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Addressing Screening Limitations Through Multi-Cancer Early Detection Tests

Announcer:
You're listening to *Project Oncology* on ReachMD, and this episode is sponsored by Exact Sciences. Here's your host, Dr. Jacob Sands.

Dr. Sands:
This is *Project Oncology* on ReachMD. I'm Dr. Jacob Sands, and joining me to discuss multi-cancer early detection is Dr. Tom Beer. Dr. Beer is the Chief Medical Officer for Multi-Cancer Early Detection at Exact Sciences Corporation. He also serves as an Adjunct Professor of Medicine at the OHSU Knight Cancer Institute in Portland, Oregon. Dr. Beer, welcome to the program.

Dr. Beer:
It's great to be with you today.

Dr. Sands:
So let's start with some background. What are the limitations of current cancer screening?

Dr. Beer:
The most important limitation is the fact that we don't have screening tests for the majority of cancers. In fact, about 70 percent of new cancer diagnoses and about 70 percent of cancer-related deaths in the United States occur due to one of these cancers for which there are no screening tests available. That's 1.9 million new cancer cases in the United States and we only have screening tests for about 30 percent of those. At an individual patient level, if you take, for example, a person undergoing screening for colorectal cancer, there are 151,000 new colorectal cancer cases in the United States per year compared to 1.9 million new cancer cases overall. So a person undergoing screening for one of these cancers has about ten times the chance of having another cancer at the same time, and we're not looking for most of those cancers. The other limitations, of course, have to do with access, adherence, and equity. Despite the fact that we have well-established, agreed-upon standard of care screening tests for four common cancers, many people aren't able to access those or don't take advantage of the available screening methods. So I think we can do better on expanding the number of cancers we can screen for, but also on getting folks screened.

Dr. Sands:
With that, let's turn our attention to a multi-cancer early detection, or MCED for short. Can you tell us how that screening works?

Dr. Beer:
So these are brand new blood-based tests that seek to detect multiple cancers from a single blood test. This is new technology. It's still in the research and development phase. It is not something that we routinely recommend today. It's made possible by understanding cancer biology that has evolved over the last several decades.

We now know that mutations, DNA methylation, changes in chromosomal structure, and proteins that are unique to cancer are all hallmarks of cancer, and that understanding has enabled the development of multi-cancer early detection tests. The other major advancement that's made it possible is the technology that enables us to detect what we call biomarkers at very low concentrations in blood. So patients with cancer see very small quantities of these abnormal DNAs and abnormal proteins in their blood, and being able to measure those is what makes multi-cancer early detection possible. So the idea here is that a single blood test would look at multiple biomarkers in the blood and would be capable of detecting multiple cancers simultaneously, and that's what we and others are working on in clinical trials.

Dr. Sands:
So with that in mind, can we discuss how MCED might address some of the limitations you outlined earlier?

Dr. Beer:
The most important contribution that MCED or MCED tests can make to the field is to expand markedly the number of cancers that could be detected early with a test. In point of fact, many of the biomarkers that we seek to detect in the blood are really common across a broad range of cancers, so these tests are not inherently limited to a subset of cancers but have the potential to detect the majority of cancers. So that's probably the most important contribution that they can make. The tests are also designed to have a high specificity to limit false positives. False positives are a common challenge for all screening tests, and these MCED tests are designed to limit the number of false positives. We can't avoid them completely, but we would like to get those numbers as low as possible.

Dr. Sands:
What about helping communities access screening when there is a defined screening test? Is there anything about MCED that would make screening more accessible for some of those communities?

Dr. Beer:
I think it starts with the studies that we're doing. It is critically important that the large-scale studies that are being done to examine MCEDs are inclusive of all of America, and we're working very hard on that at Exact. I know other folks in the field are also very focused on the fact that it's important to evaluate our tests in all Americans and in a population that is reflective of the overall makeup of our society. That way, people can have confidence that these tests perform for all communities. The next thing that's going to be really important is to get the word out and get the education about the opportunities that these tests provide to a broad range of audiences. And finally, just making them accessible across all communities in the United States, and I think because it's a single blood test for multiple cancers, it's relatively straightforward. People are used to getting blood tests. It's relatively easy to deliver that. I think there's real potential for MCED tests to break down some of the barriers to access to cancer screening, but we have to be thoughtful, deliberate, and committed to that. We know that new technologies, historically, have often exacerbated rather than reduced disparities in health care, so we have to be highly intentional, and we're committed to that beginning with how we conduct the research that is evaluating this test today and in the coming years.

Dr. Sands:
For those just tuning in, you're listening to *Project Oncology* on ReachMD. I'm Dr. Jacob Sands, and I'm speaking with Dr. Tom Beer about multi-cancer early detection testing, or MCED testing.

Dr. Beer, so if we look at the potential impact of MCED, what are some of the key takeaways that we've learned from clinical trials, such as the ASCEND and PATHFINDER studies?

Dr. Beer:
So I really appreciate that question. So the way these tests have been studied is primarily in case-control studies, meaning that samples of blood are collected from people with a known cancer and people who are believed to be cancer-free, and those samples are then compared to one another to determine how well the test performs. But there have been two prospective, interventional studies where candidate multi-cancer early detection tests have been evaluated in the intended use population, meaning in actual people getting cancer screening. The first of those was the DETECT-A study. That study was completed in 2019 and published in 2020 and evaluated a prototype multi-cancer early detection test called CancerSEEK. That was a multi-biomarker class test combining mutations in protein biomarkers, but the DETECT-A study demonstrated feasibility of using such a test. It evaluated such a test in over 10,000 women aged 65 to 75 and approximately doubled the proportion of cancers detected with a screening test. So in those 10,000 women, about a quarter of the cancers that were diagnosed were picked up with standard-of-care screening, and another quarter were picked up with this prototype early-stage multi-cancer early detection test, getting us from a quarter to about half the cancers detected with screening. So that's real potential progress.

Another prospective study reported at ASCO is the PATHFINDER study. This is a different prototype multi-cancer early detection test using deep analysis of DNA methylation. That test was evaluated in over 6,000 participants, including folks at higher risk such as smokers, people with a prior history of cancer, and people with genetic predisposition to cancer. And again, we saw this candidate multi-cancer early detection test significantly increase the number of cancers detected through a screening test, and that result serves as the basis for further development of the methylation-based multi-cancer early detection test from another company in the field.

Dr. Sands:
And with that, I just want to ask you, as a closing point, what do you see on the horizon then as far as next steps in this exciting space?

Dr. Beer:

I think we're all still very much in the R&D phase, but the R&D phase has moved to large, interventional studies in the intended-use population, and that's really, really exciting. If the studies confirm the promise of these tests, what I see in the future is a situation where people will be able to take advantage of a combination of dedicated screening tests for individual cancers that are most sensitive for that particular cancer, but also address much of the rest of their cancer risk through a multi-cancer early detection test. One of my colleagues in the field, Eric Kline, likes to describe this as instead of screening for cancers, we will move to screening people for cancer. And that's really the vision of the future that we all have.

Dr. Sands:
Well with those thoughts in mind, I want to thank my guest, Dr. Tom Beer, for joining me to discuss multi-cancer early detection testing. Dr. Beer, it was wonderful having you on the program.

Dr. Beer:
Such a pleasure to be with you today.

Announcer:
This episode of *Project Oncology* was sponsored by Exact Sciences. To access this and other episodes in this series, visit ReachMD.com/Project Oncology, where you can Be Part of the Knowledge. Thanks for listening!