CCSC - Cigarette Restitution Fund Programs (CRFP) Use of Fecal Occult Blood Testing for Colorectal Cancer Screening February 17, 2010

Outline:

- 1. Local health department experience with FOBT
- 2. Types of FOBT Take-Home tests
- 3. Incorporating FOBT into the Program
- 4. CRC Minimal Elements
- 5. Enrollment Process- Determining eligibility for the CRFP program
- 6. Results and Notification
- 7. Positive FOBT Results need Colonoscopy
- 8. Negative FOBT Results
- 9. Educate Referral Sources about your use of FOBT for CRC screening
- 10. Educate County Residents and Communities about your use of FOBT for CRC screening

Future Topics

- 11. Determining which FOBT kit to use: performance, cost, contract, availability, acceptability
- 12. Materials for FOBT Testing

Fecal Occult Blood Tests (FOBT) for Colorectal Cancer (CRC) Screening in Maryland Local Public Health Programs

- 1. Local health department experience with FOBT
 - o Graphs (**Attachment 2**): FOBTs Performed in the CRF Program by County and Fiscal Year
 - o Feedback from the local health departments, including:
 - What were the programs' prior experience in providing FOBTs
 - How did programs determine FOBT eligibility?
 - When and why did the program stop using FOBTs?
 - What challenges did the program experiences when using FOBTs?
 - Why are programs considering/reconsidering the use of FOBTs in their CRC screening programs?
 - Has a program received requests from county residents or Coalition members for FOBTs?
 - Are programs looking for less expensive testing?
 - How will programs offer FOBTs?
 - Will the program use FOBTs as a CRC screening <u>choice</u> for average risk asymptomatic clients? For initial screening? For subsequent screening in average risk clients without risk or symptoms and no findings on initial colonoscopy?
- 2. Types of FOBT Take-Home tests
 - Guaiac based tests (gFOBT) detect blood from all sources, human blood from the stomach, colon, and rectum, and non-human from foods (e.g., beef). Examples

- include standard tests and higher sensitivity tests such as Hemoccult Sensa. gFOBT requires diet restrictions in preparation for the test and drug restrictions.
- 2. Fecal Immunochemical tests (iFOBT or FIT) detect human blood only from the lower GI (colon and rectum). Examples include InSure and Hemoccult ICT. iFOBT has no diet or drug restrictions; it gives fewer false positive tests.
- 3. Incorporating FOBT into the Program (Attachment 3—FOBT Flow 02172010)
 - Rationale for use of FOBT by a program
 - o Provides screening options for clients
 - o Cost of a single test is lower than colonoscopy
 - Screen a larger number of individuals for CRC
 - Rationale for use of FOBT by a client
 - o Client may not be ready for a colonoscopy yet, for a variety of reasons
 - Invasive test; doesn't trust the health care system or program staff yet...
 - o Takes less time to complete an FOBT; don't need to take time off from work
 - o Increased acceptance of FOBT screening—FITs are without dietary restriction
 - o Home test therefore no transportation or assistance needed to complete the test
 - o No risk as this is a non-invasive procedure
 - Rationale for NOT using gFOBT or FIT testing for screening
 - Need to determine eligibility for FOBT: can only be offered to those 50+, average risk, without symptoms suggestive of CRC, not up to date with CRC screening; income $\leq 250\%$ FPG
 - Need to have enough budget to cover colonoscopy for those who are ineligible for FOBT because of risk or symptoms
 - Need to have enough budget to cover colonoscopy for those who are FOBT positive
 - Need staff to perform case management on clients who took kits but didn't return them
 - Annual testing is needed or the client is not up to date with CRC testing
 - Consult with Community Health Coalition when changing CRC screening method
 - Need Purchase order (or as required by local program) for FOBT Kits
 - May need contract with laboratory services to develop the kits
 - Need policies and procedures for FOBT testing integrated into your program (Flow Chart and policy and procedure templates)

4. CRC Minimal Elements

- Guidelines for Colorectal Cancer Screening--DHMH-CCSC- CRC Minimal Elements allow FOBT testing for initial screening of average risk asymptomatic clients as an alternative when funding is limited
- Medical Advisory will need to be consulted regarding change to the Minimal Elements for "mixed" screening schedules; namely, use of FOBT for screening after negative colonoscopy 10 years ago in average risk clients
- 5. Enrollment Process- Determining eligibility for the CRFP program
 - Those **not eligible for FOBT** include (see **Attachment 4** FOBT FIT Checklist):
 - o Non-county/State resident per local program grant/policy

- \circ > 250% of the FPG
- o Less than 50 years of age
- o Increased risk (presence of any of the risks including personal history of CRC or adenomas; no personal history of ulcerative colitis or Crohn's colitis, no personal history of endometrial or ovarian cancer diagnosed less than 50 years of age; no family history of CRC or adenoma in first degree relative)
- o Gastrointestinal symptoms including blood in stool/on tissue, penciling of stool, new constipation with abdominal pain, mass in abdomen or rectal mass on exam
- o Prior CRC screening up to date, making person ineligible for FOBT:
 - Had FOBT within the last year;
 - Had adequate colonoscopy within the past 10 years with no CRC or adenoma found (unless doctor orders an FOBT for completion of screening of average risk patient in whom the doctor couldn't reach the cecum)

1.

• Those eligible for FOBT

- o Residency and insurance eligibility per local program grant/policy
- o Household income < 250% FPG
- \circ 50 + years of age
- Average risk (or unknown risk)
- Asymptomatic or some symptoms not suggestive of CRC (e.g., chronic diarrhea or constipation without marked changes in bowel movements; abdominal pain not associated with other symptoms)
- o Not up to date with CRC screening by other methods
- Verbal confirmation of insurance status and income level is acceptable for screening and diagnostic services. (Programs may have more stringent requirements to confirm eligibility, but requirements that may be a barrier to screening are discouraged.)
 - o DHMH Non-Chargeable list for FY 2010 states that insured, underinsured, and uninsured individuals <u>can</u> get FOBT without a charge and without the need to submit to a third party insurer.
 - O Health Officer Memo #09-27 states "Maximum income level for CRFP funded services. The household income level to be eligible to receive CRFP CPEST LHD or SAHC Public Health-funded clinical services (screening, diagnosis, and/or treatment services) must not exceed 250% of the federal poverty level. Individuals with household income level above 250% of the federal poverty level are not eligible to receive CRFP CPEST/SAHC Public Health-funded clinical services (screening, diagnosis and/or treatment services)."
- Planned guidance regarding eligible clients
 - Consent form Use either Short Form (FOBT specific template) or Long Form Consent.
 - Suggest incorporating a "contract" with the client in the Consent to document that
 the client understands that the FOBT screening test must be completed annually to
 be an effective screening test for Colorectal Cancer.
 - o Determine your minimum case management regarding number of calls, notices or reminder communications to the individual to return a screening kit.
 - o Determine annual recall procedures—Discuss on teleconference

- Complete CDB forms and data entry; consider use of abbreviated "FOBT Core Form".
- Complete EDB forms/completed EDB data entry regarding education and distribution of FOBT kits on Form 1

6. Results and Notification

- Determine how the completed FOBT/FIT kit is to be mailed to the laboratory or to your program for reading
- Determine how program will receive results if performed by a laboratory
- Determine how you will notify the client?

7. Positive FOBT Results need Colonoscopy

- Approximately 10% gFOBT / 2-12% FIT (based on specific product) are estimated to have a positive result
- Budget and plan for needed colonoscopies on those with positive FOBT
- Provide verbal and written notification of positive test result to client and to primary care provided if known.
- Provide "aggressive case management" for positives (see HO Memo 08-39)
- Ensure that the client receives needed diagnostic colonoscopy and treatment (or link to treatment), as needed.
- When/if local program runs out of screening funds for the needed colonoscopies, plan for what you will do.
- Complete CRC CDB entries and record program activities in the client's record.

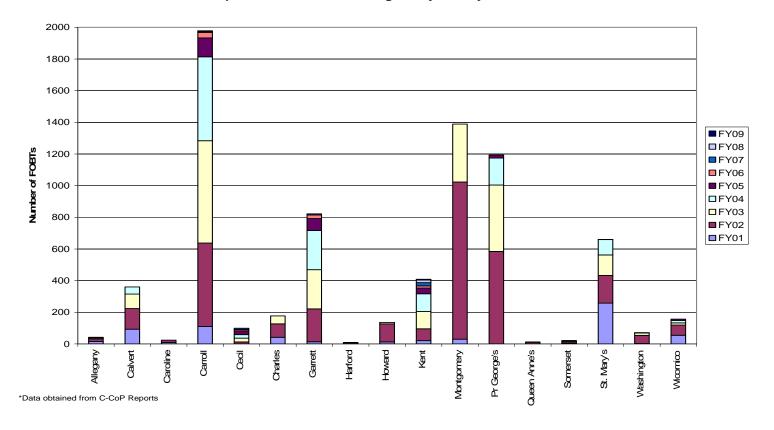
8. Negative FOBT Results

- Provide client with results letter. (CCSC will provide template letters.)
- Determine plans for annual recall for FOBT/FIT; what activities, at a minimum, will be carried out? Discuss what activities would be carried out for a more "active" recall process, e.g., self addressed reminder letters mailed in 11 months?
- Complete CRC CDB entries and record program activities in the client's record.
- 9. Educate Referral Sources about your use of FOBT for CRC screening
 - Health care providers
 - Community agencies
- 10. Educate County Residents and Communities about your use of FOBT for CRC screening
 - Community health coalition
 - Public education
 - Public education materials

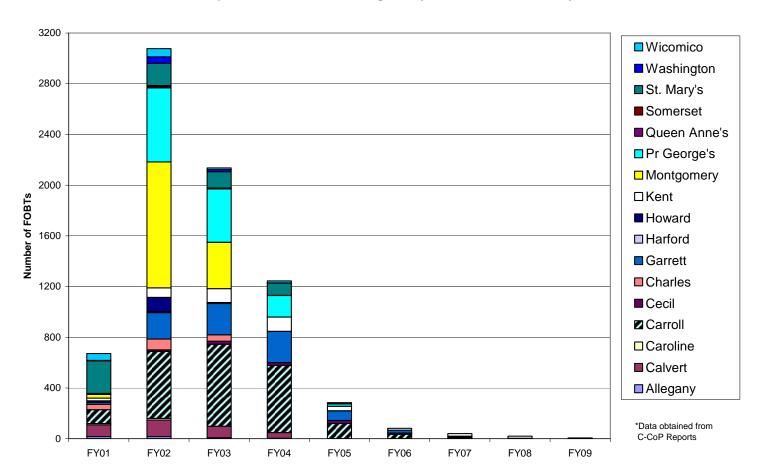
FUTURE TOPICS

- 11. Determining which FOBT kit to use: performance, cost, contract, availability, acceptability
- 12. Materials for FOBT Testing
 - Patient Education
 - Consent forms
 - CDB forms
 - Letter templates

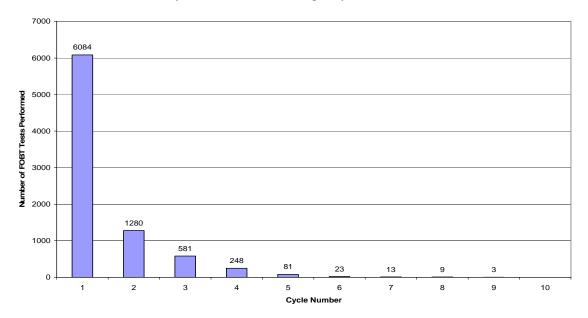
FOBTs performed in the CRF Program by County and Fiscal Year*



FOBTs performed in the CRF Program by Fiscal Year and County*

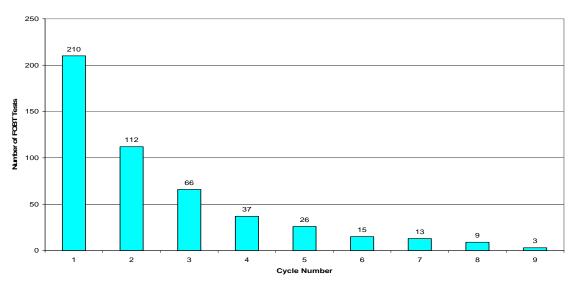


Cycle Number of FOBT Testing, Maryland 2000-2009

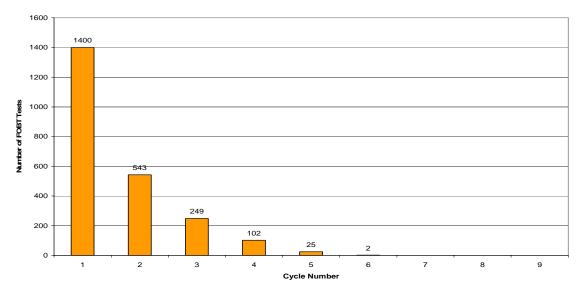


Examples

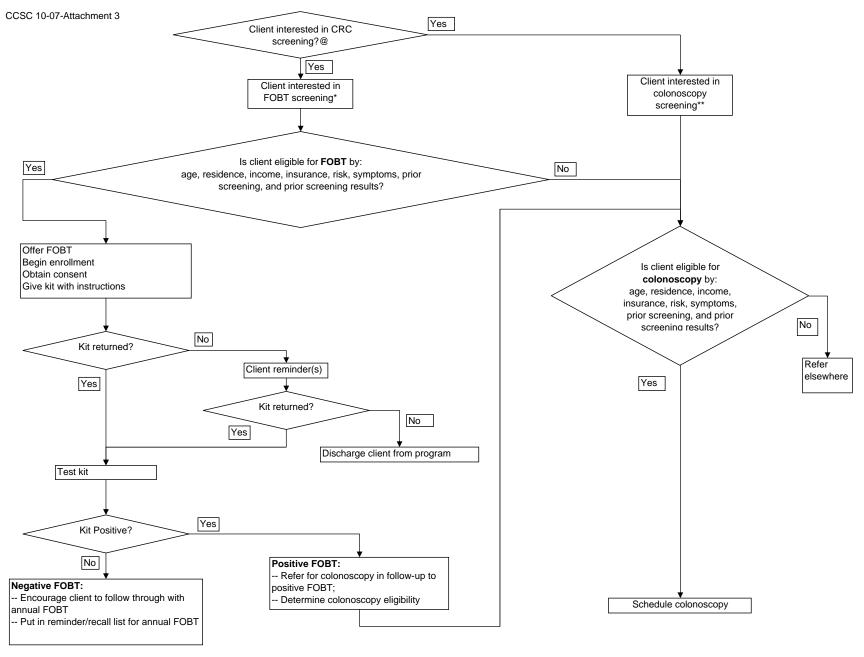
Cycle Number of FOBT Testing, Kent County Maryland, 2000-2009



Cycle of FOBT Testing, Carroll County Maryland 2000-2009



Source: By Cycle File 0203201002



[@] Decisions will need to be made as to whether this screening Flow will only to patients NEW to CRC screening (Never Screened) or to those screened by other methods in the past *FOBT screening is only for those >=50 years of age, at average risk of CRC, without symptoms of CRC, who meet eligibility by residence and income <= 250% of FPG

^{**} For those at increased risk of CRC or those with symptoms suggestive of CRC, colonoscopy should be the initial test offered

ELIGIBILITY CHECKLIST for FOBT/FIT Testing

If the answers to Questions 1-5 are "NO," the client is eligible for FOBT/FIT If any answers are "YES", the person may still be eligible for a colonoscopy in your program. Questions 6-8: "YES" answers further determine eligibility by residence, income, and insurance.

QUESTIONS	YES	NO
1. Are you 49 years of age or less?		
2. Were you screened for colorectal cancer with FOBT within the last year?		
3. Were you ever told by your doctor that you have:		
o Colorectal cancer?		
Adenomatous polyp (small growth that can turn into cancer)?		
o Ulcerative colitis (inflammation (redness and/or swelling, ulcers) in the colon or rectum)?		
o Crohn's colitis (inflammation (redness and/or swelling, ulcers) in the colon or rectum)?		
o For women: Endometrial or ovarian cancer diagnosed before the age of 50?		
 Do you have a brother, sister, son, daughter, father, or mother who had colorectal cancer or adenomatous polyps (small growth that can turn into cancer)? 		
4. Have you had an adequate colonoscopy within the past 10 years with no colorectal or adenomatous polyp (small growth that can turn into cancer) found?		
5. Have you recently experienced bleeding from the rectum or blood in the stool, change in bowel habits, abdominal mass, cramps, pain, and iron deficiency anemia that is not caused by other conditions, or change in the size of the stool (for example, the stool is thinner)?		
6. I need to ask three more questions to see if you are eligible for a fecal occult blood test: Do you live in [
7. How many people live in your household? [] What is your total household income? [\$] Program: Does the person meet eligibility of < 250% of Federal Poverty Guidelines?		
8. (Option based on local program) Do you have health insurance? [] Does your insurance cover CRC screening? [] Program: Does the person meet eligibility by insurance criteria?		