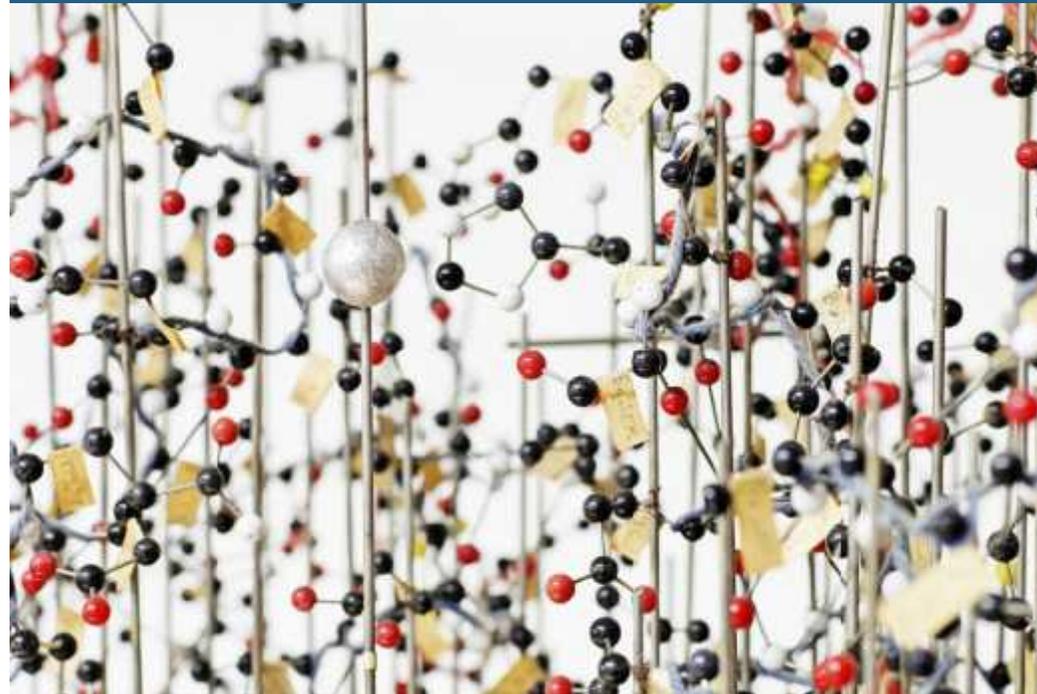


Remote Accessibility to Diabetes Management and Therapy in Operational Healthcare Networks



Liability and Ethics in eHealth

Denmark, November 13, 2013

Eugenio Mantovani, LSTS

Vrije Universiteit Brussel







Open non technological questions



- Ethical, legal, social, psychological...issues

...



-
- Safeguarding of private information
 - Autonomy of individuals/lifestyles
 - Requirement to do no harm
 - Fair and efficient use of public resources
 - Recognition of shared responsibility that protects vulnerable people
 - ICT & Ageing
 - Autonomy questions
 - Beneficence and non-maleficence
 - Justice



Ethical/legal issues

- Greater variety of people involved
- Is eHealth reliable and effective?
- Privacy and Info requirements
- Fear of burden of unclear liability



Overview of Content

- Introduction
- Legal and regulatory framework on product liability at EU level and in Denmark
- Elements of product liability
- Ethical issues in liability
- Encounter between Liability and Privacy
- Conclusions



Legislative framework

- Existing Legal Framework
 - TFEU
 - Directive 95/46 Data Protection
 - Directive 98/34 Technical standards and regulations
 - Directive 2002/58 *privacy* in the telecommunications sector
 - Directive 2000/31 e-commerce
 - Directive 2007/47 MDD
 - Directive 1997/7 distance contracts...
 - Directive 2011/24 patients' rights
 - Rome I and Rome II regulations
 - Directive 85/374/EEC
 - ...
 - ...
 - ...





Directive 85/374/EEC



COUNCIL DIRECTIVE

of 25 July 1985

on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

(85/374/EEC)

(OJ L 210, 7.8.1985, p. 29)

The Directive establishes the principle that the producer of a product is liable for damages caused by a defect in his product.



Defective product (Art. 6)

- A product (all movables) is defective where it does not
 - provide the safety which a person is entitled to expect, taking all circumstances into account, including:
 - the presentation of the product;
 - the reasonable use of the product;
 - the time when the product was put into circulation.
- Not defective if only a improved product is subsequently available



Producer (Art. 3)

- The producer of a raw material, the manufacturer of a finished product or of a component part;
- The importer of the product;
- Any person putting their name, trade mark or other distinguishing feature on the product;
- Any person supplying a product whose producer or importer cannot be identified



Liability without fault (Art. 4)

- Or strict/absolute liability: imposition of liability on a party without a finding of fault (such as negligence or tortious intent)
- Where a defective product causes damage to a consumer, the producer may be liable
- Damage can be material or health damage.
National laws on non-material damage are not affected by the Directive



The injured person

- He must prove:
 - the actual damage;
 - the defect in the product;
 - the causal relationship between damage and defect.
- However, he does not have to prove the negligence or fault of the producer or importer.



Exoneration clause (Art. 7)

For the producer who can prove that he did not put the product into circulation, that the product was not defective when put into circulation, etc.



Limitation period (Art. 11)

3 years

From the day plaintiff became aware

Applies to

proceedings for the recovery of
damages



Denmark

- *Transposition deadline: 30/07/1988*
- *Lov nr. 371 af 07/06/1989 om produktansvar. Justitsmin.L.A. 1988-46002-11. Lovtidende A haefte 58 udgivet den 09/06/1989 s.1260. JLOV.*
- *Legal act: Lov, number: 371; Official Journal: Lovtidende A, number: 58, Publication date: 09/06/1989, Page: 1260, Entry into force: 07/06/1989*



Denmark

Before the Directive, Denmark had a set of rules developed in case law. Although liability was formally based on negligence it was virtually a strict liability

Case Skov *Æg* of 2006 (C 402/03), the ECJ disallowed the Danish article 10 on vicarious liability for distributors.



Golden rule

General protection regime

“When system vendors present you with contracts that immunize them from product liability, don’t sign them. Let the facts of the case dictate who has liability.”

M. Mello, JD, PhD, a professor of law and public health in the Harvard School of Public Health



Ethical issues in liability? →

Professional liability

- Does the existence of technology change what is expected of physicians?
- New legal duties to act on it?
- Failure to adopt EHR technologies may itself constitute a deviation from the standard of care?
- The law is as yet unclear in proportioning whether problems with EHRs arise from medical malpractice or product liability.



Product and professional liability

- Encounter between Liability and Privacy
- Encounter between liability and Medical device



I. v. Finland (2008)

The ECtHR awarded I. compensation for the wrongdoing of the public authorities.

Breaches of privacy can lead to claims of liability which can be awarded substantial compensation.



Armonas v. Lithuania (2008)

The ECtHR assessed whether the fixed sums compensation applied in Lithuania were in line with Article 8 ECHR.

Low compensation can constitute a violation of Article 8 ECHR and did not meet the expectations of just satisfaction



Conclusions

- Product liability relates to the liability of the producer for harm caused by its product
- Patient has the right to redress that is cause by defective products
- European liability law includes a strict seller's liability laid down in Directive 85/374/EEC of 25 July 1985: evolved in favour of the consumer



Conclusions

- Responsible and transparent systems for data processing must be built in
- Provide information by whom and when personal data have been accessed
- Notification of a breach is important
- Providing just satisfaction in the case of breaches



Thank you!

