Smart Open Services for European Patients

Open eHealth initiative for a European large scale pilot of

Patient Summary and Electronic Prescription

OpenNCP PAC Service design and engineering details

APPENDIX C

D 3.B.2

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ABSTRACT
"OpenNCP PAC Service design and engineering details: represents a basic reproduction from the online documentation created by the OpenNCP Community while planning, executing and controlling this epSOS Phase 2 new service implementation.

Change History					
Version	Date	Status Changes	From	Details	Review
V1.0	28/12/13	Draft	L. Mano	Reproduced from yhe OpenNCP Knowledge Repository	Licinio Mano Marcello Melgara
V1.1	22/05/14	Final	M. Melgara	Included changes requested by QA and EC Review	Licinio Mano Marcello Melgara
V1.1.1	30/06/2014	Final	APM	last APM edits, line numbering, version number	

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1 Patient Access (PAC)

The purpose of this page is to provide a better clarification on the specification of the implementation of the **Patient Access Service** on the OpenNCP scope.

1.1 General considerations on Patient Access Service

The PAC service introduces several paradigm shifts in the overall epSOS Service Model approach.

First of all, it is a service provided in Country A, not in Country B, to a citizen, not to a Healthcare Professional. It is hence a B2C service, while all the others are B2B.

Another relevant paradigm shift is that a Country translates a document into a language from a different Country. This implies that:

- The trustable translation into another language has to be provided either from the Country responsible for that language, or from the SDOs responsible for the relevant code system.
- The MTC of other designations (i.e. languages) have to be downloaded from the Central Terminology Server, with the authorization of the other Country and the possible limitation to the use of the MTC (e.g. Pre-Production only, Operation).

The availability of the PAC service opens new scenarios where the citizen becomes the mediator between his Country A HealthCare Service Provider and the Country B HealthCare Professional. This approach is called "Patient Mediated".

From a legal point of view is similar to the case in which a citizen shows its paper clinical document to a HealthProfessional abroad.

1.2 How a document could be generated on Patient Access Service

Apart from the mere display of the PS into another language, other options are potentially opened:

- Print a paper version of the translated PS
- Create a pdf of the translated document
- Export in XML format the translated document

- Export in a more secure format (e.g. IHE XDM) that assures non repudiation of the XML document

Connected to these alternatives, different way of providing the "electronic" documents to the Healthcare Professional in Country B could be imagined:

- Displayed on a Citizen device
- As an electronic document on a USB key, to be loaded and displayed on the HealthProfessional device
- Made accessible by the citizen to the Healthcare Professional through a Service Providers.

All these alternatives are not included in the epSOS 2 Services. They will be carefully studies by the FP7 Project Trillium Bridge on EU-US interoperability of patient Summary and by the CIP Project EXPAND, on the consolidation of interoperability assets (including the epSOS ones, as a bridge to Connecting Europe Facility (CEF).

OpenNCP Team, in the last part of epSOS has built some components to improve PAC services and provide support to Trillium Bridge. These components will be included in OpenNCP 2.1.1, to be released in June 2014.

1.3 **Other potential scenarios related to Patient Access Service**

The paradigm shift introduced by PAC service opens further new scenarios.

The basic epSOS semantic interoperability process foresees that Country A NCP generates a valid epSOS pivot CDA, by mapping Country A document structure and coded elements in the epSOS pivot CDA and epSOS Value Sets,

Country B NCP translates the received pivot CDA in the Country B language to allow displaying it to the Healthcare Professional.

When PAC is implemented, the Country A is in the position of generating epSOS document in other epSOS languages, performing both the tasks of Country A (mapping) and of Country B (translation).

This might imply that a document is generated in Country A ready to be displayed in Country B Portal.

Two interesting scenarios can be investigated:

- Country B can display the document without the need of keeping the MTC: the implication on the need of holding Code Systems licenses might be analysed under this scenario.
- If the document is generated already including Country B language, in theory it could be encrypted in Country A, and decrypted at the Point of Care, in Country A is obliged to adopt Extended Security Safeguard.

These two scenarios are reported as a stimulus for further investigations.

2 Scenarios Clarification

2.1 Goals

The goals of the main actor, the patient, in UC.PAC.1 is to access and understand what the Health Professional has recorded in the PS or eP, in order to:

- **Participate in his or her own care, and/or to improve the information he or she gives to a New Health Professional;**

2.2 Actors

The actors involved in the epSOS PAC Use Case are:

Primary actors:
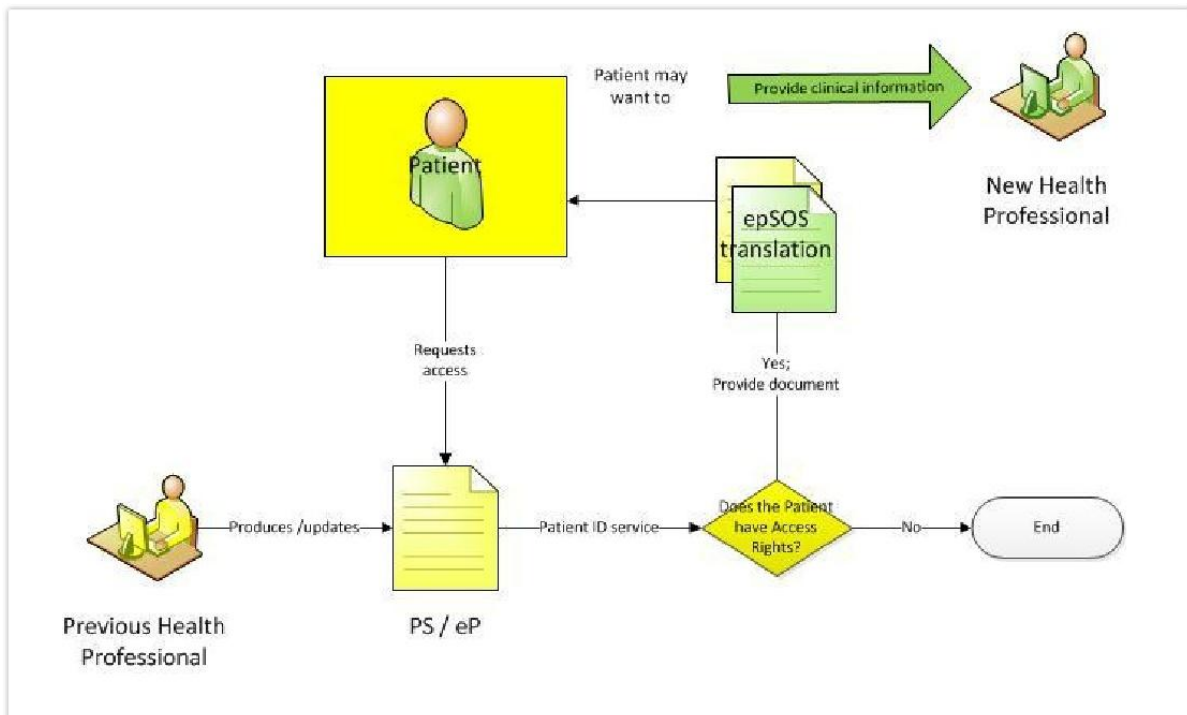
- The Patient;

Secondary actors:

- The Health Professional, acting as a Healthcare Provider, producing the medical information used in the document to be accessed;
- The Health Professional at a new encounter (New Health Professional);
- Patient identification, authentication & role authorization service;
- The epSOS Patient Access translation service;

Diagram 1: Use case diagram

2.3 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 included in one circle of trust (defined among epSOS PNs). 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 catalogues (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	**Patient identification and authentication: a univocal digital ID**
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 oeP 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:
	     1. Requester: Country of Patient identification/authentication
	     2. Country Language of the Patient accessing the PA Interface
	     3. Selected output language (translation language requested)
	     4. Language of the document (health information) accessed
	     5. Timing(time stamp) of the transformation

Associated	▪ Security reasons

Goals	▪ 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

2.4 **Service Legal Requirements**

For service legal requirements please consult the D 1.4.3, page 112;

2.5 **Service Security Requirements**

For service security requirements please consult the D 1.4.3, page 114;

2.6 **Service Clinical Requirements**

For service clinical requirements please consult the D 1.4.3, page 115.

2.7 **Service Usability and Data Presentation Requirements**

For service usability and data presentation requirements please consult the D 1.4.3, page 117.

2.8 **Additional Architecture NCP / Central Service requirements**

For additional Architecture NCP / Central Service requirements please consult the D 1.4.3, page 122.

3 Clarification

The purpose of this topic is to clarify some remaining questions and doubts about the Patient Access specification of OpenNCP.

- Can the service workflow be accomplished using the NCP-B + Portal-B?

4 Implementation Strategy Design

4.1 Overview

Multiple ways can be followed in order to implement the Patient Access service on the OpenNCP. The most direct one is to make use of existent components and implemented services. Others will require further development.

4.2 Solution A: Re-use the Portal-B + NCP-B as Patient Access and Translation Service
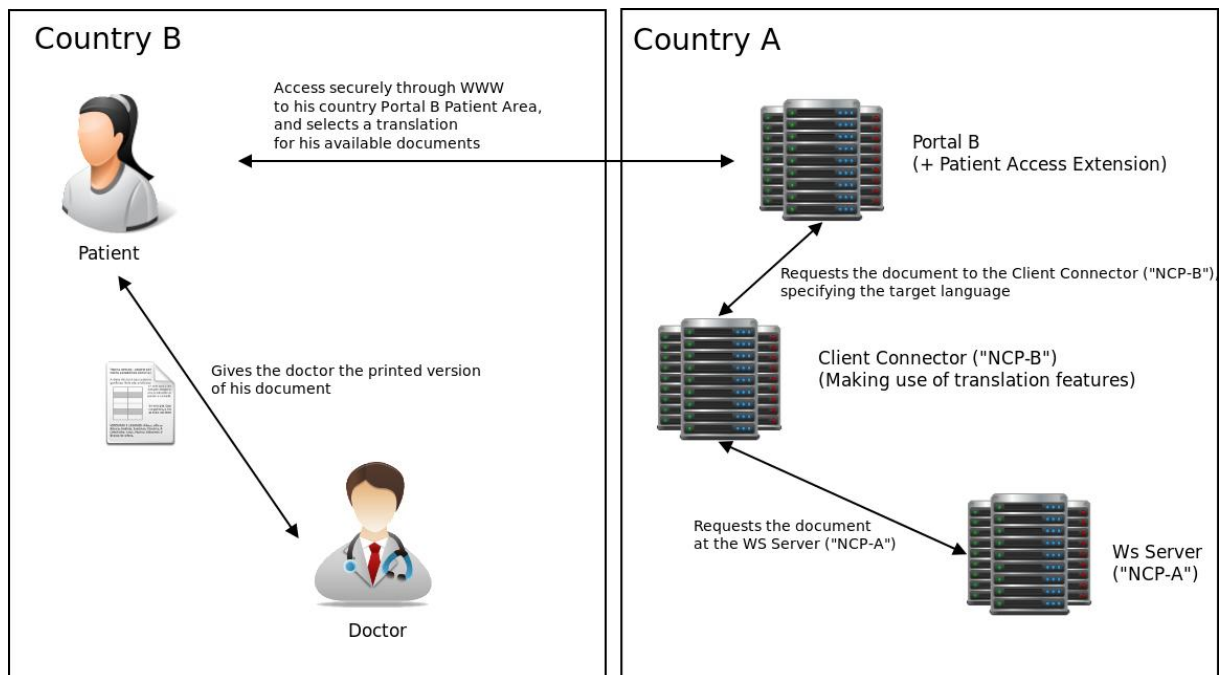
In order to promote the maximum components re-use we can define the following table to map the required PAC service elements into the existent OpenNCP components:

Mapping table of Patient Access Elements into OpenNCP components

Patient Access Required Element	OpenNCP Existent Component	Description
Country-A	Portal-B with	As a default implementation, the Patient

Patient Access Service	Patient Access Section + NCP-B	Access service can be provided by the existent Portal solution for OpenNCP. It will be necessary to implement a Patient Section.
Translation Service	NCP-B (In patient country of affiliation)	The translation service can be provided by the NCP-B of the country of affiliation, since it will support the target language selection
NCP-A	NCP-A (In patient country of affiliation)	The NCP-A can be used as it is, with no further modification.

We can also map the required steps into the following OpenNCP actions and operations:

Mapping table of required steps into components actions and operations

Steps	Actions	OpenNCP actions and operations description	To be implemented in OpenNCP	Related Profiles
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 patient will access to the **Portal-B Patient section**; ▪ The portal will use its "**Portal-B**" capabilities to query the Patient Documents based on the Patient Identifier, using the **NCP-B**; ▪ The retrieved (as whole document) or available (as list) documents are presented to the user; ▪ The patient	A Portal-B Patient Section, with the following aspects: 1. New Patient Role; 2. Section navigation filtered, according to user role; 3. Default document search, constrained to the user id (not possible to user other id);	XCPD, XCA

	the document	▪ may retrieve the document (if it isnt yet) or move to next step;		
2	The Patient requests an epSOS translation of the retrieved document	▪ (Portal GUI)	(Described further bellow)	
3	The National Patient Access system passes the request to the epSOS NCP in Country A	▪ Not required		
4	The epSOS NCP in Country A provides a dialogue for selecting the source and target language (Language A, Language B)	▪ The patient selects the target language for the document at the portal and requests the document; ▪ The **Portal** performs a request to the **NCP-B**, also specifying the translation language selected by the patient;	Target language selection for translating a document at the Portal-B patient section; 1. List of available languages must be displayed;	
5	The National Patient Access system sends the document (in Language A) to the epSOS NCP in Country A	▪ The **NCP-B** then requests the document at the **NCP-A**	Already supported;	XCA
6	The NCP-A transforms (transcodes) the document indicated (or received) from Patient Access system into a translatable epSOS	▪ The **NCP-A** request the document at the **National Connector** and	Already supported;	XCA

	pivot document and then makes this pivot document available to the translation responsible.	transforms it to epSOS Pivot		
7	The translation responsible retrieves the epSOS MTC of Language B	▪ (NCP-B operation, using TM)	Already supported by TM;	
8	The translation responsible translates the pivot document and makes the translated document in language B available to the NCP of country A	▪ The **NCP-B** retrieves the document from **NCP-A** and translates it to the target language;	Adapt Client Connector to support language specification when retrieving a document; 1. Include extra language parameter in the document retrieve request message;	XCA
9	The NCP of country A conveys the information translated into the interface of the National Patient Access system	▪ The **NCP-B** returns the document to the Portal;	Already supported;	XCA
10	The patient accesses the translated document in his specific device display	▪ The Portal displays the document using the specific XSLT resources	Adapt portal to support multiple XSLT for each language; Possibly add PDF production feature (for easier portability and printing);	
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.			

4.2.1 **Implementation Mapping with existent Workflows**

Assumptions - Example

- Country B is Greece;
- Country A is Italy;

4.2.1.1 Existing Portal-B workflow	4.2.1.2 PAC Workflow
Pharmacist accesses Greek Portal-B	Italian Patient accesses Italian Portal-B
1. hcp asserion	1. hcp asserion (needs to be specified new role and permissions for patient). I am not sure if patient is an HCP (healthcare point)
2. identification service (finds an Italian patient)	2. identification service (the system automaitcally identifies itself, the patient stores to the portal the personal identifiers needed for matching with the patient)
3. TRC Assertion	3. TRC Assertion (the system automatically creates a trca with purpose of treatment, new role has to be defined)
4. patient service	4. patient service (the system automatically retrieves list of documents)
5. Consent handling if needed	5. Retrieval and display of document

	(translation of document not needed, it's in italian language already, no transformation needed)
6. Retrieval of document (translation of document in country b language - greek in this occasion)	6. Consent handling must be part of ncp-a in order to allow patient to see its own data

Questions

- Does it needed a new audit event for this transaction?

So if the patient role had permissions on patient service he could probably see his documents

4.2.2 **Implementation Issues / Tasks:**

Portal-B

4.2.3 **Considerations**

- In this scenario we will re-use all the existent components to meet the PAC Service requirements;
- Some security issues need to be taken into account, in order to restrict the retrieval of "patient-only" documents;

4.3 **Solution B: Newly create Patient Access and Translation Service components**

- In this option we would need to expose an additional service for translation purposes only at NCP-A, skipping the re-use of NCP-B.
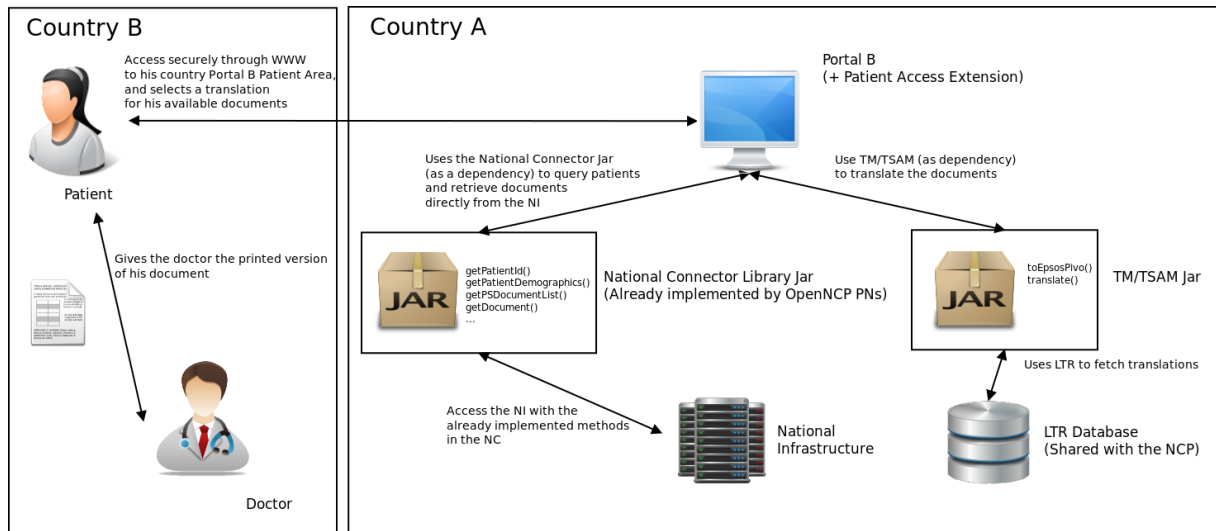- (To be completed if required)

4.4 **Solution C: Use Transformation Manager and National Connector library as Portal dependencies**

With this solution we would have the Portal **communicating directly** with the National Infrastructure, using the already implemented **National Connector** (by the OpenNCP PNs). The translation would be performed by the **Transformation Manager**, added also directly as a dependency of the Portal.
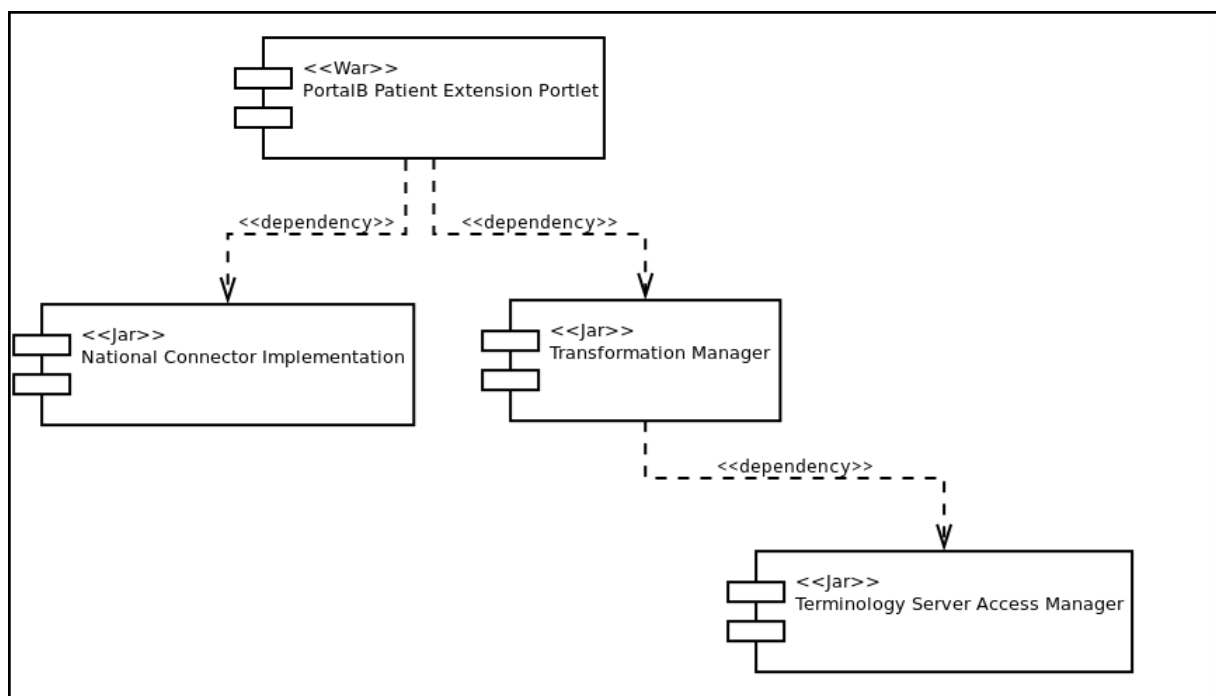
The following diagram tries to explain the proposed solution.

Basic solution diagram

In order to clarify the portal dependencies, the following diagram is presented:

Portal dependency graph

Mapping table of required steps into components actions and operations

Steps	Actions	Portal actions and operations description	To be implemented in the Portal	Related Profiles
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	• The patient will access to the **Portal-B Patient section**; • The portal will use its **National Connector** implementation dependency to query the Patient Documents based on the Patient Identifier; • The retrieved (as whole document) or available (as list) documents are presented to the user; • The patient may retrieve the document (if it isnt yet) or move to next step;	A Portal-B Patient Section, with the following aspects: 1. New Patient Role; 2. Section navigation filtered, according to user role; 3. Default document search, constrained to the user id (not possible to user other id);	NI specific

	document		
2	The Patient requests an epSOS translation of the retrieved document	• (Portal GUI)	(Described further bellow)
3	The National Patient Access system passes the request to the epSOS NCP in Country A	• Not required	
4	The epSOS NCP in Country A provides a dialogue for selecting the source and target language (Language A, Language B)	• The patient selects the target language for the document at the portal and requests the document;	Target language selection for translating a document at the Portal-B patient section; 1. List of available languages must be displayed;
5	The National Patient Access system sends the document (in Language A) to the epSOS NCP in Country A	• Not required	
6	The NCP-A transforms (transcodes) the document indicated (or received) from Patient Access system into a translatable epSOS pivot	• The **Portal** uses the **Transformation Manager toEpsosPivo()** operation to transform the document to epSOS Pivot	The **Transformation Manager toEpsosPivot()** invocation;

	document and then makes this pivot document available to the translation responsible.			
7	The translation responsible retrieves the epSOS MTC of Language B	• **Transformation Manager** operations, using the LTR, shared with the NCP;	Already supported by TM;	
8	The translation responsible translates the pivot document and makes the translated document in language B available to the NCP of country A	• The **Portal** uses the **Transformation Manager translate()** operation to translate the document to the requested language	The **Transformation Manager translate()** invocation;	
9	The NCP of country A conveys the information translated into the interface of the National Patient Access system	• The **Portal** obtains the result of the **Transformation Manager translate()** operation		
10	The patient accesses the translated document in his specific device display	• The Portal displays the document using the specific XSLT resources	Adapt portal to support multiple XSLT for each language; Possibly add PDF production feature (for easier portability and printing);	
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.			

5 Test Strategy Design

PAC service transforms an epSOS Friendly CDA, generated by the National Connector, into an epSOS Pivot, with English designations.

The epSOS pivot is then translated into the target designation, as the one made available to the Health Professional in Country B.

The Gazelle Model Based CDA Scrutiny Tests for specific service MUST be used to verify the correctness of the Country A epSOS Friendly, the epSOS pivot and the the Country B epSOS friendly.

All these tests can be performed by the Country A, independently from other Countries.

6 References

File	Modified
PDF File **D1.4.3 EED SERVICES including specifications for all services v1 0 20120911.pdf** EED SERVICES including specifications for all services	Feb 13, 2013
View Properties Delete	
PDF File **D1.4.1 EED SERVICES including use cases for all services.pdf** D1.4.1 EED SERVICES including use cases for all services	Feb 11, 2013