European Partnership for Supervisory Organisations in Health Services and Social Care

EPSO Supervision and E-health working group

Follow up of the (preconference) working group meeting at the EPSO PRISHTINA Conference 1-3 June 2016 Prishtina, Kosovo.

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Starting document of the EPSO Supervision and E-health working group

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Content

1. Aim and outcome

The aim of the EPSO Supervision and e-health working group is:

a. to stimulate the debate, thinking and research about supervision and E-health;
b. to organize a forum for exchange of ideas and practical co-operation between supervisory organizations that have responsibilities of healthcare supervision including supervision on e-health care and telemedicine;
c. to promote cross border fine-tuning, alignment and harmonization of norms and standards used by supervisory organizations for supervision on e-health and telemedicine.

2. The desired and expected outcome of the working group is :

a. a set of norms, standards and a description of best practises to use by supervisory organisations cross border in Europe to supervise – e-health services and practices,

focused on consumer related e-health services, and

- relevant from the consumer- perspective;
- not hindering new developments in e- health and not hindering of patients to make use of new techniques;
- based on the principles of good health supervision;
- practical and useful as good practice for supervisory organisations all over Europe.

b. A Forum for the exchange of ideas and experience with other countries having similar problems;
c. A better understanding of what questions need further examination / should be explored further.

3. The Process

The proposed process to follow by the EPSO working group is – based on the discussions during the first meeting of the working group in Kosovo- is as follows :

a. Share this starting document and ask for feedback to the members of the group *(June-July 2016);*
b. Ask for cases from the various countries participating in the group . The case that might be interesting to use as example can be from your own practice of e-health inspection or possibly if you do not yet have a case from your own practice , it can be a fictional inspection case of e-Health *(June-July 2016);*
c. Agree on this starting document and ask for commitment to the group members *(pre-meeting of the group in Stockholm – 28th of September);*
d. Decide on aim, definitions, desired outcome and focus of the working group *(pre-meeting of the group in Stockholm – 28th of September);*
e. Discuss the cases presented by the group members and select one case to work further by all members of the group - each from their own perspective *(pre-meeting of the group in Stockholm – 28th of September)*
f. Use the selected case to select practical methods for supervision of e-health services and practices from the Risk perspective : - identify the risk and document it by looking at what can go wrong in:
    - Procedures;
    - People
    - Information exchange and
    - Technology *(Next steps of the working group activities in 2017)*
g. Make a checklist for inspection of e-health, *(Next steps of the working group activities in 2017);*
h. Select a set of norms and standards and useful good practices from the case and share this with the EPSO members and other supervisory organisations in Europe *(Next steps of the working group activities in 2017)*

4. Definitions

As was discussed in the pre meeting of the working group in Kosovo the WHO definition of E-health will be used by the working group:

eHealth *is the use of information and communication technologies (ICT) for health. Examples include treating patients, conducting research, educating the health workforce, tracking diseases and monitoring public health. Where health refers to physical, mental and social wellbeing.*

And ***Telemedicine*** *is defined as "the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment and follow-up of patients" (European Commission Working Document on telemedicine services).*

5. Focus of the working group

The working group will focus its attention to

a. Practical solutions for supervisory organisations based on preferences of group members;
b. Consumer related health services (patient perspective);
c. Risk based approach.

6. Selection of a case

Each country chooses an example of an ongoing, planned, finished - or possibly if you do not yet have a case from your own practice - a fictional inspection or supervision case of one of these e-Health services (a possible inspection scenario what could take place under your supervision). Describe it and describe questions that arise or - if you present a fictional case- fictional questions that arise.

The working group meets in Stockholm to discuss the cases – or fictional cases - presented by the members of the working group . The group will choose one of these cases to work further on with the members of the working group to look what could be norms and standards to use and what would be best practise in this situation**.**

7. Questions regarding norms and standards for inspection / supervision of e- health

The working group will discuss the following statements in relation to the cases presented by the working group members:

a. the techniques (software, applications, hardware , devices, IT infrastructure), used for care at a distance' , are a potential risk factor in itself. The risks include the technology itself, but also the user-friendliness of the used techniques.

Question: How does the supervisory authority analyse and include these risks in the regulatory practice of supervision of quality and safety of healthcare?

b. the e- health instruments/ techniques are used by people for " care at a distance" . This is not the usual way of working ; the people who use the new e- health instruments / techniques get new responsibilities; therefore they must be trained to be able and motivated to carry out these new responsibilities; If this is not done properly, it could lead to a potential risk factor;

Question: How does the supervisory authority analyse and include these risks in the regulatory practice of supervision of quality and safety of healthcare?

c. During E-health- procedures information is created, exchanged and used in a way which differs from the traditional way of using information in healthcare; This is a potential risk factor for topics such as data integrity, data confidentiality (privacy) and availability of correct data in the healthcare process itself; This new way of working creates a special need for specific requirements regarding the quality of the data management including the availability, confidentiality, integrity of the data created and exchanged in the process of e-health.

Question: How does the supervisory authority analyse and include these risks in the regulatory practice of supervision of quality and safety of healthcare?

d. E-health introduces new processes that do not exist in traditional health care and are organised differently from the traditional healthcare processes; a. o. this concerns new processes in the chain of e-health, starting with the manufacturer , via the suppliers and health care organizations and providers ending up with the patient and the caregiver; The links in this chain are the potential weaknesses in the application of E-health and are as such a potential risk factor;

Question: How does the supervisory authority analyse and include these risks in the regulatory practice of supervision of quality and safety of healthcare?

The processes of e-health / telemedicine are often separated from the traditional care processes , e-health is seen as an additional process next to the traditional care. A risk factor is that the e-health processes are not coordinated and integrated with the processes of the traditional health care; For supervisory activities in relation to e- health this could lead to a special need to look at e-health in relation to the adjoining traditional healthcare processes.

Question: How does the supervisory authority analyse and include these risks in the regulatory practice of supervision of quality and safety of healthcare?

e. By using E-health procedures new risk factors are introduced in the fields of technology, people, information, and processes ; If the supervisory organisation considers these risks one by one, the result might be suboptimal. An integral approach of the e- health system might reduce the risk.

Question: How does the supervisory authority analyse and include these risks in the regulatory practice of supervision of quality and safety of healthcare?

f. Consumers (patients / clients / caregivers) purchase their own E-health tools such as wearables and (medical) apps / applications; Data obtained by the clients themselves are thus entered into the healthcare system . This could result in risks for healthcare of patients Integrated risk management might mitigate these risks.

Question: How does the supervisory authority analyse and include these risks in the regulatory practice of supervision of quality and safety of healthcare?

8. Actions to prepare for a follow up discussion at the EPSO Stockholm pre-meeting 28 /9/2016

The members (and potential members) of the e-health working group are being asked to:

a. <u>Please give your feedback to this document (if possible before July 15th);</u>

b. **Please think about a case from your own practice and let us know - preferably before July 15th-** if you will be able to present a case in Stockholm at the 2nd pre-meeting of the E health working group planned for the 28th of September (or if you will be able to send a case by mail so that someone else can present your case)
The case could be an example of good practice from your actual experience with e health or it could be a 'fictional case' which might be interesting to use as example of possible e-health supervision in the further discussions of the working group.