European Commission

Executive Agency for Health and Consumers

ICT PSP
ICT POLICY SUPPORT PROGRAMME

eHealth Governance Initiative
eHGI

Results gained from Break Out Session [4]

Workshop on eID for eHealth

11. February, 2013

Conclusions eID

eHealth Governance Initiative eHGI

- the eHGI proposes a trust enhancing policy to the eHealth Network;
- the eHGI elaborates a proposal for "common identification and authentication measures to facilitate transferability of data across-border healthcare on the ground of mutual recognition" while assuring high data security and respecting patient privacy;
- the eHGI reports on the main cross border implications of a common European approach of eID for eHealth and a realistic timeframe for its implementation. This should include a reference glossary of common concepts and definitions to facilitate common understanding between Member States and across sectors,
- the eHGI explores adequate models to enable interoperability between eID mechanisms in Health according to the principles, by taking into account the open issues to enable both an eHealth sector specific approach and a cross sectorial approach;
- the Member States, the eHealth Governance Initiative and all stakeholders take up an active role, within the appropriate institutional framework, in the decision making process leading to a major reform of EU legislation on data protection, as well as on eID and the eSignature package, with the aim of raising the specific needs and requirements of the health sector in such crucial domains.

Objectives- Day 1

eHealth Governance Initiative eHGI

1. What is your national position on the proposed regulation on eID/eSignature)?
2. What positive consequences have you identified with the proposed regulation for usage in health care?
3. What negative consequences have you identified with the proposed regulation for usage in health care?
4. Are there any issues you wish to address with regards to the proposed regulation?

Key Concepts

eHealth Governance Initiative eHGI

- **What is Legal Interoperability?**

  The EU and national laws create the legal basis for interoperability. This articulation of EU and national legislation for eHealth in general and cross border access to EHRs and e-prescriptions in particular is referred to as “Legal Interoperability”.

- **What is organizational Interoperability?**

  The EU and national legal frameworks define the conditions under which personal health data maybe shared, making provisions for specific safeguards that need be in place without however prescribing such safeguards.

  Creating, adopting and implementing such safeguards for **cross border** eHealth services is a pre-requisite for deployment and sustainability and – in addition to Legislation – it requires Agreements on **common policies and measures** (ref Article 14, EIF and epSOS), which then create conditions for “organizational Interoperability”.

Break Out Session on legal issues [Enter title of session]

eHealth Governance Initiative eHGI

Main issues discussed:	Discussion from two Member States very short; so deep-dived immediately into interpretation. See our conclusions.
Participating MS:	EL and ES.
Participating NGOs:	CPME, Continua Healh Alliance.

Top 5 issues identified

eHealth Governance Initiative eHGI

#	Contains
1	What is needed **in addition** to supplement the eID regulation in terms of eHealth specific context. (There are three specific issues – see 2, 3 and 4 below.)
a	Appropriate (**rather thqn high**) security issues. (This could be facilitated under article 8 – delegated acts - with the involvement of the eHealth Network.)
b	**Organisational/usability aspects** covering items e.g., the distance between on-the-spot to having online consultation. What needs to be done to accommodate different identifiers by the doctor of the patient.
c	To increase **trust** the identificqtion must be accompanied by the role sof healthcare professionals
2	**Start the discussion** qbout whether e.g., central infrastructures could be used on a voluntary basis for central authentication purposes (and other purposes).

MS position

Member State	Identified issue No.				
	1	2	3	4	5
ES and EL	Specific needs for eHealth not covered by the proposed Regulation (and cannot).	Opportunities through the eHealth Network through article 8.	Broadly, otherwise, the proposed Regulation appears to be on the right track in terms of governance and Internal Market, although it is challenging to reach full compliance.		

NGO input

NGO	Identified issue No.				
	1	2	3	4	5
CPME	The provision of easier eBusiness online may well increase the use of (clinical) services e.g., unsafe purchasing of prescribed drugs.				

Conclusion

eHealth Governance Initiative eHGI

- The Draft Regulation alone will not cover eHealth needs.
- Art 8 of the Draft Regulation provides possibilities in regard of Art 14 of the Patients' Rights/Cross-Border Directive as well as Art 30 of the Draft Data Protection Regulation.
- Tomorrow we can go more in-depth into **these** issues and other relevant issues.

Objectives – Day 2

eHealth Governance Initiative eHGI

1. What main components need to be added to the eHGI paper "Conclusions on “eID EU Governance for eHealth Services”, to take it one step further towards decision making in each Member State?
2. Are there any issues in on the conclusions as they presently stand, that you disagree with?

Roles for what?

eHealth Governance Initiative eHGI

- For increasing trust in the cross border access
- For the 2 usecases implicit in Article 14 scope
  - PS, ePr
- Authorize for what? Access to health data for
    - Emergency/unplanned care
    - Planned care
    - On line consultations (out of scope of Article 14)

Scope of the discussion

eHealth Governance Initiative eHGI

- Restricted to PS and ePR as per MWP or the more general mandate of the eHN?
  - Prioritization on current priorities but also looking forward
  - E.g. towards patient empowerment
    - The way in which patients may be part of the process of authorizing access
      - Consent policy
    - Access to their record
- Authentication for what
  - Access to records vs entitlement rights

Approach 1

- Start from what exists
  - Directive on qualification of regulated professionals – 5 health professions
  - IMI (link professional regulatory bodies together)
    - Map the organizational environment (e.g. contact points)
- Launch a mapping exercise (eHGI)
  - Are there regulatory registries in place for (5 professions)
  - For each of the exisisting registries:
    - are they one line
    - Can they validate the professional role vaild at the time of request?

Implication for Access rights

eHealth Governance Initiative eHGI

- Can we have a common definition of the care team? Who can access the eHR of the patient? Context and conditions for access
- According to professional profile -the “when in Rome do as the Romans do” principle.
  - Trust increased via MS collaboration
  - Common sets of data for monitoring and reporting
- Patient empowerment: consent process

Trust Enhancement Policy

eHealth Governance Initiative eHGI

- Common consent policy
  - Should be expressed in a way that it can be understandable everywhere
  - Should be vendor neutral,
  - support
    - technical Iop and longitudinal consent
    - Patient controlled
- Appropriate security levels
- Usability – on site vs on line

On line vs onsite access

- Identification
  - Citizen,patient
  - Usability issue-
    - many national interfaces for doctor
      - What is common? EHIC –coverqge issues; passports -not used in EU travel
    - Common mechanism for cross border patient identification (to be specified at EU level impemented by MS) e.g web portal to support interoperability
- Authentication
  - Requirements are highly dependant on the scope access vs entitlemlement

European Commission

Executive Agency for Health and Consumers

ICT PSP
ICT POLICY SUPPORT PROGRAMME

eHealth Governance Initiative
eHGI

Thank you!