eHealth Network

Recommendation Report to Go Live

for Czech Republic

Drafted and adopted by eHMSEG on 23.10.2018

Purpose of this document:

On 12/10/2018 the National Contact Point for eHealth (NCPeH) of Czech Republic, submitted to the secretariat of the eHDSI Member State Expert Group (eHMSEG) an application to 'go-live' for the services Patient Summary – country A (PS-A) and Patient Summary – country B (PS-B). The application was accompanied by the following supporting documentation: a signed declaration; test reports; and a follow-up audit report.

In accordance with the 'go-live procedure', the eHMSEG has evaluated the application. This document contains a summary of the evaluation and recommendations to the eHealth Network.

Section 1 Executive summary

The eHMSEG recommends that Czech Republic:

Regarding PS-B:
Goes-live, with observations, provided the corrective actions identified (1, 2 & 3) have been taken and this has been verified by Auditors, before entering routine operations.

- The NCPeH needs to submit a statement of the Auditors to eHMSEG (via secretariat) that all corrective actions have been implemented.
- The NCPeH can then enter routine operations without need for further approval.

Regarding PS-A:
eHMSEG notes that the CZ PS-A service is not fully compliant with the eHealth Network (eHN) PS guidelines. However, other countries are also reporting issues of compliance with those Guidelines.
There are also discrepancies within the eHMSEG on the usefulness of the CZ PS as it is.
Against this background the eHMSEG prefers not to issue a recommendation on the possibility of CZ to go live with PS-A and remits this decision in full to the eHN.

Section 2 Findings and evaluation

Section 2.1 Main findings of the conformance and functional test reports

The end-to-end functional testing aims to validate, from the user point of view, the process and the information provided by the eHDSI services to health professionals. It is expected to detect flaws or malfunctions in any step of the process, from the processing of the original document to its transfer and subsequent processing and display in the receiver country. Furthermore, health professionals participating in the testing assessed the eventual clinical usefulness of the information provided. The evaluation is carried out for all eHDSI services (Patient Summary and ePrescription/eDispensation) in an environment that intends to simulate normal operations as much as possible: e.g. a pharmacist dispensing a medicinal product or a physician in an emergency department providing care to a citizen from a different deploying country. The only difference with a real scenario is that only test data are used and no real patients are involved.

The reports submitted demonstrate that the NCPeH has passed the necessary conformance and functional tests.

Section 2.2 Main findings of the follow-up audit report

The initial audit of the NCPeH, against the readiness criteria checklist (version 1.19), took place in June 2018. The scope of the audit covered the organisation of the NCPeH and its activities in relation

to the services Patient Summary – country A and Patient Summary - country B, including sub-contracted parties. A follow-up audit was carried out at the beginning of October 2018.

The follow-up audit report concluded that:

"The NCPeH organisation is well advanced in complying with the readiness criteria pertaining to the organisational, service operations, information security and technical interoperability domains. Nevertheless, actions remain to be completed in relation to the legal basis for the cross border exchange of health data and the semantics requirements for the patient summary.

The current legal basis for the cross border exchange of patient data does not ensure that patient data coming from another Member State are protected at an equal level to patient data generated in the Czech Republic, therefore creating a risk to the confidentiality of the former.

Regarding semantics, the NCPeH is not able to produce a consolidated patient summary. At present, the patient summary can only record the data emerging from the most recent encounter with a health provider connected to the national infrastructure. In addition, the NCPeH cannot provide most of the minimally required data in the compulsory structured or coded form. As a consequence of the afore-mentioned issues, the value of the patient summary for health care provision is undermined.

In addition, there are non-compliances in relation to change management and information security awareness training, which may pose a risk to the availability, confidentiality and integrity of patient data."

Section 2.3 Evaluation

No further actions are required in relation to conformance and functional testing.

The report of the follow-up audit identifies five non-compliances and contains recommendations to the NCPeH to address each of them. The following table provides an overview of these non-compliances and recommendations, the proposed actions of the NCPeH for addressing them, and the opinion and rationale of the eHMSEG underpinning its recommendation to the eHealth Network, as shown in section 3 of this document.

	Non compliance	Audit conclusions	Recommendation	Corrective action proposed by the NCPeH
1	C.12 [critical]: The Health Care Act does not clearly provide the same level of protection to patient data originating from other Member States as it does for patient data originating from health providers in the Czech Republic.	There is a lack of clarity about the legal status in the Czech Republic of patient data originating from other Member States, which poses a risk to the confidentiality, integrity and availability of these data.	To put in place a legal basis ensuring the protection of cross-border health data, in line with readiness criterion C12.	An amendment to the Health Care Act, in order to give an equal level of protection to patient data originating from other Member States, is being discussed in the Parliament. The legislative process is expected to be completed by January 2019.
2	OS.12 [critical]: NCPeH staff interviewed were not clear about the types of changes to which the change management procedure would apply. In addition, the change management tool has not been used for changes other than technical and configuration changes.	Although service operations are largely ready for routine operations, shortcomings in change management may pose a risk to the confidentiality, integrity and availability of the services.	For all types of changes, to ensure that the change management procedure is used and the change management tool is configured, in line with readiness criterion OS.12.	The NCPeH expects the change management procedure and change management tool to be in use for all kinds of changes by the end of December 2018.
3	IS.9 [major]: The NCPeH has not completed security awareness training specifically focused on security controls applicable to the NCPeH. In addition, certain categories of staff, depending on their contracts, are not included in the security training programme.	The information security system is largely ready for routine operations. However, because information security awareness training has not been completed, the risk that NCPeH staff may act in a way that poses a risk to the confidentiality and integrity of patient data during routine operations, is not sufficiently mitigated.	To complete the security awareness training focused on security controls applicable to the National Contact Point for eHealth, in line with readiness criterion IS.9.	The NCPeH indicated that security awareness training for certain categories of staff was scheduled to take place on 15 October 2018.
4	SI.1: [critical] Regarding the compulsory health data sections in the eHDSI specifications: For medical devices and allergies, the national infrastructure is unable to provide data in structured and coded form; For medication summaries, the national infrastructure is able to provide data in structured and coded form, but this capability is not available in all healthcare providers; For the list of surgeries, the national infrastructure is unable to provide data in structured and coded form in accordance with eHDSI specifications. This is because national infrastructure has structured and coded information with higher granularity than that specified in the eHDSI	At present, the value of patient summaries is limited, because the NCPeH cannot ensure that the known essential information is provided in a friendly version of patient summaries (meaning that they contain structured and coded data, as well as that they consolidate all the relevant data on patients).	To ensure that data is provided in a structured and coded form in the compulsory data sections for the patient summary, in line with readiness criterion SI.1.	The NCPeH has a long-term strategy for consolidating patient summaries.

	Non compliance	Audit conclusions	Recommendation	Corrective action proposed by the NCPeH
	specifications, given that healthcare professionals concluded that transcoding this information to eHDSI specifications may jeopardise its clinical meaning.			
5	SI.3: There is no central repository of patient summaries and the NCPeH would be unable to build patient summaries on the fly. At present, the patient summary offered for cross border exchange contains information of the last encounter between the patient and a healthcare provider only.		To ensure the integrity of the patient summary, in line with readiness criterion SI.3.	The NCPeH has a long-term strategy for consolidating patient summaries.

Section 3. Recommendations to go live for Czech Republic

The eHMSEG recommends that Czech Republic:

Regarding PS-B:
Goes-live, with observations, provided the corrective actions identified (1, 2 & 3) have been taken and this has been verified by Auditors, before entering routine operations.

- The NCPeH needs to submit a statement of the Auditors to eHMSEG (via secretariat) that all corrective actions have been implemented.
- The NCPeH can then enter routine operations without need for further approval.

Regarding PS-A:
eHMSEG notes that the PS-A is not fully compliant with the eHN PS guidelines:
SI.1: [critical] Regarding the compulsory health data sections in the eHDSI specifications: For medical devices and allergies, the national infrastructure is unable to provide data in structured and coded form; For medication summaries, the national infrastructure is able to provide data in structured and coded form, but this capability is not available in all healthcare providers; For the list of surgeries, the national infrastructure is unable to provide data in structured and coded form in accordance with eHDSI specifications. This is because national infrastructure has structured and coded information with higher granularity than that specified in the eHDSI specifications, given that healthcare professionals concluded that transcoding this information to eHDSI specifications may jeopardise its clinical meaning.
SI.3: There is no central repository of patient summaries and the NCPeH would be unable to build patient summaries on the fly. At present, the patient summary offered for cross border exchange contains information of the last encounter between the patient and a healthcare provider only.

However, other countries are also reporting issues of compliance with the eHN PS Guidelines. There are also discrepancies within the eHMSEG on the usefulness of the CZ PS as it is. Against this background the eHMSEG prefers not to issue a recommendation on the possibility of CZ to go live with PS-A and remits this decision in full to the eHN.