

The fecal occult blood test (FOBT) to screen for colorectal cancer

Probabilities of benefits and harms

Patient's values and preferences



This document prepares the clinician to discuss scientific data with the patient so they can make an informed decision together.

Presenting the fecal occult blood test to patients

What is this test for?

▶ The **fecal occult blood test** estimates the **risk of having colorectal cancer**. If the test is positive, the physician usually offers a diagnostic test, such as colonoscopy, to verify that the individual has colorectal cancer.

How is the test performed?

▶ Stool samples are tested for the presence of occult blood every one to two years.

Who might consider being tested?

- ▶ Individuals at **average risk** for colorectal cancer, that is:
 - individuals **between 50 -75 years** of age.
 - Individuals **younger than 50** with first degree relatives who developed cancer before 50 years old, or with multiple affected first-degree relatives.
- ▶ **This test does not apply** to individuals at **greater than average risk** for colorectal cancer who should follow guidelines specific to their personal and family histories. Risk factors that put an individual at greater than average risk for colorectal cancer are¹: **inflammatory bowel disease** and certain inherited syndromes (**Lynch syndrome/hereditary nonpolyposis colorectal cancer (HNPCC), Familial polyposis syndromes**)

Why do patient preferences matter when making this decision?

▶ There are pros and cons to this screening test:



PROS: For each 1000 individuals screened every one or two years during 13 years, **1** death from colorectal cancer is prevented, but no death from all cause is prevented.²

CONS: Screening can be **inaccurate** and **cause harms**. For each 1000 individuals screened, **3** test negative with the FOBT but they will actually have a cancer, and **20** test positive but do not have colorectal cancer. Those who test positive will undergo **colonoscopy** to verify if they have colorectal cancer, and this can have **serious but uncommon side effects**.³

▶ **Both doing and not doing the test are acceptable options, so we propose that:**

- ① the clinician **shares this information** with the patient
- ② the decision takes into account the **patient's values and preferences**

← Questions to identify the patient's decision making needs:

- ▶ Do you have any questions about the benefits and harms of each option?
- ▶ Which benefits and harms matter most to you?
- ▶ Do you feel sure about the best choice for you?
- ▶ Who will support and advise you in making a choice?



State of knowledge - April 2013

Selection of the best available studies

Benefits of screening

① Increased survival

- ▶ For each 1000 individuals screened every one or two years during 13 years, **1 death (0.1%)** from colorectal cancer is **prevented**.²
- ▶ No **death from all causes** is prevented by screening.²

② Reassurance

For each 1000 individuals screened, **974 (97.4%)** are identified as being at **low risk** of having colorectal cancer.³ These individuals are **reassured**.

Harms of screening

③ False reassurance

Of the **974** individuals identified as low risk, **3** will actually have colorectal cancer.³ These individuals were **falsely reassured**.

④ False alarm

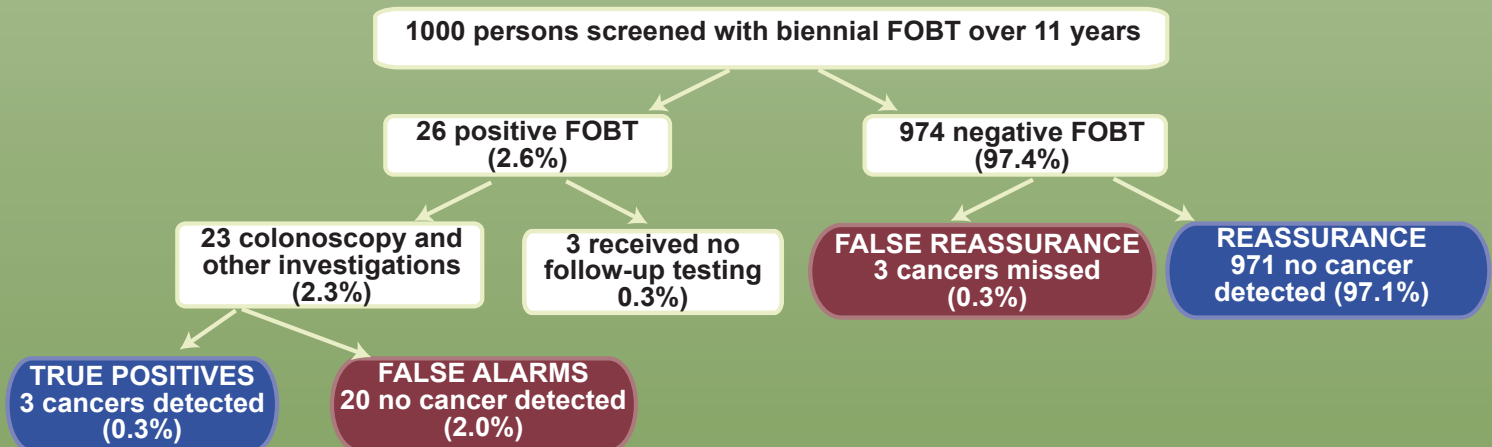
For each 1000 individuals screened every one or two years during 11 years, **26 receive a positive screening result**.³

23 of these 26 individuals (**90%**) will undergo **further diagnostic testing** (colonoscopy and/or double contrast barium enema) and **20** will be found **not** to have colorectal cancer.

Diagnostic tests can cause **complications**.³

- ▶ Less than **1%** will experience **bleeding** or a **perforation of the bowel**.

Fecal occult blood test performance³



👉 *Grading of Recommendations Assessment, Development and Evaluation (GRADE)*

How much confidence can we have in these results?

Survival (#1): High Data are based on a systematic review of 4 randomized controlled trials that shows consistent results across trials.²

Reassurance and False Alarms (#2-4): Moderate Data are based on results from the best available study that used a more accurate test (non-rehydrated samples) and followed-up all participants who originally met the inclusion criteria.³ Results are consistent across trials but are imprecise (large confidence intervals) likely because of the different methods to analyse samples (rehydration or non-rehydration of Haemoccult slides).²

Study descriptions and references:

1. **U.S. Preventive Services Task Force.** Ann Intern Med 2008,149(9), 627-37.
2. **Hewitson et al.** Cochrane Database Syst Rev 2007(1), CD001216.
Study design: Systematic review of 4 randomized controlled trials comparing screening for colorectal cancer using FOBT every 1-2 years to no screening. **Participants:** 327,043 participants from the US, UK, Denmark and Sweden, between 45-75 years old. **Length of follow up:** 8-18 years, screened at least annually.
3. **Scholefield et al.** Gut 2002, 50(6), 840-4.
Study Design: Randomized controlled trial comparing individuals invited to FOBT screening every two years with individuals not invited to be screened. **Participants:** 152,850 individuals (48% men and 52% women) between the ages of 45-75. **Length of follow-up:** 11 years. **Follow up to positive FOBT:** colonoscopy and/or double contrast barium enema.