

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

*Board on Health Sciences Policy
Roundtable on Genomics and Precision Health*

**Exploring the Current Landscape of Consumer Genomics –
A Workshop**

October 29, 2019

Keck Building of the National Academies
500 Fifth Street NW
Room 100
Washington, DC 20001

Statement of Task:

Consumer genomics, encompassing both direct-to-consumer (DTC) applications (i.e. genetic testing that is accessed by a consumer directly from a commercial company apart from a health care provider) and consumer-driven genetic testing (i.e. genetic testing ordered by a health care provider in response to an informed patient request), has evolved considerably over the last decade, moving from more personal utility-focused applications outside of traditional health care to interfacing with clinical care in non-traditional ways. As consumer genomics has increasingly intersected with clinical applications, discussions have arisen around the need to demonstrate clinical and analytical validity and clinical utility due to the potential for misinterpretation by consumers. Clinical readiness and interest for this information have presented educational and training challenges for providers. At the same time, consumer genomics has emerged as a potentially innovative mechanism for thinking about health literacy and engaging participants in their health and health care. An ad hoc planning committee will plan and conduct a one day public workshop to explore the current landscape of consumer genomics and implications for how genetic test information is used or may be used in research and clinical care. Discussions may include topics such as diversity of participant populations, impact on health literacy and engagement, knowledge gaps related to use in clinical care, and data privacy/security concerns. A broad array of stakeholders may take part in the workshop, including genomics and consumer genomics experts, epidemiologists, health disparities researchers, clinicians, users of consumer genomics research applications (e.g., consumers, patients), patient advocacy groups, payers, bioethicists, regulators, and policy makers. The planning committee will develop the workshop agenda, select and invite speakers and discussants, and may moderate the discussions. A proceedings of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

AGENDA

8:30 a.m.

Opening Remarks

GEOFFREY GINSBURG, *Roundtable Co-Chair*
Director, Duke Center for Applied Genomics & Precision Medicine
Professor, Medicine, Pathology, and Biomedical Engineering
Duke University Medical Center

MICHELLE PENNY, *Roundtable Co-Chair*
Head of Translational Genome Sciences
Biogen

8:35 a.m.

Charge to Workshop Speakers and Participants

CATHY WICKLUND, *Workshop Co-Chair*
Director, Graduate Program in Genetic Counseling
Past President, National Society of Genetic Counselors
Associate Professor, Feinberg School of Medicine, Center for Genetic Medicine
Northwestern University

GREG FEERO, *Workshop Co-Chair*
Professor, Department of Community and Family Medicine
Geisel School of Medicine
Faculty, Maine Dartmouth Family Medical Residency Program
Associate Editor, *Journal of the American Medical Association*

8:50 a.m.

Opening Keynote

ROBERT NUSSBAUM
Chief Medical Officer
Invitae

9:10 a.m.

Clarifying Questions from Workshop Participants

SESSION I: UNDERSTANDING CONSUMER GENOMICS UTILIZATION

Session Objectives:

- Explore how consumers are engaging (or not engaging) with DTC and consumer-driven genomics services and whether there are lessons that can be learned about overall health engagement
- Learn how patients and providers are using genomic data procured through consumer genomics applications along with health data from other sources to inform overall health care decision-making

Session Moderator: Tina Hesman Saey, Science News

CONSUMER GENOMICS ENGAGEMENT AND OUTLOOK

- 9:15 a.m. CINNAMON BLOSS
Associate Professor
Departments of Psychiatry and Family Medicine and Public Health
University of California, San Diego
- 9:30 a.m. **CONSUMER PERSPECTIVES**
- SARA ALTSCHULE
Freelance Writer
Bustle Magazine
- DOROTHY POMERANTZ
Managing Editor
FitchInk
- 10:00 a.m. **Panel Discussion with Speakers and Workshop Participants**
- 10:30 a.m. **Break**

SESSION II: EXPLORING THE ROLE OF DIVERSITY AND HEALTH DISPARITIES IN CONSUMER GENOMICS

Session Objectives:

- Discuss the lack of diversity in current genomics databases and biorepositories and how this may affect health disparities
- Explore how consumer genomics is (or is not) reaching diverse populations (e.g., racial, ethnic, geographic, socioeconomic) and the implications for health disparities

Session Moderator: Jacquelyn Taylor, New York University

- 10:45 a.m. JOYCE TUNG
Vice President, Research
23andMe
- 11:00 a.m. MALIA FULLERTON
Professor of Bioethics and Humanities
University of Washington School of Medicine
- 11:15 a.m. SHAWNEEQUA CALLIER
Associate Professor of Clinical Research and Leadership
George Washington University

- 11:30 a.m. SADIE HUTSON
 Director, Cancer Genetics Program
 Pikeville Medical Center
 Assistant Dean, Graduate Programs
 University of Tennessee, Knoxville
- 11:45 a.m. **Panel Discussion with Speakers and Workshop Participants**
- 12:30 p.m. **Working Lunch**

SESSION III: INTEGRATION WITHIN SCIENTIFIC AND MEDICAL COMMUNITIES

Session Objectives:

- Discuss factors that may affect how consumer genomics data is integrated with clinical care
- Examine the challenges of and opportunities for using consumer genomics for research
- Explore emerging cross-sector collaborations and potential lessons that can be learned

Session Moderator: Bruce Blumberg, Kaiser Permanente School of Medicine

- 1:30 p.m. ANDREW SINGLETON
 Senior Investigator
 Laboratory of Neurogenetics
 National Institute on Aging
- 1:45 p.m. SIOBHAN DOLAN
 Professor and Vice Chair for Research
 Department of Obstetrics and Gynecology and Women's Health
 Albert Einstein College of Medicine
- 2:00 p.m. DANIELLE BONADIES
 Director of Genetics
 My Gene Counsel
- 2:15 p.m. MATTHEW FERBER
 Associate Professor of Laboratory Medicine and Pathology
 Consultant, Division of Laboratory Genetics and Genomics, Department of Laboratory
 Medicine and Pathology
 Mayo Clinic
- 2:30 p.m. **Panel Discussion with Speakers and Workshop Participants**
- 3:00 p.m. **Break**

SESSION IV: REGULATORY AND HEALTH POLICY ISSUES

Session Objectives:

- Address data sharing, privacy, and security issues in the context of consumer genomics testing
- Explore the landscape of emerging regulatory issues in consumer genomics

Session Moderator: Victoria M. Pratt, Association for Molecular Pathology

- 3:15 p.m. AMY MCGUIRE
Leon Jaworski Professor Biomedical Ethics
Director, Center for Medical Ethics and Health Policy
Baylor College of Medicine
- 3:30 p.m. GAIL JAVITT
Member, Health Care and Life Sciences Practice
Epstein Becker Green
- 3:45 p.m. JORDAN LASER
Senior Director
Cytogenetics & Molecular Pathology of Pathology and Laboratory Medicine
Long Island Jewish Medical Center
- 4:00 p.m. **Panel Discussion with Speakers and Workshop Participants**

SESSION V: HOW CAN CONSUMER GENOMICS BE BETTER INTEGRATED TO IMPROVE HEALTH?

Session Questions:

- What is the role of consumer genomics in the health care system in the next 5 years? 10 years?
 - What is viewed as actionable information by a health system?
- Are health systems, consumers, and providers prepared for downstream challenges? If not, are there opportunities for ensuring that consumer genomics is more effective in clinical care?
- How can we make consumer genomics the best it can be for consumers and systems?
 - What needs to be better understood about low-cost consumer genomics and the implications for access and health disparities?

Session Moderator: Huntington Willard, Geisinger National Precision Health

- 4:30 p.m. **Reflections on the Day and Next Steps**

DANIELLE BONADIES
SHAWNEEQUA CALLIER
SIOBHAN DOLAN
ROBERT NUSSBAUM
DOROTHY POMERANTZ

Additional Discussant:

TIMOTHY STENZEL

Director, Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration

5:00 p.m. **Final Discussion with Workshop Participants**

5:20 p.m. **Final Remarks from Workshop Co-chairs**

CATHY WICKLUND, *Workshop Co-Chair*

Director, Graduate Program in Genetic Counseling
Past President, National Society of Genetic Counselors
Associate Professor, Feinberg School of Medicine, Center for Genetic Medicine
Northwestern University

GREG FEERO, *Workshop Co-Chair*

Professor, Department of Community and Family Medicine
Geisel School of Medicine
Faculty, Maine Dartmouth Family Medical Residency Program
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5:35 p.m. **Adjourn**
 Networking Reception