RESEARCH ARTICLES

Return Rates of Non-invasive Forms of Colorectal Cancer Screening in a Central California Community Health Center.

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ABSTRACT

Colorectal cancer (CRC) screening is pivotal for early detection and improved outcomes, yet underserved populations face significant barriers to achieving screening goals. While colonoscopy remains the gold standard, non-invasive options such as the Fecal Immunochemical Test (FIT) annually and multitargeted stool DNA (mt-sDNA) every three years are increasingly viable, especially in underserved communities with decreased access to colonoscopies.

Purpose

This study evaluates the efficacy of FIT versus mt-sDNA in a Federally Qualified Health Center (FQHC) in Central California, focusing on return rates as a proxy for screening adherence.

Methods

A retrospective analysis was performed on over 1000 patients due for colorectal cancer screening between 2022-2023 and had a FIT or mt-sDNA test ordered individually during a visit, or via bulk order. We analyzed the return rates after at minimum 60 days from time of ordering CRC screening. Chi-square test of independence was utilized with multiple test correction via Bonferroni for p-values to demonstrate statistical significance between the different groups.

Results

FIT had a return rate of 25.8%, with 7% encountering collection or processing issues. In contrast, mt-sDNA ordered in bulk yielded a return rate of 13.2%, while mt-sDNA ordered individually by provider after a visit showed a higher return rate of 46.7%. Statistical analysis demonstrated significant differences in return rates between FIT and mt-sDNA under both ordering conditions ($p < 0.05$).

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Conclusion

These findings suggest that mt-sDNA, valid for three years compared to FIT's one-year validity, may enhance long-term adherence to CRC screening guidelines. The study underscores the impact of ordering strategy on screening effectiveness, particularly in FQHC settings. It highlights the potential of mt-sDNA, especially when ordered during a visit, to improve CRC screening rates compared to FIT.

1. Introduction

Colon cancer stands as the third most common form of cancer, with a staggering 152,810 new cases diagnosed each year in both men and women in the United States. Its severity is compounded by its ranking as the second leading cause of cancer-related deaths, claiming an estimated 53,010 lives annually. Colon cancer screening prevents morbidity and mortality through detection of pre-cancerous lesions and early-stage localized lesions, which has a 90% 5-year survival rate compared to late-stage colorectal cancer (CRC) (15.7%).[1] While colonoscopy remains the gold standard for detection, acknowledging its invasiveness, non-invasive alternatives, such as the FIT (Fecal Immunochemical Test) every year and mt-sDNA (multitargeted stool DNA) every three years have emerged as viable options. Currently, the most commonly used non-invasive, affordable test is the FIT, with its 73% sensitivity and 96% specificity. However, with the FDA approval of the mt-sDNA in 2014, mt-sDNA has become an increasingly popular non-invasive option for detecting colon cancer, with a higher sensitivity of 92% and a slightly lower specificity at 90%.[2,3]

The National Colon Cancer Roundtable (NCCRT) has set a goal of 80% screening by 2024.[4] However, this challenge is particularly evident in our underserved populations. According to the most recent data (2022) from the Health Services and Human Resources Administration (HRSA), which is the primary federal agency and regulatory body responsible for access to equitable health care services for people who are uninsured, isolated, or medically vulnerable, the screening rate lingers at 40% at Federally Qualified Health Centers (FQHC) in California, and at 28% in the major FQHCs in central California.[5] Due to the shortage of providers to perform colonoscopies, the FIT has been the primary modality for CRC screening for our FQHC in Kern County, California. Organization data showed an overall rate of 32% for colon cancer screening with a FIT return rate of 25-29%. We aim to see if mt-sDNA, with its 3-year validity, would increase the rate of CRC screening by analyzing the return rate and comparing it to the rate of FIT return.

2. Methods

This retrospective study aimed to analyze the efficacy of non-invasive colorectal cancer screening, namely FIT and mt-sDNA, among patients empaneled to a FQHC. Inclusion criteria were established to ensure the

homogeneity of the patient population. Inclusion criteria: Patients over the age of 45, patients with a FIT test order in 2022 (to avoid confounding factor of concurrent mt-sDNA bulk order placed in 2023), and patients who received mt-sDNA in 2023 (via bulk or non-bulk order). The same patient registry was used to compare the 2022 FIT data to the 2023 mt-sDNA by analyzing patients with a single health plan; this single health plan was chosen since there were no issues with prior authorization or payment, which would add additional confounding factors. Exclusion criteria include patients with electronically documented colonoscopy results. Mt-sDNA tests not ordered in bulk with the single health plan was not analyzed separately due to its small sample size. Patient data were collected from the electronic health records available to the organization.

Descriptive statistics were employed to characterize the study population. Primary outcome measure was the return rate for non-invasive colon cancer screening. To assess the statistical significance of the findings, chi-square test of independence was utilized with multiple test correction via Bonferroni for p-values. Statistical significance was defined as a p-value < 0.05.

3. Results/Discussion

Table 1. Summary of Data

	# Orders placed	# with results documented	# returned with collection/ processing issues
FIT (non-bulk order)	772	199 (25.8%)	54 (7%)
mt-sDNA (bulk order) within single health plan	1854	245 (13.2%)	212 (11.4%)
mt-sDNA (non-bulk order)	696	325 (46.7%)	62 (8.9%)
mt-sDNA (non-bulk order) within single health plan	10	10 (100%)	0 (0%)

FIT: Fecal immunochemical test

mt-sDNA: multi-targeted stool DNA (commercially known as Cologuard)

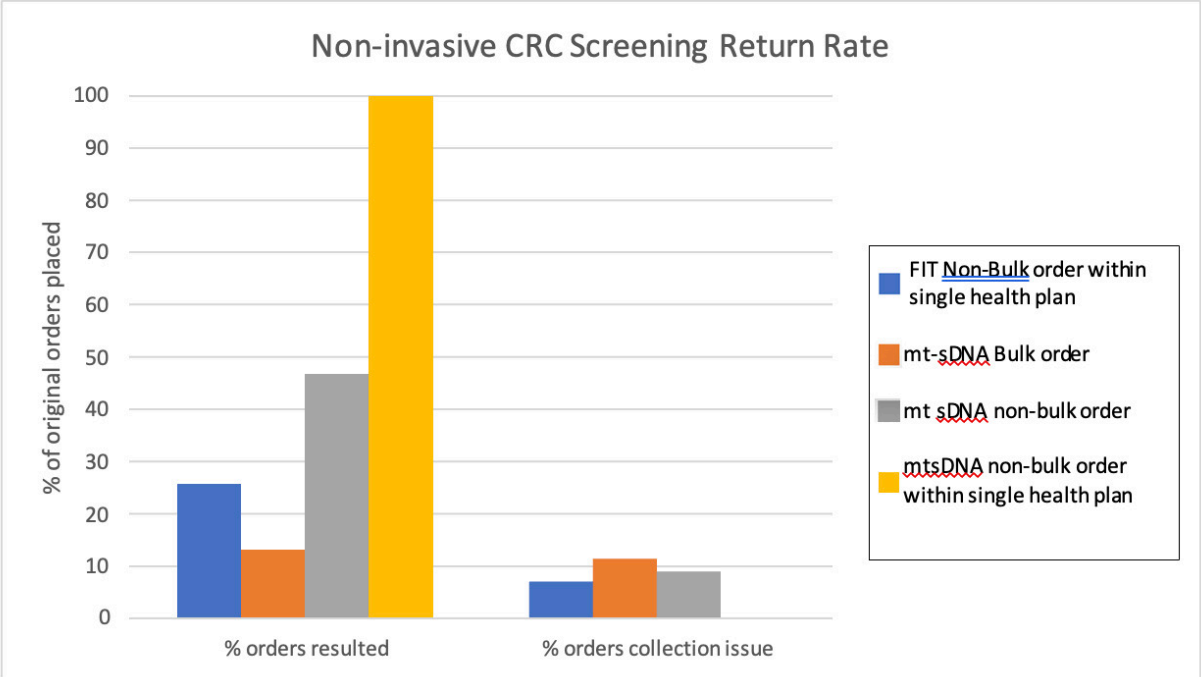

Figure 1. Graphical representation of Table 1 data

Table 2. Statistical analysis

	$\chi 2$	p-value	Adjusted p-value (Bonferroni)
FIT vs. mt-sDNA (bulk order)	60.34	3.00E-15	2.40E-14
FIT vs. mt-sDNA (non-bulk order)	68.87	<2.2E-16	6.60E-16
mt-sDNA Bulk vs. non-bulk order	324.9	<2.2E-16	6.60E-16
Overall	322.76	<2.2E-16	

4. Results

A total of 772 FIT tests (not ordered in bulk) and 2550 (1854 ordered in bulk, 696 not ordered in bulk) mt-sDNA tests were evaluated in this study. For the FIT tests, 199 tests (25.8%) returned valid results suitable for analysis, while 54 tests (7%) encountered issues during collection or processing. In contrast, mt-sDNA tests ordered in bulk demonstrated varied outcomes. Of the 1854 bulk-ordered mt-sDNA tests, 245 tests (13.2%) yielded valid results, with 212 tests (11.4%) experiencing collection or processing issues. Among the 696 mt-sDNA tests ordered not in bulk, 325 tests (46.7%) returned valid results, while 62 tests (8.9%) had issues related to collection or processing (**Table 1** and **Figure 1**).

Statistical analysis revealed significant differences in return rates between FIT tests and mt-sDNA tests under different ordering conditions. Specifically, bulk-ordered mt-sDNA tests showed a lower return rate (13.2%) compared to FIT tests (25.8%) ($p < 0.05$). Conversely, non-bulk mt-sDNA tests demonstrated a substantially higher return rate (46.7%) compared to non-bulk FIT tests (25.8%) ($p < 0.05$) (**Table 2**). These findings underscore

the impact of ordering strategy on the effectiveness of colorectal cancer screening tests, suggesting that non-bulk ordering may enhance the likelihood of obtaining valid results with mt-sDNA tests compared to FIT tests.

5. Discussion

The findings of this study highlight several key points regarding the difference in screening rates with the different type of CRC screening tests. Bulk orders of mt-sDNA demonstrated notably lower return rates compared to individual orders, which may reflect challenges in engaging patients assigned through health plans, especially in populations with a significant proportion of seasonal workers. These factors underscore the complexities in implementing widespread CRC screening programs within our FQHC setting.

Moreover, the study indicates that mt-sDNA testing exhibits a significantly higher return rate compared to FIT when ordered under similar conditions. Importantly, mt-sDNA results remain valid for three years, whereas FIT results are valid for only one year. This distinction suggests that mt-sDNA testing could potentially enhance long-term adherence to screening guidelines among our patient population, thereby contributing to increased CRC screening rates within our FQHC. Future research directions should focus on identifying and addressing barriers to effective test processing and collection, exploring the feasibility and outcomes of bulk FIT test orders, and considering provider-driven strategies for ordering mt-sDNA to optimize screening efficacy and patient participation. These efforts are crucial for advancing CRC screening efforts in underserved populations and improving health outcomes in our community.

6. Conclusion

In this study, we examined the difference in return rates, and therefore colon cancer screening rates, in our FQHC using different modalities of non-invasive CRC screening. We compared FIT ordered individually by providers, to mt-sDNA testing ordered individually by providers, and to mt-sDNA testing ordered in bulk as an organization. Our statistical analysis concluded that mt-sDNA ordered individually by providers was more effective compared to FIT ordered individually, or mt-sDNA ordered in bulk. Especially as mt-sDNA is valid for 3 years compared to 1 year for FIT, the percentage of patients with valid colon cancer screening would start to accumulate as well, especially in our underserved patients with limited access to care. Future researchers should consider comparing FIT bulk orders to mt-sDNA, and to further stratify reasons for collection or processing issues with either modality of non-invasive CRC screening.

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Supplemental Data

Table S1. Days to receive results

	Mean	Median	Range
FIT Test	36.5	81	359
Mt-sDNA (bulk order)	20	28.5	240
Mt-sDNA (non-bulk order)	28.7	24	135