

Medical research: the importance of consent

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The importance of consent

- The Council's draft of the Data Protection Reg allows secondary uses of all medical data without consent (the "research exemption". The data may be required to be "pseudo-anonymised").
- Concerns about (i) government surveillance; and (ii) commercial exploitation of health data and genomes (especially for personalised marketing).
- Incompatible with Helsinki Declaration and ethical norms; incompatible with Art. 8 ECHR (indefinite retention of biometrics without consent).
- Potential for massive loss of public trust in legitimate medical research.
- In contrast, the EP's draft is compatible with human rights.

Pseudo-anonymisation of data

- Allows further data sets to be linked in (e.g. education, social care, tax) increasing risk of de-identification and rendering privacy meaningless.
- Allows re-linking of personal risk assessments back to individuals i.e. monetisation, including commercial exploitation through personalised marketing.
- Thus, sharing pseudo-anonymised data is very different to sharing anonymised data.

Commercial exploitation

- The monetisation of prevention i.e. marketing of medicines, supplements, functional foods, skin creams etc. to persons identified as at risk of disease (and their relatives).
- Current legislation puts research data “beyond use” for commercial purposes if it is not collected with consent, but the Council’s proposals allow re-linking and feedback of risk assessments to individuals, via “click on” consent to feedback and marketing use as a “legitimate purpose”.
- Route to screening (healthy) people without medical justification. The “pre symptomatic” patient.
- Selling tests is not very profitable but doubling the market for drugs to healthy people is. This (not new drugs) is the main commercial driver for many companies.
- Genetic tests generally have poor predictive value. Significant risks of overtreatment and waste of health resources. Big shift in power and control over prognosis/diagnosis from the public sector/medical profession to the private sector.

Google and your genome

- Google has been discussing access to UK electronic medical records and genomes with the Government since at least 2008. Plans a new UK HQ in 2017.
- The Wellcome Trust has drawn up a plan to attach the whole population's genomes to medical records as a public private partnership. This is not expected to be achievable with consent as most people would not volunteer (about 7% joined UK Biobank).
- Google-funded gene testing company 23andMe is now selling DTC genetic tests in high street stores and says it wants to calculate health risks for the whole UK population.
- Feedback of risk assessments developed using data collected without consent would allow Google to monetise prevention to whole populations.

Genomes are biometrics (dual use technology)

- Your genome is like a “genetic fingerprint” which links your data to your bodily characteristics.
- It can also be used to identify your relatives.
- Police and security services can gain access to data stored in the cloud, including on foreign servers (Edward Snowden revelations, wikileaks).
- Indefinite retention of genomes without consent would mean a DNA database of the entire population of the EU could be built without people’s knowledge or consent.
- This would also be shared with private companies.

Ethical and human rights standards

- The Helsinki Declaration and the European Convention on Biomedicine require fully informed consent: privacy protection is not the only driver, people should also be informed of conflicts-of-interest. Medical professionals cannot meet these obligations if data is widely shared without consent.
- Unanimous judgment of the ECtHR in *In S. and Marper v. the UK* (2008) that the UK could not retain biological samples and DNA profiles from innocent people indefinitely without consent (this is not necessary or proportionate in a democratic society).
- The Council text is not compatible with these legal obligations.

Public trust

- In the UK, there have been many (so far) failed attempts to build a database of NHS records, allow commercial exploitation and include genomes without consent (first proposed by SKB, forerunner of GSK, in 1999).
- Attempts to build databases and share health records with private companies have been highly controversial (e.g. the Spine, Clause 152, “care.data”: 700,000 opt outs currently not implemented).
- Retaining innocent people’s DNA profiles on the UK police National DNA database was also highly controversial.
- There is potential for a massive loss of public trust in medical research if consent requirements are removed.

Implications for EU countries that want stricter safeguards

- The proposed new text allows Member States to implement stricter safeguards, but does not require these.
- The requirement for free data flows within the EU means that any cross-border sharing of data for research or medical purposes could result in this being stored indefinitely in other countries, or shared with commercial companies without consent.
- The EU should in any case ensure that human rights and ethical safeguards are implemented at EU level, to protect all citizens and provide an example to non-EU countries.

Conclusions

- The main commercial driver for getting rid of consent is not drug discovery but monetising prevention through personalised advertising (expanding the market for health products).
- Building DNA databases without consent also creates a “surveillance state”, allowing every individual and their relatives to be tracked.
- The Council’s draft removes all controls, allowing people no say over where their data ends up and no “right to be forgotten”. Data can be stored and used against people’s wishes: likely to be highly controversial.
- The proposals are not compatible with ethical norms and human rights e.g. the Helsinki Declaration and Art. 8 ECHR.
- In contrast, the EP’s proposal retains the requirement for consent to use of health data for research