



eHealth Network

Summary report

16th eHealth Network meeting 28 – 29 November 2019

Albert Borschette Conference Centre (CCAB)
Rue Froissart 36, 1040
ROOM - CCAB 2A

Brussels, Belgium

Chairs:

Anne Bucher, Director-General for Health and Food Safety, European Commission

Henrique Gil Martins, President SPMS, Portugal

Opening and approval of agenda

The 16th eHealth Network meeting was held in Brussels, Belgium, on 28-29 November 2019. The meeting was opened by both co-chairs. The draft agenda of the meeting was adopted.

1. Priorities on digital health

1.1. New Commission's priorities on digital health – *for information*

The Commission co-chair has presented new priorities for the next Commission 2019 – 2024 period. The development of new political guidelines started in summer and mission letters with new priorities were prepared and issued in autumn 2019. The new Commission started the work from the 1st December 2019. The mission letter for the Commissioner Designate for Health and Food Safety, Stella Kyriakides, states that there is a need to make the most of the potential of the e-health to provide high quality healthcare and reduce inequalities. The new Commission will work on the creation of a European health data space to promote health data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. As part of this, there is a need to ensure that citizens have control over their own personal data, based on strong foundation of data protection rules. The Commission will work closely together with Member States. There is a plan to discuss with the large community in order to advance the work on the European health data space agenda. The Commission co-chair expressed the confidence that the upcoming EU Presidencies of Croatia and Germany will have a very important contribution to this work.

1.2. Croatian's Presidency health programme – *for information*

A representative from HR has presented Croatia's Presidency 2020 health programme. The programme a strong Europe in the world of change contains main elements including a Europe that is developing, influential, connects and protects.

During the Presidency will be organised an eHealth Week in Rovinj, Croatia, on 15-17 April 2020 (see for more information - <https://www.ehealthweekcroatia.org/>). The main topics of the eHealth Week concentrates on strengthening the provision of services with actionable data, active and healthy ageing, empowering patients and communities and innovation in digital health. In the program is foreseen such events an international conference, high level meeting on eHealth and a two days eHealth Network meeting.

1.3. German's Presidency health programme – *for information*

A representative from DE has presented German's Presidency 2020 health programme with the key topics and events foreseen.

Germany has invited eHealth Network meeting to be hosted in Berlin, Germany, in November 2020 during the period of German Presidency.

1.4. Two years plan of the eHealth Network – overview of the road ahead – *for information*

The Member State co-chair has presented the need to develop two years plan for the eHealth Network meetings and sustainability for the period 2019 - 2021. The purpose of this document is to present vision for the eHealth Network meeting. In addition, to outline the policy topics to be raised for the period 2019 to 2021, including a link to the eHAction on ideas for sustainability scenarios for digital health post 2021.

In the past, meetings were organised at each 6 months circle, with the exception of joint action deliverables scheduled to be discussed. However, many other topics often arise and then are continued or sometimes discontinued. A longer-term view with attempt to bring all pieces of the digital health together is increasingly needed.

The Member States co-chair has emphasised the importance that the foreseen new plan of the eHealth Network should be aligned with the programmes of the EU Presidencies in the rounds of the trio period.

A draft document was presented in June 2019 meeting and this is a developing document. The Member States co-chair invited for members to provide their suggestions what needs to be reflected in the plan for the eHealth Network.

1.5. New multi-annual work programme of the eHealth Network as of 2021 – *for discussion / adoption*

The Member State co-chair has presented the work on multi-annual work plan (MWP) for the period post 2021.

Multi-annual work plan of the eHealth Network 2018-2021 identified four main priority areas (i) empowering people, (2) innovative use of health data, (3) enhancing continuity of care and (iv) overcoming implementation challenges on which the eHealth Network's activities for the coming years will be focussed. Each priority area contains topics that are relevant to current and upcoming policy developments. These topics will be further concretised in specific actions and initiatives.

The eHealth Network should prepare the next plan as of January 2021, to be adopted by the eHealth Network in November 2020. This plan should reflect new priorities, such as European health data space and be in line with health programmes of the EU Presidencies. In order to prepare a new programme, a sub-group of the eHealth Network should be created. The Member State co-chair has invited to establish a sub-group that would contribute to the drafting multi-annual work programme. The sub-group meetings organisation should be initiated from January 2020.

These Member States have volunteered to join the sub-group: Sweden, Finland, Portugal, Netherlands, Poland, Ireland, Estonia, Slovakia, Germany and Greece.

2. European electronic health record exchange format

2.1. Common Semantic Strategy – for adoption

The Member State co-chair, on behalf of the eHealth Network sub-group on semantics, presented the Common semantic strategy tabled for adoption. The work presented was prepared by the eHealth Network sub-group on semantics with the support from eHAction. The subgroup is co-chaired by the Commission and Germany, the Netherlands as rapporteur and the secretariat is provided by the Commission. These arrangements shall be reviewed in 2 years' time, after evaluation of its fitness for purpose.

In May 2018, the eHealth Network agreed on the need to have a common semantic approach towards standardised exchange of health information in the EU. By November 2018, the eHealth Network endorsed the development of a solid proposal for a five-year strategy. A draft proposal was discussed in June 2019 meeting.

The 3 goals of this strategy are: G1 – Structure a common approach on health semantics in the EU; G2 – Provide guidance for EU level decisions on health semantics; G3 – Ensuring establishment and continuity on health semantics in the EU.

The initial scope of this strategy is aligned with the European electronic health record exchange format (EHRxF) (patient summary, ePrescription, laboratory results, medical imaging and reports and hospital discharge letters). This strategy organizes work in a 5 year overall plan with an evaluation activity at the 4th year to analyse sustainability and the need for continuation of work.

The next steps:

- Monthly telephone conferences will start in December 2019;
- Next face-to-face meeting will be held one month prior to the next meeting of the eHealth Network to consolidate input to the eHealth Network on
 - Rules of procedure;
 - General structure and methodology for guidelines;
 - First draft guideline(s) on patient summary elements.

The proposed Common semantic strategy 2025 was unanimously adopted by the eHealth Network without further requests for clarifications or discussions.

2.2. Joint coordination process – for discussion / adoption

The eHealth Network sub-group chair on the implementation of the Communication on the Digital Transformation of Health and Care presented the document proposed for adoption.

The chair started highlighting that the document stems from two works streams (*i. Commission recommendation (C(2019)800) on a European electronic health record exchange format (EEHRxF)*; and *ii. eHealth Network Guidelines on an interoperable ecosystem for digital health and investment programmes for a new/updated generation of digital infrastructure in EU*).

It was highlighted the importance of the scope for the Joint Coordination Process: *a. Take forward the further elaboration of the EEHRxF; b) Identify and progress further health information domains and interoperability needs; and c) Support the adoption of the EEHRxF.* The sub-group chair reinforced also the idea that for this particular scope there should be only one process and not duplicated efforts.

The proposed process should support and include as much as possible the national actors to ensure an accurate understanding of the field, but also concrete implementation plans and attain real impact. The Member States consider as very important that this continues to be a shared process, prepared and executed jointly by Members States and the Commission.

The sub-group chair also underlined that the implementation is up to the Member States. The document reflects this spirit. The sub-group chair stressed that the document should be endorsed as a baseline for the Joint Coordination Process and it should be further developed by providing additional details on the work process.

One MS underlined their preference to have the full detailed process instead of having only the baseline and postpone the adoption, while admitting that the details can be set out when more evidence will be available. Other Member States highlighted the benefits of adopting the paper during the meeting, as it will provide a clear signal to European stakeholders and other global initiatives that the eHealth Network has a way forward and moving in Digital Health standardisation and interoperability. It will also create the scope and mandate for further investments in the activities associated with the process. As mentioned before, the experimentation of the different activities in the process will allow to better understand the details for execution while at the same time work is progressing and justifying further investments (e.g. meetings, time allocation).

The Commission co-chair supported the idea of starting the work using the proposed process as a baseline framework, and work on the details of each activity as we go. For the time being, it is known that “*Activity 2 - Development of Specifications and Implementation Guides*” will most likely be conducted by the upcoming Coordination and Support Action (CSA). Afterwards, more details should be added for validation (activity 2.1 and 22) and endorsement (activity 3). She strongly recommended to start the work on the technical discussions on specifications (as foreseen in the CSA) and once these are developed, they can be a test case for validation. This way, the validation discussions will be based on concrete options and decisions for the way forward. The current paper is useful as a general framework for Member States and Commission to start thinking the different steps that will be needed in order to move from priorities to deployed specifications.

The Member States co-chair highlighted that the challenge ahead “standardising clinical documents” at European level bringing together all Member States has not been done before, and this is the reason for which some degree of structure, but also flexibility is needed for the process to work and be refined along the way.

Based on the fruitful discussions, the Member States co-chair proposed two votes:

- **VOTE 1: Endorse this document as guidance on Joint Coordination Process.** *It shall serve as guidance to steer the work European electronic health record exchange format, during the next year (using it as baseline for experimentation and reflection), and linking the eHealth Network and the involved stakeholders.*

- **VOTE 2: Continuation of this the sub-group to continue elaborate/refine the process.** Namely, clarifying how the identified stakeholders will collaborate to the proposed activities. This vote also includes the change of the name of the sub-group to Joint Coordination Process.

Both votes were unanimously approved by the eHealth Network participants.

The Member States co-chair invited Member States, not yet participating, to join the sub-group activities.

2.3. Recommendations for the development of national digital health networks – for discussion

The Member State co-chair presented a draft document on a set of recommendations elaborated and discussed in the sub-group of the eHealth network. Its purpose is to help Member States in the setting up of “interoperable” national networks that can operate in an interconnected manner, between Member States as well as between them and bodies and processes outlined or to be outline under the Joint Coordination Process.

While presenting the topic, the Member State co-chair highlighted the two purposes of the recommendation:

- To help Member States formulate decisions about establishment of bodies or functions relevant to the development of a fruitful national digital health ecosystem.
- To establish a common frame of reference to which all partners in EU digital health ecosystem can refer to when they think and act vis-à-vis national level topics in digital health.

The Member State co-chair presented several examples on how these national actors could be organised, common challenges that each actor faces, the heterogeneous environment that can exist in each Member State. These examples were provided as elements relevant for a structured and diverse discussion on how to organise, establish and mature national digital health networks.

This document is not a guideline, but a recommendation, due to the fact that the eHealth network has no mandate on Member States internal affairs. Based on the comments received during the meeting and following to the meeting, it will be tailored and submitted for adoption for the next April 2020 eHealth Network meeting.

The main trends of discussion revolved around the following elements:

- Have the right representatives of all right stakeholders, including actors with relevant roles in the healthcare process (avoid having mainly policy makers and technicians).
- Further provisions on what is expected from these national networks in domains as interoperability, cybersecurity? What are the next steps for national networks?

- Powerful and possible law enforced National Authorities for eHealth with the mandate to make things happen at local and European level.
- Inter-dependencies with the Joint Coordination Process (JCP) and how these inter-dependencies may influence the way of working from the JCP and from the National Networks.

Regarding the document possible improvements, namely: *i. reinforce the vision (not so present in the document) and structure of the document; ii. Add clarity on what is being tried to achieve with the document and with the National Networks; iii. Provisions on the timeline and time plans for the provisions in the document (when, in how many years); and iv. Avoid prescriptive provisions, instead provide a comprehensive landscape of each country (how it evolved and how it is evolving) to allow learning from previous experiences and lessons learnt.*

The Commission co-chair highlighted that the work being performed by these National Digital Health Networks is the corner stone of the European health data space (EHDS), and for that reason this recommendation seems to be a relevant tool to create a common understanding on the topic.

3. Use of health data

3.1. D7.2 Best practices report on data protection at national level – eHAction – *for information*

A representative of CZ presented a report with identified recommendations on best practices and approaches on data protection at national level. The report points out to specific situations and shows approaches on data protection in healthcare at national level and the situation that new requirements of the GDPR bring to digital health. The document describes the situation of personal data protection in healthcare, the implementation of the GDPR in healthcare across the Member States and the impact of this implementation on eHealth and on healthcare provision itself.

A representative informed that a survey with a questionnaire for the data protection authorities of the Member States was distributed and only several Member States have participated and provided their answers (17 Member States out of 31).

The report identified a number of recommendations such as support of citizens' awareness on importance on their right to access health information, support activities to educate professionals on personal data handling and exchange, support guidelines development for implementation of GDPR in healthcare, and support development of standards e.g. patient summary and discharge report.

3.2. D5.2 Report on identified cross-border use cases: sharing and learning from best practices on European level - eHAction – *for information*

A representative of HU presented the latest developments on the report on identified cross-border use cases: sharing and learning from best practices at European level. There are already projects and initiatives at the European level which use innovative ways to utilise health data in the cross-border context and in the framework of the EU regulation. The report document provides analyses of the explorative literature review and in-depth interviews with partners from selected projects to derive practical use cases. The analysis confirmed that many stakeholders are facing similar challenges with regard to developing and implementing eHealth solutions in the cross-border framework. In particular, there are issues on privacy protection, ethics, data security, health assessments, data quality, interoperability of health data systems and ability to demonstrate added value to the key actors (citizens, patients and professionals) were brought up in the literature and in the interviews.

3.3. D5.1 Report on policy actions on innovative use of big data in health level – eHAction – *for discussion*

A representative of HU presented the latest developments on a draft report on policy action on innovative use of big data in health level. In the final version of this document will be delivered operationalised recommendations containing information for the eHealth Network on policy-level actions, including an initial set of enabling actions based on the recommendations of the study on big data in public health, telemedicine and healthcare in order to provide a full picture in the final report for the eHealth Network meeting in April 2020.

There is a plan to organise workshop on 21-22 January 2020 in Lisbon, on national strategies and national health data spaces: in the context of secondary use of data and European health data space under umbrella of eHAction WP5 and WP8 scopes. The Member States co-chair invited all Member States to participate on this workshop.

3.4. Initiative on secondary use of data – *for discussion*

The Commission presented the initiatives on use of health data. The Commission intends to map and assess existing Member States rules and policies in the area of health data use, including three workshops with Member States' experts on the use of health data. This project with the title "*Assessment of the Member States' rules on health data*" should be facilitated by an external contractor and should deliver a final study report summarising the main findings of this exercise. The first expert workshop is provisionally planned to take place in January 2020 (subject to confirmation). The project should be completed by the end of the first half of 2020 and the outcomes should be presented to and discussed by the EPSCO Council under the German Presidency in July 2020. The results of this work should be further used to support development of the EU Code of conduct on (secondary) use of health data.

The Commission is also planning another study for 2020, with the title "*Study assessing the state of play of the cross-border digital healthcare in the EU with particular focus on potential regulatory gaps and barriers to the provision of cross-border digital health services and products*". This study will cover specific areas including telemedicine, mHealth, artificial intelligence in healthcare and other areas that can influence the free movement of persons,

health services or products. The work on the study should start in the first half of 2020 and should be completed within 12 months.

Both studies will provide important evidence for the Commission's work on creating the European health data space.

3.5. Implications on European health data space – *for discussion*

The Commission presented its considerations and reflections towards the European health data space (EHDS) and invited Member States to contribute to the discussion on the basis of specific questions.

In the mission letter of the new Commissioner for Health and Food Safety, the creation of the EHDS is set as one of the priority areas of work. The creation of EHDS should promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. As part of this, it needs to be ensured that citizens have control over their own personal data, based on strong foundations of data protection rules. The aim is to make sure that the health data is used for providing better healthcare, but also to provide better research and better policymaking. It is important to set up a safe and trustworthy governance model, with safe data protection rules, where all stakeholders would be able to collaborate, contribute and benefit from the EHDS. To achieve that, full engagement and collaboration of all the Member States is needed.

The Member States largely supported the need to work towards EHDS.

Finland presented their experience with data permit authorities. Some other Member States shared some early reflections, namely: “Why do we need an EHDS?”, “What kind and type of data we envision in the EHDS?”; and that these questions must be answered before eHealth Network can perform the expected assignment on “explore ways on how this data can be exchanged”. Other remarks relate with “avoiding centralised approached and supercomputing” and take the path of “federation and federated learning” and possibly “edge-computing”. Also taking in consideration the possibility for “data donation” or “data altruism”. Focus on what can we can learn from data and organise these questions around use cases (e.g. research, personalised medicine). Some speakers underlined the need to also go directly to patients, which are supportive as long as they have the feed-back from research. One should not try to put data in one single space (cybersecurity risks), but decentralised/federation of health data /personal health trains models should be used instead. There is a need to set up national data spaces, as part of the European health data space. Addressing the different implementation of GDPR is key. One should also have more clarity about how different sources of data are validated and inter-connected. The communication with the commission is essential.

4. Open eHealth Network

4.1. WHO digital strategy – *for discussion*

A representative from the World Health Organisation (WHO) presented the Global Digital Health strategy and the European roadmap for digitalisation of health systems. The WHO is leading the development of a strategy on digital health in consultation with Member States and key stakeholders. The vision of the strategy is to improve health for everyone, everywhere by accelerating the development and adoption of appropriate digital health solutions achieve the health-related strategy. The strategy identifies a number of guiding principles.

The implementation of the strategy will focus to support and respond to the growing needs of countries to implement appropriate digital technologies to address their health priorities and to make progress towards universal health coverage. WHO works closely with Member States and multiple key stakeholders in order to proceed with implementation procedures. a roadmap will be developed for the digitalisation of health systems in Europe.

The Member States welcomed the WHO Global strategy and noted that it is important to have such a strategy. On the other hand, it is important to ensure that the work developed at EU level is not duplicated. The Member State co-chair agreed to explore the possibilities to find commonalities of the strategy and the next MWP and suggested to have a discussion in the next eHealth Network meeting in April 2020. Also, he has suggested that eHealth Network could participate in providing an input on draft roadmap by the September 2020.

4.2. 1 million genomes initiative – *for discussion*

A representative of the 1 Million Genomes made a presentation on the Member States initiative. Since launch of the initiative in 2018, 20 Member States, including Norway, have signed the "1 Million Genomes Declaration", committing them to building a research cohort of at least 1 million sequenced genomes accessible in the EU by 2022 (and 10 million genomes by 2025). The initiative aims to create federated framework that allow to secure and authorised cross-border access to genomic and other health data across the EU, supporting research, healthcare and prevention. This would be built on existing national and European initiatives.

Several meetings of the signatory Member States have already taken place. There is a general consensus amongst the group that the initiative should aim to develop principles for 'good genomics practice', and set in place a suitable technical infrastructure for sharing the sequenced genome information within the EU. The group has acknowledged that many issues will need to be addressed (e.g. in relation to ethics, data protection, governance, ensuring federated access etc.).

There are established thematic 10 working groups with mirroring groups at national level, selected 3 use cases (rare diseases, cancer and prevention), mapping current and future genomic initiatives and data. There is an aim to prepare a roadmap with timelines and framework for the implementation of the initiative.

The Member States welcomed the initiative. Some observer Member States expressed their willingness in the future to join the initiative. Other Member States suggested to explore options what could be the role of the eHealth Network in contribution to this initiative.

4.3. Projects presentation – *for discussion*

Developing a European health data space that enables the sharing and access of health data, within and across borders, and which is trusted by citizens and users alike, calls for innovation in infrastructures and digital technologies.

The Commission supports the projects via Horizon 2020 programme that aim to provide ‘proof of concept’ for the new infrastructures/technologies needed for the digital transformation of the health and care sector. It is essential that interesting projects are brought to the attention of the relevant policy makers, who can review them for their potential to be scaled up. The Commission has invited some stakeholders to present their projects to the members of the eHealth Network meeting such as:

- **My Health- My Data** - <http://www.myhealthmydata.eu/>
- **Smart4Health** - <https://www.smart4health.eu/>
- **BIGMedilytics** - <https://www.bigmedilytics.eu/>
- **Trillium II** - <https://trillium2.eu/>
- **Joining the dots** - <https://www.i-hd.eu/index.cfm/events/joining-the-dots-conference-27-28-november-brussels/>

4.4. Stakeholders’ views (EUHA, BEUC, COCIR, Digital Europe, EFPIA, EPF, EURORDIS, Medtech Europe) – *for discussion*

The Commission has invited different stakeholders to the session Open eHealth Network in order to receive their views and needs in the framework of the digital health. The stakeholders have represented associations of hospitals (European University Hospital Alliance-EUHA), consumers (European Consumer Organisation-BEUC), patients (European Patients’ Forum-EPF and European Organisation for Rare Diseases-Eurordis), radiological and electro-medical association (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry-COCIR), digital industry (Digital Europe), pharmaceuticals industry (European Federation of Pharmaceutical Industries-EFPIA), and medical devices industry (European trade association for the medical technology industry including diagnostics, medical devices and digital health-MedTech Europe).

The stakeholders welcomed the Commission’s initiative to open the discussion and provide the platform to share their views and reflections in the view of the new Commission priorities in the digital health framework.

5. Commission’s eHealth implementing decision

5.1. Implications and adoption

The Commission presented the objectives, scope, implications and adoption procedure of Commission Implementing Decision 2019/1765 providing the rules for the establishment, the management and the functioning of the eHealth Network.

There were no comments from the Member States on the points presented.

5.2. Data protection aspects

The Commission presented the data protection provisions of Commission Implementing Decision 2019/1765 and explained implications for the Commission (data processor) and the Member States (data controllers).

FI mentioned that they are currently analysing at national level whether joint controllership or (separate) controllership between the Member States for the patients' data processed through the eHealth Digital Service Infrastructure (eHDSI) exists. FI stressed the difficulty of this exercise which involves consultation of the national competent ministries and data protection authority. The risk management process for eHDSI should be reinforced. There should be a documented and transparent process with the primary purpose of promptly correcting any safety incidents or errors that may occur and preventing new events from occurring.

EE also mentioned that the issue of joint controllership/separate controllership between the Member States for the patients' data processed through the eHDSI is currently analysed by the Ministry of Justice. EE is also considering the option of consulting the European Data Protection Board on this issue.

The Commission explained that it is not for the Commission to enter into the Member States' decision making process in relation to the above-mentioned issue. However, taking into account that the Implementing Decision is the first Legal Act to regulate the processing of health data in this area following the adoption of the first Joint Opinion of the European Data Protection Board/European Data Protection Supervisor, the Commission is ready to provide support to the Member States to help them set out their responsibilities as joint controllers.

At the end of the debate, it was decided that eHMSEG Legal Working Group will support the Member States in complying with their data protection responsibilities and report to the eHealth Network on this at its next meeting in April 2020.

6. Patient empowerment & patient access to health data

6.1. D4.1 Policy framework on people empowerment – eHAction – *for adoption*

A representative from EE presented the final work on the policy framework on people empowerment focused on m-health, tele-health, data access and digital health literacy. The document was discussed in the previous eHealth Network meeting in June 2019 and based on those discussions and follow up work it was finalised.

The framework will become the basis for a policy proposal for Member States and EU, which will go more in detail about overcoming the key issues identified in the framework. This approach is aligned with the strategic goal of the eHealth Network to work towards the implementation of patient-centred eHealth solutions in all Member States for sustainability of healthcare systems. In the final conclusions, the four identified focus areas contribute to the

people empowerment in various ways and many activities are taking place across Member States in this areas and at the same time the area it is still fragmented.

The Commission co-chair asked whether there are intentions to look at the cross-border aspects of the 4 topics identified. EE agreed that initial aim was to do the work on the issues at national level. However, the discussion and thinking is continuing how this could be related with the new Commission agenda and to look at the cross-border level.

The document was adopted by the eHealth Network.

6.2. D4.2 Policy proposal on people empowerment (information note) – eHAction – *for information*

A representative from EE provided latest development on the work on policy proposal on people empowerment. The policy proposal builds upon policy framework work to develop key principles and define high level priority areas in close collaboration with stakeholders. It was noted that there is a lot of work is already done in this area and there is no need for duplication of the work. Therefore, the aim will be to look into the existing obstacles, gaps and connect the dots of the work where the unmet need is. The aim is to finalise the document for the next year to be adopted in November 2020.

The Member State co-chair enquired whether there is a way to assess if Member States have included in their national strategies and if it is possible to develop some indicators.

EE agreed that it is important to have to be testable and adaptable indicators how to assess digital skills, therefore there is a continuous thinking of introducing key performance indicators and monitoring mechanisms. It was suggested that eHealth Network could be a good platform to reflect that and update on the fulfilment of the goals.

6.3. D6.3 Report on e-skills for professionals – eHAction – *for information*

A representative from IE updated on the work on a draft report on e-skills for professionals. The aim of the work is to specify and measure the e-skills needed, map competences to learning outcomes to form the basis of action plan for e-skills development and to introduce e-skills instructions into medical school curricula.

In the previous meeting in June 2019, members were informed about the eHealth competence model was piloted among health professionals (doctors, nurses, midwives, pharmacists and dentists) from 5 countries (Ireland, Portugal, Hungary, Serbia, Cyprus) are doing an on-line self-assessment of e-skills competency, reusing the work done in JAseHN in terms of framework. It was decided to continue to offer the pilot to those interested until the end of 2019 in order to gather a broader spectrum of answers and encourage Member States to take participation. It was informed that on 15-16 January 2020 will be organised a workshop to analyse all results for the final report.

7. eHealth Digital Service Infrastructure current status

7.1. Future of eHDSI and eHealth financing mechanisms (Connecting Europe facility programme, Digital Europe programme) – *for discussion*

The Commission reminded that implementation of the eHDSI was financed through the years from CEF Programme. The eHDSI Core Services received the funding from CEF WP 2015 – 2019 and will receive the last funding from the CEF WP 2020. The funds for the implementation of Generic Services by Member States were available from CEF WP 2015, 2017 and 2019. Three new Member States (Latvia, Slovakia, and Bulgaria) applied for funds from CEF WP 2019 Call. The eHealth Network co-chair encouraged countries which have not yet join the eHDSI to participate in the eHMSEG and the eHealth Network meetings. RO confirmed that they will continue the active participation in the both meetings. Representatives of NO and DK asked for the further bilateral discussion in order to take a decision.

The further evolvement of the eHDSI will be financed from Digital Europe Programme (DEP), as the CEF 2 program will only focus on the infrastructure.

The Commission informed that DEP has been proposed by the Commission with the aim to increasing EU's international competitiveness as well as developing and reinforcing Europe's strategic digital capacities, including high-performance computing, artificial intelligence, cybersecurity and advanced digital skills and ensuring their wide use and accessibility across the economy and society. The consultation on DEP are ongoing. There are five objectives within DEP and for each of them there will be dedicated budget. The program will be finalised in 2020 and the first call will be published in 2021. Within the different objectives, there would be actions on both research and development.

7.2. eHDSI Work Plan 2020 – *for adoption*

The Work Plan consists of ten sections and its objective is to ensure that the eHealth Network can appropriately steer the implementation of eHealth DSI. It describes the key actions the Commission (DSI Owner and DSI Solution Provider) will do in 2020 as regards the core service implementation and support to the National Contact Points for eHealth.

The eHealth Network adopted the eHDSI Work Plan 2020, presented by the Commission. The eHMSEG discussed and adopted the eHDSI Work Plan 2020 on 17 October 2019.

7.3. Member States progress in the eHDSI operation and implementation – *for discussion*

The eHealth Network co-chair informed eHealth Network members about the general progress in the eHDSI deployment. Five Member States (Finland, Estonia, Czechia, Luxembourg, and Croatia) are already able to exchange the ePrescription and patient summaries and two more will join by the end of this year (Malta and Portugal). There are five new Member States (Sweden, Ireland, Poland, Spain and France - PS B), which are actively preparing to go live in 2020 and three which have postponed their implementation from 2019 to 2020 (Cyprus, Greece and Belgium). In 2021, following Member States are expected to

start exchanging data: the Netherlands, Slovenia, Luxembourg and additionally Italy, Hungary, Austria, Germany and France - PS A delayed from 2020.

It was decided that EEA countries should be invited to join eHealth Network and eHMSEG meetings.

All Member States debriefed on their progress. The general remarks were:

- Member States reported that many times the delays in the NCPeH implementation are caused by the policy reasons, such as: long legislative processes, organizational changes, elections.
- The eHMSEG chair encouraged Member States to start the implementation process in parallel to policy actions because only by implementing Member States can recognize and overcome issues.
- The eHMSEG chair reflected that the services provided by the Commission are on high level.
- Commission informed that the eHDSI implementation involves many Commission services, and that the financial investment in the eHDSI needs to be justified.
- It takes a lot of time and effort for the citizens to learn that the service exists and for them to start using it.
- The eHealth Network should reflect on how countries involved their healthcare professionals in the eHDSI.

The eHealth Network co-chair requested the eHMSEG to present in April 2020 the report regarding Member States readiness, progress, and situation in NCPeH implementation, deployment, operation and refinement.

The detailed remarks were:

- RO – although RO was always interested in joining the eHDSI, unfortunately the application deadline was during the election time in the country. For this reason, they didn't apply. They are still committed to deploy the cross-border services even with national funds.
- NO – have started analysing the European health initiatives in which they would like to be involved, the CEF call timeframe hasn't allowed for applying as the appropriate decision wasn't yet taken.
- DK – was looking in the option of joining the eHDSI but decided not to join. There are different priorities in the country for which the work, effort and funds would be directed.
- EL – are delayed but the work is ongoing, the preparations are continuing. The official request for an Initial Audit was postponed because of the political changes (national government elections). They expect that audit should take place in Q1 2020.

- NL – will implement the PS B first to improve the healthcare. NL will work with 6 hospitals and if the solution will turn out improving the health processes they will scale up. They advanced and tested with Wave 3 countries.
- DE – is delayed as a decision on how to connect the NCPeH to the national infrastructure should be taken (the NCP for EESSI has been designated and NCPeH, considering that it works with TESTA, but the connection has to be set up. The legal basis for the NCPeH was voted in November 2019 and German Federal Ministry of Health became the major shareholder on Gematik. The NCPeH will be run by the National Insurance Agency, but developing specifications and technical means will be responsibility of Gematik. The updated timeline will be prepared in Germany and will consider the permanent set up of the NCPeH. Germany will continue work to start the cross-border data exchange.
- FR – is of opinion that it is more important to start the cross-border exchange than to focus on the delays. FR is on track with setting up the PS B service. The PS A implementation is delayed, the access to the health data was restricted to the French health professionals, the new law clarifies which type of health care professionals have access and to which type of health data.
- AT - is delayed because of the change of national priorities caused by the change of government. This changes impacted the implementation of the eHDSI project in Austria. There is not yet a decision if AT will start the implementation of PS B in 2020. The country A services will be implemented at the next stage.
- CY – The national law which designates the NCPeH was adopted, but with the delay. Meantime, the temporary NCPeH was designated, work done by them needs to be transferred to the official NCPeH. Only the permanent NCPeH can be audited. The work will be continued in 2020.
- IT – in 2017, the national law was adopted, which allowed to build the national system for health data collection. The contract with INEA is being amended and the timeframe of project implementation is rescheduled. As all MS need to comply with Audit and Test Framework and events the progress of the work is also influenced by the fixed events.
- HU – is delayed as the reorganisation in Hungary impacted the procurement activities. The work on NCPeH should be restored in Q2 2020. The new legal proposal is under adoption.
- The eHMSEG Chair – advised that MS should start technical preparations as soon as possible. Implementation and deployment uncover the issues which need to be overcome before going live. So technical work should go in parallel with the legal and organisational one. At the same time, the eHMSEG considers that services provided by the Commission (e.g. tests, audits, support, specifications) are at very good level.
- The eHN Chair concluded that trust is important, but also the return of investments need to be justify. This issue was also raised by the Court of Auditors so the timely implementation of NCPeH is needed.

7.4. Go-live decision to exchange ePrescription and patient summary in the eHDSI – *for adoption*

The eHealth Network co-chair invited the eHMSEG chair to present the eHMSEG recommendations to the eHealth Network issued in October 2019 for Finland (receiving ePrescriptions of foreign citizens) and Croatia (exchanging patient summaries of Croatian citizens). The eHMSEG supported both countries to go-live. The eHealth Network Chair pointed out that the eHealth Network gave a mandate to the eHMSEG to prepare their recommendations, as there are the body competent to do so. For that reason, the eHN should trust the eHMSEG assessment, or reconsider its mandate or way of working.

The eHealth Network co-chair invited Finland and Croatia to present their applications to go live.

The eHealth Network agreed that Finland can go live, with observations, provided that all corrective actions identified have been taken and this has been verified by Auditors, before entering routine operations. FI informed that they plan to go live in March 2020.

The eHealth Network, by majority of votes, decided to adopt the recommendations in line with the eHMSEG one ‘Croatia goes live (PS-A) with the medications summary and active problems sections’. The NCPeH needs to submit a statement of the Auditors to eHMSEG (via secretariat) that corrective action 2 has been implemented. In addition, the Croatian National Contact Point for eHealth must follow the current Test Framework and resolve the remaining functional findings specific to those two sections. The NCPeH can then enter routine operations without need for further approval.’

Majority of the Member States were in favour of Croatia going live even with limited datasets as any data might be in use especially that during the eHMSEG meeting the PS B countries voted to accept the exchange of Croatia PS A. Countries, which are providing or will be providing the service Patient Summary country B expressed their support and willingness to consume the services provided by the Croatia as Patient Summary country A.

At the same time, the eHealth Network decided that the completeness of patient summaries should be measured and monitored for all the countries in the production. The eHealth Network asked eHMSEG to produce a proposal on how to inform eHealth Network on the Member States national plans for the services implementation, operations and refinement and national coverage (to which extend the eHDSI is deployed at national level). The guidelines are abstract in regards this topic but the project is to provide electronic services to all citizens in Europe.

Additionally, the risk management for eHDSI should be enforced. To be aware about the incident management process, we should establish it for multi professional purposes.

8. eHealth Digital Service Infrastructure development

8.1. Orphacodes – European Reference Network – *for discussion*

Director of the Orphanet presented an overview of the activities developed by Orphanet focusing in particular on the Orphacode system.

The importance of being able to count rare diseases through their accurate classification was emphasised. This is the purpose of Orphacodes, to make patients visible and identifiable, as the terminology of rare diseases (RD) is very poor. RD are included in other medical terminologies to varying levels. In the Council Recommendation (2009) a priority was identified to improve codification for RD. A timeline of the steps so far in Europe on rare disease codification was presented. Highlighting the work of the different initiative on the RD. Orphacode nomenclature is unique, stable and assigned to each disease. Only nomenclature that is specific to RD. Comprehensive, standardised, evidence-based, versioned, computable, and free. Additionally, it is multi-lingual. Guidelines, guidance and support for implementation of Orphacodes are available. Training is in preparation and will be provided by national Orphanet hubs in local language.

The mutual benefit of collaboration between Orphanet and ERNs was emphasised. ERNs already use Orphacodes (in the CPMS and registries) and should continue to do so, so as to allow for continuity of coding and portability of data.

Some Member States emphasised of the importance of the Orphacodes being simultaneous with ICD-11 and be more integrated. Classification is an issue and there is important to ensure a close collaboration with patient representation.

PT described recently implemented rare disease patient cards, on which Orphacodes are used alongside other classifications and other clinical information. In Portugal 3103 people have these cards and 961 Orphacodes have been used on them in the past two years. These cards impact upon the medicines which these patients receive, improve healthcare and make a difference.

8.2. Revision of patient summary guideline – *for discussion*

The eHealth Network discussed briefly the approach to amend the Guideline on patient summary (PS), where the scope was extended to include the planned care scenario. The proposed revision includes the extend of the scope to planned care scenario, while continue to focus on the “summary” record, with potential for cross-referencing to other, more detailed, data for specific purposes (like rare diseases). It was clarified that the extension of the eHealth Network PS guidelines scope to the planned care does not impose any changes when it comes to the citizen’s reimbursement rights.

On the other hand, the eHealth Network decided that the work should continue to clarify the processes and impact of alignment with IPS: reuse of the IPS datasets in the eHealth Network PS guidelines, eHDSI tools and fees, impact on Core Services and national infrastructures.

The eHMSEG chair presented the Recommendation issued by the eHMSEG to the eHealth Networks with regard to the adjustment of the eHealth Network patient summary datasets concerning the EN 17269 International Patient Summary standard: *‘The eHMSEG recommendations to the eHealth Network: The eHMSEG acknowledges that it is centrally technically feasible to move to International Patient Summary Standard. If the eHealth Network decides to move to the International Patient Summary Standard, the Member States*

and the Solution Provider would need to further investigate if the implementation within the Member States is feasible and in what time frame. The eHMSEG would like to highlight the significant effort for each Member State and the Solution Provider to confirm the technical feasibility at the national level.'

The eHealth Network decided that the eHMSEG should further investigate if the implementation within the Member States is feasible and in what time frame and that Solution Provider should continue the work to confirm the technical feasibility at the national level.

The eHealth Network decided that the Guideline should be further revised and the additional information on impact of IPS implementation in eHDSI should be presented in the eHealth Network meeting in April 2020.

9. National eHealth strategy

9.1. Presentation of Slovakia – *for information*

Due to intensive schedule of the meeting it was agreed with representatives of the Slovakia to postpone the presentation on national eHealth strategy for the next meeting of the eHealth Network.

10. Enhancing continuity of care

10.1. D6.1 Roadmap on future eHDSI use cases and features – eHAction – *for adoption*

A representative of DE presented a final roadmap on future eHDSI use cases and features. The document is considered final since there are no known open points. It was highlighted that the document suggests activities within and across Member States to quickly enable new eHDSI use cases within a reasonable timeframe and with minimum effort.

It was also pointed out that the documents revolves around 4 main objectives:

- Identification and prioritisation of use cases: develop and support strategies and activities to foster exchange and innovative use of health data to provide added value through use of the eHDSI.
- Communication, community and user engagement: stimulate the building and uptake of interoperable healthcare solutions by creating awareness and enthusiasm.
- Governance, strategy definition and policy: develop a collaborative European governance for the adoption of cross-border data exchange services under the eHDSI at national, regional and local levels.

- Interoperability assets and solutions: enhance interoperability of eHDSI with existing and emerging health IT systems in Member States.

The suggested activities provide a useful foundation for EU Member States and for the Commission to further plan specific steps on the road towards the implementation of selected new eHDSI use cases and features.

The Member State co-chair highlighted the quality of the work done and relevance for the creation of new health information services in the European cross-border scene.

The document was adopted unanimously by the eHealth Network.

10.2. D6.2 eHDSI legal report – eHAction – *for information*

A representative of DE presented an eHDSI legal report document. It was highlighted that the report provides an easy to understand perspective on the legal applicability and impact of EU legislation, already in place or upcoming, on the eHDSI and its services – patient summary and ePrescription/eDispensation. The report also outlines currently known open legal points, agreed or single legal interpretations in that context and tries to give guidance to the responsible governance bodies and working groups for next steps. It is identified that the eHDSI legal environment is currently changing, however, the current legal bases, enriched by national laws, are sufficient for the first cross-border data exchanges between Member States.

There is further work to be done taking in consideration the legal challenges and eventual barriers (as identified during this eHealth Network meeting). Having that in mind and acknowledging that nowadays activities and initiatives are still lacking available legal resources with adequate capacity to keep up with arising matters and proceed with the already identified tasks further support (more energy and resources) is needed from Member States and Commission.

No further updates to the document are foreseen, unless the eHealth Network requests for it.

The Member State co-chair concluded that the eHealth Network acknowledges this document and highlighted the top priority legal aspects to be addressed in the following months, namely the analysis of the impacts from the new Implementing Decision in what regards to GDPR and the work from eHMSEG legal working group.

11. Digital Identification in Health

11.1. Update on technical implementation and Member States participation in the HEALTHeID Transferathon - *for information*

The project was presented by a project coordinator from PT. The project is now finished and produced some conclusions and recommendations, namely:

- eIDAS eID appears as the only way to enable widespread adoption of patient strong authentication, as it allows to leverage the relevant EU policy and legal basis;

- It is generally agreed that patient active participation in his identification process has a significant impact on the security of the cross-border workflows, and give empowerment to the citizen;
- The minimum-disruption principle as a design guideline has resulted in insignificant modification to the implementation of the NCPeH gateway, allowing the present and "HEALTHeID Connector" workflows to co-exist at the technical level.

The project also highlighted its main outcomes. HEALTHeID has pre-demonstrated, on a demo basis, a working and reproducible technical solution that should be adopted by other Member States. Handover the HEALTHeID project's outcomes to the Commission and to Member States. It is still needed establish a Common Identification approach on the EU.

As next steps HEALTHeID will do a final demonstration to the Commission and other Member States, performing all the HEALTHeID workflow.

The Member States co-chair highlighted that the HEALTHeID project aimed to address so of the questions raised by previous documents of the eHealth Network and to explore possible solutions that could in the future be endorsed by eHealth Network.

Some Member States noted that some countries having already solid solutions on the ground regarding electronic identification and that we should avoid getting into situations where these solutions need to be replaced.

11.2. Common Strategy for the use of Digital Identification in Health in the European Union - *for discussion*

Director General of DG CNECT, Commission, Roberto Viola, introduced the topic.

Is it necessary to have a common strategy identity management framework for the healthcare sector? Most likely yes, since we cannot let private identity platforms to be the only solution possible. This should be avoided for the sake of compliance with regulation, interoperability and ethical use of health data. The high value of health data creates a tremendous conflict of interest when in the sphere of private commercial entities. But naturally, if there are no alternatives (public alternatives) we may need to continue use commercial companies platforms. We need to have a common public framework.

What is the advantage for the patient? Portability will increase flexibility when accessing to healthcare services. Separating patient data and identity, may lead to increased security. The interaction with the patient is more verifiable.

The Member State co-chair presented the work performed so far, for eHealth Network information. It was highlighted the major motivation for a common electronic identification (eID) for the secure and reliable identification of patients and professionals on the national and cross-border context.

- One of the most stressed situations relates to fraud avoidance. In order to get to a level of trust where fraud is reduced significantly, all transitions require unambiguous and reliable identity assurances of the user in from of the screen or who signed a document.

- The other point remarked was that eIDAS does not provide the means to regulate a face-to-face interaction, only applicable for online services.

Some Member States remarked that there are new technologies and possible identifiers not notified under eIDAS framework. It is important to ensure that the proposals on the table are open but new possibilities but also fit the purpose of healthcare and are not just pushed by other sectors.

The eHealth Network endorsed the way forward for this document, namely that current draft version of the Common Strategy for the use of Digital Identification in Health in the EU will evolve with the collaboration of the Member States / countries representatives under the eHAction scope in order to present a final strategic document in eHealth Network meeting (November 2020).

12. Cybersecurity collaboration

12.1. D7.3 Common security framework for eHealth – eHAction – *for discussion*

A representative of EL presented the work on common security framework for the digital health. The presentation highlighted the objectives of the document being prepared, namely to create and deliver practical guidance for operators of critical services in the healthcare sector on a priority set of security issues.

From the current work, two recommendations have been drafted but require further maturation, namely:

- Recommendation 1: Establish an official coordination steering council of national representatives and heads of cybersecurity in health
- Recommendation 2: Elaborate the Cybersecurity Guide in close co-operation with ENISA, addressing primarily health care providers at the CEO and CIO level

There was a suggestion from NL for Member States that want to start sharing information on security issues. This could be very valuable because the issues happening somewhere else may be prevented in other entities, if communicated timely.

12.2. Report on Cybersecurity workshop – *for information*

The Member State co-chair presented the outcomes from an informal Cybersecurity workshop (Lisbon, October 2019) for healthcare entities/authorities.

From the workshop resulted an initial set of ideas and initiatives of joint work that could lead and aid healthcare authorities to better address information security issues affecting healthcare organisations.

The work from the workshop continues with online teleconferences and will follow a work plan already defined for the next 12 months.

The eHealth Network acknowledge the approach of the work done so far and endorse the future work, with particular focus on work, together with ENISA and the Commission, DG CNECT, on possible proposal of a structured, more formal group (potentially as a EU Health ISAC) as well as eventual collaboration on NIS Directive support activities.

13. Integration in national policies and sustainability

13.1. D8.1 Integration in national policies and sustainability – National eHealth strategies – eHAction – *for information*

A representative from France presented the work on integration in national policies and sustainability. The objective of this work is to collect present and future of the eHealth strategies of the Member States and propose a direction to support their alignment. To analyse the collected data in order to propose ways to align strategies and projects in the future. To present a mechanism on how to follow up the evolution of eHealth strategies. It was found that health and eHealth are major concern in all countries those responded to the survey. Most of the Member States share same priorities. Implementation of the programmes and initiatives depends mainly on the political and health organisation of each country and national priorities. There is a need for common grounds on the enablers to reach European interoperability.

There is a platform developed for uploading data of each Member State to use as a tool to collect national eHealth strategies. Member States are encouraged to provide their data. The results of this work will build up on the future work of the D8.3 to define a sustainability plan for the exchange of health data among Member States.

The results of the workshop on “Secondary use of data” (Lisbon, 21-22 January 2020) will support the next steps of this work.

Member States welcomed as a great tool developed that will be very beneficial for the alignment of the Member States national health strategies across the EU.

13.2. D8.2 Policy document about technology report – eHAction – *for information*

A representative from Portugal presented an overview on the work on eHealth policy technology on report. The main key objectives of this work are on electronic health records exchange format (EHRxF) (D8.2.1), the common semantic strategy (D8.2.2) and eHealth reference architecture (D8.2.3). The work on D8.2.1 contributed to the development and preparation of the Commission recommendation on EHRxF, which was adopted early in 2019 and presented in the previous eHealth Network meeting in June 2019. The work on D8.2.2 was transferred to the sub-group of the eHealth Network for further development and was presented in this meeting under the agenda point 2.1 Common Semantic Strategy. The work on D8.2.3 with the aim to promote the importance of outlining a Reference Architecture

for the eHealth based on the Enterprise Architecture framework. A draft document will be developed and presented for the next eHealth Network meeting in April 2020.

AOB

No points for discussion.

Closing

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

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