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Title:
IMPLEMENTING LINGUISTICALLY TAILORED COLORECTAL CANCER RISK ASSESSMENT IN A MULTI-SITE PRAGMATIC CLINICAL TRIAL TO IMPROVE SCREENING IN COMMUNITY HEALTH CENTERS.

Background: Colorectal cancer (CRC) incidence and mortality disproportionately affect minority racial/ethnic groups. These groups are less likely than White populations to receive appropriate risk assessment, cancer screening and genetic testing. We describe the development and implementation of a CRC risk assessment tool in the Community Collaboration to Advance Racial/Ethnic Equity in Colorectal Cancer Screening (CARES) trial to assess appropriateness of stool based screening and ensure follow-up after abnormal screening test results.

Methods: CARES is a multilevel, multi-component pragmatic cluster randomized trial in 8 community health centers (CHCs) comparing mailed FIT and mailed FIT-DNA. Eligible participants 45-75 years, overdue for CRC screening, and at average CRC risk based on EHR documentation review (not under surveillance for prior abnormal colonoscopy result [i.e., adenoma] and no personal history of CRC or inflammatory bowel disease) that received abnormal FIT or FIT-DNA test results were offered phone-navigation for colonoscopy and CRC risk assessment. The PREMM5 model assesses personal and family cancer history to determine Lynch syndrome risk, the most common inherited cause of CRC. For the CARES trial, we developed an intake that included PREMM5 and polyposis risk. This adapted CARES risk assessment tool was administered by patient navigators via telephone. The tool allowed for real time disclosure of CRC risk stratified categories: (1) average, (2) moderate, (3) high, and (4) unable to assess (Table 1). Following risk assessment, participants were provided a one-page result summary and recommended actions via mail. All study content and navigation were provided in English or Spanish.

Results: In total, 1330 participants completed stool based testing and 101 had an abnormal result. Among participants with an abnormal result, the mean age was 56.6±8.5 years and the majority self-identified as female (n=52; 51.5%) and Hispanic/Latino (n=80; 79.2%). Risk assessment was completed in 43 (42.6%) participants with an abnormal test: average risk (n=38; 88.4%), moderate risk (n=3; 7.0%), high risk (n=1; 2.3%), and unable to assess risk (n=1; 2.3%). Among participants that did not complete the risk assessment (n=58; 57.4%), reasons included competing demands (i.e. wanting to schedule/complete colonoscopy first), no interest, and lack of time (Table 2).

Conclusions: The linguistically-tailored CARES risk assessment tool identified most patients with an abnormal result as average risk. Thus, EHR documentation review can be leveraged to identify, and risk stratify patients for appropriate CRC screening. The CARES risk assessment tool is feasible, available for implementation, and can be incorporated into clinical workflows in low resource settings. However, despite patient navigation, barriers to completion of this risk assessment tool remain.

Table 1. Risk Assessment Categories, Definitions, and Recommendations Among Participants with an Abnormal Stool Test (FIT or FIT-DNA)

Risk category	Definition	Recommendations after abnormal stool test
Average Risk	No personal history of colorectal polyps or CRC. AND No family history of CRC OR PREMM5 score < 2.5%.	- Colonoscopy
Moderate Risk	Personal history of colon or rectal cancer. OR Personal history of 1-9 colon and/or rectal polyps. OR Family history of colon or rectal cancer: a. ≥ 2 second degree relatives with CRC. b. ≥ 1 first degree relative with CRC <60 years old.	- Colonoscopy
High Risk	PREMM5 score ≥ 2.5%. OR Personal history of ≥ 10 colon and/or rectal polyps.	- Colonoscopy - Genetic counseling and genetic testing
Unable to Assess Risk	Patient does not know about their personal history of colorectal, endometrial, or other Lynch syndrome cancer and colorectal polyps. AND Does not know about family history of colorectal, endometrial, or other Lynch syndrome cancer (i.e., lack of family contact on both sides, adoption without information of biological parents, etc.).	- Colonoscopy

Table 2. Demographics, CRC Risk Assessment Completion, and CRC Risk Stratification Among Abnormal Stool Participants (N=101)

Characteristics	Overall Abnormal Stool Cohort N=101	Boston Sites		Los Angeles Sites	
		FIT n=6	FIT-DNA n=27	FIT n=37	FIT-DNA n=31
Demographics					
Age (years)					
Mean ± SD	56.6 ± 8.5	53.2 ± 6.3	56.7 ± 10.5	56.0 ± 8.6	58.0 ± 6.9
Range	45 – 75	48 – 62	45 – 75	45 – 74	45 – 72
Sex (%)					
Female	52 (51.5%)	3 (50%)	11 (40.7%)	21 (56.8%)	17 (54.8%)
Race/Ethnicity (%)					
Non-Hispanic White	12 (11.9%)	1 (16.7%)	11 (40.7%)	0 (0.0%)	0 (0.0%)
Non-Hispanic Black	5 (5.0%)	0 (0.0%)	0 (0.0%)	4 (10.8%)	1 (3.2%)
Non-Hispanic Asian	1 (1.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.2%)
Hispanic/Latino	80 (79.2%)	3 (50.0%)	15 (55.6%)	33 (89.2%)	29 (93.5%)
Other (AI/AN, NH/OPI, multiple)*	1 (1.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unknown/Declined	2 (2.0%)	1 (16.7%)	1 (3.7%)	0 (0.0%)	0 (0.0%)
Risk Assessment and Risk Assessment Categorization					
Risk assessment completion (%)					
Not Done**	58 (57.4%)	3 (50.0%)	11 (40.7%)	17 (46.0%)	27 (87.1%)
Completed	43 (42.6%)	3 (50.0%)	16 (59.3%)	20 (54.0%)	4 (12.9%)
Average risk	38 (88.4%)	2 (66.7%)	15 (93.8%)	18 (90.0%)	3 (75.0%)
Moderate risk	3 (7.0%)	0 (0.0%)	0 (0.0%)	2 (10.0%)	1 (25.0%)
High risk	1 (2.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Cannot assess risk	1 (2.3%)	0 (0.0%)	1 (6.2%)	0 (0.0%)	0 (0.0%)

*AI/AN = American Indian/Alaskan Native; NH/OPI = Native Hawaiian/Other Pacific Islander
*In cases where the risk assessment was not done, reasons included: competing demands (i.e. wanting to schedule/complete colonoscopy first), no interest, and/or lack of time.