eHealth Network

Summary report
20th eHealth Network meeting
(Teleconference)
8 November 2021

Brussels, Belgium

Co-Chairs:

Andrzej Rys, Director for the DG SANTE, European Commission

and

Ron Roozendaal, Director for the Ministry of Health, Welfare and Sports, the Netherlands

Opening and approval of agenda

The 20th eHealth Network meeting was held in a digital format (Webex) on 8 November 2021. The draft agenda of the meeting was adopted.

Commission co-chair Pierre Delsaux thanked the eHealth Network for the excellent work on successfully dealing with different challenges in the last months. The eHealth Network has concretely contributed to several fronts during COVID-19 and he welcomes the constructive work also in developing the EHDS. Member States co-chair Ron Roozendaal welcomed all participants and thanked all for constructively working together and achieving concrete results.

CNECT Director Lorena Boix Alonso thanked the eHealth Network for their very good work during the last months. Specific references were made to the DCC. At the same time it was noted that the system needs to be secure and trusted. There were reports of fake certificates and this needs to be tackled. References were also made to the eID (wallets) and specific use cases on health. CNECT focuses on use cases related to health. Brief explanation was provided on Digital Health Europe; cancer image initiatives; the work on Testing and Experimentation Facilities for AI; the genomics initiative and to the Horizon Europe programmes.

1. Council presidency

1.1 French Presidency – Presentation of presidency priorities

The French delegation provided an overview of French initiatives on eHealth when they take the presidency of the Council of the EU early 2022. Specific references were made to AI, security (health threats), digital health and health data (EHDS). Aim is to mobilize an ecosystem and discussion to take place around the EHDS, Data Governance Act, AI and digital health. Information was also provided on eHealth events during the FR presidency. Explanations were provided on the planned European eHealth agenda in the context of the preparation of the European Health Data Space. Additionally, the topics of the French EU-Presidency digital health event programme was set out including AI in health and Health Data. A rich eHealth event programme was presented that plans events which start in January 2022 and run all the way to June.

2. MyHealth@EU

2.1 Discussion on new use cases including patient access to data (EU vaccination card)

In the context of the presentation in question, it was mentioned the importance of the developments regarding the EU citizens' Vaccination Card and European Digital Identity Wallets. In particular, it was stated that based on the EU Citizens' Vaccination Card, the EU citizens, among others, will be able to access their vaccination status when moving between Member States and show it to health professionals in English or other official languages. Other possible use cases include access to Patient Summary so that they can show it to health professionals as well as access to ePrescriptions or other data in the scope of MyHealth@EU in a more streamlined way. Furthermore, proposed technical implementation formats were introduced with regard to the EU Vaccination Card and namely, three equivalent representations (HL7/CDA format, HL7/FHIR web resources exposed by an active repository, QR code reusing the COVID certificate technology).

2.2 Future of MyHealth@EU

As far as the Future of MyHealth@EU is concerned, the presentation included the on-going work on MyHealth@EU, highlighting the need to ensure confidentiality, integrity, authenticity, auditability and non-repudiation. Furthermore, the stemming challenges in the context of MyHealth@EU are affiliated with the protection of personal data, secure identification/authentication of patients and healthcare professionals, technical security of the infrastructure, circle of trust between Member States, exchange of structures/coded data and deployment of international open standards to national and local environment.

Moreover, the eHDSI impact on Czech Republic seemed to be of particular importance. Namely, it was stated that joining the eHDSI, the Czech Republic national healthcare system obtained a real cross-border element that was missing, technical/sematic knowledge as well as national strategy as part of the national eHealth infrastructure. In addition, future challenges and opportunities with regard to the eHDSI were presented. In particular, major issues were raised in the context of the future of MyHealth@EU such as the entities that will have access to it, on what format data will be shared, the type of the data shared and the new services that will be added.

3. MyHealth@EU and eID

3.1 Call for grants EU4Health Programme

The Commission (DG SANTE) informed about the possibility to apply in January 2022 for a grant for "Enlargement of the geographic coverage and scope of MyHealth@EU" from the EU4Health Programme. The duration of the contract is 36 months and the budget is 11 million euros. Priority will be given to setting up NCPeHs. The Commission informed that there will be a new wave of calls in 2022; around 22 million euros are expected and Member States are strongly encouraged to apply for this round.

This action will allow Member States to apply to achieve at least one of the following aims:

1. Set up a National Contact Point for eHealth (NCPeH) to aggregate the patient information from national electronic health records or other infrastructure and share it cross-border (for MS+EEA, which have not yet set up a NCPeH: Austria, Germany, Denmark, Romania, Norway and Iceland);
2. Deploy the ePrescriptions and Patient Summaries in Member States that have not yet launched these services;
3. Launch new services in all the Member States:
    a. Exchange of unstructured documents - original clinical documents;
    b. Exchange of structured documents - medical images and image reports, laboratory results, and hospital discharge letters.

The Commission (DG SANTE) also informed about the possibility to apply in January 2022 for a direct grant for "increase health data semantic interoperability and build national capacity on health terminologies" from the EU4Health Programme to co-finance the 60% of the Member State SNOMED CT annual fee during two years. Both current members and non-members can

apply for the grants. Current members can also be supported retroactively for costs after 4 January 2021.

There is also a grant for the "Pilot project on patients' access to translated health data", which provides patients with direct access to their health records in MyHealth@EU.

3.2 eID

DG Connect informed about the political mandate of European e-identity and the current legal framework regarding European identity wallet. At present there are a lot of challenges to the cross-border use of national eIDs – low coverage, low acceptance, low usage, low user friendliness. Also challenges from the market and technological developments have to be taken into account as the developments in the private sector and society also challenge the current status quo. For example, users want high speed, secure authentication services that protect their personal data; platforms are already playing a large role in the electronic identification domain; users increasingly demand mobile identification; self-sovereign ID is a growing trend promising to put users in control of their identity data.

Based on this ground the Commission presented the European Digital Identity Proposal – adopted in June 2021. During the meeting DG Connect presented the key principles and 3 pillars of European Digital Identity by more focusing on the European Digital Identity Wallet. It shall be issued by Member States under a notified scheme. EU digital identity wallet will not be created as a new EU structure but will build on national eID solutions. EU Digital identity will be used for online public services, private parties, very large online platforms and others relying on third party electronic identification services. Following next steps are the development of a toolbox together with MS (development of architecture/technical references and standards), to be finalised by October 2022, discussion with co-legislators and pilot implementation.

DG Connect presented the implication for the eHealth sector. A major drawback for using eIDAS cross border authentication in the eHealth sector was only a few Member States notifying eID means. Also, usage of the Wallet required for public services and by private relying parties required by law to use strong user authentication. eHealth use cases are considered a priority leveraged by the recent development of the EU DCC.

DG SANTE stressed that this question will be further elaborated in the technical subgroup of eHealth Network and the implementation part in the pilot project on patient access under EU4Health.

4 Interoperability

4.1 eHN ePrescription Guidelines revision – progress update and scope discussion

The eHealth Network subgroup on Semantics informed that there are ongoing reflections and discussions on the ePrescription guideline revision. This process requires additional time to mature, as well as needs eHealth Network guidance regarding the findings encountered so far. The eHealth Network provided the following indications:

a) **What is in the scope of the guideline and if the elements out of scope need to be addressed in another guideline as well?** The eHealth Network agreed to keep the scope limited to authorised medicinal products. Medical devices should be addressed in a separate guideline.

b) **Alignment of work with UNICOM, ePI work of EMA and the Patient Summary guideline 3?** (Inclusion of planned care and possible other use cases that might arise in the future). It was mentioned that the linkage with ePI could provide benefits for Patients, namely when abroad getting access to the product information in digital format and in their preferred language.

c) **A strategic (long term) implementation of the ISO IDMP family of standards is envisioned for, not only regulatory, but as well clinical use cases?** No feedback from eHealth Network.

MS asked for a timeline for the Medical Devices guidelines. The subgroup indicated they are not currently working on that new guideline and no concrete plans exist. It was mentioned that ideally work on the medical devices guidelines should start as soon as the work on the ePrescription and General guidelines is concluded.

The Subgroup on Semantics will then continue the revision and present a draft version to the eHealth Network in the beginning of 2022 for commenting. The aim is to have a final draft for approval in the spring meeting of eHealth Network in 2022.

4.2 eHN General guidelines revision

The eHealth Network subgroup on Semantics informed that there are ongoing reflections and discussions on the General guideline revision. The subgroup on Semantics proposed the following rationale for the revision of the eHealth Network General guidelines:

a) *The audience for the new eHealth Network general guidelines should be* **Member States and implementation initiatives/projects; and eHealth Network subgroups working on the preparation of new eHealth Network guidelines.**

b) *The new general guidelines should focus on 4 pillars (different chapters in the guidelines document):* **General provisions applicable to all eHealth Network type of guidelines, Procedure for eHealth Network guidelines, Specific template for DATASET guidelines, Interoperability Assets Catalogue.**

The eHealth Network did not provide any feedback. The Subgroup on Semantics will then continue the revision of this guideline in line with the proposed rationale. The aim is to present a draft version to the eHealth Network for approval in Spring or Fall 2022.

4.3 X-eHealth update

The aim of the discussion was to give an update on the X-eHealth project and the timing of its deliverables so that Member States can be prepared for future actions to adapt the eHealth DSI architecture in line with the outputs. The X-eHealth project is based on Commission

Recommendation on a European Electronic Health Record Exchange Format, taking it forward by developing draft technical specifications for new health information domains (lab results, medical images, hospital discharge letters). The use cases and specifications will be presented to the eHealth Network and the Commission and liaised with the eHMSEG. The project work is divided into 3 core work packages: WP5 on functional specification, WP6 on implementable specifications and WP7 on architecture integrations and system specifications. The interlinkage between the packages and deliverables were presented. The next steps are eHN Use Cases Approval in Q1 2022 and new services going live Q2 2024. X-eHealth events in 2022: professional training sessions in May – June, 2nd X eHealth Innovation Day in August and September, Interoperability awards in September.

4.4 Timeline for the eHN Patient Summary Guidelines release 3 implementation in the eHDSI

The aim of this discussion was to present the eHMSEG position about the effort and timeline which need to be taken on both Member States, Solution Provider and eHMSEG side to implement the new Release. eHN Patient Summary Guidelines V3 have been adopted by eHN on June 2021. It is developed by eHN Subgroup on semantics. This version is built upon the experiences gained from Member States feedback within eHDSI, on the alignment with the work on IPS specifications and intended to be implemented within EU4Health.

The results of a survey on Member States plans to implement PS Guidelines V3 were presented. In total 20 Member States aim to implement these V3 guidelines, in 2022 – 2023 – FR, HU, HR, CY and SE. Further it was indicated what kind of common efforts are needed. Business requirements need to be updated, creation of a new Implementation Guide and extension of the existing one, new validation rules, MVC new or extended value sets, new code system versions and implementation changes of common assets.

As regards additional needs on Member States level the following issues were indicated. Modification of current implementation, a national connector, transformation of national PS document to new eHDSI - Friendly A and if implemented from Friendly B to national representation, MTC new / extended value sets, mapping and translation, change within third party application, if integrated natively.

In addition risks were presented regarding Member States not being able to implement Guidelines release 3, specifying a new implementation guideline is work that should not be underestimated, Member States and the Commission need to provide governance structure and relevant resources, external expertise, recruitment of additional experts is needed. Member States not able to provide relevant structured data – a) new elements and sections to keep optional b) an effort on the political level in Member States needed to enforce implementation of coded and structured medical information within their healthcare domains.

Some Member States expressed their concerns about implementation of these Guidelines release 3 - ES indicted that they have voted against several of the eHMSEG change proposals, moreover – if V3 goes further, the implementation costs for ES may be too high, they need more flexibility. FR also raised concerns regarding implementation of the use cases, adding that they

are incentivizing the HCPs to fill in the data for patient summaries. FI indicated the importance of flexibility and in particular of backwards compatibility.

Co-chair of eHMSEG indicated that political will and willingness of health professional's community is needed, moreover, the sharing of lessons learned between the Member States is very important. Co-chair of eHMSEG confirmed that the implementation of the Guidelines release 3 is going to be flexible.

The Chair of the meeting suggested that the explanation work with health professionals could be a topic for future FR PRES.

4.5. Adoption of the update eHDSI policy documents (eHDSI Governance Model, Organizational Framework for NCPeH, Annex to the Agreement)

The Chair of eHMSEG gave an update on the eHDSI policy documents. The Commission informed that the written procedure is finalised on all 5 eHDSI policy documents and it is adopted with 4 positive replies from Member States and NO and no Member State was voting against. It will be published in the near future.

5. Contact tracing apps + Digital Covid Certificate

5.1 Update on DCC

The Commission presented the latest update on Digital Covid Certificate (DCC). Currently, 45 countries are connected to the EU DCC Gateway including all the Member States and EEA as well as 15 third countries. 30 additional countries are in the pipeline. More than 628 million certificates were issued. It relies on a successful collaboration between Member States, the Commission, the EEAS and the ECDC and EMA agencies. There is also international collaboration with WHO and ICAO.

There have been some high profile security incidents such as a leak of private keys, potential fraudulent activities but no security breach as such. Identity theft and forgeries are also under investigation. When confirmed, swift actions by the Commission and Member States were taken. New processes and governance are being introduced in order to manage and address these security incidents and to ensure greater coordination between the various concerned parties.

Specific provisions were added in the Regulation in order to allow the revocation of certificates. Two options are under review: either a centralized system but it implies the processing of personal data at the Gateway level and there are internal discussions as well as consultation with the European Data Protection Supervisor on whether the Regulation would allow such processing of personal data by the Commission. An alternative solution is a peer-to-peer network which is not the preferred solution due to its complexity.

A technical expiration date was introduced on the vaccination certifications but Member States have set different expiration dates which are not directly related to the duration of the immunity provided by the vaccines. A special task force of the eHN is currently investigating how to best approach this issue.

There were some requests from third countries entities to have access to the public keys in order to perform verification of EU DCC but there is currently no mechanism to connect these entities to the gateway or to publish the public keys at the Gateway. There are plans to make the public keys available.

There is enormous interest from third countries to connect to the EU DCC but it is a challenge to connect all these countries to the system and for its governance. Some initiatives are taken to better manage this influx of third countries such as to invite them at community calls organized by contractors but more work is needed in order to best manage them and to address common issues while still preserving the autonomy of the European system.

The EU DCC Regulation is currently applicable until 30 June 2022. By 31 March 2022, it is planned that the Commission will submit a report on the application of the Regulation and may propose an extension of the period of application of the Regulation in order to prevent any disruption to the freedom of movement.

AT raised some concerns about the security when onboarding third countries. The Commission indicated that the onboarding process for third countries is the same as for Member States. However, additional elements may be taken into consideration following the previous security incidents. They will be applied to all the countries currently connected to the system.

The large number of third countries joining the system will not affect its governance and the implementation of EU values and principles. It does have the added advantage of allowing Europeans living abroad to conveniently visit the Member States. However, there may be some trust issues and they should be discussed and addressed in the coordinated actions group.

NO raised the issue of American states instead of the federal state joining the system and how this request can be addressed. The Commission indicated that it is more a legal issue since the states are not countries. There is some similarities with an approach used in the case of the United Kingdom and the extension of such approach to other countries is investigated. In cooperation with the EEAS, there is also a diplomatic matter whether countries will accept that only part of their country is covered by this system.

5.2 Sustainability strategy

The eHN subgroup on technical interoperability has been fully focused on the DCC for almost a year. Moving forward, a number of other issues have been identified that require attention, including eID, expansion of MyHealth@EU and the EU Vaccination Card. For each of these issues, a complete analysis will be performed and work plan drafted. This will be presented to the eHN for their adoption and it is proposed to establish task forces to tackle them.

FR sees the value of such proposition however we need to make sure that the right people are in the right groups. It is proposed that the work plans for each task force provide information on the topic and the expected outcomes. The members of the eHN are encouraged to review and

disseminate the provided information in order to ensure efficient allocation of people in the appropriate task forces and not only in the EU DCC task force and to achieve a more balanced allocation of the available resources.

SE welcome the work on other issues aside from the EU DCC. Clear agenda and times when issues are discussed would also be helpful and allow efficient use of time instead of waiting hours for a specific issue to be addressed during a meeting. The issue of governance is important if we want to work efficiently. NL agrees with this observation. PT also welcome this initiative and noted that there is a need to have a broader overview of the participation of the Member States in the work of the subgroups.

5.3 Discussion on contact tracing apps and EFGS

The Commission presented the latest state of play of the work on mobile contact tracing and warning applications and the European Federation Gateway Service (EFGS), the European infrastructure that ensures interoperability between national decentralised contact tracing applications. There are currently 18 national contact tracing applications connected to the EFGS, with CZ having withdrawn by the end of October 2021 due to the discontinuation of its national application. There are currently 21 applications live across the EU/EEA countries.

The ECDC's mandate will be strengthened under the European Health Union and it is planned to be broadened to include digital contact tracing and their interoperability. The Commission and the ECDC are preparing the transfer of the operations of the EFGS to the ECDC by March 2022. This will not change the Joint Controllership of the EFGS by the participating Member States.

In parallel, the Commission is preparing to launch a 9-month study on lessons learned, best practices and epidemiological impact of the common European approach on digital contact tracing to combat and exit the COVID-19 pandemic. The Commission invites Member States to actively contribute to this study once it is launched. Member States emphasised the importance of building upon and aligning with research that has already been conducted on digital contact tracing in Europe by including respective results and cooperating with national evaluation partners. NL indicated they would be happy to share further information on the assessment conducted at national level. DE explained that the Robert Koch Institute (RKI) has already evaluated the German contact tracing application (Corona-Warn-App) at a national level. DE suggested to align the European evaluation study with existing (national) research on European contract tracing apps.

On the future of contact tracing applications and the EFGS, NL view was that contact tracing applications deployed during the COVID-19 pandemic would need to be discontinued and that future usage should be assessed and discussed afterwards in close contact with the public health community. The topic of the use of mobile applications and other digital technologies for public health is already part of the European Health Union discussions. The Commission agreed that closer cooperation between the digital and public health communities will facilitate making the best use of digital technologies to fight future health threats and explained that the transfer of the EFGS to the ECDC will help strengthen such cooperation.

6. European Health Data Space

6.1 Update on the procedure towards a legislative proposal and the public consultation

DG SANTE presented the scope of EHDS legal proposal and informed that it is still under internal discussions in impact assessment phase in the Commission. Commission presented what are the main problems in terms of primary and secondary use of health data. DG SANTE stressed that EHDS is building upon existing legal framework. There are a number of studies performed accompanying the impact assessment – some are already published, some will be published soon.

Further DG SANTE presented some results of the public consultation, which will be published in the near future. COM informed that the legal proposal will be adopted during FR PRES, first part of 2022. NL indicated that they would like to have more discussions on the EHDS during the next eHealth Network meetings. They asked the COM to prepare the overview of the other legal proposals where EHDS is mentioned. CY informed about recently introduced national legislation on health data including an opt-out system. FR stressed the importance to understand what is at stake and to avoid misunderstanding, taking into account the complexity of the proposal and existing national legislation.

7 Capacity building

7.1 EU4Health Grants

SANTE presented the background of the capacity building initiative. There is still insufficient exchange of health data, limited interoperability, limited control and access to data. The uptake and free movement of digital health services and products (e.g. tele-health and m-health) is also limited. Not all MS have fully functional electronic health record systems or electronic prescription systems in place. Not all MS offer services for access to electronic health data by patients.

A call for tenders under EU4Health 2021 Work Programme is in preparation. The goal is to support capacity building through a twinning approach, by supporting the exchange of expertise between Member States.

eHN Technical Interoperability Subgroup Chair explained that there are similar twinning exercises ongoing between Member States already now. A joint approach would be useful for speeding up the work on interoperability.

SE highlighted the importance of data on social care, which should be included as part of the capacity building. What is meant by this is, for example, data on specific social circumstances, such as alcohol or drug abuse, data about families receiving special support, having impact on children's well-being. Somatic and mental data is also very relevant. People living alone may have more health problems. This is not about social security, but about social services related to health. The need for health care services might be dependent on social aspects. FR supported this proposal, adding that awareness should be raised in this area, which is, at the same time, a rather sensitive topic.

A few Member States indicated either preliminary interest in the capacity building project or the need to check their position on the proposal.

7.2 RRF, ERDF and InvestEU

SANTE provided an overview of EU funding programmes supporting digital health. Statistics and a summary of health-related investments through RRF, ERDF and InvestEU was presented. MS are planning investments, inter alia, in secondary use of health data, MyHealth@EU services, tele-health, digital skills, artificial intelligence and cybersecurity.

FR presented highlights of their RRF-supported plan related to digital health. It has tight deadlines and the cornerstone in the strategy is to provide patients with access to their data. A national solution MyHealthSpace is planned for this, accessible from a mobile phone or a personal computer. FR will also strengthen national eHealth governance. Health professionals and software vendors are involved in the project. 2 billion Euros have been secured for eHealth implementation in healthcare provider institutions, enabling the production of relevant data to be fed into MyHealthSpace. There is a plan to exchange 250 million documents per year through the national infrastructure. Two laws were passed in 2021, enabling the use of a single identifier for a patient, and introducing electronic prescriptions from 2022. The infrastructure is based on standards such as FHIR, CDA, IHE profiles, DICOM, European standards for ePrescription and Patient Summary. The system is based on the "purchase on behalf" principle, meaning that public authorities will finance the delivery of compliant software to health professionals and institutions. Financial instruments are linked to nationally defined KPIs.

8. eHealth Stakeholder Group

DG CNECT introduced what is the role of eHealth Stakeholder Group and the members of the group. Webinars/workshops in 2021 were presented, where one of the topics was EHDS acceptance. On EHDS 5 working groups were created to understand better what concrete action the stakeholders recommend in the area of primary and secondary use of health data, digital health services and products, AI and the sharing of data between public and private parties. DG CNECT and the DG SANTE presented the work done under each of the Work groups and proposed recommendation towards EHDS.

9 AOB

NL on behalf of ESP raised the question on joint controllership of MyHealth@EU where discussion is lasting already for 2 years. They suggest that eHSMEG Legal Working group could discuss this question further. DG SANTE agreed that the topic is quite complex, informed, that under EU4Health 2022 the funding is allocated to support eHSMEG Legal Working group. DG SANTE underlined that one should ensure that citizens are protected in case something goes wrong with their data in the country of destination and citizens should not be obliged to fight with a foreign country in a foreign language. DG SANTE stressed the role of joint controller to protect the citizens, moreover the possibility to endanger the work on MyHealth@EU – its trust, credibility and legal certainly. Chair of the meeting concluded that this questions will be brought to eHSMEG Legal Working group.

Closing

The eHealth Network co-chairs thanked to everyone for the participation in the meeting and closed the meeting.

The 21st eHealth Network meeting is scheduled (to be confirmed) for 1-2 June 2022 in Paris, France.

*** *** ***