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Attitudes and Experiential Factors Associated with Completion of mt-sDNA Test Kit for Colorectal Cancer Screening

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Abstract

Colorectal cancer (CRC) is the third leading cause of cancer-related deaths in the United States. Despite the availability of multiple screening options, CRC screening is underutilized. We conducted a survey of patients (n = 2973) who were prescribed the multi-target stool DNA (mt-sDNA) screening test (commercialized as Cologuard® and manufactured by Exact Sciences Corporation) to understand attitudes and experiences that influence test completion and likelihood of future test completion. Using exploratory factor analyses, we developed three scales: Perceived Effectiveness, Perceived Ease of Use, and Perceived Comfort.

Keywords

Colorectal cancer, multi-target stool DNA screening test (mt-sDNA), cancer screening, perceived effectiveness, perceived ease of use, perceived comfort

Key points

1. In multivariate analyses controlling for sociodemographic and health care factors, the Perceived Effectiveness, Ease of Use, and Comfort scales were positively associated with test completion and likelihood of future test completion.
2. There were differences in predictive factors, depending on whether patients had received the mt-sDNA test kit for the first time or had completed a test previously (initial and repeat test subgroups).
3. Study findings can guide development of behavioral interventions and HCP communication messages to increase use of this FDA-approved stool test for average-risk CRC screening.

Introduction

Colorectal cancer (CRC) is the third leading cause of cancer-related deaths in the United States (U.S.) among both women and men.[1,2] Screening has been shown to reduce both CRC incidence and mortality rates through early detection and removal of precancerous lesions.[3,4] Major guideline organizations recommend screening for CRC among average-risk adults between 45 and 75 years of age.[5–7] Several stool-based and direct visualization CRC screening modalities are guideline-recommended, including an annual fecal immunochemical test/guaiac-based fecal occult blood test (FIT/gFOBT), a multi-target stool DNA (mt-sDNA) test every 3 years, and a screening colonoscopy every 10 years.[5,7] Mt-sDNA is a noninvasive test option shipping directly from the manufacturer to the patient's home with reportable results typically available within 14 days of sample receipt. The mt-sDNA test is the most recently endorsed option for average-risk CRC screening; it was added to the U.S. Preventive Services Task Force recommendations in 2016.

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Despite the availability of multiple effective screening options, CRC screening continues to be underutilized in the U.S., particularly among uninsured and underinsured individuals, socioeconomically disadvantaged communities, and racial/ethnic minority populations.[8–13] Barriers to CRC screening include lack of awareness, lack of clinician recommendation, burdensome bowel preparation regimens, logistical barriers, medical mistrust, fears about cancer, and feelings of embarrassment.[14–27] The increase in the uptake of mt-sDNA as a screening option is promising and suggests growing interest among both patients and clinicians in non-invasive stool-based screening that can be performed at home.[28]

Understanding the factors that influence completion of stool-based CRC screening is important to inform development of behavior change and communication interventions that will improve screening uptake and adherence. To further this understanding, we conducted a survey of patients whose health care providers had ordered the mt-sDNA test to explore patient attitudes, experiences, sociodemographic factors, and health care factors associated with screening completion and likelihood of completing the test in the future.

Table 1. Survey Questions to Assess Attitudes and Experiences with mt-sDNA (Cologuard®) Screening for Colorectal Cancer.

Positive Valence
1. I trust the results from the Cologuard® test.
2. I believe completing the Cologuard® test will help find any early signs of colorectal cancer.
3. I believe completing the Cologuard® test may help decrease my chances of dying from colorectal cancer.
4. I feel confident in my ability to use the Cologuard test® kit.
5. The Cologuard® test kit is convenient.
6. The instructions for completing my Cologuard® test kit are easy to follow.

Negative Valence
1. I worry about what the Cologuard® test might show.
2. I worry my health insurance may not cover the cost of the Cologuard® test.
3. I worry about the possibility of being diagnosed with colorectal cancer.
4. The Cologuard® test kit is embarrassing to complete.
5. The Cologuard® test kit is gross to use.
6. I worry about collecting a useable stool sample.
7. The instructions for sending back my Cologuard® test kit are difficult to follow.

Note: Response options were strongly disagree, somewhat disagree, neither agree nor disagree, somewhat agree, strongly agree.

Methods

We developed the questionnaire in English and Spanish, tested it with eight patients using a cognitive interviewing approach,[29] and conducted an expert review using a systematic questionnaire appraisal process.[30] The questionnaire included 33 primarily closed-ended questions created specifically for this study, including questions related to attitudes and experiences (Table 1). Respondents rated their agreement with statements using a scale from 1 (strongly disagree) to 5 (strongly agree). They also rated the likelihood of completing the mt-sDNA test in the future if their health care provider recommended it on a scale of 1 (not at all likely) to 5 (very likely). We programmed the web survey using Voxco, a commercial survey software, and created the mail survey using Teleform, which allows responses to be scanned and reduces data entry errors. The study was reviewed by the Institutional Review Board and determined to be exempt.

The study sample was created from the laboratory's national database of patients who received a provider-ordered mt-sDNA test kit. A randomized subset of patients was provided, who met eligibility criteria: aged 45 to 75 years, have a U.S. postal address, and have had an mt-sDNA kit shipped to them between May and September 2021. Patients could have received a mt-sDNA test kit for the first time (initial test subgroup) or for a repeat screening, defined as more than 3 years since completing their most recent mt-sDNA screening (repeat test subgroup). Patients were classified as "completers" if they returned the test kit within 6 months of the order date. The final sampling frame included 17,370 individuals.

The field period for the survey was March to June 2022. We sent an invitation letter by email to sample members for whom we had an email address (41.5%) or by postal mail. The email included a unique login credential to access the web survey. We sent a follow-up postcard reminder one week after the initial invitation, a letter and paper survey to non-respondents 3 weeks after the invitation, and a final postcard reminder 1 month after the invitation. A $20 incentive was provided to patients who completed the survey.

Data Analysis

Non-response Analysis. We conducted a non-response analysis to determine whether there were meaningful differences in sex, age, and test completion status between respondents (n = 2973) and non-respondents (n = 14,397). There were no other variables available in the sample file to use for comparisons between survey completers and those who did not respond to the invitation. See Appendix Table A1 for the results of the non-response analysis.

Scale Creation. We conducted exploratory factor analysis to determine whether any underlying constructs emerged from the attitudes and experiences questionnaire items (n = 13). We reverse-coded all negative valence questions so that a higher score means greater *dis*agreement with the statement and then examined correlations among items. Next, we checked polychoric correlation matrices of the questions to determine whether (1) there were any correlations between two items greater than 0.9 or (2) there were any items that correlated with all other items below 0.3. If either case

occurred, we planned to drop the item from scale consideration; however, this never occurred. Then, we conducted a reliability test was performed to see if any problematic alpha values (< 0.7) arose prior to running the EFA. Next, we created a scree plot to determine the suggested number of dimensions for the EFA. Finally, we ran an EFA with a promax oblique rotation and weighted least squares solution, given the suggested specifications from the prior steps. Factor loadings were then analyzed. If any given item loaded at less than 0.7, that item was omitted from consideration and all above steps were repeated to produce a new EFA. Using this process, we identified three scales: Perceived Effectiveness (three items - I trust the results from the Cologuard® test. I believe completing the Cologuard® test will help find any early signs of colorectal cancer. I believe competing the Cologuard® test may help decrease my chances of dying from colorectal cancer; Cronbach's alpha = 0.92); Perceived Ease of Use (three items - I feel confident in my ability to use the Cologuard® test kit. The Cologuard® test kit is convenient. The instructions for completing my Cologuard® test kit are easy to follow; Cronbach's alpha = 0.88); and Perceived Comfort (two items - The Cologuard® test kit is embarrassing to complete. The Cologuard® test kit is gross to use; Cronbach's alpha = 0.88). We computed mean scale scores for each of the three scales for each respondent to enter in the regression models. See Appendix Tables A2 and A3 for full correlation structures of the attitude (Table A2) and experience (Table A3) items.

Bivariate Analysis. We compared differences in mean scores for the items between respondents who returned and did not return the test kit (completers and non-completers). We also compared differences in mean scores between respondents who were "very likely" to complete mt-sDNA in the future and respondents who rated their future use as less than very likely (ie, somewhat likely, neither likely nor unlikely, somewhat unlikely, very unlikely). This likelihood variable was dichotomized as such because of the distribution ('very likely' n = 2282; all other categories n = 659). We assessed differences in means using t-tests.

Regression Analysis. We ran binary logistic regression models to evaluate the effects of the three scales on whether the respondent (1) returned their test kit and (2) indicated they were "very likely" to agree to completing mt-sDNA testing in the future if their health care provider recommended it. In addition, we included three individual items that were not part of the scales: (1) worry that insurance may not cover the cost of the mt-sDNA test; (2) worry about the possibility of being diagnosed with CRC; and (3) difficulty following instructions for returning the test kit. We ran the models for the full sample and then ran separate models for the initial test subgroup and repeat test subgroups. For each model, we included demographic and health care-related control variables (age, sex, education, income, race, ethnicity, marital status, employment status, health insurance status, health literacy, and health care visit in last year). Data structuring and analysis were conducted using R (version 3.6.1).

Results

A total of 2973 eligible respondents completed the survey (response rate = 21.7%). Respondent characteristics are presented in Table 2. Most respondents had completed the screening test (77.3%) and reported they would be very likely to use mt-sDNA in the future if their health care provider recommended it (76.8%). There were no significant differences in age or sex between respondents and non-respondents. Respondents in both the initial and repeat test groups were significantly more likely to have completed the mt-sDNA test kit (initial and repeat test subgroups combined) compared to non-respondents ($X^2(1) = 2296.2$, $p < .0.01$).

The bivariate analysis found significant differences between completers and non-completers (initial and repeat test subgroups combined) on all the attitudes and experiences items. Completers were more likely to agree with all positive statements about the mt-sDNA test (eg, "I trust the results from the Cologuard® test," $p < 0.001$) (Table 3). Completers were more likely to *dis*agree with most of the negative statements, including that the test is embarrassing to complete and gross to use and that they worry about collecting a usable stool sample (all $p < 0.001$). However, the pattern was reversed for two statements related to worry about test results: "I worry about what the Cologuard® test might show," and "I worry about the possibility of being diagnosed with cancer." For these statements, non-completers were more likely to *dis*agree compared to completers.

The bivariate analysis also found significant differences on most attitude and experience items between respondents who reported they would be "very likely" to complete the mt-sDNA test kit in the future and those who were less than very likely to do so ("very likely" and "less than very likely" respondents) (Table 3). The "very likely" respondents were more likely to agree with all the positively worded statements about the mt-sDNA test (eg, "I believe completing the Cologuard® test may help decrease my chances of dying from colorectal cancer," $p < 0.001$). The "very likely" respondents were more likely to *dis*agree with most of the negative statements (eg, "I worry my health insurance may not cover the cost of the Cologuard® test," $p < 0.001$). There were no differences between the "very likely" and "less than very likely groups" on two items about worry about test results: "I worry about what the Cologuard® test might show" and "I worry about the possibility of being diagnosed with colorectal cancer."

The regression analyses identified factors independently associated with completion of the mt-sDNA test and likelihood of completing the mt-sDNA test in the future, controlling for sociodemographic and health care factors (Table 4). For the full sample (ie, initial and repeat test subgroups combined), all three scales were positively associated with test completion: Perceived Effectiveness (OR = 1.282, $p = 0.003$); Perceived Ease of Use (OR = 3.676, $p < 0.001$); and

Table 2. Participant Characteristics by mt-sDNA Kit Completion[a] Status.

Respondent	Total Sample (n = 2973) % (n)	Completers[a] (n = 2299) % (n)	Non-completers (n = 674) % (n)
Age (years)	n = 2973	n = 2299	n = 674
45–54	14.7%(437)	15.88%(365)	10.68%(72)
55–64	35.15%(1045)	33.84%(778)	39.61%(267)
65+	50.15%(1491)	50.28%(1156)	49.7%(335)
Gender	n = 2973	n = 2299	n = 674
Male	34.04%(1012)	35.02%(805)	30.71%(207)
Female	65.96%(1961)	64.98%(1494)	69.29%(467)
Race	n = 2973	n = 2299	n = 674
White	87.96%(2615)	88.3%(2030)	86.8%(585)
Black/African American	6.63%(197)	6.66%(153)	6.53%(44)
American Indian/Alaskan Native	1.24%(37)	1.13%(26)	1.63%(11)
Asian	3.06%(91)	3.31%(76)	2.23%(15)
Native Hawaiian/Other Pacific Islander	0.2%(6)	0.17%(4)	0.3%(2)
Other	1.55%(46)	1.3%(30)	2.37%(16)
Ethnicity	n = 2,920[b]	n = 2264	n = 656
Hispanic	4.32%(126)	4.46%(101)	3.81%(25)
Non-Hispanic	95.68%(2794)	95.54%(2163)	96.19%(631)
Education	n = 2902	n = 2249	n = 653
High school or less	22.92%(665)	22.14%(498)	25.57%(167)
Some college	33.74%(979)	33.35%(750)	35.07%(229)
Bachelor's degree or more	43.35%(1258)	44.51%(1001)	39.36%(257)
Perceived Adequacy of Income	n = 2873	n = 2224	n = 649
Perceived low	11.28%(324)	9.26%(206)	18.18%(118)
Perceived middle	35.4%(1017)	33.9%(754)	40.52%(263)
Perceived high	53.32%(1532)	56.83%(1264)	41.29%(268)
Employed	n = 1302	n = 1024	n = 278
	44.15%(1302)	44.83%(1024)	41.8%(278)
Married	n = 1924	n = 1549	n = 375
	65.09%(1924)	67.79%(1549)	55.89%(375)
Insurance	n = 2968	n = 2296	n = 672
Private	59.7%(1772)	61.63%(1415)	53.12%(357)
Public	40.3%(1196)	38.37%(881)	46.88%(315)
Last Medical Checkup Less than 1 Year Ago	n = 2610	n = 2052	n = 558
88.29%(2610)	89.65%(2052)	83.66%(558)	
Ordering Provider			
Family medicine/general practice	64.98% (1932)	65.03% (1495)	64.84% (437)
Internal Medicine	24.82% (738)	24.62% (566)	25.52% (172)
Ob/Gyn	3.03% (90)	3.31% (76)	2.08% (14)
Gastroenterologist	1.48% (44)	1.65% (38)	0.89% (6)
Other	5.68% (169)	5.39% (124)	6.68% (45)

[a]Completed initial or repeat mt-sDNA test within 6 months of order.
[b]Demographic questions were optional. Due to respondent skip patterns, not all questions were asked of the full sample.

Perceived Comfort (OR = 1.135, p = 0.013). Respondents who were less worried about health insurance covering the cost of the test (OR = 1.151, p = 0.001) and less likely to say that instructions for sending the test kit back were difficult to follow (OR = 1.157, p < 0.001) had higher odds of test completion. Respondents who were less likely to worry about the possibility of being diagnosed with cancer had lower odds of test completion (OR = 0.765, p < 0.001). Also in the full sample, all three scales were positively associated with respondents saying they would be very likely to use the test kit in the future: Perceived Effectiveness (OR = 4.661, p < 0.001); Perceived Ease of Use (OR = 3.955, p < 0.001); and Perceived Comfort (OR = 1.181, p = 0.004). In addition, respondents who were less worried about health insurance covering the cost of the test had higher odds of saying they would be "very likely" to use the test in the future (OR = 1.113, p = 0.027).

We also developed models for the initial and repeat test subgroups separately to determine whether there were differences in the factors that influenced test completion and a user being "very likely" to complete the test in the future. For both the initial and repeat test groups, Perceived Effectiveness and Perceived Ease of Use were associated with test completion and being "very likely" to complete the test kit in the future. However, Perceived Comfort was associated with being "very likely" to complete the test in the future in the

Table 3. Differences in Attitudes About and Experiences with mt-sDNA Test Kit by Test Completion Status and Likelihood of Future use.

	Total (n = 2973)	Completers (n = 2299)	Non-completers (n = 674)		"Very likely" to use mt-sDNA in future (n = 2282)	Not "very likely" to use mt-sDNA in future (n = 659)	
	Mean (SD)	Mean (SD)	Mean (SD)	p-value	Mean (SD)	Mean (SD)	p-value
Positive Valence Statements							
I trust the results from the Cologuard® test.	4.43 (0.80)	4.54 (0.71)	4.05 (0.96)	<0.001	4.65 (0.56)	3.65 (1.01)	<0.001
I believe completing the Cologuard® test will help find any early signs of colorectal cancer.	4.51 (0.72)	4.59 (0.65)	4.21 (0.87)	<0.001	4.67 (0.56)	3.92 (0.89)	<0.001
I believe completing the Cologuard® test may help decrease my chances of dying from colorectal cancer.	4.41 (0.82)	4.50 (0.75)	4.11 (0.95)	<0.001	4.60 (0.67)	3.78 (0.95)	<0.001
I feel confident in my ability to use the Cologuard® test kit.	4.65 (0.76)	4.81 (0.50)	4.10 (1.16)	<0.001	4.84 (0.46)	4.00 (1.15)	<0.001
The Cologuard® test kit is convenient.	4.47 (0.89)	4.66 (0.68)	3.84 (1.18)	<0.001	4.70 (0.65)	3.69 (1.12)	<0.001
The instructions for completing my Cologuard® test kit are easy to follow.	4.56 (0.79)	4.73 (0.60)	4.00 (1.06)	<0.001	4.74 (0.60)	3.95 (1.03)	<0.001
Negative Valence Statements[a]							
I worry about what the Cologuard® test might show.	2.84 (1.23)	2.78 (1.20)	3.08 (1.31)	<0.001	2.83 (1.23)	2.89 (1.22)	0.323
I worry my health insurance may not cover the cost of the Cologuard® test.	3.52 (1.38)	3.59 (1.34)	3.28 (1.48)	<0.001	3.61 (1.36)	3.23 (1.39)	<0.001
I worry about the possibility of being diagnosed with colorectal cancer.	2.75 (1.23)	2.70 (1.22)	2.91 (1.23)	<0.001	2.74 (1.25)	2.77 (1.16)	0.561
The Cologuard® test kit is embarrassing to complete.	3.67 (1.30)	3.80 (1.27)	3.23 (1.33)	<0.001	3.83 (1.26)	3.10 (1.28)	<0.001
The Cologuard® test kit is gross to use.	3.58 (1.29)	3.71 (1.25)	3.14 (1.33)	<0.001	3.75 (1.25)	2.98 (1.24)	<0.001
I worry about collecting a useable stool sample.	3.40 (1.40)	3.53 (1.37)	2.94 (1.41)	<0.001	3.52 (1.39)	2.98 (1.34)	<0.001
The instructions for sending back my Cologuard® test kit are difficult to follow.	3.97 (1.38)	4.11 (1.36)	3.47 (1.32)	<0.001	4.09 (1.39)	3.52 (1.26)	<0.001

Note: 5-point scale where higher values indicate greater agreement; sample size varies due to missing responses.

[a] Negative valence statements were reverse-coded so that a higher score means greater disagreement with the statement.

initial test group only (OR = 1.308, p = 0.002) and with test completion in the repeat test group only (OR = 1.210, p = 0.003). In the repeat test group, respondents who were less worried about health insurance covering the cost of the mt-sDNA test had higher odds of both test completion (OR = 1.251, p =< 0.001 and being "very likely" to complete the test in the future (OR = 1.179, p = 0.012). Also in the repeat test group, respondents who were less worried about the possibility of being diagnosed with cancer had lower odds of both test completion (OR = 0.707, p < 0.001) and being "very likely" to complete the test in the future (OR = 0.787, p = 0.002). These factors were not significant in the initial test group. In the initial test group, respondents who disagreed that instructions for sending the test kit back were difficult to follow had higher odds of test completion (OR = 1.317, p = 0.001). This factor was not significant in the repeat test group.

Discussion

Although average-risk CRC screening in the United States has increased in the past 10 years[8] and introduction of the mt-sDNA screening test expanded the options for home-based testing,[28] it remains underutilized. The purpose of this study was to identify the patient attitudes and experiences that influence use of mt-sDNA screening to inform behavioral interventions and communication strategies to promote CRC screening.

Overall, respondents who had completed the mt-sDNA test kit and who anticipated they would complete it again in the future if ordered by their health care provider had more positive perceptions about the test compared to non-completers. Specifically, they had more positive perceptions about the value and trustworthiness of the test. In addition, these patients were more likely to view the test kit as convenient and easy to use. Conversely, negative emotional reactions to use of the screening test (eg, gross or embarrassing) appears to be a deterrent to test completion.

Exploratory factor analysis identified three underlying constructs that influence patients' decisions to complete the screening test and their likelihood of doing so in the future. The Perceived Effectiveness scale captures trust in the test results and belief that the test will help find early signs of cancer and decrease chances of dying from CRC. The Perceived Ease of Use scale captures a patient's perception that the test kit is convenient, instructions for use are easy to follow, and confidence that they can use the test kit correctly. Finally, the Perceived Comfort scale captures perceptions that the test kit is embarrassing and gross to use. The multivariate analyses revealed that these three scales were significant predictors of outcomes for test completion and likelihood of future test completion, controlling for sociodemographic and health insurance status, health literacy, and whether the patient had a health care visit in the last year. These findings highlight the importance of communicating with patients about the effectiveness, ease, and comfort of mt-sDNA screening through multiple communication channels.

The analyses revealed several differences in factors that influence test completion and likely future test completion between patients who received the test kit for the first time and patients who had completed a test kit previously. These findings suggest that prior experiences with the mt-sDNA test kit influenced decisions about completing the repeat test and expectations about completing a future test. Worry about the possibility of being diagnosed with CRC influenced outcomes in the repeat test group only; patients who were less worried about a cancer diagnosis had lower odds of both test completion and the likelihood of future test use. It may be that respondents who had completed a screening test previously where no cancer was detected had a (false) sense of assurance that they were not a risk and repeat screening was not necessary. These findings highlight the importance of communicating with patients about the need for regular screening according to guidelines to detect CRC early, when it is most treatable, or precancerous polyps can be removed to effectively prevent CRC.

Conversely, the perception that instructions for returning the test kit are difficult to follow was a predictive factor in the initial test group only. Patients who had received the test previously may have felt more familiar and comfortable with the instructions and, therefore, perceptions about the difficulty of the instructions did not influence outcomes.

Taken together, the study findings highlight the importance of developing interventions and messages to address patient concerns and strengthen positive perceptions about the effectiveness of mt-sDNA and the ease and comfort of using the test kit. Repeated communication through multiple channels is also critical. Current services provide patient information and support through a phone line (English and Spanish), reminders to complete the test (text, email, or phone), and information on a website. In the health care setting, providers can use a patient-centered communication approach[31] to understand patients' risk perceptions and their attitudes and experiences related to cancer screening, provide information in a way patients can understand, check for understanding (eg, how to use and return the test kit), and ask about and address any concerns. Utilizing patient decision aids and clinical conversation aids to facilitate screening discussion may be another promising approach to increase shared and informed cancer screening decision-making.[32–34] In terms of worries about getting a cancer diagnosis, providers can help patients understand the importance of regular screening to prevent or detect CRC early, especially for repeat test patients who may not understand the importance of regular screening. Providers can also acknowledge the anxiety associated with cancer screening ("I understand you are worried about what the test may find"), provide an empathetic response that normalizes it ("I understand your worry. Many patients feel like that") and provide information to address the worry ("Using this screening test can help to detect precancers that can be removed, as well as detect cancer early when it is very treatable").

Our study findings suggest several areas for future research, which include exploring the reasons behind initial

Table 4. Attitudinal and Experiential Factors Associated with Completion of the mt-sDNA Test Kit among All Respondents, Respondents who Received an Initial Test Kit, and Respondents who Received a Repeat Test Kit[a-c].

Coefficient	Full Sample						Initial Test Subgroup						Repeat Test Subgroup					
	Model 1: Odds of completing the test[b]			Model 2: Odds of being "very likely" to complete test in the future[c]			Model 1: Odds of completing test[d]			Model 2: Odds of being "very likely" to use test in the future[e]			Model 1: Odds of completing test[f]			Model 2: Odds of being "very likely" to use test in the future[g]		
	OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value
Perceived Effectiveness of test[h]	1.282	(1.071, 1.492)	0.003	4.661	(3.748, 5.575)	<0.001	1.581	(1.205, 2.073)	0.001	5.752	(4.293, 7.707)	<0.001	1.344	(1.068, 1.692)	0.012	4.099	(3.114, 5.395)	<0.001
Perceived Ease of Use of test[i]	3.676	(2.979, 4.374)	<0.001	3.955	(3.145, 4.765)	<0.001	6.318	(4.586, 8.706)	<0.001	4.580	(3.407, 6.156)	<0.001	3.428	(2.594, 4.530)	<0.001	3.629	(2.697, 4.883)	<0.001
Perceived Comfort in Using test[j]	1.135	(1.022, 1.249)	0.013	1.181	(1.047, 1.314)	0.004	1.123	(0.921, 1.369)	0.252	1.308	(1.107, 1.545)	0.002	1.210	(1.066, 1.372)	0.003	1.056	(0.901, 1.238)	0.500
I worry my health insurance may not cover the cost of the Cologuard® test. (reverse coded)[k]	1.151	(1.055, 1.247)	0.001	1.113	(1.008, 1.218)	0.027	1.050	(0.891, 1.237)	0.561	1.045	(0.906, 1.205)	0.547	1.251	(1.127, 1.389)	<0.001	1.179	(1.037, 1.341)	0.012
I worry about the possibility of being diagnosed with colorectal cancer. (reverse coded)[k]	0.765	(0.692, 0.838)	<0.001	0.917	(0.818, 1.017)	0.120	0.924	(0.762, 1.120)	0.421	1.081	(0.915, 1.277)	0.361	0.707	(0.628, 0.796)	<0.001	0.787	(0.679, 0.913)	0.002
The instructions for sending back my Cologuard® test kit are difficult to follow. (reverse coded)[k]	1.157	(1.066, 1.249)	<0.001	1.031	(0.934, 1.129)	0.521	1.317	(1.124, 1.542)	0.001	0.955	(0.826, 1.103)	0.529	1.102	(0.998, 1.217)	0.055	1.099	(0.968, 1.248)	0.146

[a]Models includes an intercept, as well as sociodemographic and health care control variables: age, sex, education, income, race, ethnicity, marital status, employment status, health insurance status, health literacy, and health care visit in last year.
[b]Full Sample Model 1 stats: n = 2,679, percent correctly predicted (PCP) = 82.83, proportionate reduction in error (PRE) = 22.82.
[c]Full Sample Model 2 stats: n = 2,666, PCP = 86.01, PRE = 37.42.
[d]Initial Test Subgroup Model 1 stats: n = 1,350, PCP = 90.81, PRE = 37.37.
[e]Initial Test Subgroup Model 2 stats: n = 1,343, PCP = 86.37, PRE = 45.21.
[f]Repeat Test Subgroup Model 1 stats: n = 1,329, PCP = 76.15, PRE = 20.35.
[g]Repeat Test Subgroup Model 2 stats: n = 1,323, PCP = 86.32, PRE = 30.92.
[h]Perceived Effectiveness scale includes: I trust the results from the Cologuard® test. I believe completing the Cologuard® test will help find any early signs of colorectal cancer. I believe competing the Cologuard® test may help decrease my chances of dying from colorectal cancer.
[i]Perceived Ease of Use scale includes: I feel confident in my ability to use the Cologuard® test kit. The Cologuard® test kit is convenient. The instructions for completing my Cologuard® test kit are easy to follow.
[j]Perceived Comfort in Using Scale includes: The Cologuard® test kit is embarrassing to complete. The Cologuard® test kit is gross to use.
[k]For negative valence statements, a positive association means that greater disagreement with the statement is associated with increased odds of test completion or being "very likely" to return the test in the future; a negative association means that greater disagreement with the statement is associated with decreased odds of test completion or being very likely to return the test in the future.

and repeat user differences in factors that predict test completion. Recent research found disparities by race/ethnicity and socioeconomic status indicators in awareness, knowledge, and utilization of newly-introduced CRC screening modalities including mt-sDNA and identified variations by sociodemographic factors in patient concerns and factors influencing CRC screening decision-making.[25–27,35] Further research is encouraged to identify potential sociodemographic differences in the relative importance of various attitudinal and experiential factors associated with mt-sDNA screening completion and adherence, with the goal to inform behavioral interventions and communication strategies that are better tailored to community needs and preferences.

Limitations

The study involved a national sample of patients who received the mt-sDNA test kit as ordered by a provider. The sample size allowed for comparisons across subgroups (test completion status, initial or repeat test kit) and for regression modeling with a robust set of sociodemographic, health care, and attitudes and experiences predictors. However, a few limitations are worth noting. First, sample members who returned test kits were more likely than non-completers to complete the survey. Sampled participants who did not respond to the survey may differ from those who responded in their perceptions and likelihood of completing mt-sDNA screening. Another potential limitation is recall bias, or error. Respondents received the screening test kit 6 to 10 months prior to survey completion. Their recall about using the test kit and perceptions about the test may have changed over this time period.

Conclusion

This study provided actionable insights regarding patient attitudes and experiences that positively and negatively influenced whether they completed the mt-sDNA test kit and expected to do so in the future. The findings can inform interventions and messaging to improve CRC screening rates.

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Availability of Data and Material

Study data are available upon reasonable request.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethics Approval

The data herein were retrospectively reviewed as part of ongoing laboratory (Exact Sciences Laboratories, LLC) quality management processes in compliance with the Health Insurance Portability and Accountability Act (HIPAA). The study was deemed exempt from IRB review by RTI Institutional Review Board.

Consent to Participate/Publish: Participants were provided with information about the purpose of the study, privacy procedures, and informed that their participation was voluntary.

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Appendix Tables

Table A1. Nonresponse Analysis Table.

	Total (n = 17,370)	Sample (n = 2973)	Non-Sample (n = 14,397)	Sig. Diff?
Cohort				Yes [$p < 0.001$]
Completed initial	23.03	42.08	19.09	
Completed rescreen	15.37	35.25	11.27	
Did NOT complete rescreen	30.80	14.97	34.07	
Did NOT complete initial	30.80	7.70	35.57	
Sex				No [$p = 0.96$]
Female	61.49	65.76	60.61	
Male	38.07	33.84	38.94	
Unknown	0.44	0.40	0.45	
Age				No [$p = 0.97$]
45–54	15.84	14.67	16.08	
55–64	37.89	35.18	38.45	
65+	46.28	50.15	45.47	

[a]Significant difference determined by alpha < 0.05 on a Pearson's Chi-squared test for a given section (eg, the 4 × 3 section for 'Cohort').

Table A2. Correlation Structure of Attitude Items for Scale Creation.

	I trust the results from the Cologuard® test	I worry about what the Cologuard® test might show	I worry my health insurance may not cover the cost of the Cologuard® test	I believe completing the Cologuard® test will help find any early signs of colorectal cancer	I believe completing the Cologuard® test may help decrease my chances of dying from colorectal cancer	I worry about the possibility of being diagnosed with colorectal cancer
I trust the results from the Cologuard® test	1.00					
I worry about what the Cologuard® test might show	−0.01	1.00				
I worry my health insurance may not cover the cost of the Cologuard® test	0.06	0.27	1.00			
I believe completing the Cologuard® test will help find any early signs of colorectal cancer	0.68	−0.05	0.07	1.00		
I believe completing the Cologuard® test may help decrease my chances of dying from colorectal cancer	0.58	−0.05	0.08	0.72	1.00	
I worry about the possibility of being diagnosed with colorectal cancer	0.03	0.67	0.30	−0.05	−0.08	1.00

[a]The Perceived Effectiveness scale was constructed using items "I trust the results from the Cologuard® test", "I believe completing the Cologuard® test will help find any early signs of colorectal cancer", and "I believe completing the Cologuard® test may help decrease my chances of dying from colorectal cancer".

Table A3. Correlation Structure of Behavior Items for Scale Creation.

	I feel confident in my ability to use the Cologuard® test kit	I worry about collecting a useable stool sample	The Cologuard® test kit is convenient	The Cologuard® test kit is embarrassing to complete	The Cologuard® test kit is gross to use	The instructions for completing my Cologuard® test kit are easy to follow	The instructions for sending back my Cologuard® test kit are difficult to follow
I feel confident in my ability to use the Cologuard® test kit	1.00						
I worry about collecting a useable stool sample	0.32	1.00					
The Cologuard® test kit is convenient	0.59	0.21	1.00				
The Cologuard® test kit is embarrassing to complete	0.31	0.41	0.35	1.00			
The Cologuard® test kit is gross to use	0.32	0.38	0.36	0.73	1.00		
The instructions for completing my Cologuard® test kit are easy to follow	0.54	0.23	0.55	0.24	0.24	1.00	
The instructions for sending back my Cologuard® test kit are difficult to follow	0.22	0.23	0.22	0.28	0.26	0.26	1.00

[a]The Perceived Ease of Use scale was constructed using items "I feel confident in my ability to use the Cologuard® test kit", "The Cologuard® test kit is convenient", and "The instructions for completing my Cologuard® test kit are easy to follow".
[b]The Perceived Comfort scale was constructed using items "The Cologuard® test kit is embarrassing to complete" and "The Cologuard® test kit is gross to use".