



# eHealth Network

## Summary report

### **15<sup>th</sup> eHealth Network Meeting 11-12 June 2019**

Parliament Palace, entrance C1  
IIC Bratianu meeting room,

Strada Izvor, 2-4,  
Bucharest, Romania

### **Chairs:**

**Anne Bucher, Director-General, DG SANTE, European Commission**

**Henrique Gil Martins, President SPMS, Portugal**

## **Opening and approval of agenda**

The 15<sup>th</sup> eHealth Network meeting was held in Bucharest, Romania, on 11-12 June 2019. The meeting was opened by both co-chairs who thanked for the Romanian Presidency organising the event and for members for participating at the meeting. The draft agenda of the meeting was adopted.

### **1. eHDSI implementation**

#### **1.1. Go-live decision to exchange ePrescription and Patient Summary through the eHDSI *[for adoption]***

The eHealth Network approved unanimously the going live of 3 countries MT, PT and EE. PT will offer ePrescriptions and patient summaries for own and foreign citizens (4 services), MT patient summaries for own and foreign citizens (2 services), and EE ePrescriptions for own citizens (for foreign citizens the system is already operational with more than 2800 ePrescriptions dispensed to FI citizens).

#### **1.2. International Patient Summary *[for information]* & 1.3. Transition from unplanned to planned care. Revision of ePrescription and Patient Summary guidelines *[for discussion]***

A representative of CEN presented the results of the International Patient Summary Standards Project, which was funded by the Commission with the aim to participate in the creation of an International Patient Summary specifications, at a global level, and turn this into European standard (EN 17269 International Patient Summary standard). The project was run in collaboration with Health Level Seven International - HL7 and European Committee for Standardization - CEN, which got 4 specifications almost completed in just 2 years. The International Patient Summary standard (IPS) comes from a long history. It was built taking into consideration the results of the epSOS, patient summary guidelines and the eHealth Digital Service Infrastructure (eHDSI). The IPS is applicable and extensible to new cases (e.g. EUModEX, Trillium II). The IPS standard creates opportunities not only for European exchange of data but also for national and local ones. The eHealth Network decided to revise the patient summary guidelines in order to include planned and unplanned care and to divide them on two parts: policy and datasets.

The eHealth Network decided that eHDSI Member State Expert Group (eHMSEG) will further analyse the adjustment of the guidelines on patient summary datasets with regard to the EN 17269 International Patient Summary standard and will further report on this to at next eHealth Network meeting.

The policy part will be reviewed by the eHAction with regards to the eHealth Network decision to enlarge the eHDSI scope for both planned and unplanned care, eliminating the distinction between the two. The decision followed the Member States discussion and the eHMSEG positive recommendation to address the guidelines in the neutral way, referring to healthcare.

The idea of enlarging the scope of the eHDSI and offering patients the support for both planned and unplanned care was supported by some Member States. FR has requested additional information concerning the reimbursements in case of planned care. They also welcomed the Commission's cooperation between health and social security domains.

#### **1.4. Communication activities for the eHealth Digital Service Infrastructure** *[for discussion]*

The Commission reported about the ongoing centrally coordinated communication activities, such as: press releases, Q&A, social media presence, translation of the Patient Information Notice - PIN, etc. Additionally, the plans for new communication tools (flyer or infographic, video), were presented. Those actions support the national communication activities.

The new eHDSI branding (EU emblem and common brand name working in all languages) was presented for Member States discussion and adoption. The proposal was the outcome of prior discussions of the eHealth Network and the eHMSEG members. The aim of the simplified branding is to reach easier the audience at the national level. It would come as an additional layer on top of the national branding that remains in place.

The decision was preceded by discussions. Some Member States (FR, DE, EE) criticised the branding logo as too vague on the one hand, but to technocratic on the other with the mention of the official name “eHealth Digital Service Infrastructure”. After discussion of alternative proposals (implying the term “*data*” with the risk of raising fears with the citizens, or the term “*eHealth*” with the risk of being to technocratic).

As a result a subsequent consultations the eHealth Network indicated a preference for a more streamlined branding: *My Health @ EU*.

#### **1.5. European Court of Auditors report on the implementation of Cross-Border Healthcare Directive** *[for information]*

The Commission presented the European Court of Auditors report on the implementation of the cross-border healthcare Directive, which recommends an assessment of the results of the cross-border exchange of health data via the eHDSI and of the Communication on digital transformation of health and care and its implementation. The co-chairs, supported by the chair of eHMSEG, called upon Member States to keep their timeline in joining the eHDSI or even speeding it up, and not to postpone their going-live dates. The eHealth Network needs to monitor carefully the implementation of the eHDSI and its KPIs.

## **2. Interoperability and Sustainability**

### **2.1. D6.1: Roadmap on future eHDSI use cases and features – eHAction** *[for discussion]*

A representative of DE, Gematik, presented a roadmap on the future eHDSI containing a series of recommendations on how to prepare, enable and accompany the introduction of new cases and futures for the eHDSI and also invited the eHealth Network to comment and enrich the document, which should be adopted in November 2019.

Some Member States (DE, ES, FI) underlined that the roadmap was linked to other topics like the governance and suggested the setting up of a sub-group to discuss this in an aligned manner among the diverse groups (see below also the needed alignment with Joint Coordination Process and the CSS (Point 2.4 D8.2.2). It was warned that the complexity of the new use cases should not be underestimated, including the cost of setting them up in practice. Also, it was asked not to lose focus on the present work of the eHDSI while developing new features.

## **2.2. D6.2: eHDSI legal report – eHAction** *[for discussion]*

A representative of DE, Gematik, presented the report attempting to describe the legal environment of the eHDSI to a non-lawyer audience.

The Commission praised the exchange of best practices on GDPR and announced that a study on regulatory gaps will be launched (discussed next day on 12 June 2019), and the Member State co-chair informed about a dedicated workshop in September 2019.

Some Member States (AT, FR) congratulated the work to enhance the convergence and asked for close co-ordination with the legal Task Force of eHMSEG as well as other concerned legal groups. The representative of NL offered to share a translated version of the FAQ of their GDPR helpdesk focussing on health.

The Member State co-chair also underlined the importance of articulation and alignment of work being done by different groups, suggesting as follow-up action a meeting in the last week of June 2019 between eHAction tasks 6.2 and 7.2, the eHMSEG Legal Working Group, HEALTHeID, the Commission service (SANTÉ B3) and the DE announced initiative on the application of the GDPR in the health sector.

## **2.3. D7.1: Guidelines for IT interoperability – eHAction** *[for information]*

A representative of EL presented the guidelines for IT interoperability aiming at facilitating co-operations between hospitals and announced a workshop on 10-11 July 2019 in Thessaloniki, Greece. The Commission co-chair (supported by AT) welcomed this work in view of his complementarity with the investment guidelines to which a clear link needed to be established.

## **2.4. D8.2.2: Common Semantic Strategy – eHAction** *[for discussion]*

A representative of PT presented the work on a common semantic strategy for health in the EU, announcing a series of teleconferences and a face to face workshop in Brussels on 2 - 3 September 2019. The Commission co-chair supported this project, underlined the need for alignment with the Joint Coordination Process and announced a contract for the training of national contact points for eHealth. The eHealth Network decided to set up a sub-group on semantics with participation of Member States - FI, HR, DE, PT, FR, CZ, SE, ES, HU, NL, SK, PL and RO.

This subgroup on semantics will meet twice a year, preferably back to back with eHealth Network meeting in 2019, exceptionally it will meet a few weeks before the eHealth Network meeting so that subgroup can look and endorse the proposal for the Common Semantic Strategy.

The document of the eHAction is opened for consultation between 15 of June and 15 of August 2019.

Some Member States welcomed a document and requested (FR, DE, NL, AT) to have stronger strategic aspects (e.g. culture and governance) and less on standardisation. Offered to participate in the work of the group. It was requested that the work be focused on the added value for clinicians and healthcare. It was reminded that the national semantic task force was active and underlined importance to link this work to the governance discussion, on how to bring in clinical needs and make this structure feasible and effective.

The Member State co-chair reminded that in 2013 the eHealth Network members discussed about a semantic strategy. A decision was not taken at that time, therefore the discussion now is about of creating a semantic strategy instead of revising it.

#### **2.5. D8.1: Information note on integration in national policies and sustainability – eHAction [for information]**

A representative of FR presented an information note on integration in national policies and sustainability of the eHDSI, comprising the mapping and alignment of national digital health strategies, a policy document, and post 2021 scenarios for eHealth cooperation. Both, the Commission and Member State, co-chairs underlined the importance of this work and having all Member States involved.

#### **2.6. D7.2: Best practices report on data protection at national level – eHAction [for information]**

A representative of CZ presented a draft report on best practices on data protection at national level. Questionnaires for the data protection authorities of Member States and hospitals were developed and distributed, the response rate is however low so far, deadline is 24 June 2019. A dedicated workshop on 12-13 September 2019 in Prague, Czechia, was announced.

Some Member States (DE, FR) welcomed this work, in particular the collection of best practices. With respect to further collaboration, it was proposed a structured dialogue on the GDPR implementation with Member States national experts, stakeholders and national data protection authorities was proposed, leading to policy guidance, especially with regards to secondary use of data. It was underlined the need to clarify how the role and objectives of the different initiatives fitted together. The Member State Co-chair informed that a document in this respect will be proposed for approval at the eHealth Network meeting in November 2019.

### **3. Patient Empowerment & Patient Access to Health Data - mHealth, Telehealth, Patient Literacy and Patient access**

#### **3.1. D4.1: Policy Framework on People Empowerment – eHAction [for discussion]**

A representative of EE presented a draft policy framework for empowering people focused on m-health, tele-health, data access and digital health literacy. Members of the eHealth Network were informed about a dedicated workshop in September 2019. The Member State co-chair reminded that the mHealth Hub was ready to start with some delay due to administrative issues.

It was asked about the follow up of the conclusions of the mHealth subgroup that was discontinued recently. It was flagged an interest in the topic of mHealth towards the Commission and requested that some actions be followed like the Code of Conduct, and that more information was provided on the WHO mHealth Hub. The Commission (DG CNECT) clarified that discussions on collaboration with respect of the mHealth hub were on-going and that more information would be provided at a later stage. The Commission co-chair asked whether the task intended to look at the cross-border aspects of the 4 topics identified.

Also, it was inquired about the quality of the data of the Member State. EE representative clarified that policy recommendations coming out of this eHAction task would be broad and that some recommendations might have to be developed further by other bodies, like the mHealth Hub. This meant that the mHealth subgroup might have to be reactivated in a certain moment of time. Also, EE confirmed that indeed the longitudinal data could be of better quality. For the Commission, it was pointed out that national work prevailed, but cross-border aspects could be looked up in a tiered approach.

### **3.2. D6.3: Report on e-skills for professionals (2nd Information Note) – eHAction [for information]**

A representative of IE presented an approach they had taken to the task of developing a common competence framework to measure e-skills and map training actions. Currently, there is a pilot phase till 30 June taking place in which health professionals (doctors, nurses, midwives, pharmacists and dentists) from 5 countries (IE, PT, HU, RS, CY) are doing an on-line self-assessment of e-skills competency, reusing the work done in JAseHN in terms of framework.

The Commission co-chair welcomed the work and referred to the convergence with the seminar organised with the representatives of deans and students of medical universities in Rotterdam in spring 2019.

The Member State co-chair invited Member States that has not yet applied for eHDSI deployment services to do so.

## **4. Brainstorming with EU Agencies and stakeholders on eHealth activities**

### **4.1. Expert panel - assessing the impact of digital transformation of health services [for discussion]**

A member of the Expert Panel on effective ways of investing in health – appointed by the Commission – presented the panel's recent opinion on assessing the impact of the digital transformation of health services. The panel's opinion stressed the need to use the digital opportunity wisely, to gather strong supporting evidence, as well as to effectively monitor and assess. The report was generally welcomed. One Member State highlighted the recent PWC report on telemedicine, which could offer further evidence on return on investment in the area of digital health.

### **4.2. Immunisation / vaccination**

#### **4.2.1. Activities on communicable diseases – ECDC [for discussion]**

The European Centre for Disease Prevention and Control (ECDC) stressed the need to receive better quality of surveillance data. Currently, data reported by Member States comes in different formats and varies as to the level of key information provided, given that currently there is no standard format for data collection at national level. ECDC will work more directly on the area of digital health from 2020 onward (including 2 proof of concept studies), it would be very interested in a method of extracting key information directly from source (electronic health records). In this context, ECDC would like to establish a stronger

collaboration with the eHealth Network, so as to potentially draw on its progress in the area of health data exchange (e.g. patient summary format; e-health records exchange format etc.) to benefit the public health sector. A framework that allows for the secondary use of healthcare data for public health purposes would therefore be essential.

Following comments by participants, it was agreed that a strong communication channel between the eHealth Network and ECDC should be maintained so that a common understanding can be gained. It was also agreed that key meetings on both sides should be synchronised.

#### **4.2.2. Update on coordination efforts between eHAction and Joint Action on vaccination** *[for information]*

A representative of the eHAction explained the main objective is to ensure that the work (in particular on patient summary guidelines) is aligned with the work of the Joint Action on vaccination (in particular on vaccine data sets). Several exchanges have taken place between the two sides and a formal request on the importance of alignment has been sent to the Joint Action on vaccination. A follow-up report is foreseen for the next eHealth Network meeting in November 2019.

The Commission also pointed out that DG SANTE Directorate C is preparing a feasibility study on a vaccination passport (potentially electronic). In all cases, the aim is to ensure interoperability with the work of the eHealth Network.

### **4.3. Cybersecurity**

#### **4.3.1. D7.3: Report on Common Security framework for eHealth (Information note) – eHAction** *[for information]*

A representative of EL explained that, following a reconsideration of the scope of this task, the new aims of this eHAction deliverable are 1) to facilitate exchange of best practices across borders and 2) to provide practical guidance for healthcare providers on cybersecurity issues (to be submitted to the eHealth Network in spring 2020). It will be carried out in cooperation with ENISA. This deliverable is at an early stage: a workshop is planned in July 2019, preliminary outcomes will then be shared with interested parties and a survey will be held.

Following this presentation, the Member State co-chair suggested that a meeting of those responsible for cybersecurity in the area of health in each Member State should be organised, to enable collective discussion on ways forward.

#### **4.3.2. Activities on cybersecurity – ENISA** *[for discussion]*

The European Union Agency for Cybersecurity (ENISA) provided a brief update on developments in the area of cybersecurity in digital health, including 1) the current and evolving cybersecurity landscape in the area, 2) the evolving regulatory landscape and 3) the Agency's own activities in the area. In terms of the 1<sup>st</sup> area, positive progress has been noted (e.g. in particular in terms of increasing awareness of the issue and a reduction in the number of outdated security systems), but there is still much way to go (e.g. there has been a recent spike in cyberattack incidents). In terms of the 2<sup>nd</sup> area, ENISA is continuing to monitor the ongoing implementation of the Directive on security of network and information systems, as

well as the Directive on medical devices, which has important new cybersecurity requirements. In terms of the 3<sup>rd</sup> area, the recent Cyber Security Act has given ENISA a strengthened and permanent mandate in the area. It also tasks ENISA to work on an 'EU Cybersecurity Certification Framework', which might replace national schemes and be accepted across Member States. In a first stage, the focus will likely be on horizontal sectors, but sector-specific schemes, such as for the healthcare sector, may be envisaged in a second stage. ENISA also intends to produce procurement guidelines for cybersecurity for healthcare organisations, and would be interested in aligning these with the investment guidelines produced by the eHealth Network. Finally, ENISA will organise an event 'Cyber Europe 2020', which will focus on the healthcare sector and will be a good opportunity to test healthcare provider readiness in the cybersecurity area.

#### **4.4. Use of health data, big data, health analytics**

##### **4.4.1. D5.2: Report on Identified cross-border use cases: sharing and learning from best practices on European level (draft) – eHAction [for discussion]**

A representative of HU presented a development of the work on mapping awareness raising and policy relevant actions on innovative use of big data in health. This task will join the 7.2 task of eHAction for a face to face meeting on 13 September 2019 in Prague, Czechia. An online survey will be launched soon to assess whether the recommendations translated for the EU big data study are relevant or not. It was requested to narrow down the focus of the work more and to think about other formats such as workshops in order to achieve concrete policy recommendations.

##### **4.4.2. D5.1: Report on policy action on innovative use of big data in health – eHAction [for discussion]**

A representative of FI presented a work on secondary use of health and social data in the country. FI has a large amount of good quality data collected over a long time, which can be combined via unique personal identifier. Safe access to data for authorities, institutes and companies is ensured via central licences as set out in a legislation on secondary use of health and social data adopted recently. FI expects many impacts of the new act, like faster access, combination of data, effective treatment and medicines, improved opportunities for research and product developments, new business opportunities.

Member States suggested that the learning from the FI act on secondary use of data could be part of the agreed structural dialogue on data protection and stated that some Member States are working on a similar law at national level (EE).

##### **4.4.3. Activities on big data – EMA [for discussion]**

The European Medicines Agency (EMA) presented activities on big data with a regulatory paradigm between a medicine development phase with structured data, and the post approval surveillance with less structured data. The future regulatory paradigm will require continuous scientific dialogue and analysis of Real World Data. Future data sources are extremely large, complex and multi-dimensional, unstructured and heterogeneous, and accumulating rapidly (volume, variable, variety, velocity).



The HMA–EMA Joint Big Data taskforce was formed to describe the big data landscape from a regulatory perspective in order to ensure the EU regulatory system has the capability and capacity to guide, analyse and interpret these data. The taskforce finalised a work of the first phase with a summary report, which is available on the website, with a number of recommendations. The second phase started in December 2018 operationalising the recommendations from the first phase, till December 2019.

## **5. EU eHealth Sustainability and Planning (session I)**

### **5.1. Two years plan of the eHealth Network meetings and sustainability [for discussion / adoption]**

The Member State co-chair presented a two years plan for the eHealth Network as agreed in the last meeting (November 2018). The aim of the plan to present the chairs vision for the Network's meeting outline and policy topics for the period 2019 - 2021. The plan proposes a classification/clustering of topics for the eHealth Network according to 4 criteria in order to determine their priority. He also presented priority themes to be discussed in the next meetings of the eHealth Network.

Members States welcomed this document and asked for more time in order to discuss in more detail.

## **6. National eHealth Strategy**

### **6.1. Presentation of Romania [for information]**

Representative of the Romanian Presidency presented well developed national eHealth Strategy and underlined its intention to join the eHDSI.

## **7. AOB (1<sup>st</sup> day session)**

The eHealth Network co-chairs closed the 1<sup>st</sup> day of the meeting.

The dinner allowed for an informal exchange with representatives of Chief Information Officers in the Member States.

## **8. EU eHealth Sustainability and Planning (session II)**

### **8.1. Commission Recommendation (C(2019)800) on a European Electronic Health Record Exchange Format [for discussion]**

Roberto Viola, Director General of the Commission, DG CNECT, presented the Commission Recommendation on a European electronic health record exchange format and informed the eHealth Network about a forthcoming competitive call on a Coordination and Support Action (CSA) from Horizon 2020 to develop the technical specification for the three new use cases for data exchange (laboratory results, images, and discharge letters). Member States were strongly called to apply eID/eIDAS in healthcare and to build a common European health data space. The use of emerging standards, such as HL7 and FHIR, was also raised. It was

suggested the need to propose an adapted governance for the emerging standards/technologies

In the discussion that followed, Member States (EE, NL, DE, AT, FR), welcomed the initiative but asked for a discussion of the governance for the proposed three new use cases development and implementation. PT offered to coordinate the preparation of the application for call on a CSA (call will last from July to November 2019), in regard the work on piloting the three new use cases. However this was not finally discussed.

The Commission co-chair concluded that additionally the subgroup on the implementation of the Communication on the digital transformation of health and care shall continue its work and its primary focus will be on proposing the governance for the development process of three new use cases. SE joined the subgroup.

## **9. Investment guidelines**

### **9.1. Digital health opportunities in the next MFF** *[for information]*

The Commission provided an overview of the various funding opportunities likely to be made available under the next MFF 2021 - 2027 (a more detailed overview is available in the investment guidelines). It was stressed the need for Member States to ensure that eHealth is prioritised in upcoming negotiations to define the national operational programmes for the shared management funds (ERDF and ESF+). For this, first steps must be taken internally at national level. The Member State co-chair of the eHealth Network offered to provide advice and support to members who are still unsure as to how begin this process at national level.

### **9.2. Draft eHealth Network guidelines on an interoperable eco-system for digital health and in investment programmes for a new/updated generation of digital infrastructure in Europe** *[for adoption]*

The representative of AT, who chaired the responsible subgroup, presented the draft investment guidelines. The guidelines are intended to be as a tool to orient EU actors – including the Commission, Member States, regions, procurers and even industry – in the direction of funding choices/purchasing choices that foster interoperable digital health. The guidelines are composed of recommendations (including a set of recommended technical specifications), as well as information on the funding tools that will be available at EU level under the next MFF 2021 - 2027. The guidelines recommend that the standards and specifications used in the Commission Recommendation on European electronic health record exchange format should be used in the procurements done at national level and in the enabling conditions for EU funds, while acknowledging national interoperability strategies and priorities.

The need for continuous updating of the recommendations was acknowledged in the discussion and in the guidelines. The guidelines were adopted by the eHealth Network. The Commission (DG SANTE and CNECT) confirmed commitment to raise awareness of the guidelines within relevant Commission services (e.g. DG REGIO), particularly of the upcoming negotiations on the shared management funds.

## **10. Future work on regulatory gaps**

### **10.1. Regulatory gaps of new and disruptive technologies in the field of digital health** *[for information]*

The Commission (DG SANTE) provided an outline of provisional plans to launch a study to identify potential legal and regulatory gaps in the field of digital health. Currently, the study is in the scoping process and a number of potential themes – relating to data protection, liability, administrative practices, and artificial intelligence & interoperability – have been identified. It was clarified that the scope of the study will be on cross-border, but also will be a need to assess a situation at national level in order to gain a better understanding. The Commission will take into account the outcome of the discussions of the eHealth Network meeting while developing the terms of reference for the study. The Commission will refer back to the eHealth Network for their feedback in a form (written or video/ tele-conference) to be clarified later in a process. To launch this study is foreseen by the end of this year.

#### **Closing of the 2nd day session**

The eHealth Network co-chairs thanked to everyone and the Romanian Presidency for hosting the event and closed the 2<sup>nd</sup> day of the meeting.

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