THE INSTITUTE OF MEDICINE
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RUNDOWN ON TRANSLATING GENOMIC-BASED RESEARCH FOR HEALTH

Artists: John J. Wiberg, M.D., Ph.D., Lea L. Harmel, M.D., Ph.D., Peter D. Black, M.D., Ph.D.

2008-2009 ANNUAL REPORT

MEMBERSHIP

Membership of the Roundtable includes a diverse range of stakeholders, including government, the pharmaceutical industry, academic health centers, researchers, associations, patient advocates, and others.

ROUNDTABLE STAFF

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For more information about the Roundtable on Translating Genomic-Based Research for Health, please visit our website at:

www.iom.edu/genomicroundtable

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400 First Street, N.W., Washington, D.C. 20001

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ABOUT THE ROUNDTABLE

The Institute of Medicine Roundtable on Translating Genomic-Based Research for Health brings together leaders from academia, industry, government, foundations, and associations who have a mutual interest in addressing the issues surrounding the translation of genomic-based research. The mission of the Roundtable is to advance the field of genomics and improve the translation of research findings to health-care education and policy.

Therapeutic genomic innovations involve many disciplines, and trace paths within different economic, social, and cultural contexts, generating a need for increased communication and understanding across these fields. Furthermore, these innovations have produced a plethora of new issues to be addressed, including issues such as evidence of utility, economic implications, access, and public perceptions. In a process unique for structured panels, the Roundtable fosters dialogue across sectors and institutions and frontiers collaboration among stakeholders.

To achieve its objectives, the Roundtable conducts structured discussions, workshops, and symposia, and produces authoritative statements. Specific issues and agenda topics are determined by the Rundown steering committee and are a topic of issues relevant to the translation process.

The Rundown serves as an effective or to raise new issues. Established in 1970 under the charter of the National Academy of Sciences, the Institute of Medicine provides independent, objective, evidence-based advice to policy makers, health professionals, the private sector, and the public. The mission of the Roundtable embraces the health of people everywhere.

RUNDOWN 2008-2009 FUNDING

NON-PROFIT, 23%

INDUSTRY, 45%

FEDERAL, 32%

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With the genome research front rapidly changing, the need for this kind of translation is more pressing than ever. The steady expansion of genetic science through basic medical research, translational research, and clinical trials has led to a proliferation of new genetic information. This information is often not well integrated with existing medical, psychosocial, and emotional data. As a result, clinicians are faced with the challenge of understanding how to use genetic information in order to improve patient care and make effective decisions about treatment and prevention.

In response to this challenge, the Institute of Medicine’s Roundtable on Translating Genomic Medicine into Health and Health Care held a workshop on Innovations in Service Delivery in the Age of Genomics on October 6-7, 2008, to address the following questions:

1. What regulatory issues had to be addressed in bringing the test to market?
2. What obstacles have the manufacturers or distributors experienced in obtaining widespread acceptance of the test?
3. Is there a lack of evidence concerning the clinical utility of genomic information for a particular diagnosis?
4. Are health-related research and research funding driven by genomic information?
5. How might we use the test in the treatment stage? Is there evidence for and appropriate role for the use of genetic information to predict the risk of common diseases?
6. Can one overarching process or set of standards be developed?
7. What can we learn from the translation of other new technologies?
8. If so, what are the implications of those different pathways for genomic medicine?
9. How can new evidence be integrated into clinical practice?
10. How can patient and public engagement be integrated into the process of translating genomic medicine into health care?

In addition, the Roundtable set two goals for near-term work:

1. To facilitate the translation of genomic medicine into health care practice, the report described case studies of the current system of genetic service delivery, and discussed the type and level of evidence required by different stakeholders.
2. To improve education, the report described best practices that make collaboration work; and defined the rules of engagement for such collaboration.

The workshop report summarized speaker presentations and discussions about the following topics:

1. The rapid evolution of genomic technology has led to a rise in the use and number of new genetic tests and biomarkers that can be used to diagnose, monitor, and treat a variety of diseases. However, questions remain about the appropriate time to use genetic information in making everyday health care decisions. New practice guidelines will be needed to help clinicians and patients make decisions about genetic information to help clinicians and patients make decisions about the appropriateness of genetic testing.
2. The goal of the workshop was to facilitate the design of research and development efforts that can lead to the implementation of genomic health applications that could improve health outcomes.

The report summarizes the presentations by the expert panel—national and international leaders in the field of genomics—who addressed the following questions:

1. What are the regulatory issues that needed to be addressed in bringing the test to market?
2. What obstacles have the manufacturers or distributors experienced in obtaining widespread acceptance of the test?
3. Do we have needs will change genetic information into interventions?
4. What kind of evidence is necessary to move an innovation into the clinic?
5. Can one overarching process or set of standards be developed?
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7. What can we learn from the translation of other new technologies?
8. If so, what are the implications of those different pathways for genomic medicine?
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The report also provides recommendations for near-term work:

1. To facilitate the translation of genomic medicine into health care practice, the report described case studies of the current system of genetic service delivery, and discussed the type and level of evidence required by different stakeholders.
2. To improve education, the report described best practices that make collaboration work; and defined the rules of engagement for such collaboration.

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Thriving genomic innovations involve many disciplines, and issues arise within different economic, social, and cultural contexts. Generating a need for increased communication and understanding across these fields. Furthermore, these innovations have produced a density of new issues to be addressed, including issues such as evidence of efficacy, regulatory implications, access, and public perspectives. In a setting designed to focus on the core issues, the Roundtable fosters dialogue across sectors and institutions and forms collaboration among stakeholders.

To achieve its objectives, the Roundtable conducts structured discussions, workshops, and symposiums, in addition to publishing workshop summaries. Specific issues and agenda topics are determined by the Roundtable membership and span a broad range of issues relevant to the translation process.

Therefore, the Roundtable seeks to inform the nation to improve health. Established in 1789 under the charter of the National Academy of Sciences, the Institute of Medicine provides independent, objective, evidence-based advice to policy makers, health professionals, the private sector, and the public. The mission of the Roundtable is to advance the health of people everywhere.

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MESSAGE FROM THE CHAIR

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Translating genomic innovations involves many disciplines, and issues prevail within different economic, social, and cultural contexts, generating a need for increased communication and understanding across these fields. Furthermore, these innovations have produced a diversity of new issues to be addressed, including issues such as evidence of utility, economic implications, equal access, and public perspectives. In a process-based fashion for interested parties for different perspectives to meet and discuss complex issues of mutual concern in a neutral setting, the Roundtable fosters dialogue across sectors and institutions from diverse collaboration among stakeholders.

To achieve its objectives, the Roundtable conducts structured discussions, workshops, and convenes, and publishes workshop summaries. Specific issues and agenda topics are determined by the Roundtable membership and span a broad range of issues relevant to the translation process.

The mission of the Roundtable serves as a rector to the nation to improve health. Established in 1970 under the charter of the National Academy of Sciences, the Institute of Medicine provides independent, objective, evidence-based advice to its policy makers, health professionals, the private sector, and the public. The mission of the Institute of Medicine is to improve health by promoting science, engineering, and medicine to the nation's needs.

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Ronald Mayers, Ph.D.
Department of State and Affairs
Angela Underwood, M.D.
University of Texas Health Science Center at Houston
Linda Lynn-Rodriguez, Ph.D.
National Human Genome Research Institute
Andrew Mosk M.D.
Duke University
Stephen St. John, M.D.
Michigan Medicine
Richard Suranyi, M.D.
University of California, San Francisco, School of Medicine

About the Roundtable

The Institute of Medicine Roundtable on Translating Genomic-Based Research for Health brings together leaders from academia, industry, government, foundations, and associations who have a mutual interest in advancing the issues surrounding the translation of genomic-based research. The mission of the Roundtable is to advance the field of genomics and improve the translation of research findings to health care, education, and policy.

Translating genomic innovations involves many disciplines, and issues prevail within different economic, social, and cultural contexts, generating a need for increased communication and understanding across these fields. Furthermore, these innovations have produced a diversity of new issues to be addressed, including issues such as evidence of utility, economic implications, equal access, and public perspectives. In a process-based fashion for interested parties for different perspectives to meet and discuss complex issues of mutual concern in a neutral setting, the Roundtable fosters dialogue across sectors and institutions from diverse collaboration among stakeholders.

To achieve its objectives, the Roundtable conducts structured discussions, workshops, and convenes, and publishes workshop summaries. Specific issues and agenda topics are determined by the Roundtable membership and span a broad range of issues relevant to the translation process.

The mission of the Roundtable serves as a rector to the nation to improve health. Established in 1970 under the charter of the National Academy of Sciences, the Institute of Medicine provides independent, objective, evidence-based advice to its policy makers, health professionals, the private sector, and the public. The mission of the Institute of Medicine is to improve health by promoting science, engineering, and medicine to the nation's needs.

RounDTable 2008-2009 FUNDING

FEDERAL, 32%
NON-PROFIT, 23%
INDUSTRY, 45%

RounDTable 2008-2009 Funding

MEMBERSHIP

Membership of the Roundtable includes a diverse range of stakeholders, including government, the pharmaceutical industry, academic health centers, researchers, associations, patient advocates, and others.

Kathryn Bass, M.D., Ph.D.
University of Washington
Bruce Bloch, M.D.
National Cancer Institute
Cyndiwini Caccavale, M.D.
University of California, San Francisco School of Medicine
Katherine Chen, M.D.
Genomic Health, Inc.
Adam Fish, M.D., B.S., M.Sc., N.C.C.Psych.
Pfizer Inc.
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University of California, San Francisco, School of Medicine
The Institute of Medicine’s Roundtable on Translating Genomic Medicine into Health care — 2009

To address the question: Once stakeholders agree there is sufficient evidence, what is the best approach to answer the question: How will this evidence be translated into health care? The Roundtable small groups specified workshop topics that will help fulfill goals (see “Future activities” for details).

The Roundtable held a workshop on February 12, 2009, to outline the key building blocks of a new ecosystem; to define the key components that will make up a new ecosystem for moving genomic innovations into patient care; and to evaluate how the new ecosystem would fit into existing systems, and how this matrix will be presented and discussed at the workshop.

This workshop will define the set of challenges in accomplishing the Roundtable’s mission. It will also help set the agenda for developing new regulatory and professional standards that will address these challenges.

The Roundtable small groups identified key challenges facing genomic innovations. These workshops will define the set of conditions that will make up a new ecosystem for moving genomic innovations into patient care; and the Roundtable small groups will identify which inter- constituencies will be engaged in pre-competitive collaboration.

The Roundtable’s approach to pre-competitive collaboration is different from many other collaborative efforts in science, in that the Roundtable small groups will identify which inter-constituencies will be engaged in pre-competitive collaboration.

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The Roundtable small groups will develop a strategic plan for the future activities of the Roundtable. The plan will be developed by a series of small groups, each focused on one of the Roundtable’s five work groups. The plan will be presented to the Roundtable’s annual meeting in June 2009, as a basis for the Roundtable’s budget for fiscal year 2010.

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The Roundtable on Translating Genomic-Based Research for Health held a public meeting using four case studies for an in-depth exploration of the translation of genomic innovations based on a model of intensive counseling for rare diseases. As the vision. Now, nearly 20 years later, DNA diagnosis, and treating disease based on a model of intensive counseling for rare diseases. As the vision. Now, nearly 20 years later, DNA diagnosis, and treating disease based on a model of intensive counseling for rare diseases. As the vision. Now, nearly 20 years later, DNA
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To achieve its objectives, the Roundtable conducts structured discussions, workshops, and symposia, and publishes anthologies. Specific issues and agenda topics are determined by the Roundtable membership and span a broad range of issues relevant to the translation process.

A key role of the Roundtable is to encourage dialogue among stakeholders from different perspectives. As a convening mechanism for interested parties from different perspectives to meet and discuss complex issues of mutual concern in a neutral setting, the Roundtable fosters dialogue across sectors and institutions and fosters collaboration among stakeholders.

Through the 2008-2009 Annual Report, the Roundtable shares its activities, the progress of its funding, and its accomplishments. The report includes the names of Roundtable members, sponsors, and funding sources.

### ROUNDTABLE STAFF

**Director**, Board on Health Sciences Policy

**Senior Program Assistant**

**Research Associate**

**Director**

**ROUNDTABLE STAFF**

LYSIA N. HAMMOODI

SUZAN RODRIGUEZ

ANDREW RUPES

Director, Board on Health Policy

### CONTACT

For more information about the Roundtable on Translating Genomic-Based Research for Health, please visit our website at http://www.iom.edu/genomicroundtable

### 2008-2009 FUNDING

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<th>FEDERAL, 0%</th>
<th>INDUSTRY, 65%</th>
<th>NON-PROFIT, 35%</th>
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### MEMBERSHIP

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**ROUNDTABLE 2008-2009 FUNDING**

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