eHealth Network

Recommendation Report to Go Live

for Estonia

Drafted and adopted by eHMSEG on 16.05.2019

Purpose of this document:

On 13th of May 2019 the National Contact Point for eHealth (NCPeH) of Estonia, submitted to the secretariat of the eHDSI Member State Expert Group (eHMSEG) an application to 'go-live' for the service ePrescription – country A. The application was accompanied by the following supporting documentation: a signed declaration; test reports; and a draft Initial Audit report; and a list of the corrective actions taken by the NCPeH to address the recommendations.

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 Estonia:

Goes live with observations, provided that:

1. All recommendations of the Initial audit report Reference No: 2019-6841 have been satisfactorily addressed and that this has been verified by the auditors, before entering routine operations.
    - The NCPeH needs to submit a statement of the Auditors to the eHMSEG (via the secretariat) that all recommendations have been satisfactorily addressed.
2. The necessary conformance and functional tests were passed and that this has been confirmed by the Solution Provider before entering routine operations.
    - The NCPeH needs to submit a statement of the Solution Provider to the eHMSEG (via the secretariat) that the necessary conformance and functional tests were passed.

The NCPeH can then enter routine operations without the need for further approval.

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. 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.

In the Wave 2 Formal Pre-Preparatory Tests (February 2019) Estonia has undergone the tests for the specifications and services below:

- Wave 2 specification for ePrescription service Country A - Formal PPT
- Wave 2 specifications for ePrescription service Country B - Upgrade PPT

The report submitted demonstrates that the NCPeH has passed the necessary conformance test. The functional tests report submitted demonstrate that the NCPeH should complete the tests with all the partners (in case they are available in the June 2019 test session).

Section 2.2 Main findings of the Initial audit report

The initial audit of the NCPeH, against the readiness criteria checklist (version 1.2.1), took place from 25 to 26 March 2019. The scope of the audit covered the organisation of the NCPeH and its activities in relation to ePrescription Country A, including sub-contracted parties.

The Initial audit report concluded that:

"Insufficient adaptation of processes and documentation to the new [ePrescription country A] service requirements creates risks to the confidentiality, integrity and availability of patient data.

The report contains recommendations to the Estonian NCPeH aimed at rectifying the shortcomings identified."

Section 2.3 Evaluation

No further actions are required in relation to conformance testing. As the result of the functional testing, it is recommended that Estonia should complete the tests with all the partners (in case they are available in June 2019 test session).

The Initial audit identifies fourteen 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, and the corrective actions taken by the NCPeH to address the recommendations.

	Non compliance	Audit conclusions	Recommendation	Corrective action proposed by the NCPeH
1	The data controllers and data processors for the eP-A service and their respective responsibilities have not been comprehensively identified. The Data Protection Impact Assessment has not been updated for the new eP-A service.	The incomplete identification of data processors of cross-border patient data, and the lack of a patient information notice mean that the NCPeH cannot demonstrate its accountability towards its stakeholders at national and European Union level.	To ensure that the data controllers and data processors for the new eP-A service and their respective responsibilities are comprehensively identified, in line with readiness criterion C.9.	Self assessment document will be complemented accordingly (by the 15th of May 2019). Data controllers (Population Register, Estonian Medical Prescription Center, Register of Medicinal Products, Health Information System) and processors (Ministry of the Interior, Estonian Health Insurance Fund, Estonian Health and Welfare Information Systems Centre, Agency of Medicines, Ministry of Social Affairs) will be specified.
2	The Patient Information Notice for the new eP-A service is not yet available.		To ensure that the Patient Information Notice for the new eP-A service is available, in line with readiness criterion C.14.	PIN will be published by the 15th of May 2019.
3	While there is some preliminary information on the HWISC website, a dissemination plan for the beneficiaries of the new eP-A service is missing.		To ensure that the dissemination plan for the beneficiaries of the new eP-A service is available, in line with readiness criterion O.12.	In addition to the notifying of the parties concerned we've done so far, we will include a concrete list of digital distribution channels, where we will publish informative articles. As soon as we have exact information when and what countries are going live (Estonia as eP-A) we may continue with our dissemination plan and produce different posters, information materials and publish digital banners (main focus).
4	The conformance testing process is not documented.	The lack of documented processes undermines effective planning and monitoring, and creates risks to the availability of the new eP-A service.	To ensure that the conformance testing process is documented, in line with readiness criterion T.21.	We will add separate annexes for testing, adding NCP-B Pre-Projectathon and references to the testing framework by the 15th of May 2019. Self assessment plan will be updated.
5	While the NCPeH is able to implement the measurements required by the eHDSI Monitoring Framework, the process and the associated NCPeH roles and responsibilities are not documented.		To ensure that the process and the associated NCPeH roles and responsibilities to implement the measurements required by the eHDSI Monitoring Framework are documented, in line with readiness criterion O.11.	Service pass will be amended accordingly by the 15th of May 2019. Sending of the KPIs will be specified and added references to monitoring framework, also roles and responsibilities will be updated in service pass.

6	Incident management does not distinguish between eP-B and eP-A services. This is not in line with the eHDSI Country Service Desk Guideline.		To ensure that incident management is aligned with the eHDSI Country Service Desk Guideline, in line with readiness criterion OS.8.	Jira will be amended in accordance with eHDSI service desk guide, paragraph 2.3.1 by the 15th of May.
7	Procedures to monitor service capacity for the new eP-A service are not documented nor in place.		To ensure that methods and procedures to monitor service capacity for the new eP-A service are documented and in place, in line with readiness criterion OS.21.	Expected capacity is defined in the service pass (max 8 patients per day), but some formatting changes will be made to clarify the content. We will specify monitoring of our overall services and extract eP-A data from there. Daily monitoring will be in place (time of the query, how many prescriptions have been bought etc), checking for possible errors and notifying monitoring center. Amendments in service pass will be done by the 15th of June 2019.
8	Although a Business Impact and a Risk Assessment have been performed, risks associated with the new eP-A service have not been identified.	The incomplete identification of risks, of configuration items and of possible scenarios arising from the new eP-A service creates risks to the confidentiality, integrity and availability of patient data.	To ensure that the risks associated with the new eP-A service are clearly identified in the Business Impact and Risk Assessments, in line with readiness criterion IS.3.	Most of the risks included in the assessment are applicable for both, eP-B and eP-A, but additional assessment will be ordered and conducted by the end of June 2019.
9	The Business Continuity Plan does not include requirements related to the new eP-A service.		To ensure that the Business Continuity Plan includes requirements related to the new eP-A service, in line with readiness criterion IS.11.	Documents will be updated by the end of June 2019.
10	The Disaster Recovery Plan does not consider assets which are specific for the new eP-A service configurations.		To ensure that the Disaster Recovery Plan considers all assets which are specific for the new eP-A service configurations, in line with readiness criterion IS.12.	Disaster recovery plan will be amended by the end of June 2019.
11	The NCPeH has interfaces with some new external services required under the new eP-A service (e.g. Prescriptions Centre and Population Register) and there are some other eP-A related configuration items required under OS.19 (such as firewalls, Service Metadata Publisher and International Patient Search Mask). However, these are not managed through configuration management.		To ensure that the NCPeH interfaces with new external services required under the eP-A service, as well as other eP-A related configurations required under OS.19, are managed through configuration management, in line with readiness criteria OS.19 and IS.14.	Configuration management database will be updated by the end of June 2019.

12	Policies for the processing and safeguarding of personally identifiable information related to the new eP-A service are not clearly established for the Helpdesk.		To ensure that policies for the processing and safeguarding of personally identifiable information related to the new eP-A service are clearly established for the Helpdesk, in line with readiness criterion IS.20.	Helpdesk tickets notifications will be categorized and only available to certain people. Implementation done by the end of June 2019.
13	Essential elements for the new eP-A service (e.g. Service Metadata Publisher and Terminology Services Access Manager Synchroniser) were missing in the 'Estonian Cross-Border eHealth Architecture' document and the service passport document ("Teenuse pass") provided to the audit team.	The documentation of service operations for eP-A processing activities is incomplete. This creates risks to the availability of the new eP-A service.	To ensure that relevant NCPeH technical documentation (such as the 'Estonian Cross-Border eHealth Architecture' and the "Teenuse pass") includes all the essential elements for the new eP-A service, in line with readiness criteria T.1 and T.2-1.	Update will be conducted in service pass by the end of May 2019.
14	The 'Dispensed Prescribed Medicine' workflow in the 'Estonian Cross-Border eHealth Architecture' document does not accurately describe the data processing activities related to the eP-A service.		To ensure that the 'Dispensed Prescribed Medicine' workflow in the 'Estonian Cross-Border eHealth Architecture' document accurately describes the data processing activities related to the eP-A service, in line with readiness criterion T.12.	Update will be conducted in service pass by the end of May 2019.

Section 3. Recommendations to go live for Estonia

The eHMSEG recommends that Estonia:

Goes live with observations, provided that:

1. All recommendations of the Initial audit report Reference No: 2019-6841 have been satisfactorily addressed and that this has been verified by the auditors, before entering routine operations.
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