Multi-Cancer Early Detection (MCED) Tests A New Approach in the War on Cancer

Cancer Screening in the General Population

Early detection and diagnosis have been proven to significantly improve cancer survival rates and reduce the cost and complexity of treatment for screenable cancers. In fact, the overall survival rate for cancer is four times higher when cancer is found before it spreads.

Today, cancer screening is recommended for the general population for five types of cancer—breast, cervical, colorectal, lung (smokers considered at risk), and prostate cancers. Unfortunately, because there aren't available single-cancer screenings for most cancer types, many cancers are detected too late, after they have metastasized. Treatment at this stage can be more difficult and costly.

Multi-cancer early detection tests (sometimes called liquid biopsies) are blood-based tests that complement existing cancer screenings by looking for many types of cancer at once and identifying them in earlier stages. These tests are a promising new tool in our arsenal in the war against cancer.

Cancer in the U.S.

We have been fighting a war on cancer for 50 years, and yet cancer remains the second leading cause of death in the U.S. We are diagnosing most cancers too late, and we need to transform the way we screen for cancers to detect them in earlier stages. The earlier that cancer is detected, the higher the chance of successful outcomes.



It is estimated that

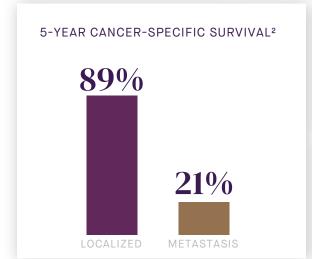
1 in 2 men and 1 in 3 women
risk developing cancer
during their lifetime.³

~600,000

people are predicted to die from cancer each year in the U.S.⁴



The lifetime risk of dying from cancer is 1 in 5 for men and 1 in 6 for women.³



Costs associated with treating late-stage cancers are

2-7x higher

than treating early-stage cancers.5

Total cost of cancer care in the U.S. will rise to

\$246 billion

by 2030, with some of the costliest treatments targeting late-stage cancers.⁴

Limitations of Current Cancer Screening

While beneficial, there continues to be limitations to recommended single-cancer screening. Today, there are recommended screenings for only five cancers; single-cancer screenings look for individual cancers, but are not designed to screen broadly for what cancer an individual may have; and compliance is suboptimal.



Cancers without widespread screening recommendations represent 85% of all cancer diagnoses⁶ and approximately 70% of cancer deaths.^{4,7}



Single-cancer screenings are optimized for sensitivity—the ability of a test to correctly identify those with a disease—allowing them to catch as many potential instances of the specific cancer as possible. This gives them a high-false positive rate.

An individual who receives all the recommended single-cancer screening tests in a year would have a cumulative false-positive rate of **31%** for men and **43%** for women.⁸⁻¹²



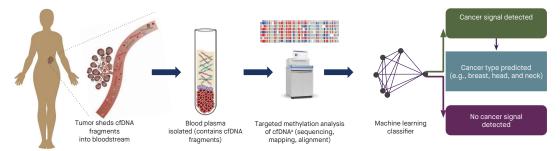
Adding more single-cancer screening tests—either as independent tests or a string of single cancer markers in a single test—is clinically and economically untenable given the high cumulative false-positive rates.¹³

Potential of MCED Tests to Improve Cancer Outcomes

New approaches are needed to detect cancer earlier and minimize overdiagnosis and false positives leading to overtreatment and psychological distress. MCED tests are our best chance to bend the cancer mortality curve.

MCED tests are designed to find more cancers at earlier stages and with as few false positives as possible, while not burdening the healthcare system.

MCED tests are designed to look for cancer signals in the blood. As an example, one MCED test uses a targeted methylation, next-generation sequencing (NGS)-based assay, analyzing cell-free DNA and utilizing machine learning to detect a shared cancer signal and predict the cancer signal origin.



cfDNA, cell-free DNA. *Bisulfite treatment; targeted probes pull out fragments matching regions of interest. Adapted from Liu MC, et al. Ann Oncol. 2020;31(6):745-759. DOI:10.1016/j.annonc.2020.02.011

MCED tests are a fundamentally different approach for early cancer detection meant to complement existing single-cancer screenings and improve cancer mortality by identifying cancer when it is still localized (not spread). A multi-cancer test that can predict a cancer location within the body can help determine next steps, enabling earlier treatment to improve survival and reduce healthcare costs.

MCED tests do not detect all cancers, and not all cancers can be detected in the blood.

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