

Ethical Implications of Genomic Data Sharing

Charmaine Royal, Ph.D.

Secretary's Advisory Committee on Genetic, Health, and Society

October 9, 2009

Issue Statement

- Collection and broad sharing of individual genomic data facilitates important research but sharing such data, even when de-identified, has ethical implications for consent, privacy, and discrimination
- Questions of interest include
 - What are the implications for consent and communication efforts if research participants are informed of findings on an ongoing basis?
 - How will genomic data sharing blur the boundaries between research and clinical practice?
 - Does genomic data provide a unique identifier that can be linked with data obtained or stored in other contexts?
 - What are the implications for privacy protections?

SACGHS Activities to Date

- In Dec. 2008, SACGHS identified ethical implications of genomic data sharing as one of its seven priority areas for future consideration and study
- In March 2009, SACGHS was briefed about recent developments:
 - IOM report *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*
 - Considerations of informed consent by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children

SACGHS Activities to Date

- At the end of the March session, SACGHS suggested that efforts be made to collaborate with the following groups:
 - HHS Office for Civil Rights
 - Secretary's Advisory Committee on Human Research Protections
 - Secretary's Advisory Committee on Heritable Disorders in Newborns and Children
 - Health Information Technology Policy Committee
 - Health Information Technology Standards Committee

Current Status

- SACGHS staff has explored collaborative approaches with other groups
- In September, the HHS Office of the Assistant Secretary for Planning and Evaluation awarded a 1-year contract to The Lewin Group to develop a report for the Department on key policy questions, based on a review of published and unpublished literature and interview with experts. The contract is also designed to provide analytical support for SACGHS' efforts and help facilitate the Committee's discussions.
- To complement the Lewin Group study, we are proposing a session to explore models of genomic data sharing

Goal for Today's Discussion

Come to consensus about action steps to continue the Committee's work on ethical implications of genomic data sharing

Proposed Action Steps

Formation of a steering group to:

- Explore models of genomic data sharing and usage through a session at the February 4-5, 2010, meeting
- Provide input to the work of The Lewin Group, as appropriate

Questions for Discussion

- Should SACGHS organize a session for the February 2010 meeting that examines models of genomic data sharing and usage?
- Should SACGHS form a steering committee to help organize the February 2010 session, if held, and provide input, as appropriate, to the work of The Lewin Group?
- Are there other actions related to this priority topic that the Committee should consider?

Questions for Discussion

- Should a session on models of genomic data sharing and usage focus on all sectors—public institutions, academic institutions, the commercial sector, and patient-initiated groups—or be more limited in scope?
- Should it focus on the use of data from clinical practice or the secondary use of data/samples collected in research?
- Should it focus on certain types of genomic data sharing (e.g., for research in common diseases? And/or rare diseases?)

Questions for Discussion

- Should the session focus on particular elements of data sharing or usage agreements?
- Should it focus on particular populations?
- Are there any drawbacks to organizing a session on this topic?
- What should be the outcome of such a session? A proceedings document? Further work that might identify best practices (which would include public comments) for genomic data sharing and usage?