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Open consent: why not?

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Outline

Five main arguments for open consent:

- Changes in ethics, context important
- The duty argument
- Misleading to trade privacy for consent
- Veracity' the better principle
- Why so concerned about privacy?

‘

Outline continued

Four main arguments against:

- Watering down of ethics for convenience?
- Risks
- Social context
- Will discourage participation?

Conclusion: ethics and pragmatism

Ethical principles: source and point

- Ethics – discovered or invented?
- Discovery – revealed religion, ‘natural’ rights
- If invention (e.g., as part of human evolution), what job is it supposed to do?
- Ethics deals with areas of life where interests conflict

Ethics and conflicts of interests

- Different interests of different people e.g. power versus freedom
- Different interests of same people e.g. liberty versus security
- Same interests of different people e.g. health care resources

Human condition

- Limited resources
- Limited knowledge
- Limited wisdom
- Limited sympathies

Central principles

- Integrity and security of the person a central concern on any picture
- The particular form of this that is the doctrine of **informed consent** emerged in a particular context
- We cannot assume that it is *simply* transferable to another context
- The context for biomedical research has changed

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The change

- ‘Emerging trends in ethics’ Knoppers and Chadwick, *Nature Reviews Genetics* 2005
- Science has a value impact
- Shift towards solidarity and reciprocity
- Both the risks and the benefits to participants different
- Focus on information and data-sharing

The **issues**: international data-sharing

3 categories

- The data
- The infrastructure
- The framework of interpretation

The data

- Informatisation of the body (van der Ploeg)
- Identifying information
- Collection, storage, sharing and access
- Interoperability and exchange
- Values and interests in tension (privacy seen as central issue here)

The infrastructure

- Privacy threatening technologies
- Privacy enhancing technologies (PETS)
- The ‘design turn’ in ethics
- Governance instruments (ethics and regulation, e.g European Directives)

Frameworks of interpretation

- Conceptual
- Ethical
- Social context
- Different spheres (security, health)
- Different **meanings**

Health: rationale for data sharing in biobanks

- Biomedical quality-assessed samples and data as well as biomolecular resources and molecular analysis tools are essential for clinical, academic and commercially-driven research to treat and prevent common and rare human diseases, including cancer. Although currently established biobanks and biomolecular resources are a unique European strength, valuable national collections typically suffer from fragmentation of the European biobanking-related research community.

Argument for ‘open consent’

- Traditional informed consent does not work in biobanking
- Hence development of broad consent etc
- ‘Minimal risk’ – consent in exchange for privacy protection
- International dimension introduces further aspects to the issue
- Strengthen or rethink ethical principles?

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Duty to participate in biomedical research?

- There has long been another strand of argument that there is a duty to participate in biomedical research
- Reinforced by turn to solidarity etc
- Emphasises benefits to society
- Also relevant to open consent

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Privacy no more...

Developments in both medical informatics and bioinformatics show that the guarantee of absolute privacy and confidentiality is not a promise that medical and scientific researchers can deliver any longer

(Lunshof, Chadwick et al, *Nature Reviews Genetics* April 2008)

Aspects of privacy

- Informational privacy concerned with limits on access to personal information – confidentiality, anonymity and secrecy are related concepts
- Genetic privacy emerged following the disclosure of the ‘invisible’ part of heredity at the molecular level as opposed to individual and family health history

Aspects of privacy

- Cf ‘informatisation of the body’
- Now rapid advances in sequencing – comprehensive data sets to establish informatics links among ten thousand to a million human genome sequences and extensive phenotype analyses enable the identification of individuals whose sequences they contain

Group privacy

- Whether it is based on genetic or other traits, conventional individual privacy protection misses the point. It does not work in the case of non-distributive generalisations about groups in which the individual profile is indiscernible from the group profile.

Categorical privacy

- The concept of ‘categorical privacy’ has been proposed to overcome the inadequacies of traditional individual-centred concepts.

Threats to privacy

- Privacy can be violated by forces beyond individual or institutional control
- Reidentification of individuals is possible through genotype - phenotype inference, and 'dictionary attacks'.

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From privacy to **veracity**

Individuals should realize that their data can be and likely will be accessed, shared and linked to other sets of information, and that the full purpose and the extent of further usage cannot be foreseen.

Alternative solutions are scarce. The most likely pragmatic solution would entail maximizing data protection while informing people about its limits.

Open consent

- Research participants expect that:
 - Their data could be included in an open access public database
 - No guarantees regarding privacy etc
 - Participation involves a certain risk to self and others
 - Participation does not benefit participants in any way

Open consent continued

- Compliance with monitoring of well-being is required
- Withdrawal is possible at any time
- Complete removal of data that have been available in the public domain may not be possible

Moral goal of open consent

- To obtain valid consent by effectuating veracity as a precondition for valid consent and effectuating voluntariness through strict eligibility criteria, as a precondition for substantial informed consent

Personal genome project

- **Why Participate in the PGP?**
- **Medical Advancement**
- Scientific research is an ongoing source of hope for individuals and families affected by illness. The promise of improved diagnoses, therapies, and prevention strategies has motivated many individuals to get more directly involved in the promotion of scientific research on conditions affecting themselves and their family members. Disease advocates have made significant contributions to medical advancement and human welfare.

Personal genome project

- **III. Privacy**
- We question the [long-held belief](#) that research endeavors involving human genome sequencing can guarantee, in perpetuity, the confidentiality or anonymity of the information revealed from a personal genome sequence. For example, it is becoming easier to glean personally identifiable knowledge from DNA sequences, including hair and eye color, height, and facial features. Protecting the identity of individuals is particularly difficult while the number of personal genome sequences existing in the world is small.

Full data release

- We want to avoid any potentially negative outcomes, both for participants personally and for the integrity of the project itself, should a participant's data get exposed without their expressed prior consent, via accidental events or carelessness or other causes.
- We feel the most ethical and practical solution to these risks at this time is for volunteers to be recruited, consented, and enrolled based on the expectation of full public data release and to purposefully exclude any promises of permanent confidentiality or anonymity. This approach may change as the possibilities and challenges become more clear.

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Collective self-deception?

- Privacy in different spheres:
 - Biometrics
 - Surveillance
 - Facebook
- Even if we could fully rely on data protection, requires a rethink

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Conclusion: ethics and pragmatism

Ethics at risk?

- Rationalisation for convenience?
- Value impact (cf reproductive technologies)
- Slippery slopes

Social context

- Potentially affects both:
 - Potential consequences for participants
 - Perception of publics in different contexts

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Conclusions

- When values or principles are in tension, different approaches include trade-off, or trumping
- From an ethical point of view, *in principle* open consent is an acceptable way of balancing respect for individual participants with goals of research

Conclusions cont.

- This is taking into account the job that ethics has to do in a particular context/sphere
- However, from a pragmatic point of view, this requires attention to social context, and preparation, identification of areas of possible conflict and listening to less heard voices
- cf discussions about ‘opt-in’ and ‘opt out’ in different contexts

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