



OVERVIEW of FIT STUDY

Evaluation of the Fecal Immunochemical Test (FIT) for Colorectal Cancer Screening in the Alaska Native Population



General Goals and Objectives of the Study

Testing for blood in the stool is one of several modalities recommended by national organizations for colorectal cancer (CRC) screening. However, CRC screening using conventional guaiac-based Fecal Occult Blood Test (gFOBT) has not been useful in many Alaska Native populations due to a high prevalence of *Helicobacter pylori* (*H. pylori*) infection in the stomach. In this population, *H. pylori* causes low grade chronic blood loss from the stomach and has discouraged use of FOBT as a screening modality. Diets high in red meat compound the problem. The immunochemical fecal occult blood test (iFOBT) is a newer human hemoglobin-specific stool blood assay which is possibly more specific and sensitive than gFOBT in the detection of colorectal neoplasia, is not confounded by upper gastrointestinal bleeding, and does not require the dietary restrictions required by the gFOBT. However, the iFOBT has not been evaluated in the Alaska Native population.

The purpose of this study is to assess whether iFOBT is a reasonable screening option for CRC in Alaska Native people. In addition, we propose to establish that among those persons with *H. pylori* infection, gFOBT does lead to a high proportion of false positives and therefore should not be recommended as a screening test in this population.

Research Objectives

- To evaluate the sensitivity and specificity of gFOBT and iFOBT for screening of colorectal neoplasia in a population with elevated prevalence of *H. pylori* infection using colonoscopy as a gold standard.
- Evaluate the association between *H. pylori* infection and false positives in gFOBT and iFOBT to determine if either of these screening tests can be utilized in this population.

Research Hypotheses

- iFOBT is more specific and at least as sensitive as the gFOBT for colorectal neoplasia detection in Alaska Native people.
- The iFOBT performs as well in a population with high rates of *H. pylori* infection as in other populations.

APPROVED BY: Alaska Area IRB, CDC IRB, ANTHC Board of Directors, and SCF Board of Directors.

Participants: Alaska Native people recruited during their pre-op visit for screening or surveillance colonoscopies at ANMC.

- Sample size: 300 persons
- Inclusion criteria: Patients may include the following:
 - a. asymptomatic patients of average risk;
 - b. asymptomatic patients with a family history of colorectal cancer; or
 - c. patients with a history of polyps
- Exclusion criteria:
 - a. Age less than 18;
 - b. Race/ethnicity is not Alaska Native;
 - c. Indication for colonoscopy is other than for CRC screening or surveillance (recent or current history of altered bowel habits or rectal bleeding, history of IBS, invasive CRC, HNPCC and FAP);
 - d. Medical contraindications to colonoscopy;
 - e. Use of anticoagulants other than aspirin;
 - f. Medical or cognitive limitations to participation;
 - g. Does not reside in a residence with a flush toilet.

Timeline:

- Anticipated start date: March, 2008
- Anticipated duration: 2-3 years

Procedure:

- **PRE-OP VISIT**
 - Eligibility determined.
 - Consent, intake questionnaire and patient instructions completed by Research Nurse Coordinator (RNC).
 - H. pylori breath test (UBT) administered by RNC.
- **AT HOME**
 - iFOBT and gFOBT performed at home.
- **PROCEDURE VISIT**
 - Tests returned by patient.
 - Questionnaire on test adherence and preferences.
 - Individual results to patient and designated PCP.
 - Incentive (\$75) will be mailed if all tests completed.

For more information, contact Peggy Cobey, ANP, Research Nurse Coordinator at 729-3968 or mcobey@anmc.org.

Study Team:

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