

## Transcript Details

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## Integrating Multicancer Early Detection into Clinical Care

### ReachMD Announcer:

Welcome to ReachMD. This medical industry feature, titled, Integrating Multicancer Early Detection into Clinical Care, is sponsored by GRAIL.

Here's your host, Dr. Sana Raouf.

### Dr. Raouf:

According to the CDC, about 30 to 50% of cancers diagnosed in the United States are related to preventable risk factors like smoking, other environmental carcinogens, maintaining healthy body weight, and receiving recommended cancer screenings.<sup>1</sup> So, what options are available for cancer screenings to promote early cancer detection?

This is ReachMD, and I'm Dr. Sana Raouf. Joining me to discuss key considerations for multi-cancer early detection is Dr. Candace Westgate and Dr. Mylynda Massart.

Dr. Westgate is the Medical Director of the AHEAD program and Chief of Staff at Adventist Health Saint Helena in northern California.

Dr. Westgate, welcome to the program.

### Dr. Westgate:

Thank you so much. It's a real honor to be here today. I'm looking forward to our discussion.

### Dr. Raouf:

And Dr. Massart is the Founder and Director of UPMC's Primary Care Precision Medicine Center.

Dr. Massart, it's great to have you with us.

### Dr. Massart:

It's great to be here with you and Dr. Westgate. Thank you so much.

### Dr. Raouf:

To get us started, let's begin with you, Dr. Westgate. Where do we stand with the cancer burden in the United States?

### Dr. Westgate:

Currently, the cancer burden in the United States is vast. It is the second most common cause of death in the US and has been for many decades.<sup>2</sup> Despite the billions of dollars of investment that the US government has placed into basic cancer research,<sup>3</sup> we really haven't seen that progress to diagnosing cancer at an earlier stage. In general, unfortunately, when cancer is caught at a later stage, the outcomes are significantly worse than when it's caught at earlier stage.<sup>4</sup> So, for example, 5-year survival rate for cancer caught at an earlier stage is around 90 percent, versus if it's caught at a later stage or metastasize, it's reduced drastically now to 21 percent.<sup>4</sup>

Now, we also know that the USPSTF does have cancer screening recommendations for us as physicians. However, the majority of cancers still don't have a recommended screening tool.<sup>5</sup> Now, we have those 5 cancers that we can screen for breast cancer, cervical cancer, colon cancer, prostate cancer for certain individuals that are at higher risk, and obviously low-dose lung cancer screening for those that have a significant pack-year history of smoking, but that is only accounts for 25 percent of the burden of cancer deaths within the United States.<sup>6</sup> So, there is a vast amount of cancers that is causing death within the United States that we do not have a screening test for to try and catch it at an earlier stage.<sup>7</sup>

### Dr. Raouf:

Thank you for those insights. And turning over to you now, Dr. Massart, what do we need in order to help improve early cancer detection?

### Dr. Massart:

So, over the last 5 years, there's been some really exciting progress with cancer screening. One example of this type of testing is called Galleri. This is a screening tool for multi-cancer early detection. It's different than the hereditary cancer testings that many of us are familiar with, which are looking for genetic mutations that make patients at an increased risk for developing cancer in their lifetime. Instead, Galleri is looking at small cell-free fragments of DNA that are floating in our bloodstream for methylation patterns that are hallmarks for cancer that's actually developing now in the body even before symptoms can appear.

Galleri is currently the only test of its kind offered in the United States that's available to us clinicians to order and is readily available for any of us in primary care, oncology, or medical genetics to order for our patients. The turnaround time for testing is around 10 days, and you can order testing and get the reports back on the online portal. Over 98 percent of your patients are going to have a result that's returned cancer signal not detected, and then less than 2 percent of the time patient results are going to come back cancer signal detected, which means at that point in time a patient has about a 1 in 2 chance of actually having cancer, and you're going to initiate a diagnostic evaluation.<sup>8</sup>

### Dr. Raouf:

That sounds very promising. So, Dr. Westgate, how could Galleri complement USPSTF recommended screening tests?

### Dr. Westgate:

And that's a very important thing to distinguish. Galleri is there to complement USPSTF, not replace the recommended screening tests.

So the promise is that in the way that they were designed was to be very specific to minimize the false positive rates and meant to complement, not replace, the current cancer screenings.<sup>9</sup> We have really good data and evidence for many years showing the value and the sensitivity and specificity of our current cancer screening guideline.<sup>9</sup> So, this new liquid biopsy space is really there in addition to, not instead of. So another example of this is that we know that mammograms and colonoscopies are highly sensitive to that one type of cancer that they are looking for, but with the Galleri test, it has high specificity, and so we can use it alongside the standard screening.

### Dr. Raouf:

For those just tuning in, you're listening to ReachMD. I'm Dr. Sana Raouf, and joining me today to talk about Galleri for multi-cancer early detection are Drs. Candace Westgate and Mylynda Massart.

So, now that we have some background on how Galleri works and how it can complement USPSTF recommended screenings, Dr. Massart, can you explain how to determine which

patients would benefit most from Galleri testing?

**Dr. Massart:**

Yes, definitely. So, all patients who are older than 50 years of age are eligible for the multi-cancer early detection, and that's because cancer rates dramatically increase at the age of 50.<sup>10</sup> I also will sometimes look at other risk factors that make patients high risk for possibly developing cancer, including their personal history—perhaps they've had a prior cancer or their family history if there's a significant family history of multiple cancers.

Also, some of my patients have genetic predisposition mutations, and we know they are at increased risk for developing cancer in their lifetime,<sup>11</sup> and then finally I look at different types of lifestyle influences—things like smoking, obesity, or job exposures, such as being a firefighter. A lot of times, physicians will ask me when do I talk about this type of cancer screening with my patients, and it's interesting how often it actually comes up in conversation. I routinely bring it up at any annual wellness exam, but I also will offer it any time patients come in with a personal concern about cancer or possibly a new family history or new family diagnosis of cancer as well.

**Dr. Raouf:**

Thanks, Dr. Massart. And coming back to you, Dr. Westgate, could you share some strategies for educating patients on the importance and benefits of Galleri?

**Dr. Westgate:**

Yes, absolutely. So, Galleri is a way for patients to take a more proactive approach to their cancer screenings, and an amazing opportunity for us as providers to help our patients stay ahead of cancer. What we're doing here is offering an asymptomatic patient a screening test, and what this is going to do is help us to better predict what's going on at that point of time in that patient's body.<sup>12</sup> Things that I talk to my patient about, just like what Dr. Massart said, it's a wonderful opportunity for you to add this in just like the way you talk about your other cancer screenings that you recommend to your patients—for example, you know, making sure they're up to date on their colon cancer screening.

This Galleri test fits right in during that same kind of conversation. So, whether it's a well woman or well man exam, depending on your specialty obviously or if it's a new patient coming in, you know, with significant high-risk factors and you're offering more of a precision-based approach to your patients' healthcare,<sup>9,12,13</sup> Galleri can be easily added in there. I really enjoy talking to my patients about this test, about this new technology, and it's been really wonderful to see how receptive and how excited they are about this and the ability to help catch cancer, when patients are asymptomatic.

**Dr. Raouf:**

Now, Dr. Massart, are there any final thoughts you'd like to leave with our audience today?

**Dr. Massart:**

Yeah. I just want to say how excited I am to finally, at this point in my career, have a screening for cancers that we have never had the ability before and to really empower our high-risk patients to complement their current screening modalities with this new technology.<sup>9,12,13</sup> I'm also really looking forward to the real-world data that is currently happening now in trials around the world, and hopefully this is going to provide enough supporting evidence to advance insurance coverage and increase access to this type of screening for everyone.

**Dr. Raouf:**

As we end our discussion, Dr. Westgate, I'll give you the final word.

**Dr. Westgate:**

Thank you. My final word is a little bit more personal. I know that there are a lot of providers out there—oncologists, even primary care docs—who often have to give the unfortunate diagnosis of cancer to their patients. When I was 16, my dad got the diagnosis of pancreatic cancer stage 4, and the words from his provider were "I'm so sorry, we haven't caught this early enough," and 7 weeks later, he passed away. Just 2 years ago, my mom got the diagnosis of breast cancer, a cancer that has a screening modality for it, and the words from her oncologist instead were a lot more positive, and he let her know "well done, we've caught this at an early stage because you've stayed up to date on your cancer screenings, and we're going to be able to get through this and this is not going to be the cause of your death," and I'm so excited for us as providers and for our patients to hear those words so much more in the future instead of "I'm sorry, we didn't catch this early enough." So, I, too, am very optimistic for the opportunity that this new technology has in our fight against cancer.

**Dr. Raouf:**

Thank you. Those are great takeaways to consider as we end today's program. I want to thank my guests, Dr. Candace Westgate and Dr. Mylynda Massart, for helping us better understand the potential of the multi-cancer early detection alongside recommended cancer screenings.

Dr. Westgate, Dr. Massart, it was great speaking with you today.

**Dr. Westgate:**

Thank you so much. The pleasure's all mine.

**Dr. Massart:**

Thank you for having us.

**Dr. Raouf:**

Before we go, let's take a moment to review some Important Safety Information.

**ReachMD Announcer:**

**Important Safety Information**

The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older. The Galleri test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. Galleri is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of Galleri is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

Results should be interpreted by a healthcare provider in the context of medical history, clinical signs and symptoms. A test result of "No Cancer Signal Detected" does not rule out cancer. A test result of "Cancer Signal Detected" requires confirmatory diagnostic evaluation by medically established procedures (e.g. imaging) to confirm cancer.

If cancer is not confirmed with further testing, it could mean that cancer is not present or testing was insufficient to detect cancer, including due to the cancer being located in a different part of the body. False-positive (a cancer signal detected when cancer is not present) and false-negative (a cancer signal not detected when cancer is present) test results do occur. Rx only.

**Laboratory/test information**

GRAIL's clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists. The Galleri test was developed, and its performance characteristics were determined by GRAIL. The Galleri test has not been cleared or approved by the Food and Drug Administration. GRAIL's clinical laboratory is regulated under CLIA to perform high-complexity testing. The Galleri test is intended for clinical purposes.

**ReachMD Announcer:**

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