SACGHS Session on Models of Genomic Data Sharing

Charmaine Royal, Ph.D.
Secretary's Advisory Committee on Genetic, Health, and Society
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Issue Statement

- Genomic data sharing is an important tool for advancing basic science and for making strides in our knowledge of common diseases.

- Collection and broad sharing of individual genomic data facilitates important research but sharing such data, even when de-identified, has ethical implications for informed consent, privacy, and discrimination.

Issue Statement

- The boundary between research and clinical care is becoming more blurred, a trend that may be more pronounced in genomic data sharing.

- New approaches to informed consent may be needed to ensure that there are adequate provisions to ensure autonomy and protect subject privacy and confidentiality without unduly hampering research or clinical care.

SACGHS Activities to Date

- Dec. 2008: genomic data sharing identified as one of seven study priorities
- March 2009: Briefing on IOM report *Beyond the HIPAA Privacy Rule* and activities of other advisory committees, i.e., SACHDNC
- Sept. 2009: Lewin Group awarded a contract to develop a report for DHHS on key policy questions and to provide analytical support for SACGHS' efforts
- Oct. 2009: steering group formed to plan session

SACGHS Steering Group

Charmaine Royal, (Chair)

Sylvia Au

David Dale

Julio Licinio

Sheila Walcoff

Kevin Fitzgerald (ad hoc)

Michael Amos, NIST

Douglas P. Olsen, DVA

Laura Lyman Rodriguez, NIH

Michele A. Lloyd-Puryear, HRSA

Staff Lead: Symma Finn

Lewin Group Activities

- Policy questions to be explored in report, e.g.:
  - Are there new issues regarding privacy and discrimination related to collection, storage, and use of genomic data? Will collection include epigenetic, metabolic, and gene-environmental data? Will storage in EHRs be possible?
  - How can the consent process be improved? What can we learn about consent needs from existing population studies?
  - What are the immediate and long-term benefits and risks of population-based disease registries and drug or device registries? What mechanisms can be used to mitigate risks?
  - How can researchers and policy makers address the concerns of indigenous peoples and other population groups about the collection, use and misuse of genetic data?

Session Goals

- Gather information about genomic data sharing models;
- Discuss existing standards and policies; and
- Decide whether there is the need to identify best practices.

Session Presentations

- Overview of Relevant Federal Agency Activities
- Future Directions in Health Information Technology
- Objectives, Mechanisms, and Policies of Five Models of Genomic Data Sharing
  - Governmental
  - Healthcare system
  - Academic
  - Commercial
  - Consumer-controlled

Questions for Discussion

- Of the five models, what are the common elements of their policies?
  - For informed consent
  - For storage of data
  - For access and secondary uses of data
  - For privacy and confidentiality
  - For protection against re-identification of genomic data
  - For handling “sensitive” data
  - For incorporation of data into EHRs

Questions for Discussion

- What elements have worked well?
- Are there issues that could benefit from further policy development efforts?

Next Steps?

- Is there a need to identify best practices for genomic data sharing? Could SACGHS make a contribution in this area?
- Should we await the Lewin Group report before preceding?
- Should additional sessions be planned in the interim?