Present Outlook on the State of MCED Technologies

March 2023

MCED
MULTICANCER EARLY DETECTION CONSORTIUM

What are MCED Tests?

Multicancer Early Detection (MCED) technologies use a blood, breath, urine, saliva, or stool sample to screen for multiple cancer types in a single test. This technology aims to serve an unmet need for early detection of a wide range of cancers. MCED screening tests currently available or in development show great promise to aid in the early detection of cancer, which could lead to new or improved treatments and potentially better health outcomes.

What are things to consider when using an MCED Test?

- These tests are meant to complement the current standard of care screening and diagnostic tests.
- As tests are developed and become available, important questions still need to be answered (see For Your Awareness) to ensure these tests work as the innovators intended.
- Prior to MCED testing for cancer screening, patients and providers should be aware of and commit to appropriate diagnostic follow-up (if available) for a positive MCED result.
- It is important for providers, hospitals, and healthcare systems to work to ensure adequate follow-up testing capacity and support services (care navigation, case management, etc.) before integrating these tests into current clinical guidelines and care plans.
- Both potential benefits and risks must also be documented and assessed. For example, there may be a perceived benefit in identifying cancer early, but there is a risk that a positive disease screening may not impact the eventual outcome for some individuals or may cause additional unnecessary testing.
- We encourage companies offering clinical tests to develop programs to capture outcomes data. And we encourage providers and patients utilizing currently available MCED tests to participate in such programs to help answer important questions.
- Healthcare providers should continue to encourage their patients to utilize other recommended cancer screening tests - ACS guidelines , CDC guidelines, Cancer Research UK, NHS Screening Guidelines.
- Collecting data from diverse populations and healthcare settings is essential to document efficacy and for equitable implementation. Visit our Workgroup Resources page on our website.

For Your Awareness - Important Questions to Consider

- What % of patients with a positive screening test have cancer?
- What % of patients with a positive screening test did NOT have detectable cancer?
- Can the tests reliably indicate where the type of cancer (breast, colon, pancreas, etc.) is located?
- What follow-up tests will be needed to diagnose cancer in the event of a positive result?
- Will early screening with these tests lead to early diagnosis and more curable stages of cancer?
- Will early diagnosis from these screening tests result in better patient outcomes?
- When should screening tests be done?
  - At what age?
  - Presence of family history?
  - How often should a patient return for MCED testing?
- Will this be true for all cancers?
- What is the best follow-up for individuals with a positive MCED screening test where no cancer is found? What type of support will these individuals need?
- What impact would these tests have on the utilization of current Standard of Care screening?
- Will these tests help close the screening gap and help address inequities?

Are MCED tests available?

In the UK,

- These tests are only available through a clinical trial. There is a current randomized clinical trial, The SUMMIT Study; however, it is fully enrolled.

In the US,

- These tests are either available in clinical trials or in some healthcare systems licensed providers may order MCED tests.
- Most US health insurance plans currently do not provide coverage for MCED tests, and most individuals must pay for these tests out of pocket. It is also important for patients to contact their insurer about coverage for follow-up diagnostic testing. Insurers may only provide limited coverage for the follow-up tests needed to diagnose cancer. The policies of insurers may vary by institution and over time.
- Companies offer these tests as Laboratory Developed Tests (LDTs), which means the tests and the laboratories have been evaluated for analytical validity under CLIA or CAP guidelines. Many tests utilizing genetic technologies are offered clinically as LDTs. At this time no MCED test has been approved by the FDA.
- Additional data must be collected to determine the clinical utility of these tests– the ability of the test to reduce the burden of cancer. At least one such randomized controlled trial is already underway (ISRCTN91431511).