Smart Open Services for European Patients

Open eHealth initiative for a European large scale pilot of Patient's summary and electronic prescription

D1.4.3 EED SERVICES including specifications for all services

Specification of the services.

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ABSTRACT

The document describes services for the following use cases:

- **extension of the epSOS Core Services - Patient Summary and ePrescription**
- **Additional Service EHIC to illustrate how to improve coordination between epSOS core services and health administration processes**
- **Additional Service 112 Emergency**
- **Additional Service Access for Patients**

History of Alteration				
Version	**Date**	**Status Changes**	**From**	**Review**
V 0.1	2011-11-17	Draft	NCZI and other organisations	TPM
V 0.2	2012-01-05	Draft	NCZI and other organisations	NEPC and C/S TFG
V 0.3	2012-02-11	Consolidated Document for Quality Assurance	NCZI and other organisations	Quality Assurance
V 0.9	2012-02-21	Consolidated Document after Quality Assurance	NCZI and other organisations	TPML
V 1.0	2012-09-11	Final after terminology harmonization	TPML, THL	

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TABLE OF CONTENTS

1 Introduction

Description of Work (DoW) for epSOS phase 2 defined the following services:

- Extension of Patient summary use cases,
- Extension of ePrescription use cases,
- Additional service - EHIC related use cases,
- Additional services - 112 Emergency use case,
- Additional services - Patient Access use cases.

The document **D1.4.1 EED SERVICES including use cases for all services - Use case description** (Appendix 6) has defined sets of use cases for above listed services. During the TPM meeting in Copenhagen (1-st September, 2011) TPM concluded principles on which the **decision on scope of specification work** has to be done.

- No intrusion into national eHealth systems but opportunity to influence national transpositions of the Directive 2011/24/EU.
- epSOS is not aiming at a federated pan-European database.
- epSOS is aiming to support each PN retaining its own responsibility for eHealth.
- In principle each PN has responsibilities under the Directive 2011/24/EU as a country of affiliation with respect to its own citizens, therefore within epSOS the decision is that:
  - epSOS access to patient's data is only possible through the country of affiliation.
  - the countries piloting the new use cases must provide means to transfer epSOS encoded medical information about the patient to the country of affiliation. This does not imply any legal consequences

Applying those principles and considering analysis of the UCs by WP2.1, WP3.A, WP1.4 and lessons learnt in epSOS phase 1, the scope of service specification work was detailed and use-cases appropriate to be further specified by KTS 1.4.6/7/8/9 were selected by all TPM.

- UC.PS.4 "Patient information will be made available by country B to country A".
- UC.MED.2 "medicine newly prescribed in country B" will be an extension to the eP service.
- UC.MED.1 "Role specific access to medication related overview" (UC.MED.2 is prerequisite – medication related overview of the patient will be available to the prescriber).
- UC.EHIC will be analysed in a service specification with a recommendation for the future.
- UC.112 will be covered by one service specification incl. data set and supporting processes.
- UC.PAC.1 "Patient Access to country A information in country B language"

Use case UC.EHIC will proceed for further processing but the result will not be in the form of specification but will end in the form of recommendation concerning possible future application.

Short description of use cases selected for further specification

UC.PS.4 - patient information will be made available by country B to country A

This use case represents the situation where one single patient summary, in country A, is always kept up-to-date, and, therefore integrates the updates sent from health professionals from country B. Based on this information, the patient summary in country A can be updated according to its own policies.

UC.MED.2 – medicine newly prescribed in country "B" will be an extension to the eP service

This implicates two extensions to the epSOS phase 1 use case

- Make the medication related overview from country A available to the prescriber and dispenser in country B, for the purpose of patient safety. This cannot be a unique solution: through epSOS the information should be made available to health professionals in country B that the country A considers appropriate for the safety of its patients. Note that the medication related overview is a technical subset of the patient summary (although a stripped patient summary is not the same as a medication related overview) from country A. This shall not lead to inconsistencies.
- Fully implement the transcoding/translation and feed-back of prescribed medication information to country A for inclusion into the history (via the Healthcare Encounter Report service)

UC.MED.1 – Role specific access to medication related overview (UC.MED.2 is prerequisite)

This implicates one extension to the epSOS phase 1 use case

- Fully implement the transcoding/translation and feed-back of prescribed or dispensed medication to country A (the epSOS1 eDispense service) for inclusion into the medication history.
- Make the medication related overview from country A available to the health professional in country B, for the purpose of patient safety.

UC.112 will be covered by one service specification incl. data set and supporting processes

UC 112 will be new service based on cross-border provision of patient data in the Emergency 112 environment. It comes from the typical case where a citizen of the Country A needs urgent medical care in the Country B.

The use-case deliverable analyses every possible alternative of cross-border scenarios assuming cooperation of 112 emergency services of participating nations. Nevertheless there will be in the end one UC 112 including service specification, data set definition and presentation of requirements for supporting processes. For the correct definition of this service extensive work in the semantic services must take place.

UC.PAC.1 Patient Access to country A information in country B language

The use case for patient access is dependent on electronic patient access to a Patient Summary or ePrescription in the patient's country of affiliation (country A). The epSOS Patient Access service provides a translation of the coded elements in the documents to be accessed. This use case serves two principal needs: A) a patient in Country A, who is not fluent in the language of the PS/eP, needs Language B access to his/her own clinical documents, and B) the patient wishes to consult someone in Language B on the basis of his/her PS or eP, for instance during an encounter with a Health Professional in Country B. Both needs are widespread, and the potential demand for this Use Case service is high.

UC.EHIC

EHIC use case KT investigated possibilities for including functions concerning patient identification and healthcare entitlement verification, using EHIC cards and being based on the EU social security coordination system, into epSOS project pilot.

Initial assessment of this problem presented by the Key Task Leader and discussed on the TPM level concluded with the decision not to implement EHIC use cases within the scope of epSOS phase 2. The main reason for this is that on the one hand it is not feasible to repeat the work done or being done in the other EU projects (EESSI, NETCARDS), and on the other hand there are still no sustainable outcomes of these projects that could be reused as the parts of epSOS solution.

1.1 Background

1.1.1 epSOS Scope and Out of Scope

The epSOS project is based on following basic principles:

- epSOS will enable the participating nations to integrate their national solutions and validate them for Cross-border interoperability of eP and PS
- epSOS LSP services must be based on a Legal and Regulatory framework which includes the signature of contractual agreements among the Participating Nations to commit to their legal responsibilities and to assure the adequate level of trust.
- epSOS will not intrude national eHealth systems.
- epSOS will neither create a federated pan-European database nor any EU-level records or documents.
- epSOS will support each PN retaining its own responsibility for eHealth.
- epSOS will develop a sustainable solution which will be beneficial in the long term.

Already at the beginning of the project definition and development, several clear and important conclusions concerning what is out of epSOS scope were approved. You can find them in [2], [3][1]. We summarize them briefly here in following items:

- It is out of scope to provide the HP with all the health information related to that patient (e.g.: complete electronic patient record, all health encounters, all laboratory tests, all X-rays reports etc.). Also other potential uses of the PS information (e.g.: public health, epidemiology, health management, etc.) is in epSOS project out of scope.
- It is out of scope to analyse the methodology that each Member State envisions to produce a valid PS and to analyse the consequences of the different methodological approaches (automated extraction of the PS, direct human intervention of a HP etc.) or their possible impact on the reliability of the information.
- It is out of scope to analyse the individual medical processes within each Participating Nation, e.g. the way the HP perform their work, the way a HP is identified and authorized etc.
- All the countries are integrated on one circle of trust (functional and technical) with respect to quality and reliability of the information exchanged between countries.

As improvement of epSOS phase 1 it is **NOT** out of scope of epSOS phase 2 to transfer clinical information from country B (country in which information about a patient is present 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'). More details of this possibility you will find in the Appendix A1, describing Health Care Encounter Report.

1.1.2 WP 1.4 Methodologies Followed

The goal of epSOS specification described in this document is to define functional service requirements for use cases which were selected on the basis of use case evaluation described in D 1.4.1 – use cases description [1]. The process to fulfil this goal was based on analysing use case definition and evolving described functions into specification requirements.

[1] [X] is a reference to a document. Documents are listed in Annex 9.1

In the process of specification requirement description, the following stages were carried out. For selected use case the assessment of PNs readiness to implement the service was analysed. Afterwards service pre-requisites were identified and the service state diagram outlined. In next steps the service process was analysed and step by step further requirements were identified - functional and non-functional requirements, ID management requirements, legal requirements, security requirements, clinical requirements, semantic requirements, service usability and data presentation requirements. At the end the additional architecture NCP and central service requirements were identified.

1.2 Scope of the Document

1.2.1 Goals

The general goal of epSOS remains “to develop a practical eHealth framework and ICT infrastructure that will enable secure access to patient health information, particularly with respect to a basic Patient Summary and ePrescription, between European healthcare systems.”

epSOS phase 2 related activities enlarge the scope of epSOS phase 1, extending the defined services, the coverage of the epSOS pilot with more participating nations and raising epSOS phase 2 to a more maturity of the operated pilot services.

The goal of this document is to define functional specifications of use cases selected from use case Deliverable 1.4.1 to serve as input data and information for next phases (see 2.2 Specification Phases and Roles) of epSOS specification.

1.2.2 Targeted Audience

Targeted audience for the functional specification deliverable will be all epSOS work packages which will use specification output as the input into their consecutive work. It will be primarily the WP 3.A – which will have to review existing epSOS architecture against the new epSOS use cases.

Work Packages WP 3.B and WP 3.C will follow with support of implementation of new use cases and new components on PN and on central level followed by validation activities to cover the development of the proof of concept testing strategy, then by providing interoperability testing and finally by providing the pre-pilot testing.

The WP 3.D will use functional specification output for improving interoperability across sectors and enabling reuse of components and services. It should also support the implementation cooperation and standardization with other projects.

Tasks of WP 2.1 aiming at analysing legal and regulatory issues both on EU and national level will base their work on service specification description. As well as WP 2.2 tasks, which on the basis of functional specification will have to update and later maintain the set of epSOS policies and organizational issues.

Other important consumers of the functional specification outputs will be PD4 WPs – in the process of covering new use cases incorporation into piloting sites, pilot implementation and later in the process of technical and organizational deployment of new services at national level.

We should also mention the connection with PD5 on the base of requirement management activities and processes and also the need of revising and overseeing semantic and security issues by way of security TFG and clinical/semantic TFG activities.

1.2.3 Structure of the Document

The goal of the document is the description of functional specification for new epSOS services. Technical and Implementational issues are out of scope of this deliverable. They will be managed in other WPs.

Comparing the list of use cases selected for further specification (see pages 8 and 9) the following mapping from use case to specification was made:
UC.PS.4, UC.MED.2, UC.MED.1 have the following corresponding specification:

- Health Care Encounter Report (HCER) Service Specification
- Medication Related Overview (MRO) Service Specification

UC.112 corresponds to Emergency 112 Service Specification
UC.PAC.1 corresponds to Patient Access Service Specification

Chapter 2 describes - in subchapter 2.1 - specification phases and roles of the epSOS specification process. Subchapter 2.2 describes Criteria and Rules for defining extended and additional services.

Next chapters – 3, 4, 5, and 6 – contain summary descriptions of extended and additional services. Detailed description of the services specification was put into Appendices:

- Healthcare Encounter Report (HCER) Service Specification – Appendix A1
- Medication Related Overview (MRO) Service Specification – Appendix A2
- 112 Emergency Additional Service – Appendix A3
- Patient Access Additional Service – Appendix A4

For the detailed specification description in appendices the next components were selected:

- Use case review
- Assessment of PNs readiness
- Service pre-requisite
- Service state diagram
- Service Functional requirements consisted of next subcomponents
    - Service ID Management Requirements
    - Service Legal requirements
    - Service Security requirements
    - Service Clinical requirements
    - Service Semantic requirements
    - Service Usability and data presentation requirements
- Service Non-functional requirements (service level requirements)
- Additional Architecture NCP / Central Service requirements

Details concerning data sets requirements of epSOS are described in the special Appendix A5 – Data Sets for epSOS Extended and Additional Services.

The main document ends with Conclusions (chapter 8) and the Annex (chapter 9) which covers References, Glossary and Abbreviations.

The section of Appendices ends with Appendix A6 - UC description. We put here only the reference on Project Place where the Deliverable D 1.4.1 – Use Case Description – can be found.

2 Specification Methodology of epSOS Extended and Additional Services

2.1 Specification Phases and Roles

2.1.1 Use Case Definition

This phase is described in the Deliverable D1.4.1 [1].

2.1.2 Functional Specification

Functional specifications of selected use cases from use case Deliverable 1.4.1 are described in this document.

2.1.3 End-to-End Service Specification

Entering in epSOS phase 2, we have to expect increasing complexity due to the enlargement to new PNs, the extension to new uses cases and functional specifications, the review of epSOS phase 1 architecture and design of infrastructure components specification or due to new knowledge and experience gained in the processes of the project governance and organization. To be able to manage this complexity a model for the epSOS end-to-end services description will help to develop a system of concepts for continuity of care in PN using epSOS services. The new epSOS services will have to be incorporated in such a model.

2.1.4 Architectural Specification

The task of Architectural specification is to identify and analyse - on the base of existing Architectural specification - the new service characteristics proposed in the functional specifications produced in KTs 1.4.6/7/8/9 and to propose changes or adding new features to existing architecture which will allow the practical implementation of new epSOS services.

2.1.5 Technical Implementation Specification

It starts from the epSOS phase 1 implementation strategy and achieved results with the goal to define the overall epSOS phase 2 implementation and testing strategy, built on role of Industry Team in epSOS phase 2 implementation process, building up on the ICT strategic go-to-market vision and approach, combined with the epSOS Policies and Strategies, defined in WP2.2.

2.1.6 Testing Strategy and Procedures

epSOS phase 2 implementation and testing strategy has to be organized in a way that is sustainable after the end of epSOS project, in the absence of an EU funded Large Scale Project and meet the breadth of national ICT environments from over 20 Member States and associated nations. On the base of epSOS phase 1 experience we can expect the following approach to testing strategy [4]

- Identify several test phases, giving to the PN the task and the responsibility to perform them, demonstrating the compliance to epSOS specification and requirement
- Appoint a Third Party (in epSOS phase 1 it was IHE Europe) to develop Testing Tools to verify the compliance of the implemented solutions to epSOS specifications
- Establish face-to-face (Projectathon - PAT) and on line testing events / sessions (PAT-on-Line), organized by third parties, to verify the compliance of solutions / services implemented by PNs or Vendors to epSOS Specification
- Run a Pre-Pilot-Testing process with the two-fold goal
    - Perform end-to-end functional testing to identify critical issues, understand and evaluate the clinical risk, propose corrective actions
    - Demonstrate the compliance of a service to start treating real patient data

2.1.7 Service Implementation and Deployment

Service implementation and deployment defines test scenarios incorporating new use cases and specify sites for system introduction, patient groups and healthcare providers involved in service delivery. After implementing the test scenarios, the pilot operation will be carried out.

2.2 Functional Specification Approach

2.2.1 Criteria to revise epSOS phase 1 Data Sets

The global principles we have used in the process of revising epSOS phase 1 Data Sets (Conceptual Information Model – CIM) were as follows:

CR1

Find the possibility how the existing data can be used in processes defined in new use cases. So the first step was to control how far existing data sets defined in epSOS phase 1 are either to be shared as they are, or how they must be modified or enlarged.

CR2

New data will be defined only in the case if they are unavoidable for covering the extended / added functionality needed in epSOS phase 2.

CR3

New data must be evaluated (assessed) by the Clinical/Semantical Task Force Group (C/S TFG) concerning their contribution to improve CIM quality. This led to defining the role of “coordinator with C/S TFG”; each specification KT was required to nominate its coordinator.

CR4

Required changes in current data sets (possibly an extension of the coverage) were suggested with the goal to maintain the flexibility and attributes required for given data sets in the epSOS phase 1.

Based on discussions with C/S TFG leader a new way of recording items in the CIM was defined.

2.2.2 Conceptual Information Model (CIM)

CIM now consists of

- 3 hierarchical levels of data item
    - also two levels are acceptable
    - it is possible to indicate repeatability of an item (1; 1..N)

Parameters of the data item

- definition of the data item; as the critical parameter needs to be clear, not misleading and unambiguous
- dataset (value: basic or extended)
- exception allowed (value: yes or no; if yes then it must be described in the comment)
- clinically acceptable “null flavours” (value: yes or no)
- comments

C/S TFG stressed the importance of next two attitudes to CIM descriptions based on lectures learned in epSOS phase 1

- If the functional expert does not specify a reasonable set of exceptional conditions (and ICT can add new ones related to the data retrieval process) we will get poor representation of them at the implementation level
- It should be clear that this table (CIM) should collect only the information needed for accomplishing the business process [most cases what HPs expect to see (problem description)]; additional information needed for completing the computational processing (including the compliance with the chosen standards) should be out of the scope of CIM; and need to be added at the information model in following phases.

Characteristics described above are only the first outline of the tool for CIM representation. We suppose its refinement and later its formalizing using formal language is planned (UML, SVBR, etc.).

3 Health Care Encounter Report (HCER) Service Specification – Summary

This service specification has started as covering the Patient Summary (PS) Extension use case description of deliverable D1.4.1 that aims to inform country A after a Patient Summary has been requested of the healthcare event that took place abroad. But also for other epSOS use cases this need for informing country A on the healthcare encounter in country B has emerged.

The Healthcare Encounter Report service not only supports the patient summary extension use case, but also supports the ePrescription extension use case and the 112 emergency use case. Therefore this service description not only covers the patient summary extension, but also the ePrescription extension and the part of the 112 emergency use case where information about the emergency encounter is sent back to country A.

The definition of a healthcare event can be broad. The HCER service is designed to offer a health professional in country B flexibility to record a wide range of medical information, enough to cover the most basic healthcare encounters. The service offers country A the basic contact information of the health professional in country B together with the medical information gathered during the healthcare encounter. Informing country A of a healthcare encounter in county B, of course, is done with consent of the patient.

3.1 Basic process

A foreign patient sees the health professional, who may use the epSOS Patient Summary service to receive more information on the patient. and gets diagnosed and possible treatment. When a health professional in the home country of the patient (country A) needs to be informed of this healthcare event, the health professional in country B can use the HCER service by taking the following steps:

- Health professional identification and authentication
- The patient's identity has to be validated in country B, the patient's identifier(s) from country A must be used for sending the HCER.
- The patient must agree with sending the HCER to country A (patient consent in country B).
- Country A needs to accept and process the HCER sent by country B, compliant with legislation of its own.

3.1.1 Patient Summary Extension

The HCER supports the patient summary extension use case UC.PS.4 as described in D.1.4.1. In this use case, after a PS is retrieved by country B, country A is informed on the healthcare encounter in country B, so country A is able to update the history of treatment events (according to its own policies).

3.1.2 ePrescription Extension

The ePrescription extension is described as UC.MED.2 in D1.4.1 is covered by the HCER service. In this use case medication is prescribed and dispensed in country B. A report (for informational purposes only) of the prescription and the dispense event is made available for country A, so country A is able to update the history of prescription/dispensation (according to its own policies).

3.1.3 112 Emergency support

In this use case a 112 emergency event occurs in country B, where a health professional (from the emergency call centre, ambulance or emergency department in the hospital) accesses the emergency data set from country A. At one point in time, one may want to notify country A on this event.

3.2 Selected Use Case Review and Assessment of PN's Readiness

The assessment of the readiness of Participating Nations (PNs) is based on the deliverable D1.4.2 and use case readiness statements of NEPCs done in as part of the activities of the KT1.4.1 use case descriptions.

As the availability of the Patient Summary in country A is not a prerequisite for sending back the HCER, the readiness of any Participating Nation has only to do with the possibility to notify country A of a healthcare event abroad.

Important issues that affect this use case are those related to patient identification, patient consent and management of data originated from another country and how to include the data into the systems whilst being compliant with the relevant legislation.

Based on the information in D1.4.2, very few PN are currently able to incorporate information from external sources both in terms of capabilities of information systems and procedures. This means that it could be that only few participating nations are able to pilot the reception of the HCER, and thus can implement the patient summary extended use case and the extended ePrescription use case in the role of country A. The 112 emergency use case is, in principle, independent of the HCER service. In a few cases country A can be informed on what has happened in country B, as not every PN supports receiving the HCER at this moment.

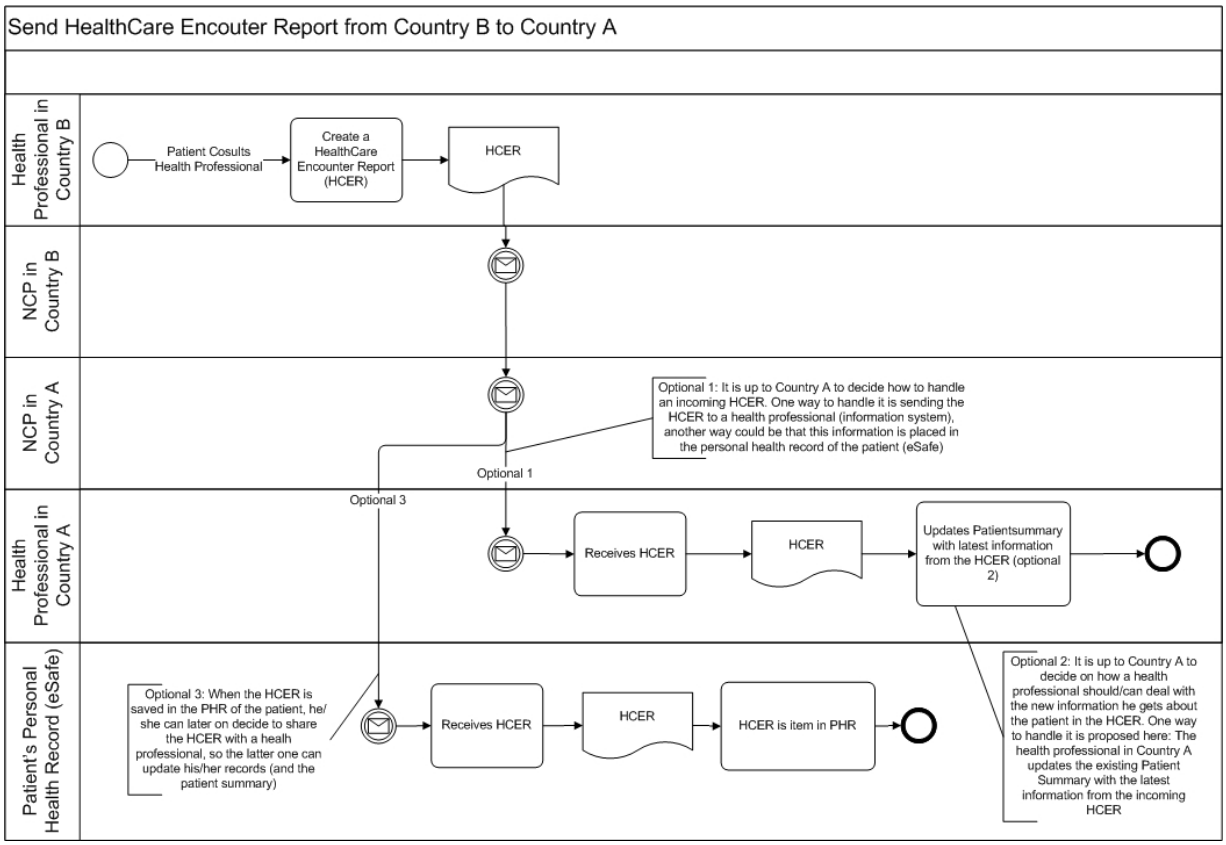
3.2.1 Implementation strategy

It seems unlikely that the national or local health information system enables an export of HCER. Therefore a more likely approach is that the health professional from country B fills in a HCER form via the epSOS portal, which is then converted to a document and send to country A.

It could be even more difficult to oblige a HP working at an Emergency Ward to generate a document only for epSOS purposes. For implementation there should be researched if it is advisable to provide a HCER generation environment or suggest to create a National Connector to transform a Country B document into a HCER.

The impact on a PN implementation versus a Common Component for dealing with HCER editing and Displaying has to be considered, and possible conflicts with epSOS 2 Implementation Strategy. This issue has to be considered together with KT1.4.10 and WP3.A for specs and WP3.B as implementation strategy.

3.3 Service State Diagram



3.4 The service preconditions:

- Country A is responsible for keeping the medical information of its own patients up-to-date. These specifications do not make any assumptions on how medical data is managed within a country A.
- Country A must provide, maintain and support the NCP supporting communication of the information identified in this section with country B and vice versa and that there must be a chain of trust between system actors in this process. Transaction logging and transport security are available in both country A and B.
- Services for identification and authentication of health professionals are available in country B, in a way that country B can provide country A with sufficient information about the authorized health professional of country B.
- Patient identification service is available: Country A shall offer the health professional in country B means to validate the identity of the patient.
- Legal compliance: Original medical document ownership (owner is both the patient and the entity where the document is stored) and medical / legal validity of transformed document shall be analysed according to the different PN's laws.

- Semantic interoperability of structured clinical content: the semantic services (e.g. terminologies, data structure) must be in place as defined by the project in order to have an understandable translation and a clinical consistency in its context.
- Scalability: The implementation should scale well with respect to the number of documents exchanged

3.5 Service Requirements

A summary of the requirements:

#	Type	Title
HCER-FR01	Functional	Health professional country B fills in HCER
HCER-FR02		Country A is informed of treatment event in country B
HCER-FR03	Service ID Management Requirements	Health professional identification, authentication and authorization
HCER-FR04		Patient identification
HCER-FR05	Service Legal Requirements	Patient consent
HCER-FR06		Information traceability
HCER-FR07	Service Security Requirements	Trust between countries
HCER-FR08	Service Clinical Requirements	Correct receipt and interpretation of sent data
HCER-FR09		Link HCERs
HCER-FR10		Viewing original documents
HCER-FR11	Service Semantic Requirements	Semantic compliance
HCER-FR12		Structured information
HCER-FR13		Equivalent information
HCER-FR14	Service Usability and Data Presentation Requirements	Understandable information
HCER-NFR01	Service Non-functional Requirements: Service Level Requirements	Service availability
HCER-NFR02		Response time
HCER-NFR03	Additional Architecture NCP/Central Service Requirements	New document type
HCER-FR14		Forwarding HCER

4 Medication Related Overview (MRO) Service Specification – Summary

The Medication Related Overview (MRO) is a document for informational purposes only that supports all possible information that might be needed in the process of prescribing, dispensing (and possibly even administering) medication to the patient in a foreign country.

The absolute minimum set of medical information in the MRO consists of all the coded prescriptions and medication dispenses available in country A. Other useful information for the medication process, such as allergies and intolerances, are in the extended data set of the MRO.

4.1 Basic process

The MRO can be used both in a situation where the prescription comes from country A (epSOS phase 1 ePrescription) as the case where the medication is prescribed by a prescriber in country B. Health professionals in country B access the MRO from a patient affiliated with country A.

The basic steps are needed to support this functionality:

- Health professional identification and authentication
- The patient's identity has to be validated in country B, the patient's identifier(s) from country A must be used for retrieving the MRO.
- The patient must agree with sending the MRO to country B (patient consent to the health professional in country A).
- Country B requests the MRO from country A. Country A processes this request and sends the MRO to country B.

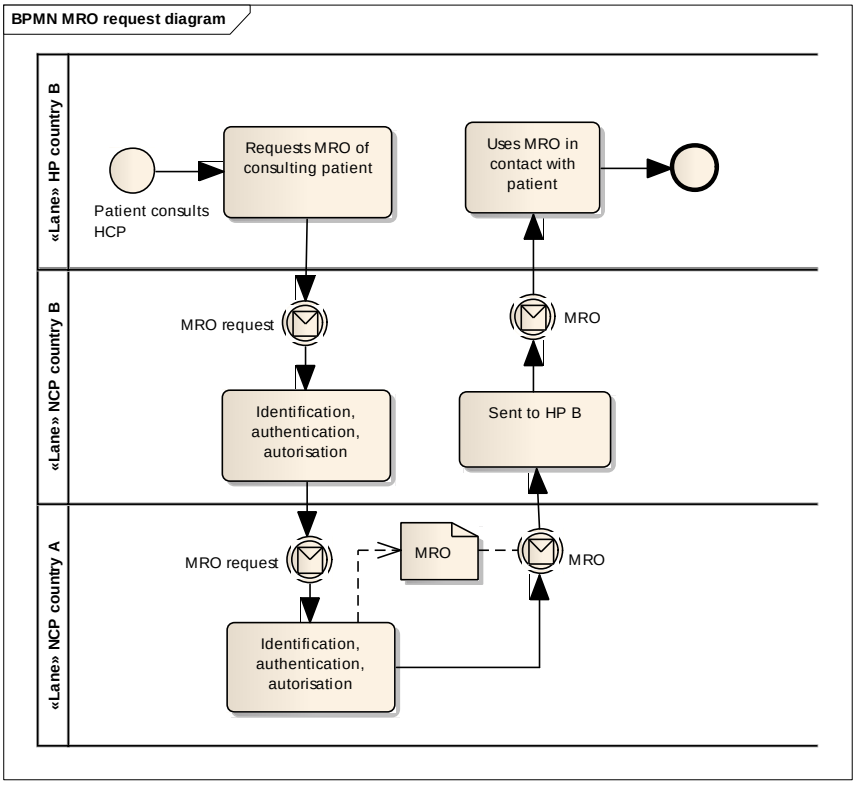
4.2 Selected Use Case Review and Assessment of PN's Readiness

Countries have been asked whether all the elements that are proposed in the MRO are available, and if so, are coded or in free text. The concluding answer on this question is that most Participating Nations do not have these elements available at the moment.

The wish to be more active in the second phase of epSOS on medication safety is somewhat tempered by the fact that only a few PN's use medication related overviews that contain coded information. Since in epSOS translation can only be achieved by transcoding, this fact offers severe limitations on pilot possibilities.

Therefore the absolute minimum set of medical information in the MRO consists of the prescriptions and medication dispenses. Other relevant information for medication safety is part of the extended data set, which should enable more countries to implement the service (as country A).

4.3 Service State Diagram



4.4 The service preconditions:

- Country A is responsible for keeping the medical information of its own patients up-to-date. These specifications do not make any assumptions on how medical data is managed within country A.
- Country A must provide, maintain and support the NCP supporting communication of the information identified in this section with country B and vice versa and that there must be a chain of trust between system actors in this process. Transaction logging and transport security are available in both country A and B.
- Services for identification and authentication of health professionals are available in country B, in a way that country B can provide country A with sufficient information about the authorized health professional of country B.
- Patient identification service is available: Country A shall offer the health professional in country B means to validate the identity of the patient.
- Legal compliance: Original medical document ownership (owner is both the patient and the entity where the document is stored) and medical / legal validity of transformed document shall be analysed according to the different PN's laws.
- Semantic interoperability of structured clinical content: the semantic services (e.g. terminologies, data structure)

must be in place as defined by the project in order to have an understandable translation and a clinical consistency in its context.

- Scalability: The implementation should scale well with respect to the number of documents exchanged

4.5 Service Requirements

#	Type	Title
MRO-FR01	Functional	Country A offers access to medication related information
MRO-FR02		Health professional in country B requests the MRO
MRO-FR03	Service ID Management Requirements	Health professional identification, authentication and authorization
MRO-FR04		Patient identification
MRO-FR05	Service Legal Requirements	Patient consent
MRO-FR06		Information traceability
MRO-FR07	Service Security Requirements	Trust between countries
MRO-FR08	Service Clinical Requirements	Correct receipt and interpretation of sent data
MRO-FR09		Original information
MRO-FR11	Service Semantic Requirements	Semantic compliance
MRO-FR12		Structured information
MRO-FR13		Equivalent information
MRO-FR14	Service Usability and Data Presentation Requirements	Understandable information
MRO-NFR01	Service Non-functional Requirements: Service Level Requirements	Service availability
MRO-NFR02		Response time
MRO-NFR03	Additional Architecture NCP/Central Service Requirements	New document type

5 EHIC Proposal of the Recommendation

5.1 Introduction

In the use case description deliverable, there were presented 3 typical procedures related to the use of EHIC (or EHIC originated data) performed in a different organizational context and a set of actors or tools involved. But if we consider this issue from another, more analytical perspective, we can enumerate several basic functions that are needed to reach the goals of these EHIC related use cases:

- identification of patient
- identification of insurer (institution that will finally bear the costs of the treatment)
- determination of patient's entitlement status
- proving patient's presence at the time of treatment
- capturing data into electronic structured format for further computer processing

If we could provide the tools to facilitate these functions in an electronic environment of the internet, it would be possible to define and implement the modern and efficient use cases, fulfilling our expectations regarding the cross border eServices. With such a result, it would be sensible to consider common elements of "EHIC related" use cases and epSOS use cases. But at the current stage, it is too early to implement it. There are some factors to be considered.

Implementation of these functions in electronic way is not only a technical challenge. Much more important is the acceptation of the fact that the solution for the above mentioned issues are in the responsibility domain of the DG Employment (DG EMPL), which animates actions resulting from Regulations 883/04 and 987/09 dealing with pan-European coordination of social security systems. If epSOS project would aim at connection of EHR data exchange with administrative data exchange, it should rather strive to collaborate with the DG EMPL in devising the best solutions than to work within the project on implementation of new technically independent tools.

That is why, instead of preparing the technical specifications of EHIC related use cases, the Project decided to do GAP analysis and come up with the Recommendations that could be the basis for further debate between DG EMPL, DG INFSO and DG SANCO about the future of the sustainable pan-European systems in healthcare area.

5.2 DG EMPLOYMENT implemented solutions

The DG EMPL work is based on a strong cooperation with all Member States (MS) whose delegates form an Administrative Commission (AC) that is being supported by Technical Commission (TC). When referring to DG EMPL throughout this document it should be understood as a global entity embracing the AC, the TC and the staff of the DG EMPL dealing with the cross-border social security coordination.

DG EMPL efforts to achieve the operational system of exchange of data, needed finally for reimbursement of medical services provided to the patients are focused on enhancing the citizens (patients) interest for achieving mobility as well as high level of health protection. This approach is similar to other EU institutions. It means that if there are limited technical or

financial means to satisfy expectations of all stakeholders in a certain process, the patient's convenience prevails.

The basic principle behind the rules of the pan-European social security coordination system was from the beginning for simplification of procedures concerning receiving treatment by patients outside their Member State of affiliation. E-111 paper forms, replaced later with plastic European Health Insurance Cards that contained validity date printed on them, were introduced to ensure patient's trust in cross-border healthcare. According to the rules of EU coordination system, patients from other EU countries should get a medical treatment on the same basis like native patients after showing EHIC with valid expiry date of the card (883/2004 regulation). Existing solutions can be perceived as satisfying only from patient's perspective. Below the issue is analysed from the perspective of other participants of coordination system: health insurance organizations and healthcare providers.

5.2.1 Health insurance organizations' view

Health insurance organizations (HIOs) must tackle the problems with issuing EHICs and paying for medical services being given to patients during the printed period of card validity. Taking into account the fact that cost of issuing cards is pretty high HIOs are trapped in two alternatives. The first option is extension of validity period printed on EHICs in order to narrow down the number of issued cards. The second option is shortening validity periods to reduce the risk of using card lawlessly by patients after losing their entitlement or changing their insurer.

If HIOs opt for the first solution they face the problem of claims for the patients that lost their insurance earlier than validity period printed on EHIC or are insured in the interim by another competent institution (CI). Recovery of such costs from patients or proper competent institution may be a very cumbersome and quite expensive procedure.

On the other hand, if they decide to shorten validity period they will increase the costs of issuing process because of increasing number of cards. In such a case the insured have to be somehow involved in the process of the cards receiving either by applying for them individually or in the best case by consciously accepting the newly delivered cards.

It should be emphasised that only a small percentage (approximately 3% per year according to estimates of NETC@RDS) of the issued EHICs are used by the cardholders. Most of the cards are kept in pockets of the citizens but never being used because there is no need of medical treatment abroad. HIOs start to think that millions of Euro spent yearly on issuing many unused EHICs could be invested better for implementation of a technologically new solution focused only on those insured that really need verification of their entitlement.

5.2.2 Healthcare Providers' view

A position of the HProvs (Health Care Providers) in the system with EHICs seems not to be as weak as HCIO's one but it has started to be not sufficient. Even if HProvs feel safe to get the payment when they have checked the validity date printed on EHIC, the procedure to get a reimbursement is not modern enough. Quite often data exchange systems for domestic patients use fully electronic procedures these days, while the EU patient treatment requires paper copying of the EHIC and mailing it to a competent institution to get a due payment.

There are signals from different countries that HProvs don't want to attend to patients in accordance with the EU coordination system and demand direct payments from patients' pockets instead, because of those burdensome procedures.
The challenge we face now is how to improve work effectiveness of the HCIOs and the HProvs without decreasing the satisfaction level of the patients.

5.3 EESSI implementation

In the middle of the last decade DG EMPL started the preparations for the replacement of the present paper based entitlement and reimbursement data exchange with the usage of E-forms between insurance institutions within the new ICT system named Electronic Exchange of Social Security Information (EESSI). The aim was to get rid of the long paper procedures in order to improve accuracy of information and to increase the speed of transactions clearings.

The main focus of the design and development was concentrated, apart from ICT architecture of the pan-European infrastructure, on the messaging system that requires conversion of the E-forms into the Structured Electronic Documents (SEDs) and implementation of the formalized protocols and routing rules for the flows of data.

Unfortunately, there is one significant drawback of the EESSI conception. Because generally speaking, the solution with plastic EHICs works well enough for the citizens' sake, there was no intention to modernize that part of the EU coordination system that concerns entitlement verification of the patients. Even if there are flows (requests) defined in the EESSI to verify patient's rights between insurance institutions, there were no expectations to do it in a real-time mode. The clerks may check this data outside the EESSI system, in off-line mode, and deliver an answer in some undefined time. It means there is no pressure to implement the connection of the EESSI infrastructure to the relevant databases (or in a broader sense - web services) with entitlement information on a national level.

Without real-time electronic (internet) function to verify the patient's entitlement, there is no way to change the present demands towards the HProvs' processes. And without it, the HIOs will not be able to decrease the costs of frauds and errors resulting from outdated procedure.

What is important to highlight: the EESSI system may work effectively on the level of social security institutions, but in healthcare sector the citizens being abroad usually get in touch not with an insurance institution but with a healthcare provider. Unless we find the solution to connect the HProvs to the EESSI, we are still only halfway to a modern system.

A roll out of EESSI was planned on 1st May 2012, but because of complexity of the system in multinational pan-European environment, the starting date has been postponed by two years. That time may be used to revise the future model of EESSI implementation in the healthcare sector and to prepare its stakeholders for the next steps.

5.4 eEHIC idea

In parallel to the EESSI development, there were frequent returns to the EHIC solution improvement attempts in the works of AC/TC. Since the time of its implementation in 2004 (or even earlier), it has been quite often concluded that EHIC is only a temporary solution of the future electronic version card (eEHIC). Some believed that thanks to the eEHIC introduction, a significant enhancement of the entitlement verification procedure could be achieved. But what was also obvious, such a tool would have needed an immense investment not only because of the much higher prices of the electronic cards but also because of the costs of the infrastructure required to read the cards at the HProvs' and to exchange the on-line messages in pan-European environment. This has been a prevailing opinion, and thus no interoperable European electronic card has been rolled out yet.

But meanwhile, some new development ideas and achievements had started to change the perception of the whole problem. In some countries, national electronic health insurance cards have been issued; in some others the similar decisions were being considered. These countries were obviously proponents of the electronic verification of the entitlement and they implemented national systems performing this task, but on the other hand they wouldn't like to be forced to hand out an additional set of electronic cards for the use in the international context only. Thus, DG EMPL decided in 2007 to establish a group within CEN framework (Committé Européen de Normalisation) to prepare a CEN Working Agreement (CWA) containing definition of the European standard for the healthcare insurance cards. With such a standard any EU member states could introduce their own national cards whenever they decided, and all these cards could be easily read in other countries when the HProvs infrastructure (mainly card readers) would be finally in place there.

The work of the group was finalized in 2009 with the resulting document named CWA 15974:2009. Unfortunately, this outcome didn't get an official support of the whole TC. Consequently, there were no other efforts to introduce pan-European CWA-compliant solution in a step by step, country by country approach. Nobody wanted to risk the standard would change in the future.

Nonetheless in most countries, domestic electronic systems were gradually implemented to exchange reimbursement data between HProvs and the payers (usually they are HIOs, sometimes municipalities). It turned out that in many countries there is no need to use dedicated electronic documents to verify who is a patient's insurer and what is his/her entitlement status. Since these data are not sensitive (in the terms of Personal Data Protection regulations), according to their legal systems, it is sufficient to have a solution for HProvs' identification with authentication in order to access a patient's reimbursement data. And this check-up is much easier to perform than patient's electronic identification and authentication.

With this observation, the possible organization of the pan-European entitlement verification should be reconsidered. If there are countries willing to give an access to their patient's data without expensive facilities required, it is worth thinking how to incorporate it into officially acceptable set of procedures.

This approach, concerning pan-European entitlement verification, is reinforced by the awareness that people going abroad not always take the document proving the entitlement. We should have a backup procedure for them. Nowadays it is the paper Provisional Replacement Certificate instead of the plastic EHIC. But it seems possible to switch to the electronic version of the PRC in the future. And it may turn out that this backup solution is more effective than the basic one.

5.5 eHealth cards idea

In some countries that started their eHealth solutions a different approach, concerning above analysed issues, was undertaken. Especially when their legal system is not focused on insurance principle and all citizens are entitled to medical care, an electronic version of the EHICs or similar national cards was deemed unnecessary. But it turned out soon that confidentiality assurance required to process medical data needs an implementation of the proper tools. The most popular solution to fulfil these requirements appeared to be electronic, the so called Health Cards.

They were issued, in some countries, on the national or sometimes on a regional level. But, while there is a European driving force related to EHIC specifications, that is not the case for

the Health Cards, where every region and/or country has implemented their own systems. Moreover, there is no alignment between the EHIC and the Health Card at a national level.

One of the reasons of such discrepancies is a common existing split between organizations dealing with eHealth (medical records) and healthcare insurance (entitlement and reimbursement). It seems that this cooperation should be strengthened – and not only on a national level. It would help a lot if European efforts on these subjects were coordinated accordingly.

Some work on standardization of Health Cards has already been started in the scope of EU projects, but it would be even better to join efforts with the bodies interested in eEHIC standard or maybe even in a broader scope of a so called EU Citizen Card.

5.6 Patient identification

In the present-day system, identification of a patient for reimbursement purposes is based on a Patient Identity Number (PID) together with a name and surname printed on an EHIC. There is no technical (electronic) authentication process involved in this procedure. The HProv should simply verify these data with an official patient's ID document containing the photo (passport, driver's licence etc.), but this is an obligation out of any control.

In general, HIOs might be interested in authentication of patients as an addition to their identification because of at least three reasons:

- To make sure that the patient is really the person for whom the EHIC was issued. Because it may happen that the EHIC is shared fraudulently, or stolen and used by unentitled person.
- To be sure that the patient was really present at HProv. Unfortunately, it may happen that a dishonest HProv, having patient's data in his database, sends a reimbursement request for the service that wasn't actually provided. Technically implemented authentication process may limit this type of frauds.
- To give the HProvs an information about the patient's entitlement status through internet. In some countries, personal protection regulations require patient's consent for such an access. In these cases, the authorization of the HProv, needed for this function, may require a sort of patient's authentication first.

In a modern system, all foregoing requirements could be fulfilled by the use of electronic cards carried by patients, but the costs of such a system (with card readers infrastructure), that would have to be implemented in all EU countries, was deemed to be too high. On the other hand, sticking to the present solution, where the reimbursement procedure relies on an assumption that a paper copy of the patient's EHIC is a proof of his/her presence at the HProv and a proof of entitlement validity seems to be already not satisfying. Depending on the internal regulations, experiences, and priorities in implementation of e-Administration systems, some member states express their interest in looking for more convenient solution for the cross border reimbursement.

The HIOs estimate that the first two problems, related to the fraudulent behaviour, are not crucial now (from the financial point of view), and their solution has probably to wait for the mass implementation of a person authentication tool (e.g. eID cards, SMS confirmation, other tokens or new concepts). Until then, responsibility for patient's authentication may be left on the HProvs. In many countries there is now a new additional tool for the verification of the treatment provision – patients' internet access to the list of all medical services delivered to

them. If they discover the reported treatment that didn't take place, a checking procedure can be initiated.

Therefore, at present, the issue of the patient's identity authentication in EESSI the system could be considered mainly in the context of entitlement verification – but, what is important, it makes sense only in an on-line (real time) solution. In fact, if the system of plastic EHICs is to be sustained, there is no identification process that could be reused in the other functions implemented in HProvs' ICT systems (e.g. those resulting from the epSOS scope). Thus, to make the future systems at HProvs consistent, it makes sense to establish the cooperation on this subject between all regulatory bodies dealing with electronic exchange of information in the healthcare field on the EU level (DG EMPL, DG SANCO, DG INFSO).

In the long term, this should lead to the creation of the common standards in identification process of the patients or in broader sense – EU citizens. One of the possible outcomes of this cooperation could be the standard for electronic cards, mentioned in the previous chapter. But to avoid focusing on a card-centric approach it is better to consider commonly agreed solutions more generally. One of the examples of such prominent work is the STORK system offering flexible solution of the identification process with different possible authentication and thus authorization levels for different applications' needs. Each country may adjust requirements towards the requests sent through STORK in accordance with the national regulations.

5.7 Recommendations

5.7.1 To connect the entitlement databases (or appropriate web services) to the EESSI system

The EESSI system is under development in all EU countries. Its central (European) part will be ready soon – in the middle of the next year. All member states should prepare their national system connections in accordance with the interfaces defined centrally, by the end of April 2014. The system will allow electronic exchange of data between all competent institutions in the social security sector throughout whole Europe. But the requirements of the system do not demand an immediate answer to the request on entitlement status.

With the present EHIC based system in healthcare sector, entitlement verification, which needs to be performed directly in competent institutions, occurs only in the case when patient does not have EHIC with him/her, and thus, has to apply for a paper Provisional Replacement Certificate. Clerks in CI are trying to react to requests sent by fax, e-mail, phones as soon as possible, but sometimes, even one day is not enough. But, patients without EHIC appear still in minority. If the future system is to be organized in a more reliable way with regard to patients' entitlement accuracy, the situation will change. Then, it will be impossible to verify all cases manually.

Certainly, there are countries which in the scope of present implementation of the national part of EESSI system will connect it directly to their entitlement databases. But it will not be a common approach.

It seems that DG EMPL should strongly promote the idea of the on-line connection of the EESSI system to the national (regional) databases (or equivalent web services) retrieving entitlement status in on-line mode. The future applications of the system could by more sophisticated due to it, and thus, more effective and reliable.

5.7.2 To make the HProv an additional beneficiary of the EESSI system implementation

Whereas in most social security sectors, the citizens contact directly competent institutions in order to sort things out, in healthcare sector it works differently. Patients in need usually get in touch with healthcare providers first. Even if the EESSI is deployed on a full scale it will not help the HProvs to reorganize their administrative work unless additional steps are undertaken.

Domestic reimbursement processes are implemented in an electronic way already in most EU countries. Unfortunately, because HCIOs in country B, directly responsible for the payment for the treatment, are obliged to have an evidence of patients' EHIC data as a proof of entitlement in clearing process with competent institution in country A, they demand from HProvs the paper copies of EHICs.

These paper copies are collected on the off chance that the competent institution in country A will challenge the payment for the treatment achieved fraudulently. If the institution in country B has a copy of EHIC, the financial responsibility for the case moves to the country A. Since this clarifying dialog may take place several months after the actual treatment had been delivered, and the payment to the HProv from the institution in country B had already been done, the only link to the past is at that time a paper EHIC copy.

The other situation to consider is when a patient does not have an EHIC with him. Somebody should apply for a Provisional Replacement Certificate in this case. The patient could do it directly with his HCIO in country A or via competent institution in country B. But usually, being ill in foreign environment he relies on HProv, asking them for help.

However, there are no homogenous European procedures to do this. Patient or doctor gets in touch with institutions in their country or country A using fax, phone, or e-mail. It is a cumbersome and expensive procedure – both for HProvs and HCIOs. Having an opportunity to use EESSI infrastructure, the needs of the system's actors could be fulfilled much more effectively.

EU regulations try to avoid interfering into national organizational solutions, but without taking into account the real needs of healthcare systems in pan-European context, it will be difficult to establish a modern, fully electronic reimbursement system.

5.7.3 To accept electronic confirmation of entitlement in reimbursement process instead of paper PRC

The most obvious realization of the above mentioned suggestions would be an implementation of direct on-line entitlement verification by HProvs with the use of EESSI infrastructure.

Probably it does not make sense to change the rules concerning the EHICs use. They were invented as an off-line tool, everybody get used to their role in the system, so it seems better not to lose a currently achieved acceptance. But, much far-reaching changes could be initiated within the PRC issuance procedure.

Provisional Replacement Certificates are signed paper documents generated by a proper competent institution (HCIO) in country A, requested usually by a HProv in country B on the patient's behalf. Why couldn't it be done by sending a digitally signed electronic document through EESSI directly to the HProv? Having electronic confirmation from the final payer, it would be quite easy to organize a fully electronic reimbursement process.

There are no technical obstacles to the implementation of such a solution. There are countries willing to introduce it in their national systems. And, what is most important, it does not exclude the well-established EHIC procedure. Both solutions can coexist. Maybe some additional elements in a set of flows designed for EESSI purposes should be implemented, but the required efforts does not seem to be extensive.

Since there are already two procedures to acquire entitlement status of a patient (based on plastic EHIC and paper PRC), it seems to be possible to add a new one, especially that it could turn out to be the best one in the future. It would be wise of DG EMPL to support this initiative to be prepared for next steps in EESSI development.

5.7.4 To implement a flexible pan-European identity verification system

There seem to be countries where domestic regulations allow for patient's entitlement verification on a basis of the HProv's authentication. The foreign HProvs (in country B), asking for the patient's entitlement status from a competent institution in country A, could be authenticated by a proper institution in country B the same way it is implemented in epSOS. No patient authentication or consent would be needed in this case.

But, in some countries it would probably be impossible to request patient's entitlement status without authorization process that includes a sort of patient's participation. In advanced case, it might require an electronic tool with PIN secret used by the patient. Sometimes, only the self-authentication function of such a tool could be enough.

In a close perspective it would be difficult to expect that all member states switch their national requirements to one pan-European solution aiming at patient's identity verification. Thus, a flexible universal system should be implemented that would allow for different national authentication scenarios giving a standard (commonly accepted) authorisation answer as an output.

Such a system could be developed as a dedicated tool for all institutions in social security sectors DG EMPL is dealing with, or, what seems to be much more sensible, an existing tool could be shared. The best candidate for such a system seems to be the STORK or SPOCS now – the system created within a project sponsored by DG INFSO. Certainly, it would need an analysis and assessment done by Technical Commission, but there are good reasons to believe it to be the right candidates to achieve the goal.

5.7.5 To define a common standard for the electronic cards

It is quite possible that in some countries, an authentication process of the patients will require the use of electronic cards. On European scale the expected results could be achieved in this case only if interoperable card readers and software were implemented in other countries (B). But such approach is not very popular today. In the next years, we can expect that more and more countries will introduce card readers at HProvs either because of electronic insurance or health cards introduction.

But, this enhancement of the cards infrastructure may be in vain unless the standards of the cards content and interface are defined for minimum the whole of Europe. The failure of the CWA standard acceptance at the DG EMPL Technical Commission should not stop the next efforts in this field. It is high time to join European activities that are trying to introduce common definition not only for health insurance but also for health cards or – even in a broader sense – citizen cards.

Standard of the citizen card could be implemented in the new national cards whatever purpose they were to be established for: insurance, health or general identification, bringing the effect of pan-European interoperability.

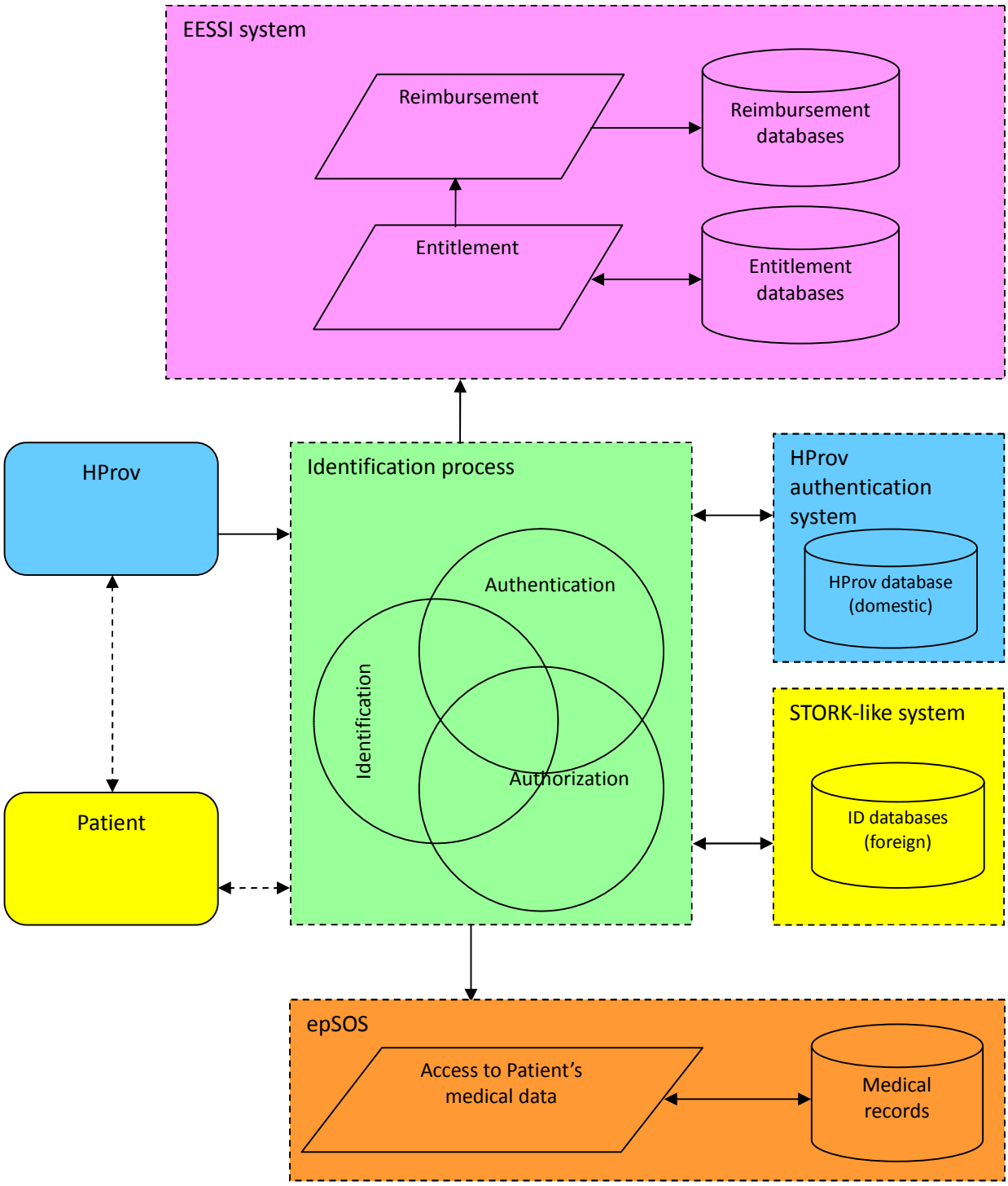
5.8 Result – the new EHIC use case description and diagram

If the above mentioned recommendations were introduced the common case of foreign patient coming to the HProv could be described as follows.

- HProv in country B is connected by internet to one of the competent institutions in his country, to which he is known and authenticated with the tools appropriate for this country. HProv may use dedicated portal with direct access to functions offered to him or use his own software with access to web services implemented by CI.
- Depending on the conditions set by country A, patient's entitlement verification process may require different actions with regard to his/her identification.
  - In some cases only patient's identification number taken from any personal document is enough. This number is input by the HProv (B) into the request sent electronically via the competent institution (B) and EESSI infrastructure to the country A, where the information about the relevant HCIO and entitlement status is fetched from the available database (or web service), and sent back to the HProv the same route. This way HProv gets all data needed for reimbursement, signed electronically by the institution in country A.
  - Some other countries may require the use of patient's electronic tools to give an access to the up-to-date entitlement information stored in their databases. Usually, no PIN input from patient is required; the card signs automatically its presence in the card reader to authorize the HProv to obtain the data from country A. But it is recommended to require also the PIN.
  - Some information needed for reimbursement (patient information) can be read from the card. The HProv doesn't have to type them in. The country A has to deliver only the competent institution code and entitlement validity date in this case.
  - Thanks to electronic capabilities of the card with the requirement of a PIN, the credibility of the patient's presence at the HProv is highly confirmed.
  - There are also conceivable other solutions required to authorize a foreign HProv asking for the patient's entitlement data.

All this options may be operated by a STORK like system. If the infrastructure in any place of country B doesn't allow for this type of actions, then backup solution like the present PRC off-line procedure can be performed.

- Information obtained by the HProv with the use of EESSI direct request may be easily used in electronic reimbursement process. No paper copies of any documents have to be required.
- Giving the HProv an access to the STORK like components, it is possible to verify the strength of the patient's authentication tool to decide on an authorization level of the HProv in the context of the medical records access. If the level is sufficient, the epSOS use cases are open to run.


EESSI system
Reimbursement
Reimbursement databases
Entitlement
Entitlement databases
HProv
Identification process
Authentication
Identification
Authorization
HProv authentication system
HProv database (domestic)
STORK-like system
ID databases (foreign)
Patient
epSOS
Access to Patient's medical data
Medical records

6 Emergency 112 Service Specification – Summary

6.1 Short description

In accordance with the Directive of Cross-border Health Services (Directive 2011/24/EU), epSOS will develop a service providing the patient with access to key information in his or her own medical record, when seeking or receiving healthcare abroad (outside his/her Country of Affiliation, Country A). The **epSOS Additional Services 112 Emergency (112)** is built upon and enhances but does not replace any National Emergency services within the Participating Nations.

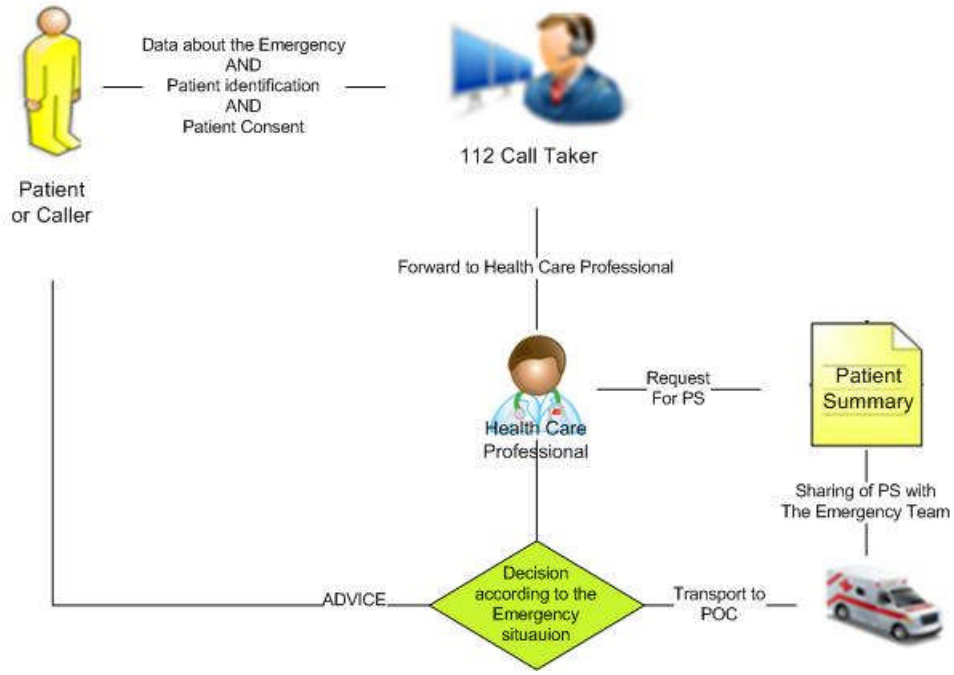
The aim is to propose how 112 emergency services can be included in existing epSOS services to allow European emergency services (112) and in particular the Emergency Medical Services to securely - and legally - access a patient summary to improve the quality of the intervention. In accordance with the epSOS Description of Work [11], this service should provide access to a Patient Summary (PS), resp. propose new data set suitable for emergency situation in a structured and coded form. According to the general approach in epSOS, only structured and coded data will be subject to translation, restricting the use of unstructured data to a copy of the original document in its original language [12] , [13]. Current specifications allow however the usage of "exceptional uncoded information" within coded element for handling exceptions.

Basic use case was elected for specifications of the services. Primary and secondary actors are all involved in it. This means Patient or Caller as primary actors, operator 112 or call taker and Health Care Professional as secondary actors acting in different roles as POC.

Proposal is oriented to the needs of all participating roles. The Patient wants to have improved quality of intervention provided by 112 Emergency services (included in epSOS services), securely and legally. The Health Care Professional wants to receive all relevant information about the Patient in different processes provided by the Emergency teams in order to increase the Patient safety and quality of services in the emergency situations.

6.2 Steps of Additional services 112 process

The basic process of provision Additional services 112 is outlined in Diagram 1.
Diagram 1: Additional services 112 Basic process:



General overview of the medical emergency handling process can be divided into three steps. In the first one, the emergency call is received in 112 Emergency Call Centre, first data about the situation are taken and medical resources are dispatched. In the second step, health professionals arrive to an emergency place and take care of the patient. The next step is when the patient arrives to the first aid department. Service description also implements a new functionality – Health Care event feedback delivery to the Patients EHR system in his Country.

Specification of 112 Emergency services contains consolidated output of KT 1.4.5 containing feedback about availability of 112 services in different PN, process of patient identification, role of healthcare professional in handling of emergency calls, availability of electronic support and connection. According to information collected was given recommendations for service proposition.

Next important part of the document is collection of opinions of NEPC-s collected from publicly accessible resource, namely questionnaire filled in by the NEPCs and inserted to the Project Place. According to this information was possible to create table of countries and readiness for Piloting 112 Emergency services.

PN	Pilot RD	Pilot scenario	Remark
France	Positive	TBD	(Analysis of PS content needed, .. impact)
Malta	Positive	Country B	
Sweden	Positive	Country B	
Greece	Positive	TBD	(Uniformity of 112 ES across the countries)
Turkey	Positive	TBD	No statement just interest in participation
Slovakia	Positive	Country A and B	
Germany	Negative	--	Legislation problem, minimal benefits
Lombardy	Negative	--	No condition to pilot

Next part of document contains recapitulation of aspects, which are relevant to depict differences among countries prom 112 Emergency services organization point of view. This summary provides information about availability of relevant functions in different countries and regions, which are already offering112 Emergency services.

Next part of document describes service pre-requisites and functional diagram.

According to upper mentioned input information was prepared proposal of following service requirements.

- **Service Functional requirements**
  Integration of national system infrastructure with 112 Emergency provider.
  Integration of POC in the role of partner of 112 Emergency services
  Connectivity of 112 Emergency teams

- **Service ID Management Requirements**
  Identification of the patient using patients ID
  Identification of not communicating patient

- **Service Legal requirements**
  Patient summary data access logging
  Uniformity of implementation of the directives in MS a PN

- **Service Security requirements**
  Inclusion of Emergency 112 identified physicians

- **Service Clinical requirements**
  Supplement the data related to Emergency 112

- **Service Semantic requirements**
  Definition of the clearly comprehensive User Interface.

- **Service Usability and data presentation requirement**
  Definition of UI for different roles

- **Service Non-functional requirements: service level requirements**
  Availability of service

- **Additional Architecture NCP / Central Service requirements**
  Availability of national Patient summary repository

Each of the above requirements has been analysed in detail. Document contains detailed description of actors, associated goals and service applicability preconditions.

7 Patient Access Service Specification - Summary

The functional requirements for patient access are based on the use case description described in [1]. **epSOS Patient Access Service (PAC)** must be in accordance with the Patient Access policy of patient's Country of Affiliation [9].

The legal underpinning to Patient Access includes the diverse national Acts to access own Medical Records following the European Directive of 1995 which requires Member States to protect people's fundamental rights and freedoms and in particular their right to privacy with respect to the processing of personal data. In practice it provides a way for individuals to control information about themselves. A key objective of Digital Agenda for Europe sets 2015 deadline for giving patients online access to their medical data (Key action 13)[2].

The epSOS Patient Access Service includes patient identification and authentication. The service first verifies that the patient has access rights to the information, and then provides the requested document(s). The patient reads copies and distributes the document as he or she considers appropriate, possibly to a new health professional at a new encounter in the language requested by the patient. The PAC enhances any National Patient Access Service by improving understanding over national (language) boundaries. The PAC does not alter the access rights of the patient. The key service provided by PAC is therefore the translation of the PS or eP.

The main pillar of patient access in epSOS is therefore the existing national Patient Access (PA) systems. These patient access services may vary from country to country and might include patient-reported outcome data, lab results (either entered by a patient or downloaded from the testing lab itself), data from devices such as wireless electronic weighing scales or collected passively from a smart phone (a patient can collect any kind of data on his smart phone like results from his diabetes medicines use or his blood sugar rates).

- PAC will increase enormously the epSOS healthcare information traffic, namely the amount of cross border patient events in epSOS pilot, since it enhances the current set of candidate cross-border epSOS patients with:
- Patients having an emergency or unplanned care episode, and visiting any Point of Care (PoC) in a foreign country that does not belong to epSOS PoC network.
- Patients residing in a country whose national language(s) are not among the languages that they feel themselves comfortable with.
- Incidental patients that need care evidence to give/offer to a foreign health professional who does not speak the same language as the patient.
- Citizens preparing a trip to a foreign country. A citizen can take a print-out and/or digital copy of his current prescription and/or patient summary, translated to the language of the country he will visit.
- Commuters and seasonal migration citizens that may govern two different patient access systems (the national one and that one of the residence country).

7.1 Selected Use Case Review and Assessment of PNs Readiness

In this functional requirements both the patient and the previous health care professional (and therefore the document to be accessed) are affiliated with Country A, but the goal of the patient is that the PS or eP document is translated into language B.

[2] http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/11/282&type=HTML

Following the results of KT1.4.5 “Country status outline”, patient identification means vary from the current “username + password” mechanism to the demand of digital certificates in 2013. Sixteen countries inform that they will have Patient Access in 2013, but nowadays it is still not so wide-spread even if it is available in six countries.

Interaction is still low with both the patient and other external sources, what is very relevant for chronic disease management. Extended functionalities such as uploading of information to the PS by the patients or incorporation of other information by the PS for chronic disease management are still very limited; only Sweden, Spain, Estonia and Turkey allow it.

7.2 Service Pre-requisites and Service State Diagram

The service preconditions consists of the following elements: (a*) Patient identification and authentication* already exists; (b) *Preexistence of national PS or eP*; (c) *Transaction logging* and transport security; (d) *Country A is the only source of data for a patient;* (e) *Semantic Interoperability:* PAC service should guarantee the smoothest semantic transformation, keeping the meaning and the value of the original document, considering the liability for the transformation, and assuring the reproducibility of the semantic transformation.

For more details see in Appendix A4 chapter 13.4 Service State Diagram. The full process depicted in the diagram considers 4 elements in the time line: (1) preconditions before patient access happens, (2) actions in national PA, (3) PAC services, (4) final use of the received document. The vertical column in the Service State Diagram considers the different processes and actors involved for which the functional requirements are defined (in Annex 2.8).

7.3 Service Functional Requirements

The scope of these functional requirements covers 3 separated services:

- Patient access requesting the translation of a PS
- Patient access requesting the translation of an eP
- Patient access requesting for the most suitable PoC in a given country

Service parameters are:

- Country of Patient identification/authentication: Country A
- Language of the stored docs/service: Country A
- Selected output language: Country B
- Location of documents information: Country A

In the document we refer to “Translation responsible” as the role responsible for the translation of the PS or eP to Country B language. This role can be played by one of the following actual actors at the technical level; this decision will be taken at the architectural design phase. Namely, the alternate “Translation responsible” actors are:

- NCP A
- Central Service (with real time access to MTC, or with buffered MTC in the NCPs)
- NCP B

Steps	Actions
	UC.PAC.1: PA in country A & translation to country B language Requirements Fulfillment, Cross border distribution 1 and 2
	FR01 & FR08 Fulfillment where the location parameters are: • Country of Patient identification/authentication : country A • Language of the stored docs/service : country A • Selected output language : country B • Location of documents information : country A
1	(This step is in the National Domain, and is a prerequisite for the PAC service) • The patient affiliated in Country A requests access to PS or eP in Country A, by contacting the Country A National Patient Access Service • The patient identifies himself • The National Patient Access system verifies the patient's authorization • The National Patient Access system retrieves the document
2	The Patient requests an epSOS translation of the retrieved document
3	The National Patient Access system passes the request to the epSOS NCP in Country A
4	The epSOS NCP in Country A provides a dialogue for selecting the source and target language (Language A, Language B)
5	The National Patient Access system sends the document (in Language A) to the epSOS NCP in Country A
6	The NCP-A transforms (transcodes) the document indicated (or received) from Patient Access system into a translatable epSOS pivot document and then makes this pivot document available to the translation responsible.
7	The translation responsible retrieves the epSOS MTC of Language B
8	The translation responsible translates the pivot document and makes the translated document in language B available to the NCP of country A
9	The NCP of country A conveys the information translated into the interface of the National Patient Access system
10	The patient accesses the translated document in his specific device display
11	The use case is finished/closed **EXCEPTIONS** • The translation responsible does not have access to the epSOS MTC of language B. • The translation responsible informs NCP of country A of the failure. • The NCP A cannot inform the Patient Access System about the failure.

Below, PAC functional requirements are summarized (more details available in the annex)

FR01	Type	Patient Access basic requirement
Description		The patient must have the possibility to access his own medical information available at his/her national PA service (affiliation's country) and get it translated into any epSOS country language. Specific PA services ask first their NCP-A for PS/eP translation service. As a consequence NCP-A requests a language translation. Each translation request from an NCP-A must return the specified parameters.
FR02	MAIN	Patient identification and authentication: a univocal digital ID
FR03		Trust between countries
FR04		Request from country A for a document translation
FR05		Delivered translation information is made available to country A
FR06		Information Traceability
FR07		Pairing both original documents and translations
FR08		Consultation of PoC through the patient access service: OPTIONAL
FR09	LEGAL	Data Consistency
FR10		Clear responsibility assignment for the transformation of information occurring using PAC functionalities
FR11		Hidden information should remain hidden to patients using PAC
FR012	SECURITY	Patient access to logs for his documents: OPTIONAL
FR13		Confidentiality of patient information
FR14		Integrity of information
FR015	CLINICAL	Labeling/Tagging of chronicity character of diagnosis: Out of scope. Included for future developments
FR16	SEMANTIC	Semantic compliance
FR17		Disclaimer of scope of the translation service
FR18	USABILITY	Understandable Information
FR19		Data presentation
FR20		Identification of the service accessed by Patient Access Service
FR21		PAC Service Availability
FR22		PAC response time
FR23	ARCHITECTURE	Patient Access platform accesses directly the PoC through www.epSOS.eu
FR24		Architectural design decision about the "Translation responsible" (3 options)

8 Conclusions

8.1 Stakeholders feedback on planning to pilot new services

The final decision on which new use-cases will be piloted in later phases of epSOS will have to take into account the feedback from stakeholders. For this reason the review of the deliverable by NEPC was joined with short questionnaire asking reviewers what are their plans concerning piloting new epSOS extended and added services.

We have got 9 answers from NEPC. The evaluation of the questionnaire is summarised in the next table.

	Number of PNs interested in piloting the service			**Number of PNs not interested piloting the service**
	A-pilot	B-pilot	Both A-pilot and B-pilot	
HCER	**1**	**2**	**5**	
MRO			**3**	**3**
112 Emergency			**2**	**5**
Patient Access	**2**		**7**	

The overall plans and the goal to extend the epSOS services require a solid and sustainable basis for ensuring the semantic interoperability and the security of the whole system. The specification of new epSOS services as is described in this deliverable is not sufficient to fulfil this goal and will have to further develop its security and semantic aspects. Great emphasis will have to be put on cooperation with both Security and Clinical/semantic expert groups to solve all security aspects and to improve the proposed Conceptual Information Model (CIM).

The new epSOS extended and added services and their illustrative UC's have been assessed and evaluated by the respective EG. The results are described in the next chapter.

8.2 Assessment of new epSOS services by expert groups (EG)

8.2.1 Assessment by Security EG

The security assessment is crucial in order to progress with the service specification into the phases of architectural design and later on to the testing and implementation phases. On the basis of requirements agreed in Final Security Services Specification Definition [15] only the patient or HP authorized by patient consent can decrypt the information sent from Country B back to Country A (extended security safeguards). This requirement will not be easy to implement and we can find it in all proposed service scenarios for epSOS extended services. It can be demonstrated on the Health Care Encounter Report (HCER) Service Scenario.

With respect of approved document D3.7.2 [15] section II - Security Services (page 30), when we operate with medical data used for decision making (and we suppose that HCER represents data of this type) in relation to object security life-cycle both ends MUST terminate in the Trust Zone III (PoC) - practically at the level of HP Information System which is used by subject who provides healthcare service to person in country B.

From the security point of view the proposed concept of PUSH-like communication implies next consequences:

a. Cryptographically secured protection envelopes must be used for protection of HCER data during transport from Trusted Zone III in country B to Trusted Zone III in country A.

b. Structured information correctness and semantic compliance checking could be done only in the level of Trust Zone III - practically only at the level of Information System in the PoC location or at the level of Information System of Health Professional in the country A (via which are the HCER data obtained and visualized).

c. Proposed scenario places demand on high availability OF ALL (potential) receiving parties in "countries A", i.e. practically it requires that all connected Information Systems of all Health Professionals must be in the High Availability mode. Not only country nodes (NCP), but all information systems connected to NCP in country A in role of potential recipient of HCER.

d. epSOS infrastructure (interconnected NCP with defined services) will acts as trusted repository of valid PKI certificates for secure exchange of messages with secured HCER data; "Helper Subsystem" for semantic compliance checking, formation of correct structure for HCER data (encapsulated in secure cryptographic envelope) and for creation of the "language bridge" - BUT the translation of the HCER data content from original (country B) language to defined/requested languages (English and language of country A) MUST be done at the level of PoC (country A) or at the level of destination information system of health professional in country A.

From practical point of view we expect that security technology for Data Exchange Security Services will be based on Asymmetrical Cryptographic Approach (PKI - Public Key Infrastructure).

To reach (practically) High Availability Mode at the level of all HPs information systems interconnected to epSOS will be extremely demanding. Financial demands for this status are enormously high and we suspect that cannot be allocated at requested level at all.

One from possible solutions should be implemented via establishing of High Available "Secure Communication Buffer" in the country A (connected directly next to NCP) that will be able to continuously (24x7 mode) receive secured data message containing HCER from PoC in country B. Secure Communication Buffer will monitor periodically availability of information system at the level of defined (needed) HP in country A and if desired system is available Secure Communication Buffer will deliver message with protected HCER. Secure Communication Buffer will deals with all necessary tasks required for confirmation of HCER delivery (after information system of health professional in country A receives the HCER secured by protection envelope).

Other possible solution should be implemented by change of communication paradigm - from push to pull scenario. But this way requires common mutual understanding about acceptable working timeframes in which the system in country B is ready to accept "request for sending of HCER data file" (if patient turns back to country A with short written paper), "navigation and ID data" that health service will provide in country B and there is HCER which holds information which patient wish to provide to HP in country A.

The fact that HCER data must be transmitted securely from Trusted Zone III in country B to Trusted Zone III in Country A and that this transfer requires mandatory access and

confirmation of some crucial PKI related information (in parallel to patient consent) is missing from extended service scenario description.

Presented HCER service scenario description is incomplete from this point of view and there is the danger that can be interpreted in wrong way - due to the fact that structured information correctness and semantic compliance checking MUST be done before HCER data is "sealed" into the protective cryptographic envelope (at the level if information system of the HP in country B). When HCER is sealed in to protective envelope and this protective (transport) envelope is taken for delivery by NCP in country B (via device at epSOS system level) any semantic or "structural" inspection in relation to HCER data content is impossible (due to the fact that HCER is protected and protection envelope could be opened only in the Trusted Zone III in country A).

8.2.2 Assessment by Clinical/ Semantic EG

The CS EG in the process of new epSOS services development follows the approach were CS EG works parallel on two tasks – on analysing and fixing known issues gained from epSOS phase 1 and then on refining and adjusting requirements of new services in the way that including them into epSOS phase 1 model a unique harmonized model will arose.

In this sense the model described in the Appendix 5 is to be considered as the first version of "published" Conceptual Information Model covering new epSOS services. All information related to the Conceptual Information Model (and related constrains) have to be subject of further revisions and possible changes in the refinement process performed firstly by clinical expert team and afterwards by other teams of CS EG.

Tasks accomplished by the C/S EG during the new epSOS services development have been:

- Review of the first and second drafts of the deliverable D 1.4.3
- harmonization and refinement of new uses cases and epSOS phase 1 Conceptual Information Models
- revision of implemented information models
- specification of (possible) new documents
- revisions and maintenance activities of the epSOS MVC
- revision of the Centralized Semantic Services requirements

The important lecture learned from epSOS phase 1 is, that we have to expect many new inputs and incentives throughout all next phases - design, testing, installation and piloting. This will be accomplished by permanently collecting feedbacks and proposing relevant actions.

This activity will involve several focus teams for the purpose of

- Assuring the consistency of the conceptual data models and terminologies used
- Supporting the revision of the currently implemented documents (CDA) and the specification of possible new ones.
- Assuring suitable Semantic Services
- Monitoring (within the semantic consistency goal)
    - the compliance of the developing project to specification
    - the compatibility of the project at MS level among all MS partners
    - the sustainability of the project at EU level and at MS levels
    - the existence and the continuity of necessary clinical/organizational support at MS level

All that will be performed along the whole epSOS project life cycle - starting in the process of use cases specifications definition and lasting till the end of the epSOS project. One of the crucial issue is to continue in further development of the Conceptual Information Model and respective data sets and catalogues both for epSOS phase 1 and epSOS phase 2 use cases.

9 Annex

9.1 References

[1] D1.4.1 EED SERVICES including use cases for all services: Use-cases descriptions
[2] D3.1.2 Final Definition of functional service requirements – ePrescription, v:1.2, 26.03.2010
[3] D3.2.2 Final Definition of functional service requirements – Patient Summary
[4] D3.B.1:epSOS Implementation Strategy v.0.12, 18.4.2011
[5] Change Requests and Recommendations for epSOS phase 1 use cases and Specs – Semantic Services, v:0.19.8.2011
[6] T3.A.1 epSOS phase 1 use cases and specs review, draft v0.2,25.10.2011
[7] D2.2.2 epSOS “end-to-end” Services Model Definition V:0.6, 3.11.2011
[8] D1.4.2 Country Status Outline and template specification
[9] D2.2.1 EED POLICY including epSOS policy options
[10] D1.1.1 EED REGFRAM including legal and regulatory requirements EU Level
[11] Description of Work, Enlargement of the pilot "epSOS" on eHealth Interoperability for patient's summaries and ePrescription
[12] D3.5.2 Semantic Services Definition, 31.5.2010
[13] D3.9.1 – Appendix B1 epSOS Semantic Implementation Guidelines
[14] D2.1.1 Legal requirements, 2.11.2011
[15] D3.7.2 Final Security Services Specification Definition, December 2001

9.2 Glossary

PAC	epSOS Patient Access Service
Language A	Language (used in Country A) in which the original documents (on which the Patient Summary, eP or other epSOS documents are based) are created and stored by Country A.
Language B	Language different from Language A, into which the PS, eP or other epSOS documents are translated by an epSOS service
Translation responsible	Instance that fulfils the task to translate the pivot clinical original document in epSOS CDA format into another CDA document in language B. This instance can be NCP A, NCP B or epSOS Central Services.

9.3 Abbreviations

CA	Certification Authority
CDA	Clinical Document Architecture
CIM	Conceptual Information Model
CI	Competent Institution
CoT	Circle of Trust
C/S TFG	Clinical/Semantic Task Force Group
DoW	Description of Work
D.x.y.z	Deliverable from WPx.y
EED	epSOS Evolving Document
EES	epSOS Extended Services
eD	Electronic Dispensation

EHR	Electronic Health Records
eP	Electronic Prescription
epSOS	Smart Open Services for European Patients
EU	European Union
PAC	epSOS Patient Access [Service]
F2F	Face to face meeting
FR	Functional Requirement
FWA	Legal Framework Agreement
GP	General Practitioner
HC	Health Care
HCER	Health Care Encounter Report
HCO	Health Care Organisation
HIO	Health Insurance Organization
HP	Health Professional
HProv	Health Care Provider
HW	Hardware
ICT	Information and Communication Technology
ID	Identity
IPSec	Internet Protocol Security
JWG	Joint Working Group WP3.8/3.9
KT	Key Task
LSP	Large Scale Project
MRO	Medication Related Overview
MTC	epSOS Master Translation/Transcoding Catalogue
MVC	Master Value Sets Catalogue
NAB	National Authority Beneficiary
NCP	National Contact Point
NCP-A	National Contact Point in country A
NCP-B	National Contact Point in country B
NDA	Non-disclosure Agreements
NEPC	National epSOS Coordinator
PAC	epSOS Patient Access Service
PHR	Personal Health Record
PKI	Public Key Infrastructure
PN	Participating Nation
PoC	Point of Care
PS	Patient Summary
PSAP	Public Safety Answering Point
PSB	Project Steering Board
QA	Quality Assurance
SLA	Service Level Agreement
SP	Security Policy
SSL	Security Socket Layer
SW	Software
TPM	Technical Project Management
TSL	Trusted Service List
WG	Working Group
WP	Work Package

10 Appendix A1 - Healthcare Encounter Report (HCER) Service Specification

This service specification has started as covering the Patient Summary (PS) Extension use case description of deliverable D1.4.1 that aims to inform country A after a Patient Summary has been requested of the healthcare event that took place abroad. But also for other epSOS use cases this need for informing country A on the healthcare encounter in country B has emerged.

The Healthcare Encounter Report service not only supports the patient summary extension use case, but also the ePrescription extension and the 112 emergency use cases. Therefore this service description not only covers the patient summary extension, but also the ePrescription extension and the part of the 112 emergency use cases where information about the emergency encounter is sent back to country A.

The definition of a healthcare event can be broad. The HCER service is designed to offer a health professional in country B flexibility to record a wide range of medical information, enough to cover the most basic healthcare encounters. The service offers country A the basic contact information of the health professional in country B together with the medical information gathered during the healthcare encounter. Informing country A of a healthcare encounter in county B is, of course, done with consent of the patient.

10.1 Basic process

The following basic steps are needed to support this functionality:

- Health professional identification and authentication
- The patient's identity has to be validated in country B, the patient's identifier(s) from country A must be used for sending the HCER.
- The patient must agree with sending the HCER to country A (patient consent in country B).
- Country A needs to accept and process the HCER sent by country B, compliant with legislation of its own country.

10.1.1 Health professional identification and authentication

The health professional in country B needs to be identified and authenticated before any epSOS service can be used. This identification and authentication is done according to country B policies.

10.1.2 Patient identification

Before country A can be informed of a healthcare event, the patient first has to be identified by the health professional in Country B. When the identity of the patient is confirmed, the identifier of the identity must be used to inform Country A on which patient the sent HCER is about. This is done via the epSOS patient identification service.

10.1.3 Patient Consent

The patient from country A should consent with sending the HCER. The epSOS patient consent service is not used for sending the HCER, as the consent of the patient in country A is

not applicable, but the consent the patient has given in country B. This consent process is a country B policy and out of scope for epSOS.

10.1.4 Sending and handling of the HCER

Country A needs to be able to accept and process the HCER. How this is done is up to country A's policies and out of the epSOS scope. The sending of the HCER is done via the HCER service, in which the HCER is send (pushed) from NCP B to NCP A. After receiving the HCER, NCP A has to send an accept acknowledgement back to NCP B.

In principle the NCP of country A cannot store, and thus be responsible for, the HCER and the medical information it contains. Here some suggestions are described how country A could process the HCER (but country A is free to come up with other procedures to handle the HCER):
Forward the HCER to a health professional the patient has a (long-term) treatment relationship with, such as his/her GP, or the health professional responsible for the patient summary
Forward the HCER to the patient's own personal health record

As described above, the HCER service not only supports the patient summary extension use case, but also the ePrescription extension and the 112 emergency use cases. Therefore all three variants are described below.

Patient Summary Extension
The HCER supports the patient summary extension use case UC.PS.6 as described in D.1.4.1. In this use case, after a PS is retrieved by country B, country A is informed on the healthcare encounter in country B, so country A is able to update the history of the patient summary (according to its own policies).

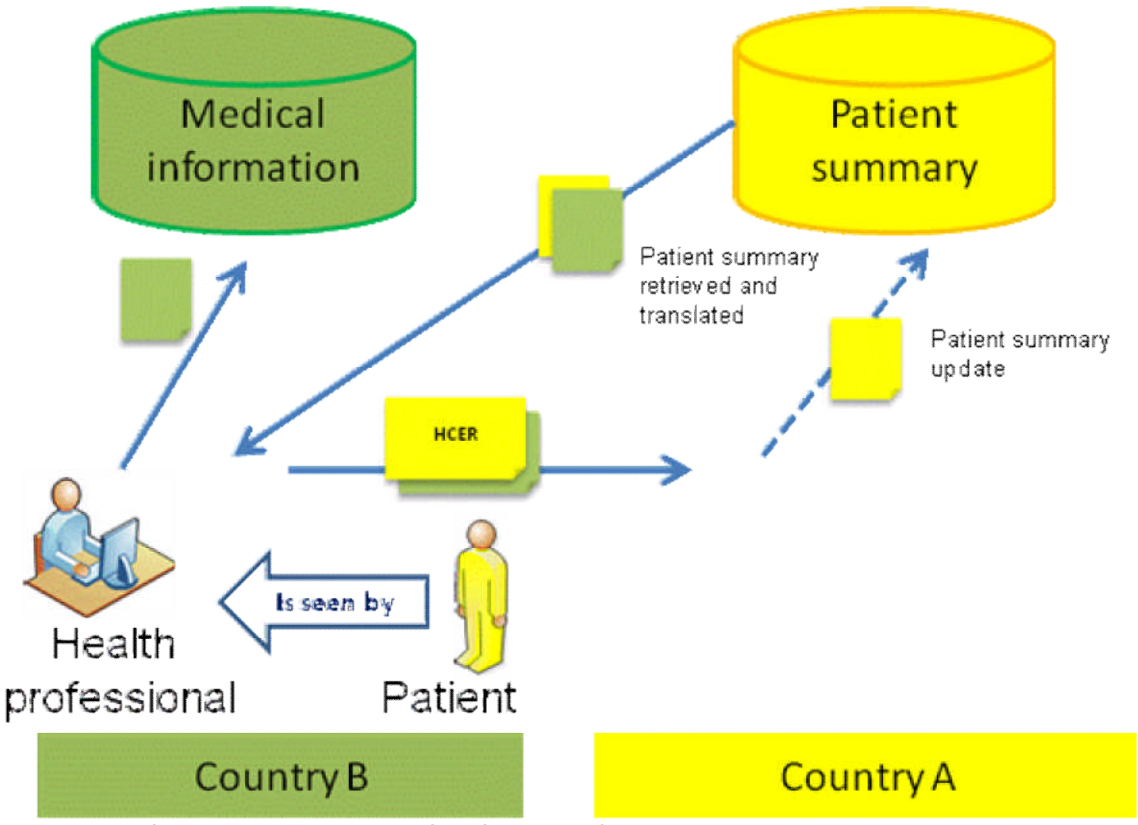


Figure 1 : Patient Summary Extension (UC.PS.6)

In the figure above a patient from country A is seen by a health professional in country B. The PS is retrieved from country A by the health professional in country B[3]. After seeing the patient, a HCER is sent to country A, so the medical information of the patient generated in country B is also available for country A. Depending on the information in the HCER, country A may decide to update the PS.

ePrescription Extension

The ePrescription extension described as UC.MED.2 in D1.4.1 is covered by the HCER service. In this use case medication is prescribed and dispensed in country B. A report of the prescription and the dispense event is made available for country A, so country A is able to update the history of prescription/dispensation (according to its own policies). Before prescribing and dispensing the medication, the prescriber and dispenser can retrieve the MRO from country A.

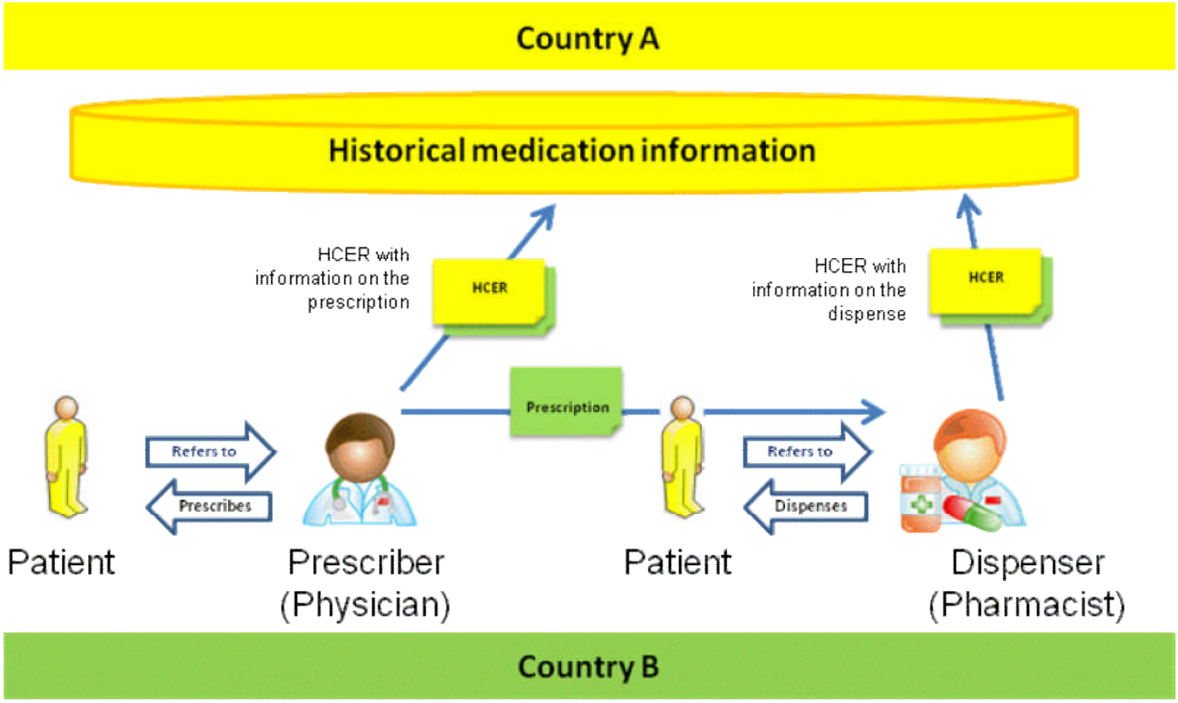


Figure 2: Medicine newly prescribed in country B (UC.MED.2)

112 Emergency support

Also additional requirements from the 112 Emergency use case on informing country A are described in this chapter. In this use case there is a 112 emergency event in country B, where a health professional (from the emergency call centre, ambulance or emergency department in the hospital) access the emergency data set from Country A. At one point in time, one wants to notify country A on this event. A report of 112 event is made available for country A, so country A is able to update the history of the Patient Summary (according to its own policies).

[3] Note that this is *not* a pre-requisite for sending the healthcare event notification to country A

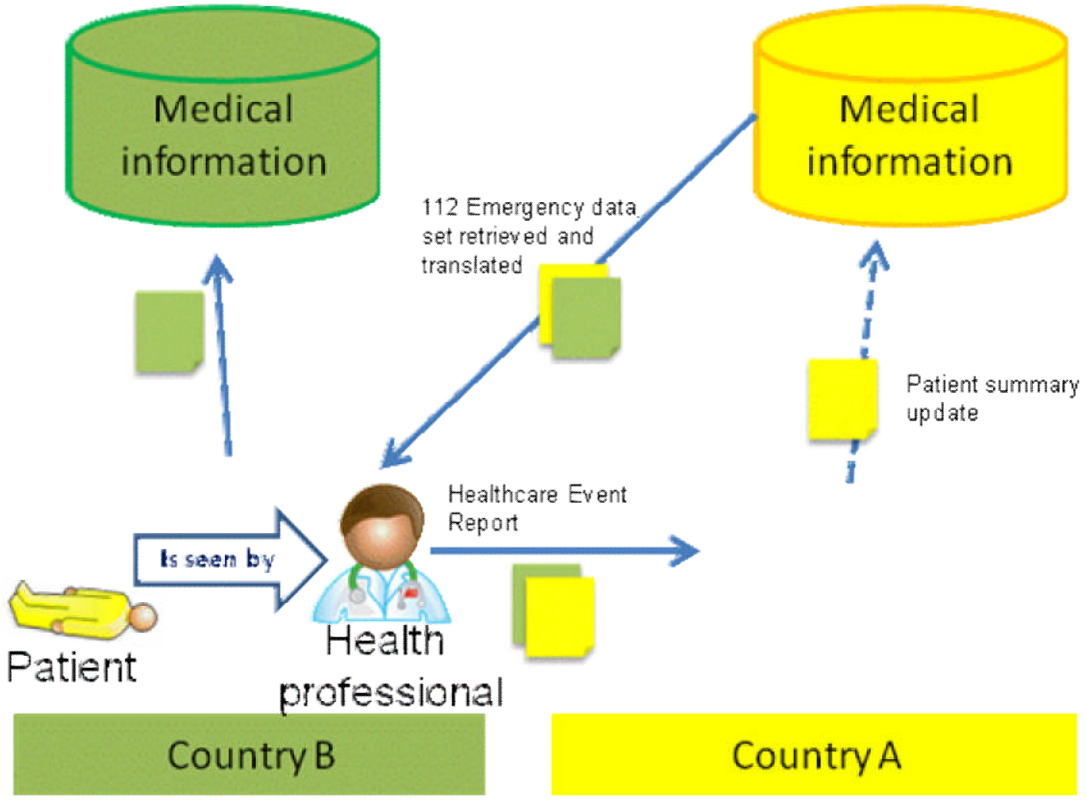


Figure 3: 112 Emergency use case

10.2 Selected Use Case Review and Assessment of PN's Readiness

The assessment of the readiness of Participating Nations (PNs) is based on the deliverable D1.4.2 and use case readiness statements of NEPCs done in as part of the activities of the KT1.4.1 use case descriptions.

As the availability of the Patient Summary in country A is not a prerequisite for sending back the HCER, the readiness of any Participating Nation has only to do with the possibility to notify country A of a healthcare event abroad.

Important issues that affect this use case are those related to patient identification and patient consent, and management of data originated from another country and how to include the data into the systems whilst being compliant with the relevant legislation.

Based on the information in D1.4.2, very few PN are currently able to incorporate information from external sources both in terms of capabilities of information systems and procedures. This means that it could be that only few participating nations are able to pilot receiving the HCER, and thus can implement the patient summary extended use case and the extended ePrescription use case in the role of country A. The 112 emergency use case is, in principle, independent of the HCER service, but in only few cases can country A be informed on what has happened in country B, as not every PN supports receiving the HCER at this moment.

It seems unlikely that the national or local health information system enables an export of an HCER. Therefore it seems more likely that the health professional from country B can fill in a HCER form via the epSOS portal, which is then converted to a document and sent to country A.

Note: As countries have been asked on the use case readiness, a new analysis of the service readiness might be a good idea, as the pre-existence of the Patient Summary services is not necessary at all and possibilities to process the HCER might not have been explored.

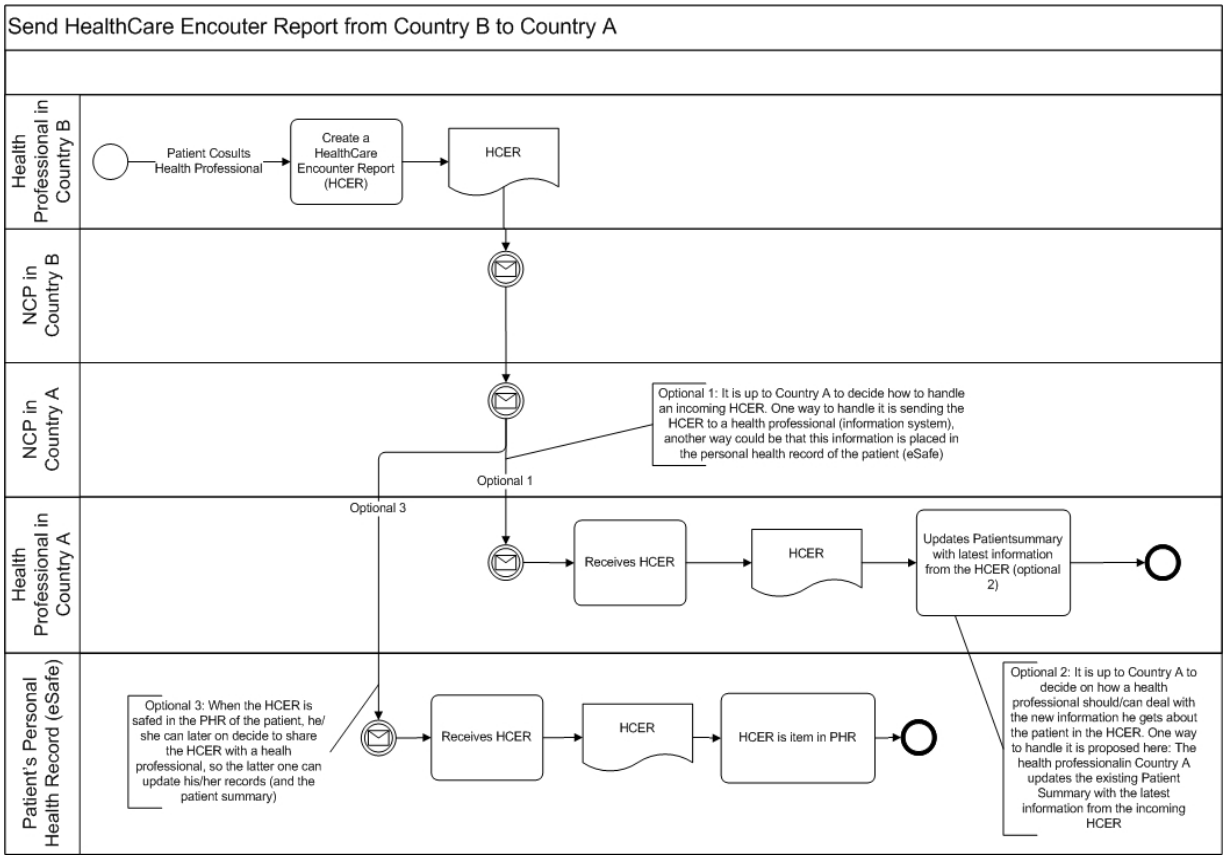
10.3 Service Pre-requisites

The service precondition consists of the following elements:

- Country A is responsible for keeping the medical information of its own patients up-to-date. These specifications do not make any assumptions on how medical data is managed within a country A.
- Country A must provide, maintain and support the NCP supporting communication of the information identified in this section with country B and vice versa and that there must be a chain of trust between system actors in this process. Transaction logging and transport security are available in both country A and B.
- Services for identification and authentication of health professionals are available in country B, in a way country B can provide country A with sufficient information to authorize the data access of the health professional of country B.
- Patient identification service is available: Country A shall offer the health professional in country B means to validate the identity of the patient.
- Legal compliance: Original medical document ownership (owner is both the patient and the entity where the document is stored) and medical / legal validity of transformed document shall be analysed according to the different PN's laws.
- Semantic interoperability of structured clinical content: information sent is understandable (in the correct context) for the receiver.
- Scalability: The implementation should scale well with respect to the number of documents exchanged

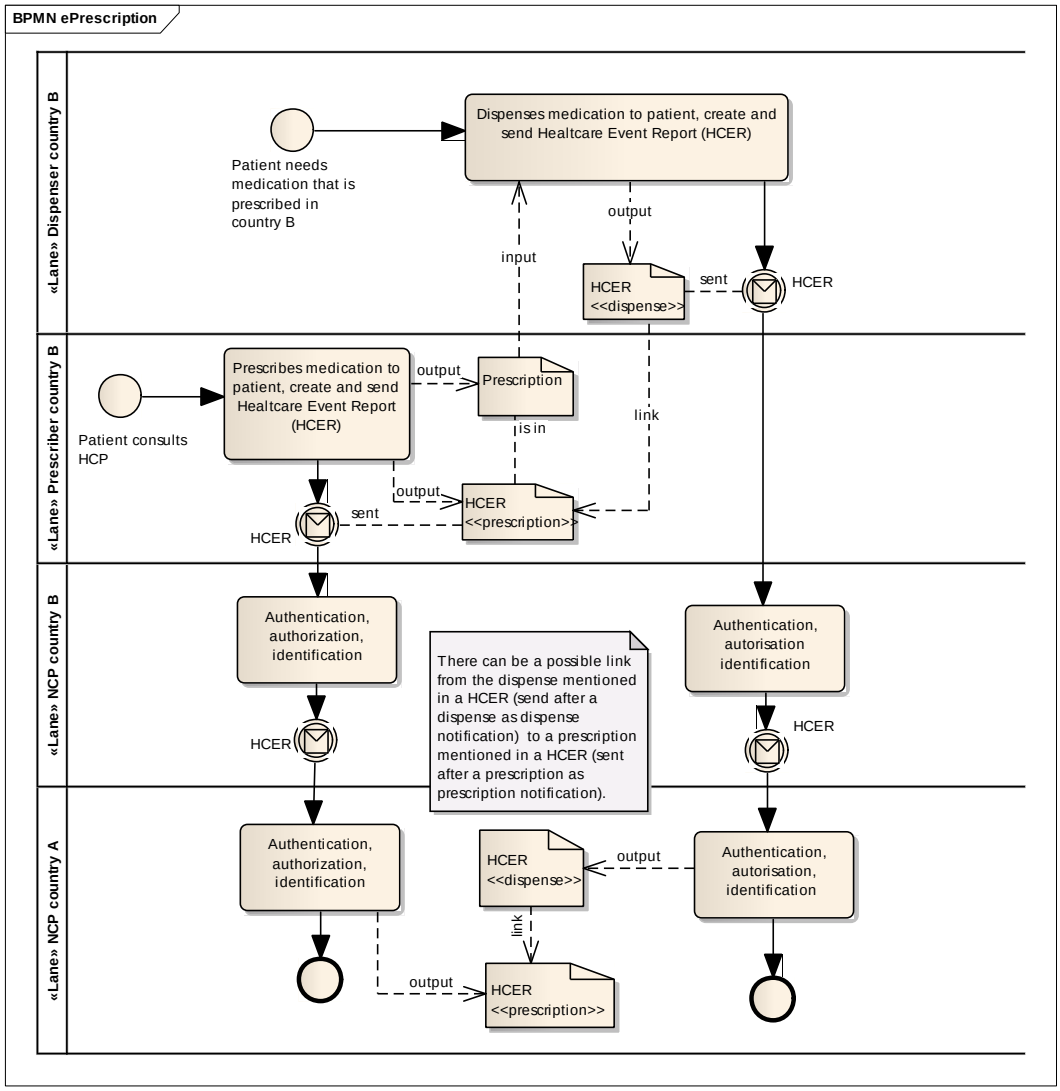
10.4 Service State Diagram

In this section the state diagram of the HCER service is depicted.



Note that the health professional in country B has to be identified and authenticated and he/she has to validate the identity of the patient and the existence of his/her consent. These steps are not depicted in the diagram above. Also: after the NCP in country A has received the HCER, it is the responsibility of country A to take further action. Country A is entitled to take no further action. This is a decision to be taken by country A and is out of scope of the epSOS phase 2 specifications.

In the case both medication is prescribed and dispensed in country B, two HCER documents could be sent to country A; one with a report of a prescription being written, and later on a second one with a report of a dispense event based on the prescription. Again, it is up to country A how to handle the HCERs, but the HCER data set offers the possibility to link the dispense data elements in the second HCER with the prescription data elements in the first one (more or less the same way the epSOS phase 1 eDispense can be linked to an epSOS phase 1 ePrescription). This process is depicted in the diagram below.


BPMN ePrescription
«Lane» Dispenser country B
«Lane» Prescriber country B
«Lane» NCP country B
«Lane» NCP country A
Patient needs medication that is prescribed in country B
Dispenses medication to patient, create and send Healtcare Event Report (HCER)
output
input
HCER <<dispense>>
sent
HCER
Patient consults HCP
Prescribes medication to patient, create and send Healtcare Event Report (HCER)
output
Prescription
is in
link
output
HCER <<prescription>>
sent
HCER
Authentication, authorization, identification
HCER
There can be a possible link from the dispense mentioned in a HCER (send after a dispense as dispense notification) to a prescription mentioned in a HCER (sent after a prescription as prescription notification).
Authentication, autorisation identification
HCER
Authentication, authorization, identification
HCER <<dispense>>
output
Authentication, autorisation, identification
link
output
HCER <<prescription>>

10.5 Service Functional Requirements

This section covers two perspectives of functional requirements, those from the viewpoint of (the health professional of) country B and those of the perspective of country A.

HCER-FR01	Health professional country B fills in HCER
Description	As it seems unlikely that any country B healthcare infrastructure offers the possibility to send an HCER document to NCP B, the health professional must be able to fill in a HCER template in the epSOS portal (of the NCP) he/she uses.
Associated Goals	Record the information for the HCER
Actors	Health professional NCP B

HCER-FR02	Country A is informed of treatment event in country B
Description	The created HCER must be sent to Country A, respecting the specified requirements in epSOS for sending a document from one PN to another PN (meaning patient identification, HP identification, permission to send and receive medical information about the patient, etc.) Country A must send a confirmation back to Country B after successfully receiving country B's HCER, stating that the document has been received in a good manner. What happens with the information after is it is received by NCP A, is out of scope of epSOS.
Associated Goals	Inform country A of the treatment event in country B NCP-B must be informed about the successfully delivered document.
Actors	NCPs

10.6 Service ID Management Requirements

HCER-FR03	Health professional identification, authentication and authorization
Description	The health professional must be univocally identified and authenticated and must be authorized based on his/her role/profile.
Associated Goals	• To provide security to the process • To ensure that the health professional is legally allowed to perform the functionalities described in this document
Actors	• Health professional • NCPs
Preconditions	• Pre-existence of healthcare professional authentication mechanism in country B • Authorization mechanism in country A (based on the information that is offered by country B).

HCER-FR04	Patient identification
Description	The patient needs to be univocally identified in a reliable way (unique and unequivocal id) to allow the health professional to consult his information[4] (after his explicit consent or authorisation). For functional and security purposes in the information usage, the univocal 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. The process of identification (positive or negative) must be recorded.
Associated Goals	To have certainty of the identity of the patient in both country A as in country B.
Actors	• Patient • Health professional • NCPs

[4] the necessary datasets for the HP

10.7 Service Legal Requirements

HCER-FR05	Patient consent
Description	The patient consent is considered to be the legal basis for lawfully processing his/her medical data by any ICT system. Consent must be given in Country B per request and informed, specific and freely given.
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	Patient Health professional

HCER-FR06	Information Traceability
Description	The information describing the process and the data involved in the process must be retrievable. This includes information such as the patient, the health professional, the exact place and time where the treatment event took place and all the medical information involved. Some of this information is not necessarily contained in the datasets exchanged between countries (as they have been considered maximum datasets) but must be able to be traced and recovered.
Associated Goals	Security reasons Legal reasons
Actors	Health professional NCPs

10.8 Service Security Requirements

HCER-FR07	Trust between countries
Description	All the countries involved in the project are integrated into one circle 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 health professional will be univocally identified and authenticated in his local system and must be identified based on his/her role/profile. On the other hand, the Health Care Provider provides the health professional a status, a function, an authentication from which the health professional trust is derived. Furthermore, Health Authorities/Institutions assign and assure the status, the function, and sometime the authentication of the health professional
Actors	NCPs

10.9 Service Clinical Requirements

HCER-FR08	Correct receipt and interpretation of sent data
Description	A PN that receives a HCER must be able to interpret and show the sent minimum data set correctly at all times. If sent data contains more than the minimum dataset and belongs to the maximum data set, this data belonging to the maximum dataset needs to be interpreted and shown correctly if the system is able to interpret and show the data. The receiving service must handle any data that belongs to either the minimum dataset or the maximum data set or to both correctly, meaning that although the receiving service or system might not use the data, it should by no means cause an error in the receiving service or system.
Associated Goals	To ensure that sent data does reach country A in a good manner as much as possible
Actors	NCP A

HCER-FR09	Link HCERs
Description	Country A has to be able to relate the prescription and dispense to each other to see if a prescription actually has been dispensed. In country A it should be possible to relate the information of one HCER with another HCER.
Associated Goals	• Link the dispensed information to the prescription • To have information complete and reliable
Actors	NCP A, NCP B

HCER-FR10	Viewing original documents
Description	Patient and health professional in country A must be able to consult a copy of the original HCER provided by country B (with NO epSOS semantic transformation).
Associated goals	• For safety reasons. It is possible that for instance a brand name of a medicine is going to be changed in case of a prescription/dispense • Traceability reasons
Actors	NCPs

10.10 Service Semantic Requirements

HCER-FR11	Semantic compliance
Description	The HCER must be filled with data that structured using international code systems as much as possible, or using national code systems for which a mapping exists or can be created to international code systems.
Associated Goals	• International standardization to ensure semantic understanding between users of communicating systems. • Safety reasons
Actors	NCPs Health professional

HCER-FR12	Structured information
Description	The information sent to another country must be structured, 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.
Associated Goals	• Guarantee the safety of the patient through a proper understanding of the received information • Ensure safe delivery of care to patients thanks to the faithful exchange of meanings between systems and between systems and people
Actors	NCPs Health professional

HCER-FR13	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 reason • Guarantee the safety of the patient through a proper understanding of the received information • Ensure safe delivery of care to patients thanks to the faithful exchange of meanings between systems and between systems and people
Actors	NCPs Health professional

10.11 Service Usability and Data Presentation Requirements

HCER-FR14	Understandable Information
Description	NCP-B must send the HCER in an intelligible way to NCP-A. If the information is sent from NCP-A to the health professional, the information must be presented to him as decided by country A (in order to ease the process for the health professional, it is recommended that the information is presented to him the way it is normally done).
Associated Goals	• Provide ease of processing incoming data for Country A. • To provide the health professional with the necessary information and in a manner he is used to. • Guarantee the safety of the patient through a proper understanding of the received information
Actors	NCPs
Precondition	It has to be known to NCP-B that it can and is allowed to send the HCER to NCP-A

10.12 Service Non-functional Requirements: Service Level Requirements

HCER-NFR01	Service Availability
Description	• Availability means the property of being accessible and usable upon demand by an authorized entity (see definition ISO 7498-2:1989). • There are different causes for technical unavailability (of communication, National Contact Points, local systems…)of the epSOS LSP service as: o failure o unplanned stop (bug, random error) o partial planned stop (not optimal running) o planned stop (maintenance, update) Every event that causes unavailability will be analysed. Each service interruption will be detected as soon as possible. The origin of the failure (health information system, National Contact Point system, central broker ...) will be explained. When there is a transition to a degraded mode, the suitable alerts will have to be defined and particularly the procedure for using a degraded mode. • Emergency mode: A special focus is required for the procedure in case of a patient emergency such as an emergency mode (like a collapsed patient or an accident where the patient is severely injured). • Indicators: The availability of the system will be measured in order to evaluate the performance of the system (time available out of total time(%), downtime on a period
Associated Goals	The system will be available at any time, 24h a day, 7 days a week. Therefore, the requirement is a truly continuous availability.

HCER-NFR02	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 circle of trust. The response time could vary depending on the chosen architecture; that is, whether it is centralized or distributed and whether there are multiple sources of information or just one. An acceptable response time not only applies to the receipt of the information, but also to the identification and authentication of health professional and patient. The system should therefore provide an end to end response time within a few seconds, possibly no more than 10 seconds[5].

[5] The feasibility of this will depend on the technical group. Also, 10 seconds is not a service level agreement but a proposal of threshold

HCER-NFR02	Response time
Associated Goals	• Information has to travel from one country to another. An acceptable time response not only applies to the receipt of information, but also to the identification and authentication of health professional and patient • 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

10.13 Additional Architecture NCP/Central Service Requirements

HCER-NFR03	New document type
Description	New document type Healthcare Encounter Report is sent by country B.
Associated Goals	The HCER is a newly introduced document type in epSOS phase 2. National Contact Points and Central Services need to be adjusted to be able to handle this.
Actors	NCPs

HCER-FR14	Forwarding HCER
Description	Depending on the internal process in country A, the received HCER in principle cannot be stored at the NCP and therefore has to be forwarded to, for example, a health professional (information system) or the personal health record of the patient.
Associated Goals	• Having up-to-date information in country A. • Not making country B responsible for the availability of healthcare information on foreign patients. • Not making the NCP responsible for the availability of medical data
Actors	NCP A Healthcare ICT infrastructure of country B

11 Appendix A2 - Prescription Extended Service Specification: Medication Related Overview

The Medication Related Overview (MRO) is a document for informational purposes only that supports all possible information that might be needed in the process of prescribing, dispensing (and possibly even administering) medication to the patient in a foreign country.

The minimum set of medical information in the MRO consists of the coded prescriptions and medication dispenses available in country A (as part of the Patient Summary). Other useful information for the medication process, such as allergies and intolerances, are in the extended data set of the MRO.

11.1 Basic process

The MRO can be used both in a situation where the prescription comes from country A (epSOS phase 1 ePrescription) as the case where the medication is prescribed by a prescriber in country B. Health professionals in country B access the MRO of a patient affiliated with country A.

The following basic steps are needed to support this functionality:

- Health professional identification and authentication
- The patient's identity has to be validated in country B, the patient's identifier(s) from country A must be used for retrieving the MRO.
- The patient must agree with sending the MRO to country B (patient consent in country A).
- Country B requests the MRO from country A. Country A processes this request and sends the MRO to country B.

11.1.1 Health professional identification and authentication

The health professional in country B needs to be identified and authenticated before any epSOS service can be used. This identification and authentication is done via country B policies.

11.1.2 Patient identification

Before the MRO can be retrieved, the patient first has to be identified by the health professional in Country B. When the identity of the patient is confirmed, the identifier of the identity is used to request the MRO is Country A. This is done via the epSOS patient identification service.

11.1.3 Patient consent

The health professional's permission to access the patient's medical data is verified through country A, the national security policy of the specific country, and, if available, through a patient privacy policy. This is done via the epSOS patient consent service.

11.1.4 Requesting the MRO

Accessing the MRO service from country A is role-based. In practice various different health professional roles in country B (e.g. physicians, pharmacists, nurses) might want to access the MRO, but is it up to the access policies of country A which roles can request the MRO.
Two use cases have been described in D1.4.1 in which the MRO could be accessed. These two variants of using the MRO service have been described below.

MRO as addition to the epSOS phase 1 ePrescription
In a situation in which the patient has prescribed medicine in country A and wants these to be dispensed in country B with the use of the epSOS phase 1 eP service that is made up of electronic prescribing and electronic dispensing, the MRO service might give useful information for patient safety to the dispensing health professional in country B.

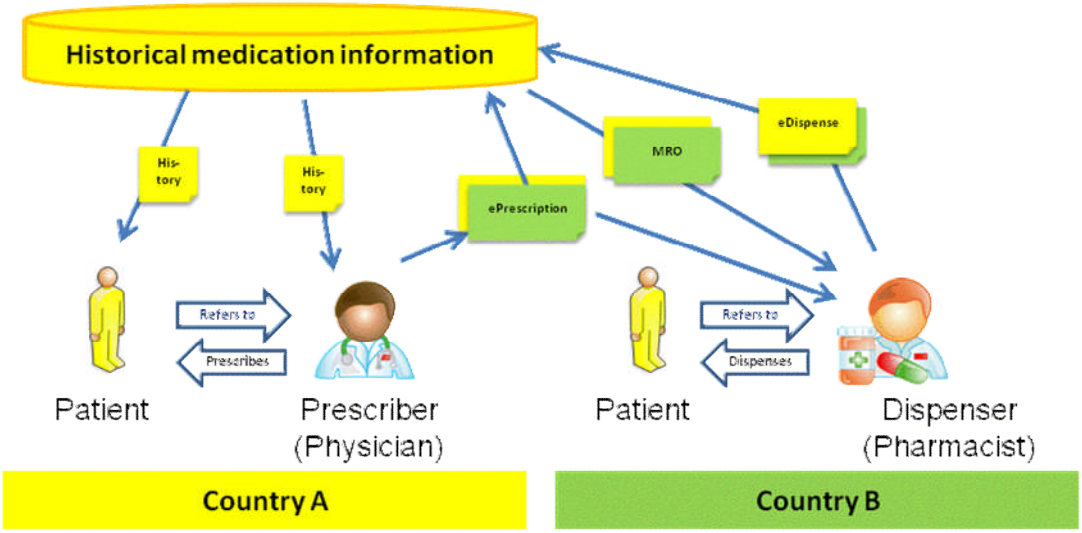


Figure 3: MRO as addition to the epSOS phase 1 ePrescription

MRO as addition to a country B prescription
In a common use case, in which the patient from country A gets medication prescribed and dispensed by health professionals in country B, the MRO could give useful information for patient safety to the prescribing and dispensing health professionals in country B. A prescriber in country B could access the patient summary as well as the MRO, but note that there is overlap between the PS and the MRO, as some medication information in the MRO can also be part of the PS.

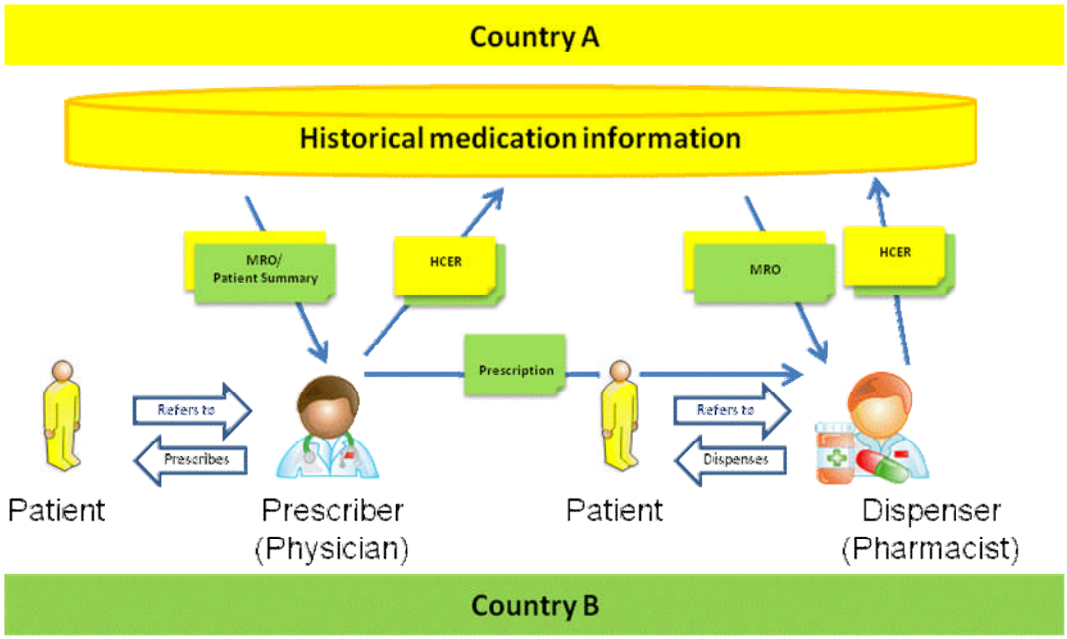


Figure 4: MRO as addition on a country B prescription

11.2 Selected Use Case Review and Assessment of PN's Readiness

Countries have been asked whether all the elements that are proposed in the MRO are present, and if so, are coded or in free text. The concluding answer on this question is that most Participating Nations do not have these elements available at the moment.

The wish to be more active in the second phase of epSOS on medication safety is somewhat tempered by the fact that only a few PN's use medication related overviews that contain coded information. Since in epSOS translation can only be achieved by transcoding, this fact offers severe limitations on pilot possibilities.

Therefore the minimum set of medical information in the MRO consists of the prescriptions and medication dispenses. Other relevant information for medication safety is part of the extended data set, which should enable more countries to implement the service (as country A).

11.3 Service Pre-requisites

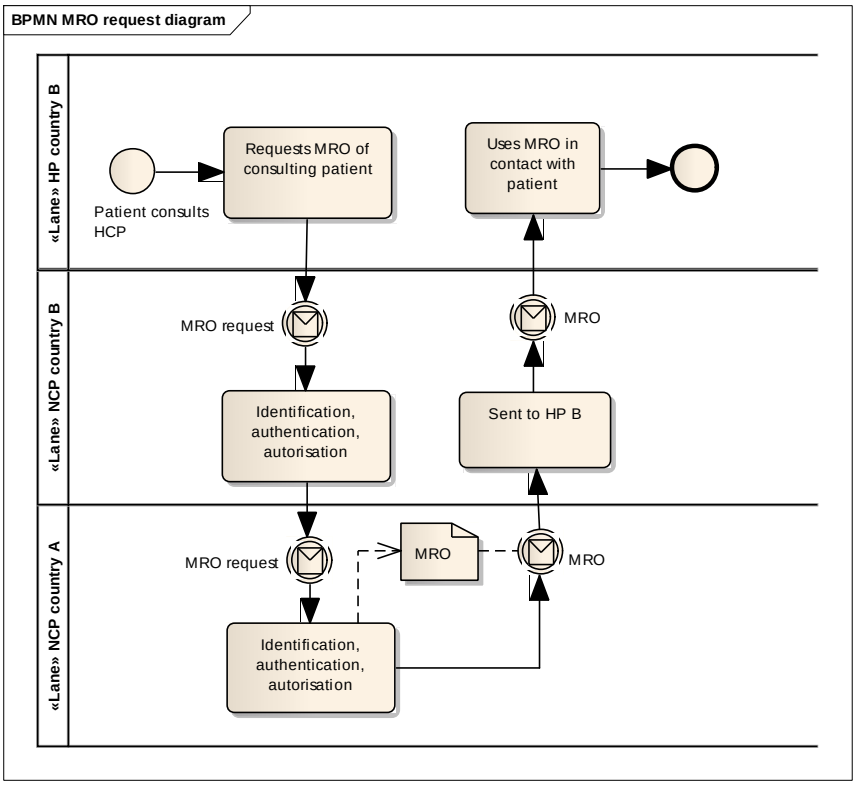
In order for the use case to take place, several preconditions are needed:

- Country A is responsible for keeping the medical information of its own patients up-to-date. These specifications do not make any assumptions on how medical data is managed within a country A.
- Country A must provide, maintain and support the NCP supporting communication of the information identified in this section with country B and vice versa and that there must be a chain of trust between system actors in this process. Transaction logging and transport security are available in both country A and B.
- Services for identification and authentication of health professionals are available in country B, in a way country B can provide country A with sufficient information to authorize the health professional of country B.

- Patient identification service is available: Country A shall offer the health professional in country B means to validate the identity of the patient.
- Legal compliance: Original medical document ownership (owner is both the patient and the entity where the document is stored) and medical / legal validity of transformed document shall be analysed according to the different PN's laws.
- Semantic interoperability of structured clinical content: information sent is understandable (in the correct context) for the receiver.
- Scalability: The implementation should scale well with respect to the number of documents exchanged

11.4 Service State Diagram

Below is shown the state diagram of of the process of requesting the MRO of country A by a health professional in country B.



11.5 Service Functional Requirements

This section covers two perspectives of functional requirements, those from the viewpoint of (the health professional of) country B and those of the perspective of country A.

MRO-FR01	Country A offers access to medication related information
Description	An overview of all relevant and available information needed in the medication process is available for request by an health professional in country B via the MRO service.
Associated Goals	• Patient safety when prescribing, dispensing or administering medication in country B.
Actors	• NCP A • Health professionals (information systems) in country A

MRO-FR02	Health professional in country B requests the MRO
Description	Via the NCP of country B, a health professional can request the MRO of a foreign patient at the MRO service of the patient's country of affiliation (country A).
Associated Goals	• Patient safety when prescribing, dispensing or administering medication in country B.
Actors	• NCPs • Health professional in country B

11.6 Service ID Management Requirements

MRO-FR03 (=HCER-FR03)	Health professional identification, authentication and authorization
Description	The health professional must be univocally identified and authenticated and must be authorized based on his/her role/profile.
Associated Goals	• To provide security to the process • To ensure that the health professional is legally allowed to perform the functionalities described in this document
Actors	• Health professional • NCPs
Preconditions	• Pre-existence of healthcare professional authentication mechanism in country B • Authorization mechanism in country A (based on the information that is offered by country B).

MRO-FR04 (=HCER-FR04)	Patient identification
Description	The patient needs to be univocally identified in a reliable way (unique and unequivocal id) to allow the health professional to consult his information[6] (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. The process of identification (positive or negative) must be recorded.
Associated Goals	To have certainty of the identity of the patient in both country A as in country B.
Actors	• Patient • Health professional • NCPs

11.7 Service Legal Requirements

MRO-FR05	Patient consent
Description	The patient consent is considered to be the legal basis for lawfully processing their medical data by any ICT system. Consent must be given in Country B per request and informed, specific and freely given.
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	Patient Health professional

[6] the necessary datasets for the HP

MRO-FR06	Information Traceability
Description	The information describing the process and the data involved in the process must be retrievable. This includes information such as the health professional, the exact place and time where the prescription was made, the identification of the pharmacy where the medicine was dispensed, the health professional that dispensed it, if there was a substitution, the original prescription, the translation of the prescription from country A to country B, the epSOS format Specifically, all information that has been considered as minimum and maximum in the prescription and dispensed medicine datasets. Some of this information is not necessarily contained in the datasets exchanged between countries (as they have been considered maximum datasets) but must be able to be traced and recovered.
Associated Goals	• Security reasons • Legal reasons
Actors	Health professional NCPs

11.8 Service Security Requirements

MRO-FR07 (=HCER-FR07)	Trust between countries
Description	All the countries involved in the project are integrated into one circle 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 health professional will be univocally identified and authenticated in his local system and must be identified based on his/her role/profile. On the other hand, the Health Care Provider provides the health professional a status, a function, an authentication from which the health professional trust is derived. Furthermore, Health Authorities/Institutions assign and assure the status, the function, and sometime the authentication of the health professional
Actors	NCPs

11.9 Service Clinical Requirements

MRO-FR08	Correct receipt and interpretation of sent data
Description	The applications within the National Infrastructure that receive a MRO must be able to interpret and show the sent minimum data set correctly at all times. If sent data contains more than the minimum dataset and belongs to the maximum data set, this data belonging to the maximum dataset needs to be interpreted and shown correctly if possible. The receiving service must handle any data that belongs to either the minimum dataset or the maximum data set or to both correctly, meaning that although the receiving service or system might not use the data, it should by no means cause an error for the receiving service or system.
Associated Goals	To ensure that sent data does reach country B in a good manner as much as possible
Actors	National infrastructure country B

MRO-FR09	Original information
Description	The health professional of country B will receive the medical information in the MRO in original version, i.e. with no epSOS transformation
Associated Goals	Show original information. The MRO is not the source on which dispenses in country B may be done. The health professional needs a valid prescription for this (epSOS ePrescription or local prescription).
Actors	NCPs

11.10 Service Semantic Requirements

MRO-FR11	Semantic compliance
Description	The MRO must be filled with data that is structured using international code systems as much as possible, or using national code systems for which a mapping exists or can be created to international code systems.
Associated Goals	• International standardization to ensure semantic understanding between users of communicating systems. • Safety reasons
Actors	NCPs Health professional

MRO-FR12	Structured Information
Description	The information sent to another country must be structured, 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 ‘active ingredient’ is properly identified in country A and translated to country B).
Associated Goals	• Guarantee the safety of the patient through a proper understanding of the received information • Ensure safe delivery of care to patients thanks to the faithful exchange of meanings between systems and between systems and people
Actors	NCPs Health professional

MRO-FR13	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 reason • Guarantee the safety of the patient through a proper understanding of the received information • Ensure safe delivery of care to patients thanks to the faithful exchange of meanings between systems and between systems and people
Actors	NCPs Health professional

11.11 Service Usability and Data Presentation Requirements

MRO-FR14	Understandable Information
Description	NCP-A must send the MRO in an intelligible and structured way to NCP-B, to make sure that Country B can produce intelligible and clear information for the users of that message in its nation in an automated manner.
Associated Goals	• Provide ease of processing incoming data for Country B. • To provide the health professional with the necessary information • Guarantee the safety of the patient through a proper understanding of the received information Ensure safe delivery of care to patients thanks to the faithful exchange of meanings between systems and between systems and people
Actors	NCPs

11.12 Service Non-functional Requirements: Service Level Requirements

MRO-NFR01	Service Availability
Description	• Availability means the property of being accessible and usable upon demand by an authorized entity (see definition ISO 7498-2:1989). • There are different causes for technical unavailability (of communication, National Contact Points, local systems…)of the epSOS LSP service as: o failure o unplanned stop (bug, random error) o partial planned stop (not optimal running) o planned stop (maintenance, update) Every event that causes unavailability will be analysed. Each service interruption will be detected as soon as possible. The origin of the failure (Health Professional system, National Contact Point system, central broker ...) will be explained. When there is a transition to a degraded mode, the suitable alerts will have to be defined and particularly the procedure for using a degraded mode. • Emergency mode: A special focus is required for the procedure in case of a patient emergency such as an emergency mode (like a collapsed patient or an accident where the patient is severely injured). • Indicators: The availability of the system will be measured in order to evaluate the performance of the system (time available out of total time(%), downtime on a period
Associated Goals	The system will be available at any time, 24h a day, 7 days a week. Therefore, the requirement is a truly continuous availability.

MRO-NFR02	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 circle of trust. The response time could vary depending on the chosen architecture; that is, whether it is centralized or distributed and whether there are multiple sources of information or just one. An acceptable response time not only applies to the receipt of the information, but also to the identification and authentication of Health professional and patient. The system should therefore provide an end to end response time within a few seconds, possibly no more than 10 seconds[7].

[7] The feasibility of this will depend on the technical group. Also, 10 seconds is not a service level agreement but a proposal of threshold

MRO-NFR02	Response time
Associated Goals	• Information has to travel from one country to another. An acceptable time response not only applies to the receipt of information, but also to the identification and authentication of HP and patient • 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

11.13 Additional Architecture NCP/Central Service Requirements

MRO-NFR03	New document type
Description	New document type Medication Related Overview is requested by country B.
Associated Goals	The Medication Related Overview is a newly introduced document type in epSOS phase 2. National Contact Points and Central Services need to be adjusted to be able to handle this.
Actors	NCPs

12 Appendix A3 - 112 Additional Service Specification

In accordance with the Directive of Cross-border Health Services (Directive 2011/24/EU), epSOS will develop a service providing the patient with access to key information in his or her own medical record, when seeking or receiving healthcare abroad (outside his/her Country of Affiliation, Country A). The **epSOS Additional Services 112 Emergency (112)** is built upon and enhances but does not replace any National Emergency services within the Participating Nations.

The aim is to propose how 112 emergency services can be included in existing epSOS services to allow European emergency services (112) and in particular the Emergency Medical Services to securely - and legally - access a patient summary to improve the quality of the intervention. In accordance with the epSOS Description of Work [10], this service should provide access to a Patient Summary (PS), resp. propose new data set suitable for emergency situation (Emergency Data Set – EDS) in a structured and coded form. According to the general approach in epSOS, only structured and coded data will be subject to translation, restricting the use of unstructured data to a copy of the original document in its original language [12], [13].

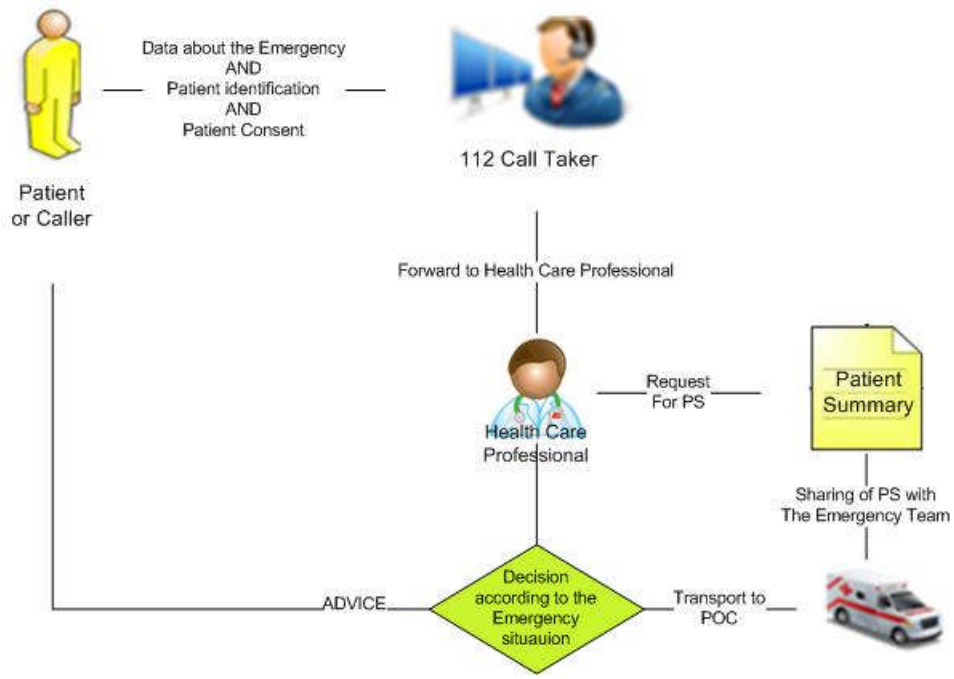
Basic use case was elected for specifications of the services. Primary and secondary actors are all involved in it. This means Patient or Caller as primary actors, operator 112 or call taker and Health Care Professional as secondary actors acting in different roles as POC.

Proposal is oriented to the needs of all participating roles. The Patient wants to have improved quality of intervention provided by 112 Emergency services (included in epSOS services), securely and legally. The Health Care Professional wants to receive all relevant information about the Patient in different processes provided by the Emergency teams in order to increase the Patient safety and quality of services in the emergency situations.

12.1 Steps of Additional services 112 process

The basic process of provision Additional services 112 is outlined in Diagram 1.

Diagram 1: Additional services 112 Basic process:



General overview of the medical emergency handling process can be divided into three steps. In the first one, the emergency call is received in 112 Emergency Call Centre, first data about the situation are taken and medical resources are dispatched. In the second step, health professionals arrive to an emergency place and take care of the patient. The next step is when the patient arrives to the first aid department. Service description also implements a new functionality – Health Care event feedback delivery to the Patients EHR system in his Country.

12.2 Selected Use case review and assessment of PNs readiness

12.2.1 General analysis - 112 emergency services organization

The 112 emergency number is available in all EU countries. Majority of countries have a regional organization for 112 emergency services and medical emergencies. In almost all countries, calls are received in foreign languages and handled by multilingual operators.

12.2.2 Identification of the patient in the call center

The epSOS PN were asked (KT 1.4.5) how the patient was identified in the emergency call center. Eighteen answers were received:

- In six PN the patient is **not identified** at all (questions about location and emergency situation are asked).
- In six countries only **the name of the patient is given**.
- In three countries information about the **address is requested.**
- Only in three countries **patient ID** or similar is demanded.

12.2.3 Role of health professionals in handling emergency calls

Only in two countries 112 **calls are taken by health care professionals** first responders, in the majority of countries 112 calls are first **responded by multidisciplinary 112 call takers** and then data or calls are **forwarded to emergency medical services, if needed**.

The citizen involved in a medical emergency situation speaks with a nurse or doctor at any point of the call in 14 countries.

In six countries citizen can obtain **medical advice** (not emergency) by dialing 112. In twelve countries this is not provided by the 112 call center and in three countries this is different, depending on the region.

12.2.4 Availability of electronic support and connection:

In 2011 electronic information is transferred from the call center to the ambulance in six countries, from the ambulance to the hospital in seven countries and from the call center to the hospital in four countries. Nine countries plan to ameliorate information transfer for 2013.

Information about what data is transmitted is not available. There are no countries that declare accessing PS in the present situation at the call center and only three countries (Belgium, Slovakia and Turkey) plan to add this possibility to the call center.

Electronic support for medical information is available at the call center in six countries in 2011, and three countries plan to include it in 2013.

In 2013, 16 countries will have electronic support in ambulances or other means of transportation and 16 will have a network connection that will support the exchange of patient summaries.

12.2.5 Number of times that different use cases take place:

Six use cases have been defined for 112 emergency services and have been included in the questionnaire. Detailed information about mentioned use-cases contains deliverable Use-cases description [1].

Each PN was asked to give a quantification of occurrence of each of possible 112 Emergency use cases. This was done to find out which use cases have a realistic setting that makes them usable in an epSOS environment. In the received answers, many PNs were not able to give quantitative data.

12.2.6 Opportunities

The 112 emergency number is available in all epSOS countries. It is worth mentioning that the European Emergency number is available in all countries of the EU and other European countries. Health professionals participate in handling emergency calls in the majority of countries. This means that they could access the Patient Summary.

12.2.7 Constraints

Electronic support is available in call centers and ambulances in about half of epSOS countries but, for the time being, it is not used for accessing the national PS. The present situation is that patient ID number or similar is only being requested in three countries in emergency call centers to identify the patient.

12.2.8 Conclusions and recommendations

The 112 Emergency Number is available in all European countries. The organization of emergency services differs from one country to another but in the majority of countries the health care professional is involved in handling of medical emergency calls.

The way of how patients can be identified is a challenge for 112 emergency call centers as, in the present situation, the patient ID number is not asked for in all countries. Electronic support is available in call centers and ambulances and data transmission is planned to be ameliorated in 2013.

The answers to the questionnaire show that in the majority of countries, a health care professional is involved in the emergency handling in medical emergency cases. It can be then concluded that health care professionals have a role in handling emergency calls in the majority of countries and the access to PS could be feasible.

12.2.9 Assessment of PNs readiness

Based on the information collected from publicly accessible questionnaire filled in by the NEPCs, a picture about the readiness of the PN can be created. Following information was collected from information present in Project place. This list only includes countries, which presented their feedback (see attached link).

https://service.projectplace.com/pp/pp.cgi/0/634947893

FRANCE
Different possible use cases are clearly described in the document. We suggest enhancing the description by adding an analysis of the possible impacts in the actual epSOS Patient Summary content. As the 112 service is called in emergency situation, it is possible that HPs working in emergency healthcare services have specific needs in terms of medical data. From the clinical point of view, a Patient Summary for emergency will not necessarily have the same content as a Patient Summary for a classic encounter with a GP. At this stage, we don't see any big technical obstacle to implementation of the proposed use cases as we think, from the technical point of view, that we only have to give access to the Patient Summary to the HPs working in emergency services. However France suggests enhancing the description by adding an analysis on the possible impacts in terms of deployment. Depending on these impacts, it will be easier to choose which use cases we want to implement. In the Extended Services and in the Patient Access UC description, the code group is giving its own recommendations on the use cases to be implemented. Will it be possible for the 112 core group to give its recommendations?

MALTA
Malta's interest in this use case as Country B is affected by the size and type of the country. There is a single emergency ambulance control system based at the main acute hospital that receives the medical calls made to the 112 service. Malta would be interested in giving epSOS service access to the health professionals who run this system. Ambulance trips in Malta are of short duration so there is little benefit to be achieved by transmitting epSOS data to emergency ambulances, most of which are based at the acute hospital A&E Department.

There should be no problem for Malta to act as Country A in this Use Case, as long as the legal need to update the epSOS consent is met accordingly.

SWEDEN
Forced to prioritize among the use cases, we recommend that the 112 emergency use case in epSOS is limited to a paper recommendation rather than implementation. If Sweden is country A: Current legislation does not allow 112 personnel to access PS. If Sweden is country B: No legal obstacles to Swedish personnel getting access to PS data from other countries.

GREECE
Concerning Emergency 112, there is very good legal certainty in what concerns the organizational aspects of Emergency services and the single European emergency call number. What still needs verification is the status and the uniformity of implementation of the relevant Directives in the member States and the participating non EU PNs the aspects of the organization of the actual services, from health systems legal perspective has the same implications as that of the Patient summary.

TURKEY
Turkey plans to improve electronic healthcare data support for 112 services. There are plans to introduce 3G services in the ambulances, improve communication of ambulances with the 112 operator and healthcare facility, etc.

Hence, **UC.112.1** and **UC.112.2** might be relevant for implementation in Turkey but of course this depends on the implementation status of the above-mentioned plans till 2013.

SLOVAKIA
Slovakia has plans to improve 112 services. Responsible professionals are developing activities leading to cooperation with neighbor countries to establish bilateral cooperation agreements. Significant activity from the Czech Republic in the field of 112 services cooperation is creating opportunities for epSOS service implementation and piloting.

SPAIN
The definition and usefulness of 112 use cases is quite clear. Difficulties here seem to be how to give access only to the HPs roles that have the right to do it. As mention in PS use cases that group can have request on clinical data to be needed /fields or term missing) and that request should be centralized in a clinical task force not to create the confusions of epSOS phase 1. PS is already thought to have it maximum usefulness on emergency situation but a further input for that clinical group could help to improve it.

NETHERLANDS
NL has used following abbreviations:

- ECC = Emergency Call Centre
- ED = Emergency Department
- GP = general practitioner

The following use cases are relevant:

- UC.112:1 - ECC (country B) gives self-care advice to visiting patient (country A)
- UC.112:2 - ECC (country B) sends visiting patient (country A) to ED (country B).
- UC.112:4 – ECC (country A) sends patient (country A) to ED (country B).

Our country has developed communication standards for service process 1. At this moment they are not operational. ICT-vendors must build the communication standards in their systems. This will take at least one year if they start from now. And if they start they will start with service process 1.

CZECH REPUBLIC
Services are theoretically applicable for CZ: call taker 112 collects ID details - passes ID details to operator of ambulance service - passes ID details over to HP with access rights (either a crew of the ambulance or first aid department). Such use case exists in CZ with IZIP but in early pilot.

GERMANY
These use cases are not applicable for Germany due to legal constraints.

The described Use Case seems to be very interesting but we do not expect additional benefits for safety and health care treatment. In Germany and in some other countries the 112 operators neither have access to a patient summary nor would they have time to wait for its delivery from abroad. In addition, in principle they are not allowed to access these personal medical data. Furthermore we see the general problem of identification and authorization of the actors, especially the patient, in this Use Case. We strongly recommend to further elaborate the use and the benefit of any potential 112 UC before and to find out which benefits from the clinical view would exist.

ITALY - LOMBARDY
The single Emergency Number (112) is active as a pilot in part of Milano province. In general the 112 Medical Emergency is operational, but it does not provide medical consultation support. Among the UCs, the possibility for the Call Center HP and the First Aid Dept. to retrieve the PS can be useful to orient the HPs on the Ambulance and at the First Aid dept. As for providing the “normal” PS to the HP on ambulance, it could be cumbersome with limited medical info. A specific Emergency document should be defined for this purpose. But this requires a significant effort in specification (medical and semantics) and SW implementation. Lombardy is not currently in the position of piloting this part of the service.

INDUSTRY TEAM
It is very uncommon that a 112 call center uses PS or eP, even in home country situation, for the following reasons:

- The main objective for the call centre is to dispatch help services to the place of emergency. Medical history hardly ever plays a role in the decision making process.
- Most call centres are staffed with non-healthcare professionals. These operators are not legally allowed to access patient information
- Reliably establishing patient identification is very hard, if not impossible, in the remote situation.

It will be uncommon that ambulance service will benefit from having (complete) PS and eP, for the following reasons:

- The main objective for ambulance personnel will be to stabilize the patient and get him/her to the nearest emergency facility. To do so, in many cases only the ‘here’ and ‘now’ is relevant.
- Legislation may limit the access of ambulance personnel to PS and eP, depending on their status and specific country situations.
- During emergency transfer of a patient to an emergency facility, ambulance staff typically has an ample time and opportunity to be occupied with a patient’s medical history or past medication. Only relevant will be allergies, current medical conditions and active prescriptions.
- Reliably establishing patient identification is very hard, if not impossible, before arriving on scene, and even at the scene it typically is very hard to reliable identify the patient and get consent for accessing medical information.

Accessing PS and eP at an emergency facility will typically be a standard health care providing organization, for which the normal rules of epSOS operation will apply and for which it is not necessary to describe a different use case, with the exception of accessing the PS and eP before the patient arrives. However, the relevance of that in an emergency situation is debatable. Added to that are the previously mentioned

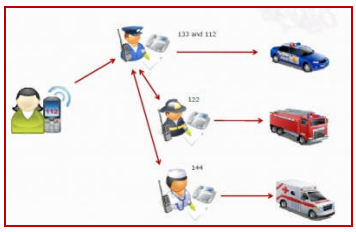
12.3 Recapitulation of aspects relevant for depiction of differences between countries regarding 112 services.

Next table summarizes the main status of relevant functions in some of the countries and regions already offering 112 services.

Organisation in different countries

Austria

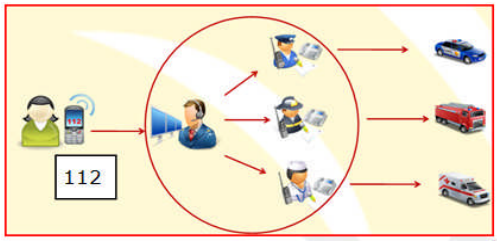
- Non-Police Calls are forwarded to the operationally and geographically responsible organisation (forward and/or conference call)
- Police and non-police PSAP's (Public Safety Answering Point) are organisationally and geographically separated



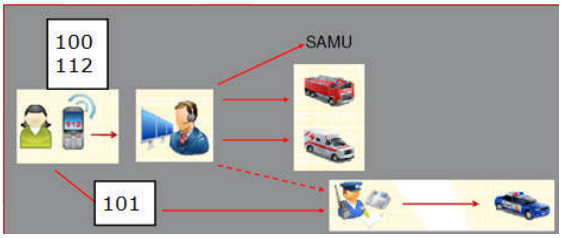
Belgium

- Depending on the region, the organisational model may be different.

Gent and Leuven Region
(in future for all regions)

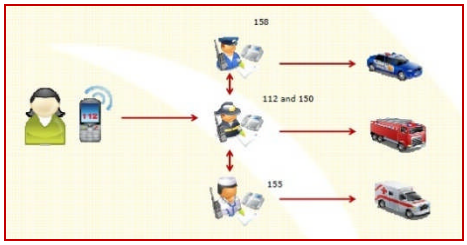


Rest of regions
(Present situation)



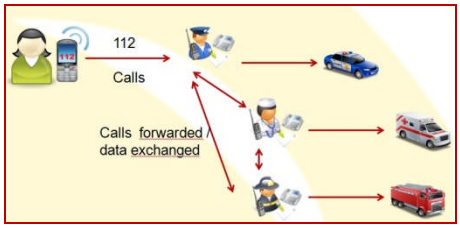
Czech Republic

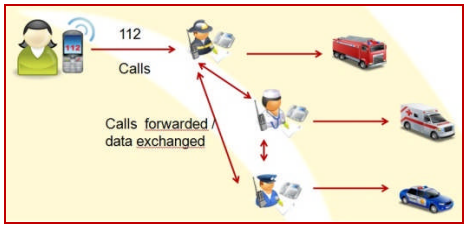
- 112 calls are managed by fire and rescue services
- All the PSAPs are interconnected



Denmark

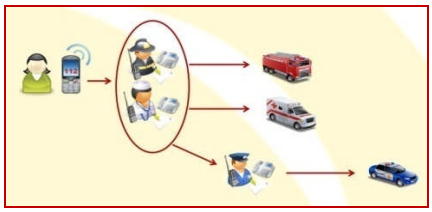
- In some parts of the country police handles 112 calls and in others 112 calls are received by fire and rescue services





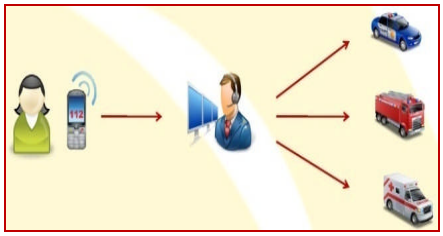
Estonia

- Fire and medical emergency services receive 112 calls and are integrated in the same coordination centres.



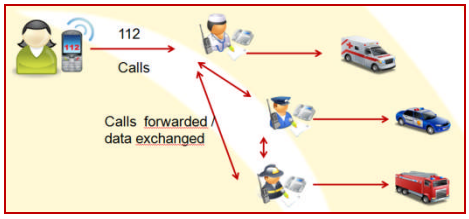
Finland

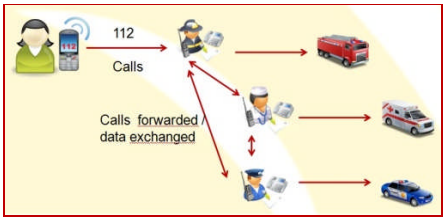
- The civilian 112 call-taker documents the answers to the questions who, where, when, what in purpose of evaluating the risk of the situation. The operator then decides the sort of the task and alarms the emergency service units if needed.



France

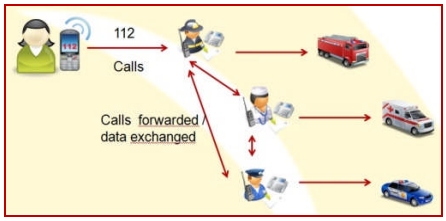
- 112 calls are handled by the fire and rescue services or by the medical emergency services local PSAP.





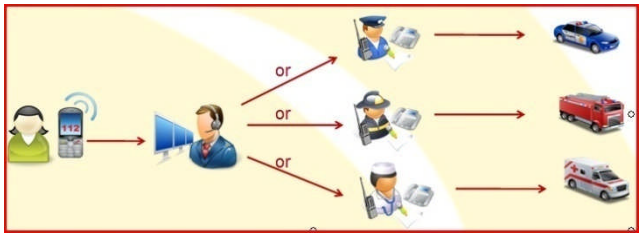
Germany

- 112 calls are handled by the fire and rescue services.



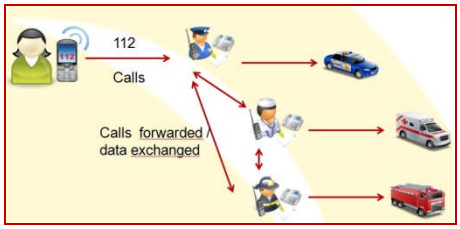
Greece

- Stage 1 PSAP operators receive the 112 calls and forward the call to the local emergency service organisation.



Hungary

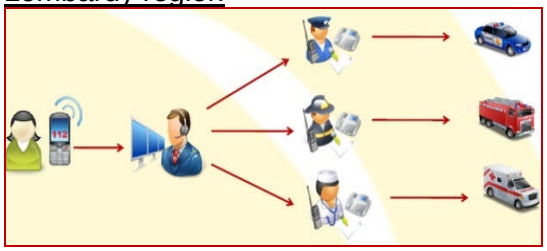
- 112 calls are handled by the police PSAP.



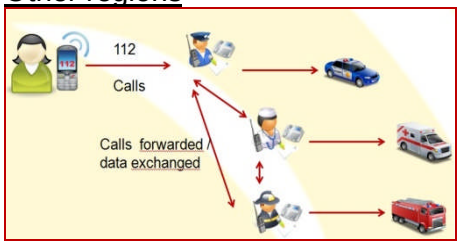
Italy

- Depending on the region, the organisational model may be different.

Lombardy region

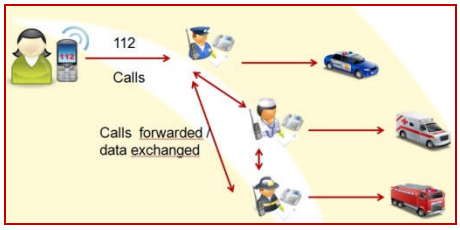


Other regions



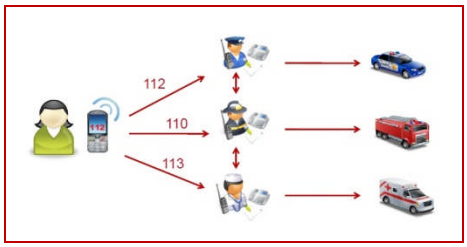
Malta

- 112 calls are handled by the police PSAP.



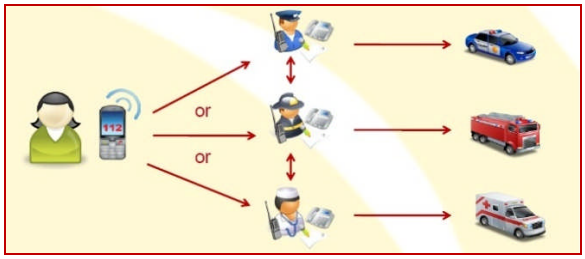
Norway

- 112 calls are received by the police.

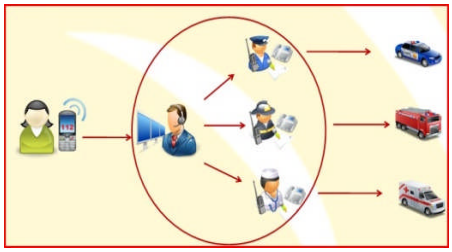


Poland

- Present situation

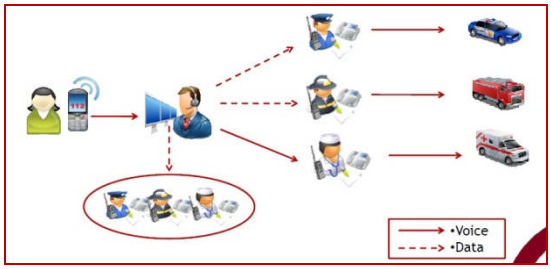


- Future situation



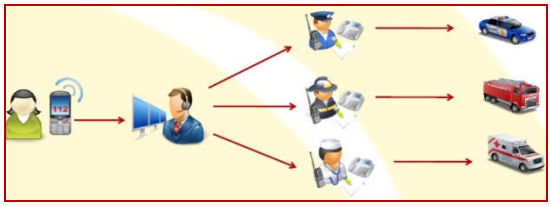
Portugal

- The call taking is done by one 1st line PSAP



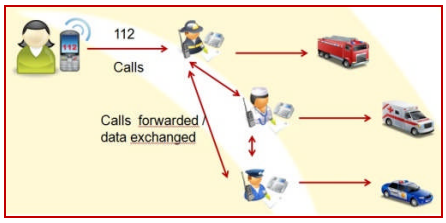
Slovakia

- 112 calls are answered by 112 call-takers, processed and forwarded to the proper emergency intervention agencies



Slovenia

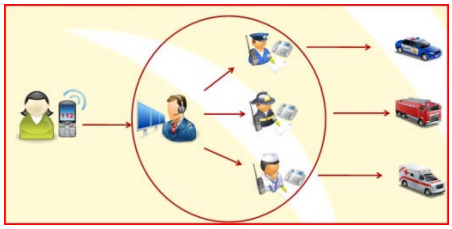
- Call filtered through PSAP and in case of Medical help needed transferred to regional emergency service



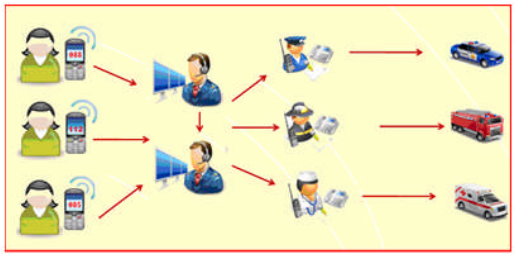
Spain

- Depending on the region, the organisational model may be different.

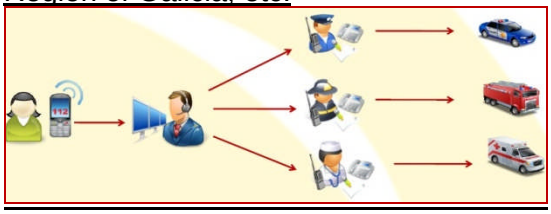
<u>Region of Castilla La Mancha</u>
<u>Region of Madrid, etc.</u>



<u>Catalonia</u>
Two operational interconnected 112 PSAPs. Fire and Police Department regional numbers redirected to the 112 PSAP.

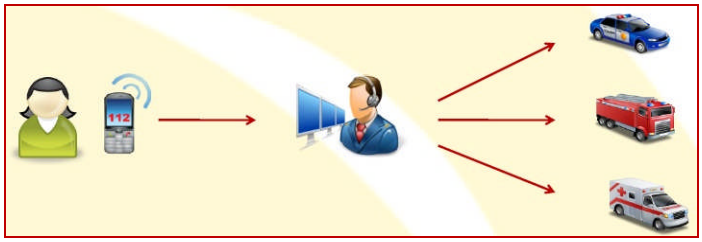


<u>Region of Aragon</u>
<u>Region of Galicia, etc.</u>



Sweden

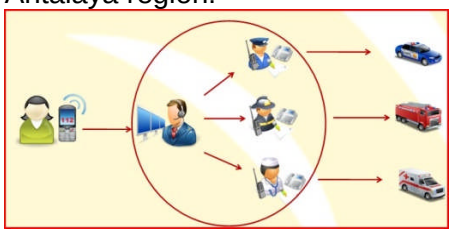
- The 112 call-taker takes the data about who, where, when, what in purpose of evaluating the risk of the situation. The operator then decides the sort of the task and alarms the emergency service units if needed.



Turkey

- Depending on the region, the organisational model may be different.

Antalaya region:



United Kingdom

- Stage 1 PSAP operators receive the 112 calls and forward the call to the local emergency service organisation.

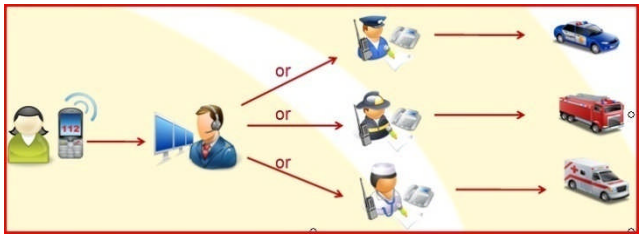


Table 1 depicts the situation in the epSOS core group countries participating in functional description, which are those with indicated readiness to pilot 112 Emergency in epSOS.

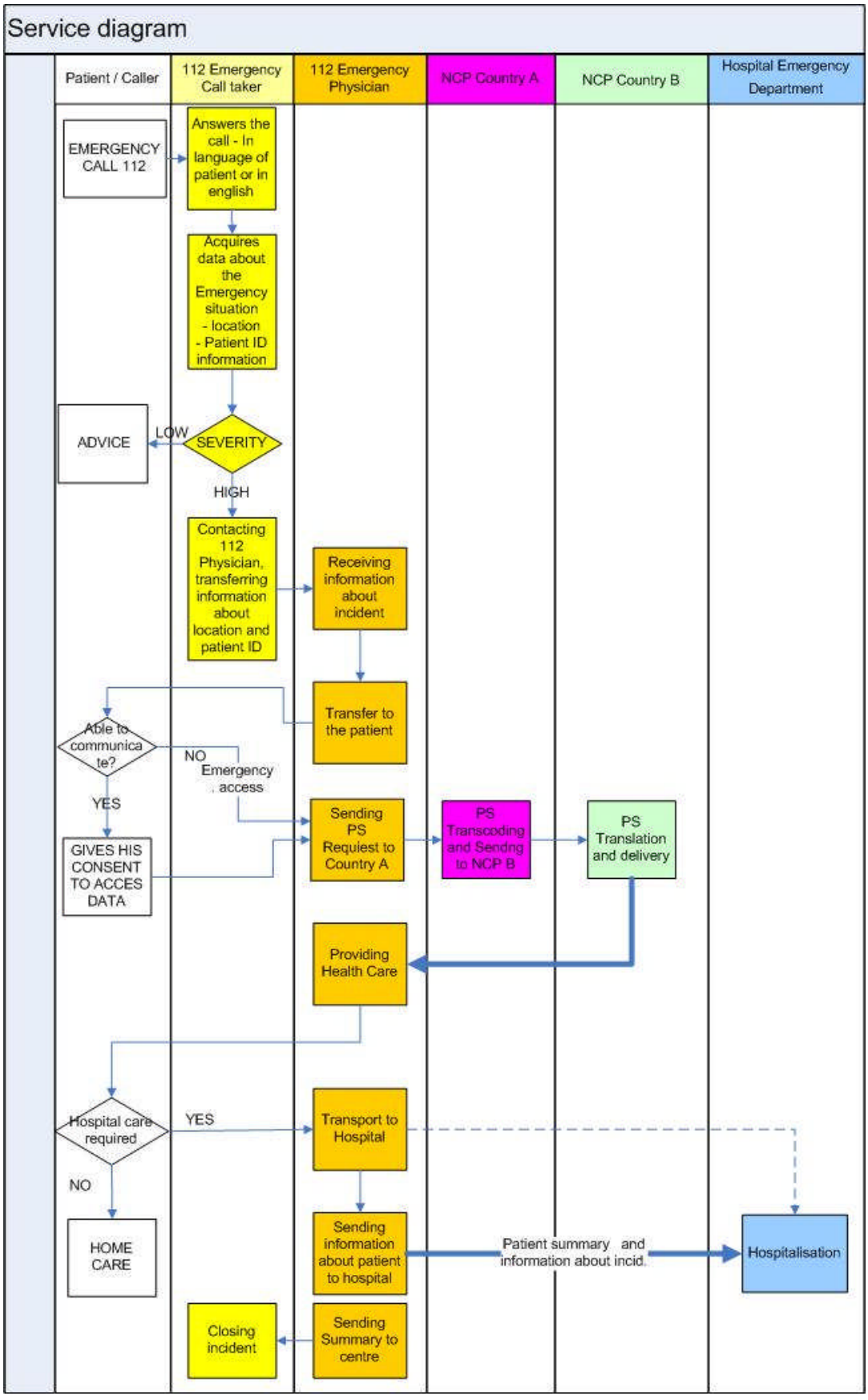
PN	Pilot RD	Pilot scenario	Remark
France	Positive	TBD	(Analyze of PS content needed, .. impact)
Malta	Positive	Country B	
Sweden	Positive	Country B	
Greece	Positive	TBD	(Uniformity of 112 ES across the countries)
Turkey	Positive	TBD	Strategy to 2013 compatible
Slovakia	Positive	Country A and B	
Germany	Negative	--	Legislation problem, minimal benefits
Lombardy	Negative	--	No condition to pilot

12.4 Service pre-requisites

The service preconditions consists of the following elements:

- Patient identification and authentication already exists
- Health Care provider identification and authentication already exist
- National 112 Service provider already exists
- National 112 Service provider is technically equipped to be connected to services enabling patient identification remotely
- National 112 Service provider is technically equipped to receive patient consent remotely
- POC is connected to NCP B and able to provide emergency event feedback do the NCPA (Patients EHR)
- Country providing Health Care has functional NCP
- The patient has filled PS in his NCP in the Country B
- 112 Emergency team member is a physician, who has access to the NCP (from legal and technical perspective).
- Existence of information channel between 112 emergency centre and 112 emergency team working in the field.
- 112 Call-taker understands the language of the patient or can communicate in English.
- Legal compliance
- Semantic interoperability

12.5 Service State Diagram



12.6 Service Functional requirements

112 FR1	**Integration of national system infrastructure with 112 Emergency provider.**
Description	Initial agreement and interaction model between national epSOS and belonging national subsystem infrastructure with the national 112 Emergency service provider. According to the results of survey, majority of countries, in medical emergency cases, a health care professional is involved in the emergency handling. It can be then concluded that health care professionals have a role in handling emergency calls in the majority of countries and the access to PS could be feasible. Part of agreement should be presence of physician having access right to PS during, or immediately after emergency phone call. During the call it will be necessary to obtain patients identification data required for epSOS purposes.
Actors	1. National eHealth operator (epSOS beneficiary) 2. Agencies responsible for local 112 Emergency services. 3. 112 Emergency Physician 4. epSOS NCP
Preconditions	- Existence of 112 Emergency service organization in the Country - Local legislation (regulation) for information exchange exist - 112 Emergency call answered or connected to physician

112 FR2	**Integration of POC in the role of partner of 112 Emergency services**
Description	Integration of Emergency departments of hospitals (Emergency POC) interacting with the 112 Emergency service providers. This integration enables access to Patient summary immediately after patient arrival from emergency situation.
Actors	1. National eHealth operator (epSOS beneficiary) 2. Agencies responsible for local 112 Emergency services.
Preconditions	- Existence of 112 Emergency service organization in the Country - Local legislation (regulation) for information exchange exist

112 FR3	**Connectivity of 112 Emergency teams**
Description	Availability of technical infrastructure to enable communication (reception and transmission of data) to and from point of care.
Associated Goals	o Transmission and reception of data in the field
Actors	1. Health Care provider – Member of Emergency Team 2. Call Center operator (optional)
Preconditions	- National 112 Service provider is technically equipped to be connected to services enabling communication of epSOS related data remotely (ambulance, Emergency dept.)

12.7 Service ID Management Requirements

112 FR4	Identification of the patient using patients ID
Description	Integration of identification mechanism based on obligatory identification based on identification document in every Participating Nations. Present situation in PN based on identification of patient based on name only is for epSOS purposes not sufficient. epSOS approach required clear, transparent identification based on same identification mechanism defined and accepted in epSOS phase 1.
Associated Goals	o Improving identification across the PN
Actors	1. Health Care provider – Member of Emergency Team 2. Citizen from Country A 3. Call Center operator (optional)
Preconditions	- Acceptance of identification mechanism by 112 Emergency provider - Electronic support is available in call centers and ambulances - Patient ID number or similar is requested in emergency call centers to identify the patient.

112 FR5	Identification of not communicating patient
Description	Identification of patient in the context of 112 Emergency technically runs in the same mode as in the case epSOS phase 1. But requires a special approach in situations where the patient cannot communicate. Services should be designed as far as possible eliminate the error, which could be linked to incorrect identification.
Associated Goals	o Improving Patient identification
Actors	1. Health Care provider – Member of Emergency Team 2. Citizen from Country A 3. Call Center operator (optional)
Preconditions	- National 112 Service provider is technically equipped to be connected to services enabling patient identification remotely

112 FR6	Patient consent and non-communicating patient
Description	Special approach requirement for situations where the patient cannot communicate. That means procedure, which allows the creation of the event recorded as inability to interact with the patient in obtaining his consent to access to his PS
Associated Goals	o Improvement of existing process o Logging of the data request
Actors	1. Health Care provider – Member of Emergency Team 2. epSOS NCP 3. Call Center operator (optional)
Preconditions	- Patients EDS exists - HP connected to NCP - Identification data (ID present)

12.8 Service Legal requirements

112 FR7	PS data access logging
Description	Distributed Environment of Services 112 requires an environment able to log the important events associated with the patient data. It is therefore requested detailed information in the form of logs allowing a transparent way to get an overview, who, when and why accessed PS.
Associated Goals	o Legal reasons o Security reasons
Actors	Health Care provider from country A NCPs

112 FR8	Uniformity of implementation of the directives in MS a PN
Description	What need to be still verified is the status and the uniformity of implementation of the relevant Directives in the member States and the participating non EU PNs the aspects of the organization of the actual services, from health systems legal perspective has the same implications as that of the Patient summary.
Associated Goals	o Legal reasons o Security reasons
Actors	112 Emergency services operators National eHealth operators

112 FR9	Selection and publication of data from epSOS patient summary to subset for 112 Emergency purpose
Description	Providers of services proposed in KT 1.4.8 (emergency teams acting in the field) need to have access to relevant Patient data which may have various form from country to country. There is a requirement to enable the configuration of content according to legislative requirements of each Participating Nation.
Associated Goals	o Legal reasons o Security reasons
Actors	112 Emergency services operators National eHealth operators

12.9 Service Security requirements

112 FR10	Inclusion of Emergency 112 identified physicians
Description	For physicians belonging to 112 emergency services will be necessary to ensure identification mechanism and distribution of electronic certificates (the same as for epSOS + physicians in the hospital) to allow access to the NCP.
Associated Goals	o Transparent access
Actors	NCPs Health Care providers

112 FR11	Authorization of persons performing configuration of PS subset for 112 Emergency
Description	Configuration of the 112 emergency subset based on epSOS Patient summary can be carried out only by an authorized person through a specialized interface allowing each PN create and administrate its own national subset and its variants.
Associated Goals	o Transparent access o Legal reasons
Actors	NCPs Health Care providers

12.10 Service Clinical requirements

112 FR12	Supplement the data related to Emergency 112
Description	Presented requirements of emergency clinicians are focused on expression of emergency situation related data into clearly comprehensible user interface based on present content of epSOS patient summary. Through these user interface will intervening physician receive data which may significantly affect the quality of health care provided in emergency situation. During emergency transfer of a patient to an emergency facility, ambulance staff typically has an ample time and opportunity to be occupied with a **patient's medical history or past medication. Only relevant will be allergies, current medical conditions and active prescriptions.**
Associated Goals	o Definition of User interface containing data relevant for emergency situation
Actors	Clinical expert team Emergency physician Semantic expert team
Preconditions	

12.11 Service Semantic requirements

112 FR13	Definition of User interface
Description	According to the opinion presented by many NEPCs and professional involved will be necessary to create user Interface for 112 Emergency purposes. Content of this UI will be tailored to the needs of 112 Emergency teams. User interface will not include new concepts, just extract of relevant terms from existing epSOS patient summary. Form and exact position of each data element will be fully configurable to fulfil all potential requirements of any Participating nation.
Associated Goals	
Actors	1. Semantic expert team 2. Clinical expert team 3. 112 Emergency physician
Preconditions	

12.12 Service Usability and data presentation requirement

112 FR14	Definition of Emergency User Interface
Description	Creation of Emergency User Interface in understandable form. The presentation layer must be designed to be as clear as possible. Relevant information must be highlighted so that the 112 Emergency personnel pointed to their seriousness.
Associated Goals	
Actors	112 Emergency teams Physicians providing Health Care
Preconditions	

112 FR15	Defining the proposition of the presented content for 112
Description	List of different proposals - (subsets) from epSOS Patient summary responding the needs of 112 emergency teams should be stored as templates representing elements chosen and their position on the screen used by different PN. Content of such template will be data relevant for 112 Emergency purpose as **patient´s identification, actual and past medication, allergies, current medical condition, implants and other relevant information.**
Associated Goals	
Actors	1. Semantic expert team 2. Clinical expert team 3. 112 Emergency physician
Preconditions	

12.13 Service Non-functional requirements: service level requirements

112 NFR16	Availability of service
Description	At the level of operators, ensuring high availability of systems providing PS. Given the nature of the Emergency services should be objectives; it provides continuous service availability and minimize the risk of technical failures.
Associated Goals	o
Actors	epSOS service provider
Preconditions	Technical infrastructure available high availability features.

12.14 Additional Architecture NCP / Central Service requirements

112 NFR17	Availability of national PS repository
Description	Availability of PS repository containing patient´s data.
Associated Goals	
Actors	1. NCPs 2. Architects on national HIS
Preconditions	-

112 NFR18	Availability of national 112 Emergency subset service
Description	Availability of service generating subsets from Patient summary. Subsets should be generated respecting national policy for content and data presentation.
Associated Goals	
Actors	3. NCPs 4. Architects on national HIS
Preconditions	-

13 Appendix A4 - Patient Access Additional Service Specification

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13.1 Patient Access service Specification

The functional requirements for Patient access are based on the use case description in [1]. These functional descriptions aim at describing system outputs and sketching processes from the user point of view. Functional "site effects" related to the architecture and design level are mentioned where appropriate.

epSOS Patient Access (PAC) must be in accordance with the Patient Access policy of patient's Country of Affiliation [10].

The legal underpinning to Patient Access includes the diverse national Acts to access own Medical Records following the European Directive of 1995 which requires Member States to protect people's fundamental rights and freedoms and in particular their right to privacy with respect to the processing of personal data. In practice it provides a way for individuals to control information about themselves. A key objective of Digital Agenda for Europe sets 2015 as deadline for giving patients online access to their medical data (Key action 13)[8]

The epSOS Patient Access Service (PAC) is based on a Country of Affiliation Patient Access that includes patient identification and authentication. The (national) service first verifies that the patient has access rights to the information, and then provides the requested document(s). The patient reads copies and distributes the document as he or she considers appropriate, possibly to a new health professional at a new encounter in the language requested by the patient. The PAC enhances any National Patient Access Service by improving understanding over national (language) boundaries. The PAC does not alter the access rights of the patient. The key service provided by PAC is therefore *the translation of the PS or eP*.

In the context of patient access, a **personal health record** (PHR) is a health record where health data is curated by the patient. The goal of patient access in epSOS is to provide a summary of an individual's medical history and/or of his active prescription still to be dispensed, which are accessible online. The main pillars of patient access in epSOS are therefore the existing national Patient Access (PA) systems. These patient access services may vary from country to country and might include patient-reported outcome data, lab results (either entered by a patient or downloaded from the testing lab itself), data from devices such as wireless electronic weighing scales or collected passively from a Smartphone.

The following requirements give the conditions under which any EU citizen must have the possibility to access his own medical information (PS/eP) available in his country of affiliation and receive it in any epSOS country language through the national epSOS NCP which forwards it to the patient access service. The added value of this is the improvement of the quality of care with patient access offering:

- Point-of-care decision support
- Rapid and remote access to patient information in other languages
- Integration of evidence

[8] http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/11/282&type=HTML

According to the general approach in epSOS, only structured and coded data will be subject to translation, restricting the PAC for unstructured data to a copy of the original document in its original language [12].

PAC will increase enormously the epSOS healthcare information traffic, namely the amount of cross border patient events in epSOS pilot, since it enhances current amount of candidate cross-border epSOS patients with these:

- Patients having an emergency or unplanned care episode, and visiting any Point of Care (PoC) in a foreign country that does not belong to epSOS PoC network.
- Patients residing in a country whose national language(s) are not among the languages that they feel themselves comfortable with.
- Incidental patients that need care evidence to give/offer to a foreign health professional who does not speak the same language as the patient.
- Citizens preparing a trip to a foreign country. Patients can take a print-out and/or digital copy of his current prescription and/or patient summary, translated to the language of the country they will visit.
- Commuters and seasonal migration citizens that may govern two different patient access systems (his national one and that one of the residence country).

13.2 Selected Use case review and assessment of PNs readiness

The actor constellations in patient access lead to two main PAC use cases. The first use case covers the actor constellations 1 and 2, where both the Patient and the previous health care professional (and therefore the document to be accessed) are affiliated with country A, but the goal of the Patient is that the PS or eP document is translated into language B. The second use case arises from constellations 3 and 4, where the Patient affiliated with country A receives care in country B (being this the member state of treatment), and wants to access a document in his own language (that of country A). (Ref.pag.5 UC definition)

For the present PA functional specifications we will only focus on the first UC (namely, constellations 1-2, where the translated data is always immediately transferred to country A, and can only be accessed through NCP A. Cross-border distribution 3-4 is not considered since in these circumstances patients should obtain a new national health-identifier in another PA system.

Further, in order to assess/reinforce the following specifications we include below a summary of the patient access status in epSOS countries.

Objective: We aimed to analyze the extent to which Patient Access (further on (PAC)) status in epSOS Participating Nations may influence the construction of the functional specifications and further piloting.

Method: We analyzed publicly available documentation of “Country Status KT.1.4.5“ relevant for PA and the information delivered by Patient Access main contributors in this key task (SP (CAT, AVS, FI, HU, IT (Lombardy), MT, and TR.

Following the results of KT 1.4.5 “Country status outline”, patient identification means vary from the current “username + password” mechanism to the demand of digital certificates in 2013.

Sixteen countries inform that they will have Patient Access in 2013, but nowadays it is still not so wide-spread even if it is available in six countries. Transaction login is relevant for offering patient access, and this prerequisite is covered by all PNs but one.

Out of this information we may estimate that in 2013 at least 8 countries can pilot patient access and epSOS Patient Access Service can double in epSOS countries later on. NO and FI informed that currently only offer Patient Access to eP, but this question about eP access was not entailed in the questionnaire; therefore we do not know how many PN grant patient access to eP. For the remaining PNs offering access to PS, they do not cover the entire country population. 16 PNs declared their willingness and FR, BE, CH will join depending on the evolvement of epSOS

Currently there are large differences among participating nations (PNs), but overall in all PNs, the deployment is incipient. The content is mostly static and only four countries allow the patient to upload information. The following elements pave the way towards patient access over Europe:

- Unique Patient Identifier and means of authentication
- Availability of PS and eP
- Structured information (coded information for the “majority of the epSOS data sets”)
- Logs of access and information about ‘when’ the action took place
- Display format identical to that seen by the healthcare professional (currently it is the case only in six countries)

Concerning entitlement to access PS of other persons only Germany, Estonia, Norway and Slovenia citizens are entitled to access other individuals’ PS. For 2013, three countries doubt about allowing it, and four more PNs expect to do so.

Patient access is nearly new everywhere therefore the percentage of population having access nowadays is irrelevant, since it is lower than 0,1% of the population.

Interaction is still low both for / with the patient and with other external sources, what is very relevant for chronic disease management. Extended functionalities such as uploading of information to the PS by the patients or incorporation of other information by the PS for chronic disease management are still very limited; only Sweden, Spain, Estonia and Turkey allow it. Denmark allows patients to record their own data, Norway admits information from national registries, Estonia is based on the service oriented architecture, while other countries can now hardly estimate patient upload of data.

Personal Health Record (Patient Access) portals are mostly not fully connected to all the national eHealth infrastructures, therefore the type and amount of data is limited (e.g. Finland, Spain and Turkey).

The next table summarizes the main status of relevant functions of patient access in some of the countries and regions already offering patient access.

Deliverable 1.4.2 can additionally offer more detailed information (such as: Type of digital ID used for PA authentication, either : a) smart card, b) token, c) digital certificate, d) username and password, Patient’s rights; Further information about: (a) Read/view only; (b) View all documents; (c) Restricted view of docs; (d) Some docs can be hidden; (e) Write/upload anything; (f) Write/upload telemetrics (vital signals); (g) Manage access rights to their own healthcare data through the consent mechanism; etc.) also elicited form the country answers to D1.4.2 Country status outline”

Table 1 depicts the situation in the epSOS core group countries participating in PAC functional description, which are those with high readiness to pilot patient access in epSOS.

Item	CATA	VAL	FI	FR	IT	MT	HU	TR
Law covering PA	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Univocal Patient ID a) HC card b) ID card c) others	*a, b*	*a*	*b*	*a*	*a*	✓ *b* ✓ *EHIC*	*a*	*b*
Recognition of external/foreign digital certificates?? a) Federated in own country b) others	*No*	*no*	*No*	*no*	*no*	*No*	*no*	*no*
Type of digital ID used for authentication a) smart card b) token c) digital certificate d) username and password	*b , c*	*and (b)*	*a and c*	*(a) social security card) without electronic certificates*	*All according to the services*	*(d); (technically (c) is also available but so far little used)*	*d*	*d (for 2011)* *a, b, c, d expected (for 2013)*
Type of process of authentication: Double check (ID log & authentication)	*Double check: HC_ID & Digital certificate*	*Double check: HC_ID & Digital certificate*	*Double check*	*own internet connection ID different from the INS)* *- PW* *- a one-time code sent by SMS or by email and valid for only one login session.*	*Differentiated according to the services*	*Double check: National ID number & national e-ID strong password*	*eGov_ID & Social security ID*	*PHR_ID that is not yet linked to the eGovernment account by 2011*
Is any consent mechanisms needed?	*No*	*No*	*No*	*No. It is needed at the creation of the DMP.*	*Yes*	*No*	*Yes*	*Yes*
Can access be granted other people (e.g. relatives of the patient)	*No*	*No (planned functionality for 2012)*	*No*	*No*	*Yes , in some cases*	*Yes (when system is launched)*	*No*	*No (but it will be available before 2013)*
Patient's rights: *a) Read/view only* *b) View all documents* *c) Restricted view of docs* *d) Some docs can be hidden* *e) Write/upload anything* *f) Writ/ upload telemetrics* *g) Manage access rights to their*	*b; Some docs after 6 months* *c* *e,* *f*	*a* *b (some documents after medical review)* *f*	*a* *d* *g* *h: manage Advance Directives*	*a),(b) and (d) if announcement encounter is needed* *(e) These documents will be stored in a specific section of the DMP*	a, b, g, h (select GP, book visit)	a	a b	a, b, e, f, g

own healthcare data through the consent *h) Others*								
Type of PA in national service *a) Internet portal* *b) Mobile phone* *c) Other*	*a),* *b)*	*a* *b*	*a*	a	a	a	a	a, b, c (Tablet)
Content available to the patient: *a) current prescriptions* *b) medication history* *c) laboratory results* *d) radiology reports* *e) discharge summaries* *f) patient summary* *g) others*	*a,b,c, d,e,* *Others: vital signals (glycaemia, weight, blood pressure..)*	*a,b,c, d,e,f* *(c&d after medical review of documents)*	*a, b (2011)* *c,d,e,f (2013)*	e , f	a, b, c, d, e, f, g	*c,d, e, g (when system is launched)* *Others: health care appoint-ments*	*A,b* *c-f to be decided*	*b, e, g (for 2011)* *a, b, c, d (not certain yet), e, f, g (for 2013)* *Others: PHR portal can communicate with biomedical sensors.* *Patients can feed his daily activities, dietary info, etc.*
Can the patient perform administrative procedures? *a) Updating administrative data* *b) Make appointments* *c) Request clinical reports*	*Yes* *b (option a is foreseen)*	*Yes* *a, b*	*a: no; b, c: not by National Patient Access. Some local services available.*	a and to post medical documents in a specific patients document section	Yes a, b, c	no	no	a
Status of your national/regional PA service *a) Under definition* *b) Under development* *c) Pilot in a restricted area (or for in use for few citizens)* *d) Go live in 2011* *e) Go live after/ during 2012*	*c , e*	*d (Dec 2011)*	*d (eP)* *b (PS)*	*d) Available for all citizens since April 2011.*	*available since several years with smart card + PIN* *D: access with Fiscal code + one-time password*	d	c , e (all patients can access it but only limited data content)	b, e

Next we recap certain aspects relevant to depict the differences in PA among countries. This concerns mainly the “current functionalities/rights” available to patients nowadays. This work was carried out inside the work of self-assessment in KT 1.4.9

13.3 Patient rights concerning type of documents accessed or viewed by the patient

France: Patients can (a) View all documents of his/her EHR, except documents that are temporarily hidden until a HP can explain them to the patient during a medical encounter. (b) Hide specific documents (in these case, documents will only be available to the patient, the author of the document and the GP in charge of the patient). (c) View a complete audit trail of the actions performed by HP in their EHR. (d) Manage access rights to their EHR by forbidding access for specific HPs. (e) Download or ask for a reprint of the EHR. (f) Request the EHR to be closed or definitively destroyed

The French Patient ID is a specific health identifier that is different from the social security identifier. Currently, this identifier (INS) is calculated based on information that are available in the social security card (carte Vitale).

Finland: The patient has a full entitlement to access all his data (radiology report, lab tests…). It is the patient who decides which documents about his health can be shared among HEALTH CARE PROFESSIONALs. Finland will pilot Patient Access with public hospitals in some regions. **Patient ID**: There is in use the unique national identifier in smart card or even the banking card can be used.

Valencia (ES): Patients may access/view all documents of his EHR with the relevant restricting feature that any radiology/lab report can only be viewed after the document is reviewed by the professional who requested the test and after patient is first informed face-to-face. There is only access to imaging reports but not to the images. This EHR can be shared among regions within the context of the national HC service (EHR) sharing; the patient can decide which documents can be hidden for another region BUT NOT within the own region (=Valencia). Service will go live in December 2011 for all population (more than 4 million patient summaries). **Patient ID:** There is a unique ID (smart card) but several certification authorities/digital certificates can be used for authentication in portal.

Lombardy (IT): Since several decades Italian citizen are identified by a unique identifier (Fiscal Code) when they are born. The federated EHR for the whole country does not exist now. EHR for Regione Lombardia is a directory of links (SISS). Documents are stored locally in the organization that created them. In Italy one GP is in charge for the care of the patient: he generates his PS. The HP or HCI who is in charge for the patient care at a given time, has the access right to the patient´s EHR.. Patients can access to most of their data with a card reader CRS+PIN through an Internet Portal, available since several years. The possibility to access without smartcard, but with fiscal code+5 last digits of EHIC + one-time-password will be released in 2011, to ease the patient access while not at home.

Malta: The patient in the *MyHealth Record system* chooses which doctors may view his data and he assigns the label “trusted doctor” which acts as a sort of filtering and decides who else may view discharge letters, medical image reports, and lab results. The release of discharge letters is automatic while the release of other documents to be viewed is based on the knowledge of the specific professional/s selected by the patient. **Patient ID:** Patients may log into the eHealth portal with the national ID number and e-ID password (the password must be changed every 3 months). There is no smart card. Technically a downloadable digital certificate is already available but there is little use of this to date. There is a pilot currently that will go live in November 2011.

Hungary: The Hungarian eGovernment portal provides a limited form of patient access: The patient can see his/her data reported to the Health Insurance Fund (OEP). By law, OEP has to destroy this data (used mainly for reimbursement, coded information to ICD10 and the Hungarian implementation of ICPM) after 10 years, consequently only the data from the last 10 years can be accessed. Access is only granted after registering at a government office, access is based on username and password (it may be strengthened in the future). The patient has to provide his social security ID, if the demographical data (name, place of birth, date of birth, mother's maiden name) stored about him does not match that stored by the OEP, the access is not granted. From 2011, GPs can access the same data of their patients, if the patient does not prohibit it (the GP must ask the patient before the first access whether (s)he wants to prohibit it).

Medical documentation has to be stored for 30 or 50 years (depending on type of documentation) by the original health care provider. A copy of the discharge reports shall be sent to the GP of the patient, but this is typically entrusted on the patient (he gets 2 copies of the discharge report).There is no real EHR service available for the health care providers (hospitals, outpatient clinics) and GPs do have their own information system, but the communication among them is very limited). Such services are under planning, they should be available in 2013.

Patient identification is by a paper-based social security card with unique social security ID (nationwide, we don't have regional health care). It cannot be used for authentication because it has no photo on it, but most HEALTH CARE PROFESSIONALs don't ask for ID card.

An electronic citizen card is planned that will also serve as an electronic health care ID card.

Catalonia (ES): Patients may access/view all documents of his EHR with the relevant restricting feature that any anatomic pathology report can only be viewed 3 months later giving time that this is first informed face-to-face and handed over by clinical professionals. There is only access to imaging reports but not to the images. **Patient ID:** Access is done through the Health Insurance number, and then the systems demands/requests for the digital certificate. Patients can access with national ID card number. Patient access is currently piloted in the area *HC_territory Maresme* (active 400 users and available for 4.000) and in Dec. the project will go live for the 7,5 million citizens (via Portal “Carpeta Personal de Salut”). This will be done step-by-step through the “release” of accessibility to more and more Health centers associated to a HC_territory “creators” of the documents.

Turkey: SRDC has been developing a Personal Health Record (PHR) system for the last few years and this system is already quite mature. Currently, within the scope of a cooperation agreement with the Turkish Ministry of Health, this PHR system is being integrated with the National Health Information System of Turkey (NHIS-T), which already contains healthcare records of more than 55 million citizens (out of 74 million). This integration will form the basis of the national PHR system. According to the current calendar, in January 2013, the national PHR system will be in place at least in a few cities. For patient authentication, the mechanisms provided by the eGoverment portal such as smart card (*as described in the previous sections*) will be facilitated in the near future; yet the username and passwords provided by the PHR system itself are used.

Currently, the PHR system can already communicate with biomedical sensors, and the patient can feed his own data such as daily activities, dietary information, migraine attack details, etc. The data that is provided by the patient is tagged; hence it is always known for a data field whether it is provided by a HEALTH CARE PROFESSIONAL or the patient himself. When the integration with the NHIS-T is completed, apart from standard information like medication history or problems history, a wide variety of data that are collected by the NHIS-T in the form of minimum health data sets (e.g. pregnancy observation, diabetes monitoring, vaccine details, 15-49 age female observation) will be available to the patients as well.

The patient will be the owner of his own healthcare data and will be able to manage access rights through the consent mechanism of the PHR system. The already available patient consent module allows both identity based and role based fine-grained access control mechanisms; this will be integrated with the national infrastructure as well.

13.4 Service pre-requisites

The service preconditions consists of the following elements:

- Patient identification and authentication already exists
- Pre-existence of national EHR/PS and eP
- Transaction logging and transport security
- Country A is the only source of data for a patient.
- **Neutrality:** The functional specifications scenario does not make any assumptions on how medical data is managed within a country A {Ref. WP 3.A Use Cases and scenario assessment}.
- **Scalability:** The implementation should scale well with respect to the number of documents exchanged (or to the number of new value sets)
- **Legal compliance**: Original medical document ownership (owner is both the patient and the entity where the document is stored) and medical / legal validity of transformed document shall be analyzed according to the different PNs' laws.{Ref. WP 3.A Scenario Assessment v.01}
- These functional specifications disclose use cases where country A has to somehow deal with medical data that is provided by a foreign physician.
- **Semantic interoperability:** PAC service should guarantee the smoothest semantic transformation, keeping the meaning and the value of the original document, considering the liability for the transformation, and assuring the reproducibility of the semantic transformation.

Legend to next graph.

The translation process mirrored in both countries is the following:

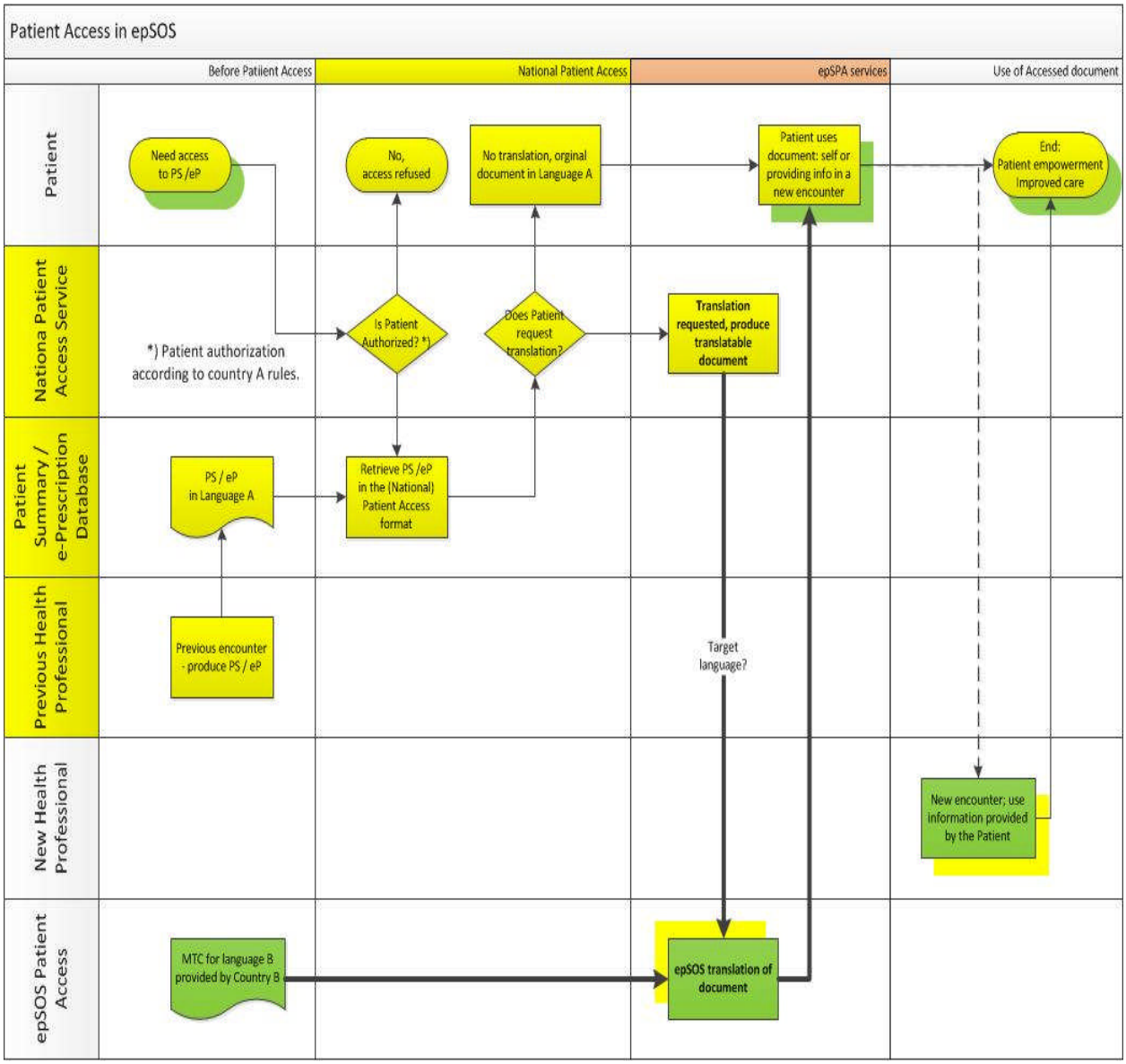
Country A Process:

1. NCP-A receives from local/national PA system a request for translation.
2. NCP-A receives original content provided by national PA infrastructure of country A
3. Validates the provided original content using XML schemas to confirm it is compliant with epSOS format
4. Parses the provided data and for each coded element (as it usually done in conventional epSOS process) (a) extracts data about concept (code, code system OID…), b) sends the concept inside a transcoding request to TSAM, (c) receives transcoding response from TSAM (d) creates translation element and adds it to the corresponding coded element). This complete procedure is handled by the Transformation Manager (TM) component on behalf of the NCP.
5. Validates final pivot content using schematron rules & provides final pivot content to country B, according to the requested target language

Return of the document translations done by Translation Responsible (either country A, country B or central services)

1. Receives epSOS pivot content
2. Validates provided epSOS pivot content using XML schemas to confirm it is compliant with epSOS format & validates provided epSOS pivot content using schematron rules to confirm references to terminologies are correct
3. The same steps 4-5 as above, this time for translation purpose instead of transcoding, in the end providing the final translated pivot content

Service State Diagram



13.5 Service Functional requirements

The scope of these functional requirements will cover 3 separated services:

- Patient access requesting the translation of a PS
- Patient access requesting the translation of an eP
- Patient access requesting for the most suitable PoC in a given country

According to use case definitions of Patient Access Service, the single Use Case for Patient Access (UC.PAC.1) is dependent on electronic patient access to a Patient Summary or ePrescription in the patient's country of affiliation (country A). The epSOS Patient Access service provides a translation of the coded elements in the documents to be accessed. This use case serves two principal needs:

- a patient in Country A, who is not fluent in the language of the PS/eP, needs Language B access to his/her own clinical documents, and
- the patient wishes to consult someone in Language B on the basis of his/her PS or eP, for instance during an encounter with a Health Professional in Country B. Both needs

are widespread, and the potential demand for this Use Case service is high – see in [1] page 55.

Main parameters involved in the PAC service are:

- Country of Patient identification/authentication : country A
- Language of the stored docs/service : country A
- Selected output language : country B
- Location of documents information : country A

In the document we refer to “Translation responsible”. This entity at the technical level may be one of the following alternative actors. Namely

- translation done by NCP-A
- translation done by Central Service (with real time access to MTC, or with buffered MTC in the NCPs)
- translation done by NCP-B

From the logical point of view and from the semantic one the LIABILITY of the translation lies in country B. However, this is an independent matter of the decision about what is the most adequate solution from the architectural point of view.

From the functional point of view we only focus on the “patient request for a document translation” and in a given “translation responsible”. In the last block of requirements “Additional architectural requirements“ the architectural decision will be handed over to WP 3.A .We also declined to keep track in a parameter of the URL of the Portal accessing the specific national Patient access service with its type of accessing device (PC or intelligent mobile) .

The next table depicts the normal sequence of actions for Use case (UC.PAC.1) in the cross-border distribution 1 and 2.

Normal sequence of actions for Cross-border distribution 1 and 2

Steps	Actions
	UC.PAC.1: PA in country A & translation to country B language Requirements Fulfillment, Cross-border distribution 1 and 2
	FR01 & FR08 Fulfillment where the location parameters are: • Country of Patient identification/authentication: country A • Language of the stored docs/service : country A • Selected output language : country B • Location of documents information : country A
1	(This step is in the National Domain, and is a prerequisite for the PAC service) • The patient affiliated in Country A requests access to PS or eP in Country A, by contacting the Country A National Patient Access Service • The patient identifies himself • The National Patient Access system verifies the patient's authorization • The National Patient Access system retrieves the document
2	The Patient requests an epSOS translation of the retrieved document
3	The National Patient Access system passes the request to the epSOS NCP in Country A
4	The epSOS NCP in Country A provides a dialogue for selecting the source and target language (e.g. Language A, Language B; this should be provided based on the language list specified by the NEPC)
5	The National Patient Access system sends the document (in Language A) to the epSOS NCP in Country A
6	The NCP-A transforms (transcodes) the document indicated (or received) from Patient Access system into a translatable epSOS pivot document and then makes this pivot document available to the Translation Responsible.
7	The translation responsible retrieves the epSOS MTC of Language B
8	The translation responsible translates the pivot document and makes the translated document in language B available to NCP of country A
9	The NCP of country A conveys the information translated into the interface of the National Patient Access interface
10	The patient accesses the translated document in his specific device display
11	The use case is finished/closed **EXCEPTIONS** • The translation responsible does not have epSOS MTC of language B. • The translation responsible informs NCP of country A of the failure. • The NCP A cannot inform the Patient Access System / interface about the failure.

13.6 Basic Service Functional requirements

FR01	**Patient Access basic requirement**
Description	The Patient must have the possibility to access his/her own medical information available at his/her national PA service (affiliation's country) and get it translated into any epSOS country language Specific PA services asks first its NCP-A for PS/eP translation service. As a consequence NCP-A requests a translation. Each translation request to an NCP-A must include these parameters 1. Affiliation country where the Patient has identified/authenticated himself 2. Language of the Patient accessing the PA Interface 3. Selected output language (translation language requested) 4. Language of document (the health information) accessed
Associated Goals	• Existing PS/eP in epSOS network must be available to patients either in his own language or in any of the languages of the participating PNs. After the identification of the patient who requests healthcare, in country A or B, the patient requests through a simple action (just a click) the visualization of the PS/eP in the selected language (that one that fits either with his own language or with that of the health care professional). • The patient must be able to access his usual national Patient Access service. • National PA service asks NCP-A for the list of available translations service , and this list is sent and presented to specific Patient access service including for each access date/time of access.
Actors	1. Patient 2. Specific national patient access service 3. NCP A
Preconditions	• Pre-existence of national Patient access service • Pre-existence of epSOS NCPs, at both sides at the country having Patient access and in the output language requested by the patient.

FR02	Patient identification and authentication: a univocal digital ID
Description	epSOS Patient Access (PAC) must be in accordance with the Patient Access policy of patient's Country of Affiliation [9]. Access by the patient to epSOS related functionalities through its National Patient Access shall not interfere with this rule. The patient will be univocally identified in a reliable way (unique and unequivocal id) to consult his information. Patient authentication will be guaranteed at national level based on the concept of mutual trust.
Associated Goals	• To have certainty of the identity of the patient • Independence of national/regional PA systems. The responsibility for patient authentication and identification should remain within the patient's country of affiliation
Actors	1. Patient 2. National Certification authority in country A
Preconditions	• Pre-existence of digital certification authority. The certification authority has already assigned a digital ID to the citizen. • There is a legal basis for access by citizens to their healthcare data in country A • Pre-existence of the Patient access service in country A

FR03	Trust between countries
Description	Country A and B are integrated on one circle of trust (technical and functional). It's necessary an agreed framework for creating trust, by establishing policies, 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 authorization mechanisms. • Security and trust mechanisms.
Associated Goals	• To enable the exchange of information between countries. Based on the recognition of given Certification authorities
Actors	• NCPs and their translation catalogs (MTC) • Certification of provider's servers/ environments • Certification authorities (CA)

FR04	Request from country A for a document translation
Description	For any provided epSOS pivot content in structured form (both CDA level 1 and level 3), Country A requests the translation of all coded elements that are used to describe the epSOS data set. Country A has to provide original data in epSOS CDA compliant form, i.e. the friendly document that has exactly the form of epSOS pivot document, (Ref.: in Specs of common components p.19)
Associated goals	none
Actors	• NCP A • Translation's responsible (either Central services, NCP-A or NCP-B) to be decided at architectural level.

FR05	Delivered translation information is sent to country A
Description	1. The translated information and metadata about the translation service must be sent to country A. 2. When creating a epSOS pivot document, in coded elements the information about code, code system and version should not be repeated in the translated element when the elements are the same as in the original data. 3. The availability of the translation of the coded elements into the target language will depend on prior decisions taken by country B. 4. The information received at the NCP-A node must be delivered (must "talk") to the specific National Patient Access service. 5. In the case that the PS or eP contain several items, this must be confirm with the agreed CDA tool. 6. Country A NCP must answer/inform translation responsible of the successful receipt of the translation.
Associated Goals	• The NCP of country A must be informed about the delivered translation. Health care actions happening in country B as a result of Patient Access won't be reported back / won't be included! This is part of Use case PS extension. • Adaptation/integration/enlargement of current national Patient access services • Security reasons
Actors	1. Country A and B NCPs – depending on translation responsible 2. Common components in central services: CDA display tools

FR06	Information Traceability
Description	1. The information describing the process and the data involved in the process must be able to be retrieved. 2. PAC functionalities include the transformation of national PS or eP into epSOS documents, using transcoding and translation mechanisms based on MVC / MTC mechanisms. These epSOS transformed documents are then made available to the patient through the National Patient Access. 3. The information describing the process and the data involved in the transformation process must be traced and recoverable. It includes such information as the identification of the requester, steps in data transformation and timing of transformation. 4. Main parameters for traceability of translation requested from an NCP-A to any translation responsible are: 5. Requester: Country of Patient identification/authentication 6. Country Language of the Patient accessing the PA Interface 7. Selected output language (translation language requested) 8. Language of the document (health information) accessed 9. Timing(time stamp) of the transformation
Associated Goals	• Security reasons • Legal and liability reasons
Actors	1. National Patient Access Service provider 2. National EHR subsystem 3. NCP-A 4. Translation responsible 5. NCP-B – depending on translation responsibility

FR07	Peering both original documents and translations
Description	Patient and healthcare professional must be able to consult a copy of the original document (with no epSOS semantic transformation) and the translated document.
Associated goals	none
Actors	1. Patient 2. Healthcare professional 3. NCP A
Preconditions	• Availability of documents (eP/PS) • Availability of the pair of language translation involved

FR08	Consultation of PoC through the patient access service- OPTIONAL
Description	For this service the steps in the country National Domain are the same as above for eP/PS. For the realm of epSOS the National Patient Access system retrieves the PoC through the NCP or from the epSOS website
	The patient must be able to consult available PoC in the area where he is interested in for any type of health care providers (e.g. hospitals, healthcare centers and pharmacies). It is a Browsing function returning the list of all PoC in the specified territory value set. The patient triggers the event; the requested Point of Care in an area is the origin of the event; the Service consumer is NCP that triggered the event
Associated goals	Give guided access to epSOS web site maps/PoC. Guided offer of a collection of retrieved PoC in www.epSOS.eu
Actors	• Patient = Active participant • Passive participant /object= Directory/Value set of epSOS PoC **www.epSOS.eu** • Patient Access system calls NCP-A for this service
Preconditions	• Availability of PoC in the requested area (not mandatory). Return value may be zero. • Correct PoC maintenance in **www.epsos.eu** is under responsibility of the NABs

13.7 Service Legal requirements

FR09	Data Consistency
	The actual epSOS Circle of Trust (CoT) consists of pairs of mutually trusted consuming and providing gateways (NCPs). Countries allowing Patient access service to PS or eP do not need to update the previously given prior agreements (PIN). Translations delivered from the translation responsible to NCP A correspond up to 100% to those information stored and available in country A and this must be fully shown NOT be hidden to the patient. It is up to the national system were the data is stored to hide the data and to ensure that the hidden data will not be visible by the patient through the epSOS Patient Access.
Actors	• National data storage systems • epSOS Framework Agreement

FR10	Clear responsibility assignment for the transformation of information by PAC functionalities
	PAC functionalities include the transformation of national EHR data or documents into epSOS documents, using transcoding and translation mechanisms based on MVC / MTC mechanisms. These epSOS transformed documents are then made available to the patient through the National Patient Access. Responsibility for each step of this transformation process shall be clearly defined in epSOS phase 2 Liability Framework, and this information shall be made available to patient who wishes to use PAC functionalities. When the patient accesses epSOS related functionalities through his National Patient Access, country A patient MUST know that the translation may take place out of patient's country. Appropriate information covering the scope of available PAC functionalities must be there. This Functional Requirement controls the liability of the translation if the translation takes place out of patient's country.
Associated Goals	• Legal and liability reasons • Information to the patient • Protecting and safeguarding the patient's medical information
Actors	1. Country A 2. National EHR 3. NCP-A 1. NCP-B
Preconditions	• None

FR11	Unavailable information should remain unavailable to patients using PAC
Description	Some national EHR system may "hide", temporarily or not, specific information to patients. For example, these information are in the patient EHR, but are not made available to the patient until a specific encounter takes place. The use of PAC functionalities by the patient should be compatible with the fulfillment of these rules.
Associated Goals	• Fulfillment of national rules concerning the level of availability of information
Actors	1. Country A 2. National EHR 3. NCP-A
Preconditions	• Rules of availability of information in country A

13.8 Service Security requirements

The epSOS NCP is a Secure Node. According to WP3.7, WP3.8 Basic Security Profile (BSP), IHE ATNA, and IEEE 2700x no administrative access (e.g., root access on a UNIX machine) is permitted. (Reference: epSOS central services_v0.4.4.doc). Therefore, here we do not need to add any further requirements.

In addition to the epSOS NCP-NCP security the citizen must be enabled with a double authorization in order to have access to his data through the patient access portal. PA portal maybe a web service, and eventually also accessible via other device (like mobile phone). This is a national decision, and therefore this is NOT a “security requirement” for epSOS.

Patients should also be able to REVOKE any access and view all accesses done to his/her data.

This is linked to the “maintenance of patient consent” and to “patient access to access logs”. Nonetheless epSOS is not now in the position to implement these services (Ref. “Use cases description in “6.3.5 Additional services where the Patient Access interface may be useful”).

The additional and minimal set of security requirements are listed in this section below.

FR012	**Patient access to logs to his documents: OPTIONAL**
Description	Patients should be in the position to view all accesses done to his/her data, either by clinicians or by authorized persons This is linked to the “maintenance of patient consent” and to “patient access to access logs”. Some National Patient Access services are implementing similar components to let patients monitor who has accessed their EHR.
Associated Goals	• To provide a transparent means about the tenancy of the information • To give confidence to the patient through technical evidence about the correct access to patient’s data
Actors	• Central services
Preconditions & Post conditions	• Security audits of the NCPs (as in standard epSOS procedures)

FR13	Confidentiality of patient information
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 any unauthorized party must also be prohibited at all times.
Associated Goals	• Manifesting the legal foundation for a lawful data processing. • Protecting and safe-guarding the patient's medical information.
Actors	1. NCP-A 2. NCP-B 3. epSOS central services
Preconditions	• None

FR14	Integrity of information
Description	The integrity of transmitted data must be guaranteed when information is transmitted between different entities (legally or technically defined). In such cases, it must be identified that transmitted data cannot be damaged or altered. Any loss of integrity of the transmitted data must be recognizable by the recipient.
Associated Goals	• Trust in the system • Safety reasons • Detection of any damage or alteration to the data
Actors	1. NCP-A 2. Translation responsible 3. epSOS central services
Preconditions	• None

13.9 Service Clinical requirements

This clinical requirement is considered a first step toward paving the way in a future epSOS Patient access empowering the patient with two new features:

- Data upload done by the patient. This is relevant for chronic patients that have continuous monitoring of health parameters relevant for his control and for telemonitoring systems.
- Tagging patients as "chronic patients"

From the functional point of view, a health care professional who is not the usual care provider benefits from knowing whether a patient's health condition is "chronic" (sometimes defined as "more than 3 months in duration") and whether a "long-term" medication is being prescribed. Two practical examples are "asthma" and "use of anticoagulant medication".

The basic requirement is that the data entities "diagnosis/condition" and "medication" have a data attribute to indicate this chronicity. In the case of "diagnosis/condition":

- a doctor could choose to switch the “chronic” label on or off, by conscious choice;
- a “chronic” label could be set on automatically in the case of certain ICD-codes; for example, ICD-9 code 571 means “chronic liver disease and cirrhosis”;
- A “chronic” label could be set on by a rule based on time; for example, if the diagnosis “asthma” is repeated within a period of three months, the condition could be labeled as being “chronic”.
- There could also be other rules that use the existence of long-term medication as evidence that a condition is chronic

FR015	**Labeling/Tagging of Chronicity character of diagnosis: Out of scope. Included for future developments**
Description	Chronic diagnosis of a patient may be labeled in the PA display tool what needs an enlargement of the value sets in PS; this will be discussed in KT 1.4.10 *“a chronic disease” label*” by which patients should be tagged would be very useful in future UC enlargement in epSOS for chronicity management. This tagging should be done out of the combination of a specific set of diagnosis and specific active medication ATC codes together with date of prescription (begin-end or permanent condition of the medication) Local terminology repositories must be synchronized for this issue
Associated Goals	• To provide a list of epSOS chronic diseases with its corresponding ICD-9/ICD-10 codes under the wide consensus of epSOS • To ensure that the doctor/prescriber is familiar with the nomenclature
Actors	• Central services • Local Terminology Repositories
Preconditions & Post conditions	• The EHR/PS or eP preexists in country A • MVC is enlarged with this new Data set and Value sets • In the future some “optional” data sets should become “mandatory” (=those relevant for chronicity)

13.10 Service Semantic requirements

FR16	Semantic compliance
Description	• Target language selection menu will be expressed at the user interface level in a familiar and well known way at every national Patient access system, but at PAC level, internally this should be kept in a form compliant with the epSOS specification (e.g. currently as a combination of ISO 639-1 (language tags) and ISO 3166-1 codes(country abbreviations). • Exchanged documents (both sent and received) must be compliant with with the level 1 or 3 epSOS CDA R2 specifications (currently defined by the D3.9.1 Appendix B1 and B2 epSOS Semantic Implementation Guidelines
Associated Goals	• none
Actors	• Local Terminology Repositories • MVC
Preconditions & Post conditions	Enlargement of the current Data sets

FR17	Disclaimer of scope of the translation service
	The patient shall be informed about the limitations of the translation
Description	This requirement demands the PAC service explains to the patient the possible translation limitations, as part of the translation request dialogue, and also along with the translated document, informing that the service *only translates the coded content* of the PS/eP. The original document accessible by Country A National Patient Access may or may not include clinical information the PAC cannot translate, and the information not translated may or may not have clinical relevance that the translated information does not cover.
Actors	Patient access service
Preconditions & Post conditions	All exceptions occurred during transcoding or translation has to be reported to Workflow Manager using response structure

13.11 Service Usability and data presentation requirements

The next list of requirements contains recommendations and NOT requirements since the presentation/display issues are under the responsibility of national systems (in affiliation's country). FR 21 and FR 22 are Non Functional requirements and therefore are also to be found under the common label "Non Functional Requirements" for all use cases.

FR18	**Understandable information**
Description	The information sent to the patient in another language must be intelligible and structured (i.e. field 'active ingredient' or any diagnostic is properly identified in Country A and univocally translated to Country B language. There are several possibilities to deal with this requirement: o Each data field of the minimum dataset is translated through the MTC nomenclature o A subgroup of the minimum dataset (for example: active ingredient + strength + pharmaceutical dose form) have a unique coding into the common language o Intelligible for the human actors that will make use of it. The information must be presented in a legible manner that is easily understood by those it is aimed at. Patients may have little or no knowledge of clinical terminology. Avoid acronyms at all times. Provide only information that is relevant to and appropriate for those it is aimed at.
Associated Goals	• Healthcare professional and patient understand the "same" for the information to be shown to them. • To provide the HEALTH CARE PROFESSIONAL with the necessary information to safely treat/prescribed medicine to the patient. • Guarantee the safety of the patient through a proper understanding of the received information • Good translation quality backing the safe delivery of care to patients. Issues to be addressed o Consistency: means that the receiving system must be able to recognize what has been sent, so it is a prime requirement for machine-machine communications and dictates the need for unambiguous identifiers. o Understandability: essential for human communication.
Actors	1. Country A NCP 2. Country B NCP 3. Patient 4. HEALTH CARE PROFESSIONAL (optional) 5. translation catalog in country B (MTC) & administration services of each national Patient access service

FR19	Data presentation
Description	Input and output data of TM public interface has to be harmonized with requirements on specific national Patient access interface. Information should be presented in such a structure that it reflects what the user is used to (i.e. a report-like layout). In order to display epSOS structured information (PS or eP) both the epSOS CDA display tool and any other specific display tool (compatible with epSOS CDA) can be used. Patients should be enabled with all the necessary information to select the right data –TARGET LANGUAGE for the translation- and to **identify at a glance** the source of the information (display of epSOS countries by means of icons, flags or pull down menus) An effort should be made to make the interface accessible and easy to use for everyone, no matter what browser he uses and whether or not he has any disabilities. To follow the Worldwide Web Consortium's (W3C) Web Content Accessibility Guidelines 1.0 and to meet all level double-A checkpoints is a good practice.
Associated Goals	• To allow patient to select the specific output/target language into which his PS or eP must be displayed (selection of a flag or selection in pull down menu) • To allow him to select a specific PAC service or eventually a piece of information to be displayed. • To empower patients in accessing and distributing their own clinical information to professionals under own responsibility
Actors	1. Patient 2. Healthcare professional in B 3. Technical environments of Patient Access portal in country A and B
Preconditions	• Cross border extended acceptance of given/specific icons and flags • Implementation of “accepted icons” for the services to be translated (see below REQ16) in order to be displayed homogeneously in all countries for several devices (PC, tablet, Smartphone, mobile phone, TV…) • CDA Display Tools using the MTC 1.7 to translate labels

FR20	Identification of the service accessed by Patient' access
Description	The PAC service needs to have all necessary information (available for the system administrator) in order to identify the correct service. Currently we envisage: 1. Display of PS in any epSOS language 2. Display of available eP in any epSOS language 3. Display of available PoC in the selected location/area by the Patient.
Associated Goals	• For a correct identification of an emergency situation for chronic or fragile patients • Easing the process of giving consent • For convenience reasons (identification of near PoC) • For safety reasons
Actors	• System administrator • Patient • National PHS (patient access systems) • Country A and B NCPs (for the translation)
Comments	The service "Give/confirm or revoke consent" was rejected by TPM because of the burden that it represents for consent management. Therefore we include no functional description for this.

FR21	PAC Service Availability
Description	The availability of PAC functionalities may lie within the availability of different services (availability of national patient access, availability of transcoding processes, availability of translation processes, etc.). Each service may be unavailable for different reasons, planned or unplanned. If possible, planned unavailability should take place during night hours and patients should be informed in advance. Unplanned unavailability should be detected and corrected or circumvented as soon as possible. In case of unplanned unavailability, procedures should be defined to allow for regular information of stakeholders and return to normal as soon as possible.
Associated Goals	• Continuous availability of PAC functionalities (> 99,5%*) • Monitoring of service availability
Actors	1. National EHR 2. NCP-A 3. NCP-B 4. epSOS central services
Preconditions	• None

FR22	PAC response time
Description	The overall response time of PAC functionalities will depend on the response time of several different services. The purpose is to deliver to the patient a global service with an acceptable response time. The system should therefore provide an end to end response time within a few seconds, possibly no more than 10 seconds*.
Associated Goals	• Acceptable response times • Monitoring of response times
Actors	1. National EHR 2. NCP-A 3. NCP-B 4. epSOS central services
Preconditions	• None

13.12 Additional Architecture NCP / Central Service requirements

The requirements REQ 23- REQ25 is a list of future alternatives to be taken into account by WP 3A. These requirements were technical and therefore they could NOT be taken into account from the “functional” point of view. These requirements forwarded to WP 3A are:

REQ 23 The use case Patient access to PoC requires from the system architecture to specify an additional interface to the PoC DB, and allow PoC entries to have mapped coordinates. This will allow the Patient Access platform through the www.epSOS.eu to access directly to the Point of Care.

REQ 24 A future possibility to consider in the architecture is the design of an epSOS Portal for Patient access

REQ25. The functional requirements for PAC define the actor *“Translation responsible”* and leaves it open the decision about WHO is the Translation responsible either NCP_A or NCP_B or central services. TSAM (our current TRANSLATION component) is a component within the NCP.
From the technical point of view the process of identification of the different elements involved will be as follows once the request for translation is arrived:

- Check for document type: element ClinicalDocument/code with value from epSOSDocumentCode valueset (eP or PS)
- Check content of the document (whether document has structured or unstructured body)
- For each CodedElement TSAM can be called for transcoding or translation.
- For all operations response structure containing result of the operation has to be provided.
- Each error or exception condition occurred will be logged, reporting both the code and its English description.
- Logging and Audit Trail: All operation results , exceptions and warnings must be logged internally

13.13 Non Functional requirements

The lists described in this chapter are the basis for NFR. Other specifications describe only modifications or extensions to this list.

Users have implicit expectations about how well a service should work. These characteristics include how easy the service is to use, how quickly it executes/performs, how reliable it is, and how well it behaves when unexpected conditions arise. The non-functional requirements define these aspects about the system.

The non-functional requirements should be defined as precisely as possible. Often, this is done by quantifying them. Where possible, the non-functional requirements should provide specific measurements that the software must meet. The maximum number of seconds it must take to perform a task, the maximum size of a database on disk, the number of hours per day a system must be available and the number of concurrent users supported are examples of requirements that the software must implement but do not change its functional behavior.

The following nonfunctional requirements are elaborated upon the standard ISO/IEC 9126 for the evaluation of Software quality, and some of the attributes are personalized for the Patient Access service. This list must be checked against the current epSOS SLA, since these are overarching principles for all epSOS services.

Category	Description	Example
Data Integrity	Integrity requirements define the security attributes of the system, restricting access to features or data to certain users and protecting the privacy of data entered into the software. They may consider or specify: • Timeliness (how current must information be) • Database replication • Process sequencing • Language translation • Accuracy (specific values, free text) • Data quality • Referential integrity • Content • Format • Robustness	**Example 1:** Replicated database synchronization occurs every 5 minutes. **Example 2:** Data attribute values are verified against the data dictionary to ensure they do indeed contain the expected values or NULL values, if applicable.
Performance	• Data throughput • Response time for transactions (real perceived, expected) • Network latency (local, national, and international usage) • Multiple applications running simultaneously on shared components of the system (web server, application server, database server) • Historic metrics	**Example 1:** The maximum response time during the peak processing period of 10:00am to 3:00pm EST is 10 seconds. **Example 2:** The network services staff monitors the network load for 2 weeks after implementation. **Example 3:** In SK and FI, there is a 5 second delay due to network latency.

Reliability	Reliability specifies the capability of the software to maintain its performance over time. These requirements address the acceptable defect rate or failure rate of the delivered product. They may consider or specify: • Degree to which the product performs to meet expectations • Anticipated frequency or timing of failures • Expected cause of failures • Acceptable recovery time (downtime) • Mechanism for recording and tracking faults and failures	**Example 1:** No more than 2 severity level 1 defects are reported in a calendar month. **Example 2:** The application runs with no system outages 99.5% of time between 7:00am and 5:00pm EST.
Robustness	These requirements address how the service will respond to • Data exceptions • System failures • Hardware failures They may consider or specify: • Alarms and triggers • System response • Levels of severity • Organization policies and processes for such events • Fault and failure recording and tracking	**Example 1:** The fail-over procedures require the system to automatically switch server B to operation when server A goes offline. **Example 2:** Validation error codes are explained in detail in the user help facility
Scalability	These requirements address the ability of the service to adapt to new technologies and to changes in post implementation metrics. They may consider or specify: • Ability of the product to accommodate product upgrades and new functionality (product releases) • Change in throughput • Change in the number of users • Change in the number of transactions processed • Change in level of support • Change in memory requirements • Horizontal scalability (adding similar components) • Vertical scalability (adding capacity to existing components)	**Example 1:** The number of users on the network increases 3% every 6 months to a maximum of 500 users. **Example 2:** New product releases are scheduled for every 3 months for 24 months. **Example 3:** The database grows by 2% per year

Usability	Ease-of-use requirements address the factors that constitute the capacity of the software to be understood, learned, and used by its intended users. Since the end-users are almost always non-technical persons in the epSOS PA service, the system shall respond to the following requirements concerning usability: • The system shall be easy to use. • The system should be easy to learn. • The system shall not contain terms related to the ICT domain. • The system should be supported with guiding material for easy and fast learning.	**Example 1:** A patient with basic computer knowledge accesses his national PA service, and without any personal assistance, translates his PS document from Country A language to the language he prefers, by just following the links, tool tips and other explanations available in the user interface.
Confidentiality	Confidentiality is defined as assurance that information is not disclosed to unauthorized individuals, processes or devices. Confidential information must only be accessed, used, copied, or disclosed by users who have been authorized, and only when there is a genuine need.	**Example 1:** In line with the national PA service specifications, a translated patient summary document should only be visible by the patient himself and (if valid) by his legal guardians. No other person in the patient role can access PS/eP document of another patient.
Non-repudiation	Non-repudiation is assuring that the sender of data is provided with proof of delivery and the recipient is provided with proof of the sender's identity, so neither can later deny having processed the data. Non-repudiation is guaranteed in epSOS with the use of digital signatures and audit trails.	**Example 1:** A patient who has used translation functionality for his patient summary document cannot later deny that he benefited from this service.

14 Appendix A5 - Data Sets for epSOS Extended and Additional Services

The provided DataSets are a DRAFT proposal to KT1.4.10 Clinical and Semantic Task Force. KT1.4.10 will provide the CONSOLIDATED DataSets for the epSOS EED Services to be implemented by PNs.

14.1 Revised epSOS phase 1 Data sets

14.1.1 Revised Patient Summary Data Set

Probably no requirements for data set change.

14.1.2 Revised ePrescription Data Set

14.1.2.1 Specialism of prescriber

Some countries need the specialty of the prescriber for the epSOS ePrescription to be seen as valid. In the epSOS phase 1 ePrescription data set, this element is not basic (minimum), therefore not always filled in. The proposal is to define the specialty of the prescriber as a basic element, so it should be filled in, if available. As it could be that this information is not available in every country, null values should be allowed.

14.1.2.2 Multiple substances in prescription

ATC is the chosen drug terminology for substances in epSOS phase 1, but ATC has problems handling combination products which have that certain countries decided not to pilot with them. ATC also has the problem that there is more than one code for a single substance. The choice of ATC or other terminology belong to the logical/implementation level. KT1.4.6 is not involved in the semantics of the data set, but only on functional specifications. In the WP3.1 specifications of ePrescriptions and eDispense the cardinality of the elements is not present, so the assumption is that the data elements *active ingredient* and *strength of medicinal product* are not repeatable, in the case of handling a combination product. Therefore we propose that these data elements become repeatable. Also we propose to add the possibility to code the active ingredient.

Active ingredient (1..*)	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: Paracetamol	Basic	No	No	Active ingredient, code and strength are linked. Repeatable in case of combination product.
Active ingredient id code (1..*)	Code that identifies the Active ingredient	Ext	Yes	Yes	
Strength (1..*)	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	No	

14.1.3 Revised eDispensation Data Set

Probably no requirements for data set change.

14.2 Health Care Encounter Report Data Set

Data that is in the epSOS phase 1 PS data set is highlighted; data that is in the epSOS phase 1 data set in a different form are highlighted

PATIENT DATA HEALTHCARE ENCOUNTER REPORT							
Data element level 1 (cardinality)	**Data element level 2**	**Data element level 3**	**DEFINITION**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
Identification [9] (1)	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	No	No	
Personal information (1)	Full Name	Given name	The Name of the patient (Example: John). This field can contain more than one element	Basic	No	No	
		Family name/Surname	This field can contain more than one element. Example: Español Smith	Basic	No	No	
	Date of Birth	Date of Birth	This field may contain only the year[10] if day and month are not available. E.g.: 01/01/2009	Basic	No	No	
	Gender	Gender Code	This field must contain a recognized valid value	Basic	No	No	
Contact information country of stay (country B) (0..1)	Address[11]	Street	Example: Oxford	Ext	Yes	Yes	
		Number of Street	Example: 221	Ext	Yes	Yes	
		City	Example: London	Ext	Yes	Yes	
		Post Code	Example: W1W 8LG	Ext	Yes	Yes	
		State or Province	Example: London	Ext	Yes	Yes	Omit when not known
		Country	Example: UK	Ext	Yes	Yes	

[9] 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.
[10] To be aligned with prescription minimum dataset (in D3.1.2 'Final definition of functional service requirements-ePrescription')
[11] Will be adapted due to the variability of the countries.

	Telephone No	Telephone No	Example: +45 20 7025 6161	Ext	Yes	Yes	Omit when not known
	Email	Email	Example: jens@hotmail.com	Ext	Yes	Yes	Omit when not known
	Preferred HP/Legal organization to contact[12]	Name of the HP/Legal organization	Name of the HP/name of the legal organization (that has been treating the patient). If it is a HP, the structure of the name will be the same as described in 'Full name' (Given name, family name/surname)	Ext	Yes	No	
		Telephone No	Example: +45 20 7025 6161	Ext	Yes	Yes	How many countries have this information?
		Email	Email of the HP/legal organization	Ext	Yes	Yes	How many countries have this information?
	Contact Person/ legal guardian (if available)	Role of that person	Legal guardian or Contact person	Ext	Yes	No	
		Given name	The Name of the Contact Person/ guardian (example: Peter. This field can contain more than one element)	Ext	Yes	Yes	

[12] A Health Professional in country A may need a contact (Health Professional/Healthcare Provider) that knows what happened to the patient during the event

		Family name/Surname	This field can contain more than one element. Example: Español Smith	Ext	Yes	Yes	
		Telephone No	Example: +45 20 7025 6161	Ext	Yes	Yes	
		E-mail	E-mail of the contact person/legal guardian	Ext	Yes	Yes	
	Estimated date of return to country A	Date of return to domestic country	Example: 17/09/2012	Ext	Yes	Yes	
Insurance information (0..1)	Insurance Number	Insurance Number	Example: QQ 12 34 56 A	Ext	Yes	Yes	

PATIENT CLINICAL DATA							
Data element level 1 (cardinality)	**Data element level 2**	**Data element level 3 (cardinality)**	**COMMENTS**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
Medical problems (0..*)	List of New Problems/Diagnosis.	Problem/diagnosis description	Problems/diagnosis that fit under these conditions: conditions that may have a chronic or relapsing course (e.g.: exacerbations of asthma, irritable bowel syndrome), conditions for which the patient receives repeat medications (e.g.: diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of medication (e.g.: dyspepsia, migraine and asthma)	Ext			
		Problem code	code that refers to the disease concept	Ext			
		Onset time	Date of problem onset	Ext			
	New 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 be known by the HP	Ext			
		Device code	Code that defines the device	Ext			
		Date of implantation		Ext			
	Executed Surgical Procedures	Procedure description	Describes the type of procedure that has been executed as part of the healthcare event.	Ext			
		Procedure code	Code that defines the procedure	Ext			
		Procedure date	Date when procedure was performed	Ext			
	Given treatments	Treatment Description	Therapeutic treatment that does not include drugs (diet, physical exercise constraints, etc.)	Ext			
		Treatment code	Normalized identifier, concept code	Ext			
		Onset time	Date of treatment onset	Ext			
	Care plan	Recommendations description	Therapeutic recommendations that do not include drugs (diet, physical exercise constraints, etc.)	Ext			
		Recommendations Id (code)	code that defines the recommendation	Ext			
	Disability or Function	Invalidity description	Need of the patient to be continuously assisted by third parties. Invalidity status may influence decisions about how to administer treatments	Ext			
		Invalidity code	Code that defines the invalidity. (if any, otherwise free text)	Ext			

PATIENT CLINICAL DATA							
Data element level 1 (cardinality)	**Data element level 2**	**Data element level 3 (cardinality)**	**COMMENTS**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
		Onset time	Date of invalidity onset	Ext			

PATIENT CLINICAL DATA							
Data element level 1 (cardinality)	**Data element level 2**	**Data element level 3 (cardinality)**	**COMMENTS**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
Medication	Prescription (0..*) (All prescribed medicine whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not.).	Prescription identification (1)	Unique identification of the prescription	Basic	No	No	
		Medicinal product code	Code that identifies the medicinal product description	Ext	Yes	Yes	
		Date of issue of prescription (1)	Date when medicine has been prescribed	Basic	No	No	
		Brand name	Original brand name of the medicine (in the language of the country in which the prescription was made)	Basic	Yes	Yes	
		Active ingredient (1..*)	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: Paracetamol	Basic	No	No	Active ingredient, code and strength are linked. Repeatable in case of combination product.
		Active ingredient code (1..*)	Code that identifies the Active ingredient	Basic	Yes	Yes	
		Strength (1..*)	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	No	
		Medicinal product package	This is the size of the package prescribed	Basic	Yes	Yes	
		Package size					

PATIENT CLINICAL DATA							
Data element level 1 (cardinality)	**Data element level 2**	**Data element level 3 (cardinality)**	**COMMENTS**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
		Pharmaceutical dose form (1)	It is the form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablets, syrup)	Basic	No	No	
		Number of packages	number of boxes that have been prescribed	Basic	Yes	Yes	
		Number of units per intake[13] (1)	The number of units per intake that the patient is taking. Example: 1 tablet	Basic	No	Yes	There has to be space for posology in free text with the possibility of a null flavor
		Frequency of intakes (1..*)	Frequency of intakes (per hours/day/month/week). Example: each 24 hours	Basic	No	Yes	There has to be space for posology in free text with the possibility of a null flavor

[13] 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							
Data element level 1 (cardinality)	**Data element level 2**	**Data element level 3 (cardinality)**	**COMMENTS**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
		Duration of treatment (1)	Example: during 14 days	Basic	No	Yes	There has to be space for posology in free text with the possibility of a null flavor
		Date of onset of treatment (1)	Date when patient needs to start taking the medicine prescribed	Basic	No	Yes	
		Route of administration		Ext	Yes	No	
		Instructions to patient		Ext		No	
		Advice to dispenser		Ext		No	

PATIENT CLINICAL DATA							
Data element level 1 (cardinality)	**Data element level 2**	**Data element level 3 (cardinality)**	**COMMENTS**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
Medication	Dispense (0..*) (All dispensed medication)	Dispense identification (1)	Unique identification of the dispensed medication	Ext	No	No	
		Medicinal product code (1)	Code that identifies the medicinal product description	Ext	Yes	Yes	
		Date of dispense (1)	Date when medicine has been dispensed	Ext	No	No	
		Related prescription	The ID of the prescription serving as the basis for the dispensation	Ext	Yes	Yes	
		Brand name	Original brand name of the medicine (in the language of the country in which the prescription was made)	Ext	Yes	Yes	
		Active ingredient (1..*)	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: Paracetamol	Ext	No	No	Active ingredient, code and strength are linked. Repeatable in case of combination product.
		Active ingredient code (1..*)	Code that identifies the Active ingredient	Ext	Yes	Yes	
		Strength (1..*)	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	Ext	No	No	
		Medicinal product package	This is the size of the package dispensed	Basic	Yes	No	

PATIENT CLINICAL DATA							
Data element level 1 (cardinality)	**Data element level 2**	**Data element level 3 (cardinality)**	**COMMENTS**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
		Pharmaceutical dose form (1)	It is the form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablets, syrup)	Ext	No	No	There has to be space for posology in free text with the possibility of a null flavor, like instruction to patient

PATIENT CLINICAL DATA							
Data element level 1 (cardinality)	**Data element level 2**	**Data element level 3 (cardinality)**	**COMMENTS**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
Medication	Dispense (0..*) (All dispensed medication)	Route of administration		Ext		No	
		Number of packages		Ext		No	

PATIENT CLINICAL DATA							
Data element level 1 (cardinality)	**Data element level 2**	**Data element level 3 (cardinality)**	**COMMENTS**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
		Number of units per intake[14] (1)	The number of units per intake that the patient is taking. Example: 1 tablet	Ext	No	Yes	There has to be space for posology in free text with the possibility of a null flavor, like instruction to patient
		Frequency of intakes (1..*)	Frequency of intakes (per hours/day/month/ week/etc.). Example: each 24 hours	Ext	No	Yes	
		Substitution		Ext		No	
		Duration of treatment (0..1)	Example: during 14 days	Ext	No	Yes	
		Date of onset of treatment according to prescription	Date when the patient needs to start taking the medicine prescribed	Ext	No	Yes	
		Date of end of treatment according to prescription (validity of prescription)	Date of the end of the treatment or prescriptions where the end of treatment has expired.	Basic	Yes	Yes	
		Date of onset of dispense	Date when the patient starts taking the medicine dispensed	Ext	No	Yes	
		Expected date of end of treatment	Expectation when the patient stops taking the medicine dispensed	Ext	Yes	Tes	
Physical findings (0..*)	Vital Signs Observations	Blood pressure	One value of blood pressure which includes: systolic Blood Pressure and Diastolic Blood pressure	Ext	No	No	
		Date when blood pressure was	Date when blood pressure was measured	Ext	No	No	

[14] 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							
Data element level 1 (cardinality)	**Data element level 2**	**Data element level 3 (cardinality)**	**COMMENTS**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
		measured					
Diagnostic tests (0..*)	Blood group	Result of blood group test	Result from the blood group test made to the patient	Ext	No	No	
		Date	Date in which the blood group tests was done. This field may contain only the year if day and month are not available. E.g.: 01/01/2009	Ext	No	No	
Vaccinations		Vaccine brand name	Brand name of the vaccination	Ext		No	
		Vaccine description	Description of the vaccine	Ext		No	
		Vaccine code	The code of the vaccine	Ext		No	
		Vaccination date	The date the vaccination was done	Ext		No	
Allergy		Allergy Display name		Basic		Yes	
		Allergy code	The code of the allergy	Basic		Yes	
		Onset date	Date when the allergy started	Ext		No	
		Agent description	Description of the allergen agent	Basic		Ext	
		Agent code	The code of the allergen agent	Basic		Ext	
Pregnancy history		Expected date of delivery		Ext		No	
Social history		Date range of observation		Ext		No	Example: from 1974 thru 2004
		Observation related to smoke, alcohol and diet		Ext		No	Example: cigarette smoker, alcohol consumption...

HEALTHCARE ENCOUNTER REPORT CONTACT DATA (Information about where the HCER data comes from)							
Data element level 1 (cardinality)	**Data element level 2**	**Data element level 3**	**Definition**	**BASIC (Basic)/EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
HCER identification (1)			Identification of the HCER	Basic	No	No	
Country (1)			Name of country B	Basic	No	No	
Topicality	Date Created (1)		Date on which HCER was generated	Basic	No	No	
	Date of Last Update (1)		Date on which HCER was created by Health Professional in country B	Basic	No	No	
Author of the HCER (1)	Author of the HCER	Author ID (1)	Author ID in country B	Basic	No	No	
		Given name (0..*)	Author's given name as specified by the organization that grants the IDs in country B				
		Family name/Surname (1)	Author's family name as specified by the organization that grants the IDs in country B				
		Role (1)	Role or specialism the author was in when sending the HCER.				
Legal entity[15] (1)	Responsible for the HCER	Healthcare Provider ID (0..1)	legal organization ID responsible for the HCER data				
		Health professional ID (0..1)	Health professional ID responsible for the HCER data				
		Health professional given name (0..*)	Given name of the Health professional responsible for the HCER data	Basic	No	No	
		Health professional Family name/Surname (0..1)	Family name/Surname of the health professional responsible for the HCER data				
		Health professional	Role the health professional is				

[15] At least an author organization (Healthcare Provider) shall be listed. In case there is no Healthcare Provider identified at least an Health Professional should be listed

		role (0..1)	in while being responsible for the HCER data				

Table 1. epSOS Healthcare Encounter Report data set

14.3 MRO Data Set

PATIENT DATA							
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**DEFINITION AND COMMENTS**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null flavour Yes/No**	**Remarks**
Identification [16]	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	No	No	
Personal information	Full Name	Given name	The Name of the patient (Example: John). This field can contain more than one element	Basic	no	Yes	
		Family name/Surname	This field can contain more than one element. Example: Español Smith	Basic	no	Yes	
	Date of Birth	Date of Birth	This field may contain only the year[17] if day and month are not available. E.g.: 01/01/2009	Basic	no	Yes	
	Gender	Gender Code	It must contained a recognized valid value for this field	Ext	Pending decision by WP3.6 (in some countries 'gender' is needed for univocal identification of the patient)	Yes	

[16] 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.
[17] To be aligned with prescription minimum dataset (in D3.1.2 'Final definition of functional service requirements-ePrescription')

PATIENT DATA							
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**DEFINITION AND COMMENTS**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes / No**	**Null flavour Yes/No**	**Remarks**
Contact information	Address[18]	Street	Example: Oxford	Ext	Yes	Yes	
		Number of Street	Example: 221	Ext	Yes	Yes	
		City	Example: London	Ext	Yes	Yes	
		Post Code	Example: W1W 8LG	Ext	Yes	Yes	
		State or Province	Example: London	Ext	Yes	Yes	
		Country	Example: UK	Ext	Yes	Yes	
	Telephone No	Telephone No	Example: +45 20 7025 6161	Ext	Yes	Yes	
	E-mail	E-mail	Example: jens@hotmail.com	Ext	Yes	Yes	
	Preferred HP/Legal organization to contact[19]	Name of the HP/Legal organization	Name of the HP/name of the legal organization. If it is a HP, the structure of the name will be the same as described in 'Full name' (Given name, family name/surname)	Basic	Yes	No	
		Telephone No	Example: +45 20 7025 6161	Basic	Yes	Yes	
		E-mail	E mail of the HP/legal organization	Basic	Yes	Yes	
	Contact Person/ legal guardian (if available)	Role of that person	Legal guardian or Contact person	Ext	Yes	No	
		Given name	The Name of the Contact Person/ guardian (example: Peter. This field can contain more than one element)	Ext	Yes	Yes	
		Family name/Surname	This field can contain more than one element. Example: Español Smith	Ext	Yes	Yes	
		Telephone No	Example: +45 20 7025 6161	Ext	Yes	Yes	
		E-mail		Ext	Yes	Yes	

[18] Will be adapted due to the variability of the countries.
[19] A foreign HP may need a contact (HP/legal organization) who knows the patient

PATIENT CLINICAL DATA							
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**Definition**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null Flavour Yes/No**	**Remarks**
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 (e.g.: exacerbations of asthma, irritable bowel syndrome), conditions for which the patient receives repeat medications (e.g.: diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of medication (e.g.: dyspepsia, migraine and asthma)	Basic	No	Yes	
		Problem code	The code that defines the problem.	Basic	No	Yes	
		Onset time	Date of problem onset	Basic	No	Yes	
	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	No	
		Invalidity code	The code that defines the invalidity	Ext	No	No	
		Onset time	Date of invalidity onset	Ext	No	Yes	

PATIENT CLINICAL DATA							
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**Definition**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null Flavour Yes/No**	**Remarks**
Medication Overview	Prescription (0..*) (All prescribed medicine whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not and all expired prescribed medicine whose period of time indicated for treatment has expired no longer than a set period (e.g. 2 years) of time ago.	Prescriptiont identification (1)	Unique identification of the prescription	Basic	No	No	
		Medicinal product code	Code that identifies the medicinal product description	Ext	Yes	Yes	
		Date of issue of prescription (1)	Date when medicine has been prescribed	Basic	No	No	
		Brand name	Original brand name of the medicine (in the language of the country in which the prescription was made)	Basic	Yes	Yes	
		Active ingredient (1..*)	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: Paracetamol	Basic	No	No	Active ingredient, code and strength are linked. Repeatable in case of combination product.
		Active ingredient code (1..*)	Code that identifies the Active ingredient	Ext	Yes	Yes	
		Strength (1..*)	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	No	
		Medicinal product package	This is the size of the package prescribed	Basic	Yes	Yes	
		Pharmaceutical dose form (1)	It is the form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablets, syrup)	Basic	No	No	

PATIENT CLINICAL DATA							
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**Definition**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null Flavour Yes/No**	**Remarks**
Medication Overview	Prescription (0..*) (All prescribed medicine whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not and all expired prescribed medicine whose period of time indicated for treatment has expired no longer than a set period (e.g. 2 years) of time ago.	Number of packages	number of boxes that have been prescribed	Basic			
		Number of units per intake[20] (1)	The number of units per intake that the patient is taking. Example: 1 tablet	Basic	No	Yes	There has to be space for posology in free text with the possibility of a null flavour
		Frequency of intakes (1..*)	Frequency of intakes (per hours/day/month/ week/etc.). Example: each 24 hours	Basic	No	Yes	There has to be space for posology in free text with the possibility of a null flavour
		Duration of treatment (1)	Example: during 14 days	Basic	No	Yes	There has to be space for posology in free text with the possibility of a null flavour
		Date of onset of treatment (1)	Date when patient needs to start taking the medicine prescribed	Basic	No	Yes	
		Date of end of treatment (validity prescription)	End date of prescription where the end of treatment has expired.	Basic	Yes	Yes	

[20] 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)**	**Definition**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null Flavour Yes/No**	**Remarks**
		Route of administration		Ext	Yes	No	
		Instructions to patient		Ext		No	
		Advice to dispenser		Ext		No	
		Substitution allowed?		Ext		No	

PATIENT CLINICAL DATA							
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**Definition**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null Flavour Yes/No**	**Remarks**
Medication Overview	Dispense (0..*) (All dispensed medication)	dispense Identification (1)	Unique identification of the dispense	Basic	No	No	
		Date of issue of dispense (1)	Date when medicine has been dispensed	Basic	No	No	
		Related prescription ID (1)	Identification of the related prescription	Basic	Yes	No	Note that this ID can be an ID from country B.
		Brand name	Original brand name of the medicine (in the language of the country in which the prescription was made)	Basic	Yes	Yes	
		Active ingredient (1..*)	Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: Paracetamol	Basic	No	No	Active ingredient, code and strength are linked. Repeatable in case of combination product.
		Active ingredient code (1..*)	Code that identifies the Active ingredient	Ext	Yes	Yes	
		Strength (1..*)	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	No	
		Medicinal product package	This is the size of the package dispensed	Basic	Yes	No	

PATIENT CLINICAL DATA							
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**Definition**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null Flavour Yes/No**	**Remarks**
		Pharmaceutical dose form (1)	It is the form in which a pharmaceutical product is presented in the medicinal product package (e.g. tablets, syrup)	Basic	No	No	
		Route of administration		Ext		No	
		Number of packages	number of boxes that have been dispensed	Basic		No	
		Number of units per intake[21] (1)	The number of units per intake that the patient is taking. Example: 1 tablet	Ext	No	Yes	There has to be space for posology in free text with the possibility of a null flavor, like instruction to patient
		Frequency of intakes (1..*)	Frequency of intakes (per hours/day/month/ week..). Example: each 24 hours	Ext	No	Yes	

[21] 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)**	**Definition**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes / No**	**Null Flavour Yes / No**	**Remarks**
Medication Overview	Dispense (0..*) (All dispensed medication)	Duration of Prescription (1)	Example: during 14 days	Ext	No	Yes	There has to be space for posology in free text with the possibility of a null flavour
		Date of onset of treatment according to prescription (1)	Date when patient needs to start taking the medicine prescribed	Ext	No	Yes	
		Date of end of prescription (validity of prescription)	End date of prescription where the end of treatment has expired.	Ext	Yes	Yes	
		Date of onset of dispense (1)	Date when patient starts taking the medicine dispensed	Basic	No	Yes	
		Expected end date of treatment	Expectation when the patient stops taking the medicine that is dispensed	Basic	Yes	Yes	
		Substitution	If a different brand name or package size has been dispensed	Ext		No	

PATIENT CLINICAL DATA							
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**Definition**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes / No**	**Null Flavour Yes / No**	**Remarks**
Vaccinations		Vaccine brand name	Brand name of the vaccination	Ext		No	

PATIENT CLINICAL DATA							
VARIABLE (nesting level 1)	**VARIABLES (nesting level 2)**	**VARIABLES (nesting level 3)**	**Definition**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes / No**	**Null Flavour Yes / No**	**Remarks**
		Vaccine description	Description of the vaccination	Ext		No	
		Vaccine code	The code of the vaccination	Ext		No	
		Vaccine date	The date the vaccination was done	Ext		No	
Allergy		Allergy Display name		Basic		Yes	
		Allergy code	The code of the allergy	Basic		Yes	
		Onset date	Date when the allergy started	Ext		No	
		Agent description	Description of the allergen agent	Basic		Ext	
		Agent code	The code of the allergen agent	Basic		Ext	
Social history		Date range of observation		Ext		No	Example: from 1974 thru 2004
		Observation related to smoke, alcohol and diet		Ext		No	Example: cigarette smoker, alcohol consumption...
Pregnancy history		Expected date of delivery		Ext		No	
Physical findings	Vital signs observations	Blood pressure	One value of blood pressure which includes: systolic Blood Pressure and Diastolic Blood pressure	Ext		No	
		Date when blood was measured	Date when blood pressure was measured	Ext		No	

Medication related overview DATA (Information about the MRO itself)							
Data element (nesting level 1)	**Data element (nesting level 2)**	**Data element (nesting level 3)**	**Definition**	**BASIC (Basic) / EXTENDED (Ext) DATASET**	**Exceptions Allowed Yes/No**	**Null Flavour Yes/No**	**Remarks**
MRO identification			Identification of the MRO	Basic	No	No	
Country	Country	Country	Name of country A	Basic	No	No	
MRO	Date of Last Update	Date of Last Update	Data on which MRO was updated (data of last version)	Basic	No	No	
Author/Nature of the MRO	Author of the MRO	Author of the MRO	To highlight if the data is collected manually by an HP or is collected automatically from different sources (e.g.: hospital doctor repository, GPs, etc.) through pre-determined clinical rules.	Basic	No	No	
Legal entity	Responsible of the MRO data	Responsible of the PS data	At least a healthcare provider shall be listed. In case there is no healthcare provider identified a health professional should be listed	Basic	No	No	

14.4 Data Set Extension for 112 Services

No requirements for data set change.

14.5 Data Set Extension for Patient Access Services

No requirements for data set change.

15 Appendix A6: UC descriptions

Deliverable D 1.4.1 – Use Case Description can be found on PP:

PD1 Analysis and Evaluation / WP 1.4 / Service Definition / WP 1.4 Consolidated Documents / UC Final Version (4th) and comments on it

At the address:

https://service.projectplace.com/pp/pp.cgi/d672697464/epSOS_use%20case%20description%20v0.42%2020111019.docx