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Noninvasive Colorectal Cancer Screening: Practice Insights and a Patient Perspective

Announcer:
You're listening to Clinicians Roundtable on ReachMD. This medical industry feature, titled "Noninvasive Colorectal Cancer Screening: Practice Insights and a Patient Perspective," is sponsored by Exact Sciences. Here's your host, Dr. Jennifer Caudle.

The content being presented today focuses on the use of Cologuard® in accordance with its approved labeling.
Information presented today is not clinical, diagnostic, or treatment advice for any particular patient. Providers should use their clinical judgment and experience when deciding how to diagnose or treat patients. Exact Sciences Corporation does not recommend or endorse any particular course of treatment or medical choice.
The healthcare providers in this program have been compensated for their time and are presenting on behalf of Exact Sciences.
This story reflects one individual's experience. Not every person will have the same treatment, experience, outcome, or result. Cologuard is prescribed by your health care provider. Talk to your provider about available screening options and whether Cologuard may be right for you. Visit cologuardhcp.com for more information.

Dr. Caudle:
In the United States of America, an estimated 44 million adults at average risk haven't gotten checked for the second highest cause of cancer deaths.1 So how can we reach this population for colorectal cancer screening? Is it a matter of overcoming barriers, or offering choices? Let's hear from a patient with a unique perspective and a physician with experience working with this population to find out. Welcome to Clinicians Roundtable on ReachMD. I'm your host Dr. Jennifer Caudle and joining me to share their perspectives on colorectal cancer screening are Dr. Timothy Quinn and Mr. Scott Cardwell. Dr. Quinn is a family medicine physician practicing in Jackson, Mississippi. So, Dr. Quinn, welcome to the program.

Dr Quinn:
Hey, thank you for having me.

Dr. Caudle:
Well, we're excited that you're here. And also with us is Mr. Scott Cardwell, a colorectal cancer survivor and patient advocate. Scott, thank you so much for being with us today.

Mr. Cardwell:
Thank you for having me.

Dr. Caudle:
Well, we're excited that you're here as well. So, let's start our discussion with you, Scott. What were your thoughts on colorectal cancer screening before you underwent screening yourself?

Mr. Cardwell:
Well, I was open to colorectal cancer screening in general, but I didn't see it as a priority because I didn't feel it was really applicable to me. The recommendation at the time was to start screening at age 50. And I figured I could wait until 55, because I felt healthier and more fit than the average guy my age. I was running five to six times a week, I'm a vegetarian. And I was unaware of any colorectal cancer family history. I really didn't have a lot of interest in screening. Uh, colonoscopy sounds scary. The only thing I heard about it was a lot of misinformation and stigmatization over the years. I preferred not to have to deal with an invasive procedure or traveling to a

medical facility and interacting with clinics and hospitals if I didn't have to. Um, so each of these felt like reason enough to delay the screening. But combined, it made total sense to me to put it off, you know, what's another five years, I thought.

Dr. Caudle:
Well, thank you for sharing your thoughts with us, Scott. And if we turn now to you, Dr. Quinn, when providers have eligible patients for colorectal cancer screening like Scott in their office who may be healthy, hesitant, or even disinterested, what should they keep in mind?

Dr. Quinn:
Sure, so it's really important for providers to remember that colorectal cancer is the second leading cause of cancer-related death in the United States after lung cancer.[2] And many patients with early-stage colorectal cancer do not experience symptoms, which is why risk- and age-appropriate cancer screening is crucial.[3] This is reflected in the current guidelines, as both the United States Preventive Services Task Force, also known as USPSTF, and the American Cancer Society, or ACS for short, now 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] The last thing I'll say here is that waiting to get a colorectal cancer screening comes with significant risk. More than half of patients are diagnosed with advanced disease, with 37 percent at stage two and three and 21 percent at stage four.[2,6] So, we know that regular colorectal cancer screening may reduce mortality rates and has the potential to save lives, which is why it is so important for providers to screen appropriate patients.[4]

Dr. Caudle:
Now as a quick follow-up to that, Dr. Quinn, Scott mentioned some perceived barriers to colorectal cancer screening in his initial thoughts. So can you elaborate on some of these barriers and what providers can do to overcome them?

Dr. Quinn:
Yes, so a recent clinical study of patients' self-reported barriers revealed that many of the common barriers were specific to screening colonoscopy.[7] These included concerns related to the procedure itself, sedation, logistical challenges such as time off work or transportation, and financial challenges. In addition, some expressed discomfort with the concept of the invasive procedure or the bowel preparation.[7] Now amid all those barriers, clinical practice guidelines from USPSTF and ACS do not recommend a preference for visual examinations, such as colonoscopies, or noninvasive stool-based tests for an average-risk patient.[4,5] In fact, both groups encourage healthcare providers to offer patients a choice in their screening method in a move towards increasing overall screening rates.[4,5,8] The impact that this shared decision-making approach can have has been seen in another clinical study, which found that only 38 percent of patients underwent screening the first year if they were offered colorectal screening only via colonoscopy. 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.[9] So what this tells us is that offering your patients the choice of a noninvasive option can lead to greater adherence as it addresses some of those common barriers we talked about earlier.[9]

Dr. Caudle:
For those just tuning in, you're listening to Clinicians Roundtable on ReachMD. I'm Dr. Jennifer Caudle, and today I'm speaking with Dr. Timothy Quinn and Mr. Scott Cardwell about how we can improve colorectal cancer screening rates. Now Scott, let's get back to your journey. Could you share with us the rest of your colorectal cancer screening experience?

Mr. Cardwell:
Sure. So, when I declined the colonoscopy, my doctor offered a non-invasive screening option that I could do at home. He said, 'Have you heard of Cologuard?' Now, when my PCP gave me another option and explained what was involved, it was like night and day. It immediately took me from the no column to the yes column. My doctor ordered the test, and it was shipped to my house. It came in just a day or two. I set the box on my kitchen counter for a couple of days. And then I started getting reminder emails from Cologuard to do the test, which was great. So I opened the box, followed the directions, and did the test, which was remarkably simple, took 10 minutes, then I sent it back and waited. My doctor then contacted me to say the results came back positive, and that we had to schedule a colonoscopy. This was October of 2020. I got a colonoscopy six weeks later, and this was during COVID, so my wife wasn't allowed to come in the hospital. But when I woke up, she was at my bedside in tears. They found a tumor. My doctor told me that they would schedule me for a colon resection, and it was really scary. After a horrible wait, the pathology finally came back as clear. My cancer was diagnosed as stage I. I've had follow-ups with oncology and surgery. And my tests have remained clear so surgery appears to be correct - curative. Cologuard alerted us to the possible presence of a problem. The colonoscopy confirmed it. And I just turned 55 this year, and that tumor would have been growing for a couple more years if I hadn't had the non-invasive screening option.

Dr. Caudle:

Well, thank you for sharing your journey with us, Scott. You know, coming back to you now, Dr. Quinn, what can you tell us about Cologuard as a screening method?

Dr. Quinn:
So Cologuard is based on proprietary stool DNA technology that can detect 11 biomarkers associated with colorectal cancer and precancer, altered DNA, and hemoglobin.[10,11] This method detects biomarkers that are continuously shed into the stool and is able to consistently detect both left- and right-sided cancers.[10,11] Cologuard is a noninvasive at-home screening method that requires no sedation or bowel preparation, has no medication or dietary restrictions prior to screening, and doesn't require transportation or time off work.[4] False positives and false negatives may occur.[2] A positive test result does require a colonoscopy though.[4] Cologuard is approved for colorectal screening in adults aged 45 years and older who are of average-risk,[11] and it's not indicated for patients with a history of colorectal cancer, adenomas, or other related cancers including:

a. Patients who have had a positive result from another colorectal cancer screening method within the last six months,
b. Patients who have been diagnosed with a condition that is associated with high risk for colorectal cancer, or
c. Patients who have been diagnosed with a relative familial cancer syndrome.[11]

Lastly, the ACS recommends screening for colorectal cancer again three years after a negative Cologuard result.[5]

Dr. Caudle:
Now unfortunately we're just about out of time for today, but before we close, Dr. Quinn, what key takeaways do you have for our audience?

Dr. Quinn:
So I'd just like to remind everyone that colorectal cancer is the second leading cause of cancer death after lung cancer,[2] but it can be treatable if diagnosed early.[12] And since colorectal cancer commonly presents without symptoms in early stages when prognosis is greatest, age- and risk-appropriate cancer screening is key.[3] However, colorectal cancer screening rates are low, partly due to perceived discomfort or inconvenience with screening colonoscopy.[7,13] That's why clinical guidelines from USPSTF and ACS recommend that providers offer patients a choice in screening method to improve screening rates.[4,5,8] And noninvasive screening methods such as Cologuard may help address several barriers to a colorectal screening that may increase adherence.[9] So to bring this all together, providers working together with patients to identify the common barriers to colorectal screening may find that Cologuard is an easy to use, convenient, and effective option for colorectal cancer screening that can be offered to average-risk patients 45 years and older.[4,10,11]

Dr. Caudle:
Thanks so much for sharing that, Dr. Quinn. And how about you, Scott? What final thoughts would you like to share?

Mr. Cardwell:
You know, I find I'm completely not unique. If I'm a guy in my early 50s, who thought, 'Nah, I'm healthy, I don't need this,' then I'm probably not the only one. It's a challenge to convince someone who looks and feels healthy that they should check that something is wrong, but for colorectal cancer, being able to detect it early and get in front of it and potentially treat it, it's such a huge return on investment of a small amount of time. A lot of people will be resistant to colonoscopy with work pressure, time off, the prep, the taboos, the invasiveness, another medical encounter, all of that. So a non-invasive at-home test was really appealing to me, um, just a person off the street. It was like night and day. I might not be here if I hadn't screened. And I would strongly encourage healthcare providers to give their patients the option to drive that message home.

Dr. Caudle:
Thank you both, these are great takeaways from our discussion on this topic. And with those final thoughts in mind, I'd like to thank my guests, Dr. Timothy Quinn and Mr. Scott Cardwell, for sharing their perspectives on colorectal cancer screening. Dr. Quinn, and Scott, it was great speaking with you both today.

Dr. Quinn:
Hey, thank you for having me.

Mr. Cardwell:
Thank you for having me.

Dr. Caudle:

I'm your host Dr. Jennifer Caudle. And please stay tuned for 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.

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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