

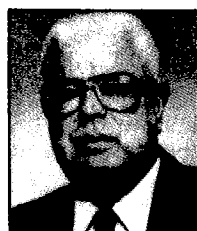
## Clinical Roundtables on Colorectal Cancer



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These Roundtables are sponsored by the Office of CME, Memorial Sloan-Kettering Cancer Center, and qualify for AAFP Prescribed Credit and AMA Category I Credit. See page 35.

The concept of screening patients for colorectal cancer has elicited some controversy during the past two or three decades. Today, we have new approaches and improved techniques for detecting the disease in asymptomatic patients. With the appropriate application of currently available screening and diagnostic techniques, primary care physicians can greatly reduce the impact of colorectal cancer on many of the patients in their care.

In this eighth of our *Clinical Roundtables*, the panel of experts focuses on how primary care physicians can screen individual patients for colorectal cancer in their everyday clinical practice. Participating on the panel are:

- Moderator: Robert E. Rakel, MD, Professor and Head, Department of Family Practice, The University of Iowa Hospitals and Clinics
- David M. Eddy, MD, PHD, Director, Center for Health and Clinical Policy; Professor of Community and Family Medicine, and Professor, Institute of Policy, Sciences and Public Affairs, Duke University
- Victor A. Gilbertsen, MD, Associate Professor of Surgery, Director, Cancer Detection Center, University of Minnesota School of Medicine
- Sidney J. Winawer, MD, Chief, Gastroenterology Service, Memorial Sloan-Kettering Cancer Center, and Professor of Clinical Medicine, Cornell University Medical College

The panelists discuss the value, application, and limitations of one of the three screening procedures—the fecal occult blood test. The third procedure—proctosigmoidoscopy—will be discussed next month, as well as proposed guidelines for screening average-risk and high-risk patients, with practical consideration for the patient benefit and cost-effectiveness of these approaches.

By addressing the indications and contraindications for screening and follow-up diagnostic procedures, the panelists provide valuable information that will help primary care physicians enhance long-term survival for their patients at risk for colorectal cancer.

## VIII: Screening in the Primary Care Office: On the Use of the Fecal Occult Blood Test

**Dr. Gilbertsen:** Rectal bleeding is the most significant and, generally, the first sign of colorectal lesions. However, unlike the overt bleeding associated with advanced cancer, the bleeding from early cancers and adenomas is intermittent and often is so slight that it cannot be identified visually—even as a thin streak along the length of a stool.

**Dr. Rakel:** Okay, then, let's discuss the use of the fecal occult blood test in screening for colorectal cancer.

Victor, some primary care physicians may not yet employ this test. Even though it's been available for many years, there's been some controversy as to its value. What have we learned about the test that now makes it an important part of the colorectal cancer screening approach?

**Dr. Gilbertsen:** Over the years, the fecal occult blood test has evolved from the early bench guaiac test to the current guaiac-impregnated paper slide. Today, it's a relatively sensitive and specific screening procedure—capable of detecting a significant proportion of colorectal lesions that bleed.

**Dr. Rakel:** I think this is an extremely important point, and I'd like for us to clarify it a bit. We often hear terms like sensitivity and specificity, but they're not well understood.

How are such terms defined?

**Dr. Eddy:** Well, basically, there are six fundamental terms that primary care physicians should know.

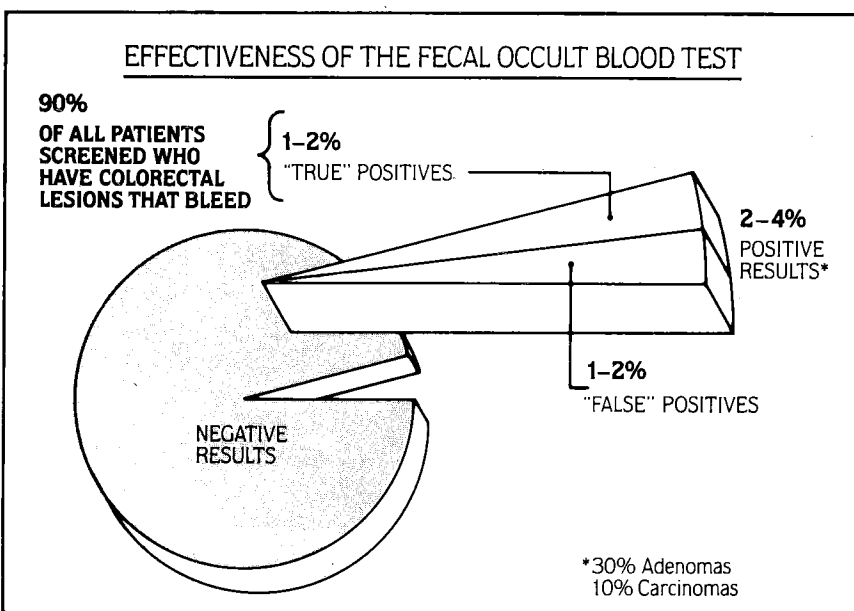
- First, there's the rate of positivity or the positive rate; this is the proportion of patients screened who have positive test results.
- Second, there's the rate of negativity or negative rate; this is the proportion of patients screened who have negative test results.
- Third, there's the *true-positive* rate; this is the proportion

of cancerous patients whose cancers are actually detected by the test. It also is known as the *sensitivity* of the test.

- Fourth, there's the *false-positive* rate; this is the proportion of patients *without* the disease who have positive test results.

- Fifth, there's the *true-negative* rate; this is the proportion of patients without the disease who have negative test results. It also is known as the *specificity* of the test.

- Sixth, there's the *false-negative* rate; this is the proportion



**Figure 1:** Results with the fecal occult blood test are favorable. The test will detect 90% of all patients screened who actually have colorectal lesions that bleed.

of patients whose cancers are not detected by the test.

**Dr. Rakel:** Okay, but how do these relate to the fecal occult blood test?

**Dr. Eddy:** Pretty well. On the initial screening of every 100 average-risk patients, about four will have positive test results (Figure 1). Of these four patients, about one or two will be found, with further workup, to have a colorectal carcinoma or adenoma.

**Dr. Winawer:** Now, this

may not sound like many, but we believe that it represents about 90% of the patients screened who have colorectal lesions *that bleed*.<sup>1</sup>

**Dr. Rakel:** In other words, Sid, most asymptomatic patients with a bleeding colorectal lesion who are screened by the physician will be detected by the fecal occult blood test. That's extremely encouraging.

**Dr. Winawer:** I agree. Now,

1. Family Practice News June 15, 1977.

in contrast, one might be discouraged by the fact that half of the patients with positive test results will not be found to have meaningful lesions. But in terms of the total number of patients screened, this false-positive rate is only about 1 to 2%—and most of these results will be due to some other pathological condition, such as ulcer or diverticulosis. Only a very small proportion of the false-positive results will be caused by conditions that are not clinically meaningful or by test failure.

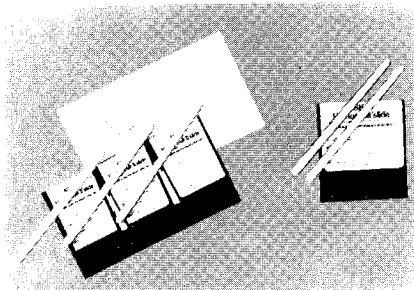
**Dr. Rakel:** That's good to know. I think some physicians have been reluctant to use the fecal occult blood test because they're afraid they'll get too many false positives. No one wants to subject a patient to unneeded tests; it's inconvenient, costly, and not without risks. So, the relatively low false-positive rate of the fecal occult blood test is comforting.

**Dr. Gilbertsen:** I hope so. The test isn't infallible, but until a better noninvasive method of detecting colorectal cancer is developed, it's the easiest, most convenient, least offensive, and one of the most sensitive methods we have.

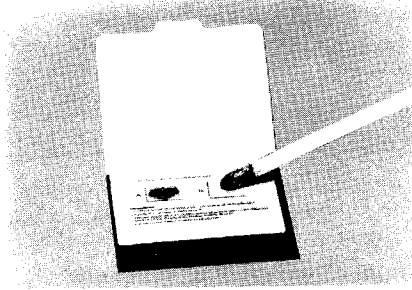
**Dr. Rakel:** Okay. Then, I think it's important for us to discuss how the fecal occult blood test is used. To obtain the most reliable results, there are a few points to consider. For example, I know some physicians do a single test at the time that they perform a digital rectal examination. Usually it's negative. But when positive, they have the patient

## Performance Of The Fecal Occult Blood Test

A. Test Formats



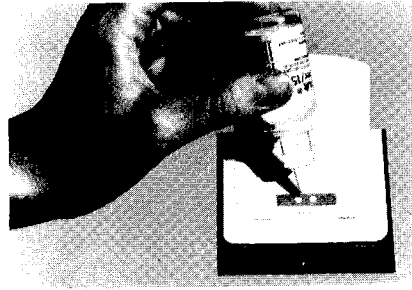
B. Specimen Application



C. Slide Development



D. Performance Test



**Figure 2:** The fecal occult blood test is a simple, noninvasive, and reliable procedure for detecting hidden blood in the stool. It comes in single- or three-slide formats for office or home use (A). Specimens are readily collected by patients (B). The test can be developed easily in the physician's office or a laboratory (C). An on-slide performance-test window assures test reliability (D).

perform a three-test series at home. Then, if this also is positive, they follow up with proctosigmoidoscopy. Is this an appropriate approach?

**Dr. Winawer:** Bob, you've raised two points. First, the single test is not a very effective method of screening. Since rectal bleeding tends to be intermittent, it's just not possible to make a valid judgement of occult rectal bleeding based on a single test. To obtain reliable results, it's really necessary to test six specimens from *three* consecutive bowel movements. Such serial testing is facilitated by the availability of three-slide units, each accommodating two stool specimens (Figure 2).

The second point you raised pertains to the performance of the fecal occult blood test in conjunction with the digital rectal examination. This really is not advisable because, in performing the digital examination, the finger could injure the rectal mucosa and cause it to bleed. The fecal occult blood test is not excessively prone to false-positive results, but any potential for eliciting such results should be avoided.

**Dr. Gilbertsen:** That's why it's important also for patients to adhere to a controlled diagnostic diet for 24 to 48 hours prior to collecting the first stool specimen and throughout the three-day testing period. This means they should refrain from eating red meat because of its hemoglobin content, and such vegetables as turnips or horseradish because of their high peroxidase content.

**Dr. Winawer:** In contrast, patients should eat plenty of fruit and vegetables. And they should eat moderate amounts of fiber-containing foods. The roughage from these kinds of foods is thought to stimulate colorectal lesions to bleed.

It's also important to instruct patients not to ingest possible gastric irritants, such as aspirin-containing compounds, antibiotics, and anti-inflammatory drugs; these may cause the normal mucosa to bleed. Another substance to be avoided is ascorbic acid because it interacts with guaiac to produce a false-negative reaction. And last, women should not be tested during or immediately following the menstrual period.

**Dr. Rakel:** Sid, I appreciate the restrictions that you and Victor have outlined, but I believe we all recognize that patients don't always comply with our instructions. So, we have to remember to explain our instructions clearly. Repeat them, if necessary. And if we're not sure our patients understand, ask them a question or two.

**Dr. Eddy:** It's also helpful to explain the rationale for the test, as well as explaining instructions. Understanding helps motivation.

**Dr. Gilbertsen:** I agree, although compliance appears to be much less of a problem with the fecal occult blood test than some physicians might suspect. Patients generally understand the need for the test and abide by the instructions, provided it's employed in a medical setting. In ongoing screen-

ing programs at several medical institutions, patient compliance with the fecal occult blood test has been about 80%. And it's felt to be even higher among patients seen regularly by physicians in private practice.

**Dr. Winawer:** When I talk to my patients, I explain the concept of screening, how the test is performed, and the appropriate diet. With women, I find it helpful to liken the fecal occult blood test to Papanicolaou's test for cervical cancer. I know the analogy is not exact, since the fecal occult blood test is not specific to colorectal cancer, but to rectal bleeding. Still, it serves the purpose. I explain that both types of cancer develop slowly and that, if either type is detected early, the prognosis is much improved. Since women have long accepted Papanicolaou's test as part of their routine physical examination, they usually have no trouble accepting the fecal occult blood test, as well.

**Dr. Rakel:** Good. Now, let's discuss how the fecal occult blood test is performed and how the results are interpreted.

**Dr. Winawer:** The typical test employed in a primary care practice is a card with a set of three slides, one for each of three consecutive testing days (Figure 2A). Each slide has a flap on the front, under which there are two rectangular cut-outs backed by guaiac-impregnated filter paper. Specimens from different portions of the same stool are applied to each cut-out with a

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Sponsored by the Office of CME, Memorial Sloan-Kettering Cancer Center in cooperation with the American Cancer Society, American Society for Gastrointestinal Endoscopy, The American Society of Colon and Rectal Surgeons, International Workgroup on Colorectal Cancer, and the NCI.

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bilized solution of hydrogen peroxide—are applied to the filter paper covering each stool specimen. This creates a guaiac-peroxidase reaction that turns the filter paper *blue* within 30 to 60 seconds, if occult blood is present in a specimen. Any trace of blue on or at the edge of *any* of the six specimens is a *positive* indication of occult blood.

**Dr. Rakel:** You mean, if you see blue about only one specimen, you shouldn't repeat the test, but should proceed directly to proctosigmoidoscopy and additional procedures?

**Dr. Gilbertsen:** That's correct. Regardless of intensity or shade, a trace of blue on even one specimen is an indication of occult blood. And once you detect bleeding, you *must* proceed with the appropriate workup of the patient. Retesting or waiting is not productive. Remember, the bleeding tends to be intermittent. So, a retest could be negative. You have to act on what you know. If you have a positive result, you have to move toward a diagnosis. It may not be colorectal cancer, but as we noted earlier, it very likely may be an adenoma that may be pre-malignant or another pathological condition.

**Dr. Rakel:** Yes, I understand that. It's just that I hesitate to subject a patient to further procedures, especially invasive procedures like proctosigmoidoscopy or colonoscopy.

**Dr. Winawer:** I know how you feel, Bob. But you have to recognize that, as Victor explained, a positive fecal occult blood test is a reliable finding.

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wooden applicator (Figure 2B).

**Dr. Rakel:** Sid, I think there's an important point to make here. Some patients don't understand that the test really requires only *very thin* specimen smears, like blood smears. Thick smears are apt to interfere with the reactivity of the test and make it difficult to interpret the results. So, physicians should make this point clear when instructing their patients about the test.

**Dr. Winawer:** Absolutely. Now, once the patient completes the three-slide series, it

should be taken to the physician or, if preferred, to a laboratory for development and interpretation of the results.

**Dr. Gilbertsen:** It can also be mailed. But, if so, it's important to assure that it's received and processed no later than three to four days after the third set of specimens has been collected. This will assure that the specimens do not become dehydrated and lose their reactivity.

**Dr. Winawer:** Right. Now, test development and interpretation are also very simple (Figure 2C). On the reverse side of each slide is another flap. This is opened and two drops of the developer—a sta-

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## The Important Role of the Primary Care Physician

**Dr. Rakel:** But what if the patient wasn't properly prepared? What if he or she didn't adhere to the diet and ate a rare steak the night before collecting a stool specimen? Or what if the patient took some aspirin for a headache? Under such circumstances, wouldn't it be prudent to repeat the fecal occult blood test before moving on to other procedures?

**Dr. Winawer:** Well, if you knew for certain that a positive test result was due to such a confounding factor, you'd know the true result was negative; so, there'd be no point in repeating the test. But the reality of the situation is that you can't be sure whether that factor had anything to do with the positive result or not. It's preferable to avoid such factors, but their presence shouldn't influence your acceptance of a positive result. Colorectal lesions usually do not bleed continuously. So, a negative finding on a repeat test very likely could be misleading. The problem really isn't whether or not to accept a spurious positive result, but what to do next. And, in my experience, that ought to be a double-contrast barium enema and proctosigmoidoscopy. Remember, in a medical setting, the fecal occult blood test has a high level of compliance and a low level of false-positive results.

**Dr. Rakel:** Okay. When you consider that, I suppose there's good reason to accept a posi-

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This material was previously distributed to approximately 50,000 primary care physicians in 1982 and 1983 by mail.

Primary care physicians comprise the one group of clinicians that is in a particularly critical position to mitigate the impact of colorectal cancer. They are most likely to see patients regularly—not only at the time of a periodic medical examination, but on other occasions of illness during the year. Accordingly, they can do much to detect the disease while it is still asymptomatic.

The responsibility of primary care physicians, however, does not end with case finding. Nor does it end with referral of the patient to a gastroenterologist or surgeon. It is appropriate for the primary care physician to become involved in subsequent discussions and to participate in the management and follow-up of patients with a colorectal adenoma or cancer. This applies to diagnostic testing, as well as to surgery and other therapy. The primary care physician is also in an ideal position to be alert for signs and symptoms of recurrence, new primary cancer, and additional adenomas.

The importance of the primary care physician's role in colorectal cancer has been clearly recog-

nized—on both a national and an international level. The American Cancer Society and the National Cancer Institute, among other organizations, are steadfast proponents of physician involvement in the efforts against this disease.

On a worldwide level, an International Workgroup was organized following the first International Symposium on Colorectal Cancer in March 1979. Subsequently, the Workgroup studied the problem of colorectal cancer and, among other conclusions, stated:

"Primary care physicians, who would be heavily involved in case finding, screening, diagnosis and follow-up of such patients, are not thoroughly acquainted with the natural history of adenomas and colorectal cancer and the best procedures to use in finding and dealing with these disorders. Educational programs must be developed and presented to the medical community."

These Roundtables are one such program.

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tive fecal occult blood test as an inducement to proceed with the workup.

**Dr. Gilbertsen:** That's true, Bob. In addition, one recent advance in the evolution of this test is an on-slide performance-test window (Figure 2D). Beneath the flap on the developing side of the slide, there's a red rectangle with two white dots. After developing each stool specimen, a single drop of developer should be applied *between* the two dots. The results can be read within 30 seconds. If the slide is operating correctly, the "positive" dot will turn blue and the "negative" dot will re-

main white. On the rare occasion when this reaction does not occur, the slide should be discarded, the developing solution retested on a fresh slide, and the test repeated.

**Dr. Rakel:** It's apparent, then, that today's fecal occult blood test is substantially superior to its predecessors. The acceptable false-positive and false-negative rates, and the inclusion of a diagnostic diet and a performance-test window, should instill greater confidence in its results. ■

*Next month:  
The Role of Sigmoidoscopy:  
Who, When, Why, and How*