„Infocommunication technologies and the society of the future (FuturICT.hu)" project
TÁMOP-4.2.2.C-11/1/KONV-2012-0013

How does the new Declaration of Helsinki approach to data privacy

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International Medical Informatics and Telemedicine Conference,
IMIT 2014, Genève, Switzerland, 13-15 April, 2014.

Content

- Some words about the Declaration of Helsinki
- The purpose of the Declaration
- The last amendment of 19th October 2013
- The origins of the last amendment
- How the data protection rules are to be changed in GDPR?

The history of Declaration of Helsinki

- World Medical Association (http://www.wma.net) was founded in 1947 by 27 victorious countries after ww2 in Prague
- Establish the highest ethical standards of the medical profession including research ethics
- Several declarations: Declaration of Geneva, Declaration of Washington, International Code of Medical Ethics
- Declaration of Helsinki in June 1964 (Ethical Principles for Medical Research Involving Human Subjects) originated from the Nuremberg Codex, 1947 (10 principles)

Paragraphs in the Declaration

- How to ask subjects for consent?
- How to give consent?
- Duties of the doctors
- The rights of the research subjects
- What if research subjects are minors?
- How to write a research protocol?
- The role of ethics committees
- Privacy and confidentiality
- Combining care with research
- Special attention to vulnerable groups
- Use of placebo in research
- …

Types of Medical Research

- With intervention
  - Research with clinical substances
  - New surgical methods
  - Obtaining human tissues
  - Psychologically demanding, etc.
- Without intervention (many times without presence of the research subjects)
  - Processing archived tissues (biobanks with consent)
  - *Processing medical data (existing or newly collected)*
- Obtaining consent is the fundamental question, but sometimes disproportionally hard in the case of research without intervention

Principles from the Declaration

- The voluntary informed consent of the human subject is essential, although the consent can be given by the legal representative in cases of legal incapacity preferably in writing
- The Human subject should be at liberty to bring the experiment to an end
- The subject or the subject's legal representative have freedom to withdraw consent at any time
- Refusal of research participation must not affect doctor–patient relationship
- In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results.
- An independent ethics committee shall review research protocols

The Declaration is changing

- II.5. If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee 1975.
- This was step-by-step removed until 2000.
- B.16. Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available 2000.

Data privacy in the Declaration

- Processing medical data or tissue is medical research (2000)
- For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee. (2008)
- For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such research. In such situations the research may be done only after consideration and approval of a research ethics committee. (2013)

Privacy rights of the subjects

- Potential subjects have to be informed even when research is done without consent
- Subjects may object or withdraw their implied consent even when research is done without consent
- If objection would pose a threat to the validity of the research then it is understood so that research subjects may not object
- This could be against the fundamental right to private life
- Therefore the „would pose a threat to the validity of the research" clause was deleted in 2013.

The role of the Declaration in Medical Research

- Moral obligation even when local legislation is different from it
- The common heritage of the mankind
- Many documents, declarations and conventions originated from it
- Council of Europe, Oviedo Treaty, ETS-164 (1997)
- The European Group on Ethics in Science and New Technologies (EGE) Group Initiative: Ethical issues of healthcare in the information society, opinion No. 13, 1999.
- UNESCO Universal Declaration on Bioethics and Human Rights (2005).

Medical database research

- What sorts of processing is medical research?
  - Management or quality improvement is not research
  - Preventing epidemics, public health is not research
- What is *identifiable* data?
  - Coded and pseudonymized data
  - De-identified data
- What is *impractical*?

- The EDPS letter to the European Parliament concerning to GDPR (General Data Protection Regulation), 15th March 2013.
- Pseudonymized data is not anonymous according to the 95/46/EC directive

Research or Quality Assurance?

- In a Hungarian scientific journal appeared a paper about the following story (March, 2014):
- The staff for quality improvement decided to inspect the quality of care documents,
- They chose randomly 80 inpatient cases and inspected the completeness of the documentation
- When they found negligence they warned doctors
- They publish their result in a paper and advise similar action to other hospitals.
- Is it a research or not?
- They did not inform the patients, did not obtain consent

What is impractical?

- NGIB (National Information Governance Board), 19th April, 2012
- Principles of Decision-Making: Exploring the concepts of 'Public Interest' and 'Reasonably Practicable', section 2.4.
- An analysis about the topic (guideline)
- Obtaining consent is impractical when:
  - It is impossible
  - When large number of subjects
  - In emergency care
  - When many subjects are anticipated to dissent

Events before the amendment of the Declaration of Helsinki

- The European Parliament is working on the GDPR (General Data Protection Regulation)
- Companies and research institutes want to execute their right to process medical data for research purposes in their legitimate interests or claiming that it is in public interests according to the 95/46/EC data protection directive, see Care.Data project
- The nomination of the second Caldicott Committee in June 2011, and its final report in March 2013
- Patients movement to opt-out (http://www.thebigoptout.org) from the national medical database (Connected for health)
- The Department of Health supported the Caldicott Report and advised to amend the Declaration of Helsinki in Summer 2013.

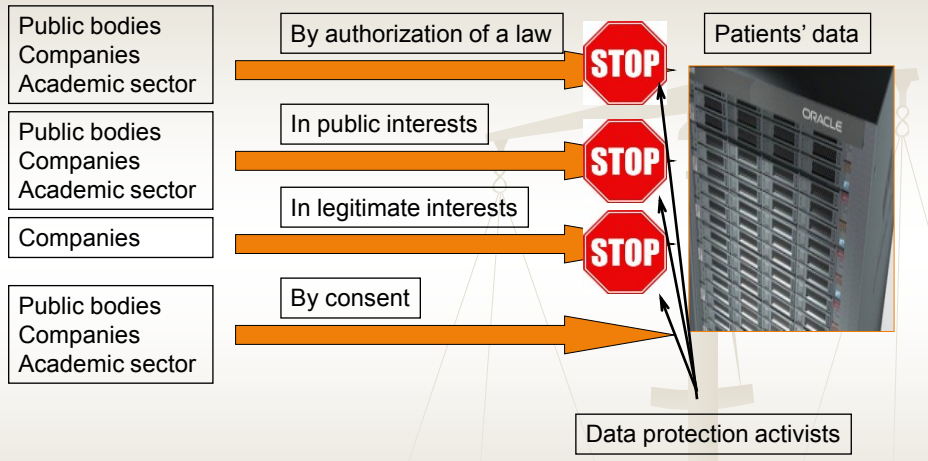
EU 95/46/EC Data protection directive

- Article 7. Member States shall provide that personal data may be processed only if:
  - (a) the data subject has given his consent; or
  - (b) processing is necessary for the performance of a contract to which the data subject is party; or
  - (c) processing is necessary for compliance with a legal obligation to which the controller is subject; or
  - (d) processing is necessary in order to protect the vital interests of the data subject; or
  - (e) processing is necessary for the performance of a task carried out in the public interest; or
  - (f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by the third party.

Legal bases for data processing

Type	Interests	Preliminary information	Right to object	Right to legal remedy
Obligatory by law	Higher-level interests of the society	Not needed	No	No
Permitted by law	Public interest	Yes	Yes	Yes
	Legitimate interest	Yes	Yes	Yes
Consented		Yes	Withdraw consent	

Research on patients' data

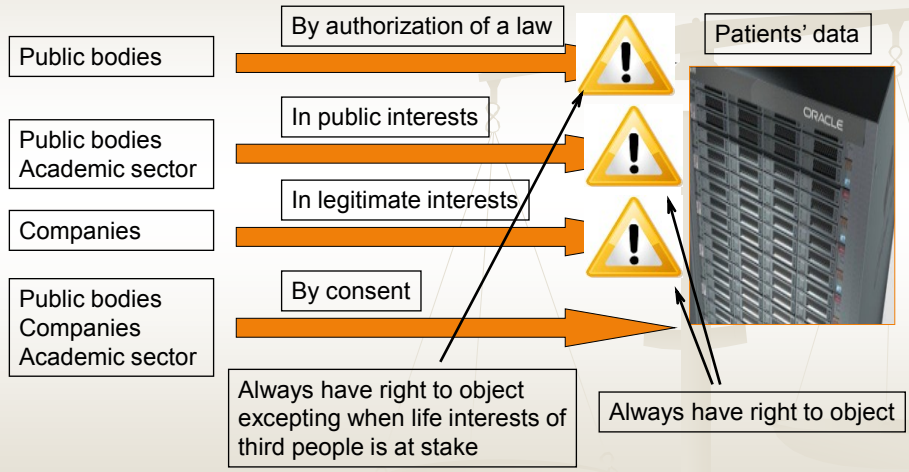


Consent or dissent?

- In April 2012 in Hungary the repository of National Health Insurance Fund was open for doctors
- It contains 15 year-long history of care accounting information about patients
- First consent was required – 800 people objected until 31st December 2012
- The policy then changed, if somebody wants to object then have to fill in a form and submit to the Health Insurance Fund
- In 2013 less than 200 people objected, altogether less than 1000, (0.01% of the population)
- It is quite similar to the UK case
- Right to object shall be respected, the others seems comfortable with their data being processed.

The new GDPR

Status on 25th October 2013.



Return to the recommendation R(97) No. 5. of the Council of Europe

- Article 4.3 Medical data may be collected and processed:
  - a. if provided for by law for (obligatory):
    - i. public health reasons [+**minimum data condition**]; or
    - ii. subject to Principle 4.8, the prevention of a real danger or the suppression of a specific criminal offence [+**minimum data condition**]; or
    - iii. another important public interest [**with right to object**]; or
  - b. if permitted by law:
    - i. for preventive medical purposes or for diagnostic or for therapeutic purposes with regard to the data subject or a relative in the genetic line [**with right to object**]; or
    - ii. to safeguard the vital interests of the data subject or of a third person; or
    - iii. for the fulfilment of specific contractual obligations; or
    - iv. to establish, exercise or defend a legal claim; or
  - c. if the data subject or his/her legal representative or an authority or any person or body provided for by law has given his/her consent for one or more purposes, and in so far as domestic law does not provide otherwise.

Summary

- The GDPR is planned to be accepted by the new European Parliament in Autumn
- It will be entered into force from 1st January 2016 (?)
- Information about data processing will be obligatory even if consent is not required
- Processing large medical databases (not only for the purposes of the research) will not need to obtain consent, but the *general* right to object is provided to the data subjects instead
- Obligatory data processing for the purposes of preventing cross-border epidemics, monitoring public health, health insurance will be allowed. The law shall be approved by the European Commission
- The approval of the ethics committee will be needed in wider circle of cases.

Thanks for the attention!

Who am I

- Since 2004, I began studying privacy issues
- Member of a regional medical research ethics committee
- Member of the Association on Fair Data Processing
- Member of the presidential board of the Hungarian Data Protection Society
- Blogger (www.magyarorszag.hu, www.tisztessegesadatkezeles.hu)
- Has cases before Civil Courts, Hungarian Constitutional Court, European Commission, ECtHR on fundamental questions of medical data processing
- Achievements: excluding unsubsidized care events from the National Health Insurance Fund database, ethics approval of medical research projects without intervention

http://www.cost.eu/domains_actions/ict/Actions/IC1206