

STUDENT VERSION

*Cases in Population-Oriented
Prevention
(C-POP)*

**A Critical Look at Prevention:
Colorectal Cancer Screening**

Authors:

John W. Epling, MD
Cynthia B. Morrow, MD, MPH
Donald A. Cibula, Ph.D.

Preventive Medicine Program
SUNY Upstate Medical University
714 Irving Avenue
Syracuse, New York 13210
315-464-2642
Email: PMP@upstate.edu



State University of New York
Upstate Medical University

Abstract:

This preventive medicine teaching case, part of the Cases in Population-Oriented Prevention series, discusses the concepts of diagnostic test evaluation, prevention, and screening using the example of colorectal cancer screening. Features of the case include a health policy exercise concerning community screening programs and an exercise in clinical prevention decision-making.

Recommended Reading:

- Chapter(s) in your epidemiology text on diagnostic tests and screening programs
- Ransohoff DF, Sandler RS. Screening for Colorectal Cancer. *N Engl J Med.* 2002; 346(1): 40-44.
- U.S. Preventive Services Task Force. Screening for Colorectal Cancer: Recommendations and Rationale. *Ann Int Med.* 2002;137:129-31.

Objectives: At the end of the case, the student will be able to:

- Calculate the characteristics of diagnostic tests: sensitivity, specificity and positive and negative predictive values.
- Evaluate screening tests in terms of their validity, results and generalizability.
- Employ the concepts of primary and secondary prevention as they relate to common clinical preventive services.
- Describe the appropriate conditions for screening in terms of characteristics of the disease, the patient and the screening test.
- Describe the appropriate study design to evaluate the effectiveness of a screening program and discuss the common biases encountered in screening program research.
- Evaluate locally obtained survey data about screening rates and attitudes and devise a community response to increase colorectal cancer screening.

Section A: Diagnostic Test Characteristics

Screening programs use diagnostic tests to screen for disease. These tests should first be evaluated by their ability to diagnose the target disease. This evaluation is accomplished by studying the performance of the test in a clinical population.

You are asked to evaluate the performance of a fecal occult blood test (FOBT) to screen for colorectal cancer (CRC). The test consists of taking two samples of stool from each of three consecutive stools and smearing the samples onto cards (one sample per slide, two slides per card). The stool samples are then tested for the presence of occult blood. The results of the stool test are reported as either positive (one or more slides positive) or negative (no positive slides). If the screening test is positive, the patient is referred for a definitive test to diagnose colorectal cancer.

Question:

- 1. What is a “reference standard” test for the diagnosis of colorectal cancer? (i.e., what is a definitive diagnostic test for the disease?)**

You have the following table of data from this hypothetical study of FOBT:

	<u>CRC present</u>	<u>CRC absent</u>
FOBT positive	40	26
FOBT negative	80	854

(FOBT=Fecal Occult Blood Testing, CRC=Colorectal Cancer)
(The “reference standard” was used to determine the actual presence or absence of colorectal cancer in the study population.)

Questions:

- 2. Calculate the following characteristics from the data in the table:**
 - a. Prevalence of colorectal cancer: _____
 - b. Sensitivity of FOBT: _____
 - c. Specificity of FOBT: _____
 - d. Positive Predictive Value of FOBT: _____
 - e. Negative Predictive Value of FOBT: _____

- 3. How would these numbers change if the prevalence of the disease were halved?**

- 4. What are the relative strengths and weaknesses of this test for use in a screening program?**

- 5. This test has a dichotomous (positive/negative) result. How would you calculate these characteristics for tests with continuous outcomes (like blood pressure, cholesterol)?**

Section B: Evaluation of Diagnostic Test Studies

Studies of diagnostic tests should be evaluated according to their validity, results and generalizability. You are now given more details about the hypothetical study introduced in Section A.

All 1000 study participants (selected from gastroenterologists' offices in 20 sites across the country) were asked to perform the fecal occult blood test (FOBT). After that, those who had a positive test (defined as one or more slides positive for occult blood) underwent a colonoscopy. Those who had a negative test were sent a survey each year for the next three years to determine whether or not they had been diagnosed with colorectal cancer.

Questions:

- 1. What are some criteria used to assess the validity of a study of a diagnostic test? Was this study valid?**

- 2. Do the results of the study (and the test characteristics derived from them) show that this test (FOBT) can accurately diagnose colorectal cancer? How precise are the results (are there confidence intervals given for sensitivity, specificity, etc.)?**

- 3. Generalizability: How well would the information from this study apply to the same diagnostic test performed in a primary care physician's office (where most screening would likely take place)?**

Section C: Concepts of Prevention

As described in your reading, colorectal cancer is a major contributor to morbidity and mortality. Screening programs for this disease have been shown to significantly reduce its impact on health. To fully appreciate the importance of screening tests, clinicians need to have an understanding of the concepts of prevention.

Questions:

1. **Define and explain the differences between the following terms:**
 - a. **Primary Prevention –**
 - b. **Secondary Prevention –**
 - c. **Screening –**

2. **The notions of primary and secondary prevention can be challenging. To further explore the nuances of these types of prevention, categorize the following tests and interventions in terms of primary and secondary prevention:**
 - a. **Counseling about smoking cessation in a healthy 40-year-old male to prevent lung cancer.**

Primary or secondary prevention
 - b. **Vaccination of a healthy infant with injectable polio vaccine to prevent polio.**

Primary or secondary prevention
 - c. **Cholesterol testing in a healthy 45-year-old male to prevent coronary artery disease.**

Primary or secondary prevention
 - d. **Prostate-specific antigen testing in healthy 50-year-old males to prevent prostate cancer morbidity and mortality.**

Primary or secondary prevention

The next questions are a little more controversial.

- e. **Papanicolaou smear in a healthy 28-year-old female to prevent cervical cancer.**

Primary or secondary prevention
- f. **Colonoscopy in a healthy 35-year-old male whose father died of colorectal cancer at age 42 to prevent colorectal cancer.**

Primary or secondary prevention
- g. **Glucose challenge testing in pregnant females to prevent gestational diabetes-related complications of pregnancy.**

Primary or secondary prevention

Section D: Screening Programs

A screening program consists of the screening test, definitive diagnostic testing, and treatment for the disease. In medical practice, physicians may choose to screen a patient for a disease based on a variety of factors, such as their training, numerous (and sometimes conflicting) guidelines, patient preferences, and common local practice. These factors can influence not only the decision to screen, but also the method of screening.

Question:

What are some criteria that would classify any one screening program as desirable and necessary for your practice? Consider factors concerning: the test itself, the disease, and the patients to be screened.

Section E: Evaluation of Screening Programs

Though a diagnostic test can accurately screen for a disease, it is still important to examine whether the adoption of the screening program leads to better outcomes for the patients screened.

Questions:

- 1. What is the best study design to evaluate the overall effectiveness of a screening program?**
- 2. There are five important biases found in evaluations of screening tests and programs: lead-time bias, length-time bias, over-diagnosis bias, selection bias and referral bias. Explain each of these (with examples) and describe ways to reduce each one.**

Section F: Health Policy Exercise- Colorectal Cancer Screening

The knowledge that you have gained in this session has made you a local expert in screening and prevention. You have been notified by an outside health policy agency of an alarmingly low colorectal cancer screening rate in your county. Your group has been commissioned by the Health Commissioner to confirm this data and to explore reasons why this rate might be lower. You work with an epidemiologist to conduct a telephone survey of the population about rates of colorectal cancer screening, the results of which are presented in Handout 2. This study was a random telephone survey of residents of Onondaga County, New York conducted in October 2000. Analysis of the demographic data revealed an under-representation of minorities in the sample.

Examine this data for “opportunities to improve,” then answer the following questions in your groups.

Questions:

- 1. What is the most important reason people do not undergo the recommended colorectal cancer screening in Onondaga County?**
- 2. What patient-related factors may contribute to the lack of recommended screening?**
- 3. What could physicians do to increase the overall screening rates in the county?**
- 4. What could the health department do for both physicians and patients to increase screening rates?**
- 5. What do you think is the best diagnostic test for a community screening program for colorectal cancer: colonoscopy, sigmoidoscopy or FOBT?**

Section G: Optional Clinical Correlation Exercise

Pretend you are an adult primary care physician. Would you offer screening for colorectal cancer to the following patients? Why or why not? What screening test would you use?

Mr. Adams is a 45-year-old male in your office for a "health maintenance" visit. Apart from occasional nocturia and a 1 pack per day smoking habit, his history is remarkable only for a family history of colorectal cancer in his uncle at age 70. He complains of no abdominal or bowel-related symptoms, and his physical examination is normal except for a mildly enlarged prostate.

Ms. Baker is a 60-year-old female who came to you at the recommendation of her gynecologist. During her most recent "well woman examination" she complained of some constipation symptoms that were new for her. On the advice of her gynecologist, she has increased her fiber intake somewhat, but that has only helped a little. She has no family history of colorectal cancer, and her physical examination, including a recto-vaginal examination, is normal.

Mr. Carlton, a 38-year-old male whose father contracted colorectal cancer at age 45 and died at age 46 presents for a visit at which he asks specifically to be screened. He notes no changes in his bowel habits, and no history of rectal bleeding. His physical examination is normal.

Mr. Davis, a 75-year-old man with emphysema on long-term steroid therapy and home oxygen asks during a recent visit when he should get his next flexible sigmoidoscopy. He has had some diarrhea, which he attributes to the almost monthly courses of antibiotics he requires for exacerbations of his emphysema. He notes no other abdominal complaints.

Ms. Edwards is a 53-year-old female who is one of your patients in a group care home for a history of mental retardation. She is somewhat interactive, but requires sedation during procedures such as dental cleanings. Neither she nor the health aide accompanying her notes any abdominal symptoms recently and she has no other significant medical history.

Handout 1: Screening Program Evaluation Criteria

In the 1970's and 1980's, Paul Frame, MD and others evaluated the research evidence behind the "complete physical," or as he termed it, the "Adult Periodic Health Examination," and published what he found in a set of articles in the Journal of Family Practice. From this was developed a set of criteria that could be used to evaluate clinical preventive services. This set of criteria, with modifications, is used by the US Preventive Services Task Force to develop their report on Clinical Preventive Services.

Listed below, adapted from Frame's original work and the outline of the USPSTF reports, are some criteria for evaluating a screening test for its usefulness in clinical prevention.

- A. Considerations regarding the disease for which to be screened:
 - 1. The disease must have an asymptomatic state, and progress to a symptomatic state.
 - 2. The disease must be sufficiently prevalent in the population.
 - 3. The disease must cause significant morbidity and mortality.
 - 4. There must be treatments available that will beneficially impact morbidity and mortality.

- B. Considerations regarding the tests for the disease:
 - 1. The screening test must be a good test (e.g. sensitivity and specificity, positive and negative predictive value).
 - 2. The evaluation of the screening program must avoid the common significant biases.
 - 3. The screening test must be cost-effective.

- C. Considerations regarding the patient(s) to be screened.
 - 1. The screening test must be acceptable to the patient.
 - 2. The patient must have sufficient life expectancy to derive benefit from the potential life gained by the screening program.

Handout 2: Health Policy Exercise Data

Highlighted results of the Colorectal Cancer Screening Survey, Onondaga County Health Department, Syracuse, NY, October 2000.

Study Participants:

Total calls - 4318

Completed - 2331

Eligible - 800

Participated - 410

Table 1. Respondents screened for colon cancer.

(FOBT <2 years OR flexible sigmoidoscopy < 5 years ago OR colonoscopy < 10 years ago)

Screened?	%
Yes	64
No	32
No information	4

Table 2. Reasons given for no recent (< 2 years ago) FOBT

(N=164, more than one response per person accepted)

Reason	n=
Don't know	21
Fear of embarrassment	3
Fear of bad news	4
No access to Dr.'s office	5
No convenient appointments	0
Doctor or nurse said screening not needed	18
No regular doctor	5
No insurance, can't afford	3
Too busy	5
Didn't think of it	23
No one told me	40
No reason/no problems	90

Table 3. Impact of physician recommendation for screening on screening rates.

	<u>Screened as Recommended?*</u>		<u>Total:</u>
	Yes	No	
Physician Advised Screening? Yes	61	151	212
Physician Advised Screening? No	6	165	171
Total	67	316	383

*Recommended screening – FOBT annually plus flexible sigmoidoscopy every five years OR FOBT annually OR flexible sigmoidoscopy every five years.

Table 4. Respondents' reported sources of information about colorectal cancer screening.

Source	%
At work	1.5
Radio	4.3
Brochures, billboards, etc.	5.0
Other	12.4
Relative, friend, co-worker	13.9
Magazine, newspaper	25.4
Television	28.8
Physician/nurse	56.7