



BUILDING BRIDGES TO IMPROVE CARE DELIVERY AND CLOSE GAPS IN HEALTHCARE EQUITY IN PRIMARY CARE PRACTICE

Three-Talk Model Approach for Discussing MCED Tests with Patients

| Patient Questions | Answers and Relevant Information |
|---|--|
| Choice or team talk | |
| What is an MCED test? | <ul style="list-style-type: none"> • An MCED test looks for multiple cancers at once, including cancers that we currently do not have other tests or screenings for. • MCED tests are offered to people who have no signs or symptoms of cancer. • Those without symptoms have approximately a 1% chance (1 in 100) of the test being positive and among those with a positive test, about 4 of 10 will be found to have cancer upon further diagnostic testing. • This test does not diagnose cancer. If the test is positive, further testing is required to determine whether cancer is present, and where it may be located. Follow-up tests may include scans and biopsies. • There are no established guidelines for the most appropriate diagnostic tests after a positive MCED test result. |
| What do MCED tests detect? | <ul style="list-style-type: none"> • MCED tests detect DNA or other cancer cell components shed into the blood. |
| What MCED tests are available? | <ul style="list-style-type: none"> • Currently, there is only one MCED blood test available: The Galleri test (GRAIL, Menlo Park, CA). |
| Who is eligible for MCED testing? | <ul style="list-style-type: none"> • The GRAIL Galleri test is available by prescription for patients aged ≥ 50 years as an addition to, not in place of, guideline-recommended cancer screening tests. However, more research is needed to determine the recommended starting and stopping ages and frequency of testing. • If you chose to have an MCED test, you should be willing to have follow-up testing and treatment if you receive a positive result. |
| How much does the test cost? | <ul style="list-style-type: none"> • The GRAIL Galleri test is listed at \$949 (USD). It is not covered by most insurers and typically must be paid out-of-pocket. • You may be able to use your flexible spending account, use your health savings account, or inquire about a patient assistance or payment plan to cover the cost. • Additional costs may arise from follow-up tests if the MCED test result is positive. |
| How long do the results take? | <ul style="list-style-type: none"> • Galleri test results are typically available about 2 weeks after the lab receives the sample. |
| How often do I get the test? | <ul style="list-style-type: none"> • Currently, GRAIL recommends testing annually with Galleri as an addition to and not in place of guideline-recommended tests. However, the optimal testing frequency is still unknown. |
| Option Talk | |
| What are the potential benefits of MCED testing? | <ul style="list-style-type: none"> • MCED tests may detect cancers that currently have no screening options. The Galleri test claims to be able to detect more than 50 cancers. |
| What are the potential limitations, harms, or uncertainties of MCED testing? | <ul style="list-style-type: none"> • We do not yet know whether MCED tests extend your life or improve quality of life. • The Galleri test does not detect all cancers, nor does it detect all cancers equally well. The ability to detect a cancer is dependent on the type of cancer. • MCED tests identify some cancers at an earlier, possibly more treatable stage and other cancers will be detected at a later stage, when treatment may be less effective. MCED tests appear to be able to better detect later-stage cancers than early-stage cancers. • A false negative is when cancer is present and it is missed by the test. The false-negative rate of Galleri is low and estimated to be 0.5% (1 in 200). A false-negative result should not replace the need for continued, regular, guideline-recommended cancer screenings. • Among those with a positive test, 4 of 10 will be found to have cancer upon further diagnostic testing. |



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| | <ul style="list-style-type: none"> Those with a positive test but no cancer found upon further testing may represent false positives. Those individuals will need to be watched carefully, including by repeating the Galleri test in a short interval of time (eg, 3-6 months) to be certain that a small cancer was not missed by the initial diagnostic testing and for symptoms that might represent cancer. The risk for false positives is 0.5% (1 in 200) and lower with MCED tests than with any other currently recommended screening tests. False positives can lead to unnecessary tests and procedures, costs, and anxiety. A positive result, whether true positive or false positive, may cause anxiety and distress. The appropriate process for evaluating a positive test is still uncertain. Follow-up invasive procedures, biopsies, or surgeries after a positive MCED result may cause harm. Overdiagnosis can occur when an MCED test detects cancer that would not have caused symptoms or affected your health. This can lead to unnecessary procedures. Overtreatment is related to overdiagnosis and occurs when excessive or unnecessary care is provided. This may expose you to avoidable procedures, treatments or therapies, side effects, and complications. Incidental findings are abnormalities unrelated to cancer that may be discovered during follow-up testing. These findings may require follow-up testing of their own and possible treatment, involving additional time, effort, risks, side effects, and costs. |
| How likely am I to experience those harms? | <ul style="list-style-type: none"> With the Galleri test, the risk of a false positive is 0.5% (1 in 200) and a false negative is 0.5% (1 in 200) The exact rates of overdiagnosis, overtreatment, and incidental findings related to MCED testing are not yet known |
| How accurate is an MCED test at predicting where the cancer is originating? | <ul style="list-style-type: none"> The Galleri test can identify the origin of cancer (also known as tissue of origin or cancer signal of origin) with approximately 90% accuracy. |
| What might a positive MCED result mean? | <ul style="list-style-type: none"> A positive MCED result may indicate detection of DNA or other components shed by cancer cells. Further testing is required to confirm a cancer diagnosis. Among individuals with cancer, the Galleri test can correctly identify 43% of them. Thus, about 4 of 10 individuals with a cancer signal detected will be found to have cancer upon further testing. MCEDs do not measure inherited genetic risk of having cancer in the future. Genetic risk can only be measured by testing the DNA in your genes (genetic testing). Examples of genetic tests are the test for <i>BRCA 1</i> and <i>2</i>. MCED tests do not test your genes. Instead, they test for DNA shed by tumor cells. |
| What might a negative MCED result mean? | <ul style="list-style-type: none"> A negative Galleri result indicates there is a very low chance (about 1 in 100) of having cancer at the time of testing, but it does not eliminate the need for regular screenings or attention to new symptoms. |
| What could happen if I do not have the test? | <ul style="list-style-type: none"> Choosing to not have the test is reasonable as we do not have all the evidence to recommend MCED testing. However, you should complete all the cancer screening tests that are recommended for you. These tests have been shown to detect cancers early when they are most treatable. |
| Decision to Talk | |
| How to decide? | <ul style="list-style-type: none"> MCED tests are not a recommended part of your routine cancer screenings at this time. MCEDs are not a replacement for guideline-recommended cancer screening tests. You should complete all the available recommended cancer screening tests for someone of your age, sex, family history, and health profile. |



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| | <ul style="list-style-type: none">• If you are unsure about getting tested, it may be best to wait. We can always revisit your decision as more information becomes available.• Another alternative is to consider participating in an MCED clinical trial that is helping to answer some of the uncertainties about MCEDs. You can learn more about MCED clinical trials at ClinicalTrials.gov.• Additional resources are available to help you make an informed decision about whether to consider an MCED test. We can refer you to them.• I will continue to be available to answer questions and provide you with support and guidance. |

Guerra CE, Litton JK, Viswanath CE, Fendrick AM. Multicancer Early Detection Tests at a Crossroads: Commercial Availability Ahead of Definitive Evidence. *Am Soc Clin Oncol Educ Book*. 2025;45(3):e473834.