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Executive Summary

Genomic Medicine 5, May 28-29, 2013, Bethesda MD

Outcomes, Needs, Next Steps

Participating Organizations and Senior Representatives:

Agency for Healthcare Research and Quality, Carolyn Clancy
Blue Cross Blue Shield Association, Naomi Aronson
Centers for Disease Control and Prevention, Muin Khoury
Centers for Medicare and Medicaid Services, Steve Phurrough
Department of Veterans Affairs, Laurence Meyer
Food and Drug Administration, Elizabeth Mansfield
Institute of Medicine Genomics Roundtable, Adam Berger
National Cancer Institute, Andrew Freedman
National Human Genome Research Institute, Eric Green
Office of the Assistant Secretary for Health, Anand Parekh
Office of the Assistant Secretary for Planning and Evaluation, Ansalan Stewart
Presidential Commission for the Study of Bioethical Issues, Lisa Lee
US Air Force Medical Support Agency, Cecili Sessions
US Army Medical Corps, Clesson Turner
US Coast Guard, Maura Dollymore
US Navy Bureau of Medicine and Surgery, Bruce Doll

Outcomes: Consensus was near-universal among participants that federal agencies should work together to use genomic technology to improve health care in a way that maximizes health benefits, minimizes costs and inefficiencies, avoids harms, and ensures equitable access.

Need: All agreed on the value of an overarching convener to coordinate discussions amongst relevant federal agencies and keep everyone heading toward a unified goal. NHGRI/NIH is willing to serve in this role for now, but as work advances it may be appropriate for others to take over if desired.

Common needs that would benefit from collaborative effort:

- Evidence supporting actionability and clinical utility of genomic variants
- Evidence for added value of genomics to current clinical care
- Common evidence standards or, at minimum, guiding principles for types of evidence suitable for major classes of genomics-guided care
- Improved bioinformatics infrastructure, including:
    - Efficient and user-friendly standards for reporting variant, phenotypic, and reference information adopted by ordering physicians, testing labs, and medical records
    - Common clinical decision support (CDS) repository that all systems could use
    - Interoperable clinical data systems that protect patient confidentiality without interfering with appropriate data sharing for clinical care and research

    - Databases that are properly curated and protected by laws regarding data privacy and misuse
- Consensus on what constitutes adequate patient consent for use of their genomic information in research and clinical care
- Improved training and CDS tools enabling clinicians to order and interpret tests appropriately
- Ethical and legal framework to protect against abuses for data collection, data sharing, and reporting results
- Government-wide assessment of research questions that need to be answered for effective implementation of genomic medicine

<u>More specific needs relevant to a few agencies</u>:

- AHRQ
    - Collaboration with guideline and quality measure developers
    - Better systems for feedback from care delivery to science
- CDC
    - Examination of why initiatives like EGAPP's Lynch syndrome recommendations were not adopted widely to study more barriers to implementation and possible solutions
    - Advanced molecular detection of infections
- CMS and Blue Cross Blue Shield
    - information on costs of tests
    - Evidence of cost-effectiveness of genomic s-guided care
- CMS and FDA: Genetic test regulation and registration
- NIH, CMS, FDA:
    - Engagement of CMS and FDA, and possibly Blue Cross/Blue Shield, in design of genomic medicine research studies to enhance NIH efforts to produce evidence useful to its sister agencies
- PCORI
    - Identification of patient-centered outcomes relevant to genomic medicine suitable to PCORI's research portfolio
    - Criteria for evaluation of patient-centered genomic research funding applications
- US military medical services
    - Identification of operational relevance of genomics guided care
    - Improved interoperability and decision support across services
    - Potential integration of CMS Meaningful Use criteria to enhance interoperability with civilian record systems
    - Data privacy and security concerns unique to military members, including lack of GINA coverage
    - Lack of large community of researchers; potential for providing secure and accountable access to collaborating civilian investigators

Other relevant agencies to be added:

- Health Resources and Services Administration (HRSA) – leads newborn screening
- Office of the National Coordinator for Health Information Technology (ONC-HealthIT) – unable to attend
- Patent and Trademark Office (PTO) – impact on cost, development, and availability of tests

Action items and next steps:

- NHGRI will circulate the matrix of genomic medicine implementation components to the federal agencies to identify high priority components for collaboration.
- NHGRI will explore engaging the Office of Science and Technology Policy in endorsing development of federal strategy.
- NHGRI will work to re-engage the Office of the National Coordinator for Health Information Technology in data standards and interoperability issues critical to collaborative genomic medicine efforts.
- Jeff Vance will send his lecture videos for the UMiami Genomic Medicine Master's program to NHGRI for dissemination, potentially through the Genetics/Genomics Competency Center (G2C2) resource.
- NHGRI and other agencies should engage DoD and VA groups in ongoing pilot and demonstration projects and future evidence generation programs.