

## Medical News &amp; Perspectives

## Pandemic Spotlights In-home Colon Cancer Screening Tests

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**A**s the coronavirus disease 2019 (COVID-19) pandemic challenges health care systems to provide preventive services, many people are finding an unfamiliar object on their doorstep: a colon cancer screening kit.

Long overshadowed by colonoscopy, stool-based screening tests that patients perform at home are getting a boost as hospitals halted and then curtailed non-emergency procedures in an effort to preserve resources and prevent novel coronavirus transmission.

Health plans including OptumCare, Humana, and Washington State-based Premera Blue Cross as well as federally qualified health centers have launched or expanded programs that send fecal immunochemical testing (FIT) kits, which detect blood in stool, to their patients who are due for screening.

Another type of test, multitarget stool DNA, branded as Cologuard, which detects cancer biomarkers and blood, could increase its market share as a result of the pandemic, officials with the manufacturer, Exact Sciences, told investors in July. Company officials noted in a statement that the US Preventive Services Task Force (USPSTF) draft recommendation issued last fall to begin screening at age 45 years instead of 50 years would add 19 million adults to the recommended screening population.

Considering the current climate, it seems that the time for stool-based testing has arrived. "People are so used to doing things from home now—work, school, meetings, etc—that at-home testing seems to fit into the new normal," internist Lisa Ravindra, MD, an assistant professor of medicine at Rush University Medical Center in Chicago, said via email.

Although hospitals have added measures to keep patients safe during procedures, Ravindra said more patients at her downtown practice have been opting for at-home screening to avoid potential COVID-19 exposure. She added, "Some patients are definitely surprised that there are options for colon cancer screening other than colonoscopy."

**Similar Effectiveness**

Screening advocates say the pandemic has highlighted the importance of offering stool tests as an option. Unlike a colonoscopy, they don't require an invasive procedure, dietary changes, or laxatives. To perform either FIT or Cologuard, a patient collects a stool sample and sends it to a lab. If the result is abnormal, a follow-up colonoscopy is recommended. False-positive results, in which an abnormal finding does not turn out to be cancer, occur with both tests but are more common with Cologuard.

Laura Makaroff, DO, senior vice president of prevention and early detection at the American Cancer Society (ACS), noted in an interview that stool tests are about as effective as colonoscopy for detecting cancer when used according to recommended schedules—annually for FIT and every 3 years for Cologuard. A colonoscopy is repeated every 10 years for patients with a normal result.

Stool tests cost less than a colonoscopy, although all screening methods are covered by insurance. For 2020, Medicare paid \$16 for FIT and \$509 for a Cologuard test.

For years, both types of stool tests have been included alongside colonoscopy in

screening guidelines for average-risk people, including those of the USPSTF. FIT has been used to increase screening rates in rural areas and underserved urban populations.

But instead of offering either type of test to their patients, many primary care physicians routinely order colonoscopies—the only method that allows for the removal of precancerous polyps. Douglas Robertson, MD, MPH, of the White River Junction Veterans Affairs (VA) Medical Center in Vermont, said in an interview that colonoscopy's high one-time sensitivity also has helped to foster a sense that it's "the go-to test for everyone."

Robertson serves on the US Multi-Society Task Force on Colorectal Cancer, a group of experts from 3 gastroenterology specialty societies, which ranks both FIT and colonoscopy as first-tier screening options based on performance, cost, and practicality.

Although colonoscopies and stool tests have never been compared in a randomized trial, Robertson said that's changing. He's coleading one of several ongoing trials to compare screening FIT and colonoscopy. In the trial, 50 000 veterans are randomized to a single colonoscopy or annual FIT for

10 years to determine which group has fewer colon cancer deaths. Results are due in 2028.

### The Time Factor

Many patients aren't aware of all their options. Gastroenterologist Thomas Imperiale, MD, of the Indiana University School of Medicine, said in an interview that before he performs a colonoscopy, he asks patients whether they are aware of other screening strategies. "I will often get raised eyebrows," he said, noting that by then patients have already done a bowel prep, taken a day off from work, and arranged for someone to drive them home from the procedure.

Imperiale said it takes longer to discuss tradeoffs of various screening strategies with an average-risk patient—20 to 30 minutes—than to actually perform a colonoscopy. That's time that primary care physicians usually don't have during a typical office visit.

UnitedHealth Group, the parent of OptumCare, found in a survey of physicians at New West Physicians in Denver, Colorado, that a majority spend only 1 to 3 minutes discussing colon cancer screening options with patients, Deneen Vojta, MD, the company's executive vice president for research and development, said in an interview.

Even Vojta, a pediatrician, was unaware of alternatives to colonoscopy when she reached age 50 years, when most recommendations indicate that screening should start. In talking with her own physician, she said, stool testing "just never came up."

Since the pandemic began, UnitedHealth has accelerated its educational ef-

forts, including the creation of an online video course. The central message: The best test is the one you actually get done. The company also fast-tracked a project to send a decision-making tool to 50 000 Medicare enrollees, along with an offer for a Cologuard test, Vojta said. Results go to an ordering physician, who can help the patient schedule a colonoscopy if a test result is abnormal.

### Improving Screening Rates

The pandemic has highlighted the pitfalls of relying not only on colonoscopies, but on physician referrals to initiate screening, known as opportunistic screening. In the US, most screening stems from a primary care physician's recommendation or a patient's request during a routine office visit. However, such interactions **dropped off** after officials urged people to stay home. According to a recent **analysis**, primary care visits fell by 24.1%, to 99.3 million, in the second quarter of 2020 compared with the average during the same periods in 2018 and 2019.

Well before the pandemic, some organizations managed to topple that screening roadblock by taking a comprehensive approach. Kaiser Permanente Northern California pioneered the use of organized campaigns to mail FIT kits to enrollees who are eligible for screening but have not had a colonoscopy or sigmoidoscopy, another type of visual examination.

A **paper** published last year described how the integrated health care system used mailed FIT to increase its screening coverage from 40% to 82% in about 1 million eligible adults. The authors noted that their re-

sults were consistent with randomized trials showing that automated FIT mailings boosted screening by 28% over opportunistic screening alone.

Kaiser Permanente's rate exceeds an **80% goal** set by the National Colorectal Cancer Roundtable, a group formed by the ACS and the US Centers for Disease Control and Prevention (CDC). Since 2014, the roundtable has pooled the resources of a range of organizations—medical professional societies, physician clinics, hospitals, advocacy organizations, government agencies, and health plans—to encourage screening.

Their efforts have produced limited success. In 2018, nearly 69% of adults aged 50 to 75 years were up to date with screening, according to CDC **survey data**. That compares with **65.1% in 2012**.

According to the 2018 data, screening was lowest among people without a regular health care provider, only 37.1% of whom were up to date. Other groups that lagged were adults aged 50 to 54 years, Hispanic individuals, and people without health insurance.

The roundtable noted in a COVID-19 response **playbook** that the pandemic threatens to undermine that progress, with a potentially disproportionate impact on groups with higher colon cancer incidence and mortality including Black, American Indian, Alaska Native, Hispanic, and low-income individuals. Offering at-home stool tests, along with identifying patients who should be prioritized for colonoscopies, can help to overcome screening interruptions, roundtable members said.

### Need for Outreach

Still, it's not as simple as mailing out a test to everyone who's due for screening. Successful stool testing campaigns require patient navigation systems with telephone support and text, email, and telephone reminders to ensure patients return the test and follow through with a colonoscopy if needed. "You can have the most sensitive test in the world, but if not everybody does it, you're not helping," Michael Sapienza, chief executive officer of the **Colorectal Cancer Alliance**, an industry-sponsored advocacy group, said in an interview.

Cologuard has its own patient navigation system, which has a **reported** return rate among Medicare enrollees of 71.1%, Sapienza noted. However, with FIT, which



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has multiple manufacturers, health care organizations must craft their own—no easy task.

A [white paper](#) summarizing the findings of a 2019 summit of FIT outreach experts noted that despite strong evidence supporting mailed FIT programs as a cost-effective way to boost screening rates, some health systems don't know how to implement them. It outlined best practices such as sending patients an invitation to be screened before a FIT kit arrives, texting or mailing reminders if tests aren't returned, and having a process to ensure that patients get a colonoscopy after an abnormal test result. The paper noted that further research is needed on such factors as how to select patients, whether to offer financial incentives to complete a test, and how to eliminate barriers to follow-up colonoscopies.

Some patients also require a more personal touch than robocalls and postcards. According to the paper describing Kaiser Permanente's program, 12% of patients completed screening only after direct contact such as a call from a primary care physician's office. But various forms of

follow-up should also consider patients' fears of or disgust with screening methods, the authors wrote.

Some industry players are taking a broader approach. Spurred by last year's drop in screenings, the alliance has launched a [public awareness campaign](#) in 15 cities with low screening rates, Sapienza said. The alliance is using social media ads and sending materials such as sample patient letters to medical practices and health systems to drive traffic to an online tool that helps users decide among FIT, Cologuard, and colonoscopy. Eventually, the [tool](#) will connect users to physicians who can order a test, Sapienza said. Sponsors of the effort include Exact Sciences Corp and other manufacturers of products that detect and treat colon cancer.

### Heading Off Cancer Deaths

It's unclear how well such efforts to educate patients and promote stool testing will address screening shortfalls. One [analysis](#) of electronic health records from 60 health care organizations found 95 000 fewer colon cancer screenings than would have been

expected from mid-March 2020 to mid-June 2020, a 64% drop. In mid-June, weekly volumes remained 36% lower than their pre-COVID-19 levels.

Many hospitals have prioritized diagnostic colonoscopies, which are performed after a positive stool test or when patients have worrisome symptoms such as rectal bleeding or weight loss, Sapienza said. "I'm still hearing from a lot of people that we're not seeing a ton of [routine] screening colonoscopies," he added.

In June the National Cancer Institute raised an alarm by [projecting](#) a potential 4500 excess colon cancer deaths in the next decade due to pandemic-related delays in diagnosing and treating those cancers.

Imperiale noted that even fellow gastroenterologists who are strong advocates for colonoscopy are not pushing back against the recent shift to stool testing. "They know if we don't screen we're going to see [patients presenting with] more advanced cases in the next 6 months, 12 months, 2 years," he said. "Nobody wants that." ■

**Note:** Source references are available through embedded hyperlinks in the article text online.