eHealth Network

Summary report

18ᵗʰ eHealth Network meeting

(Teleconference)

12-13 November 2020

Brussels, Belgium

Co-Chairs:

Claire Bury, Deputy Director-General, and Andrzej Rys, Director for DG SANTE, European Commission
and
Ron Roozendaal, Director for the Ministry of Health, Welfare and Sports, the Netherlands

Opening and approval of agenda

The 18th eHealth Network meeting was held in a digital format - teleconference (Webex) on 12-13 November 2020. The meeting was opened by the co-chairs. The draft agenda of the meeting was adopted.

1. Welcome of German's Presidency

A representative of German's Presidency welcomed the members of the eHealth Network meeting.

2. eHealth Network procedures

2.1 Election of the new Member State co-chair of the eHealth Network

The eHealth Network members thanked to the previous Member State co-chair Mr. Henrique Martins, SPMS, Portugal, who served until January 2020, for an active and dedicated work on digital health implementation across the EU.

A new Member States co-chair Mr. Ron Roozendaal, Director of Information Policy and CIO, Ministry of Health, Welfare and Sport, the Netherlands, was elected by consensus by eHealth Network members. A new co-chair will serve in this position for 2 years.

2.2. Amendment of Rules of Procedures of the eHealth Network

Following the requirement to update all EU documentation on outdated legislation references, the Rules of Procedure document was also amended. In the Article 16, two references to personal data processing and protection were amended and introduced references to Regulation (EU) 2018/1725[1] and Regulation 2016/879 (GDPR) [2].

eHealth Network adopted the amended document by consensus.

3. European Health Data Space

3.1. Update on the state of play of data strategy, the European Health Data Space and free movement of digital health services and artificial intelligence liability in health – [for information]

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[1] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).
[2] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1)

The Commission underlined that one of the main priorities of this Commission in the area of digital transformation of healthcare is the creation of a common European Health Data Space (EHDS) as set out in the European Strategy for Data adopted in February 2020, in order to achieve better healthcare outcomes, better research and innovation, and better policy-making.

The European Health Data Space will contribute to achieving better healthcare outcomes, better health research and innovation, and better health policy-making. The vision of the European Health Data Space is to promote health data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. It will deal with primary and secondary use of health data.

The work is structured along four main areas: (i) governance and rules, (ii) quality of data, (iii) infrastructure and technical interoperability, (iv) capacity building and digital upskilling.

The Commission is currently working with the Member States and stakeholders, including the Joint Action on European Health Data Space to define the best governance structure and set up the appropriate infrastructure for the European Health Data Space. While the governance for primary use of health data is ensured by the eHealth Network, the situation for secondary use of health data (for research and policy making) is less clear, but several Member States have put in place such data permit authorities.

The second pillar, related to eliminating barriers to free movement of digital health services is being analysed through a study on regulatory gaps. At the same time, Member States' implementation of the GDPR for the secondary use of data are being assessed. A pilot project will start in 2021, together with EMA, ECDC and several national public bodies, to develop an infrastructure to facilitate data access.

The first strand of activities on governance and rules will be dealt with primarily through the work on the sectoral legislative proposal establishing a regulatory framework for a European Health Data Space (EHDS), digital health services and products and artificial intelligence (AI) in health.

To build capacity on secondary use of health data, as of 2021, the Commission will work very closely with the Member States in the Joint Action on European Health Data Space, along with the eHAction on primary use of health data. The future Multiannual Financial Framework offer important opportunities to invest in the digital transformation of health and care and build the capacity of Member States: at national level, through Recovery and Resilience Facility, but also European Regional Development Fund, European Social Fund+. The Commission will also use the EU4Health, but also Digital Europe Programme and Horizon Europe to support the European Health Data Space.

3.2. View of the German's Presidency on the European Health Data Space – [for information]

A representative from German Federal Ministry of Health, gave a presentation on the German priorities for the European Health Data Space (EHDS). He underlined the difficulties experienced until now by stakeholders, in particular researchers, in accessing and sharing health data, in particular with respect to the different implementation of the GDPR in the area of health in the Member States. Since 2019, German presidency has

developed a strategic approach to a European Health Data Space, based on trustworthy AI, free flow of data, to foster a competitive Union healthcare industry. He underlined the importance of the work carried out by the Commission on the application of the GDPR in the area of health and is awaiting the final report before the end of the year. There is a political commitment to the EHDS and an opportunity to build momentum. The work on EHDS was prominently mentioned at the High Level Conference on AI on 11 November 2020. This will feed in the Council conclusions.

There is work ongoing to drive the EHDS. 22 Member States are committed in the work in the Joint Action (TEHDAS). Codes of Conduct are needed to complement the legal basis in the health data processing. There is a need for cooperation and dialogue between health community and data protection community. We must also demonstrate the need to share health data for concrete use cases, in order to save lives.

A representative from NL commented, as mentioned at the High Level Conference on 11 November, on the need for technical and semantical interoperability for the EHDS and AI to succeed. It was stressed the importance of aligning and strengthening the policies, strategies, instruments and activities regarding primary and secondary use of health data, not necessarily under one mandate and governance.

4.   EU investment programmes

4.1.   Update on EU4Health programme – [for information]

The Commission has presented the EU4Health programme. This is the Commission proposal to support of the digital transformation. The programme is under negotiation by two co-legislators the European Parliament and the Council. By the latest information the budget will be increased over EUR 5 bn, but some amounts are already ring-fenced for different priorities (such as the creation of the agency HERA). The Commission will need to revise the priorities identified for the programme. For the time being, support is suggested to be provided for MyHealth@EU, EHDS infrastructure, pilot project 2021 (EMA, ECDC, national authorities dealing with secondary use of heath data). However, the final decision will be made when the legislative proposal will be finalised in the upcoming period.

There are other funding sources apart of the EU4Health programme. The funds provided for national support RRF, ERDF, ESF+, InvestEU etc. Complemented at EU level the funds DEP and Horizon Europe.

4.2.   Update on Recovery and Resilience facility (RRF) – [for information]

The Commission presented to the eHealth Network the investment possibilities under the new Recovery and Resilience facility. The Recovery and Resilience Facility will provide grants and loans to Member State authorities to finance reforms and investments, in a number of possible sectors, to overcome the economic and social impact of the Covid-19 pandemic, addressing challenges identified in the European Semester.

According to the latest Council outcome, the total budget EUR 672.5 bn and envelope for grants would be EUR 312.5 bn and for loans EUR 360 bn. There is a target of directing at least 20% of these to the digital transformation.

Support for health reforms and resilient health systems is eligible, in line with plans (the 'Recovery and Resilience Plans' – RRPs) that will be prepared by each Member State by April 2021 and approved by the Commission.

The RRPs may include investments in eHealth, also as part of the digital transition. However, this depends on the reform and investment priorities defined by the Member States. Some Member States have already started a dialogue with the Commission on the development of the RRPs. All Member States are expected to do so and submitted draft RRPs to the Commission within 2020.

The funding is available from the 1st of January. The EU made a bold commitment on economic recovery and social and economic resilience. RRF will be linked to country specific recommendations - CSR of the European semester 20-21 and will not issue CSR in spring with some exception with fiscal requirements. MS should specifically suggest eHealth actions for certain countries – seem to be a good way also for ongoing support.

4.3. Update on Digital Europe programme (DEP) – [for information]

The Commission presented to the eHealth Network investment opportunities of the new Digital Europe Programme (DEP) and how it is related to digital transformation of health and care and the development of the European health data space.

Main objective to reinforce the technological capacity and sovereignty in Europe. One of the main challenges are the digital transformation of the health sector.

The Commission has published draft Orientations for Digital Europe, intended to shape the work programmes and calls for proposals for the programme's first two years (2021-2022).

Between July and October 2019, a consultation was held to gather views on the Orientations, open to anyone with an interest in the digital transformation of Europe's economy and society. The Digital Excellence Forum at ICT Proposers' Day, held in Helsinki on 19-20 September 2019, was also an opportunity to give feedback on the Digital Europe programme. DEP is supposed to finance the genomic initiative, cancer images, HPC, testing and experimentation facilities, cybersecurity.

The DEP will complement other funds in the transformation of health care.

4.4. Update on Horizon Europe programme – [for information]

The Commission provided information on Horizon Europe programme. Horizon Europe Cluster 1 Health will support, through its Work Programme 2021-2022, several important topics relevant for the European Health Data Space.

In order to maximise the impact of research results, synergies with relevant programs of the next MFF, such as the Digital Europe Programme (DEP), EU4Health Programme, Invest Europe and the structural funds will be carefully looked at, and in that regard the programme has been extensively co-created by relevant DGs.

The first Horizon Europe Work Programme, covering 2021 and 2022, is expected to be launched at the end of the first quarter of 2021. Several actions are being prepared to support the research dimension of the European Health Data Space

The programme was cut and might be possible for the next generation fund. HE build on H2020. This programme aim more impact than in the past and more synergies with other programmes. Data is among the areas where consistent support will be offered by HE.

5. COVID-19 Coordinated actions

5.1. Contact tracing apps and EFGS State of play / effectiveness – [for information]

The Commission presented the state of the work on contact tracing and warning apps and the European Federation Gateway Service (EFGS), the EU-wide infrastructure that ensures interoperability between national decentralised contact tracing apps. The EFGS ensures that users can rely on a single app across the Member States that are connected to it. The eHealth Network started its work in the area of contact tracing and warning apps back in March 2020, and since then it has adopted an EU toolbox with a common European approach, interoperability guidelines and interoperability specifications for the EFGS.

There is currently no interoperability solution between centralised and decentralised apps but the eHealth Network and the Commission, through their common work, will continue to support both architectures.

The Commission is supporting the Member States, through the secretariat of the eHealth Network. It has also provided guidance on data protection. On the technical side, the Commission successfully rolled out the EFGS, as per the specifications agreed by Member States. The system was deployed in September 2020, and since then 6 Member States have gone live, representing more than 40 million downloads, and 65% of the total downloads in the EU. Additional 5 Member States are currently working on their onboarding, and other 6 could join before the end of the year (but are yet to apply for onboarding).

The Member States and the Commission agreed that the deployment of the EFGS and national contact tracing apps in such a short time period has been a great success. It is now important to build on this work, particularly regarding the uptake of national contact tracing and warning apps by the population.

The eHealth Network will continue with the onboarding of new Member States, as well as with the monitoring of the effectiveness of these apps together with relevant stakeholders (e.g. ECDC). Given the legal constraints regarding data protection and public health, the Commission is looking into options for the exchange of contact tracing keys with third countries outside the EU/EEA, at the request of Member States.

5.2. Update on subgroup activities - Technical IOP – COVID-19 Use Cases – [for information]

The mandate eHealth Network subgroup on Technical IOP was adopted by the eHealth Network.

The objectives of the group are to:

- Support the eHealth Network in reaching strategic decisions, strategies and measures on technical interoperability issues, to facilitate growth and innovation in the EU eHealth landscape;

- Provide policy advice on technical interoperability aspects, complementary to and in close cooperation with the eHealth Network subgroup on Semantics;

- Work out strategies to improve adoption and implementation of interoperability standards in Member States, including aspects such as technical obstacles, business readiness, costs, and timeline that will support the eHealth Network to formulate a well-substantiated roadmap;

- Find synergies in sharing best practices and assets related to eHealth interoperability in the EU.

Above will be achieved by (1) providing the expert independent advice; (2) linking pin with the real world challenges on implementation; (3) finding synergies in sharing best practices and assets related to interoperability in eHealth in the EU; (4) connecting the dots.

Planned activities are to (1) advice on short-term approach on cross-border exchange in view of the COVID-19 crisis (COVID-19 related lab results; COVID-19 related sharing of imaging studies; COVID-19 related vaccination statements); (2) review of patient summary guidelines update; and (3) align governance- and organisation with the eHealth Network subgroup on Semantics.

5.3. Update on subgroup activities - Semantic IOP – COVID-19 Coding lessons learnt – [for information]

During the first year of activity, the eHealth Network subgroup on semantics developed work in the following matters:

a) Evolution of "eHealth Network guidelines on patient summary dataset".

b) "Process and criteria for recommendation development" to allow an open, transparent, and coherent process for development of eHealth Network subgroup on semantics recommendations.

c) Horizon scanning of "COVID-19 health data coding practices and data sources" and identify best practices in Member States that could be used as lessons learnt and, possibly, scaled up at EU level.

d) Liaison with X-eHealth and UNICOM projects, as well as engaging with the eHDSI Semantic Task Force and eHealth Network subgroup on technical interoperability.

e) Recently, the subgroup engaged with the "EU vaccination card" project, that requested the contribution and advise on the semantic aspects.

Regarding "COVID-19 health data coding practices and data sources" the eHealth Network subgroup on semantics highlighted that there are some data elements missing in patient summary guideline R2 (PS) that might be necessary and helpful. It was recommended for these elements to be considered in the ongoing revision of the patient summary guideline.

It was also recommended and agreed that work should be done to increase the visibility and accessibility of the patient summary guideline and eHDSI assets, to enable further use throughout EU-projects and as basis for use case specific extensions to enable more harmonized data collection in case of a health care emergency situation of any kind.

5.4. COVID-19 vaccination certificate – [for information]

A representative from Estonia, Guardtime company, presented the latest developments on vaccination certificate for COVID-19.

In October 2020, Estonian Prime Minister and WHO Director-General signed a Memorandum of Understanding to share the experience of Estonia and its companies in healthcare digitisation using distributed information architecture and interoperability with WHO and its member states.

The first pilot will be a digitally verifiable international vaccination certificate („Smart Vaccination Certificate"), which could potentially support the effective implementation of the COVID-19 vaccination program.

The technical leader of the project is Guardtime company, an Estonian-born cybersecurity company leveraging the EU eIDAS-accredited trust service KSI-block chain in its solution for tamperproof digital certificates. The collaboration also involves Nordic Institute for Interoperability Solutions (NIIS), SICPA and potential other partners.

Functional goals of the pilot implementation are identified as, (i) provide proof of COVID-19 tests & vaccination (certification), (ii) monitor vaccine uptake among target population, (iii) provide independent verification of the certificates, and (iv) collect insights about supply chain integrity and pharmacovigilance.

Main features of the concept were identified. Vaccination is entrusted to specific healthcare facilities that have been authorized to vaccinate in each country. Healthcare providers that have received such a right shall be registered by the relevant state authority and given permission to issue digital certification credentials. To ensure privacy, vaccination information with personal data is stored only in a health care institution and the patient is issued a vaccination certificate. The only information stored centrally is an independent digital authenticity certificate - this ensures that the vaccination attestations issued by each healthcare institution cannot be falsified or subsequently altered. The certification confirmation - QR code - can be verified from paper, as well as from pdf or mobile app versions of the vaccination attestation. Thus, the transfer/sharing of personal data takes place only by the person himself and under his control, no central health database is required for the purpose of verification. For other countries, in addition to checking the attestation and verifying the certificate, only information about the

respective country authority that issues the accreditation for vaccination is needed; in case of doubt, it is possible to make a further inquiry to the competent authority as to whether a particular healthcare provider is authorized to vaccinate.

The certificate has different components and system is based on open standards that was developed in cooperation with WHO. Currently is working to integrate two different certificate solutions and in the future should be possible to use both. There is no possibility to fake, as to have a certificate you need a unique vaccine code and personal photo ID similarly. This works in a similar way as for an airplane ticket.

The Commission noted that in Health Security Committee and Vaccine Steering group meetings were received many interesting comments. There is an option maybe to build up synergies with eHealth Network technical subgroup to look into this in more detail and future developments. The work would be reported back to the eHealth Network.

6. eHealth Network future activities

6.1. eHealth Network Recommendations for the Development of National Digital Health Networks in the EU Member States, draft proposal – [for discussion]

A project coordinator of eHAction presented the views on the prepared recommendations on national digital health networks (NDHN).

The origin of national digital networks is in the Commission recommendation on European electronic health record exchange format. To enhance the interoperability and security of national health systems and support the secure exchange of health data across borders, improvements on the relations of the eHealth ecosystem bodies should be done at national and EU levels. There is already developed a governance model that is supported by other EU bodies, such as eHDSI. More work should be done at national level to achieve a supportive, collaborative and sustainable governance model. Each Member State should set up a NDHN involving representatives of the relevant competent national authorities and, where appropriate, regional authorities dealing with digital health matters and the interoperability of electronic health records, and security of networks and information systems, and the protection of personal data.

This document provides recommendations on how this supportive national governance could be. It should (a) include the national representative of the eHealth Network; (b) national, or regional, authorities with clinical and technical competence for digital health matters; (c) supervisory authorities established under Article 51 of Regulation (EU) 2016/679; (d) competent authorities designated pursuant to Directive (EU) 2016/1148.

The results of discussions or consultations of the NDHN should be transmitted to the eHealth Network and to the Commission.

Very different organisational arrangements exist across the Member States. Supporting activities of the eHealth Network demonstrate how this heterogeneity can influence cooperation activities. In this document, the role of governance is again emphasised as a critical step towards the implementation of interoperable solutions. A Joint Coordination Process is deemed necessary, as well as the "establishment" of National Digital Health Networks within the Member States.

Purpose of recommendations identified in the document:

1.   To support the Member States to formulate decisions on the establishment of bodies or functions relevant to the development of a fruitful national eHealth ecosystem, if these do not already exist.

2.   To map and consolidate the possible interdependencies and synergies between the different nodes of a NDHN in order to further improve its functioning, as well as collaboration with NDHN from other Member States.

3.   To establish a common frame of reference to which all partners in the EU digital health ecosystem can refer when they think and act vis-à-vis national level topics regarding eHealth.

The Member State co-chair noted that the recommendation document aims to give clear solutions for the Member States and invited members of the eHealth Network to reflect in the questions: do you have already such networks at national level, are those networks in line with the model proposed in the document and what are the challenges.

The Commission noted that several discussions took place on the recommendation document. The EHRxF aims to enforce the interoperability across the borders in the EU. There is a need to understand how these NDHN will interact with each other, what would be coordination mechanism. The main focus should be on EHDS and interoperability implementation. These NDHN could feed in the work of the EHDS and common framework of the eHealth strategies. Also, it should be taken into account the upcoming funding opportunities e.g. RRF, which could be used to strengthen capacity in the different Member States and advancing on interoperability implementation across the EU Member States.

Member States welcomed the recommendations and noted that there is a need to concentrate on what is the aim to achieve and not on how to design those functions in order to achieve the alignments across the Member States on NHDN.

The document will be further developed with close collaboration with the Commission and the Member States recommendations.

6.2. Reflection on eHealth Network effectiveness & cooperation in light of recent developments – [for discussion]

A representative from the Netherlands presented the views for the future of the eHealth Network, as Member States co-chair mandate was taken by the Netherlands candidate.

The purpose to reflect on eHealth Network effectiveness and building on current digital health momentum. The response on COVID-19 in the Health Network provides relevance of effective eHealth Network collaboration with concrete positive impact in the Member States. Health data and digital health are in the spotlight. The challenge is to move from short term emergency solutions to sustainable foundations. Member State became more mature in digital health since the establishment of the eHealth Network. Better regulations, EHDS, RRR, GDPR, NIS, eIDAS: now is the time for lessons laundered to be used.

It was pointed on what are the key lessons to be used for the eHealth Network to create an impact in the own countries. There were several questions raised:

- What are the future outcomes and results of the eHealth Network?
- How to accelerate national adoption, capacity building and implementation based on shared interoperability needs?
- What role can and should the eHealth Network have in emerging related topics like pandemic management, and our relation to institutes like ECDC?
- What works and what doesn't in how the eHealth Network has operated the past years? What had the biggest impact?
- How to increase the impact of the eHealth Network? Add more legal weight, more political relevance?

The next steps suggested to have an online brainstorming session with members of the eHealth Network to gather the input on the future reflections.

Also, it was noted that there is a need to start the drafting for the next multiannual work programme (MWP) for the 2022-2024 period.

The Member State co-chair has invited members of the eHealth Network to join a subgroup on drafting the next MWP that was already established during the 16th eHealth Network meeting.

Member States welcomed the document. There were comments that eHealth Network working on several areas and needs to have a clearer roles and scope of the activities. Also, it was inquired what is the connections with international organisations e.g. WHO.

The Commission noted that at this moment is going through the process on better regulation and there is an evaluation of the Article 14 of the Directive 2011/24/EU[3], and taking into account the legislative proposal 2021, there is a probability that the legal landscape will change, but fundamental role of the Member States will not change. Also, informed that the contractor that is responsible for the preparation the study on regulatory gaps will get in contact of the members of the eHealth Network to obtain information.

7. eHealth Digital Service Infrastructure developments

7.1. Status of the project - [for information]

The eHMSEG Chair presented the general overview of the eHDSI implementation. Reassured that eHMSEG Chairs cooperate with all Member States and together with the eHDSI Owner and the eHDSI Solution Provider support Member States in their national work.

Afterwards, the eHMSEG Chair presented the detailed situation of each MS implementation status of the eHDSI. Especially, the timeline when MS committed to start routine operations, and any changes in the project duration. The services already live were indicated and MS progress on deploying the NCPeH. We have 25 MS who were granted the funds from the Connecting Europe Facility Telecom Programme (WP 2015, WP 2017, and WP 2019). The implementation of different services is very complex in

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[3] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare OJ L 88, 4.4.2011, p. 45

many dimensions: policy, legal, and technical. The eHDSI Owner and the eHDSI Solution Provider support Member States in their implementation throughout the years.

Currently, we have 7 MS who are in routine operations with their services. We have AT who dropped the implementation due to policy issues. DE who will only implement in the later stage, and BE who needed to put the project on hold to reach the national agreement. We have witnessed MS who managed to gather the team and implemented services quickly and the MS who participated many times in the test events but were not ready for the Initial Audit, so their go-live was postponed.

On 22 July 2020, the implementation of the new use case for Wave 5 was approved by the eHealth Network. On 09 September 2020, the change proposal introducing this new use case in eHDSI was adopted by the eHOMB for implementation in Wave 5. After the eHOMB adoption, the change proposal was transmitted to the relevant eHMSEG communities: eHDSI Requirements Work Group, Semantic Task Force, Technical Work Group, where Member States together with the Solution Provider work on specifying affected eHDSI Artefact, as a process of Wave 5 eHDSI Artefact preparation for eHMSEG adoption in June 2021.

The exchange of the unstructured clinical documents shall be understood as including the original clinical document as provided by the country of affiliation to the country of treatment for access by the health professionals, without being subject to any processing of the clinical content. The exchange of the following documents included in the Commission Recommendation of 6 February 2019 on a European electronic health record exchange format should be considered: laboratory results, medical imaging and reports, and hospital discharge reports.

The new use case does not affect the current eHDSI use cases and specifications for the exchange of patient summaries and ePrescription/eDispensations documents.

Regarding the financial and sustainability questions raised by Member States, the Commission aims to support Member States (by grants) in adding the remaining ePrescription and patient summary services and the new use cases from EU4Health programme, but this is still under negotiation by the Council and the European Parliament. Implementation of the new use case would be voluntary. The go-live process with the new service should follow the relevant eHDSI procedures. The new service should have to be tested and audited in a similar manner to the current eP and PS services.

7.2. eHMSEG Chairs report on IPS - [for information]

As requested by the eHealth Network the eHMSEG Semantic Task Force has analysed the Member States readiness to implement the CEN International Patient Summary (IPS) Guidelines. During the eHMSEG meeting on 20 October 2020 the eHMSEG discussed and adopted the eHMSEG recommendations to the eHealth Network.

The eHealth Network acknowledged the following eHMSEG recommendations:

'CEN International Patient Summary (IPS) Guidelines should be used as a reference for the preparation of the next versions of the eHDSI patient summary datasets and as guidance for further improvement of the eHDSI CDA IGs. Direct use of the CEN IPS standard EN 17269:2019 as part of the eHDSI artefacts cannot be endorsed by the eHMSEG at this moment, but this might be re-evaluated in the future.'

The recommendation were built on the following key points:

- The IPS datasets do not appear to be significantly more difficult to implement for MS preparing to launch eHDSI services than the currently available eHDSI PS dataset. Not all optional sections can be currently implemented by all MS, and some deficiencies have been identified with the availability of data related to mandatory sections, for both types of datasets.

- The current CDA implementations of the eHealth Network PS guidelines already fulfil the requirements of the IPS dataset to a high degree. Full IPS conformance would require only relatively small changes in the CDA implementation guide (IG).

- For Member States that are already running routine operations or that have already made significant progress in their deployment activities, changes in the CDA IGs would require considerable efforts to be spent on implementation and testing.

- MS implementations are based on the CDA IGs, not on direct use of the eHealth Network guidelines and/or the CEN IPS specification. The licencing and management model that would stem from the direct use of CEN IPS would bring additional overhead to the management of the eHDSI.

7.3. Adoption of eHDSI Work Plan 2021 [for adoption]

The eHealth Network by consensus adopted the eHDSI Work Plan 2021. The details of the eHDSI Work Plan 2021 were presented by the eHDSI Solution Provider. The document was endorsed by the eHMSEG on 20 October 2020.

The eHDSI work plan is presented for the eHealth Network approval to ensure that the eHealth Network can appropriately steer the implementation of eHDSI. The work plan 2021 describes the key actions the Commission (eHDSI Owner, eHDSI co-Owner, eHDSI Solution Provider, and auditors) will do in 2021 in relation to the core service implementation and support to the national contact points for eHealth.

Besides providing a structured perspective on how activities are organised in the eHDSI core services, the eHDSI work plan is a mechanism that enables the definition of priorities and matters to be tackled during the year in question.

7.4. Adoption of the Organizational Framework – eHealth Network guidelines [for adoption]

The eHealth Network by consensus adopted the revised Guideline on an organisational framework for national contact point for eHealth. The details of the revision were

presented by the eHMSEG Chair. The revised Guideline was endorsed by the eHMSEG on 20 October 2020.

The Organisational framework is one of the core eHDSI documents which needed to be updated. It is one of the first documents which Member States are reaching for when preparing for deployment of NCPeH.

In June 2020, the eHealth Network gave the mandate to the eHDSI owner and the eHMSEG to revise the eHDSI policy documents, such us the guideline on the organisational framework for eHealth national contact point and the legal agreement annexes. The guidelines were adopted in 2015 as one of the first eHDSI related documents. The guidelines were revised and discussed with the eHMSEG.

8. Interoperability

8.1. Draft proposal for eHealth Network patient summary guidelines (subgroup on semantics) – [for information / discussion]

The subgroup on semantics, together with eHDSI Legal Task Force and Semantic Task Force, and the eHealth Network subgroup on technical interoperability, drafted a proposal for the next release of the patient summary guidelines. The main highlights from the current draft are the following:

- Almost all articles (in guidelines and support information chapters) have been revised and enhanced;
- The new guidelines open the possibility for a broader use in cross-border and national projects, since they have been cleared from eHDSI specific provisions;
- Expansion to planned care patient summary and better support for rare diseases;
- Introduction of *preferred code systems* according to the lessons learnt in the eHDSI;
- Enlargement and alignment of the clinical dataset towards the CEN International Patient Summary;
- Inclusion of wider "Results" section to enable the communication of observation results which might have impact on future treatments, in particular i) diagnostic results (e.g. blood group, laboratory observations, imaging results etc.) and ii) physical findings (e.g. Vital signs observations).

Regarding the open questions, the following feedback was collected:

- 7 countries (NL, DE, SE, AT, NO, SI, FI) support the introduction of "preferred code systems);
- 4 countries (DE, NL, IE, PL) suggested that further discussion is needed regarding a common EU SNOMED license.
- 2 countries (NL, SI) support increase visibility of communicable diseases and related information;

- No common understanding was achieved regarding "vital signs as a standalone section".
- 1 country (FR) raised the question on how "preferred code systems" were selected and how to handle "not preferred code systems".

It was agreed that the subgroup on semantics should:

- Continue with the work and refine the document based on the remarks collected during today meeting;

- Perform a structured assessment of the preferred code systems (increase transparency of selection criteria);

- Reach out to health professionals, citizens and patients, to collect further insights that might be relevant for the evolution of the patient summary;

- Submit a final proposal for adoption at the spring 2021 eHealth Network meeting.

8.2. Results of the Member State survey on eHealth and interoperability – [for information]

The Commission presented the preliminary results of the survey on eHealth and interoperability. The aim of survey is to provide up-to-date and comprehensive overview of the current situation regarding the development of interoperable EHR systems in the Member States. It will also develop indicators, and set a baseline, for the monitoring of progress over the coming years.

The survey was introduced to the eHealth Network in June 2020 meeting and launched in August 2020 with a deadline for the contribution at the end of September 2020.

For each country, there were two respondents: from the Member States, and from a network of national experts. At the end of September, 12 Member States had responded, and 25 of the national experts – with information available to compile results on all but two countries. From early October, a further outreach to non-responding Member States is launched.

The structure of the survey is based on the Recommendation on a European electronic health record exchange format. The development of the survey tool and the field work is being carried out by a consortium involving Empirica and Open Evidence.

8.3. Update on X-eHealth project – [for information/discussion]

The X-eHealth project intends to contribute to the Digital Single Market Strategy of the Commission, in line with European electronic health record format recommendations.

The X-eHealth project aims to lay the foundations to advance the integration process of the eHealth services features into the already in place European cross-border patient summary.

The key goals are to:

- Improve the healthcare quality and safety for citizens by allowing them to access and manage their electronic health record from any place in the EU.
- Contribute to standardisation and harmonisation of eHealth services in the EU by setting European agreements on diverse levels of interoperability.
- Contribute to defragmentation of European services.
- Facilitate interaction between patients and healthcare providers, to support prevention and citizen empowerment.

Project expected impacts (in four work domains laboratory results, medical imaging, discharge letters, and rare diseases):

- Assure standardization and harmonization of digital platforms and solutions.
- Increase levels of digital literacy.
- Assure full system integration and architecture.
- Greater confidence and safety for citizens/patients.

The X-eHealth project will demonstrate the EEHRxF use cases, influence and engage eHealth Stakeholders.

Expected impacts & collaboration in EU eHealth landscape

- Support standardisation at National and EU level and implementation guidelines for local and regional level

- Clinical, functional and technical specifications included an implementation guide

- First version eHealth Network guidelines for the additional 4 domains

- Use of specs in multiple areas, such as: cross-border or portability of health data and foreseen impact in eHDSI new use cases

Collaboration in EU eHealth:

1. Collaboration with eHealth Network subgroup on semantics by sharing patient summary guidelines (release 3) and build upon them

2. Collaboration with eHealth Network sub-group on technical interoperability

3. Collaboration with eHMSEG community and build upon the existing documentation, by accessing specific assets from eHDSI upon request and decision (eHMSEG and Commission)

8.4. Update on UNICOM project – [for information]

The missing univocal identification of medicines hampers timely global pharmacovigilance reporting and warnings. It results in reports on the same active substance and, e.g., its side effects or contraindications, not easily being related to each other permitting health system actors like medical professionals, pharmacists and also patients to identify all medicinal products.

The UNICOM project is about facilitating the accurate, safe identification of medicines through a common approach to the implementation of the International Organization for Standardization (ISO) suite of IDMP (IDentification of Medicinal Products) standards.

UNICOM will propose extensions and the identification of key data elements to be added as IDMP attributes to the medicine data set in eP/eD, and in the patient summary for medication summary, allergies and vaccinations. Change proposals will be generated for consideration by the CEF eHDSI eP Cluster.

9. Cybersecurity

9.1. Update from the Work Stream 12 of the NIS cooperation group – [for information]

The chair of the work stream 12 of the NIS Cooperation Group presented the updates of the group.

The NIS Cooperation Group has been established by the 2016 Directive on security of network and information systems (the NIS Directive) to ensure strategic cooperation and the exchange of information among EU Member States in cybersecurity. From a sectorial perspective the work of the group is divided in work streams of which work stream 12, created on 29 January 2020 at the request of the eHealth Network, is dedicated to the health sector. The objective of WS12 is to exchange and promote best practices based on the experiences of Member States in addressing identification, mitigation and management of cyber risks in the health sector, especially when implementing the NIS Directive.

The Kick-off meeting of WS12 took place on 17 June 2020 and the following meetings on 21 July, 16 September and 4 November 2020. Meetings are expected to take place once per month.

The work already done NIS Cooperation Group:

- Terms of Reference approved;

- Mailing list for national cybersecurity authorities and relevant health sector authorities being set-up by ENISA;

- Survey to choose topics to be pursued by the WS (use cases / best practices of cybersecurity in the health sector; setting cybersecurity incident notification criteria, thresholds and procedures).

And the next steps for WS12:

- Define consistent cooperation and communication mechanisms with the eHealth Network;

- Collect more targeted information for use cases / best practices of cybersecurity in the health sector;

- Set cybersecurity incident notification criteria, thresholds and procedures;

- Analyse the eHMSEG proposal for the WS12 to review the eHDSI cybersecurity artefacts.

The eHealth Network was invited to nominate a contact point to the WS12 of the NIS Cooperation Group to facilitate two way communication and cooperation between both groups.

Member States welcomed this co-operation.

9.2. Reflections on Cybersecurity on the health sector – [for discussion]

The Commission introduced this point by bringing two recent cases of cyber-attacks, one in Germany and another in Spain, which triggered several reactions from the audience:

Member States supported the views on the need to have a strong cybersecurity system in the health sector. It was noted that the future of the e-health depends on good established cybersecurity system. In case the security issues arises in health sector the public trust that was built up over time will be lost very quickly, therefore cybersecurity matters. It is noted that cybersecurity should get a higher priority with the work of the eHealth Network. In the future, the participation of the e-health agencies on WS12 is a key to guarantee the decisions made in the NIS Cooperation Group would be followed and implemented at national level by the Member States. Also, it was stressed the importance of the human factor in cyber-attacks and there is a need to advocate for the cybersecurity awareness for all the actors, in particular, the patients. Some Member States enquired about the procedure to join the group.

The Member State co-chair, closed this point and committed to discuss the possibility to nominate a contact point to the WS12 of the NIS Cooperation Group.

AOB (of the 1ˢᵗ day sessions) Update on HIMSS and the Digital High Level Advisory Group for the EU – [for information]

A representative from Finland informed about the HIMSS conferences that are organised in collaboration with Finish ministries up to 2022. The next conference will take place in Helsinki, in June 2020. In connection with the Finish ministry it was established a think tank type of group – Digital Advisory High Level Group for the EU. This group is represented by high level policy makers of different Member States. The group has organised 2 workshops, the latter took place in September 2020. The backbone of the workshop was COVID-12 and digital transformation. The issues on cooperation and collegiality among the countries to work together. There is a need to have public and private sectors involvement in the cooperation and to receive the support from the international organisations. The strong message from the workshop – EHDS must be created with ambitions and possibilities for the secondary health data use should be explored much further. Creating a GDPR-2 for the health data. The group will organise further workshops, some Member States are already involved, but other Member States are also welcome to join. The DE Presidency actively contributed to the work of the group and it was thanked for great support and contribution.

10. Deliverables of Joint Action on eHealth – eHAction (see below the list)

10.1. D4.2 Policy proposal on people empowerment, final proposal – eHAction – [for adoption]

A representative from the Netherlands presented the final eHAction deliverable on policy proposal on people empowerment for the eHealth Network adoption.

The strategic goal of the eHealth Network with regard to empowering people is to work towards the implementation of patient-centred eHealth solutions in all Member States and to provide people with the adequate digital tools and skills for people empowerment. Therefore, the purpose of this deliverable is to present a policy proposal with a list of priorities and recommendations for adoption by the eHealth Network in order to improve the empowerment of their citizens.

The work package 4 (WP4) on empowering people aims to develop strategic recommendations and instruments. Digital heath has an important role to play and people need to be informed and provided with the right digital means and digital health skills. In order to meet this need, the eHealth Network has adopted empowering people as one of the priorities in the multiannual work programme 2018 – 2021 of the eHealth Network.

This policy proposal builds upon the policy framework on people empowerment (D 4.1), which was adopted in the 16th eHealth Network meeting in November 2019.

The key gaps highlighted in the D4.1 on policy framework were developed into nine priority areas for this proposal:

1. Legislation
2. Trust as key
3. Integration & interoperability
4. Quality standards & assessment
5. Users at the centre
6. Digital Health Literacy of people
7. Behavioural change through motivation
8. Awareness/involvement of the social environment
9. Awareness/involvement of health professionals

The indicated priorities for this policy proposal are plotted on one or more elements of the ability, motivation, opportunity (AMO) framework. Each priority area will present a limited number of recommendations taking into account ongoing activities within the EU in order to target critical unmet needs. The recommendations are presented to a broad list of stakeholders, each of whom should critically assess which policy actions are most needed in their context. The adoption of this policy proposal at the level of the eHealth Network would not in itself entail adopting the recommendations it contains, but it would signal to Member States, stakeholders and the Commission that the recommendations within this document are important and should be considered for policy action where relevant, in line with national strategies and priorities.

https://nictiz.preview.foleon.com/internationaal/ehaction/introduction-to-empowering-people/

The deliverable by consensus was adopted by eHealth Network.

10.2. D5.3 Paper on common principles for big data governance, draft proposal – [for discussion]

A representative from Hungary presented the latest developments on the eHAction deliverable on common principles for the data governance in the EU.

The focus is on raising awareness with patients and policy makers on the use of big data in healthcare. It needs to be transparent to patients and healthcare professionals on how, when and for which purpose their data is being used.

The main objective of the work package 5 (WP5) on innovative use of the health data is to support application of good practices in Member States/countries. Provide recommendations how to handle big data in health within the existing EU regulatory framework on secondary use of health data, and consequently to ease the uptake of innovative usage of data across the healthcare sector for the benefits of society, individuals and performance of Member States health systems.

This document includes deliverable 5.3 (D5.3): Draft proposal for the eHealth Network – Guidance for the implementation of common principles for practical governance of big data with a special focus on data to be used (and the implementation of data access and use) in public health, research and quality assurance in healthcare on a European scale.

The draft proposal provides information about the background, objectives, planned structure, working definitions and methods of D5.3, and contains recommendations on common principles for practical governance of big data.

The deliverable D5.3 is developed based on the outcomes received from the other two deliverables of the WP5: D5.2 on identified cross-border use cases and practical solutions with potential for European scale benefits (adopted in the 16th eHealth Network meeting in November 2019); and D5.1 on policy-level actions on innovative use of big data in health (adopted in the 17th eHealth Network meeting in June 2020).

The main findings of WP5 deliverables D5.1 and D5.2, a series of challenges and obstacles were identified. These are: lack of trust, gaps in the legal environment or uncertainties how to apply legal provisions, the level of digital literacy, lack of business models, interoperability issues, confidentiality issues, safety of health data, privacy, cybersecurity, intellectual property issues, unsolved issues of sharing benefits among stakeholders, and scarce resources including the number of data scientists. It is important that these hurdles should be solved or dealt with before the aim to create a European healthcare data space.

The Member State co-chair noted that it is important to bring to the attention to the current Joint Action on EHDS to make sure the uptake of the outcome of the deliverable on common principles for the big data governance.

10.3. D8.2.4 Common eID Strategy for Health in the European Union, final proposal - [for adoption]

A representative from Portugal presented a final proposal deliverable of eHAction on common eID strategy for health in the European Union.

This document aims to present the basis, the rationale, and a timely proposal for a common strategy in eID for health, not just at cross-border level, but rooted in timely adoption at national level.

In alignment with other eID initiatives and recommendations from the Commission and the eHealth Network, such as electronic health record exchange format (EHRxF, the eHAction proposes a "Common Strategy for using eID" with the following goals: (i) structure a common approach on health eID within the EU and (ii) converge development roadmaps for eHDSI services with adoption of eID cross-border services, like connectors between eIDAS nodes and NCPeHs, also to ensure phased adoption of novel requirements regarding electronic identification that are progressively more demanding.

The current proposal includes a description of the state of the art about electronic identification, a brief definition of the use cases (for patients and professionals); it proposes policy principles and a governance framework as well as presents 11 recommendations and a 5-year roadmap for the strategy implementation.

Some Member States expressed certain concerns in regard to the identified recommendations feasibility and timeline for the implementation. Members Sates requested that the document in addition to be reviewed by the eHMSEG group as identified recommendations have direct effect on the eHMSEG work programme for the next year.

The eHMSEG co-chair assured that there is no aim to block the document as such, but rather to give more time for the constructive consultation and improvement of the document. To ensure that eHMSEG group could have a thorough look into the document and provide recommendations that would fit for both, eHMSEG and for the eHealth Network.

The Commission remarked that this document should be focused in providing an overall strategy for the use of electronic identification in the context of health and healthcare services, in particular by setting a clear set of milestones to reach the desired objective. This is of up-most importance to achieve the necessary level of trustworthiness on online healthcare and health data services. This document should not be understood as establishing milestones for specific projects like "MyHealth @ EU". It should be the responsibility of each initiative to identify how and by when take advantage of the means provided by this overarching strategy, to overcome existing limitations regarding health professionals and citizen/patients electronic identification. The document should be reviewed accordingly.

The Member State co-chair noted that the document was already consulted with the members of the eHealth Network and endorsed in the previous 17th eHealth Network meeting. Taking into account the expressed concerns by some Member States it was recommended to post-pone the adoption for the next 19th eHealth Network meeting and explicitly invited those Member States (with concerns) actively participate and contribute to the document revision and improvement for the next meeting.

10.4. Update on eHAction deliverables from written procedure - [for information]

A representative from Greece provide an overview on two deliverables prepared the leaders on work package 7:

- D7.1: Guidelines for IT interoperability in large healthcare organisations

- D7.3: Cybersecurity guide for healthcare providers

In regard of D7.1 on IT interoperability guide, this is a brief high-level guide providing an overview about what interoperability is, its importance and the main areas of standardisation and quality that enable trustworthy data exchange and reuse. It has been elaborated based on the conceptual design, which was submitted for information to the eHealth Network meeting in spring 2020, in terms of its target audience, its breadth and depth of content and key design characteristics. The eHAction interoperability Guide targets the senior executive level in health care providing organisations. Its strength lies in that it pitches – in a few pages – what a hospital manager should know and appreciate about the value of interoperability. The sustainability of this guide beyond the end of the project is now the most important challenge that needs be addressed over the remaining lifetime of eHAction.The guide is made accessible as a web page on the eHAction website: http://ehaction.eu/interoperability-guide/,

For the Guide to remain current, it is important that it is reviewed at planned intervals or if significant technological or legal changes occur, to ensure its continuing suitability, adequacy, and effectiveness. eHAction explorations have resulted in a number of recommendations on a broader consultation with the eHealth Stakeholders Group and the Member States in order to arrive, timely, at a meaningful and sustainable hand-over of the guide document at the end of the eHAction. These recommendations are also part of the guide documentation brought forward for discussion.

The Commission co-chair noted that it would be wise to consult to broader stakeholder groups e.g. European hospital associations and not to be restricted only with eHealth Network stakeholder groups.

In regard of D7.3 on cybersecurity guide has been elaborated within the eHAction WP7 with the aim to provide an orientation to health care organisations and help navigate the different guidance documents that have been delivered by EU-level collaborative expert teams of Member State representatives and ENISA primarily under the 2016 Directive on security of network and information systems (the NIS Directive). There is a need to explore a potential handing over the guide document of concluded work to the WS12 NIS Cooperation Group in this way to ensure the sustainability of the guide document. It is important, that at this stage, a consultation with the members of WS12 is facilitated, to discuss the potential of this guide document to feed into their prospective work. The Cybersecurity Guide may be then updated to incorporate any potential comments or recommendations of this group and be submitted, together with the outcome of the above consultation, for discussion to the eHealth Network in spring 2021.

The Member State co-chair agreed the importance of the sustainability maintenance of the developed guides and to ensure the engagement with other identified groups to continue the work and preparation the guide documents for the next eHealth Network meeting in spring 2021.

11. Projects presentation

11.1. COVID-X - [for information]

A project leader presented the latest developments on COVID-X project. The project aims to bridge the collaboration divide between eHealth solution providers with emphasis on lean start-ups and small and medium-sized enterprises (SMEs), and the healthcare system to fight COVID-19. The purpose is to boost an end-to-end agile validation programme of cutting-edge technology in three real-world clinical scenarios, located in hotspots of the pandemic: Italy, Spain and Sweden. The project aims to attract, invest and empower a community of European eHealth SMEs – the beneficiaries of an acceleration program, selected by open calls - that will provide market-ready fast, cost-effective and easily deployable sampling, screening, diagnostic and prognostic systems and/or data-driven services and tools, already certified with -or close to receive- the CE marking (type 1 of the call).   In addition, it will actively involve some of the most relevant hospitals of Europe that have the resources, critical mass and ambition to scale-up their capabilities in the COVID-19 response through the support of an innovative data sandbox.

The cybersecurity private company and university from Spain are the technological partners involved in this project.

11.2. InteropEHRate - [for information]

A project leader presented the latest developments on InteropEHRate project. Realising a borderless access to citizen's health data is fundamental to ensure continuity of care and support research. The InteropEHRate project envisions the citizens as key partners in the processes of health data exchange, in full control of their personal data. The project promotes the adoption of common standards to ensure both the interoperability of systems and respect for citizens' rights, providing open technological solutions to enable the exchange of health data in three relevant use cases in the health and research sectors. InteropEHRate is a European Research and Innovation Action aiming at defining and experimenting, a set of open (i.e. vendor independent) communication protocols, for the secure exchange of health data among citizens, healthcare organisations and research institutions.

In regard to the H2020 Smart4Health project, indeed both projects have similar approaches, but different outcomes. As Smart4Health project focuses on development protocols and use cases for research, meanwhile InteropEHRate project aims that clouds services would be as a facultative service and focuses on mobile applications could be used both, organisations and citizens, and exchange data without internet and cloud services.

In regards to eHDSI – the focus is on healthcare approach, as the health data should be exchange among the healthcare organisations. Meanwhile, InteropEHRate project aims to develop protocols that could be used not only by healthcare organisations, but also by citizens.

11.3. WHO-ITU- mHealth - [for information]

A project leader presented the latest developments on WHO-ITU- mHealth project. It is intended to serve as a mechanism to collect, share success in mHealth across the European region and boost uptake of mHealth solutions amongst national/regional governments. The mHealth Hub has a dual focus on knowledge management & innovation, and on practical implementation (supporting EU Member States to launch large-scale mHealth interventions). The Hub will produce a set of 3 knowledge tools to provide guidance to countries for implementation of mHealth programs: (i) assessment frameworks for apps; (ii) a full national /regional ground implementation of a specific mHealth intervention and (iii) a cross cutting tool for guidance on integration of mHealth in Health Systems. The Hub will also contribute to a policy framework to support the EU Single Market and the cross-border adoption of innovations.

11.4. A trusted Health app quality label - [for information]

A project leader presented the latest developments on the project on a trusted Health app quality label - quality & reliability for health and wellness apps: CEN-ISO/DTS 82304-2. Quality and reliability of health and wellness apps - is an assignment from the Commission that went global in the cooperation with ISO. A Delphi study with 90 experts from 8 stakeholder groups from 6 continents was used to develop a Quality Requirements Conformity Assessment, alongside a Health App Quality Label, inspired by the EU Energy Label, which was tested with low health literates for adequate understanding. The new Technical Specification is in ballot in Q4 2020 and expected to be published early 2021. It was already referenced in the EU Toolbox for COVID-19 tracing apps, and piloted for the Dutch ministry of healthcare with COVID-19 symptom checker apps. It qualifies as a common framework to enable more transparency in app stores and curated app libraries in EU countries and beyond, to assist app developers in developing health apps and enable in line with the digital single market transformation of health and care uptake in clinical care pathways and reimbursement schemes.

The labels developed can be used both for the mobile apps and for the web apps.

The next consultation will be in the next weeks and Member States can provide comments in the period December-January- February. The aim to finish and publish the owkr in April 2021.

In regard to medical devices – the project was presented in a recent Medical Devices Coordination Group meeting and will take participation in the next meeting as well, in order to ensure that the work prepared in the project is not doubled.

Several Member States expressed their support on the development of the project and would like to be involved on the future work. Suggested to transfer the information to the national experts. Finland has noted that at this moment there is a legal proposal on apps data at the national Parliament level. The proposal suggest to store that data in services and data would be available for healthcare and social care professionals. In the proposal the data will be audited and tested with concentration on the apps security.

The Commission noted that work is relevant to the EHDS. The work provided trusted approach among the Member States that is very important. There is the need to explore the work of the project in the context of the current impact assessment of legal proposal

that the Commission is working at this moment. Also, there is a need to explore the linkage with medical devices.

12. Open eHealth Network

12.1. Bertelsmann Foundation recommendations - [for information]

A representative from Bertelsmann Foundation provided recommendations on the European eHealth policy.

The Bertelsmann Foundation reflects as "Think & Do Tank" in 13 programs on various societal aspects (education, economics, and civil society, healthcare). In the program "Improving Healthcare – Informing patients" the main focus is on developing ideas, supporting practical solutions, and providing empirical insights for a citizen-oriented healthcare delivery. The Digital Patient project specifically develops studies, strategic action plans and forums for debate to help promote E-Health in service to healthcare.

The wish is to have a more integrated strategic European approach for the ehealth in a long run. Existing strategies at the EU level on the ehealth are coherent health policy perspective and there is need to reduce strategic fragmentation. Need to create a common ehealth market with mutual recognition of access rules to health systems for digital innovations.   The focus should be on three selected topics: (i) EHDS, (ii) systematic exchange of knowledge, and (iii) the European "added value" for citizens.

The Member States noted that this report will be important for the reflection group on the future eHealth Network, in the subgroup on the next MWP.

The Commission also commented that the reflections provided on the EHDS gives a lot of food for the thoughts how to strengthen all those elements and how to have a coherent decision making at the EU level in the future. The Commission will need to follow up on this in the nearest future.

13. eHealth Strategy

13.1. eGovERA – eHealth Reference Architecture - [for information]

The Commission presented the work on the eGocERA and ehealth reference architecture project.

Following up an action started by eHAction on reference architecture for European eHealth, the eGovERA and eHAction teamed up to design a eHealth reference architecture for national health systems.

This joint effort aims at producing a tool that supports the design of national strategies for digital transformation of health services, by aiding decision makers identify the business capabilities to invest on to achieve certain outcomes.

This joint work started in September 2020 and a draft document on eHealth reference architecture is planned to be developed for January 2021.

It was present to the eHealth Network the work performed, methodological approach and the next steps.

The Commission noted that the purpose of the exercise is to support the capacity building in the Member States and to support the development of the national digital health strategies, including for the use of the new RRF fund. This work will be handed over to the eHealth Network and eHAction by the beginning of 2021.

The Member State co-chair welcomed the initiative and the work prepared and expressed the wish to see the final result next year to be presented in the next 19th eHealth Network meeting.

13.2. Croatia's Presidency - Update on the Workshop Building survivable e-health strategies during a crisis - [for information]

A representative from Croatia provide an overview on the identified recommendations from the workshop on building survivable eHealth strategies during crisis.

COVID-19 has posed significant challenges and has highlighted many weaknesses in the health and social care systems of countries around the world. Faced with an international public health emergency a nation's ability to generate, share and use reliable information efficiently and across national borders timely has been shown to be of critical importance. However, the majority of public health systems have been found to be lacking the level of digital data structuring, necessary infrastructure and operational systems and processes to do so. On the one hand, the pandemic has placed pressure on all agencies and building blocks of a health system: governance, financing, service delivery, medicines and equipment, health workforce and health information. On the other hand, the same challenges faced by healthcare systems at a time of extreme crisis have proven to be an outstanding driver of change.

On the 15th of September 2020, the Croatian Ministry of Health and the Directorate-General for Structural Reform Support of the European Commission of the EU organised a workshop "Building survivable eHealth strategies during crisis" to share the knowledge on how to develop a resilient eHealth strategy for the 2021-2027 Multiannual Financial Framework. The workshop gathered a broad range of digital health experts from national health ministries, health care facilities, informatics, including representatives of DG REFORM funded projects.

The paper presents several eHealth innovations developed and used at local and national levels to help coping with the COVID-19 world pandemic in spring 2020 and provides a handful of practical recommendations and action points to the EU and national stakeholders.

The Member State co-chair applauded how Member States have prepared and handled COVID-19 pandemics at national level and what are the lessons learnt from that experience. He agreed that prepared document is very useful and suggested to take the identified recommendations back home and use for the improvement of the national health strategies to better fight the current pandemics.

13.3. German's Presidency - Presentation of German's digital transformation - [for information]

A representative from German's Presidency presented national digital transformation strategy.

In the current legislative period, the German Federal Ministry of Health has drafted a number of Legal Acts to speed up with the national agenda for digital health. Introducing national EHRs by 2021 as well as various other aspects to bring digital innovations and mobile health applications into the Statutory Health Insurance System (GKV).

Enabling the future of the health care. The Gematik has also set up a national plan to open the national infrastructure for the eHDSI and the roadmap was presented in the eHealth Network meeting. In the future the patients will be able to access to their HER using a mobile app. The ePrescription app will be with biometric identification.

There are identified key pillars in the engagement: (i) technology leap – integration of state of the art technologies and used friendly solutions, (ii) coordination center for interoperability issues – roundtable with experts from key areas, interpectoral and international capability, integration of digital health applications (DiGA), and (iii) EU-connectivity – integration of the national contact point ehealth into German TI, international patient summary as first EU-compatible application, fostering structured health data e.g. the EU project X-health.

The vision is the arena for a digital health ecosystem. It was noted that will be organised an event on digital health – Digital health in the 21st century on 26 November 2020 - www.digitalhealthchallenges2020.eu.

Member State co-chair congratulated Germany for the great progress on digital transformation in the healthcare area in the country.

13.4. Portuguese Presidency - Presentation of presidency priorities - [for information]

A representative from Portugal gave an overview of the next Portuguese Presidency priorities on digital heath agenda.

On 1 January 2021, Portugal takes over the Presidency of the Council of the European Union for 6 months, succeeding the German's Presidency and being succeeded by the Slovenian's Presidency, partners of this trio of presidencies.

The digital transformation in healthcare is a key priority for the health sector. A series of events and meetings are to be held, of which the following stand out: (i) the high-level meeting of the eHealth Network, and (ii) the PT eHealth Summit event in 2021.

The main outcomes are planned to have a policy statement on the EU digital transformation in healthcare and the removal of barriers to cross-border telehealth. Also, to develop a proof of concept. The deployment of a cross-border telehealth services that will focus on (i) access to health data across borders and (ii) portability of data.

AOB

Closing

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

Next 19th eHealth Network meeting is scheduled (to be confirmed) on 1-2 June 2020, Portugal.

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