



Impact of the COVID-19 pandemic on adherence to diagnostic colonoscopy after a positive non-invasive screening test for colorectal cancer in two Indiana healthcare systems

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ABSTRACT

Objective: To describe trends in the use of non-invasive tests (NIST) and the interval between a positive NIST and diagnostic colonoscopy.

Methods: Using a retrospective time-trend design, we examined medical records of patients within two large Indiana integrated healthcare systems who had a positive NIST between January 2019 and June 2021 and quantified the proportion of patients who had not completed colonoscopy within 60, 90, and 180 days to determine the interval between NIST result and diagnostic colonoscopy in days.

Results: Of 1379 patients with positive NISTs, 930 (68 %) underwent diagnostic colonoscopy during the 30-month study timeframe. Median time to colonoscopy completion was significantly longer in 2020 compared to 2019 (50 vs. 37 days, $p < 0.01$) and 2021 (46 days, $p = 0.06$). The proportion of patients completing colonoscopy within 90 days of a positive FIT in 2019, 2020, and 2021 were 79 %, 83 %, and 72 %, respectively ($p = 0.63$), and were 86 %, 78 %, and 84 %, respectively, after positive FIT/DNA ($p = 0.07$). Median time to diagnostic colonoscopy completion was significantly longer in 2020, likely due to the COVID-19 pandemic.

Conclusions: Studies of outcomes in those who declined or delayed colonoscopy in 2020 are needed to estimate the potential subsequent colorectal cancer disease burden.

1. Introduction

Colorectal cancer is the third leading cause of cancer death worldwide and is second in the United States in men and women combined (Siegel et al., 2018). Screening with colonoscopy and with fecal blood testing reduces both incidence and mortality from colorectal cancer and is recommended by several guideline organizations beginning at age 45 years (US Preventive Services Task Force et al., 2021; Wolf et al., 2018).

Testing for occult blood is the most frequently used screening test worldwide (Navarro et al., 2017). It is a two-step process in which diagnostic colonoscopy is recommended if occult blood is detected (US Preventive Services Task Force et al., 2021). With the cancellation of

elective procedures during the late winter and early spring of 2020 due to the COVID-19 pandemic, the number of screening colonoscopies and diagnosed colorectal cancer sharply declined, raising concerns about the negative impact of the pandemic on cancer prevention (Fedewa et al., 2022; Holland et al., 2022; Liu et al., 2023; Mazidimoradi et al., 2022; Oakes et al., 2023). Shortly into the pandemic, several health care systems turned to greater use of non-invasive screening tests (NISTs), including both the well-established fecal immunochemical test (FIT) and more recently established multi-target stool DNA (FIT/DNA) test, both of which require diagnostic colonoscopy when the test is positive (Lee et al., 2022; Liu et al., 2023; Myint et al., 2021). Model-based simulation studies suggest that increased use of FIT during the pandemic could

Abbreviations: NISTs, Non-invasive screening tests; FIT, fecal immunochemical test; FIT/DNA, multi-target stool DNA fecal immunochemical test.

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mitigate the consequences of reduced colonoscopy screening during the pandemic (Issaka et al., 2021; Loveday et al., 2021).

For both NISTs, the interval between a positive test and diagnostic colonoscopy is an important factor in determining their effectiveness. For FIT, several studies and a systematic review show that the risks of any colorectal cancer and advanced stages of colorectal cancer increase when the interval between a positive test and colonoscopy exceeds six months (Corley et al., 2017; Doubeni et al., 2018). Corresponding data for FIT/DNA are not yet available. To understand the impact of the COVID-19 pandemic in two of the largest health care systems in the greater Indianapolis area and throughout Indiana, we studied the association between the stage of the pandemic and interval between a positive NIST and colonoscopy.

2. Methods

2.1. Study setting

This study was conducted on the campus of Indiana University Purdue University Indianapolis and Indiana University Medical Center from September 2021 through July 2022. The study was approved by the Indiana University Institutional Review Board with waiver of both informed consent and Health Information Portability and Accountability Act due to minimal risk.

2.2. Study procedures

We examined the time interval between all positive NISTs and diagnostic colonoscopy from January 1, 2019 through June 30, 2021 in a large, integrated health care system largely within central Indiana. We hypothesized that the number of NISTs increased during the peak of the

pandemic (roughly April to August of 2020), and that the interval between a positive NIST and colonoscopy lengthened during the same period.

2.3. Data collection

We first conducted a query of all positive FIT/DNA tests from January 1, 2019 through June 30, 2021 for a private and a public healthcare system with retrieval of the following variables: medical record number, screening test location, patient age, the specific NIST (FIT or FIT/DNA), and the date of diagnostic colonoscopy. The following Current Procedural Terminology codes were used to identify whether and when the diagnostic colonoscopy was performed: 45378, 45,379, 45,380, 45,381, 45,384, 45,385, 45,388, 45,389, 45,390, 45,392, and 45,479. Some patients had more than one colonoscopy during this timeframe, as identified by the query. Only colonoscopies performed for the indication of a positive NIST were selected.

When the code query did not find a colonoscopy date, individual medical records were manually searched to identify the date. Colonoscopies were identified by entering the terms “colonoscopy”, “FIT”, and/or “Cologuard” in the “Chart Search” function in the patient’s electronic medical record. Colonoscopy dates were found primarily by identifying the procedure notes, which were available through the electronic medical records. In some cases, the procedure report was a scanned-in document, found by searching the “Documents” tab in the patient’s electronic medical record. In the instance when a patient was referred to an endoscopy suite outside of the electronic medical record system, the “Outside Documents” tab was reviewed for any evidence of endoscopy records that had been faxed or scanned in. In some cases, the patients themselves were unresponsive to communications for scheduling a colonoscopy, and visit notes by the provider were reviewed to clearly

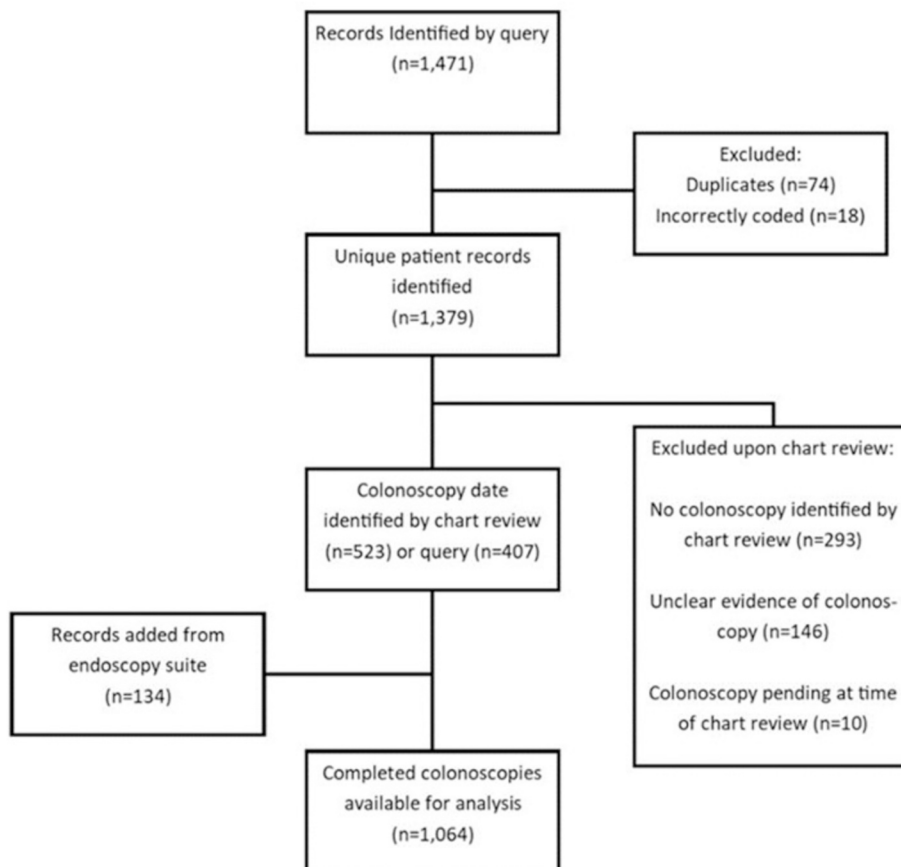


Fig. 1. Flow Diagram for Study Sample across Two Healthcare Systems.

delineate the reason. If there was insufficient data in response to external electronic medical record queries or subsequent visit notes, the patient's colonoscopy status was determined as unknown. Fig. 1 displays a flow chart of the data retrieval process.

The time between positive NIST and colonoscopy ("Time to Colonoscopy") was calculated by subtracting the respective dates. After obtaining these data, we observed that no FIT/DNA tests were identified from January 1, 2019 through June 10, 2020, with a gradual increase through the end of July 2020. To supplement the aforementioned methods, we retrieved data from an endoscopy procedural database for colonoscopies with the indication of "positive FIT/DNA test" conducted during the timeframe of January 1, 2019 through July 31, 2020. These data were used to calculate time-to-colonoscopy but were excluded from the completion rate of FIT/DNA tests. In cases where the time-to-colonoscopy exceeded 90 days, review of outpatient notes (e.g. primary care visits) and telephone encounters were conducted to identify an explanation as to why a delay in time-to-colonoscopy occurred. Results were grouped following a qualitative analysis.

2.4. Data analysis

The data were managed in Microsoft Excel and were grouped by month, year, and test type (FIT/DNA or FIT). The time-to-colonoscopy was calculated as the number of days between date of positive NIST and date of subsequent colonoscopy found on electronic medical record review. Kaplan-Meier plots were used to analyze the time to event by year and by pandemic period. Chi-squared testing was used to compare completion rates for groups at 90 and 180 days. Kruskal-Wallis testing was performed to test for differences in median time to colonoscopy both overall and by type of test, and for differences between years. Wilcoxon testing was used for pairwise comparison of median time to colonoscopy by type of test within the same year and by years. Analyses were performed in SAS software v9.4 (Cary, NC, USA).

3. Results

Between January 2019 and June 2021, we identified 1471 records by electronic medical record query, of which 1379 unique individuals were identified as having had a positive NIST (Fig. 1). We excluded three groups from time-to-colonoscopy analysis: 293 (21 %) individuals who did not complete a follow-up colonoscopy, 146 (11 %) individuals who did not have definitive evidence to suggest completion (or deferral) of colonoscopy, and 10 individuals who had pending colonoscopies at time of study completion. The remaining 930 (68 %) individuals who underwent diagnostic colonoscopy for a positive NIST were included in the analysis, along with 134 additional individuals who had a positive FIT/DNA test based on procedure database review. While FIT was available in both hospital systems, FIT/DNA was available in only one of two systems included in this study.

3.1. Baseline characteristics of NISTs and performed colonoscopies

The mean age for individuals who underwent diagnostic colonoscopy was 59.5 (SD, 11.1) years and 63.9 (8.3) years for FIT and FIT/DNA groups, respectively ($p < 0.01$). For those included in the supplemental FIT/DNA group, the mean age was 65.5 (7.7) years. Patient refusal to undergo colonoscopy was the most common reason for excluding subjects who did not have a follow-up colonoscopy after a positive NIST. Those who did not undergo a diagnostic colonoscopy had a mean age of 64.6 (11.6) years for FIT and 65.3 (8.0) years for FIT/DNA ($P = 0.54$), while those with insufficient data to determine completion of colonoscopy had a mean age of 62.7 (8.6) years and 64.5 (7.9) years, respectively ($p = 0.32$).

Completion rates of diagnostic colonoscopy were 82 % for the FIT/DNA group, and 52 % for the FIT group over the 30-month timeframe ($p < 0.01$). The exclusion of positive NISTs within the last 90 days of the

study timeframe produced comparable completion rates: 78 % for FIT/DNA and 50 % for FIT. In the FIT group, patients did not have a colonoscopy due to either 1) a negative repeat FIT test (13 %) or 2) a concordant decision by patient and physician that the test was a false positive due to the presence of hemorrhoids (11 %). In the FIT/DNA group, there were no negative repeat tests, and only two of 179 patients suspected a false positive due to hemorrhoids. The median [interquartile range] time-to-colonoscopy interval for those completing diagnostic colonoscopy was 47 [29 to 78] days.

3.2. Time trends in NISTs to colonoscopies pre- and post-pandemic

We analyzed trends in median time-to-colonoscopy intervals by quarter and by test over the 30-month study period (Fig. 2). For the FIT/DNA group, there were nonsignificant year-by-year increases during the first (50 vs. 33 days, $p = 0.85$) and last (57 vs. 34 days, $p = 0.09$) quarters of 2020, compared with 2019. For FIT, the increase in time-to-colonoscopy during Q2 2019 had insufficient data for year-by-year analysis due to sample size ($n = 3$ for Q2 2020), while the year-by-year Q4 increase for 2020 vs. 2019 was not statistically significant (77 vs. 33 days, $p = 0.09$), despite the magnitude of the increase. No positive FITs were recorded between March 17th and June 4th, 2020, and no positive FIT/DNA tests were recorded from April 28th to June 9th of the same year.

The distribution of time-to-colonoscopy in the pre-pandemic (January 1, 2019 - December 31, 2019) and pandemic (January 1, 2020 - June 30, 2021) periods is shown in Supplemental Fig. 1. When comparing time to event, there was a statistically significant difference between the two groups based on the Wilcoxon test ($p = 0.01$) but not for the logrank test ($p = 0.51$). In both groups, approximately 80 % of those who underwent diagnostic colonoscopy did so within 100 days.

Supplemental Fig. 2 shows completion of diagnostic colonoscopy by year. The largest difference is observed between 2019 and 2020, with smaller differences between 2019 and 2021 and between 2020 and 2021, consistent with results in Table 1. These findings are also consistent with Supplemental Fig. 1 in demonstrating that approximately 80 % of those who underwent diagnostic colonoscopy did so within 90 days after a positive NIST.

3.3. Impact of COVID pandemic on time to colonoscopy

Comparing FIT and FIT/DNA tests, Table 1 demonstrates median intervals and same-year comparisons for both tests. The time-to-colonoscopy for FIT/DNA was significantly longer than that for FIT in the year 2020 ($p = 0.01$). There were no statistically significant differences in time-to-colonoscopy intervals for 2019 and 2021 between the two tests ($p = 0.88$ and $p = 0.98$, respectively).

Considering intervals by year without respect to specific NIST, the medians [interquartile range] in days for 2019, 2020, and 2021 were 37 [25 to 77], 50 [31 to 84], and 46 [30 to 76] days, respectively (Supplemental Fig. 3). The time-to-colonoscopy was longer in 2020 than in both 2019 and 2021. The 2019 median time-to-colonoscopy of 37 days was significantly shorter than the median of 50 days in 2020 ($p < 0.01$). The time-to-colonoscopy for FIT and FIT/DNA during 2019 also showed a trend toward a statistically significant difference from those of 2021 ($p = 0.09$).

Table 2 shows the completion rates by type of NIST and by year at 90 and 180 days. At 90 days, completion rates during 2019, 2020, 2021 (83 % vs. 79 % vs. 83 %, respectively) were no different ($p = 0.19$); however, at 180 days, differences in completion rates were statistically significant (93 % vs. 92 % vs. 97 %, $p = 0.01$), despite a similar magnitudinal difference. Completion rates by year and NIST demonstrated a trend for a difference in FIT/DNA at 90 days ($p = 0.07$) with statistical significance at 180 days ($p = 0.01$). Analysis of FIT showed no significant differences at 90 days ($p = 0.63$) or 180 days ($p = 0.86$). Comparing the two NISTs over the course of the study, no significant differences were

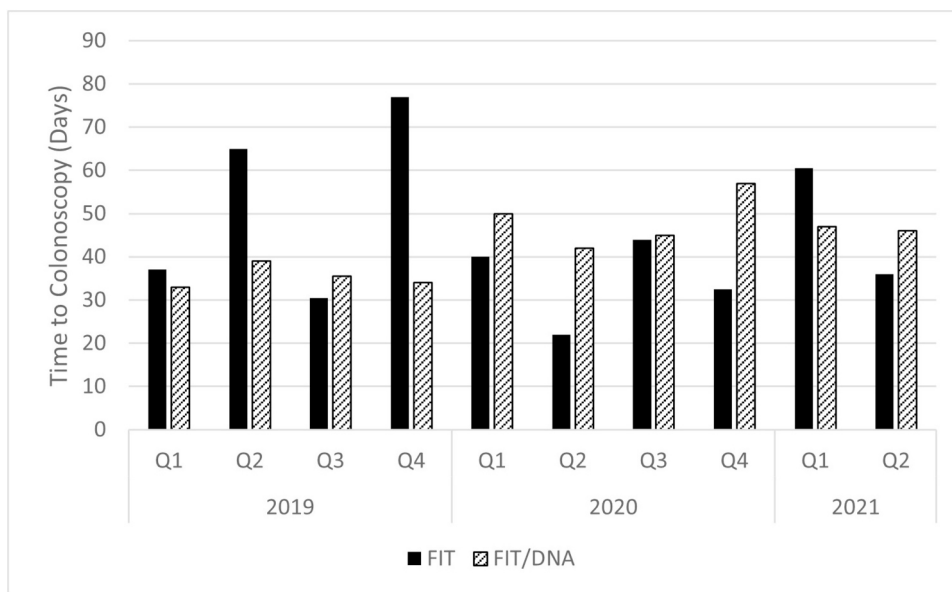


Fig. 2. Median Time Elapsed between Positive NIST to Colonoscopy (“Time to Colonoscopy”) by Quarter and Test (2019-Q2 2021) in Two Healthcare Systems. The range for time-to-colonoscopy for FIT varied from a low of 22 days in Q2 2020 to a high of 77 days in Q4 2019, while that for FIT/DNA ranged from 33 days in Q1 2019 to 57 days in Q4 2020.

Table 1

Comparison of Time Elapsed between Positive NIST to Colonoscopy (“Time to Colonoscopy”) by Test and Year (2019–2021) in Two Healthcare Systems.

Test Group and Year	N	Median Time to Colonoscopy in Days [IQR]	Comparison Group and Year	N	Median Time to Colonoscopy in Days [IQR]	P-Value
FIT 2019	53	37 [22, 82]	FIT/DNA 2019	66	33 [25,63]	0.88
FIT 2020	52	40 [19, 68]	FIT/DNA 2020	439	51 [32, 85]	0.01
FIT 2021	18	49 [21,100]	FIT/DNA 2021	397	46 [30, 75]	0.98

Abbreviations: FIT – fecal immunochemical test; FIT/DNA – multitarget stool test for FIT and DNA mutations.

Table 2

Completion Rates of Diagnostic Colonoscopy in Two Healthcare Systems within 90 and 180 days by Test and by Year (2019–2021).

Non-invasive Test and Year	N	Undergoing Colonoscopy within 90 days of a Positive NIST (%)	Undergoing Colonoscopy within 180 days of a Positive NIST (%)
FIT 2019	53	79	91
FIT 2020	52	83	92
FIT 2021	18	72	94
FIT/DNA 2019	66	86	95
FIT/DNA 2020	439	78	92
FIT/DNA 2021	397	84	97
2019	119	83	93
2020	491	79	92
2021	415	83	97
Overall	1025	81	94

Abbreviations: FIT – fecal immunochemical test; FIT/DNA – multitarget stool test for FIT and DNA mutations.

found between colonoscopy completion rates for FIT and FIT/DNA at 90 days ($p = 0.65$) or 180 days ($p = 0.23$).

4. Discussion

The purpose of this study was to describe trends in use of NISTs and in the interval between a positive NIST and follow-up diagnostic colonoscopy in a large integrated health care system located within central Indiana before, during, and in the immediate post-COVID-19 pandemic period. The effect of COVID-19 on this interval has not been well described in the state of Indiana.

We found a difference at the beginning of the time-to-colonoscopy curve ($p = 0.01$) but no overall significant difference ($p = 0.51$). The lack of overall significance between pre-pandemic and pandemic periods is likely due to a recovery of completion rates well before the end of the study period. We identified a full recovery in endoscopy completion rate following a positive NIST during the first six months of 2021, with 83 % completing colonoscopy by 90 days in both 2019 and 2021 as compared to 79 % in 2020. Thus, the effect of the COVID-19 pandemic appears to have been more impactful in 2020 than during the first six months of 2021. The pandemic’s impact may be realized from a median time-to-colonoscopy that was significantly longer in 2020 (50 days) as compared to 2019 (37 days), with borderline statistical significance when compared to 2021 (46 days). Comparison of completion timeliness in 2019, 2020, and 2021 showed a difference by 180 days ($p = 0.03$) that is most likely driven by yearly differences in FIT/DNA ($p = 0.01$) rather than by FIT ($p = 0.86$), as the sample size for FIT was 123 while that for FIT/DNA was 902. Considering these data, the increases in time-to-colonoscopy during 2020 were most likely due to the FIT/DNA group. These findings are supported by data from another large major healthcare system in the Midwest, for which there was a 43 % decrease in screening colonoscopy and a 94 % increase in stool-based screening during the first year of the pandemic compared to the year prior (Nwankwo Jr et al., 2022).

Although timeliness of colonoscopy completion was similar for both FIT and FIT/DNA groups at 90 and 180 days, completion was significantly lower for those with a positive FIT compared to positive FIT/DNA ($p < 0.01$). This finding suggests that, while patients were less likely to schedule a follow-up colonoscopy after a positive FIT (as compared to

FIT/DNA), those with positive FITs were just as likely as their FIT/DNA counterparts to complete their colonoscopy within 90 and 180 days.

Concern for contracting COVID-19 from the colonoscopy appointment was the most common reason for declining the procedure following a positive NIST, having been mentioned by 8 of the 21 individuals from whom a reason was recorded in the electronic medical record. Other reasons included waiting to get a COVID-19 vaccine before undergoing a procedure or issues with completing required COVID-19 screening before the procedure. Only two individuals (0.2 %) were found to have delayed colonoscopy due to a recent COVID-19 infection. The absence of positive FIT results from March 17th to June 4th, 2020 and of positive FIT/DNA results from April 28th to June 9th, 2020 is consistent with Myint and colleagues, who found a large decrease in endoscopies performed from March through May of 2020 (Myint et al., 2021). This finding is also consistent with those of Cheng and colleagues, who found that 50 % of cancellations due to COVID-19 were due to similar concerns (Cheng et al., 2021). These concerns existed despite data showing low risk of infection following endoscopy (Papanicolaou et al., 2021; Repici et al., 2020). We found that the COVID-19 pandemic was associated with cancellations or delays in 1.7 % of cases— a proportion much lower than the 10.9 % reported by Cheng et al. This discrepancy is most likely due to incomplete ascertainment, as unlike Cheng et al., our data did not include a specific query as to whether patients delayed colonoscopy due to COVID-19.

For a positive NIST, current recommendations require diagnostic colonoscopy within 90 days as a “reasonable” interval with time-to-colonoscopy not to exceed 180 days due to an increased risk of colorectal cancer and advanced-stage disease after this timeframe (Corley et al., 2017; Doubeni et al., 2018). Although the rates of completion were similar among those who would eventually undergo a follow-up colonoscopy, differences emerge when including the entire population. Over the 2.5-year study period, nearly 25 % of those with a positive NIST did not have colonoscopy according to same-system records. It is possible, although unlikely, that some of these patients had colonoscopy in another healthcare system. The low uptake in 2019 is most likely due to overall differences in completion of diagnostic colonoscopy between FIT and FIT/DNA (47 % vs, 72 %, respectively).

Completion of diagnostic colonoscopy after a positive NIST varies widely, ranging from less than 50 % to 80–90 % in RCTs (Selby et al., 2017). A recent study of over 32,000 individuals by Mohl and colleagues showed diagnostic colonoscopy completion rates of 43 %, 51 %, and 56 % at 90, 180, and 360 days, respectively, after a positive NIST (Mohl et al., 2023). Our completion rates were higher at all three intervals. One explanation for the higher completion rates is the exclusion of 11 % of retrieved data, where information pertaining to colonoscopy completion was unclear or absent. These individuals may have been more likely to not have received a diagnostic colonoscopy, perhaps being lost to follow-up. Alternatively, they may have scheduled their colonoscopy through a different healthcare system with a different electronic medical record. If we assume all these individuals did not undergo diagnostic colonoscopy (a “worst-case” scenario), the overall completion rates at 90 days, 180 days, and at any time decrease to 55 %, 64 %, and 68 %, respectively. These rates are still significantly numerically higher than those by Mohl et al.

In the bigger picture, the long-term effects of the disrupted colorectal cancer screening experienced in 2020 remain to be determined. A scenario analysis by van den Puttelaar and colleagues predicted 0.18 % excess colorectal cancer cases during 2020–2040 and 0.65 % excess colorectal cancer-related deaths due to screening delays, allowing for a 24-month recovery by increasing colonoscopy capacity (van den Puttelaar et al., 2023). Shorter recovery time (which was largely the case in the U.S.) was associated with reductions in the expected increases in colorectal cancer incidence and mortality.

4.1. Strengths & limitations

This study has strengths and limitations that require comment. Strengths of the study include the use of a large, integrated health care system with a broad catchment area. Individual chart review for cases not fully identified by Current Procedural Terminology code queries helped to identify medical records where outside colonoscopy data were scanned electronically. Individual manual review was also helpful in identifying cases where patient deferral of colonoscopy was not readily searchable by query.

Regarding study limitations, individual medical record review is subject to human error, and relevant documents in the chart could have been overlooked. The 11 % of charts excluded due to unclear evidence may affect the validity of the trends and uptake of diagnostic colonoscopy we found. Additionally, the relatively small sample size within this study may limit its generalizability. The lower rates of delay/cancellation due to COVID-19 (as compared to rates found by Cheng and colleagues) are likely due to incomplete ascertainment. While we looked for phone and/or provider notes documenting the reason for the delay in diagnostic colonoscopy, there was no standard ascertainment of the reason and specifically whether the pandemic affected their decision-making. Because FIT is physically handed to patients during a clinic appointment, we were unable to determine the denominator of persons to whom FITs were given, many of which were likely not completed. The fact that FIT/DNA data were not coded into the electronic medical record before June 2020 resulted in post-hoc addition of supplemental data from endoscopy units in the same health care system. Differences in this population from the original may have introduced bias. Exclusion of these data from completion rates could also have affected broader conclusions. Use of a two health care systems located in the same area may limit the generalizability of the study.

5. Conclusion

Overall, the COVID-19 pandemic appears to have a small impact on those with a positive FIT/DNA test in 2020. Although ascertainment of reasons for failure to complete diagnostic colonoscopy was incomplete, it appears that fear of contracting infection from the care encounter was most common, despite data suggesting very low risk (Repici et al., 2020). Future studies should include follow-up of those individuals who did not undergo or who delayed diagnostic colonoscopy due to COVID-19. The significant difference in diagnostic colonoscopy completion rates observed between FIT and FIT/DNA groups has not been well-reported in the literature. Subsequent research should validate and extend these findings.

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CRediT authorship contribution statement

Benjamin Richter: Writing – review & editing, Writing – original draft, Methodology, Investigation, Data curation, Conceptualization. **Sarah M. Roth:** Writing – review & editing, Project administration, Methodology, Investigation, Data curation. **Lilian Golzarri-Arroyo:** Writing – review & editing, Methodology, Formal analysis. **Vinod Kumar:** Writing – review & editing, Visualization, Conceptualization. **Rick Tuason:** Writing – review & editing, Methodology, Investigation, Data curation. **Thomas F. Imperiale:** Writing – review & editing, Writing – original draft, Visualization, Methodology, Investigation, Conceptualization.

Declaration of competing interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.pmedr.2024.102937>.

Data availability

A minimal dataset for this study may be made available upon written request to the corresponding author, and must include one or more stated aims and hypotheses along with proposed study methods and plan for analysis.

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