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Navigating a Positive MCED Test and Negative Diagnostic Workup: Real-World Data

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You're listening to *Project Oncology* on ReachMD. This medical industry feature, titled "Navigating a Positive MCED Test and Negative Diagnostic Workup: Real-World Data," is sponsored by GRAIL.

Here's your host, Dr. Charles Turck.

Dr. Turck:
With an urgent need to detect cancer at earlier stages, recent clinical trials have shown that Galleri®, a multi-cancer early detection, or MCED, test can screen for cancer and predict its origin.

Today, we'll find out more about real-world outcomes for patients who were tested with Galleri, including residual cancer risk and key considerations for patient management.

This is *Project Oncology* on ReachMD, and I'm Dr. Charles Turck. Here with me is Dr. Eric Klein, a distinguished scientist at GRAIL. He's also one of the elite investigators on the clinical studies that led to the development of the Galleri MCED test.

Dr. Klein, thanks for being here today.

Dr. Klein:
My pleasure.

Dr. Turck:
So, Dr. Klein, can you start us off with a brief overview of how the Galleri MCED test works?

Dr. Klein:
Sure. This is a blood-based test that we call multi-cancer early detection because of its ability to detect multiple different kinds of cancers. It uses artificial intelligence, a machine-learning algorithm, and targeted methylation analysis of cell-free DNA, which is released by cancer cells into the bloodstream when cancer is present, to detect a cancer signal in blood for more than 50 distinct cancer types.

It's been available by prescription since April 2021, and it's recommended for use in adults who are at high risk for cancer. And that generally includes people over age 50 and others who may have other risk factors such as a strong family history or a known genetic mutation.

What's really interesting about the biology of this test is that it detects a signal shared by many cancers, and it can also predict a cancer signal origin, which helps direct diagnostic evaluations.

Dr. Turck:
With that background in mind, let's dive into your research on the real-world outcomes of patients who had a cancer signal detected by Galleri, had a diagnostic evaluation that did not result in cancer diagnosis, and then had a subsequent retest.

Why was this particular population important to study, and what was your data collection process?

Dr. Klein:
So, patients with a Cancer Signal Detected test result, like any screening test, need to undergo a diagnostic evaluation that's directed by their healthcare provider. And it's typically directed for this test by the cancer signal origin prediction such that if the CSO, as we call

it, suggests that you have kidney cancer, then you would go to an abdominal CT scan. If it's suggested that you have lung cancer, you would start with a chest CT scan.

In some patients, cancer is not found after that diagnostic evaluation, and we're offering the opportunity for those individuals to have their healthcare provider order a repeat MCED test within 3 to 6 months to help guide patient management. This is important because we have found that individuals who have a persistently positive cancer signal detected still have a significant residual risk of cancer.

And to put that in context, the National Institute for Healthcare Excellence, also known as NICE, suggests that anybody who has at least a 3% risk of cancer undergo a diagnostic evaluation. And we found in this modeling study that individuals who have a persistently positive cancer signal detected on retest have a much higher risk than this 3% cutoff. And so, we want to sensitize healthcare providers not to ignore the results and to continue to have a high clinical suspicion of risk.

So, in order to determine what that risk was, we looked at 145 individuals in the real world who had real-world Galleri testing done through March of 2024. And we looked at what the likelihood was that someone who had a persistently positive cancer signal detected after an initial positive test and a negative diagnostic evaluation were to have cancer and compared that to individuals who went from a cancer signal detected to a cancer signal not detected after a negative diagnostic evaluation.

Dr. Turck:
For those just joining us, this is *Project Oncology* on ReachMD. I'm Dr. Charles Turck, and today, I'm speaking with Dr. Eric Klein about real-world outcomes following a Galleri MCED retest.

So, we turn now to the findings, Dr. Klein. What were the results of the MCED retest, and how can we use this information to manage patients' residual cancer risk?

Dr. Klein:
Results were very striking. Individuals who had an initial cancer signal detected, a negative diagnostic evaluation, and a persistently positive cancer signal detected had about a 30% chance of being diagnosed with a cancer in the ensuing 10 months, even though that cancer was not detected by the initial diagnostic evaluation. It's really important to understand that. These individuals were at high risk for being diagnosed with a cancer even though it was not found with the initial diagnostic evaluation, which indicates something about the sensitivity of the test.

Equally important and equally striking was that individuals who had a cancer signal detected on the initial test, and a negative diagnostic evaluation, but who converted to no cancer signal detected on retest—in none of those individuals did we see cancer over the ensuing 17 months. And so, that provides lots of reassurance, both for the individual and for the healthcare provider, that those individuals likely do not have cancer.

Dr. Turck:
Before we close, Dr. Klein, can you speak to the types of cancer detected with the MCED retest and any other key takeaways from this study?

Dr. Klein:
Just as we've seen with all our studies and all our real-world experience with Galleri, multiple different cancer types were detected. So, we saw, in this particular study, cancers of the salivary gland, the breast, and HPV-associated head and neck cancers, lung cancer, lymphoma, and cancers of the gallbladder, vagina, and testes.

What's really important here…of all those different cancers: only two of them, breast and lung cancers, have current [US Preventive Services Task Force] recommended screening tests available. And the main findings of this study: I will re-emphasize if you have a persistently positive cancer signal detected on retest, you have a what we call a high residual risk, or a high likelihood of being diagnosed with cancer over a relatively short period of time, 10 months or so, and individuals who convert to a No Cancer Signal Detected result, seem to have a very low risk of cancer.

Dr. Turck:
That's a great way to summarize these new findings and what they could mean for clinical practice. As this brings us to the end of today's program, I want to thank my guest, Dr. Eric Klein, for sharing the latest research on Galleri.

Dr. Klein, it was great speaking with you today.

Dr. Klein:
Thanks for having me.

Dr. Turck:

Before we wrap up, do you have any final key takeaways for our listeners?

Dr. Klein:
Yes. I'd like to share why I'm so excited about MCED testing. We currently screen for five different cancers in the United States: so, that's breast, colon, lung, cervical, and prostate, and all of those screening tests have been shown to reduce mortality.

Despite that, we still lose more than 600,000 people a year due to cancer, and one significant reason for that, not the only reason, but one really significant reason, is that more than 70% of those deaths come from cancers that we don't have screening tests for. And MCED is a really exciting blood-based way to be able to screen for the multiple other cancers that people die from.

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