Genetic Testing And Data Management Summit
Improving Health Outcomes, Disease Management, And Accountable Care Delivery

• March 12, 2012 •
Biotechnology Industry Organization
1201 Maryland Ave SW # 900, Washington, DC
Hosted by Genetic Alliance

Participants – your role is critical. Throughout the day we will be collecting the 'elephants in the room', the points of tension, the potential solutions and enlisting participants for crafting system improvements.

Goal of the Summit:

- Bring together diverse stakeholders to discuss state of affairs in genetic testing
- Discuss current and future trends in genetic diagnostic technologies, growth of genetic testing services, information utility and regulatory environment
- Outline elements of rational patient-centered system
- Map challenges to achieving goals and possible solutions
- Analyze best practices (e.g., cancer management)
- Identify key entities to guide system improvements

Develop Recommendations

Short-term — improve decision support tools available to patients and clinicians regarding evolving field of genetic knowledge that enhances appropriate decisions and use of clinical services.

- ***Patient-oriented strategies:*** Today individuals are faced with increasingly intensive marketing by the genetic testing industry and have limited evidence about appropriate services. Individuals, families and communities need information that will help them make decisions about whether and how to access available diagnostic information.
- ***Clinician-focused approaches:*** An overwhelming amount of genetic and genomic information is entering the health care system from the scientific community and testing industry. Clinicians face growing demands from consumers but have limited access to clear evidence about the value of certain tests, encounter conflicting guidelines from professional societies, and face reimbursement pressures from payers. They also may have limited training in the use of genetic technologies. Clinicians need better decision support aids and educational opportunities about appropriate applications of genetic medicine.

Foundation for long-term — improve approaches to developing the evidence base surrounding genetic applications, including analytic tools, decision support aids and utilization strategies to measure and monitor clinical performance, disseminate and expand best practices from providers, and identify coverage and payment approaches that support better use of genetics technologies.

Agenda

8:30 AM – Registration and continental breakfast

9 AM – Stakeholder Impact and Approaches

Engaging patients, clinicians, and other stakeholders in the payer, manufacturer and policy/regulatory community to create a sustainable system.

Sharon Terry, Genetic Alliance

9:10 AM – State of Genetic Testing

Reed Tuckson, UnitedHealth Group

Panels

Cross cutting issues that all panels will consider:

New technologies and what that does to scalability/regulation/pricing?

Diversity of testing – lumping and splitting

- *predictive vs. diagnostic vs. recreational*
- *public health vs. clinical*
- *life stage vs. cascade*
- *paired vs. independent*
- *rare vs. common vs. tumor vs. non-disease focused*
- *point of care vs. DTC vs. stored information (ex. WGS at birth)*

Data explosion, lack of analytics expertise, and the follow-up bottleneck (and cost problem)

9:30 AM – Clinical Questions to Drive the Enterprise

What are the clinical questions that should be driving the use of genetic tests? What development strategies do we need to make that happen? There have been no substantial endeavors designed to consider what clinicians and patients need and want; nor what the public health system needs to do a better job: can genetic testing address obesity, diabetes, heart disease? What are the pressing clinical questions that would benefit from genomic applications/genetic tests? How would we go about shifting to this focus from one that usually has the application driving the uptake, rather than the need driving the development of genomic applications? Are we raiding the medical commons with unnecessary follow-up?

Moderator: Marc Williams, Geisinger
Holly Peay, Parent Project Muscular Dystrophy
Kathie Sutherland, El Camino Hospital
Norman Kahn, Council of Medical Specialty Societies
Steve Gutman, BlueCross BlueShield Technology Evaluation Center

10:20 AM – Effective Decision-making for Genetic Testing

- *What constitutes informed decision-making in medicine?*
- *Decision-support tools, including electronic health records*
- *How decision-support tools are best used for consumers and providers*
- *Does genetic testing differ from other clinical testing and so need special support, i.e., genetic counseling?*
- *How to avoid unnecessary testing?*
- *How to address follow-up testing?*

Moderator: James O'Leary, Genetic Alliance
Joan Scott, National Coalition of Health Professional Education in Genetics
Dan Wattendorf, Defense Advanced Research Projects Agency
Len D'Avolio, VA Boston Healthcare System
Michael Burgess, University of British Columbia

11:10 AM – Evidence

This panel will consider the context for evidence, rather than the level of evidence, needed to move innovative technology into a clinical setting and how we will generate the needed evidence. Which evidence questions must be answered pre- market and which, if any, can be answered post-market? It will consider the often mismatched evidence requirements of patients, clinicians, test developers, regulators and payers. Collectively, we should define a burden of evidence that's appropriate for the balances of risk and speed that is appropriate in this space. This will require community-wide cooperation to collect and analyze data residing in many different places -- inside pharmaceutical companies, inside diagnostics companies and payers -- to measure outcomes and define the best use of diagnostics, and innovative methodologies to generate evidence (both in process and results).

Moderator: Adam Berger, Institute of Medicine
Patricia Deverka, Center for Medical Technology Policy
Stanley Lapidus, SynapDx
Susan Friedman, Facing Our Risk of Cancer Empowered
David Clifford, PatientsLikeMe
Roger Klein, University of South Florida Medical School

12:00 PM – Personalized Medicine: trends and prospects for the new science of genetic testing and molecular diagnostics

Overview of new working paper – Mapping the Future of Genetic Testing and Molecular Diagnostics: A payer's perspective on integrating personalized care into clinical practice
Review of results of survey of consumers and physicians about genetic testing

Deneen Vojta, UnitedHealth Group

12:15 PM – Lunch and Keynote

Whole Genome Sequencing: will the $1000 genome accelerate diagnostics and treatments, or put pressure on already stressed systems and break them or make them?

George Church, Harvard Medical School and Knome

1:15 PM – Real World Clinical Settings for Collecting Needed Data

We should focus on transparency and putting patients first. This is the way in which we can make sure that we have a conceptual framework that allows us to bring these genomic advances to practice.

- *Using available data sources to generate iterative evidence – claims and EMR and PHR*
- *What policy initiatives are needed?*
- *What models exist?*
- *What's working?*

Moderator: Emily Edelman, National Coalition for Health Professional Education in Genetics
Marc Williams, Geisinger Health System
Bruce Lin, March of Dimes
Matthew Tector, Aurora Health Care
David Ledbetter, Geisinger Health System
Eric Stanek, Medco

2:05 PM – Integrating new genetic testing technologies into clinical pathways

What is the relationship between implementation guidelines and reimbursement? Are payers the ultimate gatekeeper? Is it worth educating healthcare providers and patients?

- *Appropriate uses of genetic testing*
- *Evidence-based guidelines and flexibility*
- *Clinical management of new technology*
- *Best practices (e.g., breast cancer)*

Moderator: Robert Green, Harvard Medical School
Robert McCormack, Veridex/J&J
Thomas Musci, Novartis Diagnostics
Greg Feero, Maine - Dartmouth Family Medicine Residency and NHGRI
Deborah Heine, Claire Altman Heine Foundation

2:55 PM – Value based pricing

Reimbursement policy for new medical technologies must balance creating incentives for innovation and keeping costs affordable. Currently developers of novel and complex genetic and molecular tests are primarily reimbursed according to fee schedules How well do current reimbursement methods reflect the value of new diagnostics in patient care and provide incentives for development of products? How might new approaches to reimbursement or incorporate the value of diagnostics in providing information to providers and patients, generate patient outcomes or reducing the need for inappropriate care? This panel will consider coding issues, economics, and value remembering that no stakeholder wants to drive up healthcare costs, how do we pay?

Moderator: Steve Gutman, BCBS Technology Evaluation Center
Rina Wolf, XIFIN
Patrick Terry, Scientia Advisors
Brian Carey, Foley Hoag LLP
Elaine Jeter, Palmetto GBA

3:45 PM – Regulation

This panel will consider the effect of regulation on the appropriate use of genetic testing and their integration into healthcare. It will examine the challenges of regulating an industry with several agencies overseeing various aspects, and growth in genetics exceeding the capacity of the expertise of the oversight agencies. Are there gaps in oversight between FDA and CLIA and if so, how do they affect patients? How can they be addressed?

Moderator: Sheila Walcoff, Goldbug Strategies
Alberto Gutiérrez, FDA
Paul Radensky, McDermott Will & Emery
Alan Mertz, American Clinical Laboratory Association
Russell Enns, Cepheid

4:35 PM – Final summary discussion

Discussion of short-term and long-term foundational solutions
We will name the elephants, and also be quite practical about the potential solutions and challenges thereof

Marc Williams and Sharon Terry

Hosted by

Genetic Alliance

Thanks to our Sponsors

United Health Foundation

Bio BIOTECHNOLOGY INDUSTRY ORGANIZATION

ScientiaAdvisors

GEISINGER