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Free Fecal Immunochemical Test Disbursement in Eight Family Physician Offices

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Abstract

Colorectal cancer (CRC) is the second leading cause of cancer death. CRC screening with a fecal immunochemical test (FIT) is important as occult blood may be detected. To offer Iowa Research Network members in family physician offices the opportunity to provide FITs at no charge to patients in need and determine how many of the tests would be handed out to patients and how many would be returned to the office. Eight family physician offices agreed to participate and 50 two-day FITs were provided, potentially providing 400 patients a CRC screening test. One hundred and eighty (45 %) of the 400 FITs were handed out to patients. Of the 92 (51 %) patients who returned at least one card, 77 (84 %) had negative results, 13 (14 %) were positive, and 2 (2 %) were indeterminate. Of 13 patients with a positive result, 11 (85 %) had a follow-up colonoscopy. Providing 400 FITs at no charge to the offices was an expensive endeavor. Implementing this forced a change in office routine and the type of fecal occult blood test used. Less than half of the FITs were given out to patients and of those given out, about half of the patients returned a FIT. For those who returned FITs and had positive findings, 85 % followed-up with a colonoscopy. Office nurses implementing the CRC screening need to be included in the planning of the type of fecal occult blood test used and receptive to the project

Keywords

Fecal immunochemical test; Fecal occult blood test; Colorectal cancer screening

Introduction

Colorectal cancer (CRC) screening, both organized and opportunistic,[1] has become increasingly more common, since there are many types of screening tests available and CRC is the second leading cause of cancer death.[2] National guidelines promote any of several tests for CRC screening, including tests that pick up occult bleeding and endoscopic tests that visualize all or part of the colon.[3-5] For CRC screening campaigns, financial and manpower resources need to be taken into consideration. As such, the cascade CRC

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screening guidelines suggest that the type of fecal occult blood test (FOBT) for CRC screening must be considered and reflect the needs of the community, including other health care priorities. The screening approach offered is dependent on the available resources.[6]

In the U.S., a goal of the Centers for Disease Control and Prevention's (CDC) Colorectal Cancer Control Program (CRCCP) is to increase CRC screening prevalence to 80% which in turn would reduce CRC incidence and mortality.[7,8] To meet this goal, in 2009 the CDC funded the CRCCP for a 5-year period through a competitive application process where initially 22 states and 4 tribal organizations were funded for a total of \$22.5 million.[7,9] The main goals for funding were to provide screening for low-income, underinsured persons and promote CRC screening through public health. The Iowa Department of Public Health is an organization that received this funding and has a well-established program, Iowa Get Screened (<http://www.idph.state.ia.us/IGS/>). Currently, there are eight sites (county health departments/community health centers) in Iowa that offer the CRCCP for free or low cost screening fecal immunochemical test (FIT) or colonoscopy when appropriate.

As such, many agencies/organizations are involved in educating individuals about screening and are offering FOBTs, using either a guaiac (gFOBT) or fecal immunochemical test (FIT). [10] The newly emerging FITs are popular, as only one or two stool specimens are needed and there are no dietary or medication restrictions.[11-13] Another strong incentive for using these gFOBTs or FITs is that they are Clinical Laboratory Improvement Amendments (CLIA)-waived and can be used at the point-of-care. The fecal immunochemical test detects the globin component of hemoglobin, rather than the heme component.[11] It is highly specific for occult lower gastrointestinal bleeding, since globin is largely degraded by upper gastrointestinal enzymes. Using a one-, two-, and three-day FIT with 75 ng/ml fecal Hb threshold, researchers found the three-day test methods showed 92% sensitivity and 89% specificity for colorectal cancer, with lower percentages for the one-day test and two-day tests, at 77%/93% and 92%/91% respectively.[11]

Through a National Institutes of Health grant, a community infrastructure program was funded with the support of the Blinded, Department of Family Medicine, the Blinded (Blinded), a practice-based research network, and the University of Iowa Holden Comprehensive Cancer Center in collaboration with the Iowa Cancer Consortium. These collaborating entities developed a comprehensive program that provided the infrastructure to support community-based, cancer control research across Iowa. During this endeavor, nine four-hour training sessions and 18 "Lunch and Learns" at primary care offices were arranged for IRENE members and potential new members. Forty-two healthcare providers participated in the infrastructure program learning about CRC screening and the various types of FITs. These participants were offered the opportunity to receive 50 free patient mailers and supplies for a two-day FIT. The purposes of this study were to assess: 1) the number of FITs that would be given to patients, and 2) the return rate of the FITs. We also estimated costs of the project.

Methods

After Institutional Review Board approval, a fax describing the study was sent to the 42 participants of the infrastructure grant. The fax described the project and contained the following information: “We would like to offer you the opportunity to provide the two-day fecal immunochemical test (FIT) to 50 of your patients who are unable to afford the test. The tests and control solution will be provided at no charge to your office. However, your office will be responsible for developing the tests (they are CLIA-waived and thus can be developed in your office).”

In late November 2012, the faxes were sent with a request for response within three weeks if an office was interested in participating. Funding for all 42 offices was not available, but everyone was offered the opportunity with the anticipation that not everyone would participate. By the deadline, eight offices agreed to participate and each office selected their site coordinator. Letters of agreement were received from the eight coordinators for the Institutional Review Board application.

Individual patient consent was not required, since patient health information was not linked with patient results. It was left to the office to follow-up positive FITs in their usual manner and to provide patients with their test results.

Fecal Immunochemical Test Used in the Study

FOBTs used in this study were FITs rather than guaiac tests. In previous research, this research team has used four different liquid-based FITs (Clearview ULTRA iFOB, Alere Clearview iFOB, Complete Polymedco OC-Light iFOB, and Quidel QuickVue iFOB). [14-17] Finding problems while using these products and a review of the literature led us to realize that delayed mailing[18] and warmer weather potentially leads[19,20] to breakdown in hemoglobin (thus potentially more false negative samples) in liquid-based vials. Thus, we chose a dry-slide FIT, the Beckman/Coulter Hemocult ICT. The Beckman/Coulter Hemocult ICT requires a Collection Card, a Test Device, and buffer.

Beckman/Coulter provides a Hemocult ICT patient mailer for one-day sample, two-day sample, or three-day sample. Based on the research literature and that a one-day FIT often misses sporadically bleeding polyps that are a precursor to colon cancer, a two-day FIT was chosen.[21,22] A leading cancer authority, the American Cancer Society, recommends multiple-day colon cancer screening over one-day tests.[8]

The eight family medicine offices were provided 50 two-day patient FIT mailers, 100 Test Devices for the returned stool specimens, 12 additional Test Devices for use with the control solution, and four vials of negative and positive control solution. The mailer housing the material for patients had instructions on how to obtain the stool sample, two Collection Cards, two collection tissues (rice paper), two applicator sticks, and a return postage-paid biohazard mailer.

The 50 FIT mailers for each of 8 offices (400 total) were purchased and labeled with an identification number. Stamps (\$0.64/mailer) were applied to the return biohazard mailer so

the patient would have no cost and the mailer was to be returned to the patient's family medicine office. A letter of consent, half-page questionnaire (with identification number) for the patient to complete, and postage-paid return envelope with the researcher's address were prepared with each patient mailer. Once each office's 50 patient mailers were prepared, they were sent as a group to the participating office.

The control solution and Test Devices were shipped directly to the office. The Test Devices were shipped with an ice pack, as they need to be refrigerated to maintain the expiration date on the box. The Test Devices purchased had an expiration date of 8/31/2014.

For each office, the two packages (4 vials; 2 positive/2negative) of control solution cost \$74.74, the 100 test cards cost \$799.60, the two-day test patient mailer cost \$116.25, and the stamps for the FIT mailer cost \$32 for a total of \$1,022.59. Supplies were mailed to the sites in March 2013. The total for the 8 participating offices was \$8,180.72.

Site Coordinator Education and Role

Each clinician agreeing to participate in the study selected a site coordinator to coordinate the provision of FITs to patients. Coordinators were either an office or nurse manager. Prior to sending FITs to each office, site coordinators were educated about the project over the telephone after being mailed written instructions. An instruction sheet with a CRC screening log was emailed and paper copy sent to all coordinators. The instructions indicated that anyone with a positive FIT should be recommended to have a colonoscopy and that a repeat FIT was not appropriate. Upon receipt of the instructions, JD telephoned each site coordinator and discussed the study procedures, use of the FITs and control solution, and tracking log. Opportunities for the product sales representative to present the product at the sites were offered and an online webinar video prepared by Beckman/Coulter about that product was also provided.

Detailed instructions were provided regarding storage of the Test Devices at the appropriate temperature of 2 (35.6F to 46.4F) to 8°C. Once opened the control solution needed to be kept refrigerated and was good for only 30 days. Original plans were to hand out the FITs within two months so only a two-month supply of control solution was provided. As the study progressed and FITs were not handed out within a two-month period, additional control solution was purchased and sent to the offices as requested.

The CRC screening log included the subject identification number, first FIT card result (negative/positive/invalid), second FIT card result (negative/positive/invalid), and follow-up colonoscopy (yes/no). The site coordinator kept the log during the time period of the study. At the end of the study the log was returned to the research team. Each office was to keep track of patients who received FITs. No patient identifying information was kept on the logs.

Instrument

A four-item questionnaire was included with the patient mailer for the patient to complete and mail in a second postage-paid envelope to the research team. The questions included

birth year, gender, zip code, and total family income. Family income had four answer choices: <\$30,000, \$30,000 to \$40,000, \$40,001 to \$50,000, and > \$50,000.

Participating Offices

Of the eight participating offices, one was located in South Dakota and the others were located in Iowa. They varied in number of providers, affiliation, and city population (See Table 1). Each of the offices had at least one primary care provider who was interested in the study. Three of the providers had been participating in the Blinded research since its inception in 2001. The others were new to the Blinded. Two of the offices were Federally Qualified Health Centers.

Data Analysis

Questionnaire responses were double-entered in Microsoft Excel and verified using a SAS program. Descriptive statistics, such as means and frequencies were calculated. Chi-square was conducted to compare age groups, gender, income, and rural/urban living setting.

Age categories were generated for two groups; those less than 60 years and those 60 years and older. Patient reported zip codes were matched with the Rural-Urban Commuting Area Codes (RUCA) kept on the U.S. Department of Agriculture Economic Research Service's web site (<http://depts.washington.edu/uwruca/>). RUCA is a census tract-based classification scheme that utilizes the standard Bureau of Census Urbanized Area and Urban Cluster definitions in combination with work commuting information to characterize all of the nation's census tracts regarding their rural and urban status and relationships. Zip codes were matched to RUCA codes and collapsed 1 through 6 as urban and 7 through 10 as rural.

Results

Having planned for a two-month project to start in April 2013, it was anticipated the study would be completed by June 2013. After contacting site coordinators in early June, a decision was made to extend the study, as very few of the FITs had been handed out and only 13 questionnaires from patients had been received by the researchers. The study was concluded the end of November and 180 (45%) of the 400 FITs had been handed out to patients.

Of those 180 FITs handed out to patients, 87 (48%) returned both cards and 5 (3%) returned one card. Thus, 92 (51%) patients returned at least one FIT card and of these patients, 77 (84%) had negative results, 13 (14%) were positive, and 2 (2%) were indeterminate. Of the 13 patients with positive results, 11 (85%) had a follow-up colonoscopy (See Table 2).

Of the 11 patients with follow-up colonoscopy, five colonoscopy results were provided to the research team without request or being part of the study. Of these five colonoscopy results, three had no concerning polyps and two had concerning polyps. One had five tubulovillous and serrated adenomas (size not noted) and another had a large proximal ascending sessile clam shell polyp (attempted polypectomize and not totally successful).

Unfortunately, we did not set up the study to be able to collect results on all colonoscopies completed following positive results.

Seventy-nine (44%) of the 180 questionnaires attached to the FITs were returned by the patients. Participant's age ranged from 30 to 85 years and the mean age was 61 years. Thirty (38%) were male. Of the 71 patients reporting family income, 34(48%) had an income below \$30,000, 19 (27%) had income of \$30,000 to \$50,000, and 18 (25%) had income greater than \$50,000. Of the 74 reporting zip code, 38 (51%) lived in a rural area.

No significant difference was found in FITs returned by age group (those less than 60 years and those 60 years and older), gender, or rural/urban living setting. Percent distribution by income was 35% for those less than \$30,000, 19% for those \$30,000 to \$40,000, 10% for those \$40,001 to \$50,000, and 35% for those whose income was greater than \$50,000.

Discussion

This study offered the opportunity for eight family physician offices to provide CRC screening with a FIT to patients with low financial resources. Unfortunately, less than half of the FITs provided the offices were given to patients. This was disappointing, since it is known healthcare providers recommendation of CRC screening enhances compliance with screening.[23,24]⁴ In previous research, we found that screening rates using FIT were about 48% with a mailed FIT to patients due for screening and a 79% return when handed out to persons in a low-income population.[10,14] Our results are similar to other studies which found about half of the patients return a one-day FIT.[14,25,26] In this study, half of the patients receiving a two-day FIT returned the FIT which is a good return rate. In spite of the proven efficacy of CRC screening with FOBT, rates of use by average-risk persons remains low compared to other cancer screenings. Data from the CDC's cancer registries demonstrates that 88% women were current with a Pap test, 81% were current with a mammogram, whereas only 62% of adults were current with colorectal screening.[27]

The chance to hand out FITs to patients in the offices in this study was opportunistic rather than organized.[28] In an organized approach, various office systems would be in place, such as: 1) an office policy for specified age categories, method, and interval for screening, 2) a defined target population, 3) a management team responsible for the implementation, and 4) a health care team responsible for decisions and care.[28] Implementing this intervention was a change for the practice with a different FOBT being offered. Thus, office staff had to potentially learn about a new test and explain this to patients, as well as learn how to develop it. Similar to this study, many recipients of the Colorectal Cancer Control Program found it challenging to work with providers with limited time and overburdened practices.[7] Offices lost interest over time and had to be encouraged to give patients the FITs and maintain the tracking log.

Use of two-day FITs with a collection card may have been a barrier to participating in this study. Previous research has shown that patients prefer the tube with probe collection method rather than a stick with the collection card as used in this study.[29,30] Fortunately for those who returned FITs and had positive findings, 85% followed-up with a

colonoscopy. Participating offices were not asked to provide colonoscopy results, but five de-identified results were sent to the researchers. Those colonoscopy results indicated that the CRC screening was successful in finding some patients with pre-cancerous polyps.

Improved CRC survival is attributable to diagnosis and treatment of CRC, but also to screening for CRC, which ideally identifies pre-cancerous polyps. A great deal of time went into choosing an appropriate FIT product. Only CLIA-waived FITs were considered, so that offices were not dependent on a pathology laboratory or purchase of an expensive analyzer. A non-liquid based FIT, the Beckman/Coulter Hemoccult ICT, was chosen in order to avoid potential problems with hemoglobin degradation found with liquid-vial tests,[19] although it is not known for sure whether this is a concern in non-liquid based kits. Once the non-liquid based FIT was selected, the amounts of control solution and mailers needed for each office were determined. After the product brand was decided, the office site coordinator needed to be trained on how to use the product. When the project started, one of the eight offices did not offer FOBT to their patients. Even though this was a CLIA-waived test, offices were not used to this particular FOBT and had to change their normal way of providing fecal occult blood tests. Site coordinators were offered to have the sales representative present the FIT at their office or view an instruction video on a website. A limitation of the study was we did not track how site coordinators learned about using the product.

Offering 400 free FITs to eight primary care offices was an expensive endeavor at a cost of a little more than \$8,000, not including personnel costs at the Blinded or in the offices themselves. To have a little less than half of the FITs handed out in an eight-month time period was discouraging, although the caveat to provide them to persons in need was a component of the project and may have been a barrier to handing out the FITs in some offices. However, results indicate that at least half of the FITs were handed out to patients whose income was more than \$30,000/year. Fortunately, the product had a long shelf life and those who still have the FITs can hand them out but will need to continue purchasing control solution and testing the Test Device in a routine manner.

As with any community-based project, numerous requests from research staff to site coordinators were needed to obtain results. Even though the provider may have been enthusiastic, the site coordinators were the individuals responsible to implement and complete the project. In retrospect, it may have been useful to have a contract describing the project signed by the researchers, the interested provider, and the site coordinators. In addition knowing how and when the site coordinator learned about the product would have been beneficial. Even though site coordinators were instructed on when to use the control solution, it is unknown if that process occurred. This limitation that could have been avoided by having the coordinator record the control solution results on the tracking log.

Strengths of the study include that it was conducted in real world family physician offices where one of the offices had never been able to provide FOBTs to their patients. A mixture of patients living in rural and urban settings received the FITs. A limitation was that completed patient questionnaires were returned for whom a FIT result was not recorded on the tracking log.

This project was time-consuming, involved numerous personnel from each office, and caused a change in the office's current FOBT testing. Less than half of the FITs were given out to patients and of that group, half of the patients returned the FIT. For those who returned FITs and had positive findings, 85% followed-up with a colonoscopy. The CRCCPs are up against the same roadblocks and will have much time and effort expended in this commitment to get persons screened for colorectal cancer. Unfortunately, colorectal cancer is an ongoing problem and normal at-risk persons will always be turning age 50 years and need to be screened. Dedicated governmental agencies, state agencies, and family physician offices need to be aware of and promote screening.

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Table 1
Type of Clinic with Number of Providers and City Population

Office ID	City Population	Type of Clinic	Providers
1	7,834	Family practice clinic is located on the campus of a regional medical center.	6
2	1,486	Medical clinic affiliated with a regional health center	4
3	10,103	1 of 10 physician owned multi-specialty clinics in Iowa	10
4	2,850	1 of 3 clinics affiliated with a hospital	8
5	203,433	Federally qualified health center serving migrant and seasonal farmworkers	3
6	1,963	Federally qualified health center	2
7	6,798	Family practice clinic	1
8	33,217	Women's health clinic	3

Table 2
Number of FITs Given to Patients, Number FITs and Questionnaires Returned, Gender, Mean Age of Participants and Follow-up Colonoscopies

Office ID	FITs Given Out n (%)	FITs Returned n (%)	Questionnaires Returned n (%)	Mean Age (yrs)	Male Gender n (%)	Follow-up Colonoscopy n (%)
1	9 (18)	5 (56)	5 (56)	57	2 (40)	Not applicable
2	17 (34)	7 (41)	5 (29)	66	1 (20)	4 of 6
3	38 (76)	21 (55)	4 (11)	66	1 (20)	4 of 4
4	40 (80)	19 (48)	26 (65)	65	9 (35)	2 of 2
5	29 (58)	14 (48)	26 (90)	55	15 (58)	No applicable
6	14 (28)	10 (71)	5 (36)	61	1 (20)	1 of 1
7	13 (26)	4 (31)	2 (15)	60	1 (50)	Not applicable
8	20 (40)	12 (60)	6 (30)	66	0	Not applicable