSP WP3.2	D3.2.1 Draft definition of functional service requirements-PS
2009-02-20	Internal work document	Questionary for the content of the national PS. It collects input from all MSs about availability of the data elements	0.4	epSOS LSP WP3.2	WP3.2_Questionnaire_Structure_PS
2009-02-07	Internal work document	It describes the project plan, methodology, different working groups and tasks descrption	0.6	epSOS LSP WP3.2	Draft_3.2_project_plan (available in PP)
2009-03-04	Internal work document	It describes the action points, next milestones, meetings and it is constantly updated.	0.3	epSOS LSP WP3.2	ActionPoints_Meetings_WP3.2.xls (available in PP)

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