

Recommendations

on

Country Guide for eHealth NCP implementation

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth. The Joint Action supporting the eHealth Network (JAseHN) provides scientific and technical support to the Network.

Adopted by consensus by the eHealth Network, Amsterdam, 7 June 2016

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LIST OF ABBREVIATIONS

ACRONYM	DEFINITION
CBeHIS	Cross Border eHealth Information Services
CEF	Connecting Europe Facility
DSI	Digital Service Infrastructure
EC	European Commission
eHDSI	eHealth DSI
eHN	eHealth Network
eHN-LSG	eHealth Network Legal Subgroup
EIF	European Interoperability Framework
EU	European Union
IOP	Interoperability
HP	Health Professional
JAseHN	Joint Action to support the eHN
LOST	Legal, Organisational, Semantic, Technical
MLA	Multilateral Legal Agreement
MS	Member States (of EU)
NCP	National Contact Point for cross-border services
NCPeH	National Contact Point for eHealth
NI	National Infrastructure
OFW	Organisational Framework
OFW-NCPeH	Organisational Framework for National Contact Point for eHealth
PoC	Point of Care
ReEIF	Refined eHealth European Interoperability Framework
PARENT JA	Patient Registries Initiative Joint Action

LIST OF TERMS AND DEFINITIONS

TERM	DEFINITION
CBeHIS	Cross Border eHealth Information Services in the scope of the current
	document, namely Patient Summary and ePrescription (may include
	eDispensation)
CBeHIS	Stakeholders, relations between them and favourable infrastructures to allow
environment	the flourishing of CBeHIS
CEF eHealth DSI or	EU financial (€7.5 million) mechanism (based on call for proposals) that was
eHDSI	launched by November 2015 and may be used by MS to support CBeHIS
	provision (Preparation, Deployment and Operation of NCPeH - meaning
	generic services in CEF)
Communication	MS system that manages CBeHIS transactions with other MS and which
Gateway	connects to the NI.
	This is an entry/exit point from the MS, acting on behalf of a HP and Citizen (at
	a Point of Care), that assures the exchange of patient's medical data in a
	controlled environment.
Compliance	A well-defined set of activities and evidence used to ensure that NCPeH
Establishment	compliance can be established, maintained and reinforced
Process	
Country A	The country of affiliation. This is the country that holds information about a
	patient, where the patient can be unequivocally identified and his/her data
	may be accessed.
Country B	The country of treatment, i.e. where cross-border health care is provided

	when the patient is seeking care abroad.	
Framework A real or conceptual structure intended to serve as a support or guide for building of something that expands the structure into something useful.		
Guideline A suggested way of compliance when doing something. It is vis using or supporting the use of a particular service but there are not followed.		
Guideline for Adoption	Intended to present to the eHealth Network's members a clear guideline with the intention for it to be adopted and optionally implemented by the EU MS at national level in the next step.	
National Infrastructure	The healthcare IT infrastructure, which manages patient and HP/HCP ¹ identification and health care records in MS ¹	
NCP	National Contact Point as referred to in Article 6 of the 2011/24/EU Directive	
NCPeH	National Contact Point for eHealth, which may act as an organisational and technical gateway for the provision of eHealth Cross Border Information Services	
NCPeH Deployment	Set of activities aiming to provide evidence of NCPeH compliance with the full range of requirements (LOST) established towards CBeHIS provision	
NCPeH Implementation	Process of preparing, deploying and operating a NCPeH	
NCPeH Operation	Set of activities performed by the MS while providing the service to citizens and health professionals	
NCPeH Preparation	Set of activities aiming to set up an NCPeH	
Organisational Framework	Defines core characteristics, duties and responsibilities of an NCPeH	
PoC	Location where an EU citizen may seek healthcare services. It can be a hospital, a pharmacy or any other point of the healthcare system of Country B.	
Requirement	Definition of relevant needs (business, functional, non-functional, technical and technological) for system specification and implementation	

 $^{^{\}rm 1}$ see Article 3 (f) and (g) of Directive 2011/24/EU

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1. Executive summary

One of the biggest challenges for EU Member States (MS) willing to provide Cross Border eHealth Information Services (CBeHIS) is the absence of previous experience and mature knowledge of the practical activities needed to set up a National Contact Point for eHealth (NCPeH).

Some of the EU MS have already participated in European-wide initiatives that experienced the provision of CBeHIS. From those experiences, lessons were learnt and knowledge gained.

Based on those informational assets, there is a solid ground to build upon practical recommendations to support MS designing a localised plan of activities that can guide the MS from a starting point of willingness through to the successful preparation and deployment of the NCPeH.

The purpose of this document is to support Member States by providing a set of recommendations on how to prepare, deploy and operate a NCPeH.

2. Introduction

2.1. Scope

The overall model presented by the Organisational Framework for eHealth NCP (OFW-NCPeH) foresees several instruments to support the Cross Border eHealth Information Services (CBeHIS) Preparation, Deployment and Operation.

The following diagram (Error! Reference source not found.) depicts the overall model proposed by the OFW-NCPeH and how the "Country guide for eHealth NCP implementation" recommendation fits with this model and interacts with the other proposed instruments.

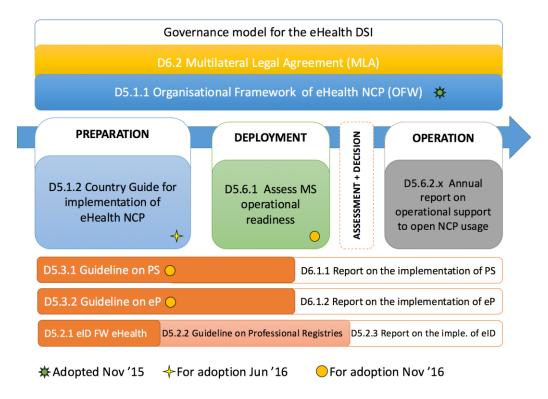


Figure 1. Alignment of CBeHIS instruments and work in progress²

The "Country Guide for eHealth NCP implementation" recommendation relates to several aspects of the preparation stage of the NCPeH, but focuses mostly on Semantic and Technical aspects. With regard to Legal and Organisational principles and requirements, this document will refer to the:

- Multilateral Legal Agreement (MLA) designed by JAseHN task 6.2 that previously acts as the eHN legal sub-group;
- Organisational Framework of eHealth NCP, designed by JAseHN.

As foreseen in OFW-NCPeH, the preparation stage is the first of 3 (three) stages towards CBeHIS operation. The OFW-NCPeH also proposes that the baseline content for the "Country Guide for eHealth NCP implementation" should, as far as possible, use key epSOS outcomes that have been reviewed and fine-tuned by EXPAND, namely:

- Requirements and Recommendations checklist;
- Sequential implementation activities;
- Project Initiation Document (Pilot Plan).

2.2. Objectives

These provide guidance on how MS can implement their NCPeH by using recommended common instruments:

Requirements and Recommendations for implementing an NCPeH;

² Source: Improvement of the figure present in the JAseHN D.5.1.1 Organisational Framework for eHealth NCP

- Service Deployment Plan;
- Service Deployment Progress Monitoring.

3. Country Guide for eHealth NCP implementation

3.1. Baseline approach

There are 3 (three) main stages towards CBeHIS operation as foreseen in OFW-NCPeH.

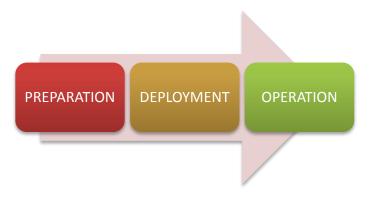


Figure 2. Compliance establishment process³

According to the OFW-NCPeH, the PREPARATION stage is:

(...) where MS design the national deployment plan and perform national preparatory activities towards the provision of cross border eHealth services;

and also

(...) The goals defined for each stage may be supported by a set of tools and mechanisms that guide MS towards each stage scope, as well as providing evidence on which the governing body may take decisions regarding "readiness level" and "quality of service".

The following table describes the tools suggested by OFW-NCPeH for the preparation stage and will be described in greater detail in this chapter.

DOCUMENT	PURPOSE	VALUE ADDED
Member State Requirements and Recommendations [CHECKLIST]	Support the MS to set up and adopt measures required for the optimal establishment of the NCPeH	Guide the MS in establishing the NCPeH
Member State Service Deployment [PLAN]	Allow the MS to share national visions and intentions towards CBeHIS provision	Knowledge about MS aims and plans, in a comparable structured way
Member State Preparation Progress	Allow the MS to report NCPeH preparation	Knowledge about MS status,

Table 1. NCPeH implementation – Preparation Stage – tools and mechanisms⁴

³ Source: JAseHN D.5.1.1 Organisational Framework for eHealth NCP

⁴ Source: JAseHN D.5.1.1 Organisational Framework for eHealth NCP

[REPORT]	activities in a structured and sharable way	activities in progress and known
		issues

3.2. Elaboration of instruments: a rational and enhanced approach

Building upon the baseline proposed by OFW, the "Country Guide for eHealth NCP implementation" presents a practical and pragmatic rationale for the elaboration of the instruments referred to:

- Requirements and Recommendations
- Service Deployment Plan and Preparation Progress Report

3.2.1. Requirements and Recommendations

Purpose:

- Pave the way for countries to acknowledge and understand the requirements and recommendations in order to be compliant while setting up the NCPeH.
- Support countries to set up and adopt measures required for the optimal establishment of the NCPeH.

Description:

 A checklist of requirements and recommendations that MUST (for requirements) and MAY (for recommendations) be fulfilled to achieve compliance with other countries while preparing, deploying and operating the NCPeH.

Tools and mechanisms:

- Provide a checklist of requirements, classified and categorised in distinct areas:
 - o Type of requirement:
 - Required: MUST be fulfilled;
 - Recommended: SHOULD be fulfilled.
 - Thematic area:
 - A specific requirement may impact several thematic areas, such as:
 - Technical, Legal, Security and Trust, Semantic,
 Dissemination & Training, Organisational, Testing,
 Operation, Evaluation.
 - Service and role:
 - Each requirement may be relevant for one or both services (PS and/or eP) as well as being relevant if you provide a service as Country A or Country B.
 - Source:
 - Each requirement is captured from a specific document (e.g. guidelines, specifications, OWF, MLA). By identifying the source, the instrument makes it possible to drill down and study the requirement and all its implications within a specific context.
 - o Fulfilled:
 - This section allows the country to state whether or not the requirements are fulfilled and present observations, namely to point out evidence for the fulfilment statement.

Value Added:

 Guide the MS in establishing the NCPeH by precisely setting requirements and recommendations to be fulfilled in the several areas of relevance for the NCPeH and the CBeHIS.

3.2.2. Service Deployment Plan and Preparation Progress Report

Purpose:

• Supports the MP in the implementation of the NCPeH and allows the MS to share national vision and intentions towards CBeHIS provision and to report the NCPeH preparation activities in a structured and sharable way.

Description:

- It describes the rationale for participation in the CBeHIS environment and identifies the scope and objectives of the MS NCPeH, the key stakeholders and their relations. It also suggests sequential implementation steps that can be used by the MS to structure their implementation activities;
- This tool combines 2 (two) instruments suggested by the OFW, the "Member State Service Deployment [PLAN]" and the "Member State Preparation Progress [REPORT]".

Tools and mechanisms:

The Service Deployment Plan (SDP) and Preparation Progress Report (PPR) provide the country with a structured common way to:

- Elaborate national Work Breakdown Structure towards CBeHIS provision;
- Report on progress of the NCPeH preparation activities.

In addition to these objectives, this tool should also function as a consolidated progress report to the CEF initiative, by providing evidence of work done and sustaining the funding requests.

This tool is made up of 2 (two) perspectives:

- Executive summary / dashboard gives an overview of the work progress for each area, status, trends and highlights to follow the action.
- SDP & PPR presents recommended steps for each thematic area (e.g. Legal,
 Organisational, Semantic, Technical, Security, Dissemination, Evaluation) and
 recommends a set of sequential implementation tasks for the countries to
 structure their activities. It also provides knowledge about country preparation
 status, progress and known issues. The data collected will automatically populate
 the "Executive summary / dashboard" perspective.

Value Added:

• Knowledge about country aims, plans and activities, status of progress and known issues, in a comparable structured way.

4. Further work

Supported by the eHN approval of the rational and enhanced approach that guides the elaboration of the "Country Guide for eHealth NCP implementation" instruments, there are joint activities that must be performed to assure the completeness, suitability and usability of these instruments, namely:

- Jointly (JAseHN and eHDSI) work to fine-tune the completeness of the instruments;
- Perform localisation exercise, with a set of countries, to evaluate suitability and usability of instruments;
- Hand over the instruments to the eHDSI, for effective usage by January 2017, when countries' preparation activities, under the CEF eHDSI, are foreseen to start.

References

This document is based on several reference materials provided by a number of EU eHealth projects. The following list provides a non-exhaustive indication of the materials considered up to and including the present version of this document:

- epSOS National Pilot Set Up and Deployment Guide (D3.8.2)
- epSOS Requirements and Recommendations
- epSOS Project Initiation Document (Pilot Plan template).