

*The National Academies of*  
SCIENCES • ENGINEERING • MEDICINE

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

## Implementing and Evaluating Genomic Screening Programs in Health Care Systems – A Workshop

**November 1, 2017**

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

### **Statement of Task:**

An ad hoc committee will plan and conduct a one day public workshop to explore challenges and opportunities associated with integrating genomics into large-scale health organizations. These initiatives have a variety of goals such as providing information about clinically actionable genetic variants, seeking diagnoses for individuals suspected to have rare diseases, and/or advancing research on the genetic contributors to human illnesses. Case studies of large-scale genomics programs and collaborative learning networks may be highlighted during the workshop as a way to understand successes and lessons learned regarding (1) economic considerations (e.g., clinical utility, value), (2) policy environments (e.g., alleviating privacy and discrimination concerns for participants), and (3) data sharing. Workshop discussions will be held with a broad array of stakeholders which may include health economists, representatives from health care delivery systems, public health officials, bioethicists, implementation science researchers, clinicians, payers, and policy makers. The committee will develop the workshop agenda, select and invite speakers and discussants, and may moderate the discussions. Proceedings of the workshop will be prepared by a designated rapporteur in accordance with institutional policy and procedures.

## *Workshop Agenda*

### **BACKGROUND:**

Genomic applications can be embedded into a broad range of clinical and research activities. Increasing amounts of genomic data are currently being generated and incorporated into a variety of health systems<sup>1</sup> in the United States and abroad and each instance presents a natural “experiment” offering the opportunity for learning about the integration of genomics into health care ecosystems. Of particular interest is genomic screening or **genomic-based screening programs**, referred to in the context of this workshop as clinical screening programs with the goal of examining genes or variants in unselected populations in order to identify individuals at risk for future disease or adverse drug outcomes for which there are clinical actions to mitigate risk. Many current genomic-based screening programs examine germline variability in specific genes that have been evaluated and recommended by groups such as the American College of Medical Genetics and Genomics, U.S. Preventive Services Task Force, and/or Evaluation of Genomics Applications in Practice and Prevention. There is potential strength in evaluating common outcomes of implementing these screening programs across multiple large health systems and organizations that incorporate data from diverse population groups in order to understand how genomics may or may not ultimately benefit all population groups. Tracking data from early implementers on the potential health benefits and harms of genomic screening programs may provide important evidence needed to assess the effectiveness and safety of genomic screening in unselected populations.<sup>2</sup>

### **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

#### 8:35 a.m. **Charge to Workshop Speakers and Participants**

W. GREGORY FEERO, *Workshop Co-Chair*  
Faculty  
Maine Dartmouth Family Medicine Residency Program  
Associate Editor, *Journal of the American Medical Association*

DAVID VEENSTRA, *Workshop Co-Chair*  
Professor and Associate Director  
Pharmaceutical Outcomes Research and Policy Program  
University of Washington

#### 8:50 a.m. **Keynote Lecture**

MICHAEL MURRAY  
Director of Clinical Genomics  
Geisinger Health System

#### 9:10 a.m. **Clarifying Questions from Workshop Participants**

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<sup>1</sup>For the purposes of this workshop, *health systems* are referred to as entities providing medical care to a select population. Examples may include a for-profit or non-profit health care delivery system or a public health system.

<sup>2</sup>The term *population* in the context of this workshop pertains to individuals in the context of a health system that has implemented or is planning to implement a genomic-based screening program.

**SESSION I: EVIDENCE CONSIDERATIONS FOR INTEGRATING GENOMIC-BASED PROGRAMS INTO HEALTH SYSTEMS**

Session Objective:

- To examine the types of clinical data and other evidence that are currently being collected by genomic-based programs at health systems and to consider opportunities for advancing knowledge of clinical utility.

Key Questions:

- What evidence will your program generate and how will it be useful in the future in terms of evaluating the value and utility of these activities?
- Are you currently sharing information from your genomic-based program or data across systems or organizations? How and with whom?
- What outcomes are important for genomic-based programs to measure? What potential impacts are there on care when deciding to invest in genomic-based programs?
- If you run into challenges such as a lack of evidence utility or any harms (e.g. privacy, discrimination) to participants from implementing a genetic test in your program, how do you plan to track these outcomes and address them?

*Session Moderator: George Isham, Senior Advisor, HealthPartners*

9:20 a.m.      KATRINA GODDARD  
Senior Investigator  
Kaiser Permanente Center for Health Research

9:35 a.m.      BRUCE KORF  
Wayne H. and Sara Crews Finley Chair in Medical Genetics  
Professor and Chair, Department of Genetics  
Director, Heflin Center for Genomic Sciences  
University of Alabama at Birmingham School of Medicine

9:50 a.m.      DEBRA LEONARD  
Chair of Pathology and Laboratory Medicine  
University of Vermont Medical Center

10:05 a.m.      **Panel Discussion with Speakers and Workshop Participants**  
KATRINA GODDARD, BRUCE KORF, DEBRA LEONARD, MICHAEL MURRAY

10:35 a.m.      **Break**

**SESSION II: FINANCIAL CONSIDERATIONS FOR IMPLEMENTING GENOMIC-BASED SCREENING PROGRAMS**

Session Objectives:

- To discuss the financial considerations associated with genomic-based programs, including:

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- Available models that can effectively evaluate genomic-based programs and the value they represent to their institution;
- Approaches to measuring return-on-investment from implementation of genomic-based screening programs; and
- Best practices for data sharing related to economic evaluations of genomic-based programs.

### Key Questions:

- What business models are available to fund genomic-based screening programs? Would this program remain a priority for your organization if the current source of funding was no longer available? Is the program built to be sustainable? How?
- Are genomic-based programs affordable? Do they provide clinical utility or other value that can justify implementing the program? Beyond the cost of the genetic test itself, what are the downstream costs of care that need to be taken into account?
- How can institutions evaluate the opportunity costs associated with genomics implementation into a health system?
- Are there models that support data sharing between individual health care systems that are implementing genomic-based programs?
- What challenges do these programs create for clinical workflow?

*Session Moderator: David Veenstra, Professor and Associate Director of Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy, University of Washington*

- 10:50 a.m.     BRADFORD POWELL  
Clinical Assistant Professor  
Department of Genetics  
University of North Carolina at Chapel Hill
- 11:05 a.m.     JOSH PETERSON  
Associate Professor of Biomedical Informatics and Medicine  
Vanderbilt University Medical Center
- 11:20 a.m.     DEAN REGIER  
Assistant Professor, School of Population and Public Health  
The University of British Columbia
- 11:35 a.m.     **Panel Discussion with Speakers and Audience Members**
- 12:05 p.m.     **Working Lunch**

### **SESSION III: CONSIDERING APPROACHES TO OPTIMIZE DATA SHARING AMONG EARLY IMPLEMENTERS OF GENOMIC-BASED PROGRAMS**

#### Session Objective:

- To explore new ideas and opportunities for collaborative networks as a way for sharing economic and clinical outcome data about genomic-based programs between and within large-scale health care organizations.

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### Key Questions:

- How could data sharing across systems and organizations affect the measurement of value and clinical utility of genomic-based programs?
- Are there incentives for overcoming cultural and technological barriers to sharing data across systems and organizations? What are the incentives? If they do not exist, what is needed?
- What common outcomes or endpoints would be useful to collect from early implementers of genomic-based programs? What are the ideal data elements that should be collected from genomic-based programs?

*Session Moderator: Marc Grodman, Assistant Professor of Clinical Medicine, Columbia University*

- 1:05 p.m.      REX CHISHOLM  
Vice Dean, Scientific Affairs and Graduate Education  
Adam and Richard T. Lind Professor of Medical Genetics  
Northwestern University
- 1:20 p.m.      ERIC BOERWINKLE  
Dean and M. David Low Chair in Public Health  
Kozmetsky Family Chair in Human Genetics  
The University of Texas Health Science Center at Houston
- 1:35 p.m.      RICHARD TURNER  
Clinical Research Fellow in Clinical Pharmacology and Therapeutics  
Royal Liverpool University Hospital and University of Liverpool
- 1:50 p.m.      LORI ORLANDO  
Associate Professor of Medicine  
Duke University School of Medicine
- 2:05 p.m.      **Panel Discussion with Speakers and Workshop Participants**
- 2:35 p.m.      **Break**

<b>SESSION IV: WORKING TOWARD THE NEEDS OF PARTICIPANTS AND IMPROVING DIVERSITY AND EQUITY</b>
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### Session Objective:

- To consider policy issues associated with implementation of genomic-based programs in health systems and potentially in public health, including:
  - Approaches to assuring data security and participant privacy;
  - Methods for assuring that genomic-based programs are accessible to a diverse group of participants.

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### Key Questions:

- Is this the right time to be studying use of genomic data and population health management in health systems? Why?
- How can genomic-based programs be designed in such a way to reach a diverse group of participants?
- How can genomic-based programs be equitably distributed regardless of educational status, income level, ethnicity, or other variables?
- If the early evidence indicates that genomic-based programs do not provide value and utility (and potentially demonstrate harms to participants), are the programs discontinued? How are the de-implemented and/or assessed again at a later date?

*Session Moderator: Vence Bonham, Senior Advisor to the NHGRI Director on Genomics and Health Disparities, NHGRI, NIH*

2:50 p.m.      SARA KNIGHT  
Professor, Division of Preventive Medicine, School of Medicine  
The University of Alabama at Birmingham

3:05 p.m.      CAROL HOROWITZ  
Professor, Population Health Science and Policy  
The Mount Sinai Hospital

3:20 p.m.      ABEL KHO  
Director, Center for Health Information Partnerships  
Northwestern University

3:35 p.m.      **Panel Discussion with Speakers and Workshop Participants**

## **SESSION V: NEXT STEPS TOWARD IMPROVING HEALTH THROUGH THE INTEGRATION OF GENOMIC-BASED PROGRAMS**

### Session Objectives:

- To discuss ideas for actionable next steps that could support the implementation of genomic-based programs in health systems.
- To consider infrastructure and resources that are needed to share data collected in clinical care across health systems for health outcomes and economics research.

### Key Questions:

- Thinking about the workshop discussions today, what would be a game-changer in terms of facilitating data sharing among early implementers of genomic-based programs?
- What next steps are critical for building an active learning model for outcome data on benefits, harms, and costs collected in genomic-based programs?

*Session Moderator: W. Gregory Feero, Workshop Co-Chair, Faculty, Maine Dartmouth Family Medicine Residency Program*

## *Workshop Agenda*

4:05 p.m.     **A Model for Accelerating Evidence Generation for Genomic Technologies in the Context of a Learning Health Care System**

CHRISTINE LU  
Associate Professor  
Department of Population Medicine  
Harvard Medical School

4:20 p.m.     **Clarifying Questions**

4:30 p.m.     **Final Panel Discussion: What policies and infrastructure need to be in place to enable data sharing across institutions?**

ABEL KHO  
KATRINA GODDARD  
GEORGE ISHAM  
DEBRA LEONARD  
MICHAEL MURRAY  
JOSH PETERSON

5:05 p.m.     **Final Remarks from Workshop Co-chairs**

W. GREGORY FEERO, *Workshop Co-Chair*  
Faculty  
Maine Dartmouth Family Medicine Residency Program  
Associate Editor, *Journal of the American Medical Association*

DAVID VEENSTRA, *Workshop Co-Chair*  
Professor and Associate Director  
Pharmaceutical Outcomes Research and Policy Program  
University of Washington

5:15 p.m.     **Adjourn**