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Multi-cancer Early Detection (MCED) Tests

What are multi-cancer early detection tests?

Multi-cancer early detection (MCED) tests have the potential to find more than one type of cancer from a single sample of blood. The blood sample is tested for certain pieces of DNA or proteins from cancer cells. If these are found, it might mean that the person has cancer, and it might also show which organ the cancer started in. Some MCED tests only test for the likelihood that there is cancer somewhere in the body, so if a person has a positive test result, they will need other tests, like imaging tests, to try to figure out where in the body the abnormal DNA or proteins came from.

Different MCED tests are being developed, and some (such as the GRAIL Galleri test) are available now by prescription through a doctor.

Why are MCED tests being developed?

MCED tests might be very useful, if they're proven to help prevent cancer deaths.

Currently, we have proven screening tests for some types of cancer (including breast, cervical, colorectal, prostate, and lung), because they've led to finding and treating these types of cancer earlier. Cancers that are found early are often easier to treat and tend to have better outcomes.

But most cancers do not have proven early detection screening tests. In fact, about 70% of all cancer deaths come from cancers for which there are currently no proven screening tests.
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MCED tests might be able to find a wide range of cancers earlier, hopefully before a person has any symptoms.

Are MCED tests FDA approved? Are they recommended?

There are many companies developing and studying MCED tests, but these tests are not yet FDA cleared or approved. However, some of these tests fall under the Clinical Laboratory Improvement Act (CLIA) regulations as lab-developed tests, which still allows them to be used if ordered by a doctor. Many of the companies developing these tests are gathering data and hope eventually to get FDA approval.

At this time, much more needs to be learned before these types of tests can be recommended for widespread use in people without any symptoms of cancer.

Most of the makers of these tests claim that they are not meant to replace screening tests currently in use (such as mammograms for breast cancer, Pap tests and HPV tests for cervical cancer, stool tests and colonoscopy for colorectal cancer, the PSA blood test for prostate cancer, and low-dose CT scans for lung cancer). Instead, MCED tests might supplement current screening tests, as well as help find other cancers for which there are no proven screening tests.

Here are some of the questions about MCED tests that still need to be answered:

- **How good are MCED tests at detecting cancer?** There is much that still needs to be learned about the accuracy of these tests for all cancers, and for individual cancer types. If an MCED test targets multiple cancers, the accuracy for each cancer type will likely be different.
- **If MCED tests are accurate at finding a specific cancer, how much earlier can they find that cancer compared to when it would be detected after symptoms start?** A successful MCED test would need to find the cancer early enough to improve the use of cancer treatment.
- **If MCED tests find cancers earlier, do people have better outcomes compared to people whose cancers were found after symptoms developed?** In particular, **does this test save lives, and, if so, by how much?** We need to be sure that MCED tests can find cancers earlier, and that treating the cancer earlier improves outcomes, including the risk of dying from cancer.
- **What about false-positive results from MCED tests?** If a test result suggests that cancer is present, but it is not, this result is called a *false positive*. False-positive test results can be stressful, costly, and can result in harm to people if they

need more testing to find the source of the positive test result. Early data show that false-positive test results from MCED tests are not common.

- **What about false-negative results from MCED tests?** If a test result doesn't detect that a person has cancer, but they actually do, this result is called a *false negative*. False-negative results might be harmful if a person assumes they don't have cancer because of the test result, when in fact they do. For example, they might be less likely to see a doctor to have possible cancer symptoms checked out, which might lead to the cancer being diagnosed at a later stage.
- **Who should be tested?** Would MCED tests best be used for general cancer screening, or in specific populations (such as in people over a certain age, or in people who are at higher cancer risk due to genetics or certain exposures, such as some workplace exposures)?
- **How often should the test be done?** If an MCED test is shown to be helpful in finding cancer early, what's the ideal amount of time between tests? Different cancers can grow at different rates. Waiting too long between tests might miss some cancers, but having a test too often (when it isn't needed) could be a waste of important medical resources.

What role is the American Cancer Society (ACS) playing in support of this science?

Research: We fund and conduct research to support advancing this science because we believe that if these tests are successful, they could save many lives that would otherwise be lost. ACS researchers have also worked with developers of some of these tests to provide advice and, in some instances, to allow them to measure the accuracy of their tests within our [population studies](#)¹ (through research collaborations).

Advocacy: If an MCED test is proven to contribute to better outcomes among people with cancer and it gets FDA approval, we will work to make sure that everyone for whom the test is recommended has access to this test.

Specific details about the GRAIL Galleri test:

This test is not FDA approved, but it is available under a CLIA waiver (because the

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time. Some individual employers might cover some or all of the cost².

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