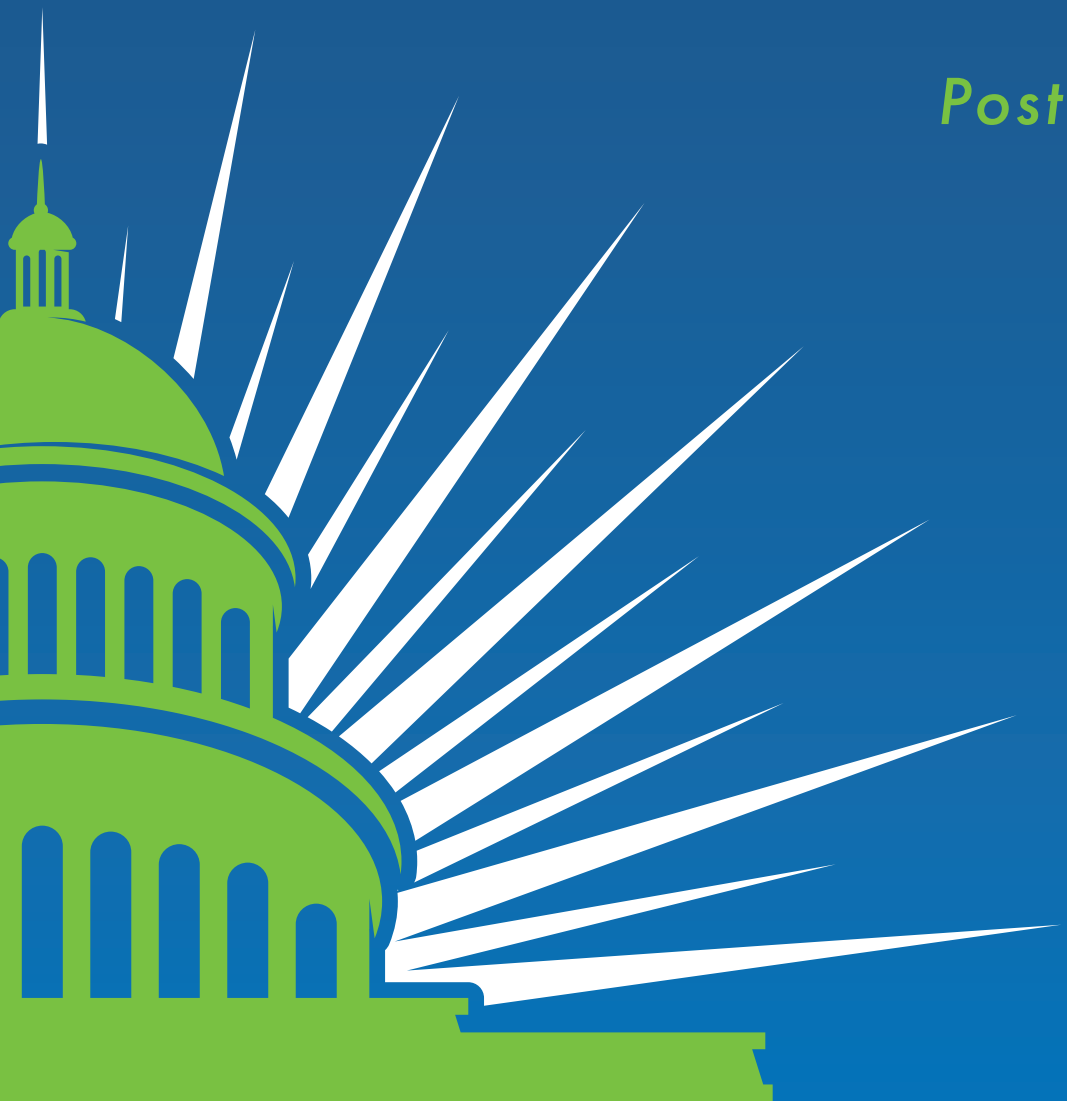
2021 PREVENT CANCER ADVOCACY WORKSHOP

A PATIENT-CENTERED APPROACH TO MULTI-CANCER EARLY DETECTION TESTING

JUNE 17, 2021

Post-event recap



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1. Executive Summary

On June 17, 2021, the Prevent Cancer Foundation held its annual Advocacy Workshop, a forum for patients, providers, advocacy organizations and other partners to engage in a dialogue around emerging technology in cancer prevention and control. The event focused on a patient-centered approach to multi-cancer early detection (MCED) testing. This topic was identified as a priority given the Foundation's mission of saving lives across all populations through cancer prevention and early detection. Finding cancer early increases the opportunity for more effective treatment and increases the chances treatment will be successful. When cancer is detected early, nine of every 10 cancer patients will live five years or longer.[1] Today, routine screening is available for only five types of cancer, which leaves the vast majority of cancers without available screening tests.

A blood test capable of detecting many cancer types could have a tremendous impact in helping people access more effective treatment. MCED is a new type of cancer screening test that utilizes advances in genomic science and machine learning to transform cancer detection.

The workshop objectives were:

- To raise awareness and provide information about the components of MCED testing, including relevant coverage and legislation
- To engage in a discussion about MCED tests within a patient-centered framework, specifically highlighting access, acceptance, affordability and accountability
- To discuss opportunities to enhance access to screening, reduce delays in diagnosis, and improve early detection and diagnosis

The Prevent Cancer Foundation's President and Chief Operating Officer Jody Hoyos opened the Workshop by addressing patients, advocates, scientific researchers and health care providers from around the globe. Ms. Hoyos cautioned that as promising as MCEDs may be in terms of early diagnosis and saving lives, "It's very important that we consider all aspects of the test. Behind each of the data points are people."

Anne Marie Lennon, M.D., Ph.D., Director, Division of Gastroenterology and Hepatology at the Johns Hopkins Medical Institutions, then presented on **MCED 101**, providing an overview of multi-cancer early detection tests, why the tests are needed, the existing challenges in detecting cancer earlier, the achievements in MCED testing, and the questions that remain unanswered.

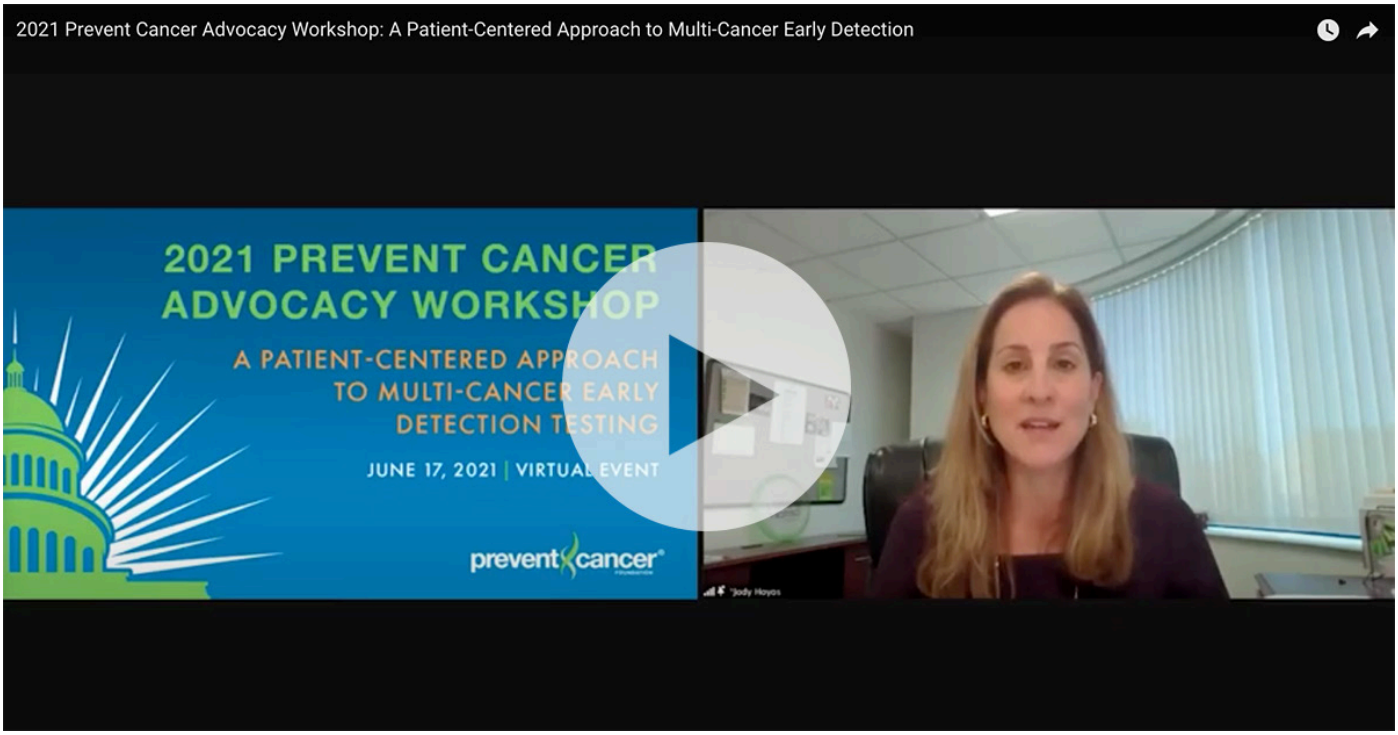
Panel presentations on **acceptance** by Phylicia Woods, J.D., Cancer Support Community, **affordability** by Anna Schwamlein Howard, J.D., American Cancer Society-Cancer Action Network, **access** by Robin Richardson, University of Texas at Austin, Livestrong Cancer Institutes at the Dell Medical School, and **accountability** by Minetta Liu, M.D., Mayo Clinic followed. Ms. Hoyos wrapped up the morning session by fielding questions from attendees and moderating an engaging panel discussion.

During the afternoon portion of the event, attendees were split into breakout sessions facilitated by the morning panelists, along with Rebekkah Schear, University of Texas at Austin, Livestrong Cancer Institutes at the Dell Medical School and Mike Capaldi, Penn Quarter Partners public affairs firm. Attendees discussed concerns and opportunities for a patient-centered approach to MCED testing, including acceptance, access, affordability and accountability.

Breakout attendees returned as an entire group and event facilitators presented their ideas and proposed solutions. Ms. Hoyos recapped the discussion by highlighting that MCED tests offer hope that one day most cancers will be detected early enough to be successfully treated. She also stressed that before MCEDs are administered population-wide, we need to ensure patient needs and preferences are considered. Ms. Hoyos also shared that the barriers are more prevalent, the screening rates are lower, and often, mortality rates are higher for racial and ethnic minority groups, those who live in rural areas, and the LGBTQ+ community. By expanding the benefits of early detection to more cancers and people, outcomes for cancer patients could also improve. As these tests move forward in development, planning and implementation, it is paramount that patients remain at the center of the conversation. Only then can we move closer to our goal of creating a world where no one dies of cancer.

2021 Advocacy Workshop Recording

Click on the image below to access the recording or go to preventcancer.org/advocacy/workshop.



2. Introduction

Ongoing clinical trials demonstrate that a new category of cancer screenings can detect more than one cancer at a time at the earliest possible stages, before noticeable symptoms occur.

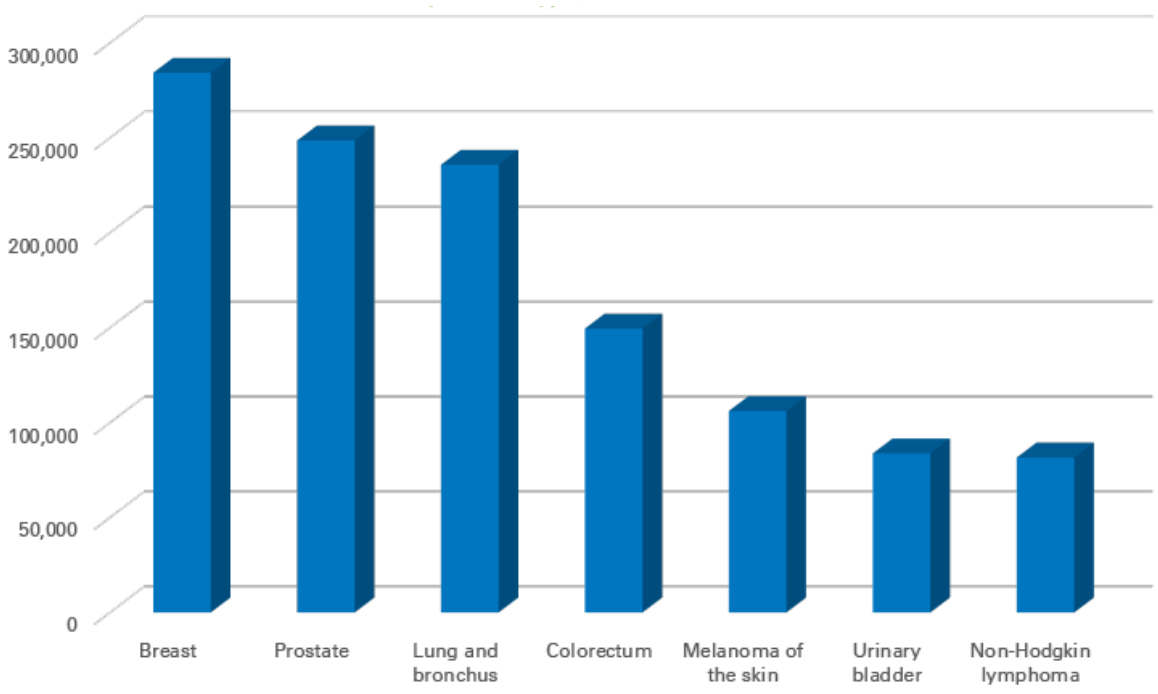
As these tests emerge into an already complex cancer screening landscape, the Prevent Cancer Foundation identified a need to discuss patient-centered considerations including access, acceptance, affordability and accountability.

Needs assessment

Early detection saves lives. Unfortunately, the important benefits of early cancer detection are not reaching enough people. The routine cancer screening tests currently available and covered by Medicare detect only five cancer types—lung (for high-risk patients), breast, cervical, colorectal and prostate—which means there are no routine screenings for most cancer types.

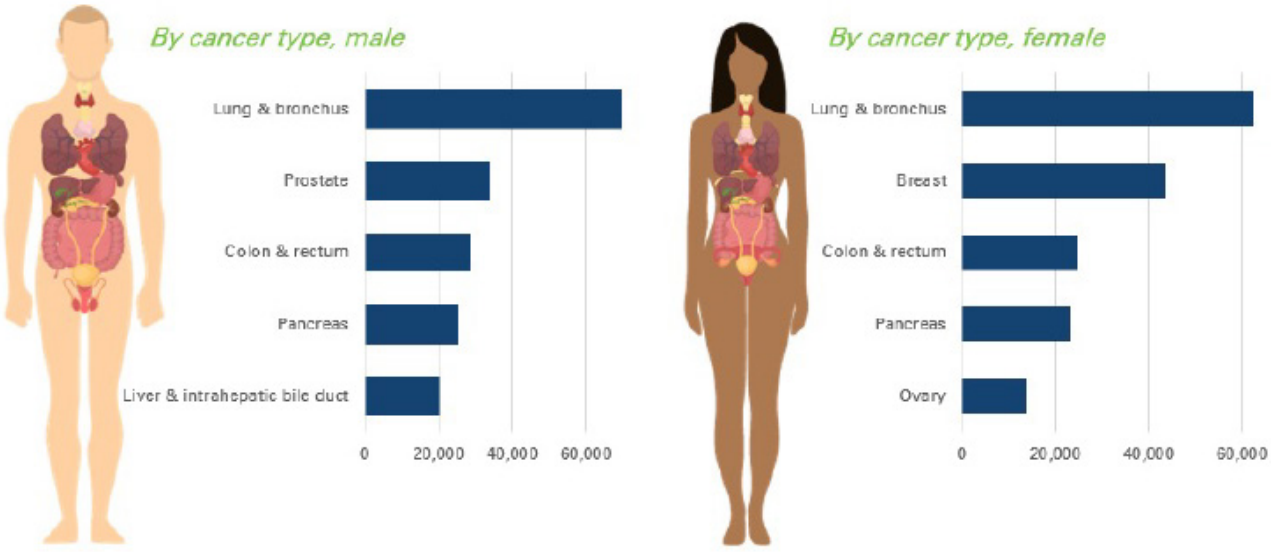
A blood test capable of detecting many cancer types—most of which have no recommended routine screening in the U.S.—could have a tremendous impact in helping people access more effective treatment.

Figure 1: Estimated new U.S. cancer cases, 2021 (by cancer type, both sexes combined)



Source: *American Cancer Society, Cancer Statistics Center; https://cancerstatisticscenter.cancer.org/*

Figure 2: Estimated U.S. cancer deaths 2021



Source: https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2021/cancer-facts-and-figures-2021.pdf

Target audience

The Workshop brought together members of national and international nonprofit organizations with a focus or interest in cancer prevention and early detection, members of the health care community and members of the patient advocacy community (patients, survivors, caregivers, etc.) who have a personal connection to cancer prevention and early detection. To that end, the target audience included:

- National cancer advocacy organizations
- Community health organizations
- Public health agencies
- Rural health agencies and advocates
- Minority health organizations and advocates
- Interfaith health advocacy coalitions
- Prevent Cancer Foundation advocates

3. MCED 101

Key terms and definitions

Multi-cancer early detection testing: blood-based screening tests (also called liquid biopsies) that are designed to identify the presence of cancer for more than one cancer at a time at the earliest possible stages, before noticeable symptoms occur.

MCED tests:

- Are designed to detect many types of cancers by looking for cancer signals in the blood.
- Are designed to be complementary to existing screenings and extend the benefits of early detection to catch more cancers in earlier, more treatable stages.
- Have received breakthrough designations from the Food and Drug Administration (FDA). Their clinical programs continue to advance, as evidenced by data published in peer-reviewed publications.[2]
- Are being developed by multiple companies in partnership with many of the top cancer research institutions in America.

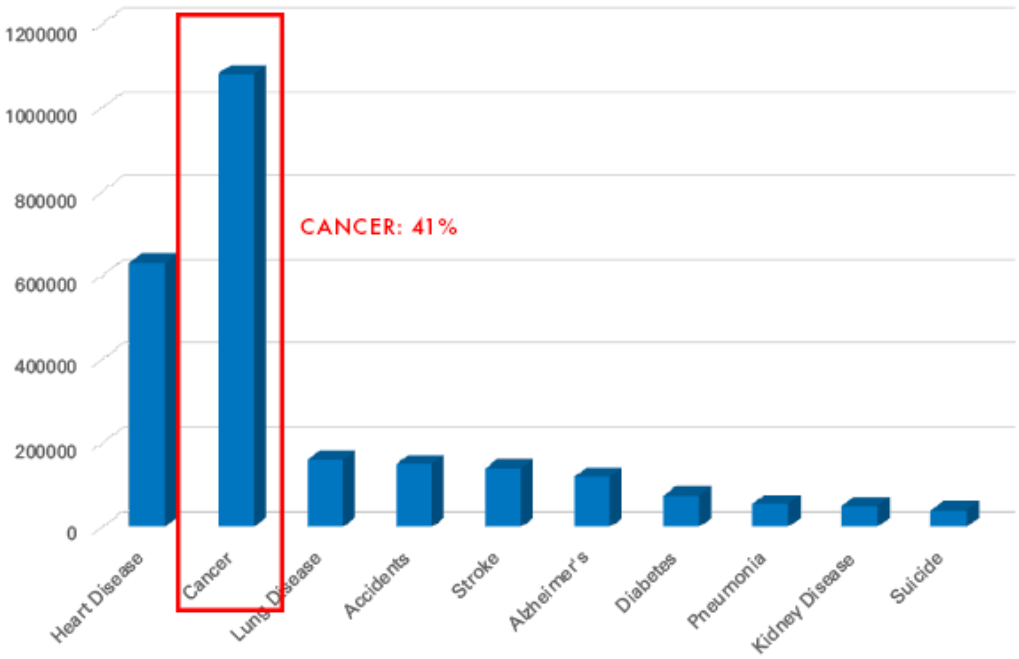
Multi-cancer early detection 101

Anne Marie Lennon, M.D., Ph.D., Director of the Johns Hopkins Division of Gastroenterology and Hepatology as well as Professor in Medicine, Surgery, Radiology and Oncology at the Johns Hopkins University School of Medicine, began the Workshop by providing an overview of MCED tests, why MCED tests are needed, the existing challenges in detecting cancer earlier, the achievements in multi-cancer early detection testing, and the questions that remain unanswered.

Why do we need MCED tests?

According to data from the Centers for Disease Control and Prevention (CDC), heart disease is currently the number one cause of death in the United States, followed closely by cancers, which account for 23% of deaths.[3] However, in looking to the future, specifically within the next 10 years, researchers have predicted that heart disease deaths will decrease, and cancer will be the most common cause of death, resulting in 41% of all deaths.[4]

Figure 3: Predicted number of deaths in the U.S. by 2030



In the United States in 2021, experts predict there will be an estimated 1.9 million new cancer cases and 608,570 cancer deaths, which translates to about 1,650 deaths per day.[5] There are many different reasons for cancer deaths, but one of the most important factors is the stage of cancer when it was first detected.

How can we detect cancer earlier?

Dr. Lennon said that there are ways to detect cancer earlier thorough routine cancer screening tests. Currently, there are five routine cancer screenings covered by Medicare—lung (for high-risk patients), breast, cervical, colorectal and prostate. However, challenges exist: these screenings are not perfect tests, some people may not be willing to undergo certain screenings or have access to screenings, and cancers identified through screenings only account for a small percentage of cancer cases. For many other cancer types, such as ovarian, pancreatic, and kidney cancers, there are no routine screening tests.

Is it possible to develop a blood test to detect cancer earlier?

Cancer cells release different elements into the blood stream, including protein markers, deoxyribonucleic acid (DNA), ribonucleic acid (RNA), and metabolites. In evaluating the performance of any blood test, we look at the ability to identify cancer, the specificity of the test and the sensitivity of the test. Researchers have now developed technology with the capability to detect tiny amounts of cancer DNA and other cancer-related markers in the bloodstream. Other factors in assessing a blood test for the detection of cancer include biological considerations—for example, is there a detectable amount of DNA from cancer cells or other features present in the blood? Researchers studied cancer DNA and patients in different stages of cancer and determined the amount of circulating tumor DNA or cancer DNA was much higher in people with advanced cancer and lower in people with early-stage cancer.[6] Clinically speaking, this means the challenges are greater in detecting earlier stage disease and examining one marker alone will not suffice. To increase sensitivity, researchers have combined different cancer markers together in a multi-analyte blood test. These tests can detect not just one cancer type but multiple different types of cancer in a single blood test.

Another consideration is the risk of unnecessary harm, which includes the risk of an MCED test triggering multiple invasive procedures, as well as the possibility that people with a negative MCED test may have a false sense of security and no longer engage in standard-of-care screening (e.g., colonoscopy, mammography). In the DETECT study, researchers evaluated the feasibility and safety of incorporating a multi-cancer blood test into the routine clinical care of 10,000 women with no history of cancer. Over a 12-month period, the blood test detected 26 cancers of different types.[7] Researchers in this study examined multiple questions around unnecessary harms, including:

1. Can a multi-cancer blood test prospectively detect cancer in individuals whose cancer was not previously detected by other means?
2. Can such a test be used to intervene in the cancer progression process, leading to therapy with intent to cure?
3. Can such a test be incorporated into clinical care and not discourage participants from engaging in standard-of-care screening?
4. Can such a test be performed safely, without incurring a large number of futile, invasive follow-up tests?

The findings resulted in 96 cancers being detected (27% by blood test, 25% by standard-of-care screening, and 48% by other presentation), which is typical of what clinicians expect to find in women in the 65-75 age group. In evaluating different types of cancers detected (such as ovarian, breast and lung) and the methods utilized (standard of care, blood test) to detect certain cancer types, researchers concluded that 25% of all the cancers were first detected with current standard-of-care screening. If the blood test had been available, researchers could have increased the number of cancers detected from 25% to 52%. Additionally, the DETECT study was able to detect not one, but many different cancer types, such as lymphoma, thyroid cancer, lung cancer, liver cancer, bile duct cancer and more. Of the cancers detected, 65% were localized or regional, meaning they were potentially curable. In

examining whether a test can be performed without incurring multiple invasive follow-up tests, out of 10,000 women studied, 62% had no further procedures, 19% had minimally invasive procedures, 16% had non-invasive procedures and 3% had surgery. Conclusions from the DETECT study include:

- Blood testing makes it possible to detect cancers, including early cancers, in individuals with no history of the disease
- It is possible to intervene on the basis of blood testing, leading to surgery with intent to cure
- Blood testing can be incorporated into routine medical care without discouraging patients from engaging in other forms of screening
- Such testing can be performed in a safe manner without incurring a large number of futile, invasive follow-up tests

Many different groups are looking at different types of tests—DNA, RNA, protein metabolomic or methylation to detect multiple different types of cancers with a single blood test. Still, questions remain that we need to answer:

- How can we effectively determine where is the cancer located?
- When should testing be repeated?
- What is the clinical utility and clinical validity?
- How cost-effective are these tests?
- What is the FDA approval process and timing?

4. A Patient-Centered Approach

Access

Phylicia Woods, J.D., M.S.W., Executive Director of the Cancer Policy Institute (CPI), presented on the topic of access. Ms. Woods emphasized that whether it is cancer patients, allies or patient advocacy groups, we want to be confident that everyone has access to much-needed health care services, especially prevention and early detection services, when it comes to cancer. Additionally, Ms. Woods said that access to no- or low-cost preventive care is essential for all, including, at minimum, coverage that provides for well services, cancer screenings and testing. Ms. Woods said these preventive services can help individuals not only prevent chronic illness, including cancer, but can help detect and treat disease as soon as possible.

Ms. Woods said the ongoing COVID-19 pandemic has reemphasized the importance of cancer prevention and early detection as screening rates plummeted for much of 2020. Single tumor screening and forthcoming innovative resources and services in screening and early detection, like MCED tests, must be available to all people, particularly those at risk for specific cancers.

Ms. Woods also emphasized that enhanced efforts to ensure access to screening and early detection is important to our nation's approach to cancer control overall and is also one key way to address disparities in cancer outcomes because we can find and treat cancer at earlier stages when patients are more likely to survive.

Across all cancer types, outcomes improve when cancer is detected early. Nevertheless, early detection tests are only available for some cancers lung (for high-risk patients), breast, cervical, colorectal and prostate. This leaves many cancers without appropriate screening tests.

Late-stage diagnoses of cancers for which there are no routine screenings available are particularly common in people of color and outcomes are far worse. Despite improvements in technology, availability of evidence-based cancer screening and rising screening rates among patients of color, disparities in access and utilization persist when it comes to new screening technologies. By expanding the benefits of early detection to more cancers and people, outcomes for cancer patients could also improve.

Cancer care disparities persist in every area of care, from cancer screening to survivorship.

Ms. Woods provided examples of disparities, including that Black men experience higher rates of new cases and death than white men for certain cancers, such as prostate cancer and kidney cancer. Black Americans have higher cancer mortality rates than any other racial group when considering all cancer types, and cancer remains the leading cause of death for Asian and Hispanic persons.[8]

Cancer disparities occur because of a host of factors, including systemic racism; lack of trust of the health care system; lower screening uptake; and challenges around access to high quality cancer care.

Common barriers to cancer screening include:

- Lack of provider recommendations
- Absence of symptoms
- Fear of detection and diagnosis
- Lack of awareness of cancer
- Mistrust in providers or the system
- Language barriers

Cost

Ms. Woods said access to screening services further decreases when factoring in screening for individuals that are disproportionately affected due to lack of resources, inequitable programs, policies, and services.

These disparities can only be meaningfully addressed when all individuals have access to, and can afford, health care services, including early detection services. Everyone should have an opportunity to achieve the best health outcomes, no matter their race, ethnicity, gender, age, sexual orientation, socioeconomic status or location. This is why MCED screening tests must be accessible—and presented as accessible—to all people from the beginning.

Finally, Ms. Woods proposed that access can be addressed in several ways:

1. Intentional outreach and education to communities of color, disproportionately affected groups, individuals living in rural areas, and the LGBTBQIA community.
    - *Allies must leverage trust from community health professionals for this outreach to be accomplished in culturally appropriate and competent ways.*
2. Increased availability of screening at health care clinics that serve uninsured or underinsured populations. Partnering with Federally Qualified Health Care Clinics, rural health clinics and community providers would be vital, as these entities are already providing outpatient services and access to screening and early detection. These services specifically target health disparities and work to empower underserved areas.
3. Purposeful hiring of health care providers with diverse ethnicities and backgrounds to reflect a diverse patient population.
4. Encouraging and promoting culturally competent communication between patients and providers and actively training clinical teams on implicit bias, microaggressions and systemic racism to address and break down injustice in delivery of care. Disparities exist among people of color even when various clinical and sociodemographic factors, such as cancer type, site of care, insurance status, income and education level are considered.
5. Collaborating among cancer advocacy groups and allies to ensure coverage of and access to early detection and screening technologies in both private and public insurance plans covering people who are medically underserved. Policy must be on par with innovation—far too often, policymakers are playing catch up to innovation. That must change, and raising our collective voices can foster change in the policy world.

Affordability

Anna Schwamlein Howard, Principal of Policy Development, Access to Care for the American Cancer Society Cancer Action Network (ACS-CAN), presented on the topic

affordability. Ms. Howard highlighted research from the American Cancer Society on the importance of prevention in detecting cancer earlier when there is a greater likelihood of a successful outcome, particularly for the Medicare population, since cancer risk increases with age and most people who qualify for Medicare do so when they turn 65. Ms. Howard said access to insurance is essential and people who have access to preventive screenings are more likely to get screened and have a greater likelihood of a successful outcome if they are diagnosed with cancer.

Existing Medicare Coverage

Ms. Howard provided an update on current Medicare coverage for preventive services. Medicare does provide coverage of certain routine cancer screening tests and has done so long before the Affordable Care Act (ACA). Congress has mandated Medicare coverage for lung (for high-risk patients), breast, cervical, colorectal and prostate screening tests, as well as other preventive services under Medicare if the services are reasonable and necessary, if they are recommended by the U.S. Preventive Services Task Force (USPSTF), and if they are appropriate for Medicare beneficiaries. Ms. Howard said that Medicare does not currently cover MCED tests, which is why a legislative approach is necessary.

Legislation in the 117th Congress

Ms. Howard said that legislation addressing Medicare coverage of MCED tests was first introduced in the 116th Congress and recently reintroduced in the 117th Congress. The Medicare Multi-Cancer Early Detection Screening Coverage Act of 2021 is a bill that would authorize the Centers for Medicare & Medicaid Services (CMS) to evaluate and cover blood-based multi-cancer early detection tests and future test methods (e.g., tests using urine or other biological material as determined by the Secretary of Health and Human Services), once approved or cleared by the Food and Drug Administration (FDA).

The House bill (H.R. 1946) was introduced with bipartisan support on March 16, 2021, and its companion bill in the Senate (S. 1873) was introduced on May 27, 2021. Ms. Howard said congressional support is rising and the challenges in gaining support are not ideological—rather there is a need to increase awareness and educate members of Congress about MCED tests, the promise these tests hold, and why Medicare beneficiaries need coverage of MCED tests.

Specifically, the legislation provides a pathway for Medicare coverage of MCED tests through the CMS National Coverage Determination Process. Ms. Howard said an important consideration in developing this legislation was that other screening tests are not impacted; if the individual and their health care provider feel an MCED test is medically necessary and appropriate, that Medicare beneficiary would have access to testing. As such, the bill does not modify or change current coverage of other cancer screening tests. The legislation also states the MCED tests should be covered once a year. Beneficiaries would be able to receive existing Medicare-covered screening tests and an MCED test.

Coverage Beyond Medicare

In closing, Ms. Howard addressed coverage beyond Medicare, noting that often (though not always) commercial payers look to Medicare in creating coverage determinations, since Medicare has established processes and evaluates scientific evidence before deciding whether a test is appropriate for Medicare beneficiaries. Commercial plans (e.g., employer-sponsored plans, marketplace plans) would not be bound by this legislation and have greater latitude in deciding what they are going to cover. Often commercial payers do evaluate the scientific evidence availability as well as what they are hearing from health care providers and patients about the need for access to certain services and tests.

In terms of Medicaid, Ms. Howard specified that states that have expanded their Medicaid programs to align with coverage of the ACA would have access to preventive screenings. State Medicaid programs can decide on a case-by-case basis whether they want to cover MCED tests and can set their own coverage parameters.

Ms. Howard also shared information about the role of the U.S. Preventive Services Task Force (USPSTF) in MCED testing. The USPSTF is an evidence-based body that has become more prominent since the enactment of the ACA. ACA-compliant plans must cover products and services for which there is an "A" or "B" recommendation from the USPSTF and must do so with no cost-sharing to the individual. Looking ahead, the USPSTF will likely look at these tests and determine "grade."

Acceptance

Robin Richardson, assistant director of care delivery transformation and community engagement at the University of Texas at Austin, Livestrong Cancer Institutes at the Dell Medical School, presented on acceptance. Ms. Richardson began her presentation with a qualification that when we explore the topic of acceptance, perception is the most important factor; not necessarily science or fact, but rather the perception of risks and benefits.

Ms. Richardson said in setting a patient-centered framework focusing on acceptance, relationships and not transactions are critical. By building relationships, trust is built, and trust profoundly impacts an individual's overall acceptance.

She also mentioned the importance of patient-directed advocacy. Ms. Richardson said diverse patient leadership is critical. Diversity should be thought about in all ways–race, ethnicity, age, gender and gender expression, geographic location, socioeconomic background and lived experience. When we have diverse engagement, we can better understand the opportunities, challenges and complexities with MCED innovation and how it relates to people's values and needs. Ms. Richardson challenged participants to think about who we are not hearing from in MCED test discussions. and encouraged the group to include all perspectives. She also said there is no single cancer story—everyone has a different and unique experience, which should be considered as we move forward.

Ms. Richardson shared feedback received from the August 2020 meeting of the Livestrong Cancer Institutes' Community Cancer Advisory Board and their perceptions about MCED testing. Overall, the group was enthusiastic and open to the idea of an MCED test and expressed interest in simplifying the screening process as well as reducing the number of invasive screenings. Importantly, Ms. Richardson said that for those who have historically faced cancer disparities (e.g., those in communities of color, those who have no insurance coverage, those with complex medical needs, young adults and others), MCED testing could be a game-changer.

Ms. Richardson said that while the Advisory Board was overall enthusiastic about MCED testing, they stated a need to critically consider transparent and equitable availability and access, as well as thoughtful communication, education and support. Ethical questions were also raised, such as what happens if a patient receives a positive cancer diagnosis and cannot afford additional screenings or cancer treatment. Advisory board members also had questions about privacy. For example, who will own the data from MCED tests and how will the data impact a person's ability to obtain health insurance, life insurance or employment? An additional concern from the group was the potential strain on our overloaded health care system.

Ms. Richardson closed with a final comment on the need for thoughtful rollout of communications around test results. As these tests become available, it is paramount that communication of the test results (both positive and negative) identifies next steps and risks, is thoughtfully planned, and considers psychosocial factors, and that any handoff to other providers is handled in a warm manner.

Accountability

Minetta Liu, M.D., Mayo Clinic, closed the panel presentations by covering the topic of accountability. Dr. Liu said that as a medical oncologist, she has been involved in liquid biopsy work for about 20 years, and in the last 10 years researchers have developed the capability to detect tumor-related DNA in the blood. Fast-forward to today and we are now able to detect multiple cancers in a single blood test.

Dr. Liu said trust is also important in a patient-centered conversation about accountability. It is essential there is trust in the regulatory bodies who oversee approval or clearance of MCED tests, as well as trust in assays (or testing), health care providers and the health care system. Dr. Liu said there are multiple MCED tests in development and one that is currently commercially available, but not yet approved or cleared by the FDA or endorsed by guidelines committees. There is a desire for the MCED testing and a responsibility of the medical community to understand how to best utilize this innovation and ensure the test identifies the cancers it is designed to detect. Additionally, there is an opportunity for the medical community to detect cancers not included in the five routine cancer screenings currently covered by Medicare (breast, cervical, colorectal, lung for high-risk patients, and prostate), such as pancreatic and ovarian cancers.

Dr. Liu said test manufacturers are accountable for ensuring good specificity and sensitivity of testing. Providers are also accountable for managing the process and planning around a positive test. How a provider follows that patient in the long term is critical.

Dr. Liu also said developers of MCED tests need to be cognizant of the price point. For individuals who meet the right criteria to access MCED testing, the test needs to be affordable. It is also critical that we identify the most appropriate providers to order and interpret test results. Dr. Liu said we are in a paradigm shifting moment, where currently there is no subspecialty that is taught how to interpret test findings and lead the diagnostic workup (if the test is positive) or follow up on future screening (if the test is negative).

Dr. Liu stressed the importance of holding health care providers and the health care system accountable for providing education about next steps. Also, providers need to be educated on what to do with test results, when to repeat testing and when not to repeat testing. The responsibility of providers does not end with the blood test. Providers also have the responsibility of ensuring the test is interpreted and communicated accurately and with all appropriate considerations.

Dr. Liu closed by emphasizing the importance of regulatory bodies in accountability. The FDA is currently in the process of evaluating and determining if these tests demonstrate clinical utility and will lead to improved outcomes. This can be a lengthy process, so we need to temper excitement with a thoughtful approach in improving the health care system and ultimately impacting lives.

5. Findings

Attendees split into four breakout groups and discussed access, affordability, acceptance and accountability. Key themes from each discussion are below.

Access

Participants in the access breakout group shared four considerations for a patient-centered approach.

1. Public health education campaigns are key.
2. Convenience and barriers to screening must be considered.
3. Building trust can be accomplished by utilizing patient navigators, nurses and other professionals.
4. Educating policymakers on all aspects of MCED testing will help with promoting awareness.

Participants shared additional questions surrounding MCED tests that need to be addressed.

- Who will first get access to tests (based on risk factors, survivorship, etc.)?
- Who will administer the tests, if not everyone has access to a primary care physician?
- With that, thinking about convenience and best use of a patient's time: Are there other health care needs that could be addressed when getting an MCED test, such as vaccinations or other necessary screenings?

Affordability

Participants in the affordability breakout group discussed various considerations around affordability.

1. Affordability of the test is only one part of the equation. Other factors, including the cost of childcare, transportation, time off work, etc., must be considered. (Patient navigation can help remove some of these barriers.)
2. Deploying vehicles or carriers to meet the patient where it is most convenient for them will help reduce affordability barriers. (For example, blood drive vehicles and mammography vans versus patients needing to travel to a hospital or doctor's office.)

Acceptance

Participants in the acceptance group highlighted three considerations for increasing acceptance of MCED testing.

- Build on the patient relationship with their existing primary care physician.
- Expense of the test is a primary factor in acceptance. Patients may be reluctant to accept the test when cost decisions are made without considering patients' ability to afford them.
- Clear messaging about MCED testing from providers who patients trust and who represent them is essential.
- Successful rollout and introduction of MCED testing to a community could include hosting town halls with a variety of representatives, having mobile blood testing units to reach rural populations and reframing the thought around screening to making it a part of a regular healthy lifestyle and 'wellness.'

Accountability

Participants shared considerations for health care provider and test developer accountability.

- Clear communication on which cancers the test does and does not detect is essential.
- Providers need to use familiar and understandable language.
- Information highlighting that MCED tests will not replace current recommended screenings needs to be shared.
- Accountable parties should include developers/manufacturers, health care providers and systems, regulatory bodies, payers and patient and advocacy organizations. Patients have a role in accountability as well.
- Patients need to be met where they are. Medical communities need to understand that patient communication should be individualized to help overcome language and knowledge barriers. Recognize the fear of diagnosis.
- Pharmaceutical companies also need to invest in creating treatments for these cancers as they are detected.

6. Common themes

- Communication utilizing familiar and understandable language about all aspects of MCED testing from a trusted provider is essential.
- Barriers to screening must be considered.
- Factors beyond cost matter to patients (convenience, transportation, childcare, time off work, etc.).

7. Conclusion

Ms. Hoyos recapped the discussion by highlighting that MCED tests offer hope that one day most cancers will be detected early enough so that they can be cured. She also stressed that before MCED tests are administered population-wide, we need to ensure patient needs and preferences are considered. By expanding the benefits of early detection to more cancers and more people, especially individuals in racial and ethnic minority groups, individuals with no insurance coverage, and people with complex medical needs, young adults and others where screening rates are low and late-stage diagnoses are high, outcomes for cancer patients could also improve. As these tests move forward in development, planning, and implementation, it is paramount that patients remain at the center of the conversation. Only then can we move closer to our goal of creating a world where no one dies of cancer.

8. Next Steps

The Prevent Cancer Foundation will broadly share the findings included in this white paper and continue our work informing all relevant groups—patient advocacy organizations, medical societies, health care providers, industry representatives, policymakers, regulators and the public—about the importance of a patient-centered approach to MCED testing.

The themes identified from the Workshop will also inform the education and outreach priorities of the Prevent Cancer Foundation as we as we work toward achieving our bold goals—goals that have the potential to change the entire landscape of cancer prevention and early detection to meet the challenge of reducing cancer deaths by 40 percent by 2035, the Foundation's 50th anniversary. Specifically, we are committed to investing:

- $20 million toward research in innovative technologies to detect cancer early and advancing multi-cancer screening.
- $10 million to expand cancer screening and vaccination access to underserved communities.
- $10 million to educate the public about screening and vaccination options.

For more information on the Prevent Cancer Foundation's ongoing work on multi-cancer early detection, please visit preventcancer.org/early.

Endnotes

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2 Lennon AM, Buchanan AH, Kinde I, Warren A, Honushefsky A, et al. "Feasibility of blood testing combined with PET-CT to screen for cancer and guide intervention." Science, July 3, 2020. Vol. 369, Issue 6499. https://science.sciencemag.org/content/369/6499/eabb9601

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Appendix

Attendee Survey Results

Figure 4: Attendee satisfaction

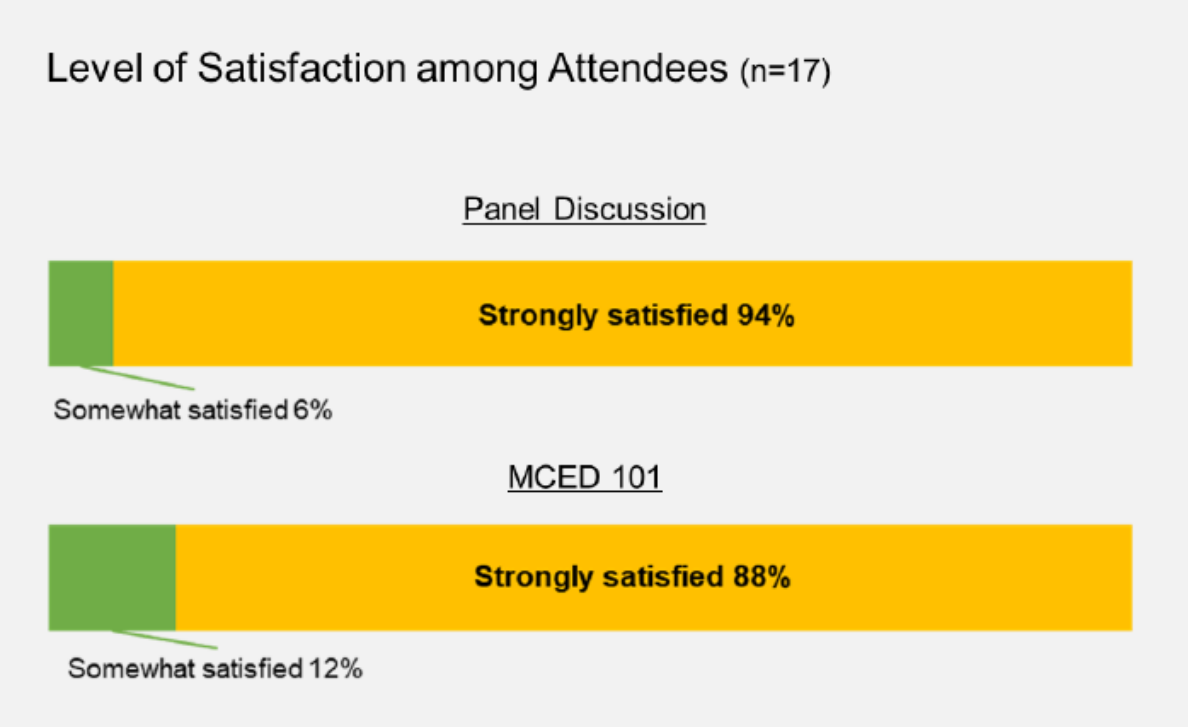


Figure 5: Understanding of MCED

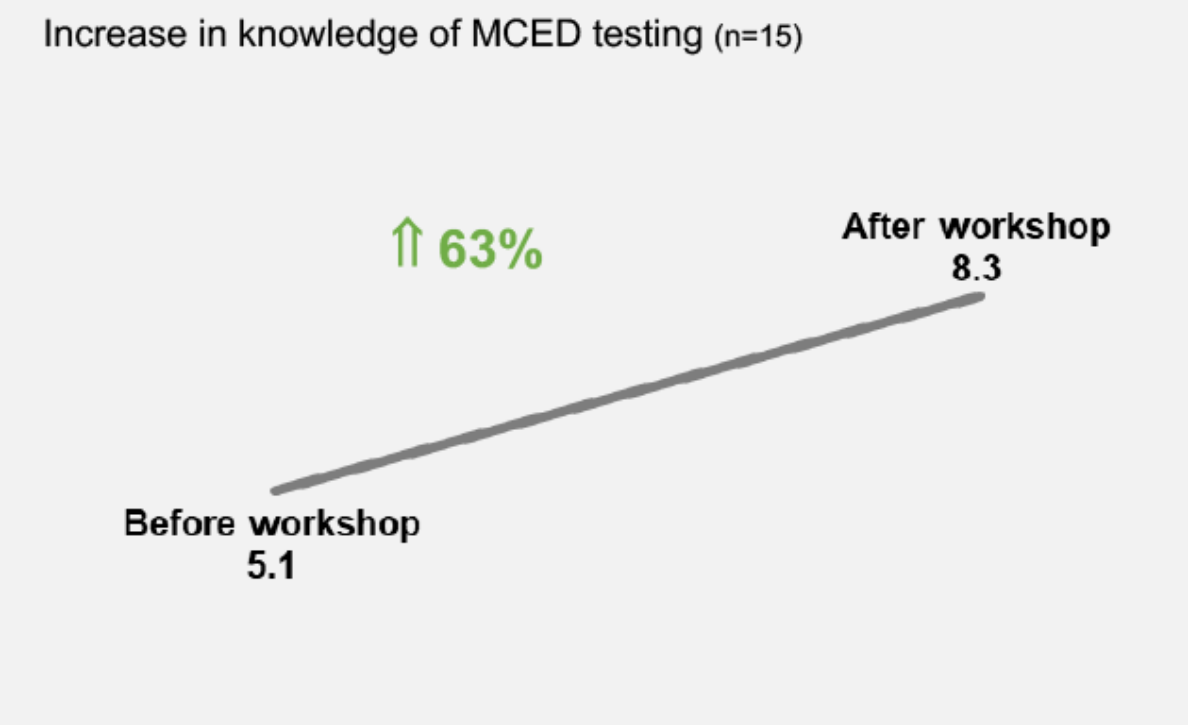


Figure 6: Support of the bill

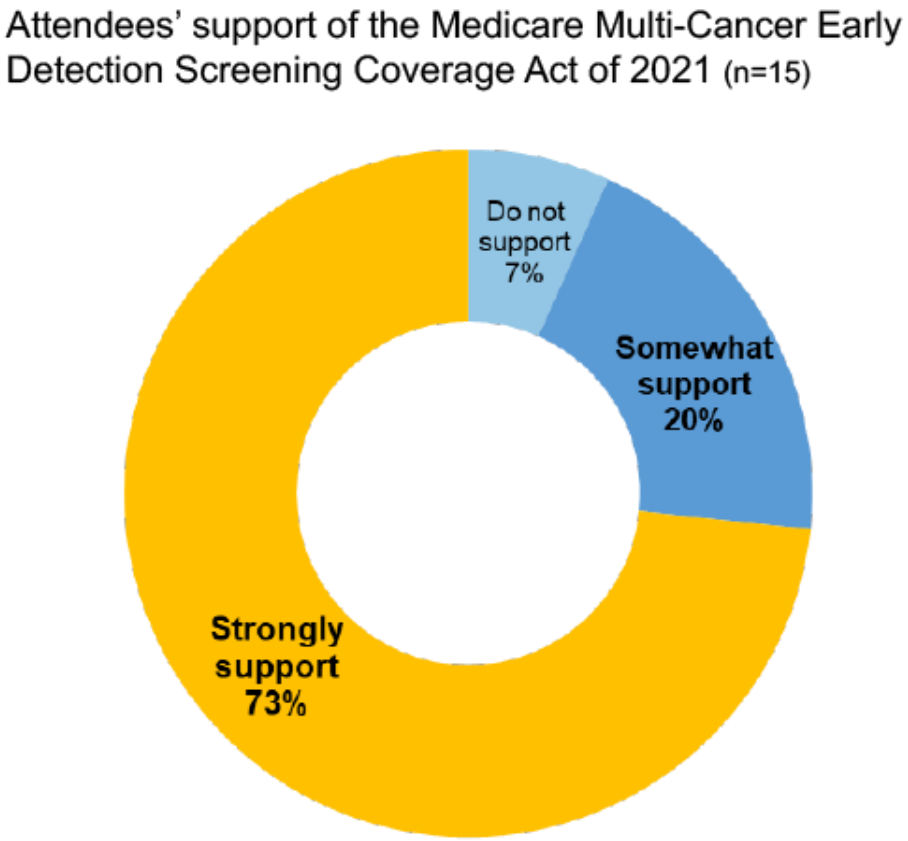
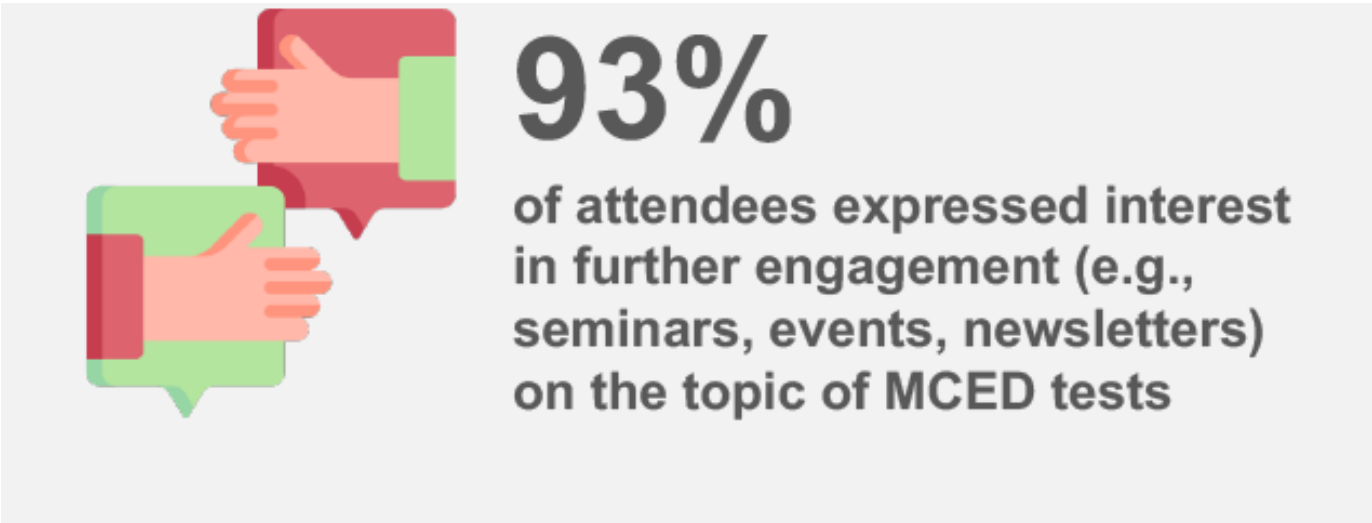


Figure 7: Interest in future engagement



Speakers and panelists

Anne Marie Lennon, M.D., Ph.D., is the Director of the Johns Hopkins Division of Gastroenterology and Hepatology. She is the Moses and Helen Golden Paulson Professor of Gastroenterology and holds joint appointments as a Professor in Medicine, Surgery, Radiology and Oncology at the Johns Hopkins University School of Medicine. She received her medical degree from the Royal College of Surgeons in Ireland and Ph.D. degree from the National University of Ireland. She completed an internal medicine residency in Dublin and at the Cleveland Clinic, followed by a Gastroenterology Fellowship in Edinburgh. She completed an Advanced Endoscopy Fellowship at Johns Hopkins and joined the faculty at Johns Hopkins in 2010. Dr. Lennon has published over 175 original research, review articles, editorials and book chapters. Her major research interests are the management of pre-cancerous pancreatic lesions and the development of markers for early cancer identification and translating these into clinical practice.

Anna Schwamlein Howard is the Principal, Policy Development, Access to Care for the American Cancer Society-Cancer Action Network (ACS-CAN). ACS-CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society (the Society), supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health program. In her role, Ms. Howard provides in-depth analysis of legislative and regulatory priorities at all levels of government and develops public policy principles for issues of importance related to access to care. She also serves as a Consumer Representative to the National Association of Insurance Commissioners (NAIC) and a member of the National Committee for Quality Assurance (NCQA) Consumer Advisory Council.

Prior to joining ACS-CAN, Ms. Howard served as the Medicare Reimbursement & Health Policy Director for Drinker Biddle & Reath LLP where she provided clients with strategic advocacy advice and helped clients advance their regulatory and legislative goals with respect to health care issues. Prior to joining Drinker Biddle, Ms. Howard was a Senior Legislative Representative for AARP's Federal Affairs Health and Long-Term Care Team, where she represented the interests of the 50+ population before the legislative and executive branches of government for a wide variety of health care matters, with a particular emphasis on Medicare and prescription drug issues.

Ms. Howard holds a law degree from The American University's Washington College of Law and a B.A. in Political Science from The American University.

Phylicia L. Woods, J.D., M.S.W., is Executive Director of the Cancer Policy Institute (CPI) where she is responsible for all aspects of the CPI, including legislative, regulatory, policy and research priorities as well as operations, fundraising and management. Most recently, Ms. Woods was a Director of Federal Relations at the American Cancer Society-Cancer Action Network (ACS-CAN), where she developed and executed strategies to ensure federal legislation, regulation and other initiatives promoted access to preventive services and quality, affordable care for people living with cancer, survivors and those at risk of cancer. She primarily focused on patient and survivor quality of life, health disparities, rising prescription drug costs, emerging sciences and clinical trials.

Formerly, Ms. Woods was Counsel to Former U.S. Senator Claire McCaskill (D-MO) on the U.S. Senate Homeland Security and Governmental Affairs Committee, and as Health Counsel on the U.S. Senate Special Committee on Aging. Before working in the U.S. Senate, Ms. Woods served as a Non-Formal Education volunteer in the U.S. Peace Corps in Nhlangano, Eswatini (Kingdom of Swaziland) as well as a Legislative Assistant to Former U.S. Congressman Russ Carnahan (D-MO-03).

Ms. Woods earned a Juris Doctor at the University of South Carolina School of Law, and a Master of Social Work and a Bachelor of Arts in Psychology from Saint Louis University. Ms. Woods serves as Vice Chair of

the Fairfax County Commission for Women, which advises the Fairfax County Board of Supervisors on policies and initiatives to promote gender equality, eliminate violence against women and honor women and girls in Fairfax County.

Robin N. Richardson, M.A., is the Assistant Director of Care Delivery Transformation and Community Engagement at Dell Medical School's Livestrong Cancer Institutes at the University of Texas at Austin, co-designing, implementing and evaluating supportive care programs with patients, survivors and loved ones. Ms. Richardson has worked in Texas and Washington, D.C. for the past 15 years on care delivery transformation, large-scale implementation and strategic planning. Ms. Richardson earned a Master's in International Human Rights with a focus on global health from the University of Denver and serves on the boards of Ground Floor Theatre and the Moving Beyond Cancer Collaborative. Her work is dedicated to public service and social justice and exploring the intersection of health and the arts.

Minetta C. Liu, M.D., conducts patient-oriented research focused on two major areas: The development of clinically relevant molecular markers to allow for the most accurate prediction of treatment benefit and patient outcomes in solid tumor malignancies, and the development of novel therapeutics to improve survival in early-stage and metastatic breast cancer.

Dr. Liu leads a collaborative effort to optimize and validate platforms for isolating and analyzing circulating tumor cells (CTCs), cell-free DNA (cfDNA), and other blood components. Although her clinical expertise is in breast cancer, her "liquid biopsy" efforts are not restricted to any particular malignancy. Dr. Liu's current work includes the characterization of breast cancer stem cells in the peripheral circulation and the development of assays for the reliable detection of BRAF, EGFR, KRAS and ESR1 mutations to assist in treatment selection and disease monitoring in melanoma, lung cancer, colorectal cancer and breast cancer, respectively.

Dr. Liu also leads several collaborative multi-institutional clinical trials through such mechanisms as the Alliance for Clinical Trials in Oncology and the Translational Breast Cancer Research Consortium. The investigational agents explored in these studies have the potential to improve outcomes in all settings of breast cancer for hormone receptor positive breast cancer, HER2-positive breast cancer, and hormone receptor negative breast cancer and HER2-negative breast cancer. This includes a series of phase I trials with oncolytic measles virotherapy as part of the Mayo Clinic Specialized Program of Research Excellence in breast cancer.

Rebekkah Schear is pioneering the strategic development, operations and implementation of clinical cancer care at the Livestrong Cancer Institutes at Dell Medical School. Ms. Schear and the team are building a new model of patient-centered cancer care and launching the CaLM Clinic—a comprehensive, clinical and supportive outpatient clinic with wraparound care offering practical, emotional, physical, social, spiritual and financial support to patients and caregivers. She and her colleagues are also building the first comprehensive young adult cancer clinic in the Austin area.

Ms. Schear is leading a community-wide engagement initiative for the Institutes, ensuring that all strategies and services are co-designed with patients, caregivers and the cancer community. Under her leadership, Austin launched a new coalition (Austin Cancer Support Coalition) in 2017 to organize and mobilize the Central Texas cancer community to implement community-wide initiatives, services, research and education for patients, survivors, families, providers and caregivers. Over the last 10 years, she has designed and implemented more than a dozen community-based, national and global cancer programs to improve quality of life for cancer survivors and their families and to educate and engage health care providers.

During her tenure at Livestrong Foundation, Ms. Schear led the Foundation's implementation of seven international

cancer control programs throughout Latin America, Africa and Asia. Her work focused on building capacity of cancer NGOs to lead and implement patient-driven policy initiatives and addressing cancer stigma through improving knowledge and changing attitudes by empowering survivors to share their cancer stories.

Ms. Schear holds a Bachelor of Arts in mass communications from the University of California, Los Angeles and a Master of International Affairs in economic and political development from Columbia University. Her career has focused on the intersection of cancer care delivery, global health and advocacy.

Mike Capaldi is a Senior Advisor for Penn Quarter Partners, a public affairs firm based in Washington D.C., where he consults with clients across the life sciences industry. He is also the Executive Director for the Institute for Gene Therapies, a nonprofit coalition established in 2020.

Prior to these roles, he had a successful 22-year career at Sanofi/Genzyme, where he most recently served as the Head of U.S. Public Affairs for the Oncology, Transplant and Consumer Health Care units.

Mr. Capaldi has a broad set of experiences, including Public Affairs/Advocacy, Government Relations, Policy & Corporate Social Responsibility. He has interfaced with a broad range of health care stakeholders, including patient advocacy organizations, trade associations and scientific societies. He also worked within the commercial organization in Sales, Training & Development, where he was responsible for the T&D of nearly 10,000 field and headquarter-based employees. Mr. Capaldi served as President of the Society of Pharmaceutical and Biotech Trainers (now L-TEN) in 2010-11. In 2007, he earned a Master of Education in Corporate Training & Knowledge Management.

Mr. Capaldi completed his certification in Leadership Coaching for Organizational Performance at American University in Washington D.C. and is actively pursuing additional certifications through the International Coaching Federation.

Jody Hoyos, MHA is President and Chief Operating Officer of the Prevent Cancer Foundation®, the only U.S.-based nonprofit organization solely dedicated to cancer prevention and early detection. Prior to joining the Foundation, Ms. Hoyos served as the Vice President of Membership and Operations at the Washington, D.C.-based Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN). AWHONN's mission is to improve and promote the health of women and newborns, and they strive to strengthen the nursing profession for 350,000 registered nurses working in women's health, obstetric and neonatal nursing nationwide.

With 25 years in the health care environment—including ten years in health care management consulting and 15 years in the nonprofit sector— Ms. Hoyos is a highly skilled executive leader. She previously held management consulting positions with Arthur Andersen, LLP as well as KPMG/Bearing Point. She has also worked as an associate at the Washington, D.C.-based Health Care Advisory Board. Throughout her career, Ms. Hoyos has developed the teams and infrastructure to create numerous programs and partnerships dedicated to improving health.

Ms. Hoyos earned a Bachelor of Business Administration degree from The George Washington University and a Masters in Healthcare Administration from the University of North Carolina at Chapel Hill.

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