

eHealth - Legal, Ethical and Social Challenges  
Tues 28th - Wed 29th October 2014  
Middlesex University, London

## eHealth in the EU

### Current legal challenges and the way ahead

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### Information and Technology Law



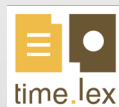
- Specialised Law Firm based in Brussels
- Traditional Legal Services
- European Commission Policy Assistance
- Horizon 2020

## time.lex and eHealth

- “Legally interoperable eHealth in Europe” (2009)
- Review of national eHealth strategies (2010) (with Empirica)
- **Legal study on electronic health records** (2014) (with Milieu)
- AEGLE (Horizon 2020)
  
- STORK (legal work package leader)
- EIDAS (expert group – secondary legislation)



## Milieu-time.lex EHR Legal Study



- eHealth Network
- Multiple facets
- Status in the MS
- Recommendations

## eHealth & the EU



- Digital Agenda for Europe
- eHealth Action Plan 2012-2020
- epSOS
- Calliope
- eHealth Task Force
- eHealth Network
- EU-US Memorandum of Understanding on eHealth
- Horizon 2020
- eHealth Stakeholders Group
- ...



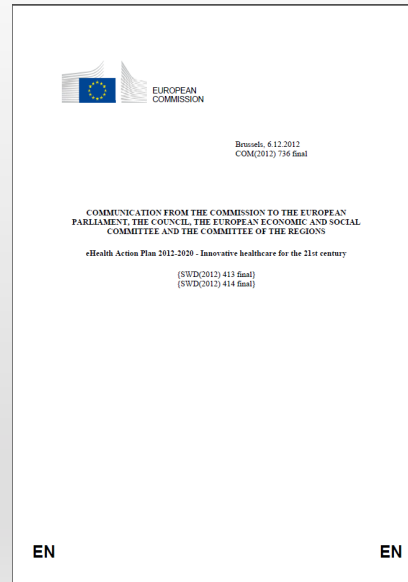
## DIGITAL AGENDA FOR EUROPE A Europe 2020 Initiative

- Action 75: Give Europeans secure online access to their medical health data
- Action 76: Propose a **recommendation** to define a minimum common set of patient data
- Action 77: Foster EU-wide standards, interoperability testing and certification of eHealth
- Action 78: Reinforce the Ambient Assisted Living (AAL) Joint Programme



## eHealth Action Plan 2012-2020

1. Interoperability
2. R&D
3. Facilitate Uptake & Deployment
4. Global Dialogue



### EU agenda for effective, accessible and resilient health systems

Strengthening effectiveness

Increasing accessibility

Improving resilience

Health systems  
performance assessment

Patient safety and quality  
of care

Integration of care

Planning of EU health  
workforce

Cost-effective use of  
medicines

Optimal implementation of  
Directive 2011/24

HTA

Health information  
system

eHealth

Source: Communication of the European Commission on effective, accessible and resilient health systems, April 2014

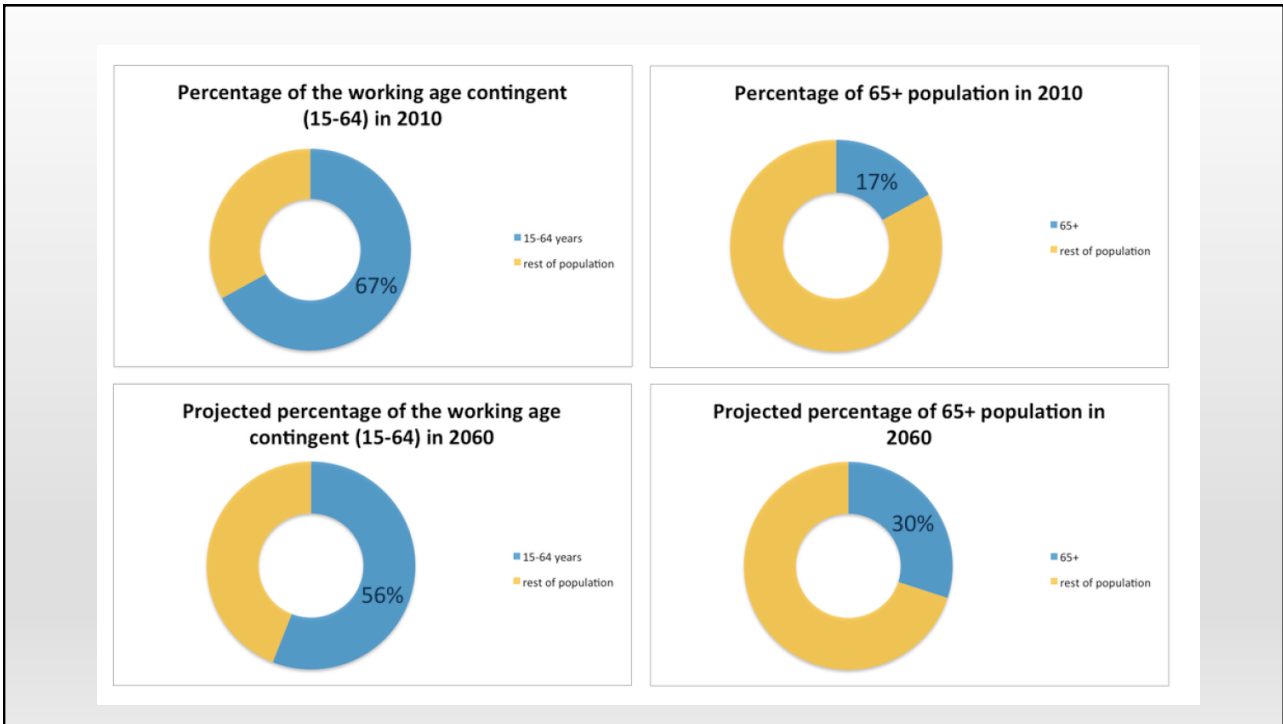


eHealth : do we have a European vision?

## eHealth Task Force



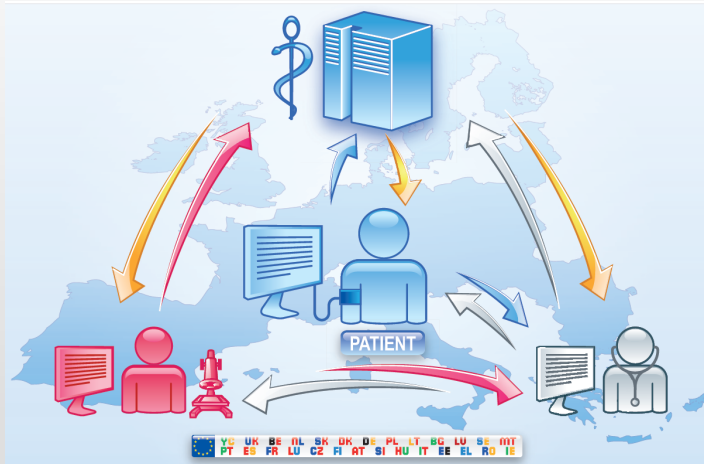
Is this a vision we share?



“We know that in healthcare we lag at least 10 years behind virtually every other area in the implementation of IT solutions.”

Toomas Hendrik Ilves  
President, Estonia



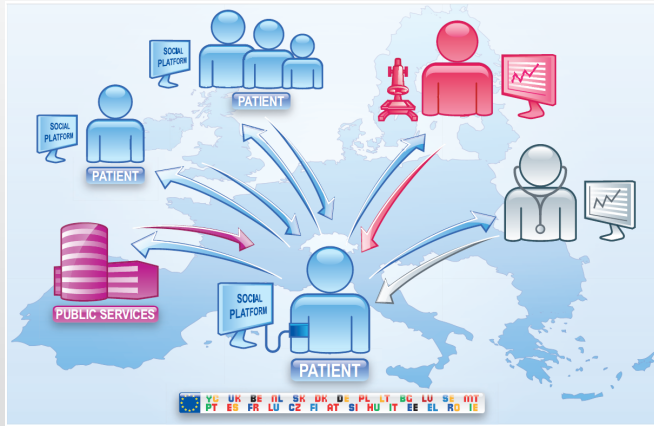


“My data, my decisions”

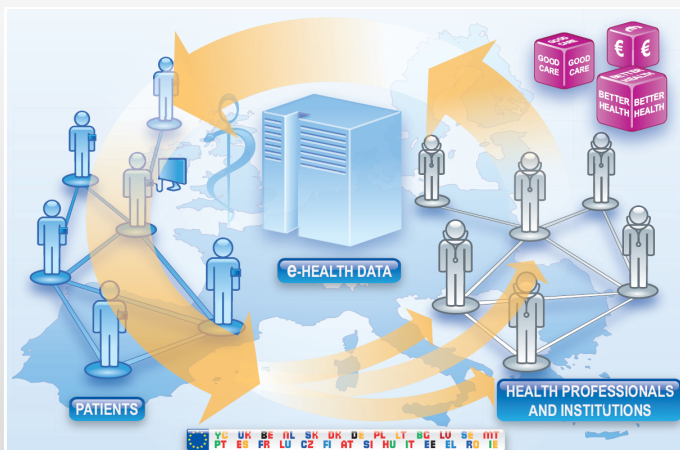


“Liberate the data”





“Connect up everything”



“Revolutionise health”







“Include everyone”



## eHealth Task Force



1. A new legal basis for health data in Europe
2. A ‘beacon group’ of Member States and Regions
3. Support health literacy
4. Use the power of data
5. Re-orient EU funding and policies



In reality healthcare remains a national competence

European legislator has only limited possibilities to regulate this field



## European legislation intervenes mostly “indirectly”

- Directive on Patients’ Rights in Cross-Border Healthcare
- Directive 95/46/EC + Draft EU Data Protection Regulation
- Safety – medical devices ... and other internal market issues
- ...



## Our recommendations

- legal (not on terminological, organisational or technical aspects)
- recommendations for whom?
  - “request healthcare providers to participate”
  - “implement the guidelines on patient summaries”



## Interoperability

- Doesn't mean uniformity
- National level: rules imposing essential requirements to achieve semantic, technical, organizational and legal interoperability
- EU level: achieve interoperability via eHealth Network agreements



## EU Level: Agreements

- terminological profile for minimum set of fields included in a patient summary
- technical profile for cross-border exchange of patient summary data (e.g. on security aspects)
- list of categories of healthcare professionals who can access patient summaries (incl. solution for cross-border authentication)
- roadmap for implementation of cross-border exchange of patient summaries

## Patient Consent

- National level: 3 step-approach
  1. create EHR: no need for consent
  2. set up EHR sharing system: possibility to opt-out
  3. actual sharing of data: explicit consent (= proof of therapeutic relationship)
- EU level: eHealth Network agreement on 3 step-approach

## Patient Access

- National level: patient should be largely (not totally) “in charge” of the EHR (access, control, download, follow-up who accessed, etc.)
- EU level: eHealth Network agreement on essential principles relating to patient access to EHR (as far as necessary for cross-border exchange)



## Liability

- National level: primarily need to inform and educate healthcare professionals
- EU level: inform and educate healthcare professionals on liability rules with regard to cross-border exchange



## Secondary Use

- National level: delegate this issue to the EU (interstate) level
- EU level: re-use of EHR data for research purposes should be regulated at EU level (start with eHealth Network agreement)



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