# Patient-Reported Barriers to Completing a Diagnostic Colonoscopy Following Abnormal Fecal Immunochemical Test Among Uninsured Patients

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***BACKGROUND:*** For colorectal cancer (CRC) screening to improve survival, patients with an abnormal fecal immunochemical test (FIT) must follow-up with a diagnostic colonoscopy. Adherence to follow-up is low and patient-level barriers for suboptimal adherence have yet to be explored.

***OBJECTIVE:*** To characterize barriers for non-completion of diagnostic colonoscopy after an abnormal FIT reported by under- and uninsured patients receiving care in a safety-net health system.

***DESIGN:*** A longitudinal, cohort study of CRC screening outreach to 8565 patients using mailed FIT kits. Patients with abnormal FIT results received telephonic navigation to arrange for a no-cost diagnostic colonoscopy.

***PATIENTS:*** Adults aged 50–64 years receiving care at a North Texas safety-net health system.

***APPROACH:*** Descriptive analyses characterized the patient sample and reasons for lack of follow-up after abnormal FIT over the 3-year outreach program. Thematic qualitative analyses characterized reasons for lack of follow-up with a colonoscopy after the abnormal FIT.

***KEY RESULTS:*** Of 689 patients with an abnormal FIT, 45% ($n = 314$) did not complete a follow-up colonoscopy. Among the 314 non-completers, 184 patients reported reasons for not completing a follow-up colonoscopy included health insurance-related challenges (38%), comorbid conditions (37%), social barriers such as transportation difficulties and lack of social support (29%), concerns about FIT/colonoscopy process (12%), competing life priorities (12%), adverse effects of bowel preparation (3%), and poor health literacy (3%). Among the 314 non-completers, 131 patients did not report a barrier, as 51% reported that that had completed a previous colonoscopy in the past 10 years, 10% refused with no reason, and 10% were never reached by phone.

***CONCLUSIONS:*** Future studies aimed at improving FIT screening and subsequent colonoscopy rates need to address the unique needs of patients for effective and sustainable screening programs.

***TRIAL REGISTRATION:*** NCT01946282

*KEY WORDS:* colorectal cancer; screening; fecal immunochemical test; diagnostic colonoscopy; safety-net.

J Gen Intern Med
DOI: 10.1007/s11606-019-05117-0


***Prior Presentations*** *None to report.*

*Received July 16, 2018*
*Revised January 2, 2019*
*Accepted March 13, 2019*

## INTRODUCTION

Colorectal cancer (CRC) is the second leading cause of cancer death in the USA.[1] Screening with the fecal immunochemical test (FIT) is among the recommended strategies for reducing CRC mortality.[2] Most CRC screening research focuses on completion of initial screening, either colonoscopy or FIT.[3, 4] However, for FIT to effectively save lives, patients with an abnormal result must complete a follow-up diagnostic colonoscopy.[5, 6] Prior studies have reported that colonoscopy completion rates after abnormal FIT are generally poor, but range from 42 to 82%.[7, 8] Low income, under- or uninsured, and minority patients have the lowest rates of both CRC screening[9] and diagnostic colonoscopy completion following an abnormal FIT.[10]

While previous literature has reported patient-procedural concerns for initial FIT screening,[3] like embarrassment of handling and mailing stool and screening sensitivity,[11] to our knowledge no study has examined patient-level perspectives to diagnostic colonoscopy non-completion after abnormal FIT. Martin and colleagues conducted a system-level perspective utilizing medical records review of patients with an abnormal FIT receiving care at a major US safety-net health system.[10] They found lack of follow-up colonoscopy to be largely due to patient- (e.g., procedure refusal or failure to show for appointment), provider- (e.g., failure to refer or provide additional information), and system- (e.g., administrative staff failure to contact patient or schedule procedure) level factors.[10] However, medical record data does not

Published online: 21 June 2019

typically include patient-reported challenges, which are important to inform future patient-level interventions.

The purpose of this study is to characterize patient-reported barriers for diagnostic colonoscopy completion after an abnormal FIT documented within the navigation encounters for under- and uninsured patients receiving care in a safety-net health system. We hypothesize the unique patient-perspective will allow us to map key intervention strategies to improve diagnostic colonoscopies following abnormal FIT results.

## METHODS

### Study Design and Population

We conducted a prospective longitudinal cohort study from 2013 to 2016 of men and women, 50–64 years old receiving care at John Peter Smith Health Network (JPS) who participated in a CRC screening outreach program using mailed FIT. JPS is a publicly funded health system serving Tarrant County, TX, and comprises a level 1 trauma center county hospital and a network of over 60 clinics. The outreach program is described in greater detail elsewhere.[12] Briefly, JPS patients aged 50–64 who were enrolled in a low-cost medical insurance program for the uninsured and not up-to-date with CRC screening recommendations were mailed a FIT kit to complete and return. Patients were mailed a FIT kit if they had no prior history of CRC or colon resection, had a complete address and phone number in their medical record, were not incarcerated, and spoke English or Spanish. All patients who returned the FIT kit received a letter with results. If a FIT was normal, then the patient was mailed a subsequent FIT the following year. A member of a quality improvement (QI) team (i.e., nurse or medical assistant) contacted all patients with an abnormal FIT by phone (up to six attempts) to arrange for a no-cost diagnostic colonoscopy. Calls were scripted, with some flexibility based on patient response. During these phone interactions, the QI team navigated patients on how to schedule a diagnostic colonoscopy. When they encountered patients who had not received a follow-up colonoscopy after navigation, they made inquiries to ascertain reasons for non-receipt and recorded those reasons in unstructured, free text.

### Analysis

We conducted a thematic analysis of phone interactions between the quality improvement team member and patients who did not complete a follow-up diagnostic colonoscopy following an abnormal FIT. Phone interactions were analyzed in multiple, iterative steps.[13] First, we read through notes documenting each interaction with the patient. Second, we tagged interactions with 43 codes compiled by the research team based on the QI team's real-time feedback on common barriers. Seven additional codes were added after reading interactions, for a total of 50 codes. Multiple codes were assigned to each interaction, as patients could have cited multiple reasons for challenges completing colonoscopy in one phone conversation. Third, we reviewed codes and identified common macro themes (see the "RESULTS" section).[13] Two authors (KKJ and JY) coded phone interactions separately. A systematic inter-rater reliability test revealed that there was a 90% agreement between coders. After review, the two reviewers discussed and came to a 99% agreement. Descriptive statistics (i.e., means, standard deviations, tabulations, and percentages) were used to summarize the sample population and prevalence of each category of reasons for failure to follow-up with a diagnostic colonoscopy. Analyses were conducted using Microsoft Excel and SPSS.

## RESULTS

### Patient Sample

In the first round of mailed FIT outreach, 8656 individuals were invited, 3134 returned a FIT (36%), and 427 had abnormal results (14%). After the first round of FIT outreach, two subsequent rounds of FIT kits were mailed annually to patients with normal results. Over the course of the study, 689 total patients had abnormal results and 314 (45%) did not complete a diagnostic colonoscopy (Fig. 1).

Table 1 describes the patient sample. Hispanics were more likely to not complete a colonoscopy after an abnormal FIT compared with other race/ethnicities (chi-square = 8.42; $p$ value = 0.02). Among patients that reported barriers, patients were more likely to report a barrier if they spoke English (chi-square = 7.44; $p$ value = 0.006) and were non-Hispanic White (chi-square = 15.74; $p$ value = 0.001).

### Patient-Reported Barriers

Among the 59% of patients who reported at least one barrier during an interaction ($n = 184$), seven themes emerged (Fig. 2). These included barriers related to health insurance (38%), comorbid conditions (37%), social barriers such as transportation issues and lack of social support (29%), concerns about FIT/colonoscopy process (12%), competing life priorities (12%), adverse effects of bowel preparation (3%), and poor health literacy (3%). Of the seven, patients reported a mean of 1.57 (SD = 0.8; range 1–5) barriers (data not shown).

***Health Insurance.*** Thirty-eight percent ($n = 68$) of patients reported health insurance–related barriers to completing a diagnostic colonoscopy. QI members documented lapsed coverage (e.g., "patient states JPS connection had dropped off. Patient needs to reapply again before rescheduling any appointments" [patient, male; 55–59 year old]), problems filling out insurance paperwork (e.g., "patient states that put paperwork in for JPS connection but they are waiting on one piece of paperwork" [male, 55–59 year old]), inability to get an ID (e.g., "patient states waiting on money to get state ID, as soon as patient gets it, patient will send in application" [female, 60–64 year old]), and not qualifying for JPS connection ("patient

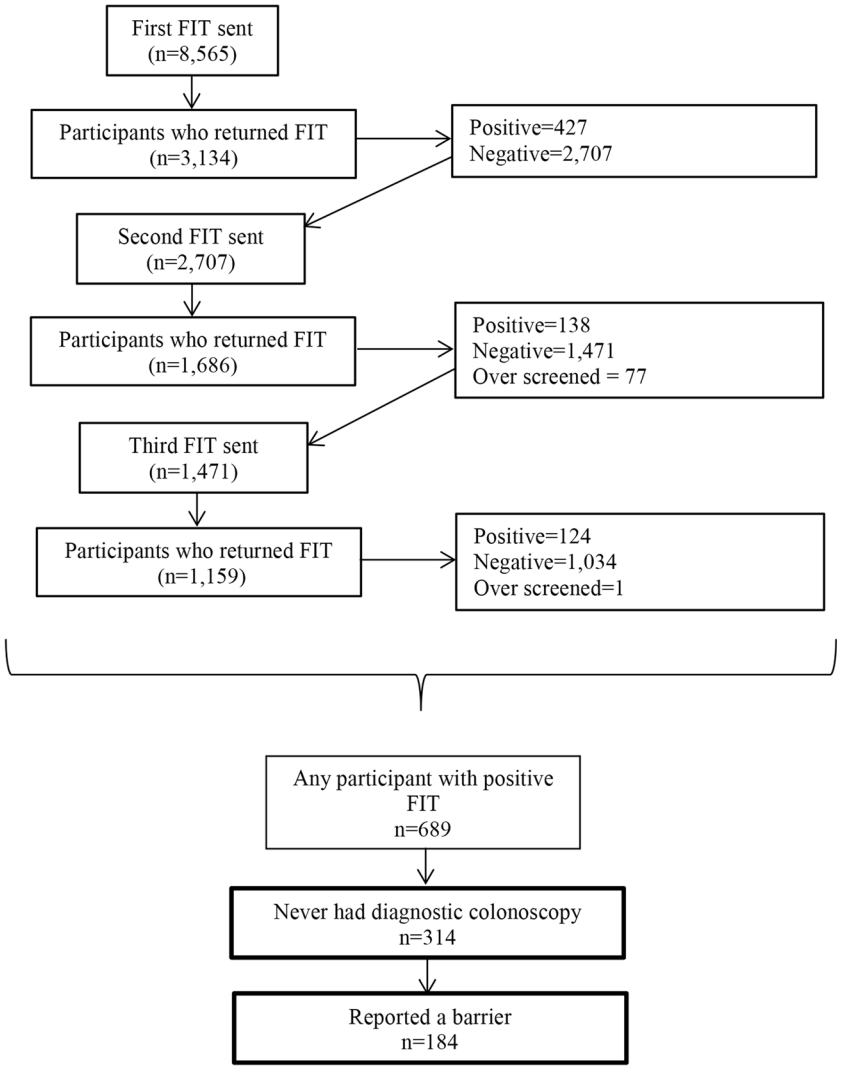


**Figure 1 CONSORT diagram.**

did not qualify for JPS connection. Patient is working and has to wait 6 months for insurance" [female, 55–59 year old]). Insurance concerns were salient, because access to no-cost colonoscopy as part of the outreach program was predicated on participation in the health system's low-cost medical insurance program for uninsured county residents.

**Table 1 Sample Description Stratified by Colonoscopy Completion and Barrier Reporting ($n = 691$)**

| | **Failed to complete colonoscopy** ***N*** **= 314** | | | | **Completed colonoscopy** ***N*** **= 376** | $\chi^2$ **or** ***t*** **test** |
|---|---|---|---|---|---|---|
| | **Total** ***N*** **(%)** | **Reported barrier** ***N*** **= 184** ***N*** **(%)** | **No reported barrier** ***N*** **= 131** ***N*** **(%)** | $\chi^2$ **or** ***t*** **test** | **Total** ***N*** **(%)** | |
| Gender | | | | 0.09 | | 0.39 |
| Female | 194 (62) | 112 (61) | 82 (63) | | 241 (64) | |
| Male | 120 (38) | 72 (39) | 49 (37) | | 135 (36) | |
| Race/ethnicity | | | | 15.74** | | 8.42* |
| White NH | 124 (39) | 86 (47) | 39 (30) | | 136 (36) | |
| Black NH | 76 (24) | 47 (26) | 29 (22) | | 104 (28) | |
| Hispanic | 94 (31) | 40 (22) | 54 (41) | | 92 (24) | |
| Other | 20 (4) | 11 (6) | 9 (7) | | 44 (12) | |
| Language | | | | 7.44** | | 0.78 |
| English | 263 (84) | 163 (89) | 101 (77) | | 324 (86) | |
| Spanish | 51 (16) | 21 (11) | 30 (23) | | 52 (14) | |
| Age (mean, SD) | 62.7 (0.24) | 62.8 (0.31) | 62.5 (0.35) | 0.73 | 62.5 (0.22) | 0.61 |

**p value < 0.05; **p value < 0.01; ***p value < 0.001*
*NH, non-Hispanic; SD, standard deviation*

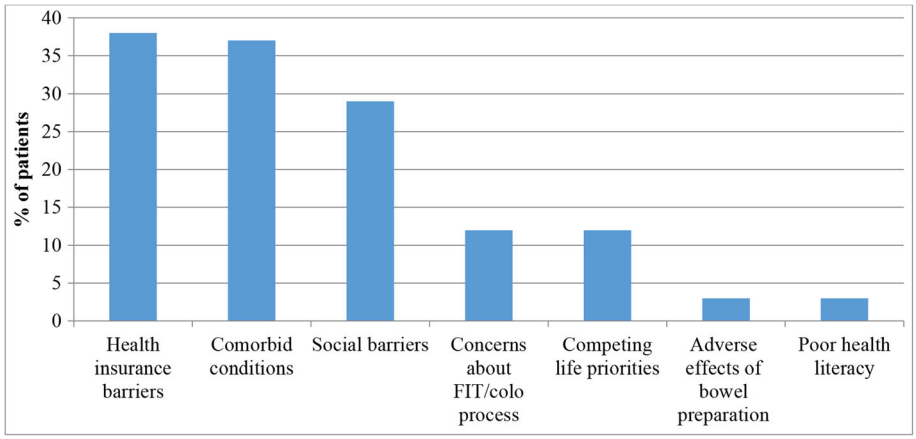


**Figure 2 Non-mutually exclusive patient-reported barriers to failure for diagnostic colonoscopy following abnormal FIT ($n = 184$).**

***Comorbid Conditions.*** Sixty-six patients (37%) reported comorbid conditions taking precedent over a colonoscopy, including heart surgery, foot surgery, eye surgery, diabetes management, shingles, broken toes, and the common cold. One QI member documented "Patient states that only 25% of heart is working. Patient is also having trouble with kidneys. Patient does not want to do colonoscopy because if they find cancer patient could not live through it" [male, 55–59 year old]. Sixteen patients reported to the QI team that their physician instructed them to hold off with a colonoscopy, mainly due to heart problems (e.g., "patient's cardiologist did not want the procedure performed at this time" [male, 60–64 year old]). Some patients reported that their physicians did not recommend a colonoscopy because of other medical conditions, (e.g., "patient said PCP said to hold off colonoscopy due to diverticulosis" [male, 55–59 year old] and "patient stated that he has supranuclear palsy and his doctors stated patient physically could not go through procedure" [male, 65–69 year old]). Seven patients (4%) cited waiting to do a colonoscopy until they could get off Plavix.

***Social Barriers.*** A third of patients ($n = 52$) reported social barriers in completing their colonoscopy. These included transportation issues, lack of social support, and competing demands of caregiving. Transportation barriers included inability to find a ride (e.g., "patient needs to cancel colonoscopy because cannot find a ride" [male, 60–64 year old]), as well as distance from clinic (e.g., "patient states does not want to drive 40 min to an appt. that will only last 10 min" [female, 65–69 year old]), and unreliable modes of transportation (e.g., "the person who was going to take patient said they were no longer available to help" [female, 60–64 year old]; "patient's car broke down" [female, 60–64 year old]).

Patients reported a lack of social support in terms of having trouble finding someone to accompany them and stay with them after the procedure (e.g., "patient does not have anyone to go with to clinic" [male, 60–64]; "Patient is not able to have anyone to stay with them at the time of colonoscopy" [female, 60–64]). QI members also documented demands of caregiving, resulting in cancelled and missed appointments (e.g., "patient missed colonoscopy due to mother is sick" [female, 60–64]; "patient has disabled child and needs to find someone who will stay with child during appointment" [female, 60–64]; "patient cancelled appointment due to household is sick" [female, 65–69]).

***Concerns About FIT/Colonoscopy Process.*** Only eight patients reported believing that FIT results were false positive due to other medical conditions including constipation, hemorrhoids, and "because blood could be there for various reasons" [male, 60–64]. One QI member documented "patient stated no interest in a colonoscopy because they spoke with doctor at last visit and doctor told them it was probably hemorrhoids and does not want test at this time" [female, 65–69]. Five patients even requested a second FIT before scheduling a colonoscopy (e.g., "patient not interested in doing a colonoscopy would rather try to do the test over again" [female, 60–64]).

Twelve patients cited fears of the procedure. Sedation was a consistent concern (e.g., "patient stated 'unless there is a way they can do it without me being put to sleep, then I'm not going to do it'" [female, 60–64]; "patient states does not know 'what' could happen while under" [male, 55–59]). Fears also stemmed from the test being too invasive (e.g., "patient not want[ing] to be probed in that part of the body" [male, 60–64]) and potentially embarrassing (e.g., "patient was worried about pooping themselves during procedure" [female, 55–59]). One QI member documented the patient reporting to be "very nervous and fearful about having colonoscopy performed [because] patient has heard lots of horror stories about colonoscopies and really does not want to have one" [male, 60–64].

***Competing Life Priorities.*** Twelve percent of patients cited other demands that prevented them from scheduling a diagnostic colonoscopy, including going out of town for

emergencies or work and not having enough time to have the procedure (e.g., "patient states they are busy working. Patient verbalized understanding but still had no time to complete the prep" [male, 60–64]) or to schedule the appointment (e.g., "patient doesn't have time to make appointment)" [female, 65–69]. QI members documented other patients reporting "having a lot going on right now" [female, 65–69] or "having some other issues going" [female, 65–69].

***Preparation Issues.*** Five patients reported adverse effects of bowel preparation, including the QI member documenting "drinking the prep made the patient have both nausea and vomiting" [female, 65–69] and "patient tried to have colonoscopy done but was unable. Patient could not keep bowel prep down" [female, 60–64].

***Health Literacy.*** While relatively rare, five patients reported not understanding the bowel prep instructions or results letter (e.g., "patient state letter is not showing positive. Reread result letter and patient understood better" [female, 65–69]). Low literacy and language barriers (e.g., "patient had hard time understanding a little English" [male, 60–64]) were cited in 3% of interactions.

## No Patient-Reported Barriers

Of the 314 patients that did not complete a colonoscopy after an abnormal FIT, 42% ($n = 131$) did not report a barrier during phone interactions. Despite several telephone calls, the QI team, mainly due to disconnected phone lines and voicemails not being returned by patients, never reached 10% ($n = 13$) of patients. Fifty-one percent ($n = 67$) of patients reported that that had completed a previous colonoscopy in the past 10 years, although it was not documented in the electronic health records. The QI medical director confirmed a majority (60%) of these cases after requesting patients to obtain proof of colonoscopy results. Finally, 10% ($n = 14$) of patients refused a colonoscopy without citing a reason. For example, the QI member documented "patient didn't want to hear about [abnormal results] and denied participating" [female, 55–59] and "patient states this has been an ordeal and did not want to have procedure done" [female 65–67].

# DISCUSSION

This is the first study assessing patient-level medical, social, and logistic barriers to colonoscopy completion following an abnormal FIT. Barriers to initial CRC screening have been well-documented,[14–20] but only one previous study has assessed barriers to colonoscopy completion after an abnormal FIT.[10] This study expands on previous literature by using a mixed-method approach to analyze interactions with safety-net patients in the context of a mailed FIT outreach intervention to offer a broader scope of barriers to completing diagnostic colonoscopy following an abnormal FIT.

As expected, safety-net patients faced unique challenges to care: high burden of comorbidities and high prevalence of competing economic and social demands, like childcare, transportation difficulties, and low social support. The most prevalent challenge to completing a diagnostic colonoscopy was lack of health insurance, specifically JPS connection medical assistance program, despite offering free FIT screening and cost-sharing diagnostic colonoscopies. Patients reported lapsed coverage, trouble with paperwork, and not qualifying for insurance as particular challenges. This finding may be explained by cohort effects, as the implementation of this study overlapped with the Affordable Care Act (ACA) roll-out. As a result, JPS connection medical assistance had to adjust programming to support, yet not interfere, with ACA. In addition, a large proportion of the sample had concerns about the FIT/colonoscopy process, including uncertainty of screening efficacy, fears of the procedure, and medical conditions superseding a diagnostic colonoscopy. This study found that some barriers to colonoscopy completion after an abnormal FIT are similar to previously reported barriers to initial CRC screening,[14–20] like fear,[21] embarrassment of handling and mailing stool, screening sensitivity,[11] and cost.[22] Moreover, our study confirmed Martin et al.'s system-level findings that non-completions are attributed to patient-level factors, like patients failing to follow-up.[10] However, the current study is the first to unfold *patient-reported* themes to diagnostic colonoscopy non-completion.

This work is significant in that it provides novel insights into potential strategies to address patient-reported challenges to follow-up of abnormal FIT (Table 2). Patients reported barriers at multiple levels—patient-level, clinician-level, and

**Table 2 Potential Multi-level Strategies to Address Patient-Reported Barriers**

| Intervention level | Patient-reported barriers | Potential intervention |
|---|---|---|
| Patient-level | -Concerns about accuracy of test<br>-Fears of procedure<br>-Competing life priorities<br>-Comorbid conditions<br>-Superseding preventative services<br>-Poor health literacy | -Patient education campaigns, like peer advocate stories around health system<br>-More active patient navigation so patients comply after acute medical issues are resolved<br>-Trainings to improve health literacy |
| Clinician-level | -Clinician instructed to wait | -Clinician education about contraindications to colonoscopies and missed opportunities for early cancer detection and prevention |
| System-level | -Poor health literacy<br>-Over screening<br>-No answers | -Language validation of study materials to improve our understanding of culturally sensitive instructions<br>-Clinical care team education on documentation of colonoscopy history at primary care visits<br>-Administrative training on systematic updating of patient information |

system-level. Suboptimal knowledge about the necessity of follow-up colonoscopy can be combated through patient education campaigns and more active navigation so patients comply after acute medical issues are resolved. In parallel, clinician education about contraindications to colonoscopies is needed, as 9% of the study sample had a clinician instruct them to wait for a colonoscopy due medical conditions and medications. In some cases, delay (i.e., need for antiplatelet agents post recent placement of cardiac stents) or complete deferral (i.e., limited 5-year life expectancy) may be justified, but in others (i.e., concern about hemorrhoids as cause for abnormal FIT in the absence of recent colonoscopy), delay may result in missed opportunities for early cancer detection and prevention. Finally, documentation of colonoscopy history needs to be improved even within an integrated health system. In our sample, 10% of our total sample were overscreened (e.g., had a colonoscopy in the past 10 years) and, of which, 60% were confirmed by a clinician. While this statistic shows patient activation of care, this is a suboptimal use of resources and time.

These results should be considered in light of several limitations and strengths. First, the qualitative data is lean, as telephone conversations were initially meant for navigating, rather than a comprehensively qualitative analysis. In this approach, patients may have reported the most salient barrier and an exhaustive list of all their barriers for completing a colonoscopy were not recorded. However, data were collected as part of usual care interactions and analyzing phone interactions post hoc gave new insight into patient-reported barriers for a large sample of patients. Second, the descriptive aspect of this study limits our ability to conclude whether barriers to completing a diagnostic colonoscopy, like negative perceptions of FIT results and the diagnostic process, are unique to safety-net populations. Third, a significant amount of resources are required to follow-up with patients after an abnormal FIT, including an average of 7 telephone calls (with a maximum of 33 calls) per patient. A QI navigation team, including two medical assistants and a nurse, verified past colonoscopies, while documenting and managing patient concerns, like sending insurance paperwork to patients. The study-specific resources may not typically be available to health systems, so additional implementation strategies should be explored.

In conclusion, the majority of research has reported patient-level barriers to completing initial FIT screening. Only one past study has analyzed system-level perspectives for diagnostic colonoscopies following abnormal FIT results. This study significantly adds to our knowledge by analyzing usual care patient interactions for patient-level perspectives. Future research should target the aforementioned intervention opportunities to improve diagnostic colonoscopy rates after abnormal FIT results in integrated health systems. Future studies should also aim to compare results across multiple health systems, as findings may differ from non-safety-net patient populations, health systems without navigation services, or among groups where FIT was offered in-office rather than by mail.

***Acknowledgments:*** *We would like to sincerely thank Ms. Madeline Roberts for her help in the cleaning of data and initial literature review.*

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***Funders*** *The study is funded by the Cancer Prevention and Research Institute of Texas no. PP120229 (Argenbright, PI).*

***Compliance with Ethical Standards:***

***Conflict of Interest:*** *The authors declare that they do not have a conflict of interest.*

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