More than 10% of samples from a stool-based colorectal cancer test may be unsatisfactory

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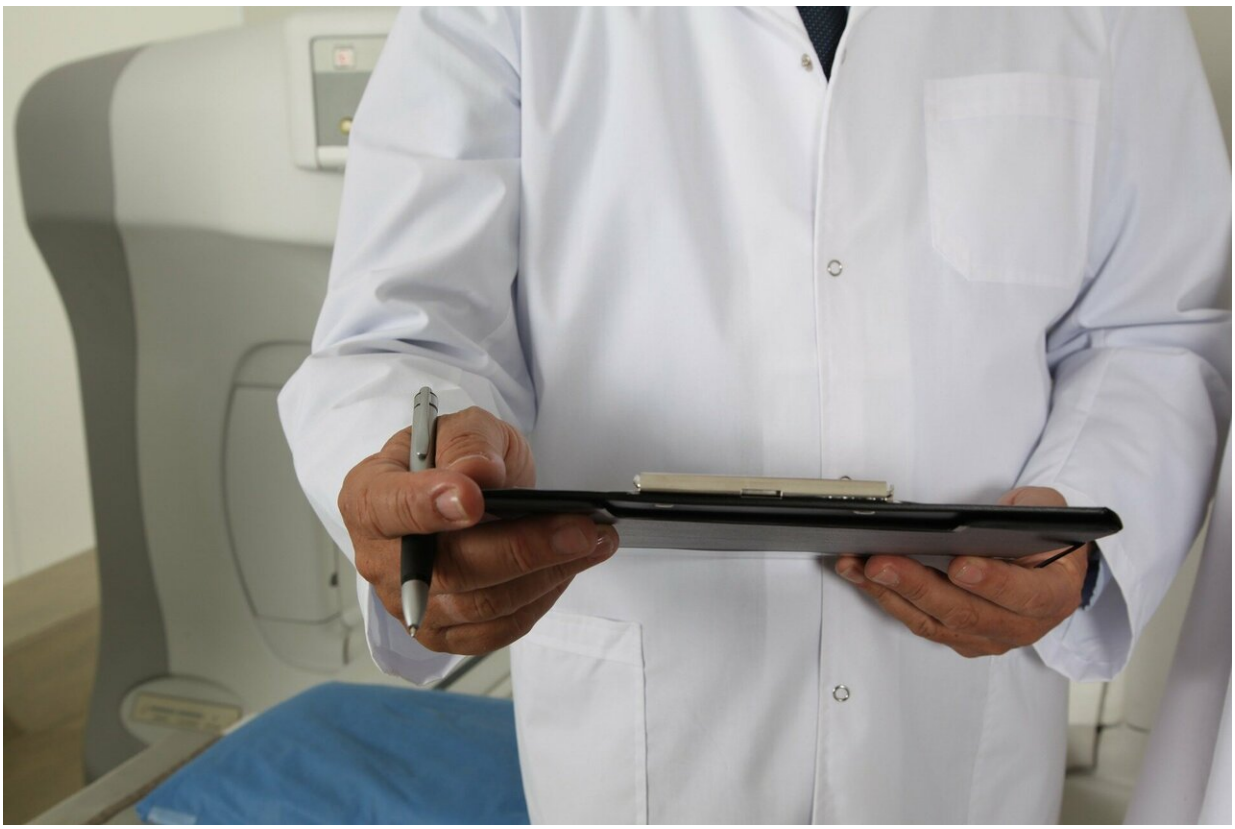

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More than 10% of fecal immunochemical tests (FIT) used for routine colorectal cancer (CRC) screening in a safety-net health system

contained unsatisfactory samples that could not be processed, according to a new study.

FIT is a self-collected test that looks for hidden blood in the stool and is recommended by the US Preventive Services Task Force for annual CRC screening among individuals aged 45 to 75.

For many—including uninsured and lower-income individuals, as well as those from medically underrepresented groups—FIT may be cheaper and more accessible than a colonoscopy or other stool-based tests that look for potentially tumorigenic DNA.

A study, authored by Rasmi Nair, MBBS, Ph.D., an assistant professor at the Peter O'Donnell Jr. School of Public Health of UT Southwestern Medical Center, and Po-Hong Liu, MD, a gastroenterology fellow at UT Southwestern Medical Center, has been published in *Cancer Epidemiology, Biomarkers & Prevention*.

"FIT is the test of choice, particularly in large population-based settings where access to screening colonoscopy is limited," Nair said. "Even when colonoscopy is available, many would prefer to do the simple, noninvasive stool test."

While previous studies have examined how to increase FIT participation, few have investigated how often screening is completed unsuccessfully due to problems with sample collection, labeling, or storage, said co-first author Po-Hong Liu, MD, a gastroenterology fellow at UT Southwestern Medical Center. Further, it is unclear to what extent patients who submit unsatisfactory samples receive follow-up testing.

"The effectiveness of FIT depends on the satisfactory completion of multiple steps—participation, test completion, follow-up of abnormal results, and repeat testing annually," Liu explained. "A break in the chain

at any point can reduce the effectiveness of CRC screening."

Nair, Liu, and colleagues examined the history of 56,980 individuals aged 50 to 74 who underwent FIT screening between 2010 and 2019 within the Dallas-based Parkland Health system, a safety-net health system that primarily provides care to uninsured, lower-income, and racial/ethnic minority individuals. The tests were performed at health care offices or via a mail order system, the latter of which automatically sent a repeat test to individuals with an initial unsatisfactory result.

Overall, 10.2% of tests were found to be unsatisfactory; the testing laboratories recorded the reasons as inadequate specimen (51%), incomplete labeling (27%), sample too old (13%), or a broken or leaking container (8%). Only 40.7% of individuals with unsatisfactory tests received follow-up FIT or colonoscopy screening within 15 months of the failed test.

"The fact that, in most instances, unsatisfactory FIT was not followed by a timely subsequent test highlights the need for systems to have a better, more comprehensive approach to tagging and following up unsatisfactory FIT," Liu said.

Mail order tests were 2.66 times more likely to produce unsatisfactory results than tests performed in a clinic, which the authors speculated may reflect the technical assistance available in a clinic. However, likely due to the automatic distribution of a repeat test, patients with unsatisfactory mail order tests were 1.92 times more likely to undergo repeat screening within 15 months.

The study also found racial and ethnic disparities in satisfactory FIT completion: Black patients were 1.46 times more likely to submit an unsatisfactory test, and patients who primarily speak Spanish were 1.12 times more likely to submit an unsatisfactory test.

This study highlights the importance of minimizing language, literacy, and logistical barriers to successful test completion, as well as the need for a comprehensive system to identify unsatisfactory tests and flag them for follow-up, Nair explained.

Based on these data and those from previous studies, the authors suggested several potential solutions to improve complete and accurate sampling. These included wordless or low-literacy instruction pamphlets to eliminate language and literacy barriers; pre-affixed patient labels or barcodes to minimize labeling errors; and automated systems for identifying and contacting patients with unsatisfactory tests.

Limitations of this study include its potentially limited applicability to safety-net systems, its reliance on the laboratory's often brief notes about reasons underlying unsatisfactory tests, and the possibility of patients receiving follow-up care outside the Parkland Health system.

Further, because the window for successful repeat testing was longer than 12 months, some of those tests may have been subsequent annual screening rather than repeat tests.

More information: Po-Hong Liu et al, Unsatisfactory Fecal Immunochemical Tests for Colorectal Cancer Screening: Prevalence, Reasons, and Subsequent Testing, *Cancer Epidemiology, Biomarkers & Prevention* (2023). DOI: 10.1158/1055-9965.EPI-23-0507

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