Ethical Issues in Pathogen Genomics

Benjamin E. Berkman

Faculty, NIH Department of Bioethics

Associate Investigator, National Human Genome Research Institute

7/22/24

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

NIH National Human Genome Research Institute

The **Forefront** of **Genomics**®

Disclaimer

- These arguments are those of the presenter and do not necessarily reflect the official views and policies of DHHS, NIH, or NHGRI.

NHGRI

Pathogen Genomics and Research Ethics

- Pathogen genomics ≠ research with human subjects
  - Deidentified samples don't generally raise the same kind of ethical concerns
  - Typically don't require IRB oversight
- But…
  - Newborn bloodspot controversy
  - Repurposing of samples in a pandemic
  - Reidentification
  - HeLa
  - Paired human-pathogen genomic research

NIH Genomic Data Sharing Policy

- Facilitates sharing of large-scale genomic data in NIH-funded research
  - Aggregation of data to analyze complex questions
- Human and non-human genomic data
- Investigators must have a data sharing plan
- Data deposited in a repository
  - Public or controlled access
- Institutional certification
  - Stipulating appropriate secondary uses of submitted data

Data Sharing: Policy Challenges

- Consent (for samples obtained from humans)
  - Expectation of explicit consent; encouragement to obtain consent for future secondary use and broad sharing of genomic (and phenotypic) data
- Older samples (pre-January 25, 2015)
  - Consent language that is not inconsistent with sharing
- Who reviews data sharing plans? Using what criteria?
- Data repository design and long-term maintenance?
- Burden of data deposition
- What counts as a substantial data set?
- When/how to grant an exemption from the requirement to share?
  - Informed consent, privacy, legal rules, contractual restrictions, feasibility

General Ethical Issues

- [Genomic sovereignty/ownership of samples]
- Individual harms
  - Psychosocial (e.g., anxiety, embarrassment, stigma)
  - Economic (e.g., workplace or insurance discrimination)
  - Non-welfare (e.g., autonomy violations)
- Group harms
  - Deidentify populations at a community level
  - Data use limitations

Ethical Issues: Repurposing

- Seattle Flu Study example
  - Repurposing samples collected for surveillance of flu to ascertain very early COVID cases
- IRB endorsed repurposing, but there was federal and state bureaucratic resistance
- When does a public health emergency justify relaxing protections for human research subjects?

Berkman BE, Mastroianni A, Jamal L, Solis C, Taylor H, Hull SC. The Ethics of Repurposing Previously Collected Research Biospecimens in an Infectious Disease Pandemic. *Ethics and Human Research* 43:1-17 (2021).

Ethical Issues: Democratization

- Open data movement: Proponents argue that anyone should be free to access and use data set
- Should non-traditional researchers (NTRs) be allowed to access broadly shared research data sets containing individual level data?
  - Citizen scientists (i.e., people without formal training and/or a formal institutional affiliation)
- Pros
  - More people = more discoveries
  - Novel scientific question and perspectives
- Cons
  - Adequate training/skills?
  - Reidentification, individual privacy concerns, group harms
  - Data misuse
    - Laundering malignant views and misinformation for ideologically motivated aims

New Models for Ethical Oversight of Pathogen Genomics

- The Common Rule (and IRBs) are often criticized for being too focused on traditional biomedical research
  - Particularly individual risks and benefits
- Public Health Emergency Research Review Board (PHERRB)
- Public health focused review could:
  - Develop unique expertise
  - Complementary perspective/framework
  - Transparency
  - Maintain trust in the public health system
  - Regulatory flexibility in an emergency

Summary

- Ethics of research with human subjects is an imperfect fit with the field of pathogen genomics, but can provide some important lessons
- NIH genomic data sharing policy can be a model for broad sharing beyond NIH-funded research
- Group harms > individual harms
- Unresolved issues
  - Repurposing
  - Opening data access to NTRs
- Public Health IRB?

Thank you

berkmanbe@mail.nih.gov