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Noninvasive colorectal cancer screening tool shows unprecedented detection rates

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Results of a clinical trial of Cologuard show unprecedented rates of precancer and cancer detection by a noninvasive test. The detection rates are similar to those reported for colonoscopy. The results were published in the March 20 issue of the *New England Journal of Medicine* (*NEJM*). Cologuard was co-developed by Mayo Clinic and Exact Sciences.

Cologuard, is a noninvasive sDNA test for the early detection of colorectal precancer and cancer. The Cologuard test is based on a stool sample that is analyzed for DNA signatures of precancer or cancer. The samples are easily collected, mailed from home, requires no bowel preparation, medication restriction or diet change.

The clinical trial, called the DeeP-C study, included 10,000 patients and was designed to determine how well Cologuard detects precancer and cancer. The study also compared Cologuard to the fecal immunochemical test for occult blood (FIT). The study was conducted at 90 medical centers throughout the United States and Canada.

"Cologuard detection rates of early stage cancer and high-risk precancerous polyps validated in this large study were outstanding and have not been achieved by other noninvasive approaches," says the study's author David Ahlquist M.D., a Mayo Clinic gastroenterologist and co-inventor of the Cologuard test. "It is our hope that this accurate and user-friendly test will expand screening effectiveness and help curb colorectal cancer rates in much the same way as regular screening, including genetic testing, has done for cervical cancer."

In the study, all patients received Cologuard, FIT and colonoscopy. Colonoscopy was the reference method. Major findings reported in the study include:

- Sensitivity of Cologuard for cancer was 92 percent overall, and 94 percent for the earliest and most curable cancer stages (stages I and II).
- Sensitivity was 69 percent for precancerous polyps at greatest risk to progress to cancer (i.e., those containing high-grade dysplasia).
- Cologuard detected significantly more cancers and significantly more precancerous polyps than did FIT.

"The most important finding of the study is the high sensitivity of Cologuard for curable stage colorectal cancer, which represents the highest sensitivity of any noninvasive test to date," says Thomas Imperiale, M.D., a Professor of Medicine at Indiana University Medical Center in Indianapolis and a study author. "It is also significant to note that these results were achieved in a robustly conducted multicenter study."

Colorectal cancer is often considered the most preventable, yet least prevented, cancer. Nearly 50 percent of adults age 50 and older have not been screened as recommended and, as a result, colorectal cancer has become the second-leading cause of cancer death in the United States. Colorectal cancer is highly treatable if found early, and it is preventable if the precancerous polyps at greatest risk of progressing can be detected.

"Dr. Ahlquist's work exemplifies our goal at Mayo Clinic, which is the relentless pursuit of innovation aimed to help our patients. This research will transform how we think about colorectal cancer screening going forward," says Vijay Shah, M.D., chair of Mayo Clinic's Division of

Gastroenterology and Hepatology.

Cologuard works by testing a patient's stool for altered DNA shed during digestion. Altered DNA is known to occur within colorectal cancers and precancerous polyps. The test also examines the stool for the presence of blood, another possible indicator of colorectal cancer. Combining the data from the stool DNA test and the blood test into a single result provides a comprehensive, powerful screening approach, which is reflected in the study results.

Because of its accessibility and ease of use, researchers hope the test will increase the number of people who will choose to be screened for colorectal cancer. Screening is important because, if cancer is detected early, removing polyps during a colonoscopy can prevent the cancer.

"This test has the potential to bring colon cancer screening to many patients who might otherwise go without any screening," says Kenneth Wang, M.D., a Mayo Clinic gastroenterologist, director of the Advanced Endoscopy Group and president of the American Society for Gastrointestinal Endoscopy. "I'm hopeful that this will increase the number of patients obtaining lifesaving colonoscopy with early detection and removal of precancerous and early cancerous polyps."

Exact Sciences is the co-developer of Cologuard. The company is in the process of seeking approval from the Food and Drug Administration for the use of Cologuard for colorectal cancer screening. The company is scheduled to appear before the Molecular and Clinical Genetics Panel of the Medical Devices Advisory Committee on March 27.

Provided by Mayo Clinic

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