

# **Workshop Summary: Reimbursement Models to Promote Evidence Generation and Innovation for Genomic Tests**

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# What's the issue?

- For promise of genomic medicine to be fulfilled, need for genomics-based tests to be reimbursed
- Coverage contingent upon clinical utility
- Insufficient evidence of clinical utility (or other healthcare enhancements)
- Question of who will do the research
- Stymie reimbursement

# Workshop Purpose: Identifying a role for NHGRI

- What research NHGRI could support in evidence development of tests
- With whom could NHGRI partner?
- How might the research make use of clinical data?
- What endpoints influence coverage decisions by health insurance issuers? Not just clinical utility
- Innovative ways in which payment being tied to ongoing collection of data

# Attendees

- **GMWG Members**
  - **Payers**
  - **Test Developers**
  - **CDC**
  - **NHGRI Staff**
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# The Case Studies

- **CMS Coverage with Evidence Development for Pharmacogenomic Testing for Warfarin**
- **United HealthCare/Genomic Health Performance-based Risk Sharing Agreement for OncotypeDX coverage**
- **Medco Health Solutions, Inc. /Mayo Clinic Pharmacogenomic Testing for Warfarin Dosage Effectiveness Study**
- **Molecular Diagnostics Services Program (MolDx)**

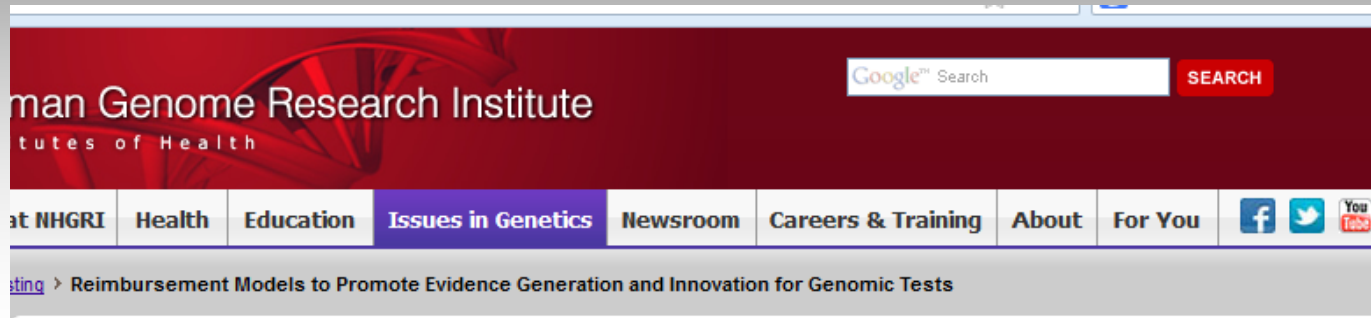
# Emerging Themes

- No consensus regarding how clinical utility/test value is defined
- Payers consider evidence other than RCT
- Medicare's statutory limitations
- Who will fund the evidence base?
- Sharing of data includes legal issues and building of trust

# Action Items

- White Paper on workshop emerging themes
- Analyze data sharing legal and policy issues
- Research on physician ordering of genetic tests
- Develop criteria for prioritizing tests for coupling evidence generation with coverage and reimbursement.
- Define a private infrastructure model to conduct clinical utility research.

# http://www.genome.gov/27552210



## Workshop Summary

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## Reimbursement Models to Promote Evidence Generation and Innovation for Genomic Tests

National Institutes of Health  
Bethesda, Maryland  
October 24, 2012



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- [Recommended Action Items](#)
- [Participants](#)

## Overview

On October 24, 2012, the National Human Genome Research Institute (NHGRI) and the Center for Medical Technology Policy (CMTTP) convened a workshop to explore innovative ways in which genomics-based tests could be covered by public and private payers while generating evidence of the test's impact on medical outcomes, and to develop an action plan enabling future reimbursement of such tests and large-scale sequencing. The workshop was structured around exploration of four case studies followed by discussions focused on developing an actionable "reimbursement policy"



# Ideas for next steps

- Engage actuaries
- Identify tests that are appropriate for:
  - (a) coverage now
  - (a) coverage if tied with some kind with evidence development
- Compare what should be covered with what *is* covered
- Fund research demonstrating test value

# Other Issues Related to Coverage and Reimbursement

- Define what is ‘reasonable and necessary’ for genomics for the Medicare population.
- Encouraging the adoption of new CPT codes, and initiatives like MolDx
- Direct billing for genetic counselors
- Research genomics indications on drug labels.
- ACA – Essential Healthcare Benefits
- Suggestions for USPSTF recommendations

# **THANK YOU!**

**Marc Williams**

**Gene Passamani**

**Laura Rodriguez**

**Laura Koontz**

**...and CMTP staff**