The Ethics of e-Health, with a particular focus on privacy and medicalization

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A little about me

- I am a member of LSTS at Brussels Free University (VUB)
- My areas of research include
  - ✍Data protection in Health Care
  - ✍Legal issues related to eHealth and mHealth
  - ✍The rights of the aged in the information society
  - ✍Autonomy at the intersection between law and medical ethics
- ➢ ✍I have worked on a number of national and EU projects that involved aspects related to mHealth
- ➢ ✍e.g IRI, MOVINGLIFE, REACTION…

What I am going to talk about :

- Scenario of m/ehealth
- Data privacy issues but not only
- EU cautious approach to ehealth

Diana and Jacob

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- Mireille Hildebrandt, 2015. *Smart Technologies and the End (s) of Law: Novel Entanglements of Law and Technology*. Edward Elgar Publishing, p. 7.
- Scenario in which a young mother, rampant professional, Diana, and her frail old father, Jacob, navigate their days accompanied by a personal digital assistance (PDAs)
- All relevant biometrics are recorded, stored and communicated, as well as matched with relevant predictive profiles (p.7) at work, on the move, at the gym…
- Jacob: his mobile allows to "exchange information with similar devices from the same service provider, and with a number of healthcare service providers […] : Jacob's family doctor, the medical specialists who treat his various conditions, the insurance that covers the cost, the pharmacies that supply his medications, and the local nursing centre that provides him with hands-on medical care [.]"

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No longer science fiction

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"The invisible inferences of personalized risks and preference profiles will increasingly afford seamless, unobtrusive and subliminal adaptations of the environment to cater to a person's inferred preferences and to target, include or exclude her on the basis of inferred risks."

(Hildebrandt,M. 2015. op.cit., p. 7)

Cautious EU approach to e-health data processing

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- In the EU, medical data can be processed only in a restricted series of circumstances. The Regulation maintains the framework rules:
- a) explicit informed – written – consent of the 'data subject';
- b) a health professional subject to the obligation of confidentiality
- c) (when data are processed in)the public interest, in particular for scientific medical research (Article 8 Directive 95/46/EC).

EU mixed regulatory framework

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- General Data Protection Regulation: centrality of consent
- Codes of conduct
- Data protection by default and by design
- Data protection impact assessment when medical data is involved
- Consent v. anonymisation rule in research (and public interest?)
- Increased (unclear) role of Data Protection Authorities (for research)

Four areas of privacy concern…

- Around medical confidentiality: Where does the data go? Risks of function creep. Can they be assessed ? Can we trust markets, employers, insurance schemes ?
- Around control of the private life by a “wonderfully autonomous” patient who is careless about his or her data (ehealth is no gadget)
- Around the medicalisation of the behaviour of healthy subjects to reduce the “risks to a disease” : sick of it already??
- Around research ethics and the secondary uses of health data.

…that go beyond privacy

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- World Medical Association (WMA, 2015)
Statement on mhealth
200th WMA Council Session, Oslo, April 2015 (pp.72-75)
World Medical Journal, 61(2), of July 2015
http://www.wma.net/en/30publications/20journal/pdf/wmj201502.pdf

- Conseil national de l'Ordre des médecins
Santé connectée – de la santé à la santé connectée
January 2015
https://www.conseil-national.medecin.fr/sites/default/files/medecins-sante-connectee.pdf

Medical ethics	WMA and CNOM
Autonomy	Trust in medical profession and medical confidentiality Where does the data go? Can function creep be assessed ? Can we trust markets, employers, insurance schemes ?
Non Maleficience	Personal and mental integrity must be protected always Intervention = risks. These must be : - commensurate with its expected benefits - weighted on valid and reliable information ehealth should not be used to improve or to encourage to improve human species' performances
Beneficience	Benefits must be obvious or deducible Quality of valid data Transparent decision processes of the app
Justice	Digital divide (technical affinity, health competence, mental or physical impairments) Those who prefer not to mHealth Do not use ehelath to sort out best/worst risk profiles, good or bad patients

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Building bridges between data privacy and medical ethics may help to determine what can be done with mhealth and if it should be done

Area of Autonomy

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a. Awareness and self-determination also through promotion of health literacy

b. The right to withdraw and the right to live outside the information society

c. How to deliver comprehensive but tailored information to allow for an informed decision

Area of beneficience

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- The primary benefits for the affected persons must be obvious or deducible (purpose binding)
- What an app does must be achieved based on valid data (impact assessment)
- Decision processes of the app must be transparent (impact assessemnt)

Area of non-maleficence

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- As any medical act, also e-health interventions entails risks. These must be proven to be :
  - commensurate with its expected benefits
  - weighted on valid and reliable information.

Justice

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- eHealth interventions must be available to everyone, without discrimination also on grounds such as technical affinity, health competence, mental or physical impairments
- Which business/insurance model ? The CNIL, 'sleep apnea treatment', and public health cover only if patient accepts to be monitored

Action points

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- *How to enact a mistrusted controller model*
- Soft regulatory approach
- *The importance of medical justification for using ehealth in healthy subjects*

Thank you

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