eHealth Network –
23rd eHealth Network Meeting

Minutes of Meeting
2023-03-30 (13:00 – 17:00)

Participants

Commission Units & Agencies: DG SANTE C1, DG CNECT H3, DG CNECT R3.

Member States: AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK.

Invited: Contractor (Infeurope/Mercury-97)

1. Opening and Approval of Agenda

The DG SANTE Head of Unit of C1 and Member States Co-Chair welcomed the participants and expressed anticipation of meeting everyone in person soon. Following an overview of the agenda and the previous meeting minutes, the items were approved.

2. Selection of Standard for the New Use Cases in MyHealth@EU

Following the previous eHealth Network Meeting in November 2022, the eHN Technical Interoperability Subgroup (Tech IOP SG) was mandated to further investigate the use of a base standard for new services in MyHealth@EU. These include Laboratory results reports, Medical images and imaging reports, as well as Hospital discharge reports. The current operational services in MyHealth@EU are based on HL7 CDA and IHE XDS, however, selection of the base standard was determined to be made for the new services prior to their implementation in eHDSI. The base standards proposed for the new use cases were HL7 CDA and HL7 FHIR, yet implementing both options in MyHealth@EU was deemed technically and practically unfeasible. In order to select the base standard, the work process was agreed to be divided into: 1) the creation of a Non-paper to describe the question at hand and analyse the potential impacts on development; 2) conducting a Survey to identify Member States' preferences and readiness to implement either CDA and/or FHIR: 3) to have the eHN take a Decision thereafter (if applicable) incorporated into the eHN guidelines; and 4) to begin Implementation – the new use cases being incorporated in MyHealth@EU in accordance with the agreed timeline.

Seeing as a Change Proposal was already submitted and accepted by the eHN, the use cases currently fall within wave 8 and 9. The first service to enter production will be Laboratory results reports in autumn 2025, while the Hospital discharge and medical images and imaging reports will begin operation in autumn 2026. Upon adoption of the Decision, the Laboratory results reports will enter the implementation phase, followed by Preparatory Pre-Production Testing, Pre-Production Testing, and Production. A new version of the Laboratory results

reports eHN guidelines is expected in June 2023. The Medical images and image reports and Hospital discharge reports eHN guidelines are currently in preparation.

Member States will begin implementation of the new use cases once funds offered through EU4HealthWP 2022 are granted. Applications have already been submitted and are currently under evaluation.

The Tech IOP SG presented on the work completed since November 2022, beginning with elaborating on the survey results. The objective of the survey was to understand the current position of the Member States in the eHN regarding the choice of the base standards as well as the expected way forward. The survey consisted of 56 questions sent to 29 countries of which 23 replied between December 7, 2022, and January 20, 2023. The conclusion of the are as follows:

- On the CDA/FHIR current use, there is a predominance of CDA use
- On the CDA/FHIR future use, there is a strong tendency towards implementation of FHIR
- For all three new cases, there is a preference for the use of FHIR for both content representation and content transmission

These results were thereafter added to the non-paper V2. The eHN now requires to make a decision on the matter. The proposed Decision stated was:

- The eHealth Network considers that HL7 FHIR should be selected as the base standard for the implementation of use cases Laboratory results and reports, Hospital discharge reports, Medical images and imaging reports.
- For these use cases, HL7 FHIR should be used for both *content representation* and *content transmission*, as described in Scenario B in the non-paper. For content transmission, the use of FHIR REST API should be the preferred option.
- It is understood that in addition to HL7 FHIR the use of further standards may be required for the listed new use cases, e.g. DICOM for medical imaging studies.
- A decision regarding the change to HL7 FHIR for the existing use cases (ePrescription/eDispensation, Patient Summary, Original Clinical Documents) should not be taken now, considering the investments Member States have made in the development and operationalisation of these services. This can be evaluated in the future.
- The choice of HL7 FHIR as a base standard only applies to the implementation of new use cases for cross-border exchange in MyHealth@EU. It is understood that in other infrastructures and at national level other choices may be made.
- The decision is not identifying a specific version of the FHIR standard yet. A specific version (e.g. R4, R5) should be selected during the next steps of technical preparatory work.

The eHMSEG endorsed the proposed Decision with the following remarks:

- Many open questions around technical choices remain to be made in the next phases – many of which are not addressed in the non-paper. The eHMSEG considers more Connectathon testing would be useful to address these operational issues. Proof of

concept implementation and the involvement of MS in the latter would be a useful instrument to align technical aspects.

- Concerning the timeline of implementation, the eHMSEG advises that flexibility needs to be offered to MS with the new use cases if based on FHIR, as the survey has shown that approx. 43% of MS indicated that more time would be needed.
- Regarding implementation profiles, further work on alignment between MS will be necessary and the eHMSEG understands the implementation (specifically of the content layer) differ across the EU. The eHMSEG recognises that this is both applicable to CDA and FHIR.
- The eHMSEG understands and recognises that more funding/grants may be necessary if FHIR is selected at later stages for ePrescriptions and Patient Summary.

DISCUSSION:

FR noted that although they strongly support the adoption of different base standards at EU level and are convinced that HL7 FHIR is a very good standard for various use cases, also the following aspects should be considered:

- There is an important level of use of CDA in Europe on the 3 considered uses cases (lab results, hospital discharge report, imaging report), especially in France where a lot of public funds on healthcare professionals' software upgrades have been invested;
- FR is wary about the ability to quickly produce FHIR implementation common guidelines with data producers and consumers for those 3 uses cases, considering for example the time it took to work at IHE level to achieve CDA XD-LAB profile. FR thinks the eHN should investigate the implementation matters further before taking a decision as the survey currently does not account for a trajectory study on how a Member State could reach this target.

EE wanted to clarify whether a decision regarding the timeline implementation has been reached or if it is still under discussion. EC responded by differentiating between timeline implementation at the Central Services in MyHealth@EU level and at Member States' level. While the implementation in MyHealth@EU has been indicated as shown in wave 8 and 9, the implementation for each Member States depends on the grants agreements that are currently under evaluation.

Following no additional comments, the Chair invited MS to cast their vote. The Decision was adopted with 24 Member States voting in favour, 1 MS voting not in favour, 1 MS abstaining, and 1 MS being absent.

3. Guidelines on Patient Summary

The eHN Semantic Subgroup (Semantic SG) provided an update regarding minor changes for adoption in the Patient Summary Guidelines, which included two aspects: 1) to increase the support for rare diseases as proposed by X-eHealth Project and 2) to review the vaccination study. In light of the selected two-step approach to adoption and implementation, only the changes regarding increasing support for rare diseases were discussed for adoption to the eHN. The Semantic SG expects to issue a recommendation regarding the use of a new code system for vaccination records for the next eHN meeting in June 2023.

In summary, the minor changes made included:

- New facilities being added to allow linking any part of the Guidelines to specific healthcare professionals/organisations and to external supporting material;
- Supporting information being added to explain these new facilities (section 3. Supporting Information, Article 10: Data);
- Two updates were made to clarify existing text in "Article 6: Patient safety" and "Article 4: Data protection".

DISCUSSION:

NL raised questions regarding the possibility of having guidelines on URL security as well as the alignment of the changes with the international Patient Summary Guidelines. The Semantic SG responded that the question of URL security has not yet been considered. However, the Subgroups are working on maintaining the European and International Patient Summary alignment.

DE noted that they agreed with the adoption of the revised PS Guidelines V3.2, and recommended to develop procedures for the connection of data with healthcare providers that meet relevant data protection requirements.

With no objections, the changes on V3.2 of the Patient Summary Guidelines were adopted.

4. MyHealth@EU Procedures on Launching New Service Pairs and on Offboarding

Two revised MyHealthData@EU procedures were proposed for adoption after receiving endorsement by the eHMSEG in March 2023.

Procedure 5 introduces a joint request for a country-pair to launch a new exchange with eHDSI secretariat instead of each individual country needing to submit an application separately. This would avoid the administrative burden whereby only one country submits a request for such a decision under a certain wave, thereby lengthening the on-boarding process.

Procedure 9 (offboarding) introduces a process to stop routine operations of an NCPeH in case of non-compliance with MyHealth@EU requirements. Procedure 9 would only be triggered as a last resort to stop operations of a NCPeH if non-compliance persists.

No objections were made and the procedures were consequently adopted by consensus.

5. eHN Work Plan 2023

The eHealth Network Work Plan 2023 was presented for adoption with 5 key priorities identified for 2023:

- **Funding** – the objective is to generate a joint paper led by Member States to identify the needs for European funding for eHealth infrastructure for primary and secondary use of health data. Responsibility for the funding expected achievements in 2023 is to be assigned to two leading countries.

- **Interoperability governance** – the objective is to achieve further technical common choices and formalise the eHealth process by defining agreed standards, adopted guidelines, and adopted document on the decision-making process. Responsibility is assigned to the Tech IOP SG in collaboration with the Semantic SG.
- **Ethics in real life** – the objective is to implement European ethical principles for digital health. Responsibility is assigned to the task force on EU ethical principles leading country (FR).
- **Best practices sharing** – the objective is to assess digital health deployment progress and best practices in EU Member States. Responsibility is assigned to EU Commission SANTE.C1 Unit and a leading country which is to be identified.
- **Effective collaboration** – the objective is to collaborate more effectively in preparation for the future EHDS. Responsibility is assigned to EU Commission SANTE.C1 Unit and a leading country which is to be identified.

DISCUSSION:

The Semantic SG noted that there is missing information and accuracies in the Workplan Annex, suggesting to exclude it from voting. In particular, organisational aspects of the different working groups have been discussed in the previous eHealth Network Meeting. It was further suggested to add the minutes from the previous meeting on this point in the Annex of the Workplan to avoid duplication of work. The Semantic and Tech IOP SG made additional comments regarding: (a) adding the assessment for the metadata guidelines to the Workplan; and (b) assessing which common elements of the guidelines can be moved to the general guidelines to avoid repetition for each of the use cases. The eHMSEG Chair agreed with the comments made and confirmed that eHN Subgroups and the eHMSEG have been engaged in collaborative work. The eHN Co-Chairs confirmed the importance to improve efficiency and asked whether there is an existing document on work process streamline. As the Tech IOP and Semantics Subgroups have started working on a draft outline regarding the alignment between the two Subgroups and the eHMSEG, members were invited to review the draft and leave recommendations.

SE commented on the importance of coordinating the activities proposed in key priority 4 – best practices sharing in EU MS and digital health deployment progress assessment – with the ongoing activities of Digital Decade.

It was agreed that the next steps for the next Coordinated Actions Meeting are to validate responsibilities of actions, present an action timeline for the next eHealth Network meeting and update annexes to the workplan.

The Work Plan 2023 was thereafter adopted (excluding the Annex) and the eHN agreed to determine the volunteers to be assigned to the different priorities tasks in the next Coordinated Actions meeting.

6. Ethical Principles for Digital Health

FR gave a presentation on the Ethical Principles for Digital Health. A dedicated task force has been working on generating a supporting document with a detailed explanation of the ethical principles for the implementation plan. The implementation plan is comprised of three phases:

1) initial preparation; 2) implementation and definition; and 3) capacity building initiative. Upon adoption of the updated version of the supporting document, the task force will enter the capacity building initiative phase.

The latter has started for 18 months with the aim to: 1) issue a capacity building plan for European ethical principles and strong Member States involvement and accomplishment rate; 2) produce a white paper on the involvement of end-users; 3) prepare a requirements catalogue; 4) define a communication plan including outcomes from the consultation of citizens and initial EU compliance status.

EC raised a question regarding the responsible party for the capacity building task. FR clarified that both a dedicated taskforce and the Contractor are working on the task, however, the dedicated taskforce is focused on the deliverables, while the Contractor is assigned to produce a set of instruments to facilitate the best practices sharing and assessment.

EC also commented by adding that the contract can be extended for an additional two years.

Following no further comments, the document was consequently adopted.

7. EU DCC Infrastructure: Next Steps (for information)

A survey consisting of two parts was conducted starting 10 March, 2023. The first part aimed at understanding MS plans to issue and verify COVID-19 certificates after the EU DCC Regulation expiry. The presented results demonstrated that there is some interest in the issuance of certificates for international travel after June 2023, while interest in verification is limited. The second part of the survey focused on the uptake of the EU DCC by the WHO. The results showed significant interest in the onboarding to the WHO Gateway and some interest in piloting.

In the discussion, EC stated that it is not likely that the existing Regulation will be extended in its current form given that there are currently no restrictions on free movement and possible future use cases of the EU DCC system are being considered. The objective is to continue cooperation with the WHO for the further development of a global digital health infrastructure/network.

EC made several additional points regarding an administrative arrangement with the WHO:

- The Commission and the WHO are working on ensuring a privileged partnership for the EU in the future development of the new system.
- All Member States are eligible to join the new system voluntarily and discussions are taking place to ensure third countries currently connected to the EU DCC Gateway can join and participate as well.
- The parties are working on ensuring backwards compatibility between the two systems.
- Although COVID Certificates are the first use case under consideration, the new Gateway can be expanded for future use cases, such as the yellow booklet.
- Regarding the timeline, the testing environment is expected to be available in April 2023, the acceptance environment should be available in May 2023, and the Gateway launch is expected to be on June 1st 2023.

- As Member States have expressed interest in pilot participation (as indicated in the survey), discussions are taking place on how to materialise this process.
- Currently, there is no plan to establish a revocation list exchange functionality at the WHO Gateway, however, a possibility to add it at a later stage may be explored depending on the interest of the WHO system participants.

DISCUSSION:

BE explained the benefits of alternative uses of the EU DCC Gateway and proposed to continue the use of a number of components in differing environments, as these components have already been developed and it would therefore be a waste of time and investment for Member States not to reuse them. While BE agrees with the fact that the EU DCC legal basis cannot be extended and reused for third countries and international travel purposes, the question of the reuse of components should be solved in horizontal discussions between all Commission units (DG SANTE C1 and DG CNECT H3, DG JUST. etc.) before the end of June 2023.

EE agreed with BE and mentioned their interest continuing under the WHO. They express their wish to find a unified solution.

ES also commented that it would be important to have some legal guarantees (i.e. SLAs) with the WHO gateway as the proposal currently is a non-binding administrative proposal. This can be achieved with the involvement of the EU Council in the on-going discussions as included in Article 218 the Treaty on the Functioning of the EU.

FR stated that they support the principle (WHO as coordinator of the EUDCC gateway), however, they regret that this is not maintained at the EU level, as it would likely allow a faster development of use cases. The WHO Gateway must be able to allow for a fast reuse and a smooth operation. They also agree with ES in ensuring guarantees from the WHO as part of the potential transfer (technical architecture in conformity with ethical principles, sovereignty, and data protection for example) to offer a secure tool in compliance with EU requirements. Furthermore, in the event of a new health crisis, FR believes that EU Member States must also be able to reactivate this system, especially if no satisfactory agreement has been reached for a takeover with the WHO.

IE mentioned that it would be helpful to know what other EU Member States plan to issue (if anything) as evidence that citizens have received a vaccination, especially considering evidence of vaccination may still be required for international travel to some countries (i.e. USA).

EC stated that the option to collaborate with the WHO in establishing a global trust network is the most viable option for international travel in the short term as there is no existing legal basis in this regard. However, this option does not eliminate the capacity of EU to reuse the technology.

The participants agreed that this discussion should continue in a separate meeting.

8. Technical IOP Subgroup: preparations for the renewal of Subgroup's mandate and for the election of Subgroup's co-chair at the June 2023 eHN meeting (for information)

The Tech IOP Subgroup was established to address technical interoperability in parallel to the already existing eHealth Network Semantics Subgroup. Preparations are taking place for the renewal of its mandate for 2 years, thereby ensuring continuity of the work. In addition, the participants were invited to identify candidates for the re-election of the Tech IOP Subgroup's Member States' Co-Chair. The topic will be discussed in more detail at the joint face-to-face meeting with the Semantics Subgroup in April 2023. The Tech IOP SG's mandate renewal and the elections will be held in the eHealth Network meeting in June 2023.

The eHN and Member States recognised the work and dedication of the current Chair of the Tech IOP SG from the NL, and expressed gratitude and thanks for his contribution to the work of the Subgroup over the course of the past two years.

9. AOB

Under any other business, an update was provided by CNECT on the Digital Decade Programme concerning the monitoring progress towards the target: having 100% of citizens with online access to their health records by 2030. Regarding the preparatory work timetable, consultations with eHN, interviews with national experts, and surveys on the potential methodology have taken place between March 2022 and January 2023. The feedback received has been subsequently integrated in the indicator and sub-indicators composition as well as most suitable survey questions formulation. The survey for baseline data collection launched in February 2023 as part of the Study for Digital Decade eHealth Indicators Development. The first annual report on the State of the Digital Decade with EU trajectories is expected in June 2023.

The annual report will play a central role in the governance framework. It consists of two elements: 1) data collected as part of DESI and 2) the usual annual DESI questionnaire re-developed to align with the Digital Decade policy programme 2030. This allows a collaborative process with MS for additional information. The report will therefore consist of an EU analysis and individual country reports to identify where the EU and each MS stands with respect to the objectives and targets, and to identify gaps, recommend policies, as well as serve as a support for a structured dialogue among MS.

The Digital Decade eHealth composite indicator takes into account: 1) electronic health records data access service; 2) types of accessible health data categories; 3) access to technology and means and 4) access to opportunities for certain categories and people.

In case the participants are interested in a dedicated presentation of the study results, CNECT will send a meeting invitation to be held in the end of April.

The second point under any other business was the announcement of the next eHealth Network meeting. The Swedish colleagues invited all participants in Stockholm where the meeting will be held from 10:00 CEST on June 1, until 14:30 CEST on June 2, 2023. After the meeting on

June 1, the Swedish Presidency are pleased to welcome everyone to a conference dinner at the Nobel Prize Museum.

The meeting was adjourned.