Point-of-Care Urine Metabolomics Test to Diagnose Colorectal Cancers in Low- and Middle-Income Countries: A Pilot Controlled Trial in Southwestern Nigeria

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ABSTRACT

PURPOSE To test the feasibility of a point-of-care (POC) real-time urine metabolomics test, evaluate its validity in diagnosing colorectal cancer (CRC) among at-risk patients, and assess the willingness of patients in Southwestern Nigeria to use and pay for the test.

METHODS This was a pilot-controlled trial carried out among 72 patients (34 cases and 38 controls) in southwestern Nigeria. The cases were those with histopathological diagnosis of CRC while controls were at-risk adults. The POC biosensor used a disposable chip and can be connected to a smart device using Bluetooth, and reported if the patient's urine contained metabolites consistent with CRC. We assessed validity of the test using sensitivity, specificity, positive predictive value (PPV) and negative predictive values (NPV), and prespecified a specificity of 50% with a goal of ≥80% sensitivity to estimate the potential of the test to half the referrals to colonoscopy. Additionally, we assessed perception toward the test and willingness to uptake the urine test using structured questionnaires.

RESULTS The overall sensitivity, specificity, PPV, and NPV for all respondents were 91.18%, 81.58%, 81.58%, and 91.18% respectively, with an area under the receiver operating characteristic curve of 0.86. With specificity fixed at 50%, the overall sensitivity for all respondents was 94.5%, and all stratifications had sensitivity >90%. Overall, 70 (98.6%) were satisfied with the urine-based CRC screening, and respondents were willing to pay a mean amount of 8,008.20 Naira (about $5.2 US dollars) for the test.

CONCLUSION Our urine metabolite early diagnosis POC test met our predetermined criteria for success and had high acceptance rates among Nigerian patients, supporting a future multi-institutional implementation trial assessing our ability to scale up utilization.

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INTRODUCTION

Colorectal cancer (CRC) is the third most diagnosed cancer globally, after breast and lung cancers.[1,2] In addition, CRC is the fourth most common cause of cancer-related mortality.[3] It is projected that low- and-middle income countries (LMICs) will experience a 70% increase in CRC incidence and a 75% increase in the number of deaths from CRC by the year 2030.[4] Researchers have found a 5-fold increase in the yearly incidence of CRC in Nigeria from 1979 to 2008.[5] In addition, as the infrastructure for colonoscopy continues to improve, the traditional thinking that colorectal polyps are rare in African populations is being disproven.[6,7]

Lack of screening and late diagnosis leads to poor CRC outcomes in LMICs: By 2025, the number of deaths from CRC in LMICs will exceed that in high-income countries (HICs).[4] The 5-year survival rate for CRC in the United States is 64%, compared with 32% in Mumbai, India, and 7.4% in Kampala, Uganda.[8] Although it is impossible to pinpoint all factors responsible for these mortality differences, the most likely result is due to a lack of CRC screening and treatment

CONTEXT

Key Objective

To test the feasibility, validity, and willingness to uptake a point-of-care (POC) real-time urine metabolomics test in diagnosing colorectal cancer (CRC) among at-risk patients in Southwestern Nigeria.

Knowledge Generated

The test met the predetermined criteria for success (sensitivity—91.18%, specificity—81.58%, positive predictive value—81.58%, and negative predictive value—91.18%). Additionally, 98.6% of respondents were satisfied with the urine-based CRC screening.

Relevance

Early diagnosis is a priority to decrease colorectal cancer mortality rates globally. Nigeria and most low- and-middle income countries do not have screening tools for CRC that have been validated. This urine metabolite test has the potential to facilitate rapid point-of-care CRC diagnosis and contribute to an early diagnosis.

services. The only interventions that can decrease the stage at presentation are screening or early diagnosis testing strategies when patients have initial symptoms such as rectal bleeding.[9] A cost-effective early diagnosis test for CRC could allow earlier-stage diagnosis and reduce the resources needed to treat a patient with CRC.[10]

Colonoscopy is the reference standard worldwide for screening patients and monitoring them for CRC. However, the costs and requirements for performing a colonoscopy make it inaccessible to many patients in LMICs. Patients with rectal bleeding, despite the recommended scope, almost never get colonoscopies because of the high cost.[10] To optimize the use of the colonoscopy services and minimize the number of negative procedures in Nigeria and other LMICs, a simple and cost-effective method to identify patients at the highest risk of CRC is needed. A myriad of CRC screening tests exist, but none has clearly separated itself as the single top choice for all situations.[11] Traditionally, stool-based testing has been used to screen for CRC and has been recommended for LMICs, but it has been found to perform very poorly in Africa compared with what has been reported in HICs.[11–13]

Metabolomics is a rapidly growing field that measures small molecule metabolites.[14] Although genomics/mutation analyses can predict the likelihood of future health conditions, metabolomics provides a current snapshot of a patient's health status. Researchers can associate certain health conditions with their phenotypic metabolite signatures in biofluids in combination with clinical features using machine learning. Metabolomic-based testing is limited in its practical application to LMICs until it transitions to point-of-care (POC) testing. Our team developed a metabolomic-based POC biosensor that reports if the patient's urine contains metabolites in concentrations consistent with precancerous lesions and/or cancer.[15] This study, therefore, aimed to pilot the POC real-time urine metabolomics test, evaluate its validity in diagnosing CRC among at-risk patients, and assess the willingness of patients in Southwestern Nigeria to use and pay for urine-based POC testing.

METHODS

We carried out this controlled trial in Obafemi Awolowo University Teaching Hospital Complex with 72 patients (34 cases and 38 controls). The cases were those with histopathological diagnosis of CRC while controls were at-risk adults who were age >40 years, had lower gastrointestinal bleeding for more than a week, and had a family history with a first-degree relative diagnosed with CRC or a history of CRC.

This pilot study is phase II of a bigger project. In phase I, using mass spectrometry, we developed and confirmed the diagnostic accuracy of the urine metabolite signature for the detection of CRC in Nigerian patients, including those previously diagnosed with CRC.[16] The metabolites included hippuric acid, diacetylspermine, and creatinine. We then built a POC biosensor device to test these in Nigeria. Phase II includes the pilot test of the urine metabolite signature in this study. The urine samples are processed by the device, and a light sensor was used to generate the concentration of each metabolite relative to creatinine. These data were then combined with data regarding the presence/absence of weight loss and change in stool caliber in an algorithm that generated a yes/no value for the presence of CRC. There was also a mixed-methods analysis of the implementation of POC testing (to be published in the future).

We recruited the cases from the ongoing NIH-funded R01 case-control study on CRC in Nigeria (Grant ID: CA246620) over a 6-month period. Data were collected by trained research assistants using a structured questionnaire. We collected tissue samples during colonoscopy sessions for histopathologic confirmation of CRC. An extensive data

cleaning process was conducted via Excel before study analysis to ensure accuracy, consistency, and reliability. Data for 88 records were stored in the Memorial Sloan Kettering Cancer Center REDCap database. Following the data cleaning process, 72 of the 88 records were included in the analysis. Of the 16 removed, 11 participants were from urine samples that had been previously banked during phase I of the study. When the pilot study testing was carried out, we were unable to go back and administer the Pilot questionnaire to these patients so these samples were excluded: one record was found to have a histopathology result of lymphoma; for one record, the histopathology report result was identified as missing; for one record, the POC biosensor test was completed before finalization of the diacetyl spermine test, and two records were tested with assays from a batch of creatinine assay kits that was expired and samples were not retested.

We determined the comparability of the two groups (ie, cases and controls) using Pearson Chi-Squared test to test for statistically significant differences in the distribution of sociodemographic characteristics and known risk factors. The sociodemographic characteristics included are age (<40, 40-49, 50-59, 60-69 or ≥70 years), sex (male or female), marital status (currently married or currently unmarried), ethnicity (Yoruba or others), education (primary or less, secondary/vocational and higher), occupation (unemployed, civil servant, trader, self-employed or others), health insurance coverage (yes or no), and household wealth index (poor, middle, or rich). The known risk factors included BMI (underweight, normal, overweight, or obesity), alcohol consumption (drank in the past, currently drinking, or not a drinker), smoking (smoked in the past, currently smoking, or not a smoker), and family history of CRC (no/do not know or yes). We also compared some suggestive symptoms and signs which include ever seen blood in stool (no or yes), change in bowel habits in the past 6 months (no or yes), bowel habits (pellet-like, constipation, watery/diarrhea, or constipation and diarrhea), weight loss (yes or no), extended fatigue (no or yes), ever had cancer screening (no or yes), and treatment for parasitic infection in the past 6 months (no or yes).

The biosensor uses colorimetric assays to quantitatively measure and normalize concentrations of the panel metabolites. The system assists users in specific chemical or enzymatic reactions of a urine sample, and an integrated red, blue, and green color sensor reads developed color that is proportional to the concentration of each metabolite marker.[16] The biosensor device can be connected to a smart device (Android or Apple mobile phones or tablets) using Bluetooth technology. An app on the connected device runs the proprietary algorithm using data about the patient's clinical features, risk factors, and metabolite information from the biosensor device. All the patients had colonoscopies before they were recruited into the study and before the urine was collected. The output reports if the patient's urine contains metabolites in concentrations consistent with cancer. We left out precancerous lesions with the final device because the metabolites selected for accuracy in identifying CRC in Nigerian patients does not have similar results identifying polyps. If the test is positive, the patient should be referred for a colonoscopy. We evaluated the validity of the test using sensitivity, specificity, positive predictive value (PPV), and negative predictive values (NPV). These were defined as shown in Table 1.

We prespecified that we would analyze the test with a specificity set at 50% with a goal of 80% sensitivity or more. We did this as we felt it was clinically relevant to remove half of the colonoscopies that did not need to be performed in the future. This was to estimate the potential of the test to reduce the number of referrals to colonoscopy by half and limit those referrals to a higher-risk population, thereby increasing the diagnostic yield of early CRC and precancerous polyps by colonoscopy.

We assessed the perception of the respondents about the urine test, their willingness to uptake the urine test, and the amount of money in Naira that they were willing to pay for the test.

The investigators obtained informed consent from each participant, and the human investigations were performed after approval by a local ethical review committee in Nigeria.

RESULTS

The sociodemographic characteristics of the respondents are shown in Table 2. The mean age for cases and controls were 57.06 ± 16.06 and 54.84 ± 13.05 years, respectively. The cases and controls were comparable considering all sociodemographic characteristics ($P > .05$) and known risk factors ($P > .05$) except for a family history of CRC which was significantly more among controls ($P < .01$). Expectedly, alarming symptoms suggestive of CRC such as change in

TABLE 1. Definition of the Parameters for Evaluating the Validity of the Point-of-Care Metabolics Test

	Disease Status		
Test Result	Cases	Control	Total
Positive	TP	FP	TP + FP
Negative	FN	TN	FN + TN
Total	TP + FN	FP + TN	TP + FP + FN + TN

NOTE. Sensitivity: Probability that the test will be positive when disease (CRC) is present. Calculated as TP/(TP + FN) × 100. Specificity: Probability that the test will be negative when the disease is absent. Calculated as TN/(FP + TN) × 100. PPV: Probability that someone with a positive test result actually has the disease. Calculated as TP/(TP + FP) × 100. NPV: The probability that someone with a negative test result is truly disease free. Calculated as TN/(FN + TN) × 100.
Abbreviations: CRC, colorectal cancer; FN, false negative; FP, false positive; NPV, negative predictive value; PPV, positive predictive value; TN, true negative; TP, true positive.

TABLE 2. Description of Colorectal Cancer Cases and At-Risk Controls in Nigeria, Enrolled in Our Pilot-Controlled Trial Assessing the Feasibility and Validity of a Point-of-Care Real-Time Urine Metabolomics Test

Variables	Confirmed Cases of Colorectal Cancer, No. (%)		*P*[a]
	No (n = 38)	Yes (n = 34)	
Sociodemographic profile			
Age group (in years)			.11
<40	3 (7.89)	6 (17.65)	
40-49	12 (31.58)	4 (11.76)	
50-59	11 (28.95)	6 (17.65)	
60-69	6 (15.79)	9 (26.47)	
≥70	6 (15.79)	9 (26.47)	
Sex			.67
Male	22 (57.89)	18 (52.94)	
Female	16 (42.11)	16 (47.06)	
Marital status			.43
Currently married	31 (81.58)	30 (88.24)	
Currently unmarried	7 (18.42)	4 (11.76)	
Ethnicity			.25
Yoruba	37 (93.37)	31 (91.18)	
Others	1 (2.63)	3 (8.82)	
Education	8 (22.22)	7 (21.21)	.57
Primary or less secondary/ vocational	7 (19.44)	10 (30.30)	
Higher	21 (58.33)	16 (48.48)	
Occupation			.75
Unemployed	8 (21.62)	6 (18.18)	
Civil servant	10 (27.03)	10 (30.30)	
Trader	7 (18.92)	10 (30.30)	
Self-employed	4 (10.81)	2 (6.06)	
Others	8 (21.62)	5 (15.15)	
Health insurance			.60
No	27 (71.05)	26 (76.47)	
Yes	11 (28.95)	8 (23.53)	
Household wealth index			.35
Poor	13 (34.21)	11 (32.35)	
Middle	15 (39.47)	9 (26.47)	
Rich	10 (26.32)	14 (41.18)	
Known risk factors			
Current BMI			.06
Underweight	3 (7.89)	7 (20.59)	
Normal	15 (39.47)	19 (55.88)	
Overweight	12 (31.58)	6 (17.65)	
Obesity	8 (21.05)	2 (5.88)	
≥10 alcoholic drinks in the lifetime	5 (13.16)	8 (23.53)	.08
Yes, drank in the past yes, currently drinking	7 (18.42)	1 (2.94)	
No	26 (68.42)	25 (73.53)	
≥5 packs of cigarette in the lifetime	2 (5.26)	2 (5.88)	.99
Yes, smoked in the past yes, currently smoking	1 (2.63)	1 (2.94)	
No	35 (92.11)	31 (91.18)	
Family history of colorectal cancer			<.01
No/do not know	31 (81.58)	34 (100.00)	
Yes	7 (18.42)	0 (0.00)	
Suggestive CRC symptoms/signs			
Ever seen blood in stool			.59
No	7 (18.42)	8 (23.53)	
Yes	31 (81.58)	26 (76.47)	
Change in bowel habits in the past 6 months			<.01
No	24 (63.16)	8 (23.53)	
Yes	14 (36.84)	26 (76.47)	
Bowel habits			.57
Pellet-like	2 (14.29)	3 (12.50)	
Constipation	5 (35.71)	11 (45.83)	
Watery stool/diarrhea	7 (50.00)	8 (33.33)	
Constipation and diarrhea	0 (0.00)	2 (8.33)	
Weight loss			<.01
Yes	9 (23.68)	31 (91.18)	
No	29 (76.32)	3 (8.82)	
Extended fatigue/tiredness			<.01
No	30 (78.95)	15 (44.12)	
Yes	8 (21.05)	19 (55.88)	
Treated for parasitic infection in the past 6 months			.37
No	32 (84.21)	31 (91.18)	
Yes	6 (15.79)	3 (8.82)	
Ever had cancer screening			.06
No	30 (78.95)	32 (94.12)	
Yes	8 (21.05)	2 (5.88)	

Abbreviation: CRC, colorectal cancer.
[a]Pearson Chi-squared test used.

bowel habits ($P < .01$), weight loss ($P < .01$), and extended fatigue/tiredness ($P < .01$) were more prevalent among the cases compared with control.

The overall sensitivity, specificity, PPV, and NPV for all respondents were 91.18%, 81.58%, 81.58%, and 91.18%, respectively (Table 3). When stratifications were done, the urine test had the highest sensitivity among those with hemorrhoids + anal fissure (100%) and the lowest among women (87.50%) and those with obesity (87.50%). The highest specificity was among men (86.36%), and the lowest was among those with weight loss (55.56%).

In Table 4, the AUC and 95% CIs were calculated for the different stratifications done. With specificity fixed at 50%,

TABLE 3. Sensitivity, Specificity, and Positive Predictive and Negative Predictive Values for Our Pilot-Controlled Trial Assessing the Feasibility and Validity of a Point-of-Care Real-Time Urine Metabolomics Test for Colorectal Cancer Screening in Nigeria

Categories of respondent	No.	Sensitivity, %	Specificity, %	Positive Predictive Value, %	Negative Predictive Value, %
All respondents	72	91.18	81.58	81.58	91.18
Female[a]	32	87.50	75.00	77.78	85.71
Male[a]	40	94.44	86.36	85.00	95.00
Bloody stool[a]	57	92.31	83.87	82.76	92.86
Obesity[a]	28	87.50	85.00	70.00	94.44
Weight loss[a]	40	90.32	55.56	87.50	62.50
Change in bowel habits[a]	40	92.31	71.43	85.71	83.33
Hemorrhoids/anal fissure[a]	18	100.00	81.82	77.78	100.00

[a]Analysis was restricted to those in this group/with this characteristic alone.

the overall sensitivity for all respondents was 94.5%, and all stratifications had sensitivity >90%, with the stratification for hemorrhoids/anal fissure, hemorrhoids/anal fissure + bloody stool, and hemorrhoids/anal fissure + bloody stool + weight loss, having a sensitivity of 100%. Except for those with weight loss who had an AUC of 0.7, all other strata including the overall for all respondents had an AUC ≥0.8, and all these were statistically significant.

The perception of the respondents about the urine test is shown in Table 5. All or nearly all of the respondents understood the purpose of the urine test (100%), had no concern about it (98.6%), understood the value of using urine for CRC screening (98.6), and could explain the screening to friends and family. Sixty-eight of them (94.4%) would do the urine-based CRC screening yearly and 66 (91.6%) would recommend the screening to friends and family. Almost all of the respondents had a positive perception of the urine-based CRC screening and had no perceived barrier to participating in CRC screening using urine tests. Most of the respondents preferred the hospital setting (75.0%) for urine sample collection, whereas 15 (20.8%) preferred taking the samples at home. Overall, 70 (98.6%) were satisfied with the urine-based CRC screening, one (1.4%) was neutral, and none (0.0%) were unsatisfied. The mean amount of money that the respondents were willing to pay for the test was 8,008.20 Naira (about $5.2 US dollars [USD]), with about half of them (49.2%) willing to pay between 1,001 and 5,000 Naira ($0.63 USD to $3.2 USD).

DISCUSSION

We carried out this study to evaluate the validity of a POC urine metabolomics test as a screening test for CRC in Nigeria and found it had high sensitivity, specificity, PPV, and NPV. Additionally, the test was well received by the participants with none of them expressing any form of dissatisfaction with it. To the best of our knowledge, this will be the first attempt to evaluate the validity of a POC urine metabolomics test for diagnosing CRC in sub-Saharan Africa. Furthermore, our findings show that the urine metabolomics test performed better than any other modalities (such as fecal immunochemical test [FIT]) in Nigeria.

The sensitivity and NPV were higher than 90%, whereas the specificity and PPV were higher than 80%. Higher rates were found when stratifications were made for the respondents with some suggestive symptoms/signs, with the sensitivity rate reaching 100% in those with hemorrhoids (n = 18, 25%). No previous screening test (apart from coloscopy) for CRC has performed better in this population and sub-Saharan Africa.[12,17] The POC urine metabolomics test in this study performed much better than the FIT, which was recommended for CRC screening in LMIC.[18]

TABLE 4. Sensitivity, Area Under Receiver Operating Characteristic Curve, and 95% Confidence When Specificity Was Fixed at 50% for Our Pilot-Controlled Trial Assessing the Feasibility and Validity of a Point-of-Care Real-Time Urine Metabolomics Test for Colorectal Cancer Screening in Nigeria

Categories of respondent	No.	Sensitivity, %	Specificity, %	AUC	95% CI
All respondents	72	94.5	50	0.8638	0.78 to 0.94
Weight loss	40	91.5	50	0.7294	0.55 to 0.91
Bloody stool	57	95.5	50	0.8809	0.80 to 0.96
Weight loss + bloody stool	32	93.5	50	0.7708	0.58 to 0.96
Hemorrhoids/anal fissure	18	100.00	50	0.9091	0.79 to 1.00
Hemorrhoids/anal fissure + bloody stool	17	100.00	50	0.9500	0.85 to 1.00
Hemorrhoids/anal fissure + bloody stool + weight loss	9	100.00	50	0.8333	0.51 to 1.00

TABLE 5. Perception and Willingness to Uptake the Point-of-Care Real-Time Urine Metabolomics Test for CRC Screening in Nigeria

Variable	Frequency	%
General attitude toward urine test for CRC screening[a]		
Have no concerns about giving urine sample	71	98.6
Understands the purpose of using urine for CRC screening	72	100.0
Understands the value of using urine for CRC screening	71	98.6
Could explain the screening to friends and family	70	97.2
Could recommend the screening to friends and family	66	91.6
Would do this urine-based CRC screening yearly	68	94.4
Negative perceptions about the urine test[a]		
Embarrassing	0	0.0
Inconvenient	1	1.4
Unpleasant	0	0.0
Unhygienic	0	0.0
Invasive	0	0.0
Time consuming	0	0.0
Positive perceptions about the urine test[a]		
Will reduce risk of advanced of CRC	64	88.9
Will help early detection of CRC	71	98.6
Will help initiation of prompt treatment	71	98.6
Barriers for participating in CRC screening using urine test		
Nil	65	90.3
Financial constraints	3	4.2
Lack of awareness	2	2.7
Fear of outcome	1	1.4
Distance to health facility	1	1.4
Preferred site for urine sample collection		
Doctor's office/clinic	28	38.9
At home	15	20.8
Hospital/clinic bathroom	26	36.1
Anywhere	3	4.2
Overall level of satisfaction with urine test (n = 71)		
Unsatisfied	0	0.0
Neutral	1	1.4
Satisfied	70	98.6
Amount (in Naira) willing to pay for urine test (n = 61)		
≤1,000	17	27.9
1,001-5,000	30	49.2
>5,000	14	23.0
Mean (8,008.2 ± 12,090.9)		

Abbreviation: CRC, colorectal cancer.
[a]Multiple responses allowed.

Our team carried out a pioneer pilot and eventual multicenter study to evaluate the effectiveness of the FIT test in diagnosing CRC in Nigeria. Our findings from the FIT tests revealed a high rate of positivity, a high false-positive rate, and a low PPV for CRC.[12,17] In the larger multicenter study among 2,330 average-risk participants, the performance of FIT as a screening test for CRC in Nigeria was very poor, with PPV of 1.1% for invasive CRC.[12] Apart from being cost-effective, the FIT test was recommended for LMICs because it was highly accurate, according to studies done in HICs. A systematic review and meta-analysis reported a pooled sensitivity and specificity of 79% and 94%, respectively.[13] Unfortunately, this high level of accuracy could not be reproduced in Nigeria. However, the findings from the POC urine metabolomics test in this study, with an overall sensitivity and specificity of 91% and 82%, respectively, compare well with the accuracy reported for the FIT test in HIC. This is also in addition to the fact that the POC urine metabolomics test is equally affordable. These findings, therefore, open up a new possibility of finding a simple and cost-effective screening test for CRC in Nigeria and possibly other parts of Africa.

Furthermore, we fixed the specificity at 50% to evaluate the possibility of achieving a high sensitivity while reducing false positivity which would mean increased access to colonoscopies for those at high risk of CRC. The overall sensitivity increased to about 95%, whereas stratifications for those with hemorrhoids/anal fissure, hemorrhoids/anal fissure + bloody stool, and hemorrhoids/anal fissure + bloody stool + weight loss increased to 100% sensitivity rates. This shows that the POC urine test may be able to half the number of coloscopies done and help to identify the high-risk patients who truly need colonoscopy. This is important for low-resource settings like Nigeria and most sub-Saharan countries with limited facilities and expertise for colonoscopy, and when available, the high cost of coloscopy in a setting where most people pay out of pocket for health care is a major impediment.

Additionally, the AUC value of approximately 0.9 shows that the test is highly accurate as a CRC diagnostic test.[19] The AUC values for the different strata ranged from 0.73 among those who reported weight loss alone to as high as 0.95 among those who reported hemorrhoids/anal fissure + bloody stool. This finding confirms that the POC urine metabolomics test performed well as a diagnostic test for CRC in this population.

Another important finding is the high level of satisfaction and acceptance of the urine test in this study, as compared with the poor patient compliance that has been reported for stool-based tests.[11] Nearly all the respondents in our study (both study and control arms) had positive perceptions and a high level of satisfaction with the test. They also showed a willingness to uptake the test for a reasonable fee of 8,000 Naira (approximately $5 USD). This is similar to the high level of acceptability and satisfaction reported by participants in the FIT test in Nigeria, which may reflect the willingness and readiness of Nigerians for a cost-effective screening test for CRC.

This study is not without limitations. We used only a small sample of patients with CRC (34); hence, the power of our

findings is limited. Although our population is quite diverse with a good mix of different age groups, sexes, occupations, educational backgrounds, and wealth profiles, despite this, it may be difficult to completely rule out some bias in sample selection because the study was hospital-based, we used just one tertiary institution, and almost all the participants were from just an ethnic group (Yoruba). These may limit the generalizability of the findings, and a larger study may be needed to validate our findings. Another limitation is the test's inability to detect polyps, which would have made it possible to prevent patients from developing CRC. Also, we did not compare our findings with that of a standard screening test. Additionally, we cannot completely rule out the possibility of spectrum bias because we used symptomatic patients with elevated risk for CRC as controls.

Overall, we developed and pilot tested a urine metabolite early diagnosis POC test that met our predetermined criteria for success and had high acceptance rates among Nigerian patients. We are planning a much larger multi-institutional implementation trial to determine whether these results can scale up.

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A.A.A. and O.I.A. contributed equally to this work as co-first authors. H.D.H. and T.P.K. contributed equally to this work as co-senior authors.

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DATA SHARING STATEMENT

Data are stored on REDCap at Memorial Sloan Kettering Cancer Center, 1275 York Ave, New York, NY 10065, and available on reasonable request.

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