“Toward a system plan for transforming cancer care to a molecular-based approach”: Recommendations from an expert panel

Leading cancer experts convened for a one day Think Tank to develop practical recommendations for transforming cancer care from an organ-based approach to a molecular-based approach. The event took place on May 30, 2013 in Chicago prior to ASCO and was keynoted by Dr. Richard Wilson, Director, The Genome Institute at Washington University School of Medicine.

Members

- Rick Wilson, Director, The Genome Institute at Washington Univ. School of Medicine
- Judy Garber, Director, Cancer Risk/Prevention Clinic, Dana Farber
- Shashikant Kulkarni, Head of Clinical Genomics, Wash. University School of Medicine
- Shyamali Singhal, Medical Director of the Cancer Center, El Camino Hospital
- Nickolas Papadopoulos, Director of Translational Genetics, Johns Hopkins Medicine
- John Sweetenham, CMO, Huntsman Cancer Institute
- Paula Rieger, CEO, Oncology Nurses Society
- Nazneen Aziz, Director of Molecular Medicine, College of American Pathologists
- Mary Zutter, Director, Tumor-Host Interaction Program, Vanderbilt Ingram Cancer Center
- Tim McDaniel, Director of Scientific Research, Illumina Inc.
- Les Paul, CMO, Caris Life Science
- Dawn Van Dam, CEO, Health Connexions
- Anthony Flynn, Associate, AcceleratorH

Think Tank Background

At the 2011 Personalized Medicine Conference1 at Harvard Medical School, 80% of attendees voted “genomic interpretation” as the top challenge in adopting genomics in routine medical care. Given the industry-wide collaboration involved in interpretation, an I-Study2 set out to determine how well the healthcare ecosystem is aligned with the goals of genomic medicine and to offer recommendations to accelerate this important advance.

The 2012 I-study conducted interviews with more than 55 industry leaders across twelve healthcare sectors: pharmaceuticals, contract research organizations, academic laboratories, commercial laboratories, diagnostic companies, decision support suppliers, healthcare providers, sequencing providers, healthcare equipment makers, care management, healthcare IT, and payers. An expert panel representing science, medical, technology, and business disciplines reviewed the transcripts and produced a comprehensive set of findings and recommendations.

One of the recommendations, originally suggested by Dr. Rick Wilson of Washington University, was: “Prepare a System Plan for Molecular-based Treatment of Cancer”. Many interviewees felt that cancer is best treated as a molecular disorder and not an organ disorder and reported frustration with the present mismatch between a molecular approach and the organ-based structure of the present healthcare system. Hence, a study recommendation called for a systematic plan to transform cancer care based on the current molecular understanding of the disease, specifically that cancer is more similar across organs than previously understood.

Recommendations

1. Establish a shared, sustainable registry of patient/tumor phenotypes/genotypes for use by the cancer research and care community.

Clinical genomics relies upon the collection of statistically valid data that is collected and analyzed to identify patterns and draw conclusions. Both the research and clinical members felt strongly that cancer care would benefit greatly if there was a shared, sustainable, de-identified registry of patient/tumor phenotypes/genotypes for use by all. Armed with this expanding collection of data, clinical teams could look for similar profiles to guide patient diagnosis and treatment while research could gain an aggregation of rich, clinical-grade data to drive discovery.

Several requirements were discussed. First, because patients and care organizations are hesitant to contribute their samples and related data to a for-profit organization, the registry should be run by a non-profit organization. Second, in order to be self-sustaining financially, the registry should have a governance program that clarifies use and establishes membership costs and compensation — organizations that consume and benefit should pay and fund the registry and organizations that contribute the data should receive payment to fund the required overhead. Third, at the outset, the registry should provide unanalyzed genotype data and basic phenotype data with importing/exporting tools and grow to provide a framework for users to apply their own analysis tools and store/share intermediate results and findings. Fourth, at the outset, the data types and fields should start with raw DNA sequence results (with a quality threshold) and available phenotype data. The system should, over time, scale to accept multi-sample/tumor/normal results, multiple types of test results (DNA, RNA, imaging), and increasingly rich phenotype information.

Today, the vast majority of cancer sequencing results are not captured and applied to general research. This registry and its broad use would offer the benefit of a “feedback loop” into genomic cancer care where the large volume of payer-subsidized, clinical-quality tests would indeed be captured and applied back into research by the entire cancer community.

Timeframe goal: A pilot organization, plan, and funding from pharma and foundations in 2014.

---

1 An annual two-day event co-hosted and presented by Partners HealthCare Personalized Medicine, Harvard Business School, and Harvard Medical School in association with the American Association for Cancer Research and the Personalized Medicine Coalition.
2 Interpretation study directed by Cambridge Healthtech Associates and GenomeQuest, Inc. and co-sponsored by the Personalized Medicine Coalition.

http://dx.doi.org/10.1016/j.atg.2014.06.002
2212-0661/© 2014 Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/3.0/).
Candidate organizations to lead: It is recommended that this registry leverages the efforts of groups creating related collaborations, including: NCI NCCs, C4Hub, CDISC, Project Data Sphere, TCGA, and CHTN. These groups offer critical knowledge, expertise, and perhaps infrastructure and data to accelerate the registry’s start and improve its long-term impact.

2. Provide physician decision-support on the latest diagnostic/treatment options and reimbursement guidelines.

With rapid developments in molecular-based cancer care, physicians are forced to spend too much time researching new diagnostic/treatment options and related reimbursement policies. Ideally, payers could work toward providing cancer care decision support in these areas that could be applied to patient cases — improving outcomes and reducing time and costs. Such a system would ideally track the latest diagnostic/treatment options, provide profile-specific standard-of-care workflows, and offer payer-specific reimbursement guidelines. 

Timeframe goal: A working system from the majority of the payers by 2015.

Candidate organizations to lead: Large payer(s), payer organization, or payer system supplier.

3. Define evidence required during this transition period.

In transitioning from organ-based care to molecular-based care, the cancer care community currently lacks clarity on what evidence is required to achieve standard of care in both clinical and payer arenas. The lack of clarity leaves a void that is slowing advancement, creating inefficiencies, and discouraging investment. Until clarity is attained, the research community seeks transitional guidelines for such evidence. Such guidelines would expand investment and discoveries, improve care, and accelerate the advance to a more stable state of cancer care.

Timeframe goal: A draft set of guidelines and parameters by 2015.

Candidate organizations to lead: NCCN lead, working in concert with payers and payer organizations.

4. Redefine clinical study methodologies to match the new realities and opportunities.

Traditionally, clinical study methodologies have been defined for and applied to large populations with non-mutating disorders. On the other hand, molecular diagnostics, treatments, and strategies for cancer care target smaller populations and disorders that rapidly mutate. This new understanding calls for studies that are smaller, more agile and time-sensitive, include molecular biomarkers, involve integrated diagnostics and treatment, and expand the domain of study to include test algorithms and treatment strategies. Overall, the situation calls for a re-definition of clinical study methodologies.

Timeframe goal: A credible organization commits to lead this effort by 2015.

Candidate organizations to lead: Patient-Centered Outcomes Research Institute (PCORI).

5. Identify where market is failing to develop required/sustainable business models and propose solutions.

The transition to a molecular-based approach to cancer care is a promising one: full of breakthrough scientific and medical opportunities. New types of companies, business models, investments and leadership are likely needed. We call on a leading business school to identify where this market is failing to organically develop new sustainable business models and propose strategies for success.

Timeframe goal: A comprehensive and funded study begins in 2015.

Candidate organizations to lead: A major business school.

6. Prepare the cancer care community for new care delivery associated with molecular-based treatment.

The US spends over $100B on cancer care annually with over 20,000 professionals serving over 1.6M new patients and 13M surviving patients.

Molecular-based treatment is fast becoming the focus of advanced cancer care and needs to be built into the mainstream practice of cancer care. As it is a relatively new and rapidly advancing field, care professionals and primary care physicians, particularly outside of academic medicine, need to be trained on the fundamentals and kept abreast of the latest developments. We propose a proficiency and continuing education program for each of these care providers.

Beyond the basics of molecular medicine, examples of new topics to cover:

- workflows to diagnose and treat different molecular profiles/patterns
- the integrated set of diagnostic readings, including: genotype, transcriptomes, epigenomes, and imaging
- drugs that treat at a molecular level and are effective across organs
- the need for “waves of diagnosis and treatment” to battle “waves of mutations”

Timeframe goal: A comprehensive and funded study begins in 2015.

Candidate organizations to lead: ASCO.

7. Perform an economic impact analysis

In an integrated healthcare model, it would be straightforward to measure and prove that a holistic, molecular testing/treatment approach leads to improved outcomes and overall cost cutting. However, given the fragmented nature of US healthcare, providers across the spectrum find it difficult to prove these benefits to policy makers, payers, and investors.

The situation calls for an economic analysis of molecular-based diagnosis/treatment of cancer care — ideally, an observational study based on costs and results over a significant period on a population of patients. Such a report would inform payers on guidelines for case workflows and diagnostic/treatment reimbursement. To guide and accelerate the study, it should be conducted in conjunction with an accountable care organization (ACO), which could serve as a pilot for implementing and measuring value-based policies.

Timeframe goal: A study is structured and commences in 2015.

Candidate organizations to lead: Major payer, ideally in partnership with a major ACO.

8. Build on success of clinical/scientific partnerships.

Some of the most advanced molecular-based cancer care treatment comes from clinical centers in close partnership with research groups; examples discussed include those at Vanderbilt University, El Camino Hospital, and Washington University. These collaborations offer significant advantages to both sides; researches have close connections to real cases, care providers can apply the latest discoveries, and often the two collaborate directly on patient diagnosis and treatment. Great benefit could come from understanding the structural lessons learned of these partnerships so they can be broadly applied across the cancer care community, including the formation of more partnerships between industry (companies invested in molecular profiling) and the academic research community. Ultimately, it's the patients who will benefit with broader access to leading-edge cancer care.

Timeframe goal: A think tank to study and document lessons learned in clinical/scientific partnerships.

Candidate organizations to lead: Cambridge Healthtech Associates

Anthony Flynn
Weston, United States
E-mail address: anthony.flynn@acceleratorh.com.
Corresponding author.

Dawn Van Dam
Health Connexions, Toronto, Ontario, Canada
E-mail address: dawn@healthconnexions.com.

26 May 2014