# Can One Blood Test Transform Cancer Screening?

Scientists answer the call in a nationwide effort to find out.

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Because early detection offers the best chance of surviving cancer, screening tests that involve one quick blood draw are generating excitement. If approved, rather than scheduling downtime and facing intimidating procedures, patients could undergo screening for multiple cancers at once, just by rolling up their sleeves during routine doctor exams.

Numerous multicancer detection (MCED) tests are being developed across the country. At least one company claims its blood assay, already available to doctors, can discover 50-plus types of cancer. The tests are being heralded as a possible game-changer, but cancer experts say there's still work to be done.

"I think it has significant potential and is very exciting," said Marie Wood, MD, director of the Cancer Clinical Trials Office at the University of Colorado Cancer Center, who predicts a MCED test could help overcome barriers to screening. "But I think it has a ways to go."

Although no MCED test has received Food and Drug Administration approval, at least one, Galleri by GRAIL, has made itself available to doctors under the Clinical Laboratory Improvement Act. Some patients are pressuring doctors for the test, and a few doctors are ordering them, Wood said.

Both Wood, a CU School of Medicine professor of medical oncology, and Amanda Winters, MD, an assistant professor of pediatric hematology, oncology and bone marrow transplantation, discourage use of the test yet, saying too many unanswered questions exist.

"It's definitely exciting," said Winters, a CU Cancer Center member who studies similar blood tests or "liquid biopsies" to help aid in cancer treatment at the CU Anschutz Medical Campus. "I just think it's going to be important to make sure that we know what we are going to do as a medical community about these tests and really understand the risks first."

## A National Priority

Large-scale trials are in the works, with President Biden last year calling for making MCED tests a national priority. Wood, who serves as the co-chair of the prevention committee for the national Alliance for Clinical Trials in Oncology (ACTO), is heading up a National Cancer Institute/ACTO effort to create a biobank to get the studies started.

The CU Cancer Center will serve as one of a number of collection sites across the country. Researchers are seeking donations from healthy people and cancer patients of all stages prior to treatment. Multicenter clinical trials ahead include a four-year pilot study with about 24,000 people followed by a randomized controlled trial with about 225,000 participants to determine the tests' accuracy and best use.

"Everybody (including CU Cancer Center Associate Director of Population Sciences Linda Cook, PhD) has just turned in their applications to create a cancer screening research network to deploy the larger studies," Wood said.

"If you look at the studies that have been done so far where they had patients with cancer and patients without cancer, they were really accurate in the patients who had advanced cancer or metastatic cancer," Wood said. "That's not a good screening test. You want to be identifying things early. So we have to move that needle. Additionally, we need to determine how to incorporate these tests with standard of care screening."

## A Difficult Balancing Act

Most MCED tests in development use a cell-free DNA-based method, looking for signals shed by tumors in the blood. "So, obviously, if you have advanced cancer, there is going to be more shedding," Wood said, leaving earlier cancers more difficult to detect.

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Winters, who treats patients with blood cancers at Children's Hospital Colorado, uses similar science in her lab, where she is working to develop a highly sensitive blood test that can find any remaining cancer in patients after therapy to guide further treatment and improve outcomes.

Current tests used to determine a tumor's response to therapy are often not sensitive enough, she said. "Generally, if there are just a few cells circulating somewhere, you're not going to pick it up with a current clinical test."

Finding the right test sensitivity for MCED tests presents scientists with a tough balancing act. Too little results in false negatives and missed cancers, potentially leading patients to skip mammography or colonoscopy screenings that would have found the disease. Too much opens a Pandora's box of false positives.

"If it's not cancer, or not immediately associated with developing cancer, then sometimes knowing that information would cause a lot of unnecessary psychological stress for that person," Winters said of false positive results or positives that detect signals that might not ever result in advanced cancer.

In addition to anxiety, a screening test could lead to years of unnecessary monitoring for patients, with more testing and financial burden on them and on the system, Winters said. The scenario could play out in countless ways with multicancer screening tests.

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Also, some MCED tests detect cancer but fail to find the disease's origin, launching providers into a trying and expensive diagnostic hunt, with some procedures having their own risks to the patients.

## First Do No Harm

Despite the hurdles, MCED tests could help overcome major cancer screening barriers, including a

lack of tests, Wood said. “We only have screening tests for a certain number of cancers: breast, cervical, lung, colon and sometimes prostate cancer.” About 70% of cancer deaths occur from cancers with no standard screening tests, according to the American Cancer Society.

Lack of access for the underinsured and uninsured is another chief barrier, as well as a dearth of screening technology in some areas, such as low-dose CT scanners for lung cancer screening, Wood said.

“The other huge issue is people don’t keep up with their screening,” she said. “It’s complicated. The protocols are complicated. They start at different times. They are done at different intervals. They are also done with different procedures. So wouldn’t it be nice if we had a one-size-fits all test?”

Seeking an MCED test right now would open patients up to a number of potential pitfalls, as well as an out-of-pocket price-tag of up to $3,000 per test, Wood said. The unapproved tests are not covered by insurance.

“We definitely don’t want to be treating people who don’t have cancer,” Winters said, “and we don’t want to be providing psychological stress or invasive testing to someone who maybe doesn’t need treatment at the time,” she said. “The knowledge and the capability that we have is pretty powerful and exciting,” she said, “but we always have to think rationally and practically and remember the Hippocratic oath of first do no harm.”

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