Cologuard® is FDA Approved, But Colonoscopy Remains Gold Standard

Steven Morris, Board Chair, Preventing Colorectal Cancer, and President, Atlanta Gastroenterology Associates

Colorectal cancer is the second leading cause of cancer deaths in the United States; it is also the most preventable. Preventing Colorectal Cancer (PCC) recognizes colorectal cancer screening colonoscopies as the Gold Standard of screening. Colonoscopy is the only test to screen, prevent, detect, treat and cure significant colon lesions during one exam.

On August 11, 2014, the FDA approved Cologuard® as the first stool-based colorectal screening test. The approval of Cologuard does not change current practice guidelines for colorectal cancer screening, nor should patients view Cologuard as an alternative to colonoscopy. Cologuard should be offered to patients only after they have explicit guidance that colonoscopy is the preeminent test for the prevention of colorectal cancer because precancerous polyps can be identified, removed and biopsied.

Call for Nominations! PCC Seeks to Recognize Champions of Colorectal Cancer Prevention

Preventing Colorectal Cancer (PCC) is now seeking nominations for the fifth annual Champion Awards of Colorectal Cancer Prevention to recognize individuals, groups and companies that provide either exceptionally high standards of care or who most effectively advocate for the prevention and early detection of colorectal cancer. Founded in 2008, PCC’s mission is to educate the public and key stakeholders about the opportunities to reduce the incidence of colorectal cancer through regular screening and care options for patients and their clinicians.

Those interested in submitting a nomination may visit www.PreventingColorectalCancer.org for details and a downloadable application. The deadline for nominations is

See Call for Nominations, page 3
What is Cologuard?
Cologuard is a new, noninvasive colon cancer screening test that does not require any preparation or dietary changes. It can be used by men and women 50 years of age and older who are at average risk for colon cancer. It should not be used by people who are at higher risk for colon cancer, including those with a history of inflammatory bowel disease or a known family history of colon cancer or precancerous polyps.

How Does Cologuard Work?
The Cologuard test is performed by collecting a stool sample at home with a kit that is provided by Cologuard. If cancerous or precancerous tissue is in your colon, those abnormal cells may be picked up by stool as it passes through your colon. This process involves placing a plastic collection bucket on the toilet seat, collecting the stool sample, scraping the sample with a collection probe and placing the remaining stool sample in a liquid solution. The stool sample needs to be shipped to a laboratory for evaluation within three days of collection. A physician will review the results of the study and will order additional tests as needed.

Cologuard is not a genetic test; it only looks for altered DNA associated with colon cancer and precancerous cells in the colon. All positive Cologuard results should be followed by a diagnostic colonoscopy. Patients should continue participating in a routine screening program even after a negative result. Guidelines have not been established for how frequently the Cologuard test should be performed.

How Does Cologuard Compare to Other Non-invasive Tests?
In clinical studies, Cologuard found 92% of colon cancers and 42% of advanced precancerous tissue in the colon; in other words, it missed 8% of colon cancers and almost 60% of advanced precancerous tissues. It was more sensitive than the FIT test in detecting colorectal cancer; however, false positives and false negatives can occur with any test. Cologuard was positive in 13% of people without cancer as compared to a 5% false-positive rate with the FIT test.

What Does Cologuard Cost?
The cost for each Cologuard test is $599. However, the fee does not include doctors’ visits, the reading and determination of lab results, etc.

Is Cologuard Covered by Insurance?
Since Cologuard is a new test, it may take some time for insurance companies to update their insurance coverage policies. Medicare recently stated they would cover the test once every three years for people between ages 50 and 85 who do not have any symptoms of colorectal cancer.

Cologuard is Not a Replacement for Colonoscopy
If a positive Cologuard test is found, a colonoscopy will be needed. In this case, the colonoscopy may be covered by insurance as “diagnostic” versus “screening”, so additional co-pays or deductibles may apply. Patients considering the Cologuard test should check with their insurance provider first to determine coverage.

A cancer prevented is better than a cancer cured. Colorectal cancer screening tests are an important tool to help detect and prevent this deadly disease. With appropriate screening and early detection, colorectal cancer can be prevented and treated. In fact, there are many options for screening available today. Colonoscopy remains the Gold Standard screening test as it can screen, detect, treat, prevent and cure most significant colon lesions during one exam.

Disclaimer: Colonoscopy remains the Gold Standard test for colon cancer screening. Please look to PCC’s other newsletter stories, issue briefs and website to learn about standard screening recommendations for different demographic and illness groups. Recommendations vary depending upon a patient’s particular age, race, existing co-morbidities and other exposure factors.
Call for Nominations!

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February 20, 2015; winners will be notified in March to coincide with Colorectal Cancer Awareness Month. “PCC is dedicated to the detection and cure of a deadly form of cancer, colorectal cancer. We applaud and seek out those individuals or institutions that make a difference in this fight, realizing that many toil in this endeavor quietly and effectively. PCC seeks to offer yearly recognition in examples of this work that are extraordinary,” says Steven Morris, MD, PCC chairperson.

According to PCC Executive Director Randall Madry, “PCC recognizes that many people and organizations are making a real difference in their efforts to increase the number of Americans screened for colorectal cancer, and they should be honored for their contributions to this critical part of the battle against colorectal cancer.”

The PCC Champion Awards Program aims to recognize:

- An individual or group practice that maintains a facility that offers the highest level of quality care and support
- An individual or group who has acted as an effective advocate for the prevention and early detection of colorectal cancer

PCC will recognize four award categories in 2015, including exceptional work in Research, Individual Pursuits, the Community and Corporate Wellness. All contenders must complete actions that contribute significantly to PCC’s mission and must have performed activities that promoted colorectal cancer screening within the last 18 months.

All applications must be received in the PCC office by February 20, 2015 for review by the Awards Committee. Winners will be notified by March 16, 2015 during Colorectal Cancer Awareness Month.

Questions related to the program announcement, proposal format or required documentation should be submitted as early possible to jbehm@PreventingColorectalCancer.org.

Visit www.PreventingColorectalCancer.org for more information and a downloadable application.

Issue Brief #10: Sneak Preview

While the annual rate of colorectal cancer incidence in patients over age 50 has been steadily declining over the last decade, young-onset colorectal cancer has been increasing. What do you need to know and do in order to increase screening rates and reduce the incidence of colorectal cancer?

Part of an ongoing series from Preventing Colorectal Cancer, this issue brief sheds light on the increasing colorectal cancer rates among patients under age 50. Find out what you need to know! To request a copy of the issue brief, please email info@PreventingColorectalCancer.org.
Insights and Developments in the Fight Against CRC

Issue Brief #9: Colorectal Cancer Screening: The Genetic Factor

Preventing Colorectal Cancer, a not-for-profit organization, encourages policymakers, health officials, health plan executives and others to support colonoscopies as the Gold Standard colorectal cancer screening method. This issue brief is one in a series of publications exploring the actions key stakeholders can take together to make a difference and serve as champions for patient safety.

The Issue
Colorectal Cancer is the second leading cause of cancer deaths in the United States. Thankfully, it is also one of the most treatable and curable cancers, if detected early. Unfortunately, a high percentage of late stage colorectal cancers are fatal, with the American Cancer Society citing a five year survival rate of Stage IV cancers as low as only 6%.1 While preventative screening colonoscopies can go a long way in helping to catch cancerous polyps early and save lives, new medical developments in the field of genetic testing can help take colorectal cancer prevention to the next level.

Colorectal Cancer is the second leading cause of cancer deaths in the United States.

What is Genetic Testing?
According to the Memorial Sloan Kettering Cancer Center, studies have discovered a genetic link between some forms of colorectal cancer and the mutation of certain genes.2 For example, mutations that cause two of the most common forms of hereditary colorectal cancer, familial adenomatous polyposis (FAP) and nonpolyposis colorectal cancer (HNPPC), also commonly known as Lynch Syndrome, can be detected through a blood test that searches for these genetic abnormalities. Aside from FAP and HNPPC, people with a family history of colorectal cancer are more likely to develop colorectal cancer, and thus are considered high-risk.

In addition, a research team at Vanderbilt University recently identified signatures of genetic mutations that form colorectal cancer. In the study, senior author Daniel Liebler, Ph.D. explained that researchers examined 95 human colorectal samples to gather proteomic data with the goal of identifying genetic abnormalities in tissue samples with cancer.3 Sections of chromosomes that were “amplified” in tumor-containing samples and that had increased protein levels contained what scientists determined to be “striking effects”. As a result of these characteristics, researchers concluded that studying protein structure and function through proteomics might help to identify the most prominent genetic abnormalities that could be candidates for new diagnostic or drug treatments. Researchers were also able to classify five variations of colon cancer based on protein type. This specification of the disease may help physicians determine which kinds of treatments to prescribe to their patients.

Genetic testing also opens the door to a new level of colorectal cancer prevention for high-risk individuals by promoting earlier and more frequent screenings. Preventative screenings, along with the removal of precancerous polyps during colonoscopies, can significantly reduce the chance of an individual

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Insights and Developments in the Fight Against CRC

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developing colorectal cancer. Similarly, proteomics seems to promise a more precise diagnosis, which means more effective treatments and, as a result, a lower morbidity rate for colorectal cancer and, hopefully, cancer in general. This kind of identification and mapping of the types of cancers and cancer subsets will help researchers to focus in on treatment types for certain subsets, and, ideally, find a cure for these variations. When combined with other genomic research, researchers will have a greater perspective on what causes and cures cancers.

How Does it Work?

Genetic testing for colorectal cancer involves a simple blood test that allows doctors to look for mutated genes that are linked to hereditary colorectal cancer. Testing positive for one of these genes means that your risk of developing colorectal cancer at some point in the future is very high. Because the results of a genetic test cannot pinpoint exactly when the cancer might develop, prevention and early detection are essential. Your doctor can recommend a prevention and treatment plan customized for you and your level of risk. This will often include more frequent screening colonoscopies that begin at an earlier age, and, in some extreme cases, removal of the colon.

Receiving a test result that does not detect any commonly mutated genes is not an indication that you will never develop colorectal cancer; it simply means that your risk is the same as that of an average person. Additional genetic mutations that have not yet been defined, environmental factors and other causes are still responsible for the majority of colorectal cancer occurrences.

Will My Insurance Cover Genetic Testing?

Despite the benefits of genetic testing, these procedures are not always covered by insurers. For example, Cigna requires patients to receive independent genetic counseling before approving coverage of genetic tests for certain hereditary conditions, including colorectal cancer. Because the complexities of genetic testing are often not clearly understood by the general public, genetic counseling can provide patients with valuable information that allows them to make medical decisions that are right for them by clarifying who should receive genetic testing and what the results mean. However, it is important not to overlook the value that physicians bring to the table in terms of their personal connection with patients and their intimate knowledge of a patient’s medical history. Physician recommendations can be extremely valuable in determining whether you are a good candidate for genetic testing, so talk to your doctor about whether genetic testing for colorectal cancer could benefit you.

Is Genetic Testing Right for Me?

It is important to talk to your doctor to decide whether genetic testing is right for you. You should also talk to your insurance plan to determine what your coverage options are if you opt for the new procedures. In some cases, you may need to pay out-of-pocket for genetic counseling or specific tests if your insurance coverage is limited.

Genetic testing may be beneficial if your family has a history of colorectal cancer, or if you’re concerned about your risk for colorectal cancer. For example, any person of Ashkenazi Jewish descent with or without a family history of colon cancer or pre-cancerous polyps should consider genetic counseling. When combined with a cancer screening colonoscopy, genetic testing may provide a fuller picture of a person’s risk of colorectal cancer, and, as a result, a more comprehensive and effective treatment plan. Prevention, of course, is the key to ensuring you do not fall victim to colorectal cancer.

As always, regular screening colonoscopies are the best way to catch pre-cancerous polyps early and prevent colorectal cancer. Colorectal cancer screening with colonoscopy, the Gold Standard, is an exceptionally effective tool in the fight against this dreadful disease, which, if caught early, is often curable. Thankfully, the future holds many bright possibilities for the fight against colorectal cancer.

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**Extra Weight Tied to Half a Million Cancer Cases Each Year**

People who think the extra pounds they carry around can’t hurt them may want to think again. Being overweight may raise the risk for cancer, a new study suggests. Click here to view full article or visit [www.dailyrx.com](http://www.dailyrx.com).

**Cancer Death Rate Drop Spares 1.5 Million Americans**

The American Cancer Society recently reported that a 22% drop in cancer deaths during the past two decades has spared the lives of more than 1.5 million people in the United States. In its annual dissection of cancer diagnoses, mortality and survival data, the group pinned the ongoing decline in cancer death rates on a downturn in U.S. smoking habits, extra attention to cancer prevention, improvements in various cancer treatments and advances in early detection methods. Click here to learn more or visit [www.nbcnews.com/health/cancer](http://www.nbcnews.com/health/cancer).

**More than a Third of People with Abnormal Results Drop Out of Bowel Cancer Screening**

Almost 40% of people who have abnormal results from bowel cancer screening tests and are referred for further investigation ignore their next screening invitation two years later, according to a Cancer Research UK study published in the *British Journal of Cancer*. In contrast, just 13% of those who had a normal result did not continue with screening. To read more, visit [www.medicalxpress.com/news](http://www.medicalxpress.com/news) or click here.