E-Health Working Group: Preparing for the Kosovo conference Questionnaire

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European Partnership for Supervisory Organisations in health services and social care

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Lay out of the presentation

- History e-Health working group
- Questionnaire -first review
- follow up- Working group

e-Health WG

- Call for new WG in Oslo 2015
  - What about supervision and e-Health ?
  - Where and when does supervision start?
  - Risks, benefits, Challenges
  - Good practice examples
  - Knowledge sharing (workshops, pilots)
- Reg. Members: NL, EST, FIN, BUL, SWE, ISL

e-Health questionnaire

http://www.epsonet.eu/ehealth.html

e-Health Working group – Survey-

Questionnaire on e-Health regarding supervisory organisations (regulators/monitoring organisations/inspectorates)

0. Introduction

This questionnaire is the instrument supporting a survey among EPSO members intended to provide an overview of what interests and responsibilities health care regulators and supervisory organisations have regarding e-Health[1]. More specifically, the questions below focus on the following issues:

- Organisational approaches to supervision of e-Health;
- Main supervisory aspects of e-Health;
- New developments in the field of e-Health.

Questionnaire

EPSO

1. Is e-Health a topic that is addressed within your organization?
If yes, what kind of issues are being discussed/ worked on?

	Medical devices	e-medicine	M(obile) Health	Telemedicine	Prevention/promotio	Other
Wales	X	X	X	X	X	
Estonia	X	X	X(as concerns medical prescriptions)	X	X (supervise advertising health services in media)	e-vaccination passport
Iceland		X			X Patient involvment	electronic health records
Sweden				X		Virtual organization provisioning healthcare servises through over internet
Finland	X		X (escpecially medical apps)	X	X	E-prescription
The Netherlands	X		X (apps that fall under medical device)			New techniques and products in delivering health care

Questionnaire

2. What are the main areas in the field of e-Health where you conduct supervision? Where takes place?

	Medical devices	e-medicine	M(obile) Health	Telemedicine	Other	Location
Wales					quality and safety, patient experience and effective and timely care	Inspect against the Health care standards within Wales
Estonia	X	X e-prescriptions	X e-prescriptions via m-phone	X marginal	medical epicrisis for E-health information system	licensed health care providers in hospitals and outpatient care and in social care homes.
Iceland		X e-prescriptions			Electronic Health Record, Personal Health Record, Icelandic Health NET	hospitals, primary health care, private practice and nursing homes
Finland	X			X	Information security	Product manufacturers, hospitals
The Netherlands	X		X			Manufacturers of medical devices as well in health care institutions

Questionnaire

EPSO

3. Do you have a special department or positions or working groups inside your organization that are responsible for supervision of e-Health?

	YES/ NO	specifics	qualification
Estonia	YES	special Dep. for e-health services, mostly part of general supervision	special training (for social worker) for e-prescriptions database enquiries
Iceland	NO	FTE's within Information Managment Division responsible for implementation and	Nurse with a PhD degree in health informatics and a computer scientist
		Supervision e-health under Division Supervision and Quality	a dentist, RNs, medical doctor
Wales	NO	Not in their organisation, but there is in Wales. Within HIW team that keeps up to date with new policies.	
Finland	YES	10 people in Valvira's health technology group. Also other sections of social and health care supervision and licensing(mainly patient safety and information security)	Professionals with different background (etc. technical and healthcare)
The Netherlands	YES	4 inspectors at the medical device department are responsible for supervision of eHealth/ IT in health care/ Domotica(home care techn.)	One of the 4 inspectors studied Medical Informatics

Questionnaire

4. Based on what (legal)standards, guidelines or laws does your organization practice supervision on e-Health?	
	supervision based on:
Estonia	Section 60 of Health Services Organization Act,
	Subsection 2 of section 2 of the Personal Data protection Act
Iceland	Medical Director of Health and Public Health Act No. 41/2007.
	· Act on Patient´s Rights No. 74/1997
	· Health Records Act No. 55/2009
	· Regulations on Health Records No. 550/2015
	Data Protection Act No. 77/2000
Finland	Medical Device Directive MDD 93/42/EEC
	MEDDEV 2.1/6 Guidelines on classification of standalone software
	Medical Devices Act (629/2010)
	EC/EN 62304 Medical Device – Software Life Cycle Processes
The Netherlands	· 93/42 EEC Medical Device Directive/ MEDDEV 2.1/6
	· (Dutch version of the) ISO 27001 on information security
	· ISO 13131 on telehealth
	Dutch law on Delivering good quality of care: one specific subsection/ guideline on putting new techniques into service in a safe way

Mentioned Risks

- Information security
- Quality of data
- Software issues, failure of technics
- Misuse (person behind the e-ID)
- High costs and rapid development
- Human factors, e.g. staff resistance and lack of support from management/authorities (also financial)
- Lack of skills /training
- Lack of standards and interoperability

Mentioned Benefits

- More efficient Health Care
- Increased access into services (esc.in remote places)
- Easier data transformation and consultations
- Person centered HC, promotion of healthier lifestyles and patient respnsbl(taking care of their own health)
- Reduced medical costs(less procedures, med.images)
- Secure and timely access (i.e. for ambulance)
- Information sharing, cross-boarder HC
- Increased opportunity for continuity of care
- Better planning and provision etc. etc.etc.

Mentioned Good Examples

- NL:

We have supervised many services in which patient collects his own data and uses it. For example monitoring own medicine, blood pressure or blood sugar.

- EST:

Some doctors seem not to be aware that prescriptions on paper are digitalized and can still be followed in the e-prescriptions data base. In some cases it has become apparent that prescriptions to psychiatric drugs were given to the wrong patient or for too big amounts.

Questions, questions, questions

- WHAT are the risks?
- What to focus on?
- WHERE can these risks be expected?
- WHO is participating? (resource planning)
- WHAT laws/ guidelines/ standards can we base supervision of eHealth on?
- Etc etc etc

Questionnaire
Important developments

- FDA's guidance on medical apps and their approach to supervising these products.
- The International Medical Device Regulators Forum is developing guidance for manufacturers/ developers of eHealth products on how to develop good quality of products.
- Development of specialized software that helps to track violations.
- Use of common indicators to measure e-Health usage and satisfaction for cross country comparison (e.g. Nordic eHealth Benchmarking, 2014)

e-Health WG next steps

- Preparing for EPSO 21st conference in Kosovo- one of the main topics. Pre-conference WG meeting in Kosovo
- Everybody is welcome to join the WG and to fill in the questionnaire, give feedback, share ideas .
- Updates at our webpages and via e-mail
- http://www.epsonet.eu/ehealth.html

Conclusions

- E- Health is hot topic – wide range different approaches
- Supervision of telemedicine - most EPSO members are interested
- Supervision of telemedicine - only few EPSO members have experience in this field

How to organise exchange of knowledge and various experiences between interested EPSO members

Interesting suggestions for further steps

- EST – Sharing ideas how to develop specialized software for supervisory bodies that has a capacity to draw information from other databases, analyse it and help to detect risk areas;
- ISL / NL /FIN – Learn more about experience of using telemedicine
- SWE/ FIN Information security

Info and coordination via EPSO

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