Multi-Cancer Early Detection (MCED) Tests

A New Approach in the War on Cancer

Cancer Screening in the General Population

Early detection and diagnosis of cancer have been proven to significantly improve survival rates and reduce the cost and complexity of treatment for cancers with recommended screenings.[1] In fact, the overall survival rate for cancer is four times higher when cancer is found before it spreads.[2]

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

Multi-cancer early detection (MCED) tests are blood-based tests that complement recommended cancer screenings by detecting a cancer signal shared by a broad range of cancers.

These tests are a promising new tool in our arsenal in the war against cancer. Added to standard care, a MCED test could reduce 5-year cancer-related mortality in detected cancers by 39% or 26% of all cancer related deaths (modeled data in an elevated risk population age 50-79).[3]

Cancer in the U.S.

Despite 50 years since waging the war on cancer, it remains the second leading cause of death in the U.S. We need to transform the way we screen for cancers to detect them in earlier stages than they most often are today. The earlier that cancer is detected, the higher the chance of successful outcomes.

It is estimated that

~40%

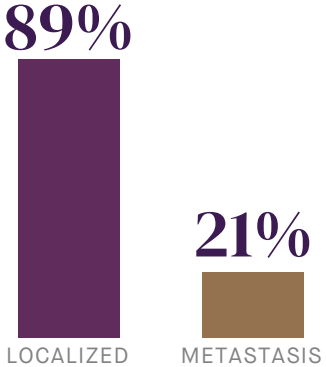
of men and women

will develop cancer during their lifetime.[4]

More than 609,000 deaths from cancer are expected in the U.S. each year.[4]

The lifetime risk of dying from cancer is **1 in 5 for men** and **1 in 6 for women**.[4]

5-YEAR CANCER-SPECIFIC SURVIVAL WHEN DIAGNOSED[2]



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.[6]

Limitations of Current Cancer Screening

Recommended single-cancer screenings are powerful tools that can help find cancer at an early stage. While beneficial, however, there are limitations.

Cancers without widespread screening recommendations represent **71%** of all cancer diagnoses[7] and approximately **70%** of cancer deaths.[8]

Each single cancer screening test has a unique false positive rate; administering multiple single cancer screening tests results in a high cumulative 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.*[9-13]

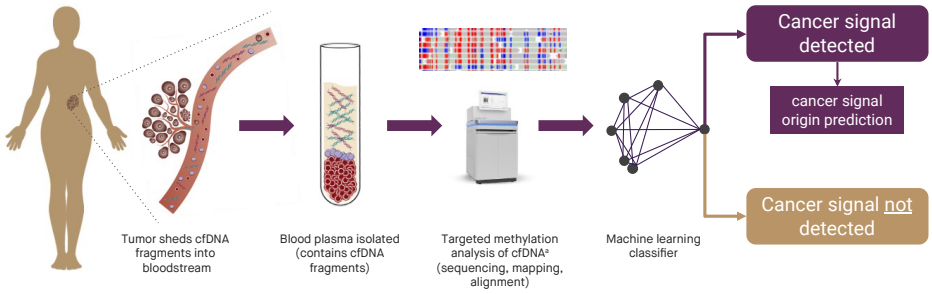
Even if single screening tests—either as independent tests or a string of single-cancer markers in a single test—were available for each individual cancer type, such an approach would be impractical, inefficient, cost-prohibitive and would overwhelm the healthcare system with false positive results.[7]

Potential of MCED Tests to Improve Cancer Outcomes

New approaches including MCED tests are needed to enable population-scale screening to maximize the overall cancer detection rate. MCED tests complement existing single-cancer screenings and represent the best chance to bend the cancer mortality curve.

MCED tests are designed to find more cancers at early stages, minimize overdiagnosis and false positives, and maximize efficiencies by providing information to guide diagnostic workups.

They are designed to look for cancer signals in the blood. As an example, one MCED test uses a targeted methylation, next-generation sequencing-based assay, analyzing cell-free DNA and utilizing machine learning to detect a shared cancer signal and predict the tissue type or organ associated with the cancer signal. This enables clinicians to focus their diagnostic evaluation, which can allow earlier treatment and may reduce healthcare costs.



cfDNA, cell-free DNA. aBisulfite 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.

To be used in a general population, MCED tests should have a high specificity of more than 99% to ensure a low false positive rate; the ability to detect multiple cancers across stages; and the ability to predict the tissue type or organ associated with the cancer signal with high accuracy to help guide next steps.[14]

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

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