1. DISCUSSION PAPER

ON THE FUNDING OF EHEALTH SERVICES BY THE CONNECTING EUROPE FACILITY

Proposed by the eHealth Governance Initiative

Date: 13 May 2014

At its third and fourth meetings, the eHealth Network discussed options for fostering the cross-border interoperability of eHealth services by utilising funds from the Connecting Europe Facility (CEF).

In particular, the Network agreed to set up a subgroup to investigate the funding mechanisms further. The subgroup met on 10 February 2014. Additional input was provided by the eHGI and an information paper commissioned by DG SANCO for a workshop on 1 April 2014 (Appendix 1).

Based on this investigation, it was concluded that CEF funds may be used to fund technically mature and sustainable eHealth services. The standing coordination group discussed at the last meeting of the Network would however not be eligible for CEF funds.

Four potential eHealth services eligible for CEF funding were identified:

1) Cross-border ePrescription and eDispensation service[1]
ePrescription and eDispensation as piloted by epSOS extended by additional core services such as eSignature and eIdentification

2) Cross-border patient summary service[2]

[1] Denmark, Finland, Greece, Italy, Spain and Sweden are currently piloting the ePrescription service in epSOS. Croatia and Hungary will join shortly.

[2] Austria, Estonia, France, Italy, Luxembourg, Malta, Portugal, Slovenia, Spain and Switzerland are currently piloting the patient summary service in epSOS. Hungary will join shortly.

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: B232 8/55 - Tel. direct line +32 229-593

Patient Summary as described in the guidelines of the Network extended by additional core services such as eIdentification and eAuthentication

3) eHealth services for European Reference Networks

Virtual communication tools and telemedicine services for low-prevalence, rare and complex diseases including telemonitoring, virtual clinical boards, shared patient and knowledge databases and virtual training

4) Infrastructure services for interoperable Patient Registries

Registry of registries, registry assessment tools, repository of common data and process models for building patient registries, open source software components for building interoperable patient registries and to support data exchange between registries

Members of the eHealth Network are invited to express their interest and to comment on the proposal based on the following questions:

1) Does your Member State have an interest in sharing eHealth services for cross-border exchange of health data with other Member States at the European level?
2) Does your Member State agree with the preliminary choice of the four candidate eHealth services for CEF funding?
3) Does your Member State plan to deploy the national components of these eHealth services from 2015-2020 (funding period of CEF)?
4) Would your Member State be prepared to finance the national infrastructure necessary for these eHealth services and to work towards their long-term sustainability?

Core services (cross border infrastructures) are likely to be given priority in terms of the CEF funding, meaning that the funding of generic services (connection between the national and international infrastructures) is not guaranteed.

Next steps

Based on the expression of interest of Member States in the eHealth Network, the Commission may issue a call for CEF funding of eHealth services in 2015. A first contribution from the eHN to the CEF governance in DG CONNECT is provided here after ("the draft position paper"), for endorsement.

Final contributions from the eHN should be sent out in May/June 2014 for the preparation of the 2015 work programme and mapping out of the management provisions of the DSI deployment. In this respect, interested Member States may form a consortium to apply for funding in 2015.

Finally, services may benefit from funding from the end of 2015 till 2020.

EUROPEAN COMMISSION
DG HEALTH AND CONSUMERS
DG COMMUNICATIONS NETWORKS, CONTENT AND TECHNOLOGY

eHealth-units

2. DRAFT POSITION PAPER OF THE EHEALTH NETWORK TO THE CEF GOVERNANCE BOARD, ON PRIORITISATION OF 4 DIGITAL SERVICES INFRASTRUCTURE ON EHEALTH

First contribution to the preparation of the 2015 work programme

1. INTRODUCTION

The eHealth Network (eHN) set up by Directive 2011/24, article 14 endorsed this position paper on 13 May 2014.

Voting provisions? Prioritisation among the 4 DSI? Individual MS positions? To be filled in after 13 May 2014

This position paper was prepared by the eHN secretariat on the basis of the conclusions of an eHN sub-group workshop (10th February 2014) and the eHealth Governance Initiative meetings (eHGI, 1st and 9th April 2014), which is the operational arm of the eHN. Rapporteurs were appointed for each of the 4 DSI, namely:

- Appointed Spanish expert for the DSI on exchange of patients summary (PS) data
- eHGI subgroup for ePrescription (eP)
- SANCO for European Reference Networks (ERN)
- Appointed Slovenian expert for the patients registries (PR)

Seeking the financial support under the CEF is necessary to reach the overall objective of article 14 of Directive 2011/14, namely to "facilitate the cooperation and the exchange of information among Member States (…), to work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications (…)". It is also needed to implement the specific objective of the same article, namely "to support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare".

Seeking the financial support under the CEF is necessary as well for the implementation of the guidelines on eP, as foreseen in article 11.2.b, and deployment of ERN, as foreseen in article 12 of Directive 2011/24.

Seeking the funding of infrastructures of the DSI is not eligible under the scope of the Regulation 282/2014 setting up a third EU health programme for the period 2014/2020.

The individual contributions from the 4 rapporteurs are available and summarised in part 2 of the position paper.

2. INFRASTRUCTURE INVESTMENTS NEEDED FOR THE HEALTH DSI'S

2.1. Preamble

When adopting this position paper, the eHN is fully aware of the eligibility criteria for CEF funding, ie:

- Technical maturity of the services to be deployed
- The operationality of the services to be deployed (24/24h, 7/7d)
- The sustainability of the services, when CEF funding ends

In addition, the eHN is supportive of the need to avoid duplication of funding, notably by making proper reuse of some core DSIs to be deployed (eID, eDelivery, eInvoicing) and of other specific DSIs such as the multilingual platform and the social security platform for exchange of information on reimbursement of cross border care services, provided that health specific considerations are taken on board, notably to secure the security of transactions and the protection of the patients data.

The operationality and the post CEF sustainability of the services is a major challenge to be addressed by Member States and the Commission, in order to identify relays of and complementary funding, notably for the costs to be incurred at national/ regional levels. The business model of some DSIs such as PS and eP can evolve very rapidly, from a limited deployment today to full deployment within a couple of years (*eP in Belgium, Croatia, Denmark, Estonia, Finland, Greece, Sweden etc).*

Banning the CEF funding today would clearly discourage those Member States willing to deploy and to take over, despite understandable uncertainties.

The technical maturity of the DSI is evidenced by the deliverables of the EPSOS large scale pilot (PS and eP), the two existing ERN and the PARENT Joint Action on Patient Registries.

The eHN should also be properly consulted and incorporated in the governance structure of the CEF, as mentioned in its multiannual work programme 2015/2018.

The overall budget estimated in §3, 38,3 millions €, aims at covering 100% of the cross border infrastructures and national connections to it ("core and generic services"). In fine, when clearly identified, the generic services part should be covered at max 75%, hence leaving 25% to national co-funding.

Costs of deployment at national and regional levels are not included.

For PS and eP, assumptions were made on the number of MS using the services, the number of patients and health professionals, the multi lingual combinations, and the assets supported.

The overall budget highlighted in §3 corresponds to 4 DSI only, for which budgetary commitment is expected in the 2015 work programme of the CEF, with payment appropriations being scattered over the period 2015/2020. Should other services be identified in the upcoming years, such as deployment of telemedicine ones, a new call for funding will be made by the eHN.

2.2. Patients summary data

2.2.1. Description of the service

When a citizen makes an unplanned cross-border healthcare visit to a health provider in the European Union, both patient and health professional will have access to the person's Patient Summary and other relevant Electronic Health Record documents.

In addition to ensuring improved and enhanced healthcare in Europe, the service will be supported by effective technology and more meaningful and efficient data exchange, thus enhancing a European digital health space.

For being able to render this service, there is a need for a European eHealth infrastructure which can transform ("transport, transcode and translate") information products that are in different languages and use different coding systems, in response to requests and actions occurring between healthcare systems of different Member States.

<u>Specific objectives:</u>

Deploy and operate a common and shared infrastructure for digital services regarding eHealth-based on mature ICT solutions and sustainable business models.

Set up the necessary assets to enable Member States to exchange interoperable extracts based on electronic health record (EHR) systems that are already in place or may be adopted in the future.

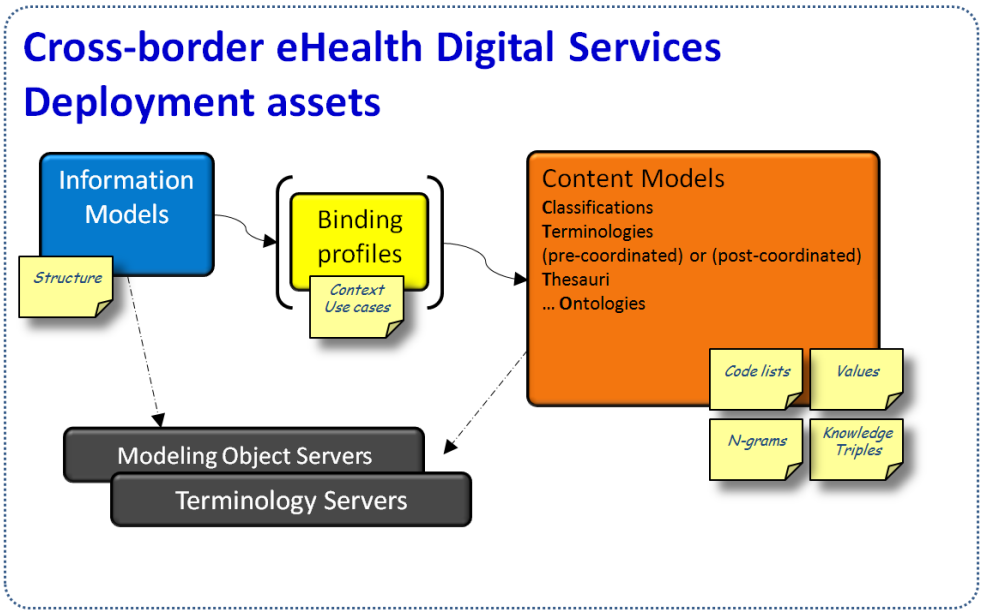
Coordinate and support real-time cross-border exchange of patient data for healthcare episodes on the basis of a set of real-world services.

Provide transcoding, translation, mapping, analysis, and validation service modalities for services such as the exchange of a Patient Summary, which can also be applicable to ePrescription & eDispensing documents, Reference Networks data sharing, Patient Registries database coordination, and later other types of services such as Request and results sharing workflow for radiology, Requests and Results sharing workflow for laboratory, Remote monitoring and care of people at home or on the move using sensor devices.

Provide guidelines, instructions, practical advice, frameworks, synergies identification, and practical support on how to improve the model of meaning

(matching the meaning of the document labels with the meaning of the associated value(s), in order to facilitate cross-language interpretation of document data) of existing patient information products.

2.2.2. Infrastructure needed



The information models

A repository of information models for different data exchange situations is a valuable asset for the EU; cross-border agreements on structure are established beforehand, and citizens can receive optimum healthcare with adequate information represented in a meaningful structure.

Rules of the exchange are clear for both MS involved. Individual instances (information components, full documents, complete folders) can be validated and potential errors marked for alerting the receptors. Translation of labels can be performed in real time, according to pre-existing rules. Context for each data item can be fully understood by healthcare providers and patients alike.

Administration of modeling objects can be done using a repository controlled via application(s). The modeling servers allow search, retrieval classification, tagging, versioning, maintenance, specialization, etc. Improving the models can be shared as well.

The content models

When clinical content is elaborated, free text is still very important. Capability to have exchange of interoperable medical data strongly depends on structured and encoded data capture. Since different encoding standards are used in different countries, having the encoding resources accessible and cross-referenced in a shared platform and accessible to Member States.

2.2.3. Budget estimates

2015: 1,4 million €

2016/2020: 19 million €

Total: 20,4 million €

2.3. ePrescription

2.3.1. Description of the service

Guided by the principles of continuity of care and patient safety, ePrescriptions and eDispensations support the concept that a patient being abroad can receive the equivalent same medical treatment that he would receive in his home country.

The objectives are to:

- Allow dispensation of ePrescriptions across all Europe
- Support the documentation of dispensed drugs.
- Cross-border ePrescription and eDispensations services in Europe will become even more essential with a move of additional countries to electronic prescriptions particularly since their counterpart cross-border paper prescriptions - have as already been achieved.
- Patient safety while staying abroad will be increased since an electronic prescription can much more easily been translated, e.g. using multi-lingual classifications and nomenclatures.
- Using Dispensation data from the dispensing pharmacy in the country of temporary stay, the health services in the home country can update the medication record of the patient, making health care and prescriptions for him safer.
- Although Reimbursement services are out of scope of the epSOS eDispensation service, any characterisitics of the service that will assist patients claim reimbursement would also be a significant element of the service. Defining European wide interoperability measures will also support to establish the ePrescription and eDispensation services in countries that have not yet implemented them. Any synergy with the EESSI infrastructure should be sought.

2.3.2. Infrastructure needed

- Solving interoperability issues inherent to ePrescriptions, particularly in the semantic domain (identification of drugs, information for patients, drug use instructions) and for issues of substitution.
- Analyse different scenarios of gradual adoption, e.g. paper-like prescriptions transmitted in PDF format.

- Seek collaboration with regulatory bodies with respect to semantic interoperability (generic and brand-name consistency, similarities of dosage), prepare use of a EU common database on medicinal products.

- Deploy and validate a European-wide reference for drug nomenclature provided by EMA in the context of cross-border prescribing - linking it to the requirements and current practice in Member States.

- Develop processes to involve National Contact Points (NCPs) in confirming the validity of a prescription - cross-checking with the concept of end-to-end encryption.

- Processes to routinely access professional registration databases for validating ePrescriptions.

- Link the identification of health professionals with their authority to prescribe verify existence of doctor/patient relationship.

- Define assurance levels for eID for cross border ePrescription services

- Build on common identification and authentication measures for eHealth to foster their use within ePrescription services across Europe.

- Establish access to authorisation datasets of Member States' competent authorities including linkages to professional bodies

- Implement ePrescription Guidelines (to be adopted by the eHN in November 2014)

- Semantic adaptation of epSOS achievements

- Maintenance, evolution and deployment of technical and semantic interoperability assets based on the ePrescription guidelines and common NCP assets

2.3.3. Budget estimates

The budget estimates provided are for EU contribution to building the key elements for the Digital Service Infrastructure dedicated for cross-border ePrescriptions. They do not include any national or regional implementation costs nor any licensing fees that may be needed to enable service operation.

2015: 1,4 million €

2016/ 2020: 6, 8 million €

Total: 8,2 million €

2.4. European Reference networks ERN

2.4.1. Description of the service

Directive 2011/24/EU provides for cooperation in the specific areas where the economies of scale of coordinated action between all Member States can bring significant added value to national health systems. This is the case for European Reference Networks, as the objectives of the Networks set in Article 12 of the Directive – e.g. European co-operation on highly specialised healthcare, pooling of knowledge, improvement of diagnosis and care in medical domains where expertise is rare, helping Member States with insufficient number of patients to provide highly specialised care - cannot be sufficiently achieved by the Member States by themselves and can be better achieved at Union level.

Establishing European Reference Networks will help to provide affordable, high-quality and cost-effective healthcare and to improve these patients' access to the best possible expertise and care available in the EU for their condition.

The service will provide all the healthcare providers, members of a European Reference Network, with the capacity to communicate and exchange medical information in a similar manner as if the professionals were working in the same physical environment by means of virtual tools and eHealth solutions. The networking dimension and in particular the IT tools and eHealth solutions are the key elements for the success of the European Reference Networks.

The service aims to improve the exchange of expertise and clinical data through the network and across the EU; allow the swift and smooth contact between providers and between patients and providers at a distance and to maintain and support collaborative/cooperative actions and systems

The service will allow healthcare professionals to:

- Strongly interact and cooperate on clinical cases by:
- Multi-disciplinary virtual boards (e.g. tumour boards) (multilateral connection)
- Bilateral consultation between two centres
- Transmission of and consultation on clinical images (XRay, scans, patology etc..)
- Tele-consultation involving patients
- Interactive production of guidelines, technical documents etc
- Diagnosis support tools: Shared decision trees/other diagnostic tools
- libraries of technical documents
- Training and at distance learning activities

- Research activities: shared protocols for clinical trials, shared databases

- Patient registries for secondary use of information

2.4.2. Infrastructure investments needed

The initial amount for 2015 represents mainly initial investment costs and is an estimate for the establishment of 2 Medium Size ERN (25 centres & 100 users). Running costs (annually) would represent an estimate of 20% the initial costs). More detailed cost estimation is needed. Estimated budget for 2016-2017 includes the investment costs of 2 new ERN per year and the running costs of the previous ones.

- Initial costs includes costs for Hardware, SW-Licenses and activities for set-up, configuration and Integration
- Running costs include operations, maintenance and support (2nd level helpdesk)
- Cost included: Includes central costs and raw average costs at individual centres(e.g. PACS integration, rough estimate here: 5-10k€/Center)
- Implementation costs only, costs for related design of organisation aspects not included and assumed to be completed at the start of infrastructure set-up
- Standard Internet based communication - costs for high reliable or high security network services are not included
- Some of the services/tools/components may be shared by more than one RN in the future
- Training costs are not included

2.4.3. Budget estimates

2015: 1,4 million €

2016-2017: 3,7 million €

Total: 5,1 million €

2.5. Patients registries

2.5.1. Description of the service

Cross-border services for support of interoperable patient registries‘ will be comprised of a set of interoperability assets and services aimed at (1) supporting establishment of patient registries that contain interoperable data; (2) improvement of interoperability of existing patient registries; (3) facilitating exchange (including but not limited to cross-border exchange) of registry data.

Specific components will be:

(1) tool to provide online access to Patient Registries Guidelines and

Recommendations

(2) Registry of Registries (parent-ror.eu)

(3) Registry (self) assessment tool

(4) Repository of registry related common data and process models for building patient registries

(5) Repository of best practices

*(6) SW components for interoperable patient registries and for support of data exchange across registries

**(7) Registry-as-a-service for micro-registries

And additionally

(7) consulting services to registry holders

(8) Supporting services: asset support services, further improvement of the assets, overall management and governance

2.5.2. Infrastructure needed

See specific components above

2.5.3. Budget estimates

2015: 0,9 million €

2016-2020: 3,6 million €

Total: 4,5 million €

3. OVERALL BUDGET ESTIMATES

The eHN asks the secretariat to make a bid for the CEF WP 2015 of ***38.3 million €***

DSI, in m€ at 100%	2015	2016-2020	Total to be claimed WP 2015
Patient summary	1,43	19,00	20,43
ePrescription	1,43	6,79	8,21
EU REF Network	1,43	3,71	5,14
Patients registries	0,86	3,64	4,50
Total	5,14	33,14	38,29

Should other services be identified in the upcoming years, such as deployment of telemedicine services, a new call for funding will be made by the eHN.