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Fecal Immunochemical Test Program Performance Over 4 Rounds of Annual Screening:

A Retrospective Cohort Study

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Abstract

Background—The fecal immunochemical test (FIT) is a common method for colorectal cancer (CRC) screening, yet its acceptability and performance over several rounds of annual testing are largely unknown.

Objective—To assess FIT performance characteristics over 4 rounds of annual screening.

Design—Retrospective cohort study.

Setting—Kaiser Permanente Northern and Southern California.

Patients—323 349 health plan members aged 50 to 70 years on their FIT mailing date in 2007 or 2008 who completed the first round of FIT and were followed for up to 4 screening rounds.

Measurements—Screening participation, FIT positivity (≥20 μg of hemoglobin/g), positive predictive values for adenoma and CRC, and FIT sensitivity for detecting CRC obtained from Kaiser Permanente electronic databases and cancer registries.

Results—Of the patients invited for screening, 48.2% participated in round 1. Of those who remained eligible, 75.3% to 86.1% participated in subsequent rounds. Median follow-up was 4.0 years, and 32% of round 1 participants crossed over to endoscopy over 4 screening rounds—7.0% due to a positive FIT result. The FIT positivity rate (5.0%) and positive predictive values (adenoma, 51.5%; CRC, 3.4%) were highest in round 1. Overall, programmatic FIT screening detected 80.4% of patients with CRC diagnosed within 1 year of testing, including 84.5% in round 1 and 73.4% to 78.0% in subsequent rounds.

Limitation—Screening detection, rather than long-term cancer prevention, was evaluated.

Conclusion—Annual FIT screening was associated with high sensitivity for CRC, with high adherence to annual follow-up screening among initial participants. The findings indicate that annual programmatic FIT screening is feasible and effective for population-level CRC screening.

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Colorectal cancer (CRC) is the second leading cause of cancer death in the United States (1–3), and screening with fecal occult blood tests (FOBTs) reduces CRC incidence and mortality (4–6). In randomized trials (7–11), annual or biennial guaiac-based FOBTs reduced CRC incidence by 17% to 20% and CRC mortality by 15% to 33%. Thus, the U.S. Preventive Services Task Force (4) and U.S. Multi-Society Task Force on Colorectal Cancer (12) recommend annual FOBT as an option for CRC screening for average-risk patients, defined as those aged 50 to 75 years with no history of CRC or adenoma, with no first-degree relatives with CRC, and who are not up to date with CRC screening according to other methods (that is, sigmoidoscopy within 5 years or colonoscopy within 10 years). Annual highly sensitive FOBTs are believed to be as effective as screening colonoscopy performed every 10 years if levels of adherence are high (13), although colonoscopy is recommended for those with a family history of CRC.

Fecal blood tests are noninvasive and can be delivered by mail (14). In contrast to guaiac-based stool tests, fecal immunochemical test (FIT) screening can be done without dietary or medication restrictions, which allows it to achieve higher patient acceptance in organized CRC screening programs (15). This test also has higher detection rates for CRC and advanced adenomas than guaiac-based stool tests (15–17).

In a recent meta-analysis (18), the sensitivity of a single FIT application was 79% for CRC diagnosed within 2 years of testing; however, little is known about performance characteristics over several rounds of annual screening, particularly in community practice. The present study was conducted to evaluate FIT sensitivity for CRC and other performance characteristics over 4 rounds of annual testing in a U.S. community-based CRC screening program.

Methods

Study Population

This retrospective longitudinal study was performed in a fixed cohort of Kaiser Permanente Northern California (KPNC) and Southern California (KPSC) health plan members. These integrated health care delivery organizations serve approximately 7 million persons in urban, suburban, and semirural regions throughout California. Kaiser Permanente health plan membership in California is diverse and similar in socioeconomic characteristics to the region's census demographics (19–21).

Study Oversight

The study was approved by the institutional review boards of KPNC and KPSC, both of which waived the requirement for informed consent. The listed authors had sole responsibility for the study design, data collection, decision to submit the manuscript for publication, and drafting of the manuscript. This study was conducted within the National Cancer Institute–funded Population-based Research Optimizing Screening through Personalized Regimens (PROSPR) consortium, which conducts multisite, coordinated, transdisciplinary research to evaluate and improve cancer-screening processes.

Organized CRC Screening Program

The KPNC and KPSC initiated similar organized FIT screening programs between 2006 and 2008; the KPNC program has been described previously (14). Briefly, each year, the programs mail a FIT kit to eligible health plan members aged 50 to 75 years without a record of a colonoscopy within 10 years, sigmoidoscopy within 5 years, or fecal blood test within the prior year. The kit includes the FIT (OC FIT-CHEK; Polymedco), a standardized letter from the patient's primary care provider, directions for completing and mailing the test, and a preprinted laboratory requisition order form. Outreach includes in-person, mail, secure e-mail, and telephone reminders as needed. The kits are returned by mail to regional laboratories and analyzed on or shortly after the return date using an OC-Sensor Diana automated system (Polymedco) with a cutoff level of 20 μg of hemoglobin/g of buffer for a positive result. Patients with a positive FIT result are referred for follow-up colonoscopy.

Study Eligibility Criteria and Participant Tracking

The study cohort included CRC screening program participants aged 50 to 70 years on the date an initial kit was mailed to them in 2007 or 2008. Patients were excluded if they had been enrolled in the health plan for less than 1 year before the round 1 FIT mail date (to allow for the recording of prior out-of-system endoscopy procedures). They were also excluded if they were mailed a kit but subsequently had sigmoidoscopy or colonoscopy, were diagnosed with CRC, died, or terminated membership in the health plan before returning the initial FIT or within 1 year after their round 1 mail date if no FIT was returned. A total of 670 841 health plan members was mailed the initial kit in 2007 or 2008 and met the study eligibility criteria; 323 349 (48.2%) returned a FIT within 1 year after the mail date (Figure). The analytic cohort comprised these round 1 participants who were tracked from their baseline mail date (cohort entry) through up to 4 rounds of testing for mail dates; result dates; results (positive or negative); whether follow-up colonoscopy was performed within 1 year after a positive FIT result; and diagnoses of adenoma, adenoma with advanced histology, and CRC. Cohort members were followed for CRC through the follow-up screening rounds, even if they subsequently became ineligible for screening because of sigmoidoscopy or colonoscopy. Patients were censored at the time of CRC diagnosis, death, or termination of membership in the health plan if they did not rejoin.

Defining Annual Screening Episodes

For each patient, the initial kit mail date in 2007 or 2008 was the anchor date for round 1 and for each subsequent round of testing. However, because subsequent mailing dates varied each round, mail dates within 3 months before to 12 months after each subsequent round's anchor date were counted as having been distributed during that specific round. For example, a patient with a round 1 mail date of 15 March 2007 had subsequent anchor dates of 15 March for rounds 2 through 4 (2008, 2009, and 2010, respectively). If their next FIT was mailed on 15 January 2008, the test was considered to be distributed in round 2 because the second mail date occurred within 3 months of the round 2 anchor date.

The FIT results recorded within 1 year of each mail date, and colonoscopies performed and adenomas or CRC diagnosed within 1 year after FIT results, were considered part of a single screening episode for the round when the FIT was distributed. Among round 1 participants, FITs with no recorded mail dates returned in rounds 2 through 4 were assumed to be distributed through in-reach methods (such as a clinic visit) and were counted in the follow-up round returned. In general, the first result per patient was counted in any given round.

The earliest possible date of cohort entry (first mail date) was 1 January 2007, and the last possible date of follow-up was 31 December 2013 (12 months after the last possible FIT result date of 31 December 2012).

Data Sources

The FIT-related dates and results were obtained from the CRC screening program and laboratory databases for each region, respectively. Endoscopy procedures were identified using Current Procedural Terminology codes (22). Adenoma diagnoses used Systematized Nomenclature of Medicine codes. Prior validation studies have confirmed high levels of

sensitivity and accuracy for capture of colonoscopy examinations and assignment of adenoma status (23).

Colorectal adenocarcinomas and disease stage were obtained from the KPNC and KPSC cancer registries, which report to the SEER (Surveillance, Epidemiology, and End Results) registry. Cancer databases capture more than 98% of cancer diagnoses within the KPNC and KPSC populations. Advanced-stage cancer was defined as stage III (regional disease with spread to regional lymph nodes only) or stage IV (distant metastasis) according to the American Joint Committee on Cancer staging system; for patients who did not have such staging, advanced-stage cancer was defined as code 3 (disease in the regional lymph nodes), code 4 (regional disease with direct extension and spread to regional lymph nodes), or code 7 (distant metastasis) according to the SEER Program Coding and Staging Manual 2013 (24).

Data Analysis

The following performance characteristics were calculated for each round of screening and overall: 1) participation (percentage of eligible patients who were distributed and completed a FIT within 1 year of their mailing date), 2) FIT positivity (percentage of participants who completed FITs and had positive results), 3) follow-up colonoscopy (percentage of participants with a positive FIT result who received follow-up colonoscopy within 1 year after their result date), 4) positive predictive values (PPVs) for adenoma and advanced adenoma (among participants with a positive FIT result receiving follow-up colonoscopy within 1 year after their result, the percentage of those in whom an adenoma or advanced adenoma [that is, with villous or tubulovillous histology] were diagnosed), and 5) PPV for CRC (percentage of participants with a positive FIT result who had CRC diagnosed within 1 year after their result date).

In addition, FIT sensitivity for CRC was evaluated in 3 ways: by screening round (the percentage of patients with CRC who received positive FIT results in the year before diagnosis), number of rounds of participation (stratified by the total number of rounds of participation per patient), and look-back period (the percentage of patients with CRC and positive FIT results looking back up to 4 years before diagnosis). This analysis was also stratified by colon location. Proximal cancer was defined as cancer located in the cecum, ascending colon, hepatic flexure, or transverse colon; distal cancer was defined as cancer in the splenic flexure, descending colon, sigmoid colon, or rectum.

Performance measures were stratified by sex, age (50 to 64 years and ≥65 years), and region (KPNC and KPSC). We also examined the frequency of advanced-stage CRC at diagnosis by FIT status in the prior year (positive, negative, or unscreened) among all patients with CRC. Analyses used SAS, version 9.3 (SAS Institute), and Stata, version 10.1 (StataCorp).

Role of the Funding Source

The study was funded by the National Institutes of Health, which had no role in the conception, design, analysis, or conduct of the study.

Results

Participation and Patient Characteristics

A total of 670 841 patients meeting the study eligibility criteria was mailed the test kit in 2007 or 2008, and 323 349 (48.2%) completed the test within 1 year of the mail date (Figure). Round 1 participants had a mean age of 58.5 years (SD, 5.7), 46.4% were men, and 55.4% were white (Table 1). Median follow-up was 4.0 years (1 180 816 person-years). A total of 32.0% of round 1 participants crossed over to endoscopy during the 3 subsequent rounds of screening, including 7.0% because of a positive FIT result (Figure). Of the participants who remained eligible for screening and were distributed subsequent kits, participation was 75.3%, 83.4%, and 86.1% in rounds 2 through 4, respectively (Table 2). Across all screening rounds, 63.8% of distributed tests were completed within 1 year of mailing. Participation was higher at KPNC than KPSC (67.2% vs. 59.8%) (Table 2) and in older (≥65 years) than younger (50 to 64 years) patients (77.5% vs. 60.3%) (Appendix Table, available at www.annals.org).

FIT Positivity and Receipt of Follow-up Colonoscopy

In the first round, 5.0% of test results were positive; positivity estimates were lower in subsequent rounds (3.7% to 4.3%) (Table 2). The FIT positivity rate was higher at KPSC than KPNC (4.7% vs. 4.1%) (Table 2), in men versus women (5.1% vs. 3.7%), and in older versus younger patients (5.2% vs. 4.1%) (Appendix Table).

Overall, 78.4% of participants with positive FIT results had follow-up colonoscopy within 1 year of their test result, and estimates were similar by region (Table 2). The median time from result date to follow-up colonoscopy was 45 days. More than 96% of participants had some degree of follow-up within 12 months of their positive result: colonoscopy (78.4%), sigmoidoscopy (2.1%), gastroenterology consultation (5.4%), or primary care visit (10.7%).

Adenoma and CRC PPVs

Adenoma predictive value estimates were available for KPNC only. The PPVs for adenoma were highest in round 1 (51.5%) and were lower but stable in subsequent rounds (47.4% to 48.5%) (Table 2). Values were higher in men than women (55.5% vs. 42.2%) and in older than younger patients (52.7% vs. 48.2%) (Appendix Table). A similar pattern across rounds was seen for adenomas with advanced histology, and the overall value was higher for men than women. The PPVs for CRC were also highest in the first round (3.4%); estimates were lower but stable in subsequent rounds (2.1% to 2.3%), and estimates were similar by sex or age.

FIT Sensitivity for CRC and Distribution of Cancer, by FIT Screening Status

By screening round (Table 3), the FIT sensitivity for CRC was highest in the first round (84.5%); estimates were lower but stable in subsequent rounds (73.4% to 78.0%). The pattern was similar when sensitivity was evaluated by the total number of rounds of participation per patient (Table 3).

With look-back intervals of up to 1, 2, 3, and 4 years from CRC diagnosis to FIT screening for all patients with CRC (Table 3), 79.7%, 76.3%, 75.4%, and 75.3% of such patients had positive results beforehand, respectively. Sensitivity estimates were somewhat lower for proximal cancer (72.9% [360 of 494 patients]) than distal cancer (77.0% [690 of 896 patients]); 21 patients had cancer in an unknown location.

Finally, patients with positive FIT results in the prior year had advanced-stage CRC less often (26.9% [262 of 974 patients]) than those who were not screened in the prior year (37.1% [72 of 194 patients]) and those with CRC who had negative FIT results in the prior year (33.1% [80 of 242 patients]); 1 had unknown-stage CRC.

Discussion

Our findings of lower but stable FIT performance characteristics after the first round of testing, high adherence to repeated rounds of FIT screening, and high levels of abnormal colonoscopy examination results after a positive FIT result have implications for CRC screening programs and provide population-level estimates for colonoscopy quality metrics and CRC screening studies.

For organized FIT screening programs to be effective, patients need to participate. Participation estimates from 50% to 63% have been reported for up to 6 rounds of biennial FITs (25, 26) and FOBTs (27, 28) in European populations. In randomized trials comparing colonoscopy with FIT screening, participation was higher for FIT than colonoscopy (29–31). In our study, 670 841 patients were mailed a kit in round 1 and 48.2% completed FIT screening within 1 year of the mailing date. Of those who completed the initial FIT and remained eligible, adherence to annual screening was high and reached 86.1% in round 4. These findings suggest that annual screening may be feasible for populations in similar settings.

Effective CRC screening requires follow-up colonoscopy after a positive FIT result. About 78% of participants received colonoscopy within 1 year after a positive result, with a median time of 45 days. Relatively few participants were lost to follow-up because nearly 97% had lower-bowel endoscopy, gastroenterology consultation, or primary care provider visit within 1 year of their positive test result. Investigating factors associated with failure to receive a follow-up may inform efforts to increase CRC screening adherence and avoid inappropriate screening among persons who decline or cannot complete subsequent testing.

The FIT positivity rates and PPVs for adenomas, adenomas with advanced histology, and CRC were highest in round 1 of screening and were lower but relatively stable in subsequent rounds (Appendix Figure, available at www.annals.org). This pattern is consistent with more prevalent cases of adenoma and CRC in the initial round of screening and more incident cases in subsequent rounds. A similar trend has been reported in previous FOBT trials with biennial testing of 3 to 6 rounds (7, 27, 28). The FIT positivity estimates observed in the current study (3.7% to 5.0%) are similar to estimates reported over 4 rounds of biennial FIT screening in a small cohort of 2959 patients in Italy (3.7% to 4.4%) (25) and over 2 rounds of biennial testing in a larger Italian cohort (5.8 to 6.2%) (26). The PPVs in our study ranged

from 2.1% to 3.4% for CRC and 47.4% to 51.5% for adenoma, with the highest values for each observed in round 1. Our adenoma values are higher than those of the Italian cohort, which ranged from 36.6% to 37.7% (26). The stable FIT positivity rates and predictive value estimates in subsequent rounds, if sustained, suggest that regular FIT screening may offer protection against death from interval adenomas and CRC that develop after starting a screening program.

Our PPV estimates for adenomas and adenomas with advanced histology may help to inform colonoscopy quality guidelines. Professional societies recommend tracking physician adenoma detection rates for screening colonoscopy examinations as a quality metric (32), and target detection rates were recently increased to 20% or more for women and 30% or more for men (33). At present, there are no formal target adenoma detection rates for colonoscopy examinations after a positive FIT result. In the present study, we observed an adenoma detection rate of approximately 50% in such patients, including 42% for women and nearly 56% for men. These population-level estimates, if replicated, may inform guidelines about minimum rates of adenoma detection in those receiving colonoscopy after a positive FIT result.

For a screening test to be effective, it must reliably detect cancer. A recent meta-analysis of 19 FIT studies reported a pooled sensitivity for CRC of 79% (95% CI, 69% to 86%) for a single FIT application (18). In our study, the FIT sensitivity for CRC was highest (84.5%) in the first screening round, which is consistent with the detection of more prevalent cancer. In subsequent rounds, sensitivity estimates declined to a more steady state (range in sensitivity, 73.4% to 78.0%), which is consistent with the prior removal of most patients with prevalent cancer from the screened population and the ongoing detection of incident (new) cancer. The pattern was similar when evaluated by the total number of rounds of participation per patient. In addition, when looking back up to 4 years between the cancer diagnosis and FIT screening, we found that sensitivity did not change substantially with a longer follow-up after screening. Thus, patients must be advised that annual FIT screening is important—the first screening detects about 85% of patients with CRC, and each subsequent year of testing detects an additional 75% of cancer cases in the population (primarily incident cancer). Cancer detected by positive FIT results was also diagnosed at an earlier stage than cancer not screened by FIT the year before diagnosis and cancer that had negative results in the previous year. The former finding aligns with expectations about cancer progression, but the latter may be due to chance or because cancer missed by FIT screening the previous year may have a different biology. Finally, sensitivity was somewhat lower for proximal than distal cancer. Overall, our findings, similar to those of randomized trials of efficacy, suggest that FIT screening can be effective in large community-based settings.

To our knowledge, the current study is the largest evaluation of FIT performance to date. Strengths include a comprehensive capture of FIT outreach and test results in a large, diverse, community-based population with urban, semirural, and rural areas; validated and comprehensive approaches for capturing pathology data and follow-up diagnostic colonoscopy examinations; histologic confirmation of adenomas; comprehensive capture of patients with CRC and disease stage through SEER-affiliated cancer registries; up to 4 rounds of annual testing; and many patients with CRC. Potential limitations include that the

population screened by FIT may differ from the population screened by other methods, and the study does not compare FIT outreach to usual care or other screening methods. Censoring patients at the termination of health plan membership may have led to the underascertainment of CRC. Sensitivity calculations used longitudinal follow-up limited to up to 4 years rather than colonoscopy for all patients, including those with negative FIT results; as a result, long-term cancer prevention from polyp removal and possibly the underdetection of CRC could not be assessed. However, FIT sensitivity for CRC did not change substantially with longer follow-up: 80.0% of those with cancer had positive FIT results within 1 year of follow-up, whereas the capture of additional CRC diagnoses with longer follow-ups of 2 and 4 years only decreased sensitivity to 77.3% and 76.9%, respectively.

In conclusion, in a large community-based cohort that was offered annual FIT screening, the test's positivity, predictive values, and sensitivity declined slightly after the first round but then remained relatively steady. Among persons starting screening, subsequent participation was high (>75% annually) over 3 additional rounds of testing. About 80% of patients diagnosed with CRC over 4 rounds of testing were detected by screening within the year before diagnosis. These findings suggest high FIT sensitivity for CRC over several rounds of testing, inform colonoscopy quality metrics for adenoma detection in patients with positive FIT results, and indicate that annual programmatic FIT screening is both feasible and effective for CRC screening in a large community-based setting.

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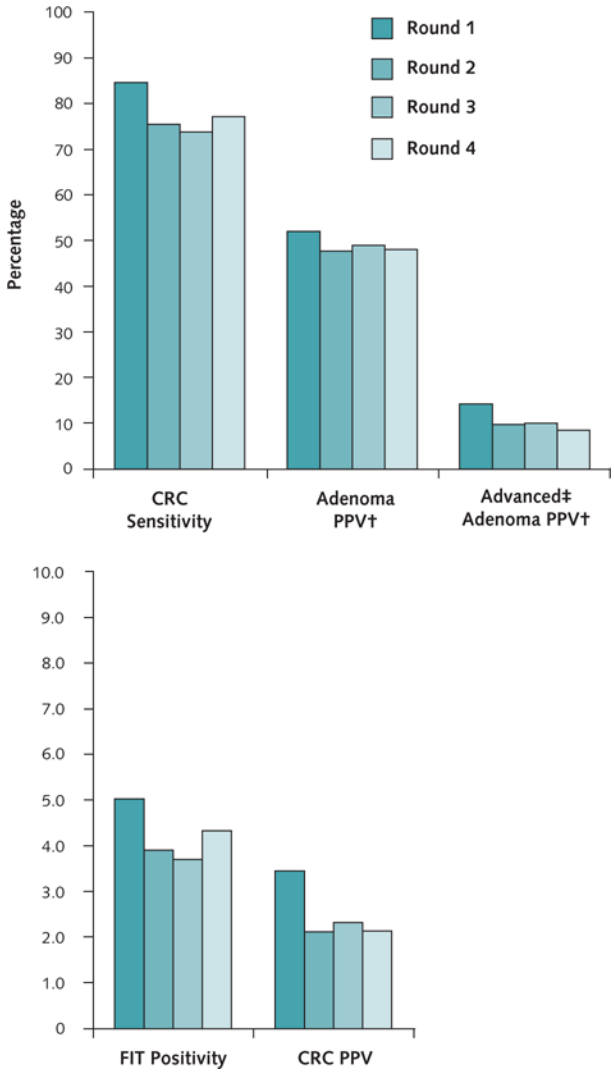
Appendix



Appendix Figure. Pattern of FIT performance measures over 4 rounds of annual screening*
CRC = colorectal cancer; FIT = fecal immunochemical testing; PPV = positive predictive value.

*See Tables 2 and 3 for numerators, denominators, and percentages.

†Data available for Kaiser Permanente Northern California only.

‡Advanced adenoma defined as adenomas with villous or tubulovillous histology.

Appendix Table

Overall FIT Performance Characteristics, by Sex and Age

Variable	Participants, *n/N (%)*
FIT participation	
Men	372 522/595 543 (62.6)

Variable	Participants, *n/N (%)*
Women	443 548/684 320 (64.8)
50–64 y	614 401/1 019 657 (60.3)
≥65 y	201 669/260 206 (77.5)
FIT positivity	
Men	19 078/372 522 (5.1)
Women	16 415/443 548 (3.7)
50–64 y	25 015/614 401 (4.1)
≥65 y	10 478/201 669 (5.2)
Follow-up colonoscopy	
Men	14 933/19 078 (78.3)
Women	12 878/16 415 (78.5)
50–64 y	19 708/25 015 (78.8)
≥65 y	8103/10 478 (77.3)
Positive predictive values	
Adenoma [*]	
Men	4506/8117 (55.5)
Women	2862/6778 (42.2)
50–64 y	5136/10 659 (48.2)
≥65 y	2232/4236 (52.7)
Advanced adenoma [*†]	
Men	1027/8117 (12.7)
Women	671/6778 (9.9)
50–64 y	1194/10 659 (11.2)
≥65 y	504/4236 (11.9)
CRC	
Men	508/19 078 (2.7)
Women	450/16 415 (2.7)
50–64 y	653/25 015 (2.6)
≥65 y	305/10 478 (2.9)

CRC = colorectal cancer; FIT = fecal immunochemical test.

[*] Data available for Kaiser Permanente Northern California only.

[†]Adenomas with villous or tubulovillous histologic characteristics.

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EDITORS' NOTES

Context

The fecal immunochemical test is an effective way to screen for colorectal cancer, but we know more about how well it does the first time it is used and less about how well it does in later years with repeated testing.

Contribution

The researchers show that, after 4 years of repeated testing, patients continued to use the test and it continued to identify colorectal cancer.

Caution

This study did not measure whether identification of cancer changed outcomes.

Implication

The fecal immunochemical test is acceptable and effective for repeated testing.

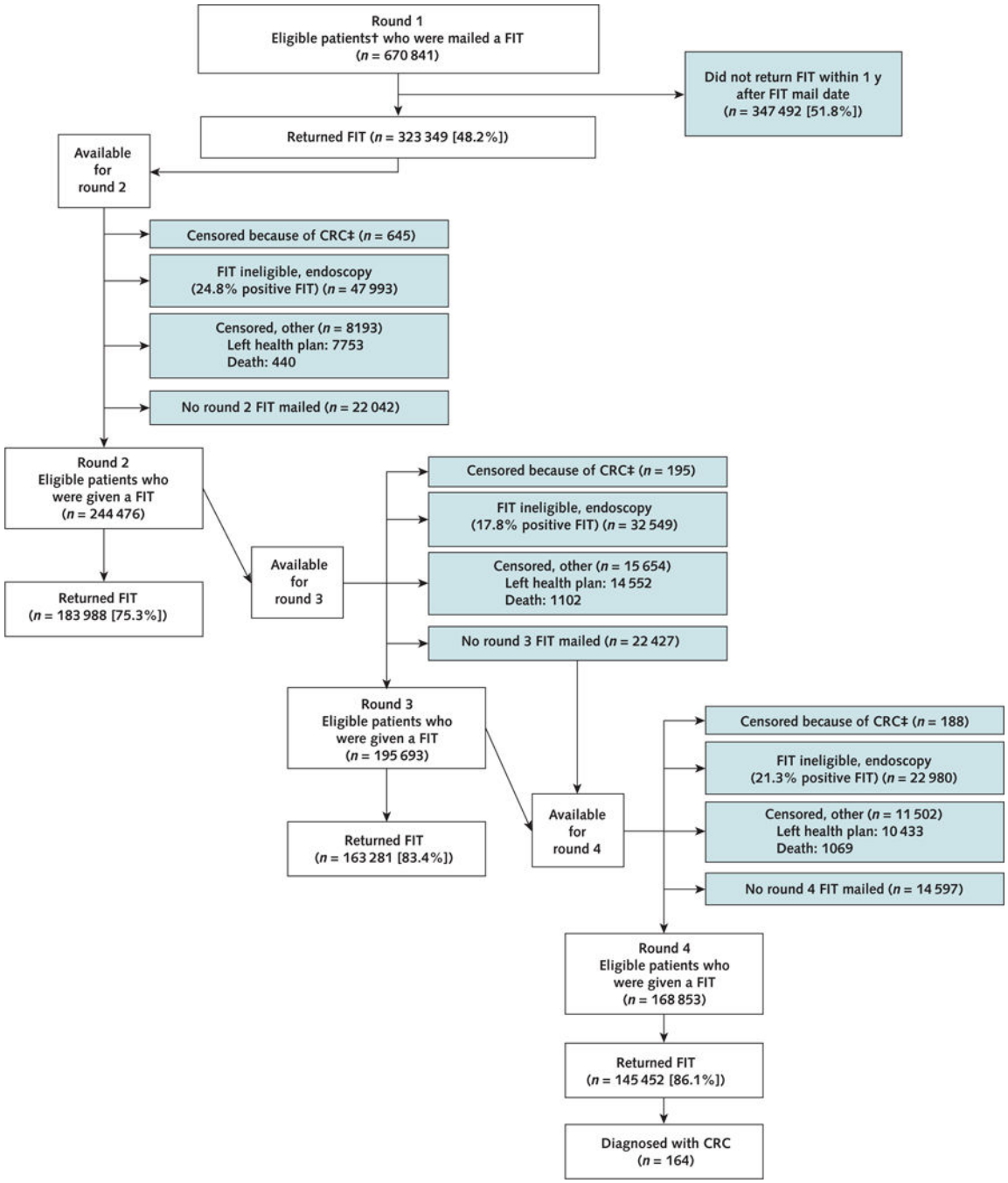

Figure. Study flow diagram.*

The figure includes 1192 patients with CRC who were screened by FIT the year before diagnosis. Further, there were 118 additional patients with CRC diagnosed more than 1 y beyond the FIT screening date and 101 additional patients diagnosed with CRC who either crossed over to endoscopy in subsequent rounds or terminated health plan membership but then rejoined. CRC = colorectal cancer; FIT = fecal immunochemical test.

*Shading indicates where patients were censored or became ineligible for subsequent FIT screening.

[†]Patients were eligible for the initial FIT mailing if they were aged 50 to 70 y and had ≥1 y of membership. See Methods section for exclusions.

[‡]Number censored because of CRC and includes patients with CRC diagnosed within 1 y after their FIT result.

Table 1

Characteristics of Round 1 FIT Participants*

Characteristic	KPNC	KPSC	Total
Total	179 423 (55.5)	143 926 (44.5)	323 349 (100.0)
Men	83 390 (46.5)	66 614 (46.3)	150 004 (46.4)
Aged 50–64 y†	147 346 (82.1)	116 049 (80.6)	263 395 (81.5)
Mean age (SD), y†	58.4 (5.7)	58.7 (5.7)	58.5 (5.7)
White	107 853 (60.1)	71 136 (49.4)	178 989 (55.4)
Black	10 074 (5.6)	12 514 (8.7)	22 588 (7.0)
Asian	27 114 (15.1)	14 882 (10.3)	41 996 (13.0)
Hispanic	17 938 (10.0)	32 309 (22.5)	50 247 (15.5)
Other race	16 444 (9.2)	13 085 (9.1)	29 529 (9.1)

FIT = fecal immunochemical test; KPNC = Kaiser Permanente Northern California; KPSC = Kaiser Permanente Southern California.

*Values are numbers (percentages) unless otherwise indicated.

†At initial FIT mail date.

Table 2

FIT Performance Characteristics at Each Round of Screening and Overall*

Variable	Round 1	Round 2	Round 3	Round 4	Total
FIT participation					
KPNC	179 423/348 510 (51.5)	104 255/133 652 (78.0)	93 999/111 190 (84.5)	85 695/96 634 (88.7)	463 372/689 986 (67.2)
KPSC	143 926/322 331 (44.7)	79 733/110 824 (71.9)	69 282/84 503 (82.0)	59 757/72 219 (82.7)	352 698/589 877 (59.8)
Total	323 349/670 841 (48.2)	183 988/244 476 (75.3)	163 281/195 693 (83.4)	145 452/168 853 (86.1)	816 070/1 279 863 (63.8)
FIT positivity					
KPNC	8495/179 423 (4.7)	3781/104 255 (3.6)	3303/93 999 (3.5)	3507/85 695 (4.1)	19 086/463 372 (4.1)
KPSC	7542/143 926 (5.2)	3362/79 733 (4.2)	2799/69 282 (4.0)	2704/59 757 (4.5)	16 407/352 698 (4.7)
Total	16 037/323 349 (5.0)	7143/183 988 (3.9)	6102/163 281 (3.7)	6211/145 452 (4.3)	35 493/816 070 (4.3)
Follow-up colonoscopy					
KPNC	6396/8495 (75.3)	2962/3781 (78.3)	2657/3303 (80.4)	2880/3507 (82.1)	14 895/19 086 (78.0)
KPSC	5717/7542 (75.8)	2785/3362 (82.8)	2255/2799 (80.6)	2159/2704 (79.8)	12 916/16 407 (78.7)
Total	12 113/16 037 (75.5)	5747/7143 (80.5)	4912/6102 (80.5)	5039/6211 (81.1)	27 811/35 493 (78.4)
PPV					
Adenoma for KPNC	3297/6396 (51.5)	1403/2962 (47.4)	1288/2657 (48.5)	1380/2880 (47.9)	7368/14 895 (50.1)
Advanced adenoma† for KPNC	895/6396 (14.0)	295/2962 (10.0)	265/2657 (10.0)	243/2880 (8.4)	1698/14 895 (11.4)
CRC					
KPNC	322/8495 (3.8)	84/3781 (2.2)	75/3303 (2.3)	71/3507 (2.0)	552/19 086 (2.9)
KPSC	223/7542 (3.0)	63/3362 (1.9)	63/2799 (2.3)	57/2704 (2.1)	406/16 407 (2.5)
Total	545/16 037 (3.4)	147/7143 (2.1)	138/6102 (2.3)	128/6211 (2.1)	958/35 493 (2.7)

CRC = colorectal cancer; FIT = fecal immunochemical test; KPNC = Kaiser Permanente Northern California; KPSC = Kaiser Permanente Southern California; PPV = positive predictive value.

*Values are numbers/totals (percentages).

† Adenomas with villous or tubulovillous histologic characteristics.

Table 3

FIT Sensitivity for CRC Among the Cohort That Completed Round 1 of FIT Screening

Variable	CRC Sensitivity in Participants With Positive FIT Results/FIT-Screened Participants, by Screening Round and Overall, *n/N (%)* (*n* = 1192 participants)*				
	Round 1	**Round 2**	**Round 3**	**Round 4**	**Total**
KPNC	322/380 (84.7)	84/106 (79.2)	75/97 (77.3)	71/89 (79.8)	552/672 (82.1)
KPSC	223/265 (84.2)	63/89 (70.8)	63/91 (69.2)	57/75 (76.0)	406/520 (78.1)
Total	545/645 (84.5)	147/195 (75.4)	138/188 (73.4)	128/164 (78.0)	958/1192 (80.4)
	CRC Sensitivity in Participants With Positive FIT Results/FIT-Screened Participants, by Total Rounds of Participation, *n/N* (%) (*n* = 1192 participants) *				
	1 Round	**2 Rounds**	**3 Rounds**	**4 Rounds**	**Total**
Total	545/645 (84.5)	228/290 (78.6)	123/171 (71.9)	62/86 (72.1)	–
	CRC Sensitivity in Participants With Positive FIT Results Who Had CRC/Total Participants With CRC, by Look-Back Period, *n/N* (%) (*n* = 1411 participants)†				
	≤1 y	**≤2 y**	**≤3 y**	**≤4 y**	**Total**
Total	975/1223 (79.9)	1024/1342 (76.3)	1045/1386 (75.4)	1063/1411 (75.3)	–

CRC = colorectal cancer; FIT = fecal immunochemical test; KPNC = Kaiser Permanente Northern California; KPSC = Kaiser Permanente Southern California.

*The percentage of FIT-screened participants with CRC who had positive FIT results in the year before the cancer was diagnosed.

†The percentage of FIT-screened participants with CRC who had positive results on FIT up to 1, 2, 3, and 4 y before the CRC diagnosis. This analysis comprised 1411 total participants with CRC, including 1192 participants with CRC diagnosed with 1 y of FIT screening, 118 diagnosed >1 y after the prior FIT screening date, and 101 who had crossed over to endoscopy in subsequent rounds or terminated health plan membership but then rejoined.