Time, top ten innovations of 2009

Biobanks: Typology and Overview

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Biobanks: Basic Definition

- Organized collections of human biol. material w/in health care systems & the med. sciences
- Often combined w/ some of the following info:
  - Personal, Medical (records), Genealogical, Environmental, Lifestyle
  - Richer the data set, more value
- Cf. “genomic database”

Two main types

1. Collections of biological specimens from patients or donors

2. Population-based biobanks with biological samples from (parts of) the general public, with or without disease

(new IT and genotyping changes their value)

Retrospective v. prospective distinction: distinction with a difference

- Unforeseen uses of previously collected material
  - Pathology collections (e.g., hospitals, army)
  - Dried blood spot collections
- Prospective collections
  - Population genomics (general population or special group)
    - UK Biobank, HapMap, Havasupai

Diverse agencies

Public

- State agencies, state operated (V.A., Children's Health Study, U.K. Biobank)

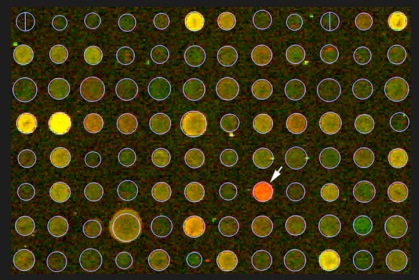
Private

- Tissue purchase and lease operations
- Pharmaceutical companies
- Genetic testing companies
- Private clinics care orgs.

Quasi public

- Non-profit clinical care + research institutions (AMCs)
- Non-profit HMOs (Kaiser)
- Consumer organized disease banks (Genetic Alliance)

The potential value of disease biobanks



- Discovery of biomarkers using e.g. protein arrays, genomic analysis, gene expression analysis to:
  - Indicate present disease state
  - Predict future disease state
  - Predict responsiveness to drug therapy (companion diagnostics)

- Pharma interested in tissue banks as labs of "personalized medicine"

Potential value of population biobanks

- Useful to have large-scale collections of biological materials that can be genotyped, along with rich sets of phenotypic and environmental data
- Find factors of disease through correlations, and develop drug targets or genetic markers for PGx
- Disappointing results on common diseases from GWAS studies to date; movement toward “rare alleles” and sub-poputions

Limits on the research use of tissue:

OHRP Guidance on Biological Specimens (2008)

1. obtaining *identifiable* info or a specimen for research purposes = human subject research;
   - The act of collecting itself is considered research
   - Samples/info of the deceased don't qualify as "human subjects"

2. doing research on coded samples and or phenotypic info falls → outside the regulations
   - (so long as contractual provisions in place preventing the investigator from access to the key)

Regulatory gaps under the Common Rule

- Acceptability of broad consent with de-identification
- No right to withdraw sample or leave research
- No representation or formal accountability to participants
- No constraints on sale or lease of tissue

My own work on biobank governance

- Research biobanks are at the center of a complex web of ethical interests and obligations involving:
  1. The aggregating institution
  2. Individual donor-participants
  3. The donor-participant collective
  4. The public

- Biobank aggregators are currently making important choices about how to invest the commercial and research value of biobanks

- We need more transparent constitutions (and power sharing?), because aggregating institutions may not adequately represent the other stakeholders