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## Fecal-Based Colorectal Cancer Screening Among the Uninsured in Northern Manhattan

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### Abstract

**Background**—Colorectal cancer (CRC) screening reduces CRC mortality; however, for many reasons, uninsured individuals are less likely to utilize CRC screening tests.

**Purpose**—To compare CRC screening behaviors and outcomes with guaiac fecal occult blood testing (gFOBT) from 1998 to 2006 and fecal immunochemical testing (FIT) from 2006 to 2010 in a community-based program serving uninsured patients in northern Manhattan.

**Methods**—In 2013, we conducted a retrospective record review of individuals aged 50 years who received fecal-based CRC screening at the Northern Manhattan Cancer Screening Partnership between 1998 and 2010. Included were those with household income  $\leq$  250% of the federal poverty level, no medical insurance coverage, and who were not up to date with CRC screening. We assessed screening positivity rate, positive predictive value, differences in the use of diagnostic colonoscopy, colonoscopic findings, and adenoma detection rates for gFOBT versus FIT.

**Results**—In total, 7,710 patients completed CRC screenings (4,951 gFOBT and 2,759 FIT). The majority were female, Hispanic, foreign born, and young at age of first screening. Compared to gFOBT, FIT detected twice as many positive tests (3.2% vs 1.5%,  $p = 0.001$ ) and had a higher adenoma detection rate (18.2 vs 11.8,  $p=0.002$ ).

**Conclusions**—The improved positivity and adenoma detection rates with greater number of screening tests over time favor the use of FIT over gFOBT for colorectal screening among uninsured populations in northern Manhattan.

## Introduction

It is important but challenging to screen uninsured people for colorectal cancer (CRC). Nationwide, an estimated 59% of adults aged 50–75 years were up to date with CRC screening in 2010; however, only 21% of those without medical insurance had completed CRC screening.<sup>1</sup> In New York City in 2009, 66% of all adults aged 50 years and older were screened for CRC, including 77% of those with the highest income versus 55% with the lowest income.<sup>2</sup> The impact of these screening differences is significant, as uninsured or low-income people are more likely to be diagnosed with late-stage, incurable cancers.<sup>3,4</sup>

Acceptable tests for CRC screening include colonoscopy, flexible sigmoidoscopy, and stool testing for occult blood.<sup>5</sup> Among these modalities, stool testing for occult blood is the least expensive, which has led to its first-line use in population-based screening programs.<sup>6</sup> Testing of the stool for occult blood can be done via guaiac fecal occult blood testing (gFOBT) or fecal immunochemical testing (FIT), which utilizes antibodies to human globin. Among insured populations, the performance of FIT appears to be superior to gFOBT,<sup>7–9</sup> but the performance of FIT relative to gFOBT among uninsured patients is unknown.<sup>10–15</sup>

The Northern Manhattan Cancer Screening Partnership (NMCSP) is funded by the New York State Department of Health (NYSDOH) and the CDC. The NMCSP has provided free breast, cervical, and colorectal cancer screening, community-based outreach, education, and case management services to uninsured residents of northern Manhattan since 1998. From 1998 to 2006, the NMCSP utilized gFOBT for CRC screening. In 2006, the NMCSP worked with the NYSDOH Cancer Services Program to pilot the feasibility of the use of FIT, the results of which were utilized to inform programmatic policy.

The findings of the pilot study suggested that patients preferred FIT over gFOBT because of the ease of specimen collection (brush versus stick); fewer specimens required (two versus three); and the lack of dietary restriction for FIT. The amount of time from distribution to final results was also reduced using FIT. Based on the findings of the pilot study and other evidence supporting the advantages of FIT, the NMCSP transitioned from traditional gFOBT to FIT as the primary modality for CRC screening among average-risk individuals.

Screening behaviors and outcomes with FIT versus gFOBT were examined by conducting a retrospective study among NMCSP participants from 1998 to 2010. The current study documents the program's experience using both gFOBT and FIT to screen uninsured, minority, low-SES individuals in northern Manhattan for colorectal cancer over a 13-year period. Specifically, annual CRC screening behaviors with gFOBT and FIT, screening positivity rate, positive predictive values for each test, and colonoscopic findings among participants with positive fecal-based screening tests are reported here.

## Methods

### Screening Program

The NMCSP, through grants received from NYSDOH and CDC, provides no-cost cancer screening services to uninsured, disadvantaged residents of New York City. Approximately

20% ( $n=17,452$ ) of the population of the NMCSP catchment area is composed of individuals aged 50–64 years, living at or below 250% of the federal poverty level, with no medical health insurance.<sup>16</sup>

Recruitment to the program is accomplished through a vast outreach network that interfaces with local businesses, churches and faith-based organizations, schools and health fairs, political liaisons, social and cultural groups, senior centers, housing projects, and social clubs using bilingual lay health educators. Residents, aged 50 years, who have no medical health insurance coverage, with family household income  $\leq$  250% of the federal poverty level, are at average risk for colorectal cancer, and due for CRC screening are eligible to receive a fecal-based CRC screening test.

Using a standardized screening intake form, sociodemographic information was ascertained. All patients were asked a series of questions to assess CRC screening history (ever screened in the past, where screened, type of test used, and date of last screening) and risk for CRC (personal and/or family history of CRC or adenomatous polyps in one first-degree relative before age 60 years or two first-degree relatives at any age, family history of hereditary CRC syndromes, or personal history of inflammatory bowel disease, chronic ulcerative colitis, or Crohn's disease). Those who were current with CRC screening (fecal-based test within the past 12 months, flexible sigmoidoscopy within the past 5 years, or colonoscopy within the past 10 years) were ineligible to receive CRC screening services at that time and were recontacted in the future.

As described elsewhere,<sup>17</sup> those at average risk for CRC were offered a fecal-based screening test. Individuals reporting a personal or family history of colorectal cancer or adenomatous polyps, inflammatory bowel disease, and hereditary CRC syndromes were referred for a gastroenterology consult, usually leading to colonoscopy. Those presenting with symptoms, such as abdominal or rectal mass or prolonged rectal bleeding with change in bowel habits, were not eligible for fecal-based or endoscopic screening through this program. Any person diagnosed with CRC through the program is eligible to receive case management services, including treatment and assistance in obtaining insurance coverage through the New York State Medicaid Cancer Treatment Program.

### **Fecal-Based CRC Screening Tests**

From January 1, 1998, through December 31, 2006, patients at average risk for CRC were given a traditional gFOBT kit with three individual specimen slides (Hemocult® II, Beckman Coulter, Inc., Brea CA) that were purchased from and tested by the Columbia University Medical Center laboratory. In September 2006, fecal immunochemical testing was introduced and new patients were provided InSure® (Enterix, Inc., Edison NJ), which required two rather than three sequential specimens and no dietary restrictions.

### **CRC Education and Kit Distribution**

Eligible participants were educated by lay health educators at the time of enrollment about colorectal cancer, risk factors, and the importance of early detection. Using the “teach back” method,<sup>18</sup> education was performed in either English or Spanish at the preference of the

patient by bilingual lay health educators. All written program materials were translated into Spanish and back-translated into English to ensure accurate communication of the original intent by native speakers. Materials were prepared at the sixth-grade reading level determined by the Flesch–Kincaid method.<sup>19</sup> Each educational session was approximately 10–12 minutes in duration.

For traditional gFOBT, patients were asked to collect a portion of three separate sequential bowel movements and inoculate test cards. Both written and verbal instructions, in English or Spanish, regarding dietary restrictions and specific preparation of the toilet were provided. For FIT, a physical demonstration of the fecal specimen collection procedure using PlayDoh® as simulated feces was also performed to facilitate self-efficacy in the specimen collection process.

As approximately 30% of those screened with FIT in the year this test was introduced had previously screened with gFOBT, this specimen collection simulation was introduced to demonstrate the technique and highlight the differences between the two procedures. Participants were provided a fecal test kit and instructed to complete the test at home and return it within 2 weeks of final specimen collection (the third for gFOBT and the second for FIT).

All laboratory forms were pre-filled, leaving only the date of specimen collection to be entered by the patient. Patients were given the option of hand-delivering the completed kit to the Partnership or mailing it directly to the laboratory in a provided self-addressed, stamped envelope. Written and telephone reminders were deployed after 2 weeks to provide support, answer questions, and encourage the participant to return the kit. Replacement kits were provided as needed.

## Data Analysis

De-identified records of all uninsured persons aged  $\geq 50$  years and at average risk for CRC who sought colorectal cancer screening services through the NMCSP were examined. Those who completed a fecal-based screening test between January 1, 1998 and December 31, 2010 were included in this analysis. To evaluate demographic characteristics, the first screening record for each patient in the data set (unduplicated sample,  $n=7,710$ ) was examined and, to assess screening characteristics, all patient encounters over time (duplicated sample,  $n=11,489$ ) were included.

Age at first screening; self-reported race (Asian, black/African American, white, and other) and ethnicity (Hispanic versus non-Hispanic); and country of origin dichotomized as U.S.-born versus foreign born was collected at time of program intake. Any single positive fecal sample was considered a positive screening test. The mean number of days between kit distribution and test result was calculated among those who completed screening. Clinical findings were categorized as colorectal cancer, adenomatous polyps, or non-neoplastic findings, including inflammatory bowel disease, hemorrhoids, and diverticular disease.

The number of colorectal cancers detected per year was also calculated as well as positive predictive value (number of true positive FIT/FOBT tests defined as those followed by a

colonoscopy that detected precancerous polyps or CRC divided by the number of true positive FIT/FOBT tests plus positive FIT/FOBT tests where the colonoscopy results were negative [false positive FIT/FOBT], expressed as a percentage) and adenoma detection rate (number of colonoscopies that detected precancerous polyps divided by the number of total colonoscopies performed as a result of a positive FIT/FOBT). Based on the low rescreening rates and low positive test rates, we estimated that correlation related to multiple individuals screened multiple times in the program would be minimal and thus assumed independence between observations for analysis of the duplicated sample.

Descriptive analyses using chi-square and Student's *t*-tests were performed to assess associations between test methodology and covariates, respectively. Values of  $p < 0.05$  were considered statistically significant. Study procedures were approved by the Columbia University Medical Center and New York State Department of Health IRBs, and all analysis was conducted in 2013 using SAS, version 9.2 (SAS Institute Inc., Cary NC). A waiver of written consent and Health Insurance Portability and Accountability Act authorization was approved.

## Results

A total of 7,710 patients aged  $\geq 50$  years completed CRC screenings (4,951 gFOBT and 2,759 FIT) at the NMCSP between 1998 and 2010. Patients were young (48.6% aged 50–54 years) at first screening through the program, predominantly female (82.2%); Hispanic (45.2%); and foreign born (88.5%) (Table 1). Among those using gFOBT versus FIT, more Asians (45.6% vs 26.0%) and other races (27.4% vs 13.8%) and fewer whites (18.6% vs 44.1%) and blacks (8.4% vs 16.1%) were screened using gFOBT than FIT. Those completing FIT were younger (50–54 years) ( $p < 0.001$ ); female ( $p < 0.001$ ); white ( $p < 0.001$ ); and Hispanic ( $p < 0.001$ ) compared with those using gFOBT.

Compared with those who screened with gFOBT, FIT users were more likely to have a positive CRC screening test (3.2% vs 1.5%,  $p < 0.0001$ ) and the adenoma detection rate of colonoscopies following positive FIT was greater than those following positive gFOBT (18.2% vs 11.8%,  $p = 0.002$ ) (Table 2). The positive predictive value of the screening test, proportion of those who completed diagnostic colonoscopy, and clinical findings on colonoscopy were comparable between the two fecal-based screening tests (Table 2). Cancers detected per year (0.67 for gFOBT vs 0.5 for FIT) were comparable for each test type. The mean turnaround time between kit distribution and test result for returned tests was shorter for FIT than for gFOBT (23.3 days vs 26.5 days,  $p < 0.001$ ).

## Discussion

The NMCSP, funded by the NYSDOH and the CDC, has provided free breast, cervical, and colorectal cancer screening to uninsured adults in Manhattan since 1998. The current study examined annual CRC screening compliance with gFOBT and FIT over a 13-year period, with the aim of evaluating repeat screening adherence and colonoscopic findings among those testing positive with these two fecal-based tests.

Compared with those who screened with gFOBT, FIT users were younger at first CRC screening and more likely to have a positive CRC screening test. The test positivity rate with FIT was double that of gFOBT in this patient population, and although the FIT positivity rate was relatively low in comparison to rates reported among European populations,<sup>20–22</sup> the finding of a higher positivity rate for FIT over gFOBT is consistent with that observed by others.<sup>15,23,24</sup> More important, adenoma detection was significantly greater ( $p=0.002$ ) using FIT, indicating a higher likelihood of detecting precancerous lesions and preventing future cancer.

This study presents findings of a community-based CRC screening program that provides fecal-based CRC testing for average-risk, low-income, uninsured adults. The patient population is composed of predominantly female and foreign-born persons residing in northern Manhattan. Many patients are not fluent in English and have low literacy levels, even in their native language,<sup>25</sup> thus necessitating special measures to accommodate their particular language, educational, and literacy needs. Therefore, the NMCSP has historically provided face to face CRC education at the time of kit distribution by bilingual health educators, whose role is comparable to that of patient navigators in that they keep in contact with the patient until the screening test is complete, assess barriers, and provide counseling and education.

Other studies have demonstrated that the high level of effectiveness of patient navigators is attributed to their training to identify and address barriers, their cultural and linguistic concordance with the targeted patient population, and their ability to provide tailored, relevant education and assistance, particularly to minority and disadvantaged populations.<sup>26–28</sup>

Several RCTs have shown that FIT enhances screening participation and is superior to gFOBT in detecting advanced neoplasia.<sup>9,12,15,23,29</sup> In Europe, where population-based CRC screening with fecal occult blood testing is commonplace, FIT screening completion rates range between 49.7% and 64.7%.<sup>20–22,30</sup> Whereas European programs typically identify eligible individuals using national databases and invite screening participation, generally by providing test kits through the mail, the NMCSP relies predominantly on hospital in-reach and community outreach with face to face education and personalized follow-up.

This study provides insight to CRC screening with fecal tests in a community setting and demonstrates the recruitment, education, and patient management systems utilized to effectively reach and screen a vulnerable population—disadvantaged, minority, low-income residents of New York City who are medically uninsured. This program exemplifies many of the key findings reported regarding the implementation of the CDC Colorectal Cancer Screening Demonstration Program, specifically the importance of tailored outreach and education that defers to the local culture and wisdom.<sup>31,32</sup>

After introduction of FIT, the mean number of days between kit distribution and test result decreased by 3 days. These findings can be partially explained by the fact that FIT requires less fecal manipulation, fewer test samples, no dietary restrictions, is generally more

preferable to patients,<sup>7,33,34</sup> and is promoted by one-on-one education and patient navigation. It is also possible that the implementation of FIT specimen collection demonstration may have contributed to patient self-efficacy in performing the specimen collection and thus, the higher rates of compliance with FIT over gFOBT.

As with all studies, there were several limitations to this study. Two different sets of patients over two different time periods were compared to make generalizations about the relative differences in the two types of fecal-based CRC screening tests. Although there were statistically significant differences in demographic characteristics in those who screened with FIT versus gFOBT, these differences more likely reflect the environmental changes, program policy modifications, and fluctuations in the composition of the study population rather than true differences related to the test alone. It is also possible that the assumption of independence among multiple observations over time may have biased the findings.

During the study period, public service campaigns, such as Katie Couric's televised colonoscopy and a citywide program to increase colonoscopy screening launched by the New York City Department of Health and Mental Hygiene,<sup>35</sup> heightened public awareness of CRC and may have increased the demand for CRC screening during the study period. In addition, in 2008, the U.S. Preventive Services Task Force issued a recommendation endorsing the use of high-sensitivity tests such as FIT to screen for CRC.<sup>5</sup> Although these historic events contributed to overall CRC screening in New York City over the study period, many of these efforts were primarily aimed at insured populations, guiding those with medical coverage to seek out colonoscopy at hospitals through referrals made by their primary care providers.

The population served by NMCSP is primarily a disadvantaged, Hispanic, and Asian population, which may limit the generalizability of these findings to other settings and persons of other cultural backgrounds. Some patients had previously screened for CRC using gFOBT and may have been more amenable to adopting FIT; however, this is unlikely to impact the findings of higher test positivity and greater adenoma detection with FIT.

This study is also limited in that data were collected by the NYSDOH for administrative reasons, not research. For example, although the system allowed and the program encouraged documentation of all distributed kits, this was not performed consistently by all sites. Thus, it was not possible to determine rates of screening by test type because it was not possible to identify all persons who were educated and given test kits but who refused to complete CRC screening.

Reasons for the shift in age at first screening with FIT over gFOBT is likely reflective of improved staffing levels after 2008 and more intense recruitment from the breast cancer screening arm of the program, where women are eligible for services at age 40 years and are captured for CRC screening as soon as they become age-eligible. Racial differences observed between the use of the two tests may be indicative of changes in program outreach efforts and availability of resources during the respective time frames. Because the studied patient population is highly transient and often lost to follow-up, examining adherence to fecal-based CRC screening over time was not possible.

## Conclusions

In population-based screening settings, fecal-based CRC screening is an effective method for early CRC detection and prevention among uninsured individuals who lack a usual source of care and have limited healthcare system access. The improved adenoma detection rate and greater number of screening tests over time favor the use of FIT over gFOBT for CRC screening among uninsured populations in northern Manhattan. Building upon these findings, future studies adjusting for different screening tests, multiple tests per person, and patient demographics would further increase the understanding of population-based CRC screening using fecal tests.

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**Table 1**

Demographic characteristics of uninsured, average-risk individuals aged  $\geq$  50 years obtaining fecal-based CRC screening, *n* (%)

	Total ( <i>n</i> =7,710)	gFOBT ( <i>n</i> =4,951)	FIT ( <i>n</i> =2,759)
<b>Age at first screening (years)</b>			
50–54	3,751 (48.6)	2,264 (45.7)	1,487 (53.9)
55–59	2,013 (26.1)	1,310 (26.5)	703 (25.5)
60–64	1,268 (16.4)	890 (18.0)	378 (13.7)
65	678 (8.8)	487 (9.8)	191 (6.9)
<b>Gender</b>			
Male	1,374 (17.8)	972 (19.6)	402 (14.6)
Female	6,336 (82.2)	3,979 (80.4)	2,357 (85.4)
<b>Race</b>			
Asian	2,975 (38.6)	2,256 (45.6)	718 (26.0)
Black/African American	858 (11.3)	414 (8.4)	444 (16.1)
White	2,139 (27.7)	922 (18.6)	1,217 (44.1)
Other	1,739 (22.4)	1,359 (27.4)	380 (13.8)
<b>Ethnicity</b>			
Hispanic	3,486 (45.2)	2,065 (41.7)	1,421 (51.5)
<b>Nativity</b>			
Foreign born	6,824 (88.5)	4,449 (89.9)	2,375 (86.1)

*Note:* Other race includes American Indian, Alaskan Native, Native Hawaiian, Pacific Islander, more than one race, and others.

CRC, colorectal cancer; FIT, fecal immunochemical testing; gFOBT, guaiac-based fecal occult blood testing

**Table 2**

Characteristics of CRC screening using fecal-based tests, *n* (%) unless otherwise noted

	<b>gFOBT (<i>n</i>=7,209) 1998–2006</b>	<b>FIT (<i>n</i>=4,280) 2006–2010</b>	<i>p</i>
<b>Test results</b>			<b>&lt;0.0001</b>
Positive	109 (1.5)	139 (3.2)	
Negative	7,100 (98.5)	4,141 (96.8)	
<b>Positive predictive value (%)</b>	27.5	28.1	0.92
<b>Completed colonoscopy after positive screen</b>	84 (77.1)	117 (84.2)	0.16
<b>Clinical findings</b>			0.08
Colorectal cancer <sup>a</sup>	6 (7.1)	2 (1.7)	
Adenomatous polyps	24 (28.6)	37 (31.1)	
Non-neoplastic findings <sup>b</sup>	54 (64.3)	80 (67.2)	
<b>Adenoma detection rate</b>	24 (11.8)	37 (18.2)	<b>0.002</b>

Note: Boldface indicates statistical significance.

<sup>a</sup>gFOBT: 6 CRC/9 years = 0.67 CRC per year versus FIT: 2 CRC/4 years = 0.50 CRC per year

<sup>b</sup>Inflammatory bowel disease, hemorrhoids, other benign findings, and diverticular disease CRC, colorectal cancer; FIT, fecal immunochemical testing; gFOBT, guaiac-based fecal occult blood testing