Vilhjálmur Árnason

Biobanks

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The issues

- Obtaining information
- The question of consent
  - articles 24 and 25
- Protecting information
- Access to information
  - Article 23
- Returning information
  - article 33

What kind of biobanks?

- In my discussion, I am concerned with organized collection of human biological samples – and the data (medical, genealogical, life-style) associated with them – used for research purposes. In particular, I have in mind large population-based biobanks as resources for genetic research
- These biobanks have raised various challenges for existing ethical frameworks, but I will only address three which are pertinant for a possible revision of DoH

Entering a biobank

- A major ethical challenge raised by biobanks concerns the question of consent
- The DoH states (art 24)
  - In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, … the anticipated benefits and potential risks of the study and the discomfort it may entail …
- This is ill suited for database/biobanks research where future research uses cannot be specified at the time of consent which might require frequent recontact. Hence the need for a separate article:

Article 25 (2008)

- “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.”

Analysis

- Specific informed consent no longer required
  - "consent for collection, analysis, storage and/or reuse"
- Is this sufficient?
- It depends on how "consent" is fleshed out
- Two main options
- One time open consent
- Wide consent with the right to withdraw

Permission based on trust

- Open consent relying on ethics committees to decide on the use of samples
- It is debated whether this can be regarded as a consent at all since the participants‘ decision is not based on any knowledge of the use of the samples. It is a permission based on trust
  - One argument for this policy is that it would maximize the research flexibility and thus the benefits to be reaped from the biobanks resource

The question of benefits

- Clear public benefits can be used as an argument to counter emphasis on consent (context of reciprocity). The medical benefits of population biobank research remain controversial.
- The ethos of voluntariness (DoH, 22), the objectives of non-deception and non-coercion, are also important public benefits or interests at stake
  - Participants should not be regarded as a passive resource to be mined for maximum benefits, restricting ethical issues to those of protection and security. There is a public interest in facilitating conditions for agency

Consent with a right to withdraw

- The ethos of voluntariness and the ethos of trust can be reconciled through a policy of a broad consent for participation in biobank research, provided that participants
  - are informed on a regular bases of the nature of the ongoing research using the biobank
  - are given ways to withdraw from particular research projects
  - these procedures would underpin trust and public awareness/engagement

A suggestion

- Change to article 25
  - “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 all cases, participants should be informed of ongoing research and have a right to withdraw. The** research may be done only after consideration and approval of a research ethics committee.”

Protection

- Secure protection of confidentiality of samples should not be used as a reason against obtaining consent or the right to withdraw from research
- It should serve as a reason for participants to decide whether to enter samples into biobanks and not withdrawing from research projects
- This amounts to controlling access to the data and their use and ensuring that medical and personal information is exclusively used for research purposes and is not shared with third parties

Returning information

- While samples have been collected for many biobanks with the intention of doing basic genetic research for production of generalizable knowledge, the question of responsible return of information to individuals is increasingly discussed.
- This relates to DoH, article 33
  - At the conclusion of the study, patients entered into the study are entitled to be informed about the outcome of the study and to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

Guidelines

- Managing return needs to be based on the ethical principles of non-maleficence, beneficence and respect for autonomy
- Incidental findings should be returned iff they
  - are analytically valid
  - reveal risk of a serious health condition that can be acted upon, cured or prevented
  - There is no indication that the recipient would prefer not to know

Responsible return

- Was the question of return raised in the initial consent form?
- Answer to this does not provide a necessary condition for returning results. This needs to be assessed in a context of clinical counselling.
- The relevant thing is to find out whether people would like to be informed of a genetic finding for which there are established therapeutic or preventive interventions or other available actions that might change the clinical course of the disease.

Addition to DoH

- In light of recent developments in biobanks research and future prospects, there is a need to add a statement about return of findings in the DoH
- This could possibly be done by adding a sentence to article 33 that would specifically address responsible return of incidental findings in the course of research on human material or by a short new article.

Sources

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Thank you!