

# Fecal Immunochemical Test as a Screening Method for Colorectal Cancer in University College Hospital Ibadan, Nigeria

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**PURPOSE** Colorectal cancer (CRC) is a disease of public health importance because of the increasing incidence of the disease and presentation in advanced stage of the disease in Western Africa. CRC is amenable to screening because of the long course of premalignant lesions before final development of the disease. Despite this, the practice of CRC screening is inadequate at the sites in this study. The fecal immunochemical test (FIT) is one of the recommended noninvasive methods for CRC screening. It has a sensitivity of 96%, specificity of 90%, and an overall accuracy of 95%. We aimed to determine the practicability of FIT for CRC screening in patients aged 40 to 75 years who attended primary care clinics in the University College Hospital, Ibadan, Nigeria.

**PATIENTS AND METHODS** A total of 422 patients selected by systematic random sampling were recruited and offered free FIT screening. Participants with a positive finding had additional GI examination, including a digital rectal examination, proctoscopy, and colonoscopy, if no lesion was biopsied during proctoscopy.

**RESULTS** The mean ( $\pm$  standard deviation) age of the respondents was  $62 \pm 9.61$  years. The prevalence of a positive FIT in the study was 10.1%. The FIT was not completed by 3.8% of patients, and the rate of completion of additional evaluation after a positive FIT reduced as the investigations became invasive, with 36.8% and 71.1% noncompletion rates for proctoscopy and colonoscopy, respectively.

**CONCLUSION** A FIT-based screening for age and risk-appropriate patients is practical in this environment, where the capacity and acceptability of colonoscopy are limited.

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## INTRODUCTION

The recommended strategies for colorectal cancer (CRC) screening fall into two broad categories: stool tests (ie, fecal immunochemical test [FIT], guaiac fecal occult blood test) and colonoscopy. Screening for CRC has been proven to greatly reduce mortality and may also prevent the onset of disease through the removal of precancerous polyps.<sup>1-3</sup> With specificity and sensitivity both  $> 90\%$ , FIT has been reported to detect adenoma and CRC.<sup>4</sup> It also has better participation and detection rates compared with the fecal occult blood test (FOBT).<sup>5,6</sup> The clinical presentation of CRC varies, but rectal bleeding is the most prominent of the quartet of typical signs and symptoms, including change in bowel habit, weight loss, and abdominal pain.<sup>7</sup> Rectal bleeding has a positive predictive value of approximately 8.1% for CRC and warrants immediate investigation irrespective of whether other symptoms are present, and more so when it occurs after the fifth decade of life.<sup>8</sup>

Most international bodies, including the US Preventive Services Task Force and those in the European Union,

recommend CRC screening for individuals at average risk who are between ages 50 and 75 years.<sup>9,10</sup> However, in Nigeria and other African countries, the average age at diagnosis of CRC is approximately 40 years; hence, screening from that age is needed.<sup>11-13</sup> Globally, CRC incidence in economically transitioning countries, including those in sub-Saharan Africa, is on the rise because of increased exposure to risk factors such as smoking, decreased physical activity, alcohol consumption, and inappropriate diet.<sup>14,15</sup> In Nigeria, there has been an increase in the incidence of colon cancer from 18.2 cases per annum in the precolonial era to 86.8 per annum between 1991 and 2007.<sup>16</sup>

Early recognition of colorectal cancer is critical because of the opportunity to intervene early; the stage of the tumor at presentation is an important prognostic factor for survival.<sup>11</sup> Unfortunately, in developing countries, many patients ( $\leq 88.7\%$ ) present with advanced-stage disease as a result of poor or no screening.<sup>11,17</sup> In a resource-limited country like Nigeria, a screening test such as FIT may increase the level of participation in CRC screening. Before the

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## CONTEXT

### Key Objective

Is fecal immunochemical test (FIT) applicable for colorectal screening in a resource-constrained environment?

### Knowledge Generated

FIT positivity was 10.1%. Though the acceptability of FIT was good in terms of test completion, further evaluation following a positive FIT was poor and acceptability of procedures reduced as invasiveness increased.

### Relevance

The study shows there is a need to make FIT kits available and to educate people more on the importance of follow-up evaluations after a positive FIT.

study, FIT screening kits were unavailable in our study center. And although colonoscopy was available, it was mostly used for diagnostic purposes and unaffordable to many, with a resultant decline in the screening practices of physicians, and patients were not routinely offered CRC screening. The prevalence of positive FITs is yet to be determined in our study center. We aimed to determine the proportion of patients with positive FIT results and the practicability of FIT screening in the study area.

## PATIENTS AND METHODS

The study population consisted of adult patients aged 40 to 74 years who attended general outpatient and geriatric clinics of the University College Hospital Ibadan. Approval of the Ethical Review Committee of the University of Ibadan (approval no. NHREC/05/01/2008A) was obtained. Departmental approval was obtained from the Head of Department of Family Medicine and the Geriatrics Center.

The sample size of 422 participants was calculated after adjusting for a 90% nonresponse rate using the Leslie Kish formula, with prevalence of 45%.<sup>18</sup> Patients who were asymptomatic and not up to date with their CRC screening irrespective of previous screening offers were recruited by systematic random sampling after informed consent was obtained. The procedure for FIT, possible outcome of the FIT, and the need for follow-up evaluations were explained. Patients with hematochezia, severe comorbidity, or who were acutely ill were excluded.

The general practice physical activity questionnaire<sup>19</sup> was used to assess the level of physical activity, and adequate fruit intake was described as consumption of five fruit servings per day. The stool collection was performed using the Accutest Immunochemical Chemical Test kit (item number CS625, lot number 1512206; Jant Pharmacal, Encino, CA). It was a single stool collection test that required patients to use an applicator to collect samples from six different parts of a single stool specimen; the applicator then is placed in a buffer solution. The patients were provided with a specimen collection hat. The patients were taught how to apply stool samples to the kit and were expected to return the test kit to the clinic within a maximum of

10 days after kit collection to limit the rate of forgetfulness and apathy that may occur if kit return is prolonged. Patients were asked to apply stool samples at 5 days before they plan to return the kit at the earliest, with an explanation provided on proper storage of the kit at room temperature. A reminder call was placed on the seventh day after FIT kit collection if samples had not been returned. The duration from collection to returning of the kit was noted, as was the reason for nonreturn of kits. The test was conducted immediately on return of kits and the result of the test and implication were made known to the patients. The test was a rapid, visually read, qualitative, immunochemical chromatographic method for detecting human hemoglobin from blood in fecal samples.

Patients with a positive FIT had underwent abdominal and rectal examinations and were referred for a surgical review. Proctoscopy was performed to evaluate if a rectal mass could be palpated or visualized and biopsied, because of the unaffordability of colonoscopy. Patients were offered a colonoscopy if no biopsy specimen was obtained during proctoscopy.

## RESULTS

Of the 3,450 patients seen in both clinics over 3 months, 422 who were not up to date with their CRC screening were recruited by systematic random sampling over the 3 months between December 2016 and the end of February 2017 after informed consent was obtained.

The male to female ratio of the participants was 1: 2.2; the mean ( $\pm$  standard deviation [SD]) age was  $62 \pm 9.61$  years. Of the 422 participants, 207 (49.1%) had tertiary-level education. The predominant body mass index categories were overweight and obese in 152 (36%) and 166 (39.2%) participants, respectively. Alcohol consumption was reported by 54 respondents (12.3%). Only two participants (< 1%) smoked cigarettes. The physical activity

**TABLE 1.** Prevalence of Positive FIT Among the Respondents

FIT Test Result	Frequency (No.)	% (N = 375)
Positive	38	10.1
Negative	337	89.9

Abbreviation: FIT, fecal immunochemical test.

level was low and most participants ( $n = 291$ ; 69%) were physically inactive. Approximately 77 (18%) had diabetes mellitus; a family history of CRC was reported in only five (1.2%).

### Proportion of Patients With Positive FIT Results Among the Screened Population

The prevalence of positive FIT results among the respondents was 10.1% ( $n = 38$ ); most respondents had negative test results ( $n = 337$ ; 89.9%; Table 1). Of 422 participants, 47 (11.1%) did not return their test kits.

### Noncompletion of FIT Test

Sixteen respondents returned the test kits without stool samples and were replaced by other participants selected by systematic random sampling. Reasons given for non-completion included to manage index illness before CRC screening ( $n = 3$ ), discouragement from friends and family members ( $n = 8$ ), and no reason ( $n = 5$ ).

A total of 47 participants (11%) did not return their kits and attempts to collect from their home was unsuccessful. The participants who were lost to follow-up mostly were women and had a tertiary level of education, which may be a reflection of the population recruited. No statistical significance was found between sex, level of education, marital status, and FIT completion. The duration before kit return from the day of collection is shown in Figure 1.

### Noncompletion of Additional Evaluation Procedures After Positive FIT Results

After a positive FIT result, additional evaluation was recommended to the patient. In this study, noncompletion of evaluation procedure after a positive FIT was observed with a decreasing number of participants as the invasiveness of the procedure increased. These findings are presented in Table 2. Among the 38 study participants with positive FIT results, all consented and had a digital rectal examination (DRE). These participants also were offered proctoscopy,

but only 24 (63.2%) agreed and only 11 (28.9%) of the participants with positive FIT results have proceeded to have colonoscopy as of this writing.

### Colonoscopy Findings of Patients With Positive FIT Results

Of the 11 patients who underwent colonoscopy, 45.5% ( $n = 5$ ) had premalignant lesions, 36.4% had inflammatory lesions, and other colonic abnormalities were seen in 36.4% ( $n = 4$ ). One person had a normal colonoscopy (Table 3). Polyps were removed during colonoscopy where technically possible. The association between risk factors for CRC and positive FIT results is shown in Table 4. There was no statistically significant association between the risk factors for CRC and the FIT.

### DISCUSSION

We set out to determine the relevance, appropriateness, and practicability of FIT, a relatively cheap, sensitive, and noninvasive test as a screening for CRC in primary care clinics in a tertiary hospital in Nigeria.

The male to female proportion was 1:2.2. The high proportion of women in the study may be a reflection of the high proportion of women seeking hospital care, rather than a reflection of the uptake of FIT. Findings in this study show that FIT positivity was equally distributed among the various age groups. Though not statistically significant, the majority of the positive results were among those aged 60 to 69 years. Paszat et al<sup>20</sup> in Ontario, Canada, reported a similar finding of almost equal distribution of positivity among the age groups, with the highest positivity rate also among patients aged 60 to 69 years. A possible reason is that in both studies, the modal population age was between 60 and 69 years.

Most of the participants in our study had a tertiary level of education, which possibly is a reflection of the high level of education of patients who attend the clinic and does not necessarily indicate a better uptake of the screening process by people in this category. Javadzade et al<sup>21</sup> reported a higher level of education among individuals who had FOBT screening for CRC; Arnold et al<sup>22</sup> found that participants of high literacy were probably aware of CRC screening and alluded to its benefits. That such an educated population is not up to date with their screening may be indicative of poor awareness. This finding may not be a reflection of CRC screening practices, because we set out to include participants who did not purposely visit the hospital for screening purposes.

Up to 45.5% of patients who underwent colonoscopy after a positive FIT had lesions that were premalignant for CRC in this study. With worldwide decline in CRC rates by up to 3% during the last decade, our finding buttresses the fact that reducing CRC death rates could be accelerated by improving access to the use of screening tests.<sup>23</sup>

More than two-thirds of respondents were either obese or overweight. Although obesity is a major health problem and

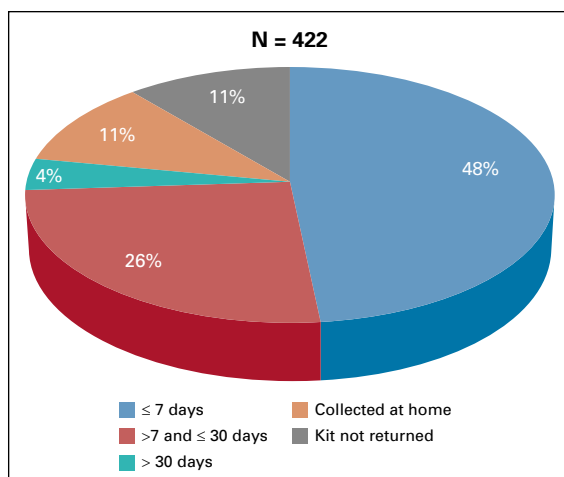


FIG 1. Timing of return of kits by participants.

**TABLE 2.** Evaluation After Positive FIT

Post FIT Evaluation	Complete, No. (%)	Noncomplete, No. (%)
Digital rectal examination	38 (100)	0 (0)
Proctoscopy	24 (63.2)	14 (36.8)
Colonoscopy	11 (28.9)	27 (71.1)

Abbreviation: FIT, fecal immunochemical test.

a documented risk factor for CRC, the prevalence of obesity in West Africa is increasing, as reported by Abubakari et al.<sup>24</sup> The prevalence of obesity in this study is similar to that described in the United States by Ogden et al<sup>25</sup> and is an indication that even in developing countries, people are becoming increasingly more at risk for obesity. The high level of inactivity reported in this study may contribute to the level of overweight and obesity. Oluyombo et al,<sup>26</sup> with a predominant study population similar to that in our study, reported a lower prevalence of generalized obesity of 8.5% in southwestern Nigeria; the predominant occupation, however, was farming, which could translate to a higher level of physical activity.

The prevalence of positive FITs reported in this study was 10.1%, similar to findings in most studies. In Romania, Miutescu et al<sup>27</sup> reported a FIT positivity rate of 6.3% among participants aged 50 to 74 years (mean  $\pm$  SD, 62.3  $\pm$  12.3 years), which was similar to the mean age in this study. The positivity rate was higher in women compared with men, also similar to the findings of our study. This could be accounted for by the higher proportion of women among the sample population in both studies. Shin et al<sup>28</sup> in Korea and Symonds et al<sup>29</sup> in Australia reported a FIT positivity rate of 7.28% and 11.1%, respectively, with a higher rate in men. Likewise, Paszat et al<sup>20</sup> in Canada also reported a higher prevalence in men, with an overall prevalence of 5.2%, even though women were more numerous in the study population. The explanation for the higher prevalence in men can only be speculative, because the age groups of the different sex were not stated. Possibly there were younger participants who were women with a lower positivity rate. Conversely, in a study in Agbor, Delta state, Nigeria, by Ugwuoke et al,<sup>30</sup> in which stool samples of 225 patients who were aged 15 to 75 years were tested for occult blood, a prevalence of 46% was reported. This is a surprisingly high prevalence but suggests there may be extremes of prevalence of positive FIT within the country. Also, the sensitivity and the specificity of the kit used were not stated, which may be a factor affecting the positivity rate.

Even when facilities for CRC screening are provided for eligible patients, it does not translate into completing the CRC screening. In this study, up to 3.8% returned the screening kit unused after a mean duration of a month. An additional 11.1% of respondents did not return their test kits for various reasons, including misplaced test kits, traveling out of town, or the patients could not be reached by telephone. The rate of noncompletion of the test could have been more if reminder

calls were not made and the sample collected in the patient's home, in some cases. The noncompletion rate in this study is lower than that reported by Daly et al<sup>31</sup> in Iowa, in which only 51% of participants returned the kits, and by Steele et al in Scotland<sup>32</sup>, who reported a nonreturn rate of 39.4% despite the provision of prepaid mailing of kits; no reminder calls were made. The use of reminder systems for both the patient and doctor has been reported by Baker et al<sup>33</sup> to increase the rate of completion of the FIT.

Of all patients who had a positive FIT in this study, abdominal examinations and DRE were normal in all participants. Similarly, proctoscopy was conducted for 63.2% of those with a positive FIT result, with findings of internal hemorrhoids in > 80%. Even though it has been reported that most rectal tumors can be palpated on rectal examination, 7.7% of the tumors were accessible only by proctoscopy and sigmoidoscopic examinations.<sup>17</sup>

The findings show that even though we are in a resource-constrained society, abdominal examination, DRE, and proctoscopy are not sensitive enough for additional evaluation of patients with a positive FIT test, so a colonoscopy must be recommended. This finding is supported by Chiang et al,<sup>4</sup> who suggested that findings of hemorrhoids should not be the sole explanation for a positive FIT result or hamper the indication for colonoscopy, because of the similar prevalence of hemorrhoids in those with a positive fecal test result (15.4%) and those with a negative test result (13.3%).

In this study, colonoscopy was performed in only 26.3% of patients over 3 months after a positive FIT result. This is despite the subsidy of the cost of the colonoscopy offered by the management of the University College Hospital Ibadan to increase colonoscopy acceptance. Some patients did not come in for the procedure even after having bowel preparation. Many patients did not give a reason for their refusal of colonoscopy. One exception was a patient who initially had refused a colonoscopy but agreed to screening after vague abdominal symptoms. This could imply that patients were unwilling to have an invasive

**TABLE 3.** Colonoscopy Findings in Participants With Positive FIT

Age (years)	Sex	Findings
48	Female	Inflammatory polyp
58	Female	Inflammatory polyp with mild atypia
47	Female	Adenomatous polyp
50	Female	Sessile polyp
69	Male	Diverticulosis/sessile polyp
44	Male	Inflammatory bowel disease
66	Male	Diverticulosis
54	Female	Colitis
60	Female	Hemorrhoids/proctitis
65	Male	Normal study
42	Male	Colonic diverticulosis

**TABLE 4.** Association Between Common Risk Factors for CRC and FIT Result

Characteristic	Negative FIT, No. (%)	Positive FIT, No. (%)	$\chi^2$	P
Age, years			1.97	.969
40-49	56 (90.3)	6 (9.7)		
50-59	45 (88.2)	6 (11.8)		
60-69	157 (89.7)	18 (10.3)		
$\geq 70$	79 (90.8)	8 (9.2)		
Sex			0.627	.428
Male	103 (88)	14 (12)		
Female	234 (90.7)	24 (9.3)		
Obesity			2.16	.540
Yes	131(87.3)	19 (12.7)		
No	206 (91.6)	19 (8.4)		
Diabetes mellitus			1.46	.227
Yes	62 (93.9)	4 (6.1)		
No	275 (89)	34 (11)		
Low fruit diet			0.98	.320
Yes	260 (89.0)	32 (11.0)		
No	77 (92.8)	6 (7.2)		
Inactivity			0.21	.644
Yes	227 (89.4)	27 (10.6)		
No	110 (90.9)	11 (9.1)		
Family history of CRC				.584
Yes	5 (100)	0		
No	332 (89.7)	38 (10.3)		

Abbreviations: CRC, colorectal cancer; FIT, fecal immunochemical test.

screening procedure when they were asymptomatic. This is a source of concern, because it has been reported that there is a significantly increased risk of neoplasia associated with colonoscopy delay.<sup>34</sup> The aversion to having a screening colonoscopy has been reported in other studies; Van Rossum et al<sup>6</sup> found that despite written and verbal information about colonoscopy before and after performing an FOBT, up to 16% of participants with a positive test result refused this follow-up examination; anxiety was the ultimate reason for the refusal. Baker et al<sup>33</sup> in Chicago, Illinois, also found that despite interventions to encourage the completion of annual FOBT screening, only 17 of 29 patients with a positive FOBT result completed diagnostic colonoscopy (59%), although transportation was provided and colonoscopy

was free. Additional studies of barriers to uptake of screening colonoscopy is recommended.

In conclusion, the FIT is a practicable initial screening test for CRC in the University College Hospital Ibadan. It is inexpensive and less invasive and an acceptable screening option; findings in this study indicated reduced compliance with screening as the invasiveness of the procedure increased. In a resource-limited country like Nigeria, an affordable screening test such as the FIT may increase the level of participation in CRC screening. If screening programs readily offered in family practice are linked to generic family health programs engaging both sexes, it may be a more cost-effective option to offering treatment of advanced cancers.

## AFFILIATIONS

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## AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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