**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]](#footnote-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.

The respondents are asked to fill in the questionnaire according to the questions above, but should feel free to add any comments whenever they think it’s important to contextualize the answers.

If any doubt or difficulty occurs, please send an e-mail to mmurel@epsonet.eu

**1. Questions**

**Section A – Respondent identification**

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| Country (or region) to which the answers correspond: Iceland |
| Name: Gudrun Audur Hardardottir |
| E-mail: audur@landlaeknir.is |
| Telephone (landline/mobile): +354-510-1900 |
| Organization: Directorate of Health in Iceland |

**Section B – Organizational approaches to supervision of e-Health**

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)Health2 (for example medical apps)**
* **Telemediecin3 (consultations via internet etc)**
* **Prevention/promotion via e-health**
* **others**

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| The Directorate of Health (DoH) in Iceland is responsible for the implementation and development of electronic health records, drug prescriptions, patient involvement as well as discussion of e-Health in general. However, supervision of e-Health is included in the supervision of the healthcare in general. |

1. **What are the main areas in the field of e-Health where you conduct supervision (medical devices, mhealth[[2]](#footnote-2), telemedicine[[3]](#footnote-3), e-medicine etc.)? And if you do, where does that supervision take place (hospitals, nursing homes etc.)?**

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| The DoH is responsible for the implementation of an Electronic Health Record (EHR), implementation of e-Prescription and Personal Health Record (PHR). Furthermore, the DoH has developed and implemented the Icelandic HealthNet for secure health information exchange. This is all at a national level, including hospitals, primary health care, private practice and nursing homes. The overall goal is to increase patient safety and enhance the quality of health care delivery. |

1. **Do you have a special department or positions or working groups inside your organization that are responsible for supervision of e-Health? If yes, what type of qualification do they have (IT- related, health management, medical doctors etc.) and how many people are working on this topic?**

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| No. However, there are two FTEs within the Information Management Division who are responsible for implementation and development of e-Health. Their qualifications consist of a nurse with a PhD degree in health informatics and a computer scientist. Supervision of health care institutions, including e-Health, falls under the auspices of the Division of Supervision and Quality, which consists of five persons, a dentist, three RNs and the head of division who is a medical doctor. |

1. **Based on what (legal) standards, guidelines or laws does your organization practice supervision on e-Health (if applicable)?**

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| The overall work falls within the Medical Director of Health and Public Health Act No. 41/2007.  Work on e-Health within the Directorate of Health is supported by the:   * 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 |

1. **What are your plans to implement supervision on e-Health in the future?**

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| Continue with ongoing plans for implementation and surveillance of e-Health on a national level. As it is today supervision of healthcare is not divided into supervision of e-Health and other healthcare but this will have to be developed both with respect to the quality and safety of patient care as well as to quality and safety of data and the use of data. |

**Section C – Main Supervisory aspects of e-Health**

1. **How does your organization organize supervision of e-Health in the health care sector? For example, by visiting health product manufacturers, monitoring the implementation of new medical systems, based on claims, or other methods**

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| By issuing mandated regulations, coding standards and guidelines as well as site visits when needed. Furthermore, by collecting log data on health information system usage and reports on data protection and security issues from health care institutions. Recently also by surveying health professionals to measure e-Health usage and satisfaction. Health consumers will be surveyed in near future. |

1. **What are the main risks and benefits for the health care sector when implementing e-Health?**

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| The main **risks** include, but are not limited to:   * Human factors, e.g. staff resistance and lack of support from management/authorities * Lack of financial support from the government * Lack of skills and/or training by project management responsible for health information system implementation * Lack of standards and interoperability between health information systems * Breach of confidentiality (e.g. access to information without authorization) * Loss of important patient information due to inadequate backup of data * “Alert fatigue” * Inadequate health information system uptime * Health information system slowness * Health information system does not support workflow   The main **benefits** include, but are not limited to:   * Secure and timely access for authorized health professionals to important patient information at point of care * Person centered health care supported * Information sharing across health care institutions and geographical boundaries * Increased opportunity for continuity of care * Increased patient safety * Enhanced quality of health care delivery * Improved patient outcomes * Reduced duplication * Improved collaboration of health professionals * Increased efficiency within the health care system * Cost savings * Secure access for citizens to their own health information * Increased patient participation in own health care supported * Big Data opportunities and knowledge discovery |

1. **Does your organization have good examples of (supervising) e-Health?**

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| Yes. An electronic health record has been implemented in every hospital and primary health care center within the country. Moreover, they are all interconnected via the Icelandic Health Net. Hence, health care professionals have seamless and secure access to important health information about their patients at point of care. Everything is logged at an individual level and health care institutions need to adhere to mandated regulations and guidelines on data protection and security. |

1. **Do you have examples of health care organizations that experienced problems/ issues when implementing e-Health? If yes, please elaborate.**

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| Yes, mostly due to lack of interoperability between systems, e.g. buying specific systems like hospital electronic medication management systems that lack integration with the electronic health record that has already been implemented. Moreover, issues where medical devices cannot be integrated with the EHR. |

1. **What are the main challenges for your organization concerning supervising e-Health?**

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| The main challenges include financial restrictions and low manpower. |

**Section D – New developments in the field of e-Health**

1. **Are you interested in certain topics in the field of e-Health (to learn more/ share knowledge)?**

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| We are interested in most topics of e-Health. |

1. **Do you organize (among staff, care facilities) e-Health related training?**

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| To a limited extent, but not on a regular basis. |

1. **What do you consider important developments for supervisory organizations in Europe concerning e-Health?**

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| * Issuing mandated standards and regulations * Law needs to support e-Health implementation * Use of common indicators to measure e-Health usage and satisfaction for cross country comparison ( e.g. Nordic eHealth Benchmarking, 2014)   + Health professionals   + Health consumers * Sharing of data on a larger scale e.g. in relation to cross border health care. |

1. **Is there anything you would like to learn about/ share experience concerning e-Health?**

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| We would like to learn more about most aspects of e-Health, in particular experience of using telemedicine and other means to overcome problems with uneven access to specialized healthcare. |

1. **Do you have any further comments and/or feedback (about all sections of this questionnaire)?**

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| The questionnaire is about supervision of e–Health. Since Directorate of Health in Iceland is responsible for both supervision and implementation of some aspects of e-Health, the supervision of e-Health is not easy to separate from supervision of healthcare in general. |

**3. Follow-up**

Results of this survey will be used as a basis of the e-Health working group and will be presented and discussed at the Helsinki conference.

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| **Are you or/and one of your colleagues available/interested to co-operate and/ join the EPSO e-Health working group?** | (Yes or No)  Yes, we are interested to co-operate and if possible to join the EPSO e-Health working group. However, we have limited resources and our economic situation may not allow us to attend all meetings abroad. But we need to be updated on ongoing work in this field. The contact person is Sigríður Haraldsdóttir, chief of division at the DoH. E-mail: shara@landlaeknir.is |

Work group is co-ordinated by EPSO secretary, contact :Mari Murel

+316 316 84526, e-mail: mmurel@epsonet.eu

1. In this context we are defining e-Health as follows: “*eHealth is the term for delivering healthcare supported by electronic products”* (Stefan Visscher, Dutch Health Care Inspectorate) [↑](#footnote-ref-1)
2. **mHealth** is defined as “*medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices”(*WHO “mHealth – New horizons for health through mobile technologies, Global Observatory for eHealth series – Volume 3”, page 6*)* [↑](#footnote-ref-2)
3. **Telemedicine** is defined as *"the provision of healthcare services, through the use of ICT, in situations where the health professional1 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) [↑](#footnote-ref-3)