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DG HEALTH AND FOOD SAFETY
DG COMMUNICATIONS NETWORKS, CONTENT AND TECHNOLOGY

eHealth and Health Technology Assessment Unit
eHealth and Wellbeing Unit

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FINAL UPDATED SUMMARY MINUTES
7TH MEETING OF THE EHEALTH NETWORK
12 MAY 2015, RIGA

1. INTRODUCTION

These summary minutes were prepared by the Secretariat of the eHealth Network in accordance with the rules of procedures. They will be posted on the European Commission (EC) website (http://ec.europa.eu/health/ehealth) after having taken into account any comment provided by Network's members.

2. OPENING

The EC Chair (Andrzej Rys, Director for Health Systems and Products, DG Health and Food Safety) and the EU Member State Chair (Clemens-Martin Auer, Director General of Federal Ministry of Health, Austria) welcomed the members of the eHealth Network.

The Member State (MS) Chair underlined that the eHealth Network is moving towards implementation of eHealth. Furthermore, it was mentioned that the speech made during the plenary opening of the eHealth Week by the President of Estonia made many supportive comments towards the work of the eHealth Network.

He thanked the Latvian delegation for their hospitality and noted:

- All 28 member states were present including Norway as an observer.
- There were no comments on earlier minutes.
- The agenda was unanimously adopted.

In reply to a question, the MS Chair will consult the Council about the procedures with regards to a possible participation of Switzerland.

EC Chair presented the recently adopted Digital Single Market (DSM) strategy. He recommended Members to have a look at two documents: the strategy itself and the analysis part. The DSM is one of the top 10 priorities of the Juncker Commission. The strategy has a fast implementation timeline and is therefore ambitious.

Paul Timmers (Director for Sustainable & Secure Society Directorate, DG CONNECT) will elaborate further under Topic 6 how DSM can be viewed in light of the standardisation plans.

3. TOPIC 1: UPDATE ON THE GUIDELINE ON PATIENT REGISTRIES BY PARENT

Introduction

Tapani Piha, Head of Unit for eHealth and Health Technology Assessment) presented the state of play of the PARENT guideline. The project ran from 2012 to April 2015, extended till November 2015. The extension benefits the work of PARENT as they are now able to look how to link their deliverables to the European Medicines Agency's work on registries.

The deliverables are:

- Registry of registries: contains 150 registries (not all EU registries). PARENT plans to expand the number of registries. The assessment of the quality of registries is not part of the original PARENT programme.
- Methodological guidelines: it gives advice on how registries should be organised to make them interoperable.
- Producing an IT-based advance knowledge management tools: these tools are looking at the datasets used in the registries.

PARENT has asked the Commission to think how to make the deliverables sustainable. A workshop on the guidelines is rescheduled to 19 May 2015.

Discussion

A discussion concerned in particular how to link eHealth records. There is a need to find a strategy because there might be some conflicts. Concerns were expressed that the same thing is looked at from a different point of view, and not being consistent.

A registry should have an element that guards the quality of the content. Since this was not part of the project, the question is how this could be done after the project. Something on quality could be done before the endorsement, or the issue should become part of the endorsement recommendation in November 2015.

It was mentioned that the deliverable of PARENT should not be called a guideline as it is more an implementation guide.

The Commission will use these guidelines and promote them in the European institutions and projects. The eHealth Network's members should have a look at the work of PARENT since they have technical knowledge to determine whether it is in line with the work the eHealth Network is doing.

Conclusions

MS experts could contribute to the PARENT workshop by sending their recommendation or comments on a specific topic before the workshop.

The eHealth Network should not endorse the extensive guideline produced by PARENT but encourage their use and give recommendations on their follow-up. The Network should also create visibility for them. The Commission will suggest how the Network could endorse the guidelines, in particular in the field of interoperability.

4. TOPIC 2: REPORT FROM THE EHEALTH NETWORK LEGAL SUBGROUP

Introduction

Aneta Siskovic, Coordinator of the Legal Subgroup (LSG), presented the state of play. The Subgroup works through a 2-level process. There general LSG made up of lawyers or experts from Ministries. The drafting core team consists of SE, FI, ES, AT and the Commission. The general LSG had its first meeting in February 2015.

The aim of the LSG is to create a sustainable legal basis and set basic requirements for exchange of data between health systems as national legislation does not cover these issues. The LSG is working towards a multilateral legal agreement (MLA). The MLA will complement existing EU legislation. It should not in itself require changes of national legislation. Any change in national legislation is to be decided by the MS. Participation in MLA is voluntary.

The core group has written a document with the principles for the contents of the future MLA. As an example, the draft agreement between SE and FI was included in working documents. The SE/FI agreement is only for ePrescriptions but the MLA will also include Patient Summary. The core group has started the process to set key topics to be included in the MLA as well as identifying possible conflict areas.

Some key topics including some possible conflict areas are:

- Patients' consent: countries have different solutions in their national legislation, such as the option of opting-in or opting-out. The MLA cannot operate on having both options. All processing of data in cross-border exchange has to be based on the patient's consent. Patients need to be properly and fully informed of the implications of participating in the system e.g. the differences in secondary use of data (may vary between the participating MSs).
- Number of eHealth NCPs (NCPeh) per MS: for security reasons it would be better to have as few exchange points as possible between MSs but due to the differences in legal systems, their number per MS and technical requirements has to be solved.
- Liability: this is treated differently in different MSs and the MLA needs to set one standard for solving liability situations.
- Jurisdiction: the MLA needs to set clear borders which jurisdiction is prevailing during cross-border exchange. The core group aims at creating a system where the processing of data is under the jurisdiction of the country of processing the data. The core group aims at excluding forum shopping (patients choosing which jurisdiction is applicable). As the data exchanged is sensitive, it is very important that the infrastructure is secured through the NCPehs and the core group prefers a system with one NCPeh per MS. For security reasons the sending NCPeh needs to send the data according to their national legislation. This needs to be formally accepted by the recipient NCPeh and with that acceptance it assumes the responsibility for the continued processing.
- Identification: the MLA must set a standard for the identification of patients and authorisation of professionals involved in the process.

To prevent quick changes in the agreement, there will be a slow process for changing the MLA. Due to rapid technical progress, many details, such as pharmacology, semantics, technical solutions, will be included in annexes, which should have a faster process for changes. There will be requirements for MSs to participate in the MLA; these requirements must be fulfilled to assure inter-

operability. The MLA will mainly cover legal questions but will also set basic requirements for technical solutions to be used.

Discussion

EC Chair opened the discussion by mentioning that the possibility should be explored to use the infrastructure already set in place for the cross-border healthcare NCP. It is important to understand that the NCP under Article 6 of the Cross-border Healthcare Directive is different in nature than the eHealth NCP used in epSOS and dealt with by the LSG. Further, it might be possible to use elements of the agreements that are made for the European Reference Network (ERN) with other entities in the field.

A strong concern was that the timing of the MLA is not known and what its impact would be on existing infrastructures. There is a lack in knowledge of the different national legislation and possible conflicts between MSs.

A question was raised whether the agreement is to be signed by healthcare providers. It was underlined that the MLA is only between MS. The MLA is voluntary but a significant number of countries signing is necessary not to lose momentum.

The MLA will be based on existing and upcoming legislation of the EU, and the solutions need to be found within the boundaries of EU legislation.

With regards to the scope and the use of data, patients need to know what they consent to and assurance that it is not used for other purposes. Data quality and integrity in particular is important because the responsibility moves to the recipient NCP that accepts the data, there should be something in place on the quality of data.

A comment was made that the CEF provides the technical interoperability, guidelines semantic interoperability, and the MLA the legal interoperability. When it comes to ePrescription, in one Member State the pharmacist is responsible of the quality of data and can amend or refuse the data if the quality is not good. The patient does not always get the medication if the quality of data is not good.

An issue that needs to be solved is building a circle of trust between MS legal systems which must happen by way of a legally binding agreement. Concern was expressed of a method to be selected and whether it would take into consideration instruments already in place.

MS Chair underlined the importance of timing. After the call for the CEF proposals, MS start implementation in 2016 or early 2017. The MLA work is to be concluded for the presentation to eHealth Network firs part of 2017. The JAseHN has to identify critical issues to build in the architecture.

A question was raised whether the earlier building block of epSOS can still be used to prevent duplication of work already done. In the epSOS framework, some deliverables gave clear recommendations on how to deal with different levels of interoperability and especially legal interoperability. The MLA will not only be used for ePrescription but also for Patient Summary. Under epSOS it was decided that there was only one eHealth NCP per MS regardless of the structure of the country.

A question was asked whether the MLA takes into account the difference between planned care and unplanned care. In the previous eHealth Network meeting it was mentioned that also other people than lawyers should be on board in the LSG.

The usage of the data is to be specified in the MLA's definition/scope. The scope must precise, without being too narrow. There is no definition of the scope yet.

When it comes to the quality of data, a solution should be found to the problem that MS are dealing the quality of health data differently. The LSG already started to contact other professionals.

The Commission underlined the legal issues mentioned in the discussion: 1) what should be the status of the agreement and 2) who should sign the agreement. A classical international treaty to be signed between the MS might have to go through a burdensome national procedure for the ratification. Therefore a lighter arrangement would be better, an agreement signed at lower administrative level.

SANTE follows closely the process on the Data Protection Regulation and is fully aware of the implication for the MLA, which needs to be compliant with the Regulation. However, the principles on how to handle private health data are already written in the existing Directive.

Conclusions
More countries should send experts to the general LSG.

The LSG will be in contact with other eHDSI groups for alignment of common issues. The LSG will aim at re-using the knowledge that exists from other working groups either current or past, including documents issued by epSOS.

The LSG will be merged in the JAseHN after the next Network meeting.

5. TOPIC 3: UPDATE ON CONNECTING EUROPE FACILITY

a) CEF 2015 Call for Proposals

Introduction
Giovanni Patella (SANTE D3) presented the status of the Connecting Europe Facility (CEF) activities for the implementation of the eHealth Digital Service Infrastructure (eHDSI).

The presentation highlighted the inclusion of the IT infrastructure for the European Reference Network (ERN) into the CEF work programme 2015. No specific eHealth service is expected to be included in the Work Programme 2016. The Patient Registry digital services may be included later. The attention was raised on the fact that concrete proposals in this regard have to be put forward by the first quarter 2016 to have them included in the CEF work programme 2017.

Henrique Martins, chair of the subgroup on "Implementation of eHealth DSI" reported on the activities of the subgroup. The subgroup focused on the preparation of recommendations to be handed over to the Commission for the preparation of the Call for Proposal for the implementations of the generic services under CEF.

He illustrated the main principles that were debated during the subgroup meetings and summarised the criteria and scenarios suggested in the meeting document.

The proposal included also the idea of having the participating MSs grouped into two cohorts, in relation to their readiness in implementing the eHealth services.

Discussion

MS chair stressed the concrete nature of this phase and invited members of the Network to participate actively in this regard.

MSs raised issues related to the lack of clarity around the definition of the Core services, to be implemented by the Commission, and the Generic services, to be implemented by the MS. Patella replied that the relevant Commission service will produce specific documents to clarify the different scope of the two services.

The need was also raised to clarify the scale (regional/national) of implementation of the generic services as well as the governance model for the eHealth Digital Service Infrastructure.

Conclusions

No objections were raised on the proposed recommendations prepared by the Implementation of eHealth DSI subgroup.

b) Proposal for an Organisational Framework of eHealth National Contact Point and Member States semantic coordination

Introduction

The implementation of the generic services by MSs will include the integration of the National Contact Point for eHealth (NCPeh) into national healthcare systems. This integration is expected to be done not only at a technical level, but also taking into account semantic, organisational and legal aspects. A proposal for an organisational framework to prepare, establish and govern NCPehs in the scope of cross border care services deployed under the CEF is needed.

The subgroup "Implementation of eHealth DSI" has expressed the need to develop a common methodology to help national centres responsible for semantics in dealing with cross-border exchange of health data. The subgroup has drafted a proposal to discuss their recommendations in this regard.

Discussion

EC chair clarified that this topic was introduced for information purposes and to start discussing the organisational structure of national contact points. He stressed that the documents presented are in draft as the work is still in progress.

Henrique Martins, the leader of the Work Package 7 and the chair of the subgroup that prepared the discussion papers, emphasised the importance of taking into account the developments and recommendation coming from previous large scale projects such as epSOS. He also noted the need of a semantic coordination at EU level and to have a national semantic expert in every MS involved in cross-border exchange of health data.

Conclusion

MS Chair invited members of the eHN to have a closer look at the proposals presented. The strategic advice of the network is very important. This is especially

true considering that with the real life implementation of the eHealth services under CEF, the eHN decisions may have long-term consequences.

Decisions on the organisational framework and semantic issues are expected in the future eHN meetings.

6. TOPIC 4: JOINT ACTION TO SUPPORT THE EHEALTH NETWORK

The new Joint Action to Support the eHealth Network (JAseHN) consists of 40 beneficiaries (23 associated partners, 2 affiliated entities and 15 collaborating partners).

The activities and corresponding components of each of the four main priority areas defined in the Network's Multiannual Work Plan 2015-2018 correspond to the tasks and deliverables of the content-related work packages of JAseHN. They were translated into a timeline.

The implemented governance structure of JAseHN foresees the delivery of any document agreed upon in the Strategic Project Steering Committee for quality control and consensus building before being submitted to eHN.

Major deliverables and papers to be endorsed or adopted by the eHN foresee a minimum 2 step approach: a discussion in the first meeting and endorsement or adoption in the second of the Network.

MS Chair made clear that JAseHN will arrange a focussed involvement of eHealth stakeholders acting at EU level. Because JAseHN and interaction with the eHN is a MS owned process, the MSs shall decide how stakeholders are involved.

7. TOPIC 5: NATIONAL EHEALTH STRATEGIES

Latvia, Belgium and Finland presented their national eHealth strategies.

Presentation on the Latvian national eHealth strategy

Questions:

- Implementation level: put in place interoperability platform, working on ePrescription and sickness leave in September. From January 2016 it will be mandatory to use it.
- Costs: € 6.9 mill. at the moment but will be € 11 million until the end of the year.
- ROI and which part is built with EU funds: everything is built with EU funds.
- Commercial: 4 private companies developing software going to provide services for the hospitals and GP's. The hospitals and GP's will pay for this.

Presentation on the Belgian national eHealth strategy

Questions

- Incentive for active use of the Hubs/Metahub system: Hospitals have received a financial incentive of €12,000 per year per hospital since 2010 to have the system implemented. Healthcare professionals (doctors, nurses, physiotherapists

etc.) receive a financial incentive of approx. €800/year if they use “registered” software compatible with the Hubs Metahub system. From 2015 on, shifting to a meaningful use policy (e.g. effective production of patient summary or ePrescription etc.).

- Registers: Already existing registers will slowly adapt to the new rules and governance: reduce the number of requested data if already available elsewhere, change semantics to align with new standards etc. All new registers have the obligation to go through a validation committee before they are created.
- The proof of therapeutic relationship is the condition to have access to the data: the only part of the population not covered is illegals. If you lose your EID card, you need to request a new one but existing relationships are preserved. Proof of long term relationship is provided by specific official online database.
- Time response of the system: it is speedy almost instant. In most hospitals you will see in the same window the documents produced in the institution and those coming from other hospitals/ healthcare providers.
- Consent patient: there is no time limit but a formal process. If the consent is given via a health care professional, he receives then a formal confirmation in written that he has given consent.
- Legal basis for registries: either by law of specific authorisation of the privacy commission or private consent.
- The patient is fully empowered that specific information can be hidden for specific providers.

Presentation on the Finnish national eHealth strategy

Questions

- Incentive for the implementation of ePrescription: legislation with the "stick" and giving funds to the ones who first implement ePrescription because they did a lot of work for others.
- Consent process: The consent process is quite similar to the Belgian one. You give consent once making your information available (mostly electronically). Then if you want to deny or close information that is possible too (light opt-in and opt-out). Doctors could not see the information that is hidden. But there is a legislation proposal where doctors are still able to see hidden information on medication if deemed necessary for the safety of the patient. When patients see that information is wrong, they cannot delete that, but they can inform the provider telling them to correct it. Patients can decide who could look at his/her health information.
- Guarantee that information on social and healthcare on the web is correct: own health information, there is identification system for patients where they have to identify themselves so that they can look into their own information. Then there is a health library which is held nationally.
- Use of SNOMED CT: FIN is not using SNOMED CT but so far using epSOS. But FIN is considering on using SNOMED CT. Currently discussing which part of SNOMED CT is good for FIN.
- Use of web by elderly: 92% using web for age under 75. Over 75 only 27% is using the web. Healthcare providers are also providing services conservatively to service the elderly not using the web.

8. TOPIC 6: STANDARDISATION AND INTEROPERABILITY

a) Proposal for a platform consisting of the relevant standards developing organisations

Introduction

The JAseHN Work Package 5 on Interoperability and Standardisation, led by NICTIZ-NL and the Swedish eHealth Agency, had prepared a proposal for a Standardisation Platform that could address the needs of the eHealth Network on standardisation issues.

Michiel Sprenger (NICTIZ), co-leader of WP5, presented a paper proposing to initiate a platform consisting of the relevant Standards Developing Organisations (SDOs) and members of the Joint Action. The platform seeks to support the Network on standardisation matters, enhancing its role in alignment, convergence and cooperation in eHealth standardisation, both at EU and international level.

The presentation illustrated the inspiring principles for setting up the platform, highlighting the added value for the eHN in this regard. The phases of the implementation of the platform were also presented including the organisation of a workshop with relevant SDOs to discuss their participation in the platform.

Discussion

Some MSs raised questions about the duration of the platform and the relationship with the existing Multi-Stakeholder Platform and the eHealth Stakeholder Group.

MS Chair emphasised the necessity to bridge the gap between the strategic dimension of the eHN and the standardisation world. This is a long standing need, taken into account in the eHN's Multiannual Work Plan 2015-2018.

Conclusions

The Network welcomed the proposal for initiating the Standardisation platform, with the exception of one Member State that was not favourable to such a platform.

WP5 will continue working on the implementation of the platform for its possible adoption during the next eHN meeting.

b) Concept of a European Interoperability Framework

Introduction

Paul Timmers presented the European Interoperability Framework, which is a set of recommendations which specify how Administrations, Businesses and Citizens communicate with each other within the EU and across MSs borders. It was adopted by the Commission in December 2010.

The Commission, in the eHealth Action Plan 2012-2020, set out the objective to develop a specific Interoperability Framework to enhance European eHealth interoperability in its four areas: legal, organisational, semantic and technical. The first proposal of an eHealth European Interoperability Framework (eEIF) was defined by the study, known as the "Deloitte study", published in July 2013. Starting from this basis, the Antilope project focused on the dissemination and adoption of the eEIF, delivering a refined version of it in February 2015.

Michiel Sprenger of NICTIZ, partner of the Antilope project, presented the outcomes of the project. The different interoperability layers were illustrated with the roadmap for having the eEIF possibly adopted during the next Network meeting.

Paul Timmers emphasised the importance of the adoption of the eEIF for interoperability at EU level as demonstrated by the previous discussions on legal, organisational and sematic issues.

Conclusions
Joint Action WP 5 will further refine the eEIF for adoption at the next Network meeting.

9. TOPIC 7: EUROBAROMETER REPORT ON DIGITAL HEALTH LITERACY

Paul Timmers presented the results of the survey on health literacy.

Health literacy was surveyed in 2012 and found that still a significant number of people have insufficient health literacy. The report concluded that many people find the information on the Internet useful but have limited understanding on how to use that information for their health or on specific diseases.

The report underlined the needs of everyone to have access to the Internet. It is also important to increase awareness of what are trustworthy sources of information.

10. TOPIC 8: EUROPEAN COMMISSION'S MHEALTH ACTIONS

Paul Timmers presented an update of the mHealth Green Paper. The industry is working on a Code of Conduct, which should be ready by October 2015. Every app developer, who signs the Code of Conduct, must comply with the rules. The Code will be submitted to Article 29 Working Party in the Council.

One Member State referred to the conclusions of the Presidency working lunch of 11 May 2015, because of the interesting ideas mentioned. Furthermore, it was asked how the EC could assure that the rights of consumers are well reflected in the Code.

11. CLOSING

The Network member of Luxemburg, Mike Schwebag, is leaving the ministry in Luxemburg and will become the patient ombudsman. Mike Schwebag was thanked for his contribution in the eHealth Network.

The next meeting will be in Brussels on 23 November 2015.