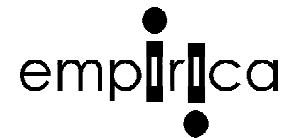


National eHealth strategies in EU Member States

- Legal eHealth challenges -

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Outline

- **Study objectives**
- **Status quo and progress made –**
Legal, privacy and data protection challenges
- **Outlook**

Objectives

- **Analysis of national eHealth policies and implementations - update**
- **Objectives**
 - **Describe, measure and assess**
 - national eHealth policies, strategies and implementation measures
 - progress achieved, focusing on selected eHealth Action Plan priorities
 - **Identify good practice cases of national activities**
- **Output**
 - **Country reports**
 - **European overview and progress report / brochure**

Status quo and progress made

Summary overview: Priority and activity fields mentioned in Member States policy documents

Reported eHealth activities	Total 2007 eH ERA	Total 2010 eH Strategies	DELTA
EHR/Patient summary	27	27	+0
Standards (technical and semantic)	19	27	+8
ePrescription	16	22	+6
Citizen card	22	25	+3
Professional card	7	18	+9
Patient ID	24	26	+2
Professional ID	13	22	+9
Telemedicine	23	27	+4
Evaluation	5	21	+16
Legal Activities	14	22	+8

Legal issues in eHealth

- In many countries the use of eHealth is currently regulated **only by the general legal framework**, in particular by laws on patient rights and data protection
- **New** legislation is often still in the process of being enacted, but slowed down
- Amongst the **forerunners** in designing a legal framework adapted to the use of eHealth are Denmark, England, Estonia, Finland, France, Norway, Scotland, Slovakia, Sweden
- Almost all other countries dispose of some regulation on health data, if only through the transposition of article 8 of the **EU Data Protection Directive**

Legal issues for EHRs

- Nearly all European countries **legally enforce** the keeping of a carefully updated and safely stored health record.
- In the vast majority of the countries the choice to keep the health record *either electronically or on paper* is still open.
- In very few countries, for example Finland, **electronic copies of health record are obligatory.**
- Countries like Belgium, France, Italy, Spain, Iceland and Switzerland have chosen an **opt-in EHR system** whereby the explicit consent of the patient is required before a shared electronic health record may be created for her/him.

Legal issues for ePrescription

- In some countries, ePrescription in primary care is **not being used** in part due to national legislation issues regarding the electronic transmission of prescriptions and the use of electronic signatures.
- The **legal requirements** concerning ePrescription mostly deal with *authentication and electronic signatures, patient consent, the possibility to obtain a paper copy, and in some countries the obligation to prior clinical examination.*
- The introduction of electronic pharmaceutical care/medication records is on the rise.

Legal issues for telehealth

- The use of telehealth services is generally regarded to be less problematic under current legal frameworks so that the usefulness of legal provisions dealing with telehealth specifically is questionable.
- The three most common **regulatory issues** for telehealth are:
 - a) the requirement to treat a patient in person
 - b) accreditation is not available for professionals
 - c) the liability of the provider of telehealth services is obscure.

Outlook

- Tackle the lack of a **governance structure and leadership** which provides the **framework for legitimate uses** of individual medical data, legal framework to govern the EHR-type services
- **Data protection and security** are needed to achieve a high level of acceptance from the public and from healthcare providers
- Develop a **framework addressing security, access (including patients) and consent aspects as well as other legal issues**. The centralisation of ‘sensitive’ data causes a great deal of discussion, e.g. whether this collection of individual data is necessary and where the limits for collection will be set
- The legitimate **secondary use** of data should be addressed

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The views expressed in this presentation are solely those of the authors. and do not necessarily reflect those of the European Commission.

Thank you for your attention!

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