



European Partnership for
Supervisory Organisations
in Health Services and Social Care

EPISO PRISHTINA Conference June 2016

¹Questionnaire and Note on Supervision and E-health – to be completed by those EPISO members who want to participate in the debate on supervision and E-health at the **preconference working group meeting in Prishtina Kosovo** (Start of the EPISO Supervision and E-health working group).

The pre- conference meeting of those EPISO members who want to participate in the Supervision and E-health debate will be held at the Emerald Hotel- conference room : June 1 15.00-17.00

This Questionnaire / Note is sent to you to prepare for the debate on **Supervision and E- Health** which is organized by EPISO as a preparation for the start of a new EPISO working group on E- Health and Supervision in 2016.

This Questionnaire and note is prepared by the organizing committee but please feel free to send us your reaction so that we can share reactions with the other participants in the preconference. If you do not have time or inspiration to share your ideas before arriving at the conference in Kosovo please feel free to bring your own opinions on this topic to Kosovo and participate in the debate.

If you or any of your colleagues want to participate in the working group please let us know at any time before or at the Conference.

The aim of this E- health and Supervision working group is:

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

The main questions -as seen by organizing committee - to be answered and discussed are the following :

¹ This questionnaire was made in co-operation between :

Wouter Meijer, Foundation Quality Assurance E-Health (QAEH), Netherlands March 26, 2016

Jooske Vos EPISO 29-4-2016

Tove Gemzell IVO , Sweden 3-5-2016

- What is the difference between supervising /monitoring /regulating of E-health services and supervising monitoring or regulating traditional care services? Or in other words: to what extent does supervising of E-health services vary from supervising the traditional care services?
- Do we need special norms and standards for monitoring e-health and telemedicine?
- Do we need special methods tools and instruments to supervise e-health and telemedicine?
- Is there a special need to work together cross-border to protect quality and safety in healthcare with regard to quality and safety of e-health and telemedicine?

Question 1 do you agree with the following statement and sub statements a-f related to roles and responsibilities of the supervisory authority in relation to e- health , e-care and telemedicine?

Statement 1 and sub- statements a-f

Supervision and Monitoring of E-health, E-care and telemedicine will differ from the traditional monitoring and supervision because the following aspects of E- health, E-care and telemedicine have to be taken into account .

- a. the techniques (software, applications, hardware , devices, IT infrastructure), used for care at a distance' , are a potential risk factor in itself. Therefore, these techniques must meet all requirements of quality and safety; this includes requirements related to the technology itself, but also requirements related to user-friendliness of the used techniques.
- b. the techniques are used by people for “ care at a distance” . This is not the usual way of working in the traditional health care system ; the people who use the new e- health instruments / techniques are being given new responsibilities; therefore they must be trained to be able and motivated to carry out these new responsibilities ; these responsibilities should be organized in an embedded way; If this is not done properly, it could lead to a potential risk factor; therefore there is a need to demand for skilled people and the use of good practice by healthcare providers , healthcare workers , patients and all those who use the technology. This includes attention for well managed risk procedures;
- c. During E-health- and telemedicine 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; Therefore there is a special need for specific requirements such as quality (availability, confidentiality, integrity) of the data created and exchanged; this entails also to specific requirements for data management.
- d. E-health introduces new processes that do not exist in traditional health care; amongst others 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 with 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 ;
The processes of E-health / telemedicine are often separated from the traditional care processes , e-health is seen as something extra / as an additional process next to the traditional care while at the same time the traditional care is not changing .
As a result the potential benefits of e-health are insufficiently achieved; an important risk factor is that the E-health processes are not well equipped, especially when E-health is not coordinated and integrated with the processes of the traditional health care; For supervisory activities in relation to e-

health and telemedicine and for monitoring of e- health and telemedicine this means that there is a need to look specifically at procedures related to the processes of e-health in relation to the adjoining traditional healthcare processes.

- e. By using E-health procedures and making use of telemedicine new risk factors are being introduced in the various fields of technology, people, information, and processes (procedures); If we consider these risk factors separately one by one, there is a risk of sub-optimization (sub-optimization occurs when the approach is restricted to the various sub-systems and when the supervisory authority or the management only strives for optimization and maximization within one of these single subsystems separately); Monitoring of these risks factors in e- health should not be considered separately one from one another. To reduce these risks supervision and monitoring must be approached as an integral system. The policy should be that the risk factors are managed within the same framework of standards.

The conclusion should be that an integral risk management system is necessary. Keywords for this integral approach are: procedures, information, people, technology.

- 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 . The result of this data transfer is the onset of the so called ‘consumer e-health’ . As a result of this the care provider is faced with data and information transfer by clients and patients themselves . He will not always be able to judge the reliability of the data , while these consumer data and information actually become part of his health care work in practice. This creates problems both in the field of the technical aspects of the healthcare services (the recording and reading of such data is often not possible on the information systems of the health care provider), as well in the field of the actual quality of the healthcare delivered by the healthcare providers (reliability of the data provided by the patient / client etc.)
To mitigate these risks, integrated risk management is needed. Keywords are again: procedures, information, people, and technology.

Question 2 Does your organisation have tasks and responsibilities in the field of supervision on e-health and telemedicine and if the answer is yes : Do these responsibilities differ from the ‘normal ‘responsibilities’ to supervise health care services?

Question 3 Do you see any kind of special goals, problems or do you have special wishes in relation to do the activities of the EPSO working group on Supervision and E- health and telemedicine ?

Question 4 Do you see any need or wish for co-operation between inspectorates and supervisory organisations in Europe, directed towards common or shared norms and standards for supervision/ monitoring/regulation and E-health/ telemedicine?