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Use of Fecal Immunochemical Tests in the Iowa Research Network

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Abstract

Although the fecal immunochemical test (FIT) has recently emerged as an effective and affordable colorectal cancer screening option, many family physician offices continue to use guaiac-based tests. The purpose of this study was to assess the use of FITs in the blinded and to assess physicians' knowledge about FITs. A cover letter and questionnaire were faxed twice to the 291 physician members followed up by a mailing. One hundred and seven (37%) questionnaires were returned. Participants' mean age was 55 years with 78 male responders. Fifty-two (49%) of the physician's offices were in a non-metro area. Fifty-one (49%) reported using guaiac-based tests and 39 (39%) reported using FITs. Many physicians were unsure of the answers for the FIT knowledge questions. FIT use is not widespread in blinded physician offices, and not all physicians are aware of the type of fecal occult blood test being conducted in their office.

The fecal occult blood test is a relatively inexpensive method for conducting colorectal cancer (CRC) screening. Guaiac-based tests or fecal immunochemical tests (FIT) are the two types of available fecal occult blood tests. The U.S. Preventive Services Task Force suggests one acceptable screening strategy is annual screening with a sensitive fecal occult blood test, reserving colonoscopy for those with positive tests or at high risk for colon cancer [1].

Guaiac-based tests were introduced in the early 1900s [2], and Medicare began reimbursement for the tests in 1998. The FIT was developed in the 1970s [3], with Centers for Medicare and Medicaid Services initiating reimbursement in 2004. Colorectal cancer (CRC) is the second [4] leading cause of cancer death in the U.S., yet it is estimated that 60% of colorectal cancer cases could be prevented with appropriate screening [5]. CRC screening allows for the detection and treatment of precancerous polyps and cancer in its earliest stages, which results in high cure rates. However, despite available tests, over one-third of adults 50 and older are not adherent with CRC screening guidelines [6].

Guaiac-based tests are noticeably different from FITs. The main difference between the two is in the performance characteristics. The FIT detects the globin molecules in hemoglobin,

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rather than the heme molecule assayed by guaiac-based tests [7]. FIT is highly specific for occult lower gastrointestinal bleeding, as globin is largely degraded by upper gastrointestinal enzymes [7]. Adherence with FITs is generally higher than adherence to guaiac-based fecal occult blood tests [8, 9].

In a recent study comparing the Beckmann Coulter Hemocult ICT FIT with a guaiac-based test, results indicated the FIT had higher sensitivity and specificity for detecting left-sided colorectal cancer and concluded that the FIT may be a useful replacement for guaiac-based tests [10]. Using three stool samples, the automated FIT (OC-SENSA MICRO) has shown better performance characteristics than guaiac-based (Beckman Coulter Hemocult II) tests for detecting advanced colorectal neoplasia [7]. The guaiac-based test sensitivity and specificity were 14%/92% for detecting advanced adenomas, 31%/92% for cancer, and 17%/93% for advanced colorectal neoplasm, compared to FIT sensitivity and specificity at 34%/91% for detecting advanced adenomas, 85%/90% for cancer, and 44%/92% for advanced colorectal neoplasm [7].

Findings from 1266 physicians responding to the 2006–07 National Survey of Primary Care Physicians' Recommendation and Practices for Breast, Cervical, Colorectal, and Lung Cancer Screening indicated that 80% recommend fecal occult blood testing [11]. Among those 1134 primary care physicians who reported ordering or performing fecal occult blood testing in the 2006–07 survey, 22% used the higher-sensitivity guaiac tests and 9% used fecal immunochemical tests [12]. Although the FIT has recently emerged as an effective and affordable CRC screening option, many family physician offices continue to use guaiac-based tests. The purpose of this study was to assess the use of FITs in the blinded (blinded) offices and to assess physicians' knowledge about FITs. Blinded is a primary care practice-based research network with 291 participating physicians in 179 offices located in 71 Iowa counties whose mission is to create new knowledge and improve clinical practice, especially in rural communities.

Methods

Institutional review board approval was obtained for this study. Study design was a faxed/mailed questionnaire. Return of completed questionnaire implied consent.

The one-page, 12-item questionnaire was developed by the researchers and included the following items: use of guaiac-based tests, name of guaiac-based test, number of stool specimens for guaiac-based test requested of patient, use of FIT, name of FIT, number of stool specimens for FIT requested of patient, development of test in office, four knowledge questions, and whether the office has tracking system for the tests. The knowledge questions included sensitivity and specificity for cancer by FIT, dietary and medication restrictions warranted for FIT, and the component of hemoglobin molecule used for conducting FIT. The questionnaire was piloted by five Department of Family Medicine research faculty.

A cover letter and questionnaire were faxed to the 291 blinded physician members in June 2012. Two weeks later, a duplicate cover letter and questionnaire were faxed to the non-responders. Two weeks after that, the cover letter, questionnaire, and a postage-paid return envelope were mailed to non-responders. Each questionnaire had an identification number to document returned questionnaires. Potential subjects were advised that participation was voluntary and that they could opt out of the study by returning a blank questionnaire by fax or in the postage-paid return envelope.

Data analysis

To test for significant differences between responders and non-responders, gender and office location (metro/non-metro) were compared by using Pearson chi-square tests, and age was compared using a two-tailed independent samples t-test.

The distributions of answers to each of the four completed knowledge questions were independently compared by whether a physician worked in a metro or non-metro area and by whether or not a physician utilized FITs. Physicians not using any fecal occult blood tests, those not reporting using FITs, and those listing a guaiac test as a FIT were grouped together as not using FITs. A physician could answer a knowledge question with “True,” “False,” or “Don’t Know,” but for the comparisons, “False” and “Don’t Know” were collapsed into one category, making the response to each question a dichotomous variable. Age and sex were considered potential confounders of the relationship between knowledge question response and office location or FIT use, so logistic regression was used to determine if models containing both of the potential confounders had appreciably changed odds ratios for the relationships between question response and office location or FIT use, as compared to models without them. No evidence was found to consider age or sex confounders, and there was no indication that fitting multiple regression models with both office location and FIT use as covariates would be useful for interpretation, so comparisons were simplified to eight Pearson chi-square tests. The Bonferroni correction was used to account for the multiple testing that resulted from these comparisons.

As with most questionnaires, not every participant provided answers to all questions, so for the proportions used to describe the sample’s responses, any missing data was removed from the denominator used for calculation and none of the questions utilized to calculate these proportions had more than seven missing responses (mean 3.9 missing responses per question). All tests were evaluated for significance at $\alpha = .05$ unless otherwise noted.

Results

Of 291 questionnaires sent, 107 usable questionnaires were returned, a 37% return rate. Seventy (24%) were returned after the first fax, 11 (4%) were returned after the second fax, and 31 (11%) were returned by mail. Participants’ mean age was 55 years with an age range of 32 to 78 years, with 78 (73%) male responders. Fifty-two (49%) of the physician’s offices were in a non-metro area.

Comparing the blinded non-responders ($n = 184$) to responders ($n = 107$) showed no significant differences by gender ($p = 0.547$, non-responders 70% male, responders 73% male) or office location ($p = 0.759$, non-responders 47% non-metro, responders 49% non-metro). Mean age of responders was 55.33 years (95% CI 53.69 to 56.96) and significantly different ($p < 0.001$) from non-responders who had a mean age of 51.07 years (95% CI 49.73 to 52.40).

Fifty-one (49%) reported using guaiac-based tests, one physician was unsure. One physician reported requesting one stool sample and 48 (98%) reported requesting three stool samples for guaiac-based tests. The guaiac-based tests stated as used by physicians were Beckman Coulter, Beckman Coulter Hemocult, Beckman Coulter Hemocult II, Clearview, Colocare, ColoScreen Helena Laboratories, EZ Detect Biomerica, Green Card One, Hema Screen Immunostics, Hemocult, Hemocult Sensa, and Propper Serocult. The most commonly listed test was the Beckman Coulter Hemocult, used by 14 physicians. Thirteen did not list the type of guaiac-based test used.

Thirty-nine (39%) reported using FITs, and three physicians were unsure. Twenty-two (58%) physicians reported requesting one stool sample, five (13%) reported requesting two stool samples, and 11 (29%) reported requesting three stool samples. The FITs used were described as Check OC Polymedco, Colocare Helena Laboratories, HemaScreen Immunostics, Hemasure, Hemoccult ICT, Hemoccult II SENSE, Quidel iFOB, Insure, and QuickVue Quidel. The most commonly used test was the Polymedco FIT, by 6 physicians. Nine did not list the type of FIT used.

Seventeen (16%) reported not using either a guaiac-based test or FIT in their office, 9 (8%) reported using or not using one type but did not provide a response regarding the other, 84 (79%) reported using at least one type, and 6 (6%) physicians reported using both types. Of those six, two physicians reported both a guaiac-based and FIT name; two listed only a guaiac-based test; one listed a guaiac-based test for both categories; one listed no guaiac-based test and listed a guaiac-based test for the FIT name.

Seventy-eight (77%) of the physicians reported that the fecal occult blood test is developed in their office. Forty (39%) indicated that they have a system in place to track which patients are given a fecal occult blood test and if they complete the test annually.

Seventy-one (68%) of the physicians correctly stated that dietary restriction is not necessary in preparation for collecting a FIT stool sample. Many physicians were unsure of the answers for the FIT knowledge questions (See Table 1). By comparing the group of 39 (36%) physicians classified as using FITs with those 68 (64%) physicians who were not, significant differences ($\alpha = .0125$) in knowledge about the FIT were found (See Table 2). Those physicians using FITs correctly answered the questions about increased sensitivity/specificity and dietary and medication restrictions more often than those not using FIT. No knowledge difference was noted between the groups regarding the heme and globin component for determining occult blood differences in guaiac-based tests and FITs.

By comparing the group of 55 (51%) physicians classified as having an office in the metro area with those 52 (49%) physicians who had an office in the non-metro areas, significant difference ($\alpha = .0125$) in knowledge about the FIT was found (See Table 3).

Discussion

In this study of family physicians in Iowa, of the 84 physicians using fecal occult blood tests, more than half still use a guaiac-based test. Thirty-nine percent of the responding physicians used FIT, compared to only 9% reporting FIT use in the 2006–07 National Survey of Primary Care Physicians' Recommendation and Practices for Breast, Cervical, Colorectal, and Lung Cancer Screening [12]. Physicians using a guaiac-based test or not using any fecal occult blood tests were not current with FIT information, which may indicate why they have not transitioned to the newer fecal occult blood test. Physicians in large medical centers have pathology laboratories and the expertise of pathologists to guide them in their use of fecal occult blood tests, whereas physicians in solo or rural practices may not have that added expertise and advice.

Fecal occult blood test product names are confusing. Physician responses describing the product names were diverse and unclear, as some gave the manufacturer's name and no product name or referred to the test as a guaiac test. As noted, 22 physicians did not list the name of their fecal occult blood test and several did not know what type or brand of fecal occult blood test is used in their office. It is presumed that physicians should know all the different types of tests conducted in their office and their corresponding test characteristics.

Noted in the response list of guaiac-based tests was a FIT; and the FIT list included guaiac-based tests. The main products being used by the responding physicians were from Beckman Coulter Company, which has provided fecal occult blood tests for more than 40 years. An initial Beckman Coulter product was the Hemocult test, which was superseded by the Hemocult II SENSE, an enhanced Hemocult product that provides improved readability and higher clinical sensitivity. Beckman Coulter also provides a FIT called Hemocult ICT.

There are several limitations to this study, including a low response rate. All physicians were part of the Iowa Research Network, limiting the geographic area surveyed. The cost of the two types of fecal occult blood tests was not addressed. FITs cost more to purchase than guaiac-based tests. For example, for a recent pilot study 20 liquid-vial FITs and testing cassettes were purchased at \$333, while 20 dry-slide cards and test cassettes were purchased for \$132. In addition, a patient's postage expense to return a liquid-vial test is four times that of a dry-slide card.

Another limitation is that the type of FIT used, either manual or automated, was not asked of the physicians. In larger medical centers FITs can be analyzed by a machine, compared to being manually read by a healthcare provider. In addition, physicians were not asked which type of guaiac-based test, dry-slide or test pad in the toilet, was used. Most guaiac-based tests are read in the office after pouring the test solution on the paper, but others are read by the patient after placing the test pad in the toilet water after defecation. Two physicians did report using the test pad in the toilet, which is not approved by the American Cancer Society, as scientific evidence of its accuracy has not been documented [4].

In conclusion, FIT use is not widespread in blinded physician offices, and not all physicians are aware of the type of fecal occult blood test being conducted in their office. However, through a research infrastructure grant award, education sessions have been provided to blinded office staff regarding the newer fecal occult blood tests.

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References

1. U.S. Preventive Services Task Force. Screening for colorectal cancer: U.S. preventive services task force recommendation statement. *Ann Intern Med.* 2008; 149(9):627–637. [PubMed: 18838716]
2. Irons GV Jr, Kirsner JB. Routine chemical tests of the stool for occult blood: An evaluation. *Am J Med Sci.* 1965; 249:247–260. [PubMed: 14273312]
3. Songster CL, Barrows GH, Jarrett DD. Immunochemical detection of fecal occult blood--the fecal smear punch-disc test: A new non-invasive screening test for colorectal cancer. *Cancer.* 1980; 45(5 Suppl):1099–1102. [PubMed: 6965607]
4. American Cancer Society. Colorectal cancer facts & figures 2011–2013. Colorectal Cancer Facts & Figures Web site. <http://www.cancer.org/acs/groups/content/@epidemiologysurveillance/documents/document/acspc-028323.pdf>. Accessed 28 September 2011.
5. Centers for Disease Control and Prevention (CDC). Screen for life: Colorectal cancer, basic facts on screening, publication #99-6949. http://www.cdc.gov/cancer/colorectal/pdf/Basics_FS_Eng_color.pdf. Accessed 5 June 2012.
6. Centers for Disease Control and Prevention (CDC). Colorectal cancer screening saves lives. Centers for Disease Control and Prevention Web site. <http://www.cdc.gov/Features/VitalSigns/CancerScreening/>. Accessed 23 July 2012.
7. Park DI, Ryu S, Kim YH, et al. Comparison of guaiac-based and quantitative immunochemical fecal occult blood testing in a population at average risk undergoing colorectal cancer screening. *Am J Gastroenterol.* 2010; 105(9):2017–2025. [PubMed: 20502450]

8. Birkenfeld S, Belfer RG, Chared M, et al. Factors affecting compliance in faecal occult blood testing: A cluster randomized study of the faecal immunochemical test versus the guaiac faecal occult test. *J Med Screen*. 2011; 18(3):135–141. [PubMed: 22045822]
9. Wilschut JA, Hol L, Dekker E, et al. Cost-effectiveness analysis of a quantitative immunochemical test for colorectal cancer screening. *Gastroenterology*. 2011; 141(5):1648–55. [PubMed: 21784045]
10. Allison JE, Sakoda LC, Levin TR, et al. Screening for colorectal neoplasms with new fecal occult blood tests: Update on performance characteristics. *J Natl Cancer Inst*. 2007; 99(19):1462–1470. [PubMed: 17895475]
11. Klabunde C, Lanier D, Nadel MR, McLeod C, Yuan G, Vernon SW. Colorectal cancer screening by primary care physicians: Recommendations and practices, 2006–2007. *Am J Prev Med*. 2009; 37(1):1–7. [PubMed: 19423273]
12. Nadel MR, Berkowitz Z, Klabunde CN, Smith RA, Coughlin SS, White MC. Fecal occult blood testing beliefs and practices of U.S. primary care physicians: Serious deviations from evidence-based recommendations. *J Gen Intern Med*. 2010; 25(8):833–839. [PubMed: 20383599]

Table 1FIT Knowledge Questions and Answers ($N = 107$).

	True^a No. (%)	False No. (%)	Unsure No. (%)
FIT has higher sensitivity and specificity for detecting CRC than guaiac. ($n = 104$)	65 (63)	2 (2)	37 (36)
Dietary restriction is not necessary before collecting FIT stool sample. ($n = 105$)	71 (68)	6 (6)	28 (27)
Medication restriction is not necessary before collecting FIT stool sample. ($n = 105$)	63 (60)	8 (8)	34 (32)
FIT detects globin component rather than heme as guaiac detects. ($n = 103$)	45 (44)	2 (2)	56 (54)

^aThe correct answer to all questions was "True."

Table 2

Comparison of FIT Knowledge Between Users and Non-users of FIT.

	Uses FIT in Office		Doesn't Use FIT in Office		p-value ^b
	True ^a No. (%)	False No. (%)	True ^a No. (%)	False No. (%)	
FIT has higher sensitivity and specificity for detecting CRC than guaiac. (uses FIT <i>n</i> = 39; doesn't use FIT <i>n</i> = 65)	33 (85)	6 (15)	32 (49)	33 (51)	<0.001 *
Dietary restriction is not necessary before collecting FIT stool sample. (uses FIT <i>n</i> = 39; doesn't use FIT <i>n</i> = 66)	36 (92)	3 (8)	35 (53)	31 (47)	<0.0001 *
Medication restriction is not necessary before collecting FIT stool sample. (uses FIT <i>n</i> = 39; doesn't use FIT <i>n</i> = 66)	35 (90)	4 (10)	28 (42)	38 (58)	<0.0001 *
FIT detects globin component rather than heme as guaiac detects. (uses FIT <i>n</i> = 39; doesn't use FIT <i>n</i> = 64)	20 (51)	19 (49)	25 (39)	39 (61)	0.225

^aThe correct answer to all questions was "True."

^b*a* = .0125

* = Significant

Table 3

Comparison of FIT Knowledge Between Physicians in Metro and Non-metro Offices.

	Metro		Non-metro		p-value ^b
	True ^a No. (%)	False No. (%)	True ^a No. (%)	False No. (%)	
FIT has higher sensitivity and specificity for detecting CRC than guaiac. (metro <i>n</i> = 53; non-metro <i>n</i> = 51)	35 (66)	18 (34)	30 (59)	21 (41)	0.447
Dietary restriction is not necessary before collecting FIT stool sample. (metro <i>n</i> = 53; non-metro <i>n</i> = 52)	42 (79)	11 (21)	29 (56)	23 (44)	0.010*
Medication restriction is not necessary before collecting FIT stool sample. (metro <i>n</i> = 53; non-metro <i>n</i> = 52)	37 (70)	16 (30)	26 (50)	26 (50)	0.038
FIT detects globin component rather than heme as guaiac detects. (metro <i>n</i> = 53; non-metro <i>n</i> = 50)	26 (49)	27 (51)	19 (38)	31 (62)	0.258

^aThe correct answer to all questions was "True."

^b*a* = .0125

* = Significant