Assessing Genomic Sequencing Information for Health Care Decision Making: A Workshop

February 3, 2014

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

MEETING OBJECTIVES

- Provide a forum for diverse stakeholders to present approaches for assessing genome sequencing information for clinical use
- Compare and contrast evidence evaluation processes for different clinical indications and across stakeholders
- Identify key challenges in the evidence evaluation process
- Elicit pragmatic approaches to facilitate the effective translation of genomics into the clinic by improving evidence-based policy development

AGENDA

8:30–8:35 A.M. **Welcoming Remarks**

Sharon F. Terry, *Roundtable Co-chair*
President and CEO
Genetic Alliance

Geoffrey Ginsburg, *Roundtable Co-chair*
Director, Genomic Medicine, Duke Institute for Genome Sciences & Policy; Executive Director, Center for Personalized Medicine, Duke Medicine; Professor of Medicine and Pathology, Duke University Medical Center

Charge to workshop speakers and participants

8:35–8:45 A.M. David Veenstra
Professor, Pharmaceutical Outcomes Research and Policy Program
University of Washington

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SESSION I: HOW EVIDENCE IS GATHERED AND ASSESSED/GRADED/EVALUATED

Moderator: Debra Leonard, University of Vermont

8:45–10:15 A.M.

Systematic Evidence Gathering and Actionability Determination

- What process do you use to identify studies and data?
- How are you selecting tests/variants for full evidence review and assessment?
- How do you critically assess the data and synthesize for conclusion?
- How do you present the results of the evidence review and evaluation to policy makers?
- How do you determine if clinical action is recommended or taken for specific genomic variants?
- How do you define actionability?
- What are the challenges you have encountered?
- What have you done to overcome these challenges?

Jonathan Berg
Assistant Professor
Department of Genetics
University of North Carolina School of Medicine

Katrina Goddard
Senior Investigator
Kaiser Permanente Center for Health Research

Shashikant Kulkarni
Director of Cytogenomics and Molecular Pathology
Genomics and Pathology Services
Washington University School of Medicine

Heidi Rehm, Partners
Associate Professor of Pathology, BWH and Harvard Medical School
Director, Laboratory for Molecular Medicine
Partners Healthcare Center for Personalized Genetic Medicine

Madhuri Hegde
Executive Director, Emory Genetics Laboratory
Professor, Department of Human Genetics
Emory University School of Medicine

Mark Robson
Clinic Director, Clinical Genetics Service
Department of Human Genetics
Memorial Sloan-Kettering Cancer Center

10:15–10:30 A.M. **BREAK**

10:30–11:30 A.M. **Discussion with Speakers and Attendees**

11:30–12:30 P.M. **WORKING LUNCH**

SESSION II: PROCESS FOR DECISION-MAKING ONCE EVIDENCE IS ASSESSED/GRADED/EVALUATED

Moderator: Bruce Blumberg, Kaiser Permanente

12:30–1:00 P.M. **Reimbursement Decisions**

- Under what process (existing or novel) would genome or multi-gene panel sequencing be evaluated? Describe the process.
- What are your criteria for coverage?
- Does the extent to which information is reported in the EHR affect your decision?
- Under what circumstances are high-throughput sequencing tests covered by payers?

Robert McDonough
Head of Clinical Policy and Research
Aetna

Louis Jacques
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services

1:00–1:35 P.M. **Discussion with Speakers and Attendees**

Moderator: Muin Khoury, Centers for Disease Control and Prevention

1:35–2:20 P.M. **Guideline Development**

- How are you applying your guideline development process to next generation sequencing?
- What do you think are the top three challenges to developing guidelines in the era of NGS?
- Do you consider the IOM recommendations for developing clinical practice guidelines in your process?

Robert C. Green
Director, Genomes to People (G2P) Research Program
Associate Director for Research, Partners Center for Personalized Genetic Medicine
Division of Genetics, Department of Medicine
Brigham and Women's Hospital and Harvard Medical School

Howard M. Saal
Director, Clinical Genetics
Division of Human Genetics
Cincinnati Children's Hospital Medical Center

Gary Lyman
Co-Director, Hutchinson Institute for Cancer Outcomes Research
Fred Hutchinson Cancer Research Center
University of Washington

2:20–2:55 P.M. **Discussion with Speakers and Attendees**

2:55–3:10 P.M. **BREAK**

Moderator: W. Gregory Feero, Maine Dartmouth Family Medicine

3:10–4:10 P.M. **Patient Care and Health Decisions**

- Upon what evidence is the decision made to use large-scale sequencing over a more targeted approach?
- Does reimbursement play a role in ordering a whole genome test?
- How do you see the role of patient preferences in what testing is done and what information is disclosed?

- How well do patients understand discussions about genomic testing? And, what is the patient response to reports of incidental findings?

Kathleen Hickey
Assistant Professor of Nursing
Columbia University School of Nursing

Jessica Everett
Clinical Instructor, Internal Medicine
Certified Genetic Counselor
Cancer Genetics Clinic
University of Michigan

Amy Hower
Patient

Michael Gambello
Associate Professor of Human Genetics and Pediatrics
Section Chief, Division of Medical Genetics
Emory University School of Medicine

4:10–4:45 P.M. **Discussion with Speakers and Attendees**

SESSION III: NEXT STEPS AND ADDRESSING CHALLENGES

Moderator: David Veenstra, University of Washington

4:45–5:30 P.M. **Developing transparent and pragmatic frameworks for evidence evaluation and policy development in the absence of an ideal evidence base**

- What are the top three challenges to developing clinical and reimbursement policies in the era of genomic testing?
- What approaches do you think can help address these challenges?
- To what extend does clinical context matter?
- How do risk-benefit tradeoffs influence evidentiary requirements?

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Clinical Instructor, Internal Medicine
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5:30–5:45 P.M. **SUMMARY AND CONCLUDING REMARKS**

5:45 P.M. **ADJOURN**