Impact of Spanish Language Outreach on Multi-Target Stool DNA Test Adherence in a Federally Qualified Health Center in the **United States**

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Abstract

Introduction: The objective of the current study was to examine the impact of Spanish-language patient outreach and navigation services on adherence to initial colorectal cancer (CRC) screening with multitarget stool DNA (mt-sDNA) testing in a predominantly Spanish-speaking patient population receiving care at Federally Qualified Health Centers (FQHCs).

Method: This study included patients aged 45 years or older who identified as Hispanic from FQHCs in a California Health System who were new to mt-sDNA testing and shipped a Cologuard® collection kit between 10-1-2022, and 1-1-2024. Patient outreach was provided only in English prior to 1-22-2023 (pre-intervention period). From 1-23-2023, onward, patient outreach was offered in either English or Spanish based on the patients' preferred language selection (post-intervention period). Patients were classified into two subgroups: Spanish language preference (SLP) or non-Spanish language preference (NSLP). It was hypothesized that adherence would be greater in SLP patients when patient outreach was provided in Spanish compared to the NSLP.

Results: The final sample comprised 20 341 Hispanic patients who met the study criteria, comprising 15 702 patients with SLP and 4639 with NSLP, stratified across pre- and post-intervention periods. Overall, adherence to initial mt-sDNA testing within 180 days following the index date was 51.4% for SLP patients and 41.3% for NSLP patients, with a significant post-intervention improvement observed after the intervention for SLP patients (47.1% to 52.7%, P < .001), compared to a non-significant improvement (40.7% to 41.4%, P = .713) among NSLP patients.

Discussion: Following the introduction of Spanish-language patient outreach, adherence to mt-sDNA testing improved significantly among SLP patients. The preference of Hispanic individuals for stool-based tests, combined with the non-invasive nature of mt-sDNA testing, supports its suitability as a CRC screening option for this population.

Keywords

health disparities, Hispanic, colorectal cancer, mt-sDNA, adherence, adherence

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Introduction

The Hispanic population is one of the fastest growing minority groups in the United States (US), rising from 9.6 million people in 1970 to 65.2 million in 2023¹ and is projected to reach 90.5 million by 2050² and 111 million by 2060.³ One particular health concern in this growing population is

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colorectal cancer (CRC), which, in individuals of Hispanic descent, is the third most commonly diagnosed cancer and second leading cause of cancer death overall.⁴ It is estimated that there were 17 100 new cases of CRC and 5300 deaths due to CRC among the U.S. Hispanic population in 2024.⁴

Routine screening for CRC can help detect cancer early, which can in turn facilitate treatment and increase chances of survival.⁵⁻⁷ Unfortunately, the CRC screening rates for Hispanic individuals has been found to be significantly lower than for non-Hispanic White individuals, with some studies suggesting that less than half of eligible Hispanic adults receive CRC screening ⁸⁻¹² compared to 59%-72% of the eligible US population. ¹³⁻¹⁵ Consequently, CRC in Hispanic individuals is often diagnosed at a more advanced stage, leading to increased healthcare burden, higher mortality rates, and exacerbating health disparities. ^{8,16-18}

Previous work to identify the antecedents of lower CRC screening in Hispanics have pointed to a number of potential factors including distrust in the healthcare system¹⁹ and cultural beliefs about masculinity,²⁰ as well as limited knowledge of CRC and CRC screening.^{21,22} However, one of the most salient barriers to CRC screening in Hispanic individuals in the US is a lack of English proficiency,²³⁻²⁸ given that an estimated 28% of Hispanics have limited English proficiency (LEP) and 27% are Spanish dominant.^{29,30} One factor contributing to CRC knowledge barriers and lower screening completion rates among Spanish speakers is suggested by a recent study that found instructions for stool-based CRC testing were typically not provided in Spanish nor were language translation services offered when scheduling a colonoscopy.²³

Research has shown that the modality of CRC testing is critical to increasing screening rates overall. ¹⁵ Furthermore, Hispanic patients have been found to be up to 82% more likely to undergo stool-based CRC screening than non-Hispanic Whites. ³¹ One such stool-based testing option for CRC screening in individuals at average risk is the multi-target stool DNA (mt-sDNA; eg, Cologuard) test, a non-invasive, at-home screening tool recommended in several guidelines, including those of the American Cancer Society and the American College of Gastroenterology. ^{32,33} Of the available at-home, stool-based testing options for CRC screening, the mt-sDNA test has the advantage of being recommended once every three years when compared to annually for the fecal immunochemical test (FIT) or the high-sensitivity guaiac-based fecal occult blood test (gFOBT).

The objective of the current study was to examine the impact of Spanish-language patient outreach on adherence to initial CRC screening with mt-sDNA testing in a Hispanic patient population receiving care at Federally Qualified Health Centers (FQHCs). Nationwide, more than 35% of Hispanic individuals seek their healthcare services at FQHCs, 11 where only about 40% of the screen-eligible population treated in these centers are up-to-date with CRC screening overall. 14

Methods

Study Design and Sample Selection

This study included patients of Hispanic or Latino origin or descent aged 45 years or older from FQHCs in a California Health System who did not have a prior claim for mt-sDNA testing and who were shipped a Cologuard® collection kit between October 1, 2022, and January 1, 2024, from Exact Sciences Laboratories LLC (Madison, WI). The index date was the date of the first shipment on the first prescription order (CPT 81528) for the Cologuard test. Patients were required to be continuously enrolled in a health plan for a minimum of one year before and 180 days after the index date. Patients who had multiple orders or were returning patients were excluded. These data were de-identified and compliant with the Health Insurance Portability and Accountability Act (HIPAA); the current study was exempt from Institutional Review Board (IRB) review.

Patient outreach included welcome messages, reminders, and notifications of test result availability via letters and phone calls which all patients received. Patients were also assigned to one of two outreach channels either 'full digital' (short message service [SMS] plus email) if the referring health system provided both their phone number and email, or 'partial digital, SMS only' if the referring health system only provided the patents' phone number. Patients who were shipped their mt-sDNA testing kit prior to January 23, 2023, were provided all of the above patient outreach in English (pre-intervention period) regardless of language preference. From January 23, 2023, onward, patient outreach and test navigation services were offered in either English or Spanish based on the patients' preferred language selection (postintervention period) determined by their medical records. To reiterate, in the pre-intervention period patients received all patient outreach in English as is normally provided to all patients. In the post-intervention period, the same material was simply provided in Spanish to patients that preferred Spanish.

In both the pre- and post-intervention periods, patients were classified into two subgroups based on their language preference: Spanish language preference (SLP) or non-Spanish language preference (NSLP). Therefore, in the preintervention stage both SLP and NSLP patients received patient outreach in English. At the postintervention stage patents in the SLP group received patient outreach in Spanish while NSLP received patient outreach in English.

Variables and Outcomes

The primary outcome of this study was adherence to initial mtsDNA screening, which was defined as a completed and returned test kit, with a valid test result obtained by Exact Science Laboratories, LLC within 180 days of the shipment date. Specifically changes in adherence in the SLP group from pre- to post-intervention were compared to changes in the

NSLP. It was hypothesized that adherence would increase in the SLP patients when they were given patient outreach and test navigation services in Spanish compared to the NSLP patients at both time points

In addition to language preference and outreach channel, patient demographic characteristics included age, gender, ethnicity, payer type, urban/rural classification, Social Vulnerability Index (SVI) score, ³⁴ and median household income by ZIP code.

Statistical Analyses

Study measures and outcomes were summarized using counts and percentages for categorical variables and means with standard deviations (SDs) for continuous variables. Descriptive statistics were used to summarize unadjusted differences in patient characteristics at the index date as well as adherence between the pre-intervention and postintervention periods separately within the SLP and NSLP subgroups. Logistic regression was used to examined predictors of adherence (yes/no) and tested whether providing patient outreach and instructions in Spanish during the postintervention period significantly increased adherence in the SLP subgroup after controlling for demographic characteristics. All analyses were performed using R version 4.4.0 (The R Foundation for Statistical Computing, Vienna, Austria). The reporting of this study conforms to STROBE guidelines.35

Results

Patient Characteristics

The final sample comprised 20 341 Spanish-speaking patients who met the study criteria, comprising 15 702 patients with SLP patients and 4639 with NSLP, stratified across pre- and post-intervention periods. (Table 1) During the pre- and postintervention periods, two-thirds (63%) of SLP patients and over half (55%) of NSLP patients were aged 50-64 years, and roughly two-thirds (64%) of SLP patients were female. In the pre-intervention period, nearly half (49%) of SLP patients and over half (55%) of NSLP patients lived ZIP codes with median household incomes between \$75K and \$100K. In terms of payer type, more than half of both SLP (54%) and NSLP (56%) patients in the post-intervention period were covered by a manage care organization (MCO), followed by commercial insurance (26%). Outreach channel utilization varied between SLP and NSLP patients, with the majority of SLP patients (61%) in the pre-intervention period reaching outreach through 'partial digital, SMS only' channels, increasing to nearly 79% in the post-intervention period. Among NSLP patients, the distribution was reversed in the pre-intervention period, with the majority (64%) engaged through 'full digital' outreach; however, in the post-intervention period, the proportion of NSLP patients receiving 'partial digital, SMS only'

increased to 65%, while those engaged through 'full digital' declined to 35%. Lastly, over three-quarters (75%) of SLP patients and 61% of the MSLP, in both pre- and post-intervention periods, were classified as "most vulnerable" in the SVI quartile.

Adherence Rate

Overall, adherence to initial mt-sDNA testing within 180 days following the index date was 51.4% for SLP patients and 41.3% for NSLP patients, with a significant post-intervention improvement observed for SLP patients (47.1% to 52.7%, P <.001), compared to a non-significant improvement (40.7% to 41.4%, P = .713) among NSLP patients (Table 2). Subgroup analyses revealed consistent adherence improvements for SLP patients across key demographic and socioeconomic groups, compared to differences observed among NSLP patients. Statistically significant improvement in adherence rates after the intervention with SLP were observed among patients aged 50-64, (46.9% vs 53.9%, P < .001), compared to a nonsignificant increase (38.4% vs 40.7%, P = .346) for NSLP patients. Adherence rates among male SLP patients increased significantly (47.3% vs 52.4%, P = .001), compared to male NSLP patients who showed no improvement (43.1% to 42.6%, P = .892). A similar trend was observed among female patients, though the magnitude of change differed slightly: adherence rates for female SLP patients increased significantly (47.0% vs 52.9%, P < .001), while female NSLP patients experienced a non-significant increased (39.3% to 40.7%, P = .567).

Significant differences in adherence rates across payer types were observed. Both SLP and NSLP patients covered by commercial health insurance demonstrated significant increases in adherence rates with SLP patients improving from 37.7% to 52.7% (P < .001) and NSLP patients increasing from 30.6% to 44.4% (P < .001). Lastly, among Medicaid-insured patients, SLP patients experienced a significant improvement in adherence from 19.6% to 32.4% (P = .022), while no significant differences were observed for NSLP patients.

Predictors of Adherence

Adjusted predictors of adherence to initial mt-sDNA screening were assessed using multivariable logistic regression, with results presented in Table 3. Patients aged 65 years and older had 18% lower odds to adhere compared to those aged 45-49 years (P = .001). Compared to those covered by commercial insurance, patients with MCOs and Medicare Advantage had 33% and 64% higher odds to adhere, respectively (P < .001). Similarly, patients covered by Medicare exhibited 35% higher odds of adherence (P = .001) when controlling for other variables in the model including age. In contrast, Medicaid-insured and self-pay patients had 59% and 83% lower odds to be adherent, respectively, compared to

Table I. Patient Characteristics at Index Date.

	Spanish language preferred			Non-Spanish language preferred		
	Pre-intervention period ^a (N = 3718)	Post-intervention period ^b (N = 11 984)	P- value	Pre-intervention period ^a (N = 1073)	Post-intervention period ^b (N = 3566)	P- value
SVI quartile, n (%)			.45			.24
I – Least vulnerable	29 (0.8%)	66 (0.6%)		22 (2.1%)	46 (1.3%)	
2 – Less vulnerable	151 (4.1%)	449 (3.7%)		81 (7.5%)	291 (8.2%)	
3 – More vulnerable	677 (18.2%)	2235 (18.6%)		275 (25.6%)	931 (26.1%)	
4 – Most vulnerable	2802 (75.4%)	9033 (75.4%)		655 (61.0%)	2197 (61.6%)	
Unknown	59 (1.6%)	201 (1.7%)		40 (3.7%)	101 (2.8%)	
Age, n (%)			.32			.11
45-49 years	471 (12.7%)	1411 (11.8%)		357 (33.3%)	1199 (33.6%)	
50-64 years	2340 (62.9%)	7582 (63.3%)		575 (53.6%)	1981 (55.6%)	
65+ years	907 (24.4%)	2991 (25.0%)		141 (13.1%)	386 (10.8%)	
Gender, n (%)			.01			.11
Male	1278 (34.4%)	4422 (36.9%)		399 (37.2%)	1426 (40.0%)	
Female	2440 (65.6%)	7562 (63.1%)		674 (62.8%)	2140 (60.0%)	
Patient ethnicity, n (%)	,	, ,	<.01	,	, ,	<.01
Hispanic or Latino origin or descent	3718 (100.0%)	11 984 (100.0%)		1073 (100.0%)	3566 (100.0%)	
Urban/Rural classification, n (%)			<.01			<.01
Metropolitan	3718 (100.0%)	11 984 (100.0%)		1073 (100.0%)	3566 (100.0%)	
ZIP median household income, n (%)			<.01			.10
<\$50K	88 (2.4%)	337 (2.8%)		14 (1.3%)	51 (1.4%)	
\$50K-\$75K	1492 (40.1%)	5364 (44.8%)		363 (33.8%)	1339 (37.5%)	
\$75K-\$100K	1829 (49.2%)	5336 (44.5%)		589 (54.9%)	1829 (51.3%)	
\$100K-\$125K	228 (6.1%)	734 (6.1%)		78 (7.3%)	277 (7.8%)	
\$125K+	81 (2.2%)	213 (1.8%)		29 (2.7%)	70 (2.0%)	
Payer type, n (%)	,	` ,		,	, ,	
Commercial	1025 (27.6%)	2298 (19.2%)		385 (35.9%)	921 (25.8%)	
MCO	1800 (48.4%)	6428 (53.6%)		487 (45.4%)	2007 (56.3%)	
Medicare advantage	470 (12.6%)	1804 (15.1%)		79 (7.4%)	314 (8.8%)	
Medicaid	97 (2.6%)	296 (2.5%)		29 (2.7%)	64 (1.8%)	
Medicare	108 (2.9%)	388 (3.2%)		46 (4.3%)	117 (3.3%)	
Self-pay	218 (5.9%)	770 (6.4%)		47 (4.4%)	143 (4.0%)	
Digital channel, n (%)	` ,	, ,	<.01	` ,	` '	<.01
Partial digital, SMS only	2253 (60.6%)	9456 (78.9%)		387 (36.1%)	2323 (65.1%)	
Full digital	1465 (39.4%)	2528 (21.1%)		686 (63.9%)	1243 (34.9%)	

Abbreviations: MCO: Manage Care Organization; SMS: Short Message Service; SVI: social vulnerability index.

those with commercial insurance (both P < .001). Additionally, adherence was also inversely associated with social vulnerability. Patients in the 'less vulnerable' SVI quartile had 39% lower odds to adhere compared to those in the 'least vulnerable' quartile (P = .007), while those in the 'more vulnerable' and 'most vulnerable' quartiles had 45% and 49% lower odds to adhere, respectively (P = .001 and P < .001). Outreach method significantly influenced adherence, with patients engaged through 'full digital' outreach having 29%

higher odds to be adherent compared to those who received 'partial digital, SMS only' outreach (P < .001). Language preferences was also a strong determinant of adherence in this study, with SLP patients having 45% higher odds to adhere to mt-sDNA testing compared to NSLP patients (P = < .001) in the pre-intervention period. Lastly, the interaction effect between patient language preference (SLP vs NSLP) and intervention period (pre- vs post-intervention) was statistically significant (P = .010), with SLP patients

^aPatients who were shipped their testing kit prior to January 22, 2023 (patient outreach and test navigation services only in English).

^bPatients who were shipped their testing kit from January 22, 2023, onward (patient outreach and test navigation services in either English or Spanish based on patient language preference).

Table 2. Adherence Rate^a Stratified by Language Preference.

	Spanish language preferred			Non-Spanish language preferred		
	Pre-intervention period ^b	Post-intervention period ^c	P- value	Pre-intervention period ^b	Post-intervention period ^c	P- value
Patient preferred language	47.1%	52.7%	<.001	40.7%	41.4%	.713
SVI quartile						
I – Least vulnerable	55.2%	71.2%	.198	50.0%	65.2%	.350
2 – Less vulnerable	57.0%	58.8%	.763	38.3%	43.6%	.461
3 – More vulnerable	48.7%	53.5%	.033	42.5%	44.3%	.665
4 – Most vulnerable	46.0%	52.1%	<.001	40.5%	39.5%	.696
Unknown	49.2%	53.7%	.638	32.5%	39.6%	.554
P-value	.068	.001		.644	.001	
Age						
45-49 years	47.8%	49.9%	0.456	45.4%	41.0%	.199
50-64 years	46.9%	53.9%	<0.001	38.4%	40.7%	.346
65+ years	47.3%	50.9%	0.061	38.3%	45.1%	.197
<i>P</i> -value	.930	.002		.091	.285	
Gender						
Male	47.3%	52.4%	0.001	43.1%	42.6%	.892
Female	47.0%	52.9%	<0.001	39.3%	40.7%	.567
P-value	.911	.665		.431	.3	
Ethnicity						
Hispanic or Latino origin or descent	47.1%	52.7%	<0.001	40.7%	41.4%	.713
ZIP median household income	!					
<\$50K	45.5%	52.8%	0.267	57.1%	35.3%	.242
\$50K-\$75K	47.4%	51.3%	0.007	42.1%	38.0%	.170
\$75K-\$100K	45.7%	53.4%	<0.001	39.4%	43.2%	.109
\$100K-\$125K	51.8%	56.3%	0.262	41.0%	45.5%	.568
\$125K+	61.7%	56.3%	0.481	41.4%	47.1%	.762
P-value	.033	.040		.679	.014	
Payer type						
Commercial	37.7%	52.7%	<0.001	30.6%	44.4%	<.001
MCO	55.5%	57.1%	0.233	50.1%	42.0%	.001
Medicare advantage	58.5%	56.0%	0.363	55.7%	47.5%	.236
Medicaid	19.6%	32.4%	0.022	20.7%	14.1%	.617
Medicare	48.1%	51.8%	0.573	47.8%	48.7%	1.000
Self-pay	9.2%	16.4%	0.011	6.4%	7.0%	1.000
P-value	<.001	<.001		<.001	<.001	
Digital channel						
Partial digital, SMS only	43.5%	52.2%	<0.001	34.6%	40.2%	.043
Full digital	52.6%	54.5%		44.2%	43.7%	.875
P-value	<.001	.049		.003	.048	

Abbreviations: MCO: Managed Care Organization; SMS: Short Message Service; SVI: social vulnerability index.

demonstrating 23% higher odds of adherence compared to NSLP patients in the post-intervention period relative to the pre-intervention difference. The interaction effect is decomposed in Figure 1, where SLP patients experienced a significantly greater increase in adherence post-intervention

compared to NSLP patients. Counterfactual estimates (represented by the dashed lines) for SLP patients suggest that, in the absence of the targeted outreach intervention, adherence rates would have remained similar to preintervention levels.

^aAdherence rate was calculated as the percentage of eligible patients who completed and returned the test kit, with a valid test result obtained within 180 days of the initial shipment date.

^bPatients who were shipped their testing kit prior to January 23, 2023 (patient outreach and test navigation services only in English).

Patients who were shipped their testing kit from January 23, 2023, onward (patient outreach and test navigation services in either English or Spanish based on patient language preference).

Table 3. Multivariable Logistic Regression Predicting Adherence^a

Coefficient	Estimate	Odds ratio (95% CI)	P-value
Intercept	-0.05	0.95 (0.63, 1.44)	.822
SVI quartile (reference = I – Least vulnerable)		,	
2 – Less vulnerable	-0.50	0.61 (0.42, 0.87)	.007
3 – More vulnerable	-0.60	0.55 (0.39, 0.77)	.001
4 – Most vulnerable	-0.67	0.51 (0.36, 0.73)	<.001
Unknown	-0.70	0.50 (0.34, 0.74)	.001
Age (reference = 45-49 years)			
50-64 years	-0.01	0.99 (0.91, 1.07)	.750
65+ years	-0.20	0.82 (0.73, 0.92)	.001
Gender (reference = female)			
Male	0.05	1.05 (0.99, 1.11)	.127
ZIP median household income (reference = <\$50K)		, ,	
\$50K-\$75K	-0.01	1.00 (0.83, 1.20)	.989
\$75K-\$100K	0.05	1.05 (0.87, 1.27)	.596
\$100K-\$125K	0.13	1.13 (0.91, 1.41)	.267
\$125K+	0.12	1.13 (0.85, 1.50)	.414
Payer type (reference = commercial)		,	
MCO (0.29	1.33 (1.24, 1.43)	<.001
Medicare advantage	0.49	1.64 (1.45, 1.84)	<.001
Medicaid	-0.89	0.41 (0.33, 0.51)	<.001
Medicare	0.30	1.35 (1.13, 1.61)	.001
Self-pay	-1.78	0.17 (0.14, 0.20)	<.001
Digital channel (reference = partial digital, SMS only)		,	
Full digital	0.25	1.29 (1.21, 1.37)	<.001
Spanish language outreach implemented (reference = N	lo [pre-intervention period	, ,	
Yes (post-intervention period)	0.06	1.06 (0.92, 1.22)	.423
Patient language preference (reference = non-Spanish)		,	
Spanish	0.37	1.45 (1.25, 1.67)	<.001
Spanish language outreach implemented X patient langu		,	
No (pre-intervention) X Spanish interaction	0.21	1.23 (1.05, 1.45)	.010

Abbreviations: MCO: Manage Care Organization; SMS: Short Message Service; SVI: social vulnerability index.

Discussion

This study evaluated the impact of Spanish-language outreach and multichannel navigation on adherence to CRC screening with mt-sDNA test within a Hispanic patient population receiving care at FQHCs. SLP patients adherence increased from 47% to 53% after patient outreach and test navigation services were provided in Spanish, while NSLP patients adherence remained the same. Coupled together, these findings suggest that the 6% increase in adherence in the SLP patients can be directly attributable to the patient outreach and test navigation services being offered in Spanish to this population of Hispanic patients.

The adherence rates observed in this study are consistent with findings from broader studies that have indicated that individuals with LEP, particularly within Hispanic communities often exhibit lower CRC screening rates compared to English-proficient populations. 12,28,36,37 Notably, the improvement in adherence rates observed in our study among

SLP patients was higher after implementation of the intervention compared with adherence rates reported in prior studies examining CRC screening among Hispanic individuals using FIT/FOBT tests. 38,39 For example, a previous study examining FOBT usage among Hispanic adults living in Puerto Rico ranged from 20.5% in 2012 to 45.6% in 2020, while on the US mainland, FOBT usage ranged from 9.9% in 2012 to 16.7% in 2020. 12 This observed difference between may be partially attributable to less frequent testing intervals for mt-sDNA (every three years) compared to FIT/FOBT (annually), as well as the additional impact of tailored Spanish-language outreach in addressing barriers specific to LEP populations. Previous research has highlighted that individuals with LEP are more likely to encounter structural barriers in access to healthcare, including inadequate health insurance coverage⁴⁰ and ineffective patient-physician communication. 41 These language barriers can impede comprehension of screening recommendations and access

^aAdherence rate was calculated as the percentage of eligible patients who completed and returned the test kit, with a valid test result obtained within 180 days of the initial shipment date.

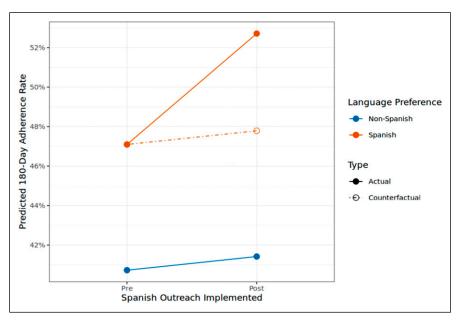


Figure 1. Predicted Adherence Rates Pre- and Post-Implementation of Spanish Outreach.

to healthcare information, resulting in significantly lower CRC screening rates compared to English-proficient populations³⁶

Additionally, adherence rates after the intervention with Spanish language varied significantly by demographics and socioeconomic status, with SLP patients in the most socially vulnerable quartile demonstrating significant adherence improvement post-intervention. This observation is notable as language barriers often intersect with other forms of social disadvantage, creating compounding obstacles to healthcare access and utilization. 42 Age also influenced adherence, with SLP patients aged 50-64 years showing the largest improvement, while older SLP patients (65+ years) exhibited smaller, non-significant improvements. This trend observed may suggest that age-related factors, such as health literacy, mobility, or competing health priorities, may affect adherence differently across age groups. Limited health literacy has been associated with lower screening uptake, and interventions aimed at improving health literacy have been shown to enhance adherence to CRC screening⁴³ and older individuals often manage multiple health conditions, which may lead to competing health priorities and deprioritization of preventive services like CRC screening. Other characteristics associated with significant improvements in adherence included gender, with a similar trend for females, patients who received 'partial digital, SMS-only' for both SLP and NSLP patients, income status (\$75K-\$100K), as well as patients covered by commercial insurance and Medicaid.

Results from the multivariable logistic regression analyses in our study revealed important factors influencing adherence to mt-sDNA screening among Hispanic patients in this sample of FQHC patients. Older SLP patients (aged 65 years and above) were less likely to adhere compared to younger

patients aged 45-49 years. The issue of cost as a barrier to adherence also played a significant role, as SLP patients covered by MCO, Medicare Advantage, and Medicare insurance tended to have higher adherence rates compared to Commercially insured patients, potentially reflecting better coverage or fewer out-of-pocket costs associated with these programs. In contrast, Medicaid-insured and self-pay patients exhibited lower adherence rates compared to the same reference group, suggesting that financial barriers remain a critical challenge for these groups despite targeted outreach efforts. Outreach methods also influenced adherence rates in our study; at the descriptive level patients engaged through partial digital outreach experienced increases in adherence from pre- to post-intervention and results from the logistic regression suggested that full digital outreach significantly improved adherence controlling for other factors. These findings have important implications for intervention design, highlighting the potential value of communication strategies in improving screening adherence, particularly among diverse populations. Lastly, the odds of adherence were 23% higher for SLP compared to NSLP in the post-intervention period (when SLP received outreach in Spanish) relative to the preintervention, reflecting the success of linguistically tailored outreach in addressing barriers specific to limited LEP populations.

Study Limitations

This study has a few limitations. First, the data were obtained from a single health system in California, which may limit the generalizability of the findings to other regions or populations, as it may lack detailed clinical information and potentially underestimate adherence rates. Specifically, we cannot

ascertain whether any patients included in this study were experiencing minor symptoms attributed to colorectal cancer that prompted them to undergo mt-sDNA testing. Additionally, we do not know if those who did not complete the mtsDNA test recently underwent other forms of screening for CRC that would render the mt-sDNA test redundant and unnecessary. Second, while the study relied on self-reported language preference, additional details regarding bilingualism or the frequency of Spanish use were not captured, which could influence the observed effects of Spanish-language outreach. Third, the study's observational design precludes causal inference regarding the impact of the intervention, as other factors could have contributed to the observed improvements in adherence rates. Finally, though many differences between the two cohorts were controlled for in the logistic regression it is likely that inherent differences between cohorts may have contributed to bias in our results. A random controlled trial would help to further our findings by providing more insight to causality and providing a greater level of control.

Conclusion

Our findings highlight the significant role of Spanish-language outreach in improving adherence to CRC screening with mtsDNA testing among a predominantly Hispanic population. Following the introduction of Spanish-language patient outreach, adherence to mt-sDNA testing improved significantly among SLP patients. Additional factors beyond the Spanish language intervention influencing adherence included older age, gender, payer type, and full digital outreach (SMS plus email). The preference of Hispanic individuals for stool-based tests, combined with the non-invasive nature of mt-sDNA testing, supports its suitability as a CRC screening option for this population. These findings demonstrate that by addressing language barriers through linguistically tailored communication and navigation services, healthcare systems can foster engagement adherence greater and screening recommendations.

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Ethical Statement

Ethical Approval

The study was considered exempt research under 45 CFR § 46.104(d)(4) as it involved only the secondary use of data that were de-identified in compliance with the Health Insurance Portability and Accountability Act (HIPAA), specifically, 45 CFR § 164.514.

Author Contributions

All authors have made substantial contributions to the conception or design of the study, or the acquisition, analysis, or interpretation of data, drafting the manuscript and revising it critically for important intellectual content, and have provided final approval of this version to be published and agree to be accountable for all aspects of the work.

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Declaration of Conflicting Interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: MG, TP, ABO, DB, and JK are employees if and own stock in Exact Science Corporation. JVRL and MD have no conflicts to report.

Data Availability Statement

The data that support the findings of this study are available from Exact Sciences Laboratories LLC. Restrictions apply to the availability of these data, which were used under license for this study. Data are available from the authors with the permission of Exact Sciences Laboratories LLC.

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