



EUROPEAN DATA
PROTECTION SUPERVISOR

European Data Protection Supervisor

Trustworthy eHealth: a big challenge for the EU

Herke Kranenborg

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ECHR: I./Finland

“The protection of personal data, in particular medical data, is of fundamental importance to a person’s enjoyment of his or her right to respect for private and family life as guaranteed by Article 8 of the Convention.”

“Respecting the confidentiality of health data is [...] crucial not only to respect the sense of privacy of a patient but also to preserve his or her confidence in the medical profession and in the health services in general.”



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ICT and Healthcare



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ICT and Healthcare = a big challenge



- Ensuring security/confidentiality
- Determining responsibility
- Ensuring self-determination of patients
 - EDPS speech of 2-12-2009 (www.edps.europa.eu)



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Privacy-by-design

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ICT and Healthcare and the EU

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ICT and Healthcare and the EU

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an even bigger challenge



European perspective

- Consequences:
 - Security/confidentiality
 - Responsibility
 - Applicable law
 - “Medical data”?
 - Semantic issues



European perspective

- European scale is unavoidable
- Europe-by-design...
- EU hands are tied: Art. 168 TFEU
- However: Art. 114 TFEU



European perspective

- EU concern: lack of interoperability
 - Recommendation on interoperability of EHRs (2-7-2008)
 - Communication on telemedicine (4-11-2008)
 - Patients' rights Directive (9-3-2011)



European perspective

- Patients' rights Directive, Art. 14 on eHealth
 1. The Union shall support and facilitate cooperation and the exchange of information among Member States working within a **voluntary network** connecting national authorities responsible for eHealth designated by the Member States.
 2. The objectives of the eHealth network shall be to:
 - (a) work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of **trust and security**, enhancing continuity of care and ensuring access to safe and high-quality healthcare;
 - (b) draw up **guidelines** on:
 - (i) a non-exhaustive list of data that are to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and
 - (ii) effective methods for enabling the use of medical information for public health and **research**;
 - (c) support Member States in developing **common identification and authentication measures** to facilitate transferability of data in cross-border healthcare.The objectives referred to in points (b) and (c) shall be pursued in due observance of the **principles of data protection** as set out, in particular, in Directives 95/46/EC and 2002/58/EC.
 3. The Commission shall, in accordance with the regulatory procedure referred to in Article 16(2), adopt the necessary measures for the establishment, management and transparent functioning of this network.



European perspective

- Directive 95/46/EC on data protection (Art. 8)
- Amend data protection rules?
- Review of the data protection framework
 - http://ec.europa.eu/justice/policies/privacy/review/index_en.htm



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Any questions?

Thanks for your attention!

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