



2020 Prevent Cancer Foundation Advocacy Workshop—Genetics, Genomics and Biomarker Testing: Impacts on Cancer Prevention

Executive Summary

**Speakers:**

**Panel moderator: Lisa Schlager**, Vice President, Public Policy, Facing Our Risk of Cancer Empowered (FORCE)

**Panelists:**

**Heather Hampel, MS, LCG**, Associate Director, Division of Human Genetics; Associate Director, Biospecimen Research; Professor, Internal Medicine; Licensed Genetic Counselor The Ohio State University Comprehensive Cancer Center

**Jennifer R. Leib**, Founder, Innovation Policy Solutions, LLC

**Nikki Martin**, Director of Precision Medicine Initiatives, LUNGevity

**Becky Nagy**, Vice President of Medical Affairs, Guardant Health, Inc.

**Brandi Preston**, Founder, Kamie K. Preston Hereditary Cancer Foundation

**Overview**

On September 9, 2020, the Prevent Cancer Foundation held its annual Advocacy Workshop. The focus was on genetics, genomics and biomarker testing, with speakers addressing the role of genetic and biomarker testing and their application to cancer prevention. This topic was identified as important in cancer prevention and early detection because the ability to screen for germline (inherited) mutations and hereditary conditions such as Lynch syndrome, as well as somatic (acquired) mutations and biomarkers, can help providers determine a person's risk for cancers associated with the mutations.

The Workshop was split into two sections. Attendees spent the first half of the Workshop learning about the basics of genetic testing and barriers that impede the availability and utilization of those tests. During the second half, attendees split into breakout sessions to

discuss these barriers to access and propose potential solutions. After the breakout discussions, attendees returned to share the potential solutions from their respective sessions, which provided ideas and opportunities to collaborate and discuss ways we can work together.

### **Genetics and Genomics 101**

Heather Hampel, MS, licensed genetic counselor and researcher at The Ohio State University Comprehensive Cancer Center, started the day with a presentation on the basics of genetics, covering both germline (inherited) and somatic (acquired) mutations, and how they impact cancer prevention.

Germline mutations are inherited from one's parents and occur in every cell of the body. These mutations increase the risk of developing a hereditary cancer syndrome, which predisposes individuals to certain types of cancer. Some of the most common syndromes are the Hereditary Breast-Ovarian Cancer Syndrome (HBOC) and Lynch Syndrome, which increase the risk for breast and ovarian cancers and colorectal cancer, respectively.

Somatic mutations are acquired during one's lifetime, typically after age 60. Unlike germline mutations, they appear only in tumor cells of the related cancer. Moreover, while someone with a germline mutation likely has a family history of cancer, someone with a somatic mutation may not be aware of their risk. Therefore, genetic and biomarker testing can save lives.

### **Panel Discussion**

While growth of genetic and genomic testing, as well as targeted therapies, has fueled the promise of personalized medicine, several factors hinder access and efficient utilization of genetic information.

Lisa Schlager, Vice President of Public Policy of Facing Our Risk of Cancer Empowered (FORCE), moderated a discussion about these barriers with panelists Heather Hampel, Jennifer Leib, Nikki Martin, Becky Nagy and Brandi Preston.

One of the biggest challenges for patients is the cost of testing services. The cost of germline testing originally started around \$4,000. Thanks to advancements in testing, many individuals can now receive tests for \$250. While this is a significant cost savings, the cost can remain a barrier. The cost of biomarker testing has not dropped as quickly, but some insurance plans offer options that can help cover at least a portion of the cost.

Provider awareness is also a challenge. Those who live in rural areas may not have access to a specialist who can offer information about genetic or biomarker testing, so their mutations may go unidentified. Some providers in established health systems may not even ask about family history during the screening process.

For patients with a somatic mutation, providers may not offer biomarker testing to help determine the course of treatment. These tests provide insight on the makeup of the tumor, which can tell providers which treatments may be most effective but also—perhaps more important—which treatments will not, saving time and sparing patients from the potential side effects of ineffective treatment. Despite the crucial information these tests provide, most patients report they were never asked or offered the option for biomarker testing.

Even after receiving a test, many patients do not know how to access the results. Some tests are sent to third party labs that analyze the samples (both blood and tissue samples), who sometimes do not share the results with patients. Those who can track down the results are often not told what to do with the information. Providers can use the results to match patients with clinical trials.

Sometimes patients are unable to access screening because they don't meet the eligibility criteria based on screening guidelines. For example, the U.S. Preventive Services Task Force (USPSTF) determines coverage requirements for private insurers. Under the Affordable Care Act (ACA), any screening service rated by the USPSTF with an "A" or "B" must be covered by insurers with no cost-sharing. Currently, the USPSTF provides only a "B" rating for genetic screenings in women with a personal or family history of breast, ovarian, tubal, or peritoneal cancer or an ancestry (Ashkenazi Jewish) associated with certain genetic mutations (BRCA1 and BRCA2). This means anyone with a germline mutation associated with a cancer syndrome, such as Lynch Syndrome, or a somatic mutation is not covered. Men can also have a BRCA1 or BRCA2 mutation and are not covered under the recommendation.

### **Breakout Sessions**

After the keynote presentation and panel, attendees broke into separate groups to discuss solutions to these barriers to screening services.

The topics included:

- Public policy and reimbursement for hereditary cancer (germline) testing
- Public policy and reimbursement for biomarker (somatic) testing
- Testing guidelines and expansion of testing eligibility (germline and somatic)

Summaries from each session are provided below:

#### **Public policy and reimbursement for hereditary cancer (germline) testing**

The main barriers to hereditary testing are cost and lack of awareness (for both patient and providers).

There are misconceptions about testing. If patients don't know what their options are, they can't make informed decisions. Many depend on general practitioners, and if those providers aren't recommending tests or screenings, most will defer to them instead of advocating for themselves or seeking another opinion.

In medically underserved communities, fear and lack of awareness is a significant challenge. Some patients don't want to be screened or tested because they don't want to know the results. One way to overcome the fear in those communities is by working with faith-based organizations.

Many people fear the cancer they saw their loved ones battle. Patient advocacy organizations can provide information that can mitigate fears and arm patients with knowledge about their options. We can tell you your risk AND some options to address risk—such as preventive surgeries, taking oral contraceptives or more frequent screening.

Physicians and oncologists often have large time constraints. Nurses and patient navigators and their groups may provide a better route to communicate with patients.

### **Public policy and reimbursement for biomarker (somatic) testing**

One of the biggest barriers to biomarker testing is that it is complicated and inconsistent. There are multiple protocols and guidelines from a variety of medical authorities and institutions with no real consensus. Patients often do not understand what they need and what they should be looking for. It may be helpful to incentivize providers to follow consistent guidelines through increased reimbursement rates.

There are no quality measures to follow on biomarker testing, so it's hard to set a standard of care. We need to include research that measures the impact on patients across all populations to create equitable standards.

Identifying policy solutions for increasing access to somatic testing would be helpful. We could consider insurance coverage and reimbursement to providers, and make sure patients and providers are aware of their options. Advocating for research on biomarkers to show utility for patients could increase access and advance options for patients.

We need to form a coalition of stakeholders, such as patient advocacy organizations, pharmaceutical and testing companies, and large employers to speak to Congress about the economic benefit for these types of tests.

### **Testing guidelines and expansion of testing eligibility (germline and somatic)**

There is a lack of awareness around guidelines, and the public needs clear and concise information to improve access.

We need to engage nontraditional stakeholders to create opportunities to raise awareness and improve coverage. For example, employers can provide information about genetic testing services covered under their health plans.

There is a need for consistent terminology. It is challenging for patients when there is confusion caused by the use of multiple terms in the field of genetic and biomarker testing.

The advocacy community needs to demand changes to national guidelines, such as those developed by the National Comprehensive Cancer Network (NCCN) and the USPSTF. Successful challenges to USPSTF guidelines can expand insurance coverage for patients across the U.S. and increase access for all populations, including medically underserved communities. A potential avenue for that is the USPSTF Transparency and Accountability Act, which would implement requirements for how the USPSTF develops guidelines (e.g., requiring content experts on every committee), ensure transparency in development of guidelines, and codify the methodology for the “letter grades” that determine whether or not tests are covered by insurance.

We also need to address billing and reimbursement for genetic testing. Payers are hesitant to cover large panel testing, which assess multiple genes for mutations as opposed to one specific gene. Companion diagnostics, utilizing a patient’s cells to measure their reaction to a drug or therapy, are often not covered by payers. Better billing codes and payment structures can make it easier for providers and patients.

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