Examining Clinical Guidelines for the Adoption of Genomic Testing: A Workshop

Tuesday, October 29, 2024

PURPOSE

A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize and conduct a public workshop to examine how clinical practice guidelines can impact adoption of genomics into routine medical care. The workshop will examine how guidelines for genomic testing are developed by various organizations and implemented within clinical practice, with a focus on exploring inconsistencies across guidelines.

The workshop's presentations and discussions may focus on:

- Exploring the processes and methodologies used by different professional societies, organizations, and collaborations to gather evidence and develop clinical guidelines for appropriate genomic testing.
- Understanding how clinicians, payers, test developers, laboratory partners, and others decide which guideline(s) to follow and how they use these guidelines in practice.
- Examining elements that are consistent and those that differ across clinical guidelines for genomics and how these areas impact patients (e.g., access, coverage, and equity in care), clinicians, payers, test developers, laboratories, and others.
- Discussing opportunities for a possible path forward for more compatible clinical guidelines for genomics to improve patient care.

The planning committee will organize the workshop, develop the agenda, select and invite speakers and discussants, and moderate or identify moderators for the discussions. A proceedings-in brief of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

SESSION I: Opening Remarks

8:30 AM ET

Welcoming Remarks

Catherine (Cathy) Wicklund (she/her/hers), *Roundtable Co-Chair*
Representing National Society of Genetic Counselors
Senior Manager and Medical Science Liaison, Clinical Strategy Lead
Myriad Genetics
Adjunct Professor of Obstetrics and Gynecology (Clinical Genetics)
Feinberg School of Medicine, Center for Genetic Medicine
Northwestern University

W. Gregory (Greg) Feero (he/him/his), *Roundtable Co-Chair*
Representing *Journal of the American Medical Association*
Professor, Department of Community and Family
Medicine, Geisel School of Medicine
Faculty, Maine Dartmouth Family Medicine Residency Program

8:40–8:50 AM

Introduction and Charge to the Workshop Speakers and Participants

Mylynda Massart (she/her/hers), *Workshop Planning Committee Co-Chair*

Associate Director, Clinical Services
UPMC Primary Care Precision Medicine Center
Associate Professor
University of Pittsburgh

Victoria (Vicky) Pratt, *Workshop Planning Committee Co-Chair*
Representing Association for Molecular Pathology
Director, Scientific Affairs for Pharmacogenetics
Agena Biosciences

SESSION II: Why Guidelines Matter for Genomic Testing

Moderator: W. Gregory Feero (he/him/his), Representing Journal of the American Medical Association

Objectives

- Understand how clinical practice guidelines for genomic testing impact patient care, clinical practice, and other relevant areas, specifically considering impacts on equity in each of these spaces.
- Discuss challenges patients, clinicians, and others face surrounding guidelines.
- Explore how genomic testing guidelines could be advanced to move the needle towards better, more equitable care.

8:50–9:05 AM

Robyn Temple-Smolkin (she/her/hers)
Senior Director, Clinical & Scientific Affairs
Director, Guideline Development
Association for Molecular Pathology

9:05–9:15 AM

Vimal Scott Kapoor
Public Health & Preventive, Occupational and Emergency Physician
University of Toronto
Markham Stouffville Hospital

9:15–9:35 AM

Panel of Reactants

Lindsay Zetzsche (she/her/hers)
Owner
Science Geek Games
Consultant
Integrity Genetics Consulting LLC

Brianne Phillips (she/her/hers)
Nurse Practitioner
University of Pittsburgh Medical Center

Aishwarya Arjunan (she/her/hers)
Senior Medical Science Liaison
GRAIL

9:35–10:05 AM

Panel Discussion

10:05–10:20 AM

Break

SESSION III: Guidelines for Genomic Testing Today

Co-Moderators: Wanda Nicholson, George Washington University Milken Institute School of Public Health & Rebecca Morgan (she/her/hers), Evidence Foundation

Objectives

- Discuss the benefits and challenges of the current clinical practice guideline development process for genomic testing.
- Explore patient-centric models of guidelines development and how equity is and can be incorporated.
- Consider options for circumstances in which guidelines are not compatible or available.

10:20–10:25 AM — **Introduction to the Session**

10:25–10:35 AM

Jennifer S. Lin (she/her/hers)
Director, Evidence-based Practice Center
Kaiser Permanente, Center for Health Research

10:35–10:45 AM

Kelly Caudle (she/her/hers)
Director
Clinical Pharmacogenetics Implementation Consortium (CPIC)
Associate Member
St. Jude Children's Research Hospital

10:45–10:55 AM

Funda Meric-Bernstam (she/her/hers)
Chair of the Department of Investigational Cancer Therapeutics
Medical Director of the Institute for Personalized Cancer Therapy
The Nellie B. Connally Chair in Breast Cancer
MD Anderson Cancer Center

10:55–11:05 AM

Heidi Rehm (she/her/hers)
Director, Genomic Medicine Unit
Center for Genomic Medicine
Massachusetts General Hospital
Institute Member and Clinical Laboratory Director
Broad Institute of MIT of Harvard
Professor of Pathology
Harvard Medical School

11:05–11:40 AM — **Panel Discussion**

11:40 AM–12:35 PM — **Lunch Break**

SESSION IV: How Genomic Testing Guidelines Impact Payer Decisions

Co-Moderators: Trish Brown (she/her/hers), CVS Health & Gabriel Lazarin, Myriad Genetics

Objectives

- Examine the role guidelines play in payer decisions (e.g., coverage, reimbursement).
- Discuss opportunities for advancing patient care and access related to these

decisions.
- Explore levers for aiding payer decisions such as establishment of or compatibility across guidelines and other possible facilitators.

12:35–12:40 PM	**Introduction to the Session**
12:40–12:55 PM	**Trent Haywood** (he/him/his) Founder Knowality, LLC
12:55–1:10 PM	**Gillian Hooker** (she/her/hers) Chief Scientific Officer Concert Genomics
1:10–1:25 PM	**Gautum Agarwal** (he/him/his) Director of Precision Medicine Mercy Health
1:25–1:55 PM	**Panel Discussion**

SESSION V: Clinical Care Implementation of Guidelines for Genomic Testing

Moderator: Pim Suwannarat (she/her/hers), Mid-Atlantic Permanente Medical Group, Kaiser Permanente

Objectives

- Understand how and when clinical practice guidelines for genomic testing are currently being implemented, or could be implemented, in the clinic.
- Explore the gaps in clinical implementation and what support may be needed to drive better, more equitable care.

1:55–2:00 PM	**Introduction to the Session**
2:00–2:15 PM	**David Chambers** (he/him/his) Deputy Director for Implementation Science Division of Cancer Control and Population Sciences National Cancer Institute National Institutes of Health
2:15–2:30 PM	**Charles Jonassaint** (he/him/his) Associate Professor University of Pittsburgh
2:30–2:45 PM	**Naveen L. Pereira** (he/him/his) Consultant for the Department of Cardiovascular Diseases Professor of Medicine Associate Professor of Pharmacology Mayo Clinic College of Medicine
2:45–3:15 PM	**Panel Discussion**

3:15–3:30 PM **Break**

SESSION VI: Guideline Development in a Rapidly Evolving Field – A Look Ahead

Moderator: Mary Nix (she/her/hers), Agency for Healthcare Research and Quality (AHRQ)

Objectives

- Consider the pace of advances in genomics and what opportunities there are for synergy between this field and guideline development.
- Discuss potential challenges ahead and what work could be started now to alleviate possible obstacles to care.

3:30–3:35 PM **Introduction to the Session**

3:35–3:50 PM

Kandamurugu Manickam (he/him/his)
Clinical Geneticist
Nationwide Children's Hospital
Associate Professor of Clinical Pediatrics
Ohio State College of Medicine

3:50–4:05 PM

Karli Kondo (she/her/hers)
Director, Evidence Synthesis
American Cancer Society

4:05–4:20 PM

Sandra Zelman Lewis (she/her/hers)
Past President, Founder
EBQ Consulting, LLC

4:20–4:50 PM **Panel Discussion**

SESSION VII: Final Reflections

4:50–5:05 PM **Wrap Up**

Mylynda Massart (she/her/hers), *Workshop Planning Committee Co-Chair*
Associate Director, Clinical Services
UPMC Primary Care Precision Medicine Center
Associate Professor
University of Pittsburgh

Victoria Pratt, *Workshop Planning Committee Co-Chair Representing Association for Molecular Pathology*
Director, Scientific Affairs for Pharmacogenetics
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