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### Bridging Gaps with Blood-Based CRC Screening

#### ReachMD Announcer:

You're listening to *On the Frontlines of Colorectal Cancer* on ReachMD. And now, here's your host, Ryan Quigley.

#### Ryan:

This is *On the Frontlines of Colorectal Cancer* on ReachMD. I'm Ryan Quigley, and joining me to discuss the real-world impacts of blood-based colorectal cancer screening is Dr. Aasma Shaukat. She's the Robert M. and Mary H. Glickman Professor of Medicine in the Department of Medicine and a professor in the Department of Population Health at NYU Grossman School of Medicine. She's also the Director of Outcomes Research in the Division of Gastroenterology and Hepatology at NYU Langone Health.

Dr. Shaukat, welcome to the program.

#### Dr. Shaukat:

Thank you so much for having me. It's always a pleasure, Ryan.

#### Ryan:

Absolutely. So, Dr. Shaukat, to start us off, despite strong recommendations, colorectal cancer screening remains a bit underused among average-risk adults. What do you see as the biggest real-world barriers keeping this population from getting screened?

#### Dr. Shaukat:

That's a great question—one that is of significance at the population health level and when we think about making an impact on every community. So, right now, nationally, we're at about a 59 percent screening rate when we include 45 to 49-year-olds, who were recently added to average-risk screening, which, of course, means one in two individuals is currently unscreened or not up to date on screening. The factors have been pretty thoroughly studied. It probably won't come as a surprise to you, but lack of health insurance is cited as one of the big reasons, although colon cancer screening is covered by all insurance carriers and also Medicare and Medicaid and available through states for uninsured or underinsured individuals. But other than that, it's actually lack of recommendation from their provider. Many patients just don't go in often enough to see their provider and really get that recommendation that they are eligible for screening and should consider completing screening. So essentially, we need to do a better job at getting individuals to the screening fold that are eligible.

#### Ryan:

Now, you recently co-authored a study evaluating a circulating tumor DNA-based blood test for colorectal cancer screening. How does this modality compare with other screening options, and what were your findings on sensitivity and specificity?

#### Dr. Shaukat:

Again, we're trying to tackle this question of, what will it take to get more individuals screened? Currently, we have screening modalities that fall into two broad categories. One is a screening colonoscopy-based strategy—and the other is stool-based testing. We have fecal immunochemical test—FIT—or we have the multi-target stool DNA test. So there's still some reluctance in uptake of these two modalities. Many people are just scared of colonoscopy. It requires time off, requires taking a prep, and is an invasive procedure with rare complications, and with the stool-based tests, people just perhaps don't care about handling stool or have that "ick" factor.

So for the last 10 or 20 years, we've really been holding on to this holy grail that perhaps we'll have a blood test for colon cancer screening, and adding that modality will really motivate people to complete screening—those who so far haven't signed up for either a stool test or a colonoscopy. So with that idea, multiple blood tests have been under development, and it is such an exciting time that we

finally have a blood test that we put through a very robust clinical validation study across the US, and that's the study that you're referring to that we recently published on. This blood test looks for any abnormal DNA signature in the blood, and the idea is perhaps a tumor that's growing is shedding small amounts of DNA that we can detect in the blood and essentially understand who might need a colonoscopy to look for anything worrisome. This was a clinical validation study of a blood test, and it performed pretty well, meaning there are some standards that Medicare has set as bars for what would be acceptable for a blood test, and it met and exceeded those bars for performance. So the sensitivity was about 80 percent, and the specificity was 91 percent for colorectal cancer detection, so it compares favorably to stool tests. However, where the test fell short was its detection of these advanced adenomas, or what we call precursor lesions that are on their way, we think, to turning into cancers. It was quite low at 13 percent. So, at the moment, we're positioning the test as an option for individuals that are currently unscreened despite being offered colonoscopy or stool-based test. It's better than no screening, but we still want people to undergo possibly a stool test or a colonoscopy first. But if they're unwilling or unable to do those, then the blood test becomes an option.

**Ryan:**

Thank you very much for that detailed breakdown. And now, given those findings, how do you see this blood-based screening test contributing to clinical practice or broader screening strategies in these average-risk patients?

**Dr. Shaukat:**

We think the test has potential to improve that unscreened screening rate and bring it up to much higher. We ideally want to get to 80 percent in every community, and we think by offering this as another option to undergo screening, it will actually enable the providers as well as the patients—having a convenient option to complete the test. There are studies that compared a stool test versus offering a blood test, and there was a higher uptake or interest in the blood test. So, by capitalizing on that enthusiasm, we are hopeful that if a patient is reluctant to undergo a colonoscopy or doesn't really want to do a stool test, the clinician can order this blood test and send the patient to the lab. It could be coupled with other blood tests that we get for screening or prevention, and then it ensures that the test gets done, and that would be a huge advantage to getting unscreened individuals brought into the screening fold.

**Ryan:**

For those just tuning in, you're listening to *On the Frontlines of Colorectal Cancer* on ReachMD. I'm Ryan Quigley, and I'm speaking with Dr. Aasma Shaukat about how blood-based screening could help bridge gaps in colorectal cancer prevention.

So, Dr. Shaukat, when it comes to patients who remain unscreened, which populations might benefit the most from having a blood-based screening option available to them?

**Dr. Shaukat:**

That's a great question. We think everybody in the screening age from 45 to 75 stands to benefit from getting the blood test as a convenient option if they are reluctant or unable to undergo a colonoscopy or a stool-based test. When we think of younger individuals—45 to 50-year-olds—they're busy. They have careers and young families, so taking time off to get that colonoscopy might be burdensome. So a blood test makes total sense. And when we think of older individuals, say between 65 and 75, perhaps they have several health conditions or don't have anybody to drive them, so they might be more able to undergo a blood test along with their other routine blood tests that they're getting at the doctor's office. It really stands to benefit anyone.

The important point to remember is that the blood test itself obviously doesn't save anybody's lives. It essentially tells us who is at risk for having a worrisome lesion, so the next step is a colonoscopy. So if the test is positive, that patient needs a colonoscopy, but the idea is that at least then patients will be more likely to get a colonoscopy because they know the likelihood of finding something is much higher, and then the benefit definitely is worth going through the effort of undergoing a colonoscopy. And a vast majority will have a negative test, and they're good for three more years.

**Ryan:**

And how might this screening modality help address disparities across socioeconomic or geographic or racial and ethnic groups? Is that something that's been part of the focus here?

**Dr. Shaukat:**

There aren't explicit studies to see how it performs in underserved populations, although we have some anecdotal data showing that, because it's convenient to be offered in a clinic, it actually may remove some of the barriers that underserved patients face when it comes to completing screening. And when we think about rural patients, they don't have access to a gastroenterology practice for easy scheduling of a colonoscopy. The drive time is really long, there's multiple visits, and there's taking the prep, so at least a blood test overcomes those barriers. Again, it's up to us to implement these tests in a way that it reduces these disparities that we see across socioeconomic, racial, ethnic, or geographic lines and use them to our advantage to overcome those barriers.

**Ryan:**

Thank you for that. And, Dr. Shaukat, before we close here, as clinicians think about the future of colorectal cancer screening, what key takeaways would you like them to keep in mind as we close out this program?

**Dr. Shaukat:**

Clinicians should absolutely look at the study we published and other studies on this topic because patients are already hearing about this and will be asking them, "What about a blood test? Can you tell me my options?" So it's really important to understand the studies and where stool-based testing fits in versus blood-based testing and which patients they should offer it to. Their decision point should be offering a stool-based test or a colonoscopy first, and for patients who still don't complete it, trying to get them to do the blood test and basically screen as many patients on their panel that are eligible as possible because we know screening leads to reduction in colon cancer cases as well as death from colon cancer. So it has a population benefit, and we just need to use every modality possible to maximize that benefit.

**Ryan:**

Thank you very much for that. I think that's a great way to round out our discussion. I want to thank my guest, Dr. Aasma Shaukat, for joining me to explore how blood-based screening could shape the future of colorectal cancer prevention. Dr. Shaukat, it was so great having you on the program.

**Dr. Shaukat:**

Yeah, thank you so much for having me. Always a pleasure.

**ReachMD Announcer:**

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