

# Think Tank Meeting

## November 4, 2014

### Dallas, TX

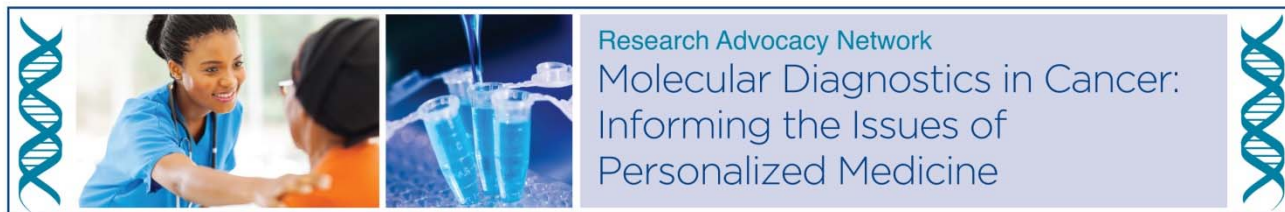
## Notes

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## Think Tank Meeting

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### About the project

This meeting was held as part of a larger project to bring an awareness to advocates and patients of issues of molecular diagnostics in cancer. To reach our goal we will have several components that build on each other:

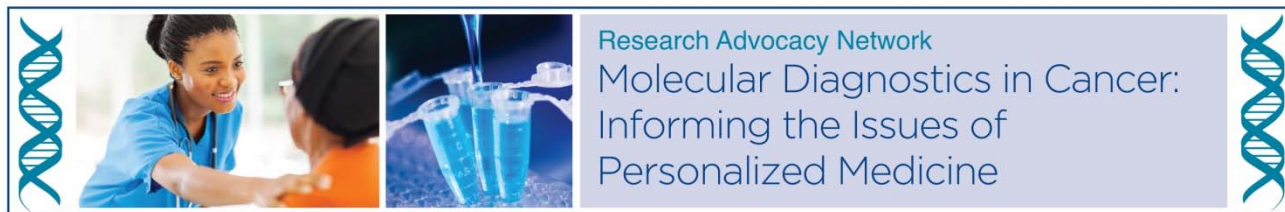
- Expert interviews
- Backgrounder document with a literature search
- Think Tank Meeting
- Report from Think Tank Meeting
- Symposium in April (Indianapolis, IN)
- Discussion group online

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### Funder information

We gratefully acknowledge funding from Genomic Health for the Think Tank Meeting and underwriting the development of the backgrounder brief.

The expert interviews that were conducted to inform the preparations for this meeting were funded by Novartis.




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## Think Tank Participants

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Attendees at the Think Tank meeting, November 4 are listed below in alphabetical order.

***Karen Anderson MD, PhD***

Associate Professor, Biodesign Institute at Arizona State University, Virginia G. Piper Center for Personalized Diagnostics  
 Medical Oncologist and Associate Professor of Medicine at Mayo Clinic Arizona

***Cynthia Chauhan***

Advocate and Cancer Survivor  
 Think Tank Facilitator

***Sara Chenault***

Senior Director, Patient Advocacy Genomic Health

***Deborah Collyar***

President  
 Patient Advocates in Research

***Karen Durham***

Breast Cancer Research and Patient Advocate  
 Susan G. Komen for the Cure Advocates in Science Steering Committee and Komen Scholar

***Mark Fleury, PhD***

Principal, Policy Development - Emerging Science  
 American Cancer Society Cancer Action Network, Inc.

***David E. Gerber, MD***

Associate Professor of Internal Medicine, Hematology/Oncology Division  
 UT Southwestern Medical Center  
 Co-Director, Experimental Therapeutics Program

***Mike Katz***

Vice President  
 International Myeloma Foundation

***Pei Koay, PhD***

Research Manager  
 Center for Medical Technology Policy (CMTTP)

***Susan Mantel***

Senior Vice President, Research and Education  
 LUNGeivity Foundation

***Virginia (Ginny) Mason, RN***

President and Executive Director  
 Inflammatory Breast Cancer Research Foundation

***Glenn Mills, MD FACP***

Professor of Medicine LSUHSC-Shreveport  
 Director of the Feist-Weiller Cancer Center  
 PI Minority Based CCOP LSUHSC-Shreveport

***Gary Palmer, MD, JD, MBA, MPH***

Senior Vice President, Medical Affairs  
 Foundation Medicine, Inc.

***Elda Railey***

Co-Founder, Research Advocacy Network

***Mary Lou Smith, JD, MBA***

Co-Founder, Research Advocacy Network

*The following summarizes the discussion of each topic. Slides were displayed with each round of discussion that listed the salient points garnered from the expert interviews. A graphic of those slides is included in each section.*

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## **I. Pros and cons of molecular diagnostic testing in the treatment planning and care of patients**

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### **I. Pros and cons of molecular diagnostic testing in the treatment planning and care of patients**

- Dr. Hahn: Documented added value beyond what is currently available with proven improved response in the selected population
- Dr. O'Neill: The test must facilitate a meaningful clinical decision and be a good predictor of treatment response.
- Dr. Messner: Documented demonstration of clinical usefulness and usable universal guidelines.
- Dr. Schilsky: The test must clearly inform a medical decision, have adequate payment plans and regulatory clearance.
- Dr. Schneider: Legal issues of intellectual property and test ownership must be clarified as well as marketing issues. Education as to the value and usefulness of the test is important.
- Dr. Sing: Provide information that makes the test readily useful for physicians in discussing tumor characteristics and determining treatment decisions with patients.

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### **Discussion:**

- Just beginning to see a shift in oncology - grateful for living longer but also living better
- Major obstacle of including QOL and getting reimbursement
- Academic to community - more tests now being used in community
- Commercialization - Ads from some institutions are setting up expectations of genomic testing for everyone, and concern about what is being done with results of the testing.
- Need to understand how people want to receive the information
- Also need to consider the elderly and other special populations
- How we integrate testing into clinical practice and the standard of care

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## II. Barriers and hurdles to the use of molecular testing.

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### II. Barriers and hurdles to the use of molecular testing.

- Dr. Hahn - Barrier to use if the test is not user friendly for both the patient and the physician. Also, a molecular tumor board needs to be available for best implementation.
- Dr O'Neill - Lack of access or inadequate biologic samples. Also, physician education is a hurdle - currently doctors are overwhelmed with so much information and have trouble filtering out the "noise"
- Dr. Schilsky - Biggest barriers are developing clinical evidence that can be measured and will be informative to a medical decision.

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During this session we had a presentation by Stan Hamilton, MD who presented the NCI MATCH trial and brought to our attention some of the issues regarding molecular diagnostics encountered in planning this trial. A handout of Dr. Hamilton's slides are available at: <http://bit.ly/1F3V8xf>

#### Discussion:

- Reimbursement is a big hurdle.
- Availability of services may be location specific/ based on patient population and indigent/ underserved.
- Community practices may be using Foundation Medicine and other tests as a marketing tool to keep folks in the community rather than going to larger centers
- How do advocates carry the message? We need a distinct message that is focused on the patient. There is not just one patient voice.
- The source of the information can be a factor in acceptance by patients. If disseminated by a patient advocate organization may be a higher acceptance rate. Should be a collaborative effort so that it is not market driven.
- Materials need to be multi-lingual and culturally sensitive
- Need to understand that these tests may bring uncertainty (intermediate or undetermined ranges)
- Need to ask "So what?" (e.g., What does it mean that the test actually measures the copy number?)
- Information should come from patient need. Patients need useful and honest information.
- Inadequate tissue (biospecimen) sample is an issue. Consider the clinical environment for obtaining biospecimen / biopsy material. Use a needle biopsy when possible.

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### III. Ideas for overcoming the barriers and jumping the hurdles.

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#### III. Ideas for overcoming the barriers and jumping the hurdles.

- Dr Hahn - Better education for all members of the medical practice and having the resources
- Dr. Messner – Payers/insurance and funding for tests and treatments are primary barriers. Need to be more conscious of the trade-offs we are making here. High level of need, then marker with lesser level of evidence and an available drug. Patient at beginning and well established options then less uncertainty is needed. For physicians guidelines are helpful.
- Dr. Schneider - Test to market is an educational thing. Academia is trying to help scientists who have zero education in business to work with industry. Researchers need to know how to better market a product.

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#### III. Ideas for overcoming the barriers and jumping the hurdles. (continued)

- Dr. Sing – GHI has conducted clinical utility studies which showed effectiveness – risk stratification resulted in benefit to patients and cost savings and physicians were using the test appropriately. They defined a new approach and have done a lot of education around clinical validation using a legacy clinical trial.
- Dr. Schilsky -
  - Partner with a research group for biospecimens where the outcome is known. Validate the test repeatedly using a prospective - retrospective design.
  - Develop tests following the basic concepts of a) intended use b) test in population where the results will be interpreted.
  - All large clinical trials collect biospecimens correlated to outcomes.

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#### Discussion:

- We need to be sharing what has worked so that we can learn from each other
- GHI has conducted a clinical utility study and found their test changes the treatment decision 30% of time
- We need education about the mechanics of tissue collection
- Need education and work with payers to help with the reimbursement issue
- There is a concern that payers are not responding to what's been learned in science.
- More difficult economic times
- Processes of diagnostics development need to be as rigorous and defined as the drug (therapy) development process.
- Approval process may involve a type of decision - tree algorithm.
- Language is important - what we call "it" matters. The different terminology used is confusing.
- Need to develop a 3 minute elevator speech. What it is. What it means.
- We need to also advocate for the research - that's where the answers will come from.
- Visuals are important. Need to use words and visuals that make sense and resonate with patients.
- Medical community is a long way from getting to know what test to use / when/ and how to communicate the results.
- Setting realistic expectations about the information received from molecular testing is a concern.
- Materials need to be tailored to specific audiences. Different needs call for different approaches.
- Almost everyone is illiterate when it comes to this topic. Language used when discussing these types of tests is not in our everyday vocabulary.
- Need to prove the value of molecular testing for reimbursement. In lung cancer it is going to be hard to prove value because of the cost( of the treatments?).
- Literacy is important. Need to not fall back on how tests work but what is relevant to the patient/ physician.
- Need to consider if molecular testing valuable from a public health/ policy perspective

- One idea for overcoming barriers is to develop an action oriented partnership or coalition with members from advocacy, professional societies, etc. that could communicate the value of molecular testing. This collation would create a united voice to payers.
- Need one voice / terminology and a common language
- Web based tumor board might help address the lack of expertise in local communities.
- Trials need to be conducted to prove validity of the test. Then focus can be put on specific interventions and funds can be leveraged.

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#### IV. Providing test results to patients. Pros and cons/ Who When How

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**IV. Providing test results to patients.**

- Dr. O'Neill- Need to guard against being overly enthusiastic and wait for evidence that the tests provide meaningful results ( eg, adoption into practice without evidence)
- Dr. Schneider - Pretend you are a patient and how do you explain what your test will tell a patient. Have to figure it out. Make it simple. A major barrier is understanding the test and the implications of the test. We must provide alternative to problem identified – not just telling them something is bad.
- Dr. Schilsky - The traditional interface in medicine will need to change to accommodate the new testing. A dr will need to consult with pathology about what test / what material is needed then will need to consult on interpretation of the test results. The big limitation is who pays for all the expertise and time for these consultations. Also, another limiting factor is the lack of molecular pathologists.

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#### Discussion:

- Focus on actionable mutations
- Careful not to give false hope. Explain in language patients can understand. Payment / reimbursement for consultation a concern.
- No informed consent requirement. Difference between genetic/ genomic is important.
- How are incidental findings handled?
- With some tests the physician orders the test but the patient doesn't know it has been ordered
- Best scenario - Physician orders test, goes over results with patient and they determine together what course of action to follow.
- Could have a "smart" document with checklist of things so can select/ tailor rather than provide an encyclopedia - explain
- Need to provide results to patient AND family/caregiver so can be a joint decision making process
- Some want to know everything - some want to know nothing. Need to be able to provide the level of information the patient wants.

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#### IV. Providing test results to patients. Pros and cons/ Who When How (continued)

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- Molecular diagnostic tests are much different than other tests (x-rays, etc.) may need consent before and after
- Just because there is a test doesn't mean there is a treatment
- Understanding the difference of what it means for a test to be positive (example: HER2 positive, ALK positive or negative).
- Who, what, when is important - patients may soon be able to get results directly from the lab
- Patients have the right to have results. Need this in writing.
- Provide pre-test counseling and for secondary incidental findings.
- The cost of these counseling sessions may be prohibitive.
- Expertise is needed to communicate information about molecular tests but it does not have to be MD/PhD level. Assimilation from current knowledge bases is important in training who communicates.
- There is a need for a molecular tumor board. Electronic health records (MyChart, etc.) must be activated to share all results in the chart.
- Industry needs to provide concise reports.
- Results need to be provided to both patient and physician within 2 weeks
- Incidental findings are a huge concern. Physician should be the one to make the decision about sharing the results with the patient.
- Reports need to be integrated into medical record - not just as a pdf attachment. The first page of the Foundation One report is now available in a transferrable format so it can be integrated into the record.
- HIPPA issue because systems aren't allowed to talk to each other
- Results are not static - tests are improved and can deliver better information (example - BRCA test in 2003 not as accurate as 2014) but there is no way to inform the patient of the progress

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#### V. The advocate as facilitator / implementer / interpreter.

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V. The advocate as facilitator / implementer / interpreter.

- Dr Hahn
  - Help with patient identification and recruitment for clinical trials since these types of trials require a subset of patients.
- Dr. Schilsky
  - Help with education about biospecimen collection
  - Help with educating patient and setting expectations

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#### Discussion:

- Consortium approach is important
- Educating about the importance of biospecimen collection is an ongoing issue and advocates are important in addressing



- Advocates bring us back to the issues and help set expectations
- Advocates are essential to accruing for clinical trials. But need to help patients look for right trial for them and not just concentrate on finding one trial.
- Don't guess- test. Important message for newly diagnosed
- Advocates serve as an interpreter/ translator of the research results and what it means for patients.

Think Tank Activities (from flip chart):

- Enabling access to tests/ trials, Advocates work together on issue / clinical trials
- Web page/ blog - exciting things MDx, interested group live beyond today and talk together/ reinforce connection. Continuing the conversation
- Clear approach to sharing results, clear guidelines about communication with patients/professional / advocacy groups together to address issues
- Examine differences in platforms (splitter/ lumpers)
- Clinical trials and what is available to patients outside clinical trials
- Potential education materials about platforms
- Molecular testing available in the community with appropriate guidance
- Put pressure on payers to reimburse for tests.
- Potential straw vote survey