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Colorectal Cancer Screening: Overcoming Patient Barriers with a Noninvasive Screening Method

Announcer:
You're listening to Clinicians Roundtable on ReachMD. This medical industry feature, titled "Colorectal Cancer Screening: Overcoming Patient Barriers with a Noninvasive Screening Method," is sponsored by Exact Sciences. Here's your host, Dr. Charles Turck.

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Dr. Turck:
Welcome to *Clinicians Roundtable* on ReachMD. I'm Dr. Charles Turck and joining me to discuss how a noninvasive method can help us address common patient barriers to colorectal cancer screening is Dr. Lanre Jimoh. Dr. Jimoh is a dual board-certified internist and gastroenterologist practicing in Charlotte, North Carolina. Dr. Jimoh, welcome to the program.

Dr. Jimoh:
Thank you very much Dr. Turck. Happy to be here.

Dr. Turck:
Let's begin by reviewing what we know about colorectal cancer. Dr. Jimoh, what can you tell us about the burden of disease in the US?

Dr. Jimoh:
Well, after lung cancer, colorectal cancer is the second leading cause of cancer-related death in the United States.[1] In 2022, an estimated 52,600 deaths[1] were from colorectal cancer, and an estimated 151,000 new cases[1] of colorectal cancer were diagnosed. Now early detection in colorectal cancer is vital as five-year relative survival rates drastically diminish in the later stages 91 percent in stages one and two versus only 15 percent in stage four distant disease.[1,2] But unfortunately, many patients with early-stage colorectal cancer don't experience any symptoms, which is why risk- and age-appropriate cancer screening is crucial.[3]

Dr. Turck:
Now as I understand it, some major medical organizations recently updated their clinical practice guidelines to lower the starting age for colorectal cancer screening to 45. So can you tell us more about this decision, Dr. Jimoh?

Dr. Jimoh:
Of course. So the U.S. Preventive Services Task Force, or USPSTF for short, and the American Cancer Society, also known as the ACS, both recommend screening patients who are at average risk for colorectal cancer starting at age 45.[4,5] In part, that's because the incidence of colorectal cancer in patients younger than 50 years has increased by 51 percent since 1994.[5] And between 2004 and 2015, about 52 percent of new cases in patients younger than 50 were diagnosed in more advanced stages, compared to 40 percent of new cases in patients aged 50 and older.[6] And while we know that regular screening may reduce mortality rates and has the potential to save lives,[4] current rates of screening in eligible adults are inadequate. In fact, only 48 percent of adults aged 50 to 54 years and 21 percent in those aged 45 to 49 have undergone colorectal cancer screening.[7] To put it another way, about 44 million average-risk people aged 45 and older remain eligible or overdue for colorectal cancer screening.[8]

Dr. Turck:
So with that number in mind, what do the clinical practice guidelines recommend as an appropriate screening method for average-risk patients?

Dr. Jimoh:
So the screening methods currently available include visual studies such as colonoscopy or flexible sigmoidoscopy, which are both invasive procedures, and CT colonography, which requires bowel preparation. The other class of recommended screening techniques are stool tests, which are noninvasive and can be performed at home.[4] Among the available high-quality screening tests, clinical practice guidelines from USPSTF and ACS do not offer a preference for one test over another for average-risk patients.[4,5] In fact, national colorectal cancer screening guidelines have encouraged offering patients a choice in screening method for more than five years in an effort to increase screening rates.[4,5,9]

For instance, the ACS in 2018 stated that "Offering patients a choice of CRC screening tests rather than recommending a single test improves adherence."[5] And in 2021, the USPSTF recommended that "Discussion…with patients may help better identify screening tests that are more likely to be completed by a given individual."[4] And if we offer patients a choice, this can help remove potential barriers to screening hesitancy.[10]

Dr. Turck:
So then let's dive into that idea a bit more, Dr. Jimoh. What are some of the barriers that can keep patients from getting screened?

Dr. Jimoh:
Well, one study of patients' self-reported barriers to colorectal cancer screening revealed that many common barriers were specific to a colonoscopy.[11] These concerns related to the procedure itself, sedation, logistical challenges such as time off work or transportation, and financial challenges. In addition, some experienced discomfort with the concept of the invasive procedure or the bowel preparation.[11] Perceived barriers like these may lead to nonadherence,[11] and in my experience, a shared approach between the patient and the provider to address or remove barriers to care is ideal. In fact, the impact of this kind of shared approach was shown in another clinical study, which found that patients who were offered colorectal screening only via colonoscopy resulted in 38 percent of the patients undergoing screening the first year. However, when patients were given a choice of two screening options, including colonoscopy and a home testing method, adherence rates nearly doubled to 69 percent.[12] So offering your patients the choice of a noninvasive option can lead to greater adherence.[12]

Dr. Turck:
For those just tuning in, you're listening to Clinician's Roundtable on ReachMD. I'm Dr. Charles Turck, and today I'm speaking with Dr. Lanre Jimoh about colorectal cancer screening and the importance of considering patient preferences. So Dr. Jimoh, given the barriers to screening that many patients report, let's turn our attention to noninvasive testing, and in particular, Cologuard multi-target stool DNA testing. But before we dive in, let's review some important safety information.

Announcer:
Cologuard Indications for use
Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by colonoscopy. Cologuard is indicated to screen adults of either sex, 45 years or older, who are at typical average risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

Dr. Turck:
With that important safety information in mind, Dr. Jimoh, can you tell us more about Cologuard?

Dr. Jimoh:
Of course. So Cologuard is a noninvasive at-home colorectal cancer screening method for adults 45 and older who are at an average risk of colorectal cancer. It is not for high-risk individuals. Cologuard requires no sedation or bowel preparation, has no medication or dietary restrictions prior to screening, and does not require transportation or time off work.[4] These characteristics may make it an appealing option for patients who express barriers to screening via colonoscopy. However, a positive test does require a follow-up colonoscopy.[4] And the ACS recommends screening for colorectal cancer again 3 years after a negative Cologuard result.[5]

Dr. Turck:
And how does Cologuard compare to another noninvasive screening technique called fecal immunochemical testing, or FIT?

Dr. Jimoh:
So Cologuard is based on proprietary stool DNA technology that can detect 11 biomarkers associated with colorectal cancer and precancer, altered DNA, and hemoglobin.[13,14] This method detects biomarkers that are continuously shed into the stool and is able to detect both left- and right-sided cancers.[13,14] FIT, on the other hand, detects one colorectal cancer biomarker, which is hemoglobin in stool from polyps or lesions that bleed intermittently.[15] And as we're about to see, FIT detection of proximal cancers has been demonstrated to be inferior to Cologuard.[13] In the pivotal study of 10,000 patients aged 50 to 84 years who were at an average risk for colorectal cancer,[13] Cologuard testing showed superior sensitivity compared to a leading FIT in detecting both colorectal cancer and advanced adenomas.[13,14] For all colorectal cancers stages one through four, Cologuard demonstrated a 92 percent sensitivity compared to 74 percent for FIT.[13] And for advanced precancer, Cologuard showed 42 percent sensitivity, almost double the 24 percent sensitivity of FIT.[13] Further data from the study determined that FIT failed three times more total colorectal cancer findings across stages one to four[13] and missed eight times more sessile serrated polyps in comparison to Cologuard testing.[13] Lastly, I think it's important to note that Cologuard demonstrated an 87 percent overall specificity compared to 95 percent for FIT.[13]

Dr. Turck:
Now what about the risk of false positives and false negatives? What do we need to know about that?

Dr. Jimoh:
The same pivotal study I referred to earlier found that false positives, meaning patients without colorectal cancer or advanced adenomas received a positive result, were 13 percent with Cologuard. False negative results, which refers to patients with colorectal cancer who received a negative test result, was eight percent. The study also demonstrated a 99.94 percent negative predictive value of Cologuard,[13] meaning a patient that received a negative test result has a 99.94 percent chance that no colorectal cancer is present. In clinical practice, these patients would not need to undergo a follow-up colonoscopy.[13]

Dr. Turck:
Thanks for walking us through all that data, Dr. Jimoh. But since we're almost out of time for today, what are some key takeaways you would like to leave with our audience?

Dr. Jimoh:
I think it's important to remember that colorectal cancer is the second leading cause of cancer death after lung cancer,1 but it can be treatable if diagnosed early.[16] However, screening rates are low, in part due to perceived discomfort or the inconvenience that comes with a colonoscopy.[7,11] This has led to about 44 million average-risk people aged 45 or older eligible or overdue for colorectal cancer screening.[8] That is why clinical guidelines from USPSTF and ACS recommend that providers offer patients a choice in screening methods to improve screening rates.[4,5,9] And as we discussed, noninvasive methods like Cologuard may help address several barriers to screening[12] as it is a convenient, noninvasive, and an effective method that can be offered to average-risk patients 45 years and older.[4,13,14]

Dr. Turck:
Those are certainly some great takeaways to keep in mind, and with that, I want to thank my guest, Dr. Lanre Jimoh, for having this discussion with us on colorectal cancer screening with Cologuard. Dr. Jimoh, it was great speaking with you today.

Dr. Jimoh:
Thank you very much Dr. Turck, pleasure was mine.

Dr. Turck:
I'm Dr. Charles Turck. Please stay tuned to hear some important safety information.

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Cologuard Contraindications

- Cologuard is intended for use with patients, age 45 years and older, at average risk who are typical candidates for CRC

screening. Cologuard was not clinically evaluated for the following types of patients:

- Patients with a history of colorectal cancer, adenomas, or other related cancers.
- Patients who have had a positive result from another colorectal cancer screening method within the last 6 months.
- Patients who have been diagnosed with a condition that is associated with high risk of colorectal cancer. These include but are not limited to:
  - Inflammatory Bowel Disease (IBD)
  - Chronic ulcerative colitis (CUC)
  - Crohn's disease
  - Familial adenomatous polyposis (FAP)
  - Family history of colorectal cancer
  - Patients who have been diagnosed with a relevant familial (hereditary) cancer syndrome, such as Hereditary non-polyposis colorectal cancer syndrome (HNPCC or Lynch Syndrome), Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner's syndrome, Turcot's (or Crail's) syndrome, Cowden's syndrome, Juvenile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, or Familial Hyperplastic Polyposis.

Warnings and Precautions

The performance of Cologuard has been established in a cross-sectional study (i.e., single point in time). Programmatic performance of Cologuard (i.e., benefits and risks with repeated testing over an established period of time) has not been studied. Performance has not been evaluated in adults who have been previously tested with Cologuard. Non-inferiority or superiority of Cologuard programmatic sensitivity as compared to other recommended screening methods for CRC and AA has not been established.

The clinical validation study was conducted in patients 50 years of age and older. ACS Guidelines recommend screening begin at age 45. Cologuard performance in patients ages 45-49 was estimated by sub-group analysis of near-age groups.

CRC screening guideline recommendations vary for persons over the age of 75. The decision to screen persons over the age of 75 should be made on an individualized basis in consultation with a healthcare provider. Cologuard test results should be interpreted with caution in older patients as the rate of false positive results increases with age.

A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Patients with a negative Cologuard test result should be advised to continue participating in a colorectal cancer screening program with another recommended screening method. The screening interval for this follow-up has not been established.

Cologuard may produce false negative or false positive results. A false positive result occurs when Cologuard produces a positive result, even though a colonoscopy will not find cancer or precancerous polyps. A false negative result occurs when Cologuard does not detect a precancerous polyp or colorectal cancer even when a colonoscopy identifies the positive result.

Patients should not provide a sample for Cologuard if they have diarrhea or if they have blood in their urine or stool (e.g., from bleeding hemorrhoids, bleeding cuts or wounds on their hands, rectal bleeding, or menstruation).

To ensure the integrity of the sample, the laboratory must receive the patient specimen within 96 hours of collection. Initiate the return process within a day of collecting your sample to allow enough delivery time. Refer to the shipping instructions provided in this box, or ask your prescriber, for more information.

Patients should be advised of the caution listed in the Cologuard Patient Guide. Patients should NOT drink the preservative liquid.

The risks related to using the Cologuard Collection Kit are low, with no serious adverse events reported among people in a clinical trial. Patients should be careful when opening and closing the lids to avoid the risk of hand strain.

Rx only.

Announcer:

This medical industry feature was sponsored by Exact Sciences. If you missed any part of this discussion, visit ReachMD.com/CliniciansRoundtable. This is ReachMD. Be part of the knowledge.

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