



Barriers associated with inadequate follow-up of abnormal fecal immunochemical test results in a safety-net system: A mixed-methods analysis

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ARTICLE INFO

Keywords:

Colorectal cancer
Fecal immunochemical test
Electronic health records
Colonoscopy
Safety-net

ABSTRACT

In safety-net healthcare systems, colonoscopy completion within 1-year of an abnormal fecal immunochemical test (FIT) result rarely exceeds 50%. Understanding how electronic health records (EHR) documented reasons for missed colonoscopy match or differ from patient-reported reasons, is critical to optimize effective interventions to address this challenge. We conducted a convergent mixed-methods study which included a retrospective analysis of EHR data and semi-structured interviews of adults 50–75 years old, with abnormal FIT results between 2014 and 2020 in a large safety-net healthcare system. Of the 299 patients identified, 59.2% (n = 177) did not complete a colonoscopy within one year of their abnormal result. EHR abstraction revealed a documented reason for lack of follow-up colonoscopy in 49.2% (n = 87/177); patient-level (e.g., declined colonoscopy; 51.5%) and multi-factorial reasons (e.g., lost to follow-up; 37.9%) were most common. In 18 patient interviews, patient (e.g., fear of colonoscopy), provider (e.g., lack of result awareness), and system-level reasons (e.g., scheduling challenges) were most common. Only three reasons for lack of colonoscopy overlapped between EHR data and patient interviews (competing health issues, lack of transportation, and abnormal FIT result attributed to another cause). In a cohort of safety-net patients with abnormal FIT results, the most common reasons for lack of follow-up were patient-related. Our analysis revealed a discordance between EHR documented and patient-reported reasons for lack of colonoscopy after an abnormal FIT result. Mixed-methods analyses, as in the present study, may give us the greatest insight into modifiable determinants to develop effective interventions beyond quantitative and qualitative data analysis alone.

1. Introduction

Colorectal Cancer (CRC) is the second leading cause of cancer-deaths in the U.S. (Siegel et al., 2020). Screening is cost-effective (Heitman et al., 2010) and saves lives (Mandel et al., 1993); however, participation remains suboptimal, especially among racial/ethnic minorities and

low-income populations (David and Liss, 2014). In 2018, 67% of age-eligible adults in the U.S. were up-to-date with CRC screening, well below the national screening goal of 80% (Roundtable, 2019). In the same year, screening rates were even lower in Hispanic (59%), Asian (58%), and American Indian/Alaska Native (56%) individuals and low-income populations (57%) (American Cancer Society, 2020). In safety-

Abbreviations: CRC, colorectal cancer; FIT, fecal immunochemical test; EHR, electronic health record; FQHCs, federally qualified health centers; EBIs, evidence-based interventions.

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<https://doi.org/10.1016/j.pmedr.2022.101831>

Received 10 November 2021; Received in revised form 9 May 2022; Accepted 15 May 2022

Available online 18 May 2022

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net health systems and federally qualified health centers (FQHC's), where many racial/ethnic minorities and low-income populations receive care, CRC screening improves when fecal immunochemical test (FIT) is offered alongside colonoscopy (Singal et al., 2016). For FIT to be effective, however, a colonoscopy must be completed after an abnormal result. Missed or delayed colonoscopies are associated with late-stage diagnoses and increased CRC mortality (Corley et al., 2017; Lee et al., 2019; Doubeni et al., 2019; San Miguel et al., 2021). Despite these concerns, the proportion of patients with an abnormal FIT result who complete a follow-up colonoscopy rarely exceeds 50% in most safety-net systems and FQHCs (Chubak et al., 2016; Issaka et al., 2017; Roundtable and Reach, 2018).

Colonoscopy is a complex process that requires effective communication and coordination between patients, clinicians, and the healthcare system. Systematic reviews of interventions to improve colonoscopy completion after abnormal stool-based CRC screening tests could not determine the overall effectiveness of any intervention because of few available studies (Dougherty et al., 2018) and lack of representation from safety-net health systems or FQHCs (Selby et al., 2017). Mixed-methods studies, especially those that include safety-net health systems and FQHCs, could fill an important knowledge gap and may aid in the development of interventions to reach the U.S. Multi-Society Task Force on CRC (USMSTF) follow-up colonoscopy goal of 80% (Robertson et al., 2017). Our overall aim was to identify reasons for lack of follow-up colonoscopy 1-year after an abnormal FIT result from the provider and patient perspective. Accordingly, the primary aim of this study was to characterize electronic health record (EHR) documented and patient-reported reasons for lack of follow-up colonoscopy completion in a safety-net population. The secondary aim was to determine if EHR documentation (quantitative) matched or differed from patient-identified (qualitative) factors in semi-structured interviews. By understanding provider- and patient-reported barriers to follow-up, our goal is to inform interventions to improve CRC outcomes in safety-net health systems and FQHCs.

2. Methods

This convergent mixed-methods study was conducted at Harborview Medical Center (HMC) between November 2019 and September 2021 (Supplemental Fig. 1). This study adhered to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) (von Elm et al., 2007) and the Consolidated Criteria for Reporting Qualitative Research (COREQ) (Tong et al., 2007) reporting guidelines. The study was approved by the Fred Hutch/University of Washington Cancer Consortium's institutional review board. All interview participants provided verbal consent to be recorded and to have their data responses published. Participants received a \$50 cash incentive for their time.

2.1. Study setting and population

HMC is a safety-net county teaching hospital system in Seattle, Washington, with 7 primary care clinics that provide care to historically underserved populations in King County, including individuals of lower socioeconomic status, who are uninsured, and whose primary language is not English. All HMC clinics share a single integrated EHR and a centralized clinical laboratory for FIT processing through their affiliation with the University of Washington – a large, integrated academic tertiary care center in Washington state. In this setting, CRC screening and follow-up of abnormal results are managed by primary care providers.

2.2. Study design

With assistance from our institution's Clinical and Translational Science Institute (CTSI), we queried EHR data to identify patients with the following inclusion criteria: 1) ages 50–75, 2) assigned to a HMC

clinic and primary care provider, 3) had an abnormal FIT result between 9/1/2014 and 8/31/2018 (retrospective analysis) or 1/1/2017 and 3/31/2020 (semi-structured interviews), and 4) a billable primary care encounter in the prior three years. Patients with a history of CRC, colectomy, and advanced comorbidities (inflammatory bowel diseases, advanced cardiopulmonary diseases, and metastatic cancer) were excluded (Issaka et al., 2020). Patients were also excluded if they had no primary care encounter in the prior 3 years. Colonoscopy data was collected through September 2019 (retrospective analysis) or March 2021 (semi-structured interviews), allowing at least 1 year of follow-up for each patient.

2.3. EHR data collection

After identifying the patient cohort, we extracted patient demographics (age, gender, race, primary language, insurance, and marital status). Two authors (RBI & JK) manually reviewed the EHR for gastroenterology referrals, primary care visit notes, and other patient communications and abstracted documented reasons why a colonoscopy was not completed within 1-year after an abnormal FIT result. Reasons for lack of follow-up colonoscopy were initially categorized using a-priori themes from previous research with additional categories included as they emerged (Issaka et al., 2017; May et al., 2019).

2.4. Interview guide development

The semi-structured interview guide was developed through several iterations with the study team and was informed by Social Cognitive Theory (Bandura, 1977), which was selected for three reasons: (1) It is consistent with the social-ecological perspective that the health and behavior of individuals are determined by factors at multiple levels ranging from the personal to the societal; (2) It is a widely used theoretical framework in public health because it gives explicit guidance about methods for intervention development that promote health-enhancing behavioral change; (McAlister et al., 2008) and (3) It has been successfully applied to develop interventions to address a wide variety of health conditions and behaviors (Bandura, 1986). The interviews took an average of 30 min to complete.

2.5. Interview data collection

Between March 2020 and September 2021, eligible patients were invited by telephone to participate in semi-structured interviews. Three authors (RBI, ABB, and DLA) conducted and recorded interviews through telephone calls. All participants were assigned numbers and de-identified to the remaining research team. Interviews were transcribed verbatim, verified against the recordings, and uploaded to the data management software by participant number. Following accepted standards of rigor in qualitative research, we collected data until no new themes emerged and confirmed thematic saturation by conducting an additional small subset of interviews (Morse, 2015). The final number of interview participants was consistent with published data that states thematic saturation is achieved between 9 and 17 semi-structured interviews (Hennink and Kaiser, 2022).

2.6. Analysis

EHR and interview data were analyzed separately, compared, and then integrated during the data analysis phase. Patient demographic information was described as proportions or medians and interquartile ranges (IQR). For our quantitative analysis, differences between groups were assessed using chi-square test or student's *t*-test as appropriate. We performed univariate logistic regression to determine the factors associated with colonoscopy completion after an abnormal FIT result. Accompanying odds ratios (ORs), 95% confidence interval (CI), and *p* values were reported in all instances and *p* values less than 0.05 were

considered statistically significant. We used Stata/SE (version 17.0; StataCorp LP, College Station, TX) for quantitative data analysis.

For our qualitative analysis, we applied a hybrid approach combining inductive and deductive methods (Hsieh and Shannon, 2005). We have described our process in detail elsewhere (Issaka et al., 2021), but in brief, two authors (RBI & ABB), developed an initial list of codes and definitions in a deductive fashion informed by the social cognitive theory. Then in an inductive approach, the coders independently reviewed a subset of the same interviews, created additional subcodes to reflect participants' responses, and compared common themes and relevant quotes to ensure intercoder reliability. The lead coders (RBI and ABB) independently applied the final codebook across all interviews and extracted quotes illustrative of emergent themes for inclusion in the manuscript. All discrepancies were resolved through discussion and consensus between the lead coders. We used Dedoose (version 9.0; Socio-Cultural Research Consultants; Los Angeles, CA) for qualitative data management.

We then combined and compared quantitative and qualitative data and organized the data according to the Predisposing, Reinforcing, and Enabling Constructs in Educational Diagnosis and Evaluation (PRECEDE) model. This model recommends analyzing the cause of health problems at multiple ecological levels and considering multiple determinants of health-related behavior and environment. Thus, the PRECEDE model can help define the problem, the ecological levels that affect the problem, and the stakeholders who will have relevant input about the solutions (Bartholomew Eldredge et al., 2016).

3. Results

3.1. Retrospective cohort patient characteristics

For our quantitative analysis, a total of 299 patients met inclusion criteria. The median (IQR) cohort age was 60.0 (11.0) years, 193 (65.0%) were men, and the cohort was racially diverse (43.8% White, 31.4% Black or African American, 18.1% Asian, and 6.7% other). 154 (51.5%) were insured through Medicare, 90 (30.1%) were insured through Medicaid, and 28 (9.4%) were commercially insured (Supplemental Table 1).

3.2. Documented EHR reasons for missed colonoscopy after an abnormal FIT

Of the 299 patients identified, 59.2% (n = 177) did not complete a colonoscopy within one year of their abnormal FIT result. EHR review revealed documentation about lack of follow-up colonoscopy in 49.2% (n = 87/177). There were no sociodemographic differences between patients with or without an EHR documented reason for lack of follow-up colonoscopy. We categorized the reasons for lack of follow-up colonoscopy into four categories: patient-, provider-, or system-level, or multifactorial (Fig. 1). Multifactorial reasons are categorized as such because they may fall into multiple categories (i.e., both patient- and provider- level). The most frequently documented reasons were at the patient-level (51.5%) and included declined colonoscopies, competing health issues, lack of transportation, cancelled colonoscopy by patient, and patient no-show to colonoscopy. Multifactorial reasons accounted for 37.9% of cases and included unstable housing and reported death shortly after an abnormal FIT. Provider-level reasons accounted for 10.3% of cases and included discovering a recent colonoscopy and repeating a FIT exam which was subsequently normal. Review of EHR data did not reveal any documented system-level reasons (e.g., system scheduling challenges) for lack of follow-up colonoscopy completion (Fig. 1).

3.3. Characteristics associated with colonoscopy completion

There was no association between gender, marital status, race, primary language, or type of insurance and colonoscopy completion one year after an abnormal FIT result (Supplemental Table 1).

3.4. Interview participant characteristics

For our qualitative analysis, a total of 205 patients met inclusion criteria and were invited to participate in an interview; 156 (76.1%) did not respond to recruitment calls, 31 (15.1%) actively refused, and 18 (8.8%) agreed to be interviewed. Of the 18 participants, 6 (33.3%) had completed a colonoscopy by the time of our interview and 12 (66.7%) had yet to complete a colonoscopy. Although 6 participants had completed their colonoscopy by the time of our study outreach, given colonoscopy completion well over 1-year after their abnormal FIT results, they were included in the analysis as their interviews provided valuable insight into barriers and facilitators to completing a follow-up

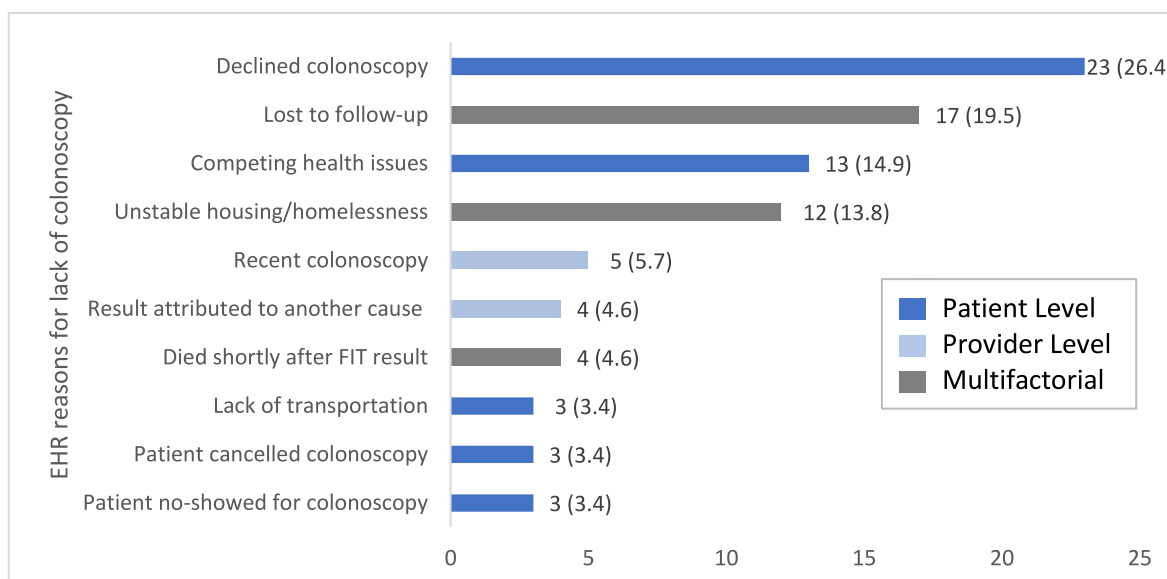


Fig. 1. Documented electronic health record (EHR) reasons for lack of colonoscopy completion.

colonoscopy. The median (IQR) participant age was 65.0 (15.8) years and 15 (83.3%) were men. There were 10 participants (55.6%) who self-identified as White, 6 participants (33.3%) who self-identified as Black or African American and 2 participants (11.1%) who self-identified as multiracial or other (Supplemental Table 2).

3.5. Patient reported reasons for missed colonoscopy after an abnormal FIT

Among the patients who had yet to complete a colonoscopy, each participant reported at least one barrier to follow-up. Reasons for lack of follow-up colonoscopy categorized by ecological level and representative quotes are summarized in Table 1. Patient-level barriers to follow-up colonoscopy included fear of colonoscopy, lack of transportation, inability to tolerate the bowel prep, competing health issues, and lack of social support. Provider-level barriers to follow-up colonoscopy included failure to alert patients of abnormal FIT results and abnormal results being attributed to another cause. System-level barriers included

Table 1
Key themes, subthemes, and supporting quotations from patient interviews.

Theme/Subthemes	Supporting Quotation
Barriers to follow-up colonoscopy	
Patient Level	
Fear of Colonoscopy	"I'm kind of nervous about it. It's kind of intrusive. I'm pretty sure a lot of guys are freaked about that."
Lack of transportation	"Yeah. Well, I know that Hopelink does [transportation] stuff, but see, I don't qualify for any. You know, they say I make too much money."
Unable to tolerate bowel prep	"The problem with that was all the fluid, I tried to drink all that fluid, and I'm a little person and I couldn't get it all in. But now they have another plan where it's half that size, so I might be able to do that."
Competing health issues	"I asked them when I first got the Hepatitis C years ago, you know, about how long I probably would, you know, be before I had severe symptoms, and they told me. And I asked them what it's like, if you know, something happens, and they told me, and it was not good. And, you know, basically, like even if I was at the hospital, if my liver was to rupture, you know, they wouldn't be able to save me. So, uh, yeah, I kinda prepared myself, but it still, um, gave me some anxiety."
Lack of social support	"My doctor told me to ask my family if they can do that [bring me for the colonoscopy]. But my brother, he lives near Canada. On the East side of the state. It's pretty far away."
Provider Level	
Lack of patient awareness of abnormal result	"But if you guys aren't gonna follow up on your part, and nobody's monitoring me or nobody's following up or responding back, I guess it really doesn't matter. You know? If the patient is not concerned, well, you're just another statistic."
Result attributed to another cause	"Well, the way it was explained to me, it's not critical and it could get to be an error and it could be that I was rubbing the skin on my anus too hard to where I was causing the skin to bleed. So, I put it off for right now."
System Level	
System scheduling challenges	"Someone was supposed to call me to schedule the [colonoscopy] but they never called me."
COVID-19 pandemic	"Once we got done with this COVID-19 mess and things are back to normal, I'll feel a whole lot better. Right now, I don't feel safe going to hospitals or going into places where there's crowds"
Multifactorial	
Lack of comprehensive health insurance	"What I wish that as I couldn't do the Golytely is that there would be something else, but part of the problem is it deals with insurance. The insurance won't cover, how shall we say it, the latest and greatest advancements in the prep work. And that's what comes into play in the situation also."

the need for pre-colonoscopy COVID-19 testing and lack of procedure scheduling by staff (Table 1). Among the participants who completed a colonoscopy (n = 6/18), a clinician's recommendation or knowledge about the public health impact of CRC facilitated their final decision.

3.6. Integration of EHR data and patient interviews

A comparison of EHR documented and patient reported reasons for lack of follow-up colonoscopy revealed overlap in only three areas (competing health issues, lack of transportation, and abnormal FIT result attributed to another cause). In interviews, patients provided additional details around the circumstances that led to lack of follow-up colonoscopy that were often missing from the EHR (Table 2 & Fig. 2).

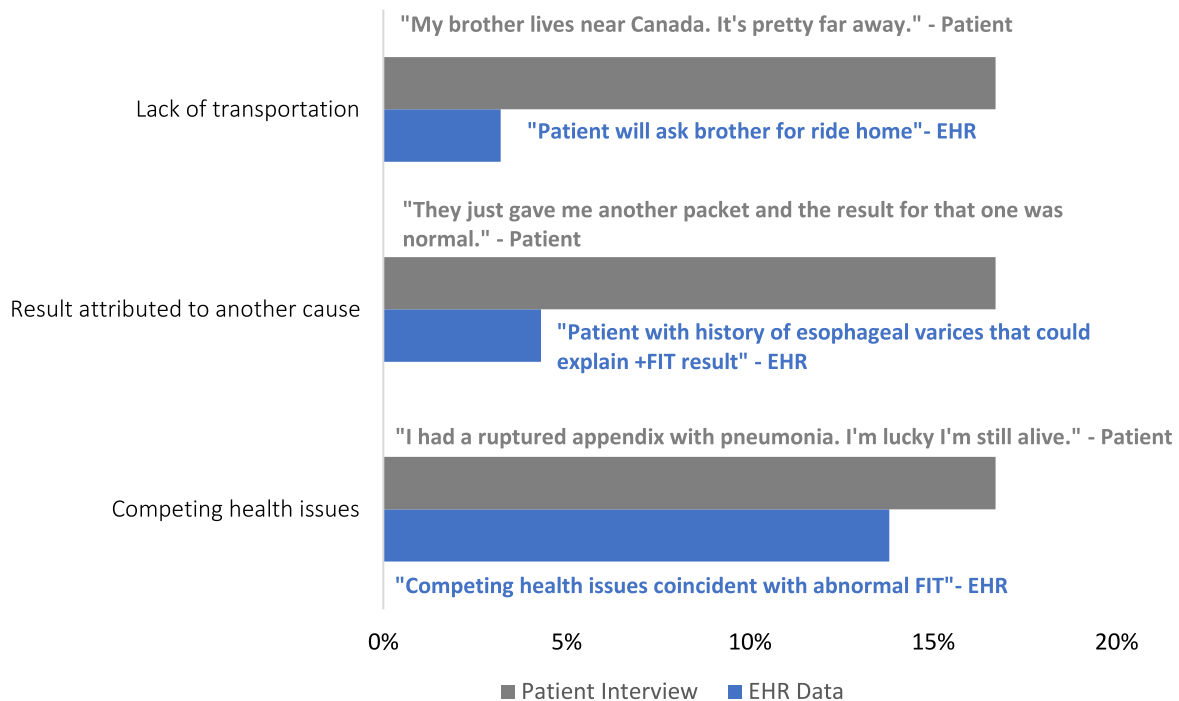
4. Discussion

To reach the USMSTF goal of 80% follow-up colonoscopy completion, multi-component interventions that address barriers at the patient-, provider-, and system-level are needed. We conducted a convergent mixed-methods study to determine the extent to which EHR documented reasons for lack of follow-up colonoscopy in patients with abnormal FIT results aligned with patient-reported reasons in semi-structured interviews. Our analysis found that in a safety-net population with abnormal FIT results and no follow-up colonoscopy within 1-year of this result, only 53.1% had a documented reason in the EHR that might explain why a colonoscopy was not completed. While our EHR review found several potential patient level, provider level, and multi-factorial reasons for lack of follow-up colonoscopy, patient semi-structured interviews identified additional reasons that were not documented in the EHR. Overall, there was discordance between EHR documented and patient reported reasons for lack of follow-up colonoscopy with only three areas of overlap identified in our analysis (competing health issues, lack of transportation, and abnormal FIT result attributed to another cause).

Adding to the existing literature, our study found that only a fraction of patients with an abnormal FIT and lack of follow-up colonoscopy within 1-year had a documented reason in the EHR (Issaka et al., 2017; Martin et al., 2017). When present, the most common reason was that patients declined the procedure (May et al., 2019; Partin et al., 2017). Documentation in the EHR is not a perfect indicator of the quality of patient care or managing abnormal results. There is evidence that the

Table 2
Concordance of electronic health record (EHR)-reported and patient-reported reasons for lack of follow-up colonoscopy.

	EHR data	Patient interviews
Patient-related		
Declined colonoscopy	24.5%	Absent
Competing health issues	13.8%	Present
Lack of transportation	3.2%	Present
Cancelled Colonoscopy	3.2%	Absent
No showed to colonoscopy	3.2%	Absent
Fear of colonoscopy	0%	Present
Unable to tolerate bowel prep	0%	Present
Lack of social support	0%	Present
Provider-related		
Recent colonoscopy	5.3%	Absent
Result attributed to another cause	4.3%	Present
Failure to alert patient about FIT result	0%	Present
System-related		
System scheduling challenges	0%	Present
COVID-19 pandemic	0%	Present
Multifactorial		
Lost to follow-up	18.1%	Absent
Unstable housing	12.8%	Absent
Deceased	4.3%	Absent
Lack of health insurance	0%	Present
Other		
No documented reason	7.4%	Absent



**Patient interview percentages on the x-axis denote concordance with reasons for lack of follow-up from EHR data review and are not statistically representative

Fig. 2. Joint display of overlapping electronic health record (EHR) and patient reported reasons for lack of follow-up colonoscopy and illustrative quotes** Patient interview percentages on the x-axis denote concordance with reasons for lack of follow-up from EHR data review and are not statistically representative.

EHR both under- and over-documents patient information (Weiner et al., 2020). For example, a conversation about follow-up colonoscopy may occur in a clinical setting and never be documented. Indeed, the contribution of EHR documentation to physician burnout cannot be ignored (Melnick et al., 2021). Nonetheless, the EHR remains the definitive document of issues addressed during a visit and medical-legal proceedings and should reflect as many details discussed as possible. Our analysis suggests that when determining reasons for lack of follow-up colonoscopy, reviewing the EHR alone may be insufficient.

Mixed-methods analyses, as in the present study, might give us the greatest insight into intervention development beyond quantitative and qualitative data analysis alone. Through semi-structured patient interviews, we identified several additional reasons for lack of timely follow-up colonoscopy (e.g., fear of colonoscopy procedure, lack of awareness about abnormal result, system-scheduling challenges, etc.) that were not documented in the EHR. These findings are consistent with the limited number of qualitative studies that include safety-net patients (Jetelina et al., 2019; Schneider et al., 2020; Sharma et al., 2020). Colonoscopy is a complex process that may be especially challenging for patients in safety-net health systems who experience fragmented care. For example, in the Los Angeles safety-net system, patient navigation increased follow-up colonoscopy after an abnormal FIT result by 5.4% (40.6% to 46.0%) (Idos et al., 2021). While promising, these results signal that it is unlikely that a simple, one-size fits all intervention will move the needle and that additional interventions are needed to reach the USMSTF 80% goal. The differences between provider-reported and patient-reported reasons for lack of follow-up colonoscopy in the present study, offers additional guidance for developing multi-component interventions to address this problem in safety-net populations.

Awareness about how mixed-methods approaches could help improve follow-up colonoscopy is increasing (Azulay et al., 2021;

Bertels et al., 2022; Selby et al., 2019). In an Israeli population, Azulay et al. found in telephone surveys (quantitative) that lack of comprehension regarding test completion, the abnormal result, and subsequent recommendations were the strongest predictors for lack of follow-up. In their qualitative analysis (focus groups and in-depth interviews), the authors found that lack of test results awareness and physician workload, were the most frequently reported reasons for lack of follow-up colonoscopy (Azulay et al., 2021). These results differ from our study where the most common EHR documented (quantitative) barrier to follow-up colonoscopy was patient declining the procedure and the most common patient-reported (qualitative) barrier was fear of the procedure. The study by Azulay et al. highlights the importance of patient knowledge as a barrier to care and that the main drivers for lack of follow-up, may differ by patient population. Specifically, safety-net patients may have different barriers to follow-up colonoscopy, which if defined, could lead to more effective interventions in these settings.

Our study has several strengths. The use of a convergent mixed-methods design led to a deeper understanding of the patient-, provider-, and system-level barriers to follow-up colonoscopy than EHR or patient interviews alone. Our qualitative interview guide and data analysis were grounded in the Social Cognitive Theory and the PRECEDE model and provides guidance for intervention development to address this important issue. Our study also included a diverse participant population whose practice setting fills an important void in the existing literature. There are also limitations worth noting. First, our study was conducted in an urban, safety-net county teaching hospital and given this unique patient population; our findings may not be generalizable to different primary care settings. Second, as qualitative studies often rely on smaller samples than quantitative studies, it is possible that the reasons identified by participants in our study may differ from those who were not interviewed, and this might have limited the identification of

other possible barriers to follow-up colonoscopy. Third, out-of-network colonoscopies, especially for individuals over 65 years who qualify for Medicare, may not have been completely captured in this study.

In conclusion, our findings have several implications for clinical practice and future research. In this mixed-methods study we identified barriers to follow-up colonoscopy at the patient-level (e.g., declined colonoscopy and fear of colonoscopy), provider-level (e.g., not alerting patients of abnormal FIT results and attributing result to another cause), and system-level (e.g., colonoscopy scheduling challenges and COVID-19 procedures) for which there are practical solutions. For example, addressing logistical barriers to colonoscopy including transportation assistance at the patient-level (Bell-Brown et al., 2022), education about abnormal FIT follow-up in patients with a recent colonoscopy at the provider-level, and population health management tools that streamline FIT-based CRC screening at the health system-level, could lead to improvements in follow-up colonoscopy in safety-net systems. Determining which combination of interventions will most effectively improve colonoscopy completion after an abnormal FIT result and testing these interventions is an important next step. In doing so, we will also learn the mechanisms that lead to intervention success, modifications needed for diverse healthcare settings, and the tools needed to sustainably address one of the most persistent challenges in cancer prevention and control for safety-net and other medically underserved populations.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

Author Contributions: Dr. Issaka had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Issaka.

Acquisition, analysis and interpretation of data: Issaka, Bell-Brown, Kao, Snyder, Atkins.

Drafting of the manuscript: Issaka.

Critical revision of the manuscript for important intellectual content: All authors.

Approval of the final manuscript: All authors.

Obtained funding: Issaka.

Funding/Support: Research reported in this publication was supported by the National Cancer Institute of the National Institutes of Health under Award Number K08CA241296 (Issaka).

Role of the Funder/Sponsor: The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Additional Contributions: We thank the interview participants who shared their experiences with us.

Data Sharing Statement: The datasets generated during and/or analyzed during the current study are not publicly available due to protected health information.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.pmedr.2022.101831>.

References

- Siegel, R.L., Miller, K.D., Goding Sauer, A., Fedewa, S.A., Butterly, L.F., Anderson, J.C., Cercek, A., Smith, R.A., Jemal, A., 2020. Colorectal cancer statistics, 2020. *CA Cancer J. Clin.* 70 (3), 145–164.
- Heitman, S.J., Hilsden, R.J., Au, F., Dowden, S., Manns, B.J., 2010. Colorectal cancer screening for average-risk North Americans: an economic evaluation. *PLoS Med.* 7 (11), e1000370.
- Mandel, J.S., Bond, J.H., Church, T.R., Snover, D.C., Bradley, G.M., Schuman, L.M., Ederer, F., 1993. Reducing mortality from colorectal cancer by screening for fecal occult blood. Minnesota Colon Cancer Control Study. *N. Engl. J. Med.* 328 (19), 1365–1371.
- David, T., Liss, D.W.B., 2014. Understanding current racial/ethnic disparities in colorectal cancer screening in the United States: the contribution of socioeconomic status and access to care. *Am. J. Prev. Med.* 46 (3), 228–236.
- National Colorectal Cancer Roundtable. 80% in Every Community. National Colorectal Cancer Roundtable. <https://nccrt.org/80-in-every-community/>. Published 2019. Accessed January 15, 2020.
- American Cancer Society, 2020. Colorectal Cancer Facts & Figures 2020–2022. American Cancer Society, Atlanta.
- Singal, A.G., Gupta, S., Tiro, J.A., Skinner, C.S., McCallister, K., Sanders, J.M., Bishop, W.P., Agrawal, D., Mayorga, C.A., Ahn, C., Loewen, A.C., Santini, N.O., Halm, E.A., 2016. Outreach invitations for FIT and colonoscopy improve colorectal cancer screening rates: A randomized controlled trial in a safety-net health system. *Cancer* 122 (3), 456–463.
- Corley, D.A., Jensen, C.D., Quinn, V.P., Doubeni, C.A., Zauber, A.G., Lee, J.K., Schottinger, J.E., Marks, A.R., Zhao, W.K., Ghai, N.R., Lee, A.T., Contreras, R., Quesenberry, C.P., Fireman, B.H., Levin, T.R., 2017. Association Between Time to Colonoscopy After a Positive Fecal Test Result and Risk of Colorectal Cancer and Cancer Stage at Diagnosis. *JAMA* 317 (16), 1631.
- Lee, Y.C., Fann, J.C., Chiang, T.H., et al., 2019. Time to Colonoscopy and Risk of Colorectal Cancer in Patients With Positive Results From Fecal Immunochemical Tests. *Clin. Gastroenterol. Hepatol.* 17 (7), 1332–1340 e1333.
- Doubeni, C.A., Fedewa, S.A., Levin, T.R., Jensen, C.D., Saia, C., Zebrowski, A.M., Quinn, V.P., Rendle, K.A., Zauber, A.G., Becerra-Culqui, T.A., Mehta, S.J., Fletcher, R.H., Schottinger, J., Corley, D.A., 2019. Modifiable Failures in the Colorectal Cancer Screening Process and Their Association With Risk of Death. *Gastroenterology* 156 (1), 63–74.e66.
- San Miguel, Y., Demb, J., Martinez, M.E., Gupta, S., May, F.P., 2021. Time to Colonoscopy After Abnormal Stool-Based Screening and Risk for Colorectal Cancer Incidence and Mortality. *Gastroenterology* 160 (6), 1997–2005 e1993.
- Chubak, J., Garcia, M.P., Burnett-Hartman, A.N., Zheng, Y., Corley, D.A., Halm, E.A., Singal, A.G., Klabunde, C.N., Doubeni, C.A., Kamineni, A., Levin, T.R., Schottinger, J.E., Green, B.B., Quinn, V.P., Rutter, C.M., 2016. Time to Colonoscopy after Positive Fecal Blood Test in Four U.S. Health Care Systems. *Cancer Epidemiol. Biomarkers Prev.* 25 (2), 344–350.
- Issaka, R.B., Singh, M.H., Oshima, S.M., Laleau, V.J., Rachocki, C.D., Chen, E.H., Day, L.W., Sarkar, U., Somsouk, M.a., 2017. Inadequate Utilization of Diagnostic Colonoscopy Following Abnormal FIT Results in an Integrated Safety-Net System. *Am. J. Gastroenterol.* 112 (2), 375–382.
- National Colorectal Cancer Roundtable. Colorectal Cancer Screening Rates Reach 44.1% in FQHCs in 2018. National Colorectal Cancer Roundtable. <https://nccrt.org/colorectal-cancer-screening-rates-reach-44-1-in-fqhc-in-2018/>. Published 2020. Accessed August 20, 2020.
- Dougherty, M.K., Brenner, A.T., Crockett, S.D., Gupta, S., Wheeler, S.B., Coker-Schwimmer, M., Cubillos, L., Malo, T., Reuland, D.S., 2018. Evaluation of Interventions Intended to Increase Colorectal Cancer Screening Rates in the United States: A Systematic Review and Meta-analysis. *JAMA Intern Med.* 178 (12), 1645.
- Selby, K., Baumgartner, C., Levin, T.R., Doubeni, C.A., Zauber, A.G., Schottinger, J., Jensen, C.D., Lee, J.K., Corley, D.A., 2017. Interventions to Improve Follow-up of Positive Results on Fecal Blood Tests: A Systematic Review. *Ann. Intern. Med.* 167 (8), 565.
- Robertson, D.J., Lee, J.K., Boland, C.R., Dominitz, J.A., Giardiello, F.M., Johnson, D.A., Kaltenbach, T., Lieberman, D., Levin, T.R., Rex, D.K., 2017. Recommendations on Fecal Immunochemical Testing to Screen for Colorectal Neoplasia: A Consensus Statement by the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology* 152 (5), 1217–1237.e3.
- von Elm, E., Altman, D.G., Egger, M., Pocock, S.J., Gøtzsche, P.C., Vandenbroucke, J.P., 2007. The Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *Ann. Intern. Med.* 147 (8), 573.
- Tong, A., Sainsbury, P., Craig, J., 2007. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int. J. Qual. Health Care* 19 (6), 349–357.
- Issaka, R.B., Akinsoto, N.O., Strait, E., Chaudhari, V., Flum, D.R., Inadomi, J.M. Effectiveness of a ed fecal immunochemical test outreach: a Medicare Advantage pilot study. *Therap Adv Gastroenterol.* 2020;13:1756284820945388.
- May, F.P., Yano, E.M., Provenzale, D., Brunner, J., Yu, C., Phan, J., Bharath, P., Aby, E., Dinh, D., Ehrlich, D.S., Storage, T.R., Lin, L.D., Jamaluddin, N.N., Washington, D.L., 2019. Barriers to Follow-up Colonoscopies for Patients With Positive Results From Fecal Immunochemical Tests During Colorectal Cancer Screening. *Clin. Gastroenterol. Hepatol.* 17 (3), 469–476.
- Bandura, A., 1977. *Social Learning Theory*. Prentice-Hall, Englewood Cliffs.
- McAlister, A., Perry, C., Parcel, G. *How individuals, environments, and health behaviors interact: Social Cognitive Theory. In: Health Behavior and Health Education: Theory, Research and Practice*. San Francisco: Jossey-Bass; 2008.

- Bandura, A., 1986. Social foundations of thought and action. Prentice Hall, Englewood Cliffs, NJ.
- Morse, J.M., 2015. Critical Analysis of Strategies for Determining Rigor in Qualitative Inquiry. *Qual. Health Res.* 25 (9), 1212–1222.
- Hennink, M., Kaiser, B.N., 2022. Sample sizes for saturation in qualitative research: A systematic review of empirical tests. *Soc. Sci. Med.* 292, 114523.
- Hsieh, H.F., Shannon, S.E., 2005. Three approaches to qualitative content analysis. *Qual. Health Res.* 15 (9), 1277–1288.
- Issaka, R.B., Bell-Brown, A., Snyder, C., et al. Perceptions on Barriers and Facilitators to Colonoscopy Completion After Abnormal Fecal Immunochemical Test Results in a Safety Net System. *JAMA Netw Open.* 2021;4(8):e2120159.
- Bartholomew Eldredge, L.K., Markham, C.M., Ruiter, R.A.C., Fernandez, M.E., Kok, G., Parcel, G.S., 2016. Planning Health Promotion Programs: An Intervention Mapping Approach, 4th ed. Jossey-Bass, San Francisco, CA.
- Martin, J., Halm, E.A., Tiro, J.A., Merchant, Z., Balasubramanian, B.A., McCallister, K., Sanders, J.M., Ahn, C., Bishop, W.P., Singal, A.G., 2017. Reasons for Lack of Diagnostic Colonoscopy After Positive Result on Fecal Immunochemical Test in a Safety-Net Health System. *Am. J. Med.* 130 (1), 93.e1–93.e7.
- Partin, M.R., Gravely, A.A., Burgess, J.F., Haggstrom, D.A., Lillie, S.E., Nelson, D.B., Nugent, S.M., Shaikat, A., Sultan, S., Walter, L.C., Burgess, D.J., 2017. Contribution of patient, physician, and environmental factors to demographic and health variation in colonoscopy follow-up for abnormal colorectal cancer screening test results. *Cancer* 123 (18), 3502–3512.
- Weiner, S.J., Wang, S., Kelly, B., Sharma, G., Schwartz, A., 2020. How accurate is the medical record? A comparison of the physician's note with a concealed audio recording in unannounced standardized patient encounters. *J. Am. Med. Inform. Assoc.* 27 (5), 770–775.
- Melnick, E.R., Fong, A., Nath, B., et al. Analysis of Electronic Health Record Use and Clinical Productivity and Their Association With Physician Turnover. *JAMA Netw Open.* 2021;4(10):e2128790.
- Jetelina, K.K., Yudkin, J.S., Miller, S., Berry, E., Lieberman, A., Gupta, S., Balasubramanian, B.A., 2019. Patient-Reported Barriers to Completing a Diagnostic Colonoscopy Following Abnormal Fecal Immunochemical Test Among Uninsured Patients. *J. Gen. Intern. Med.* 34 (9), 1730–1736.
- Schneider, J.L., Rivelli, J.S., Gruss, I., Petrik, A.F., Nielson, C.M., Green, B.B., Coronado, G.D., 2020. Barriers and Facilitators to Timely Colonoscopy Completion for Safety Net Clinic Patients. *Am J Health Behav.* 44 (4), 460–472.
- Sharma, A.E., Lyson, H.C., Cherian, R., Somsouk, M., Schillinger, D., Sarkar, U., 2020. A root cause analysis of barriers to timely colonoscopy in California safety-net health systems. *J. Patient Saf.*
- Idos, G.E., Bonner, J.D., Haghghat, S., et al., 2021. Bridging the gap: patient navigation increases colonoscopy follow-up after abnormal FIT. *Clin. Transl. Gastroenterol.* 12 (2), e00307.
- Azulay, R., Valinsky, L., Hershkowitz, F., Elran, E., Lederman, N., Kariv, R., Braunstein, B., Heymann, A., 2021. Barriers to completing colonoscopy after a positive fecal occult blood test. *Isr. J. Health Policy Res.* 10 (1).
- Bertels, L., Knottnerus, B., Bastiaans, L., Danquah, A., van, H., Dekker, E., van, K., 2022. Decision-making in screening positive participants who follow up with colonoscopy in the Dutch colorectal cancer screening programme: A mixed-method study. *Psychooncology* 31 (2), 245–252.
- Selby, K., Jensen, C.D., Zhao, W.K., et al., 2019. Strategies to improve follow-up after positive fecal immunochemical tests in a community-based setting: a mixed-methods study. *Clin. Transl. Gastroenterol.* 10 (2), e00010.
- Bell-Brown, A., Chew, L., Weiner, B.J., Strate, L., Balmadrid, B., Lewis, C.C., Hannon, P., Inadomi, J.M., Ramsey, S.D., Issaka, R.B., 2022. Operationalizing a rideshare intervention for colonoscopy completion: barriers, facilitators, and process recommendations. *Front. Health Serv.* 1.