Good biobank governance in the age of personalized medicine:

From theory to practice

Presentation held at the University of Hong Kong 06 11 2018

Disclaimer

The opinions expressed in this presentation and on the following slides are solely those of the presenter and not necessarily those of ISBER or of the presenter's two employers, Norges teknisk-naturvitenskapelige universitet (NTNU) and St. Olav's hospital HF.

My personal «journey» in biobanking

- 1998: 1. contact with Professor Jostein Holmen, one of the founders of HUNT – https://www.ntnu.edu/hunt
- 2001: Part of national delegation to visit the Umeå Biobank (Sweden), including spin-out Uman Genomics AB
- 2002: Published article on ownership and user rights to human biological material (in Norwegian, publication «Lov & Rett»)
- 2003: 1.contact with Professor Jostein Halgunset, The Regional Hospital of South Trøndelag
- 2005-2007: Involved in most of the legal work related to setting up HUNT Biosciences AS, including drafting a custodianship agreement
- 2011: Revision of the HUNT Bio custodianship agreement
- 2013 - 2015: Employed part time as General Counsel at HUNT Biosciences AS/Lifandis AS
- 2014: Co-author «Beste praksis for norske biobanker» (BioBank Norway)
- 2014: Co-author «A comparative analysis of the requirements for the use of data in biobanks based in Finland, Germany, the Netherlands, Norway and the UK « (Medical International Law)
- 2017: Appointed as new Member of the ISBER Governance Committee, jf http://www.isber.org/

What is a (research)biobank?

- The **Norwegian Health Research Act of 2009**:

«A collection of human biological material that is used in a research project or shall be used in research.»

- **Belgian law (Royal Decree 2018):** «the structure which, for the purposes of scientific research, with the exception of research with human medical applications, obtains, when appropriate treats, stores and makes available human body material, as well as, human body and donor data if the opportunity arises."

- A **possible <u>alternative</u> definition** *(de lege ferenda/as the law should be)*:

A business or part of a business that has as its main purpose to collect/obtain and manage human biological material; including any data and metadata pertaining to such material, for use in research.

What is personalized medicine (PM)?

*"**Personalized medicine** or precision medicine, is a medical model that separates people into different groups—with medical decisions, practices, interventions and/or products being tailored to the individual patient based on their predicted response or risk of disease. The terms personalized medicine, precision medicine, stratified medicine and P4 medicine are used interchangeably to describe this concept, though some authors and organisations use these expressions separately to indicate particular nuances.*

While the tailoring of treatment to patients dates back at least to the time of Hippocrates, the term has risen in usage in recent years given the growth of new diagnostic and informatics approaches that provide understanding of the molecular basis of disease, particularly genomics. This provides a clear evidence base on which to stratify (group) related patients."

(Quotation from Wikipedia)

What is governance?

"On the most basic level, governance means the management of interdependencies. The concept signifies a shift from a centralized decision making and implementation process (government) towards a more dispersed mode of collective ordering, in which process participants agree on collaborating for the purpose of a (set of) common aim(s) (Mayntz 1993; Nowotny and Testa 2011). On the one hand, this does not mean that governing activities by political institutions and public administrations are not involved in managing these interdependencies any longer and top-down decision making processes can be neglected altogether (Peters and Pierre 1998). Obviously government action with regard to funding and regulation has to be an important element in every analysis of biobank governance (see "Biobanks and models for financing research infrastructures" and "Ethics in biobank governance: connecting and separating biobanks from its body constituency"). On the other hand, biobank governance processes have been too often reduced to building a stable legal framework and ethical environment for biobank projects by creating different types of regulation."

(Quotation from «**Biobank governance: heterogenious modes of ordering and democratization», H. Gottweis and G. Lauss, Journal of Community Genetics, 2012**)

A claim: PM increases the complexity and interdependencies in the biobanking business

- The demand for samples and data will (typically) not be satisfied by one biobank alone
- National and international biobank networks, collaborations/PPPs and non- profit interest organizations/RIs all play an increasingly important role in supporting biobanks and satisfying biobank customers:
  - National biobank networks: Biobank Norway and Biobank Sweden
  - Large Population-based biobanks: UK Biobank
  - International non-profit interest organisations and research infrastructures (RIs):
    - ISBER - https://www.isber.org/
    - BBMRI–ERIC - http://www.bbmri-eric.eu/
    - ESBB - https://esbb.org/
- PM and genetics also create unique business opportunities for commercial companies
  - A need for cross-sectorial Knowledge Transfer and Open Innovation actions

  Two interesting examples from the Nordics: (a) deCODE genetics (Iceland)
  (b) FARGEN (the Faroe Islands)

Words matter: If personalized, it is personal

- A claim: Perception is «everything»
- Probable effects on donors/patients perception of biobanks and the relative importance of their own biological material
- If a shift in donor perception is occuring or is likely to occur in the near future:
  - What to do?
  - My recommendation: Three focus areas for good governance in the time to come:
    - Increased stakeholder involvement
    - Data management and privacy
    - Return of Individual Research Results

Increased stakeholder engagement: Key to future biobank governance

- The stakeholder landscape
- Trust is a key asset in biobanking
  - Hard to build, easy to lose
  - Typically decreases with increased geographical distance between donors and end users
  - Typically decreases when end users are commercial entities
- A variety of potential engagement actions are available

Some examples:

- Include lay people in the biobank board (if applicable)
- Interact/collaborate with patient interest organisations
- Hire an engagement specialist as part of the biobank staff

Big Data: Data management and privacy as critical biobank sustainability factors

- PM creates Big Data, typically through genotyping large cohorts
- As analytical tool capacities increase, anonymity becomes increasingly difficult to promise and de facto secure
- Health data lost/out of control is a major threat to the trust relationship between biobanks and donors/patients
  - Theory: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5791870/
  - Practice: https://www.theguardian.com/society/2017/oct/16/nhs-data-loss-scandal-deepens-with-162000-more-files-missing
- The General Data Protection Regulation (GDPR): Reshaping data privacy in Europe:
  - Some new rules
  - But mostly about a new enforcement scenario if non-compliant

Return of Individual Research Results (IRRs): No longer an option, but a must?

- A possible definition of IRRs: *«results discovered during the course of research, which concern an individual participant, and having potential health or reproductive impact.»* *(Knoppers et al: Population studies: return of research results and incidental findings policy statement, Eur J Hum Genet 2012)*

- *The donor/patient must always be given the choice <u>not</u> to receive such results.*

- *Just actionable results or more?*

- *Responsible return of IRRs poses substantial challenges to biobanks, both in terms of governance (including procedures) and resources*
  - *a definite need for close, interdisiplinary interaction/collaboration*

Thank you for your attention!