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Estimating the long-term health impact and program cost-effectiveness of providing direct screening services to low-income, medically underserved patients through the Colorectal Cancer Control Program (CRCCP)

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Abstract

Purpose: The Colorectal Cancer Control Program (CRCCP) aimed to increase colorectal cancer (CRC) screening among U.S. medically underserved populations through promotion and provision of CRC screening. We used simulation modeling to estimate the lifelong health impact and program cost-effectiveness of direct screening services, typically a single cycle of routine screening/follow-up testing provided through the CRCCP (“intervention”).

Methods: Data for this study were from CDC’s Colorectal Clinical Data Elements (CCDE), which captured screening and follow-up services received from CRCCP between 2009 and 2020. We used microsimulation to model the evolution of polyps and CRC for average-risk individuals in intervention and “counterfactual” (control) groups, under multiple scenarios. We calculated and compared lifetime CRC outcomes (cases, deaths, life-years) for individuals with and without

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Ethical approval This study received an exemption from further review by the Institutional Review Board at the University of North Carolina at Chapel Hill (#19–1946).

the CRCCP intervention. Clinical and implementation costs incurred by the CRCCP were used to estimate programmatic/intervention costs. Results are reported overall and by initial screening modality received (colonoscopy or stool testing) and assumed lower vs. higher “background” (non-intervention) screening scenarios.

Results: With conservative assumptions, our findings suggest that CRCCP-provided screening averted 806 CRC cases, avoided 392 CRC deaths, and added 5,368 life-years per 100,000 individuals vs. no intervention. Cost-effectiveness analysis revealed that the program’s cost per life-year gained varied by screening modality and scenario assumptions—ranging from \$25,740 to \$27,583 for colonoscopy screening and \$70,410 to \$75,979 for stool testing.

Conclusion: CRCCP-provided screening/testing services were found to produce substantial potential health gains. Our analysis estimates the cost-effectiveness of providing one cycle of screening/testing to medically underserved individuals to inform programmatic decisions.

Keywords

Colorectal cancer screening; Simulation; Economic evaluation; Medically underserved populations

Introduction

Improving colorectal cancer (CRC) screening prevalence is a high public health priority [1, 2]. In 2020, 126,240 new cases of CRC were reported, and 51,869 people died of CRC in the U.S. [3]. If pre-cancerous polyps or early stage cancers are detected through routine screening, new CRC cases may be prevented or detected earlier, improving longer-term health outcomes including survival [4]. The current U.S. Preventive Service Task Force (USPSTF) recommendation is for screening average-risk individuals ages 45–75 for CRC, which was updated in 2021 from the previous recommended ages of 50–75. These recommendations include screening every year by stool testing, every three years by stool DNA testing, every five years by flexible sigmoidoscopy or computed tomography (CT) colonography, or every ten years by colonoscopy [4].

While CRC screening reached 72% of the age-eligible U.S. population as of 2020 [5], screening among medically underserved populations is substantially lower [6, 7]—where “medically underserved” means having limited access to acceptable, accessible, and/or affordable healthcare services [8]. For example, privately insured individuals and Medicare enrollees are more than twice as likely to be up-to-date with CRC screening than uninsured individuals [9]. Individuals with low household incomes report being up-to-date at lower rates, by a difference of 13 percentage points, compared to those with higher incomes [9]. Increasing CRC screening specifically among persons who are low-income and/or medically underserved is necessary to effectively reduce the burden of CRC [10, 11].

Since 2009, the Colorectal Cancer Control Program (CRCCP), funded by the Centers for Disease Control and Prevention (CDC), has aimed to increase CRC screening among persons who are low-income and medically underserved to address existing disparities in screening prevalence [1, 12]. Historically, the CRCCP funded recipients, such as state health departments and tribal organizations, to partner with health system clinics to provide direct

CRC screening services to individuals ages 50–64 who had low incomes [$\leq 250\%$ of Federal Poverty Level (FPL)] and were un- or under-insured. Qualifying individuals outside of this age range who had increased risk for CRC due to personal history of polyps or CRC, or family history of CRC, were also eligible for screening. The CRCCP paid for these direct screening services, which included routine colonoscopies or stool tests, as well as follow-up colonoscopy after abnormal stool tests. In addition, the CRCCP has supported recipients in implementing evidence-based interventions (EBIs) in partnering clinics to promote CRC screening more broadly, for example by implementing patient and provider reminders [13–15]. The program has transitioned over time from primarily funding direct screening services to supporting EBI implementation intended to promote CRC screening. All 26 recipients from 2009 to 2015 were funded for direct screening services, compared to 6 of 30 recipients from 2015 to 2020. The CRCCP previously demonstrated the effectiveness of implementing EBIs in increasing CRC screening prevalence within its partnering clinics [1, 16, 17]. Additionally, through direct screening provision, the program has extended screening to 82,973 unique patients from 2009 to 2020 [18]. Despite these achievements, the long-term consequences of EBI implementation and direct screening provision, such as their impact on CRC incidence, mortality reduction, gains in life-years, and program cost-effectiveness have not been thoroughly examined. This paper aims to address this gap by: (1) estimating the long-term potential health benefits of the CRC screenings provided by the CRCCP from 2009 to 2020, and (2) evaluating the cost-effectiveness of provided screenings from the CDC program perspective. This investigation is part of a broader research initiative which involves developing and using a computer simulation model to estimate the potential long-term health gains and programmatic cost-effectiveness of increased CRC screening because of the CRCCP.

Methods

We used a microsimulation model to estimate the potential long-term health outcomes (CRC cases and deaths averted, life-years gained) associated with the direct CRC screening provided through the CRCCP, which is defined as the study intervention. Screening is defined as receipt of screening colonoscopy or stool testing (fecal immunochemical test or FIT, and fecal occult blood test or FOBT) followed by diagnostic colonoscopy if a FIT/FOBT is positive. We used a model of CRC progression previously calibrated to the general North Carolina population ages 50–75 [19–24], and recalibrated for the population served by the CRCCP [18]. The recalibration was based on differences in the CRCCP patient population (in terms of insurance status, demographics, polyp incidence), and informed by patient-level CRCCP data which was also the main data used for this study. We simulated health outcomes for the cohort of individuals who received CRC screenings through the CRCCP compared to their “simulated equivalents” or “counterfactuals,” [18, 25] e.g., individuals with the same characteristics but who did not receive direct CRC screening through the program. Given uncertainties, especially about subsequent screening patterns, we considered a set of scenarios with varied counterfactuals and probabilities of background screening (Fig. 1). Program costs required for the CRCCP to reach and provide CRC screening to these individuals were derived from the literature [26] and used to estimate the

cost-effectiveness of the intervention by modality and across simulated scenarios, compared to no intervention from the CDC/CRCCP program perspective.

Data

Study data represent low-income and un- or under-insured individuals who received at least one CRC screening through the CRCCP between 2009 and 2020, where the screening included a full cycle of initial testing and any follow-up testing needed to complete the screening process (e.g., colonoscopy after an abnormal FIT/FOBT). Since the program's inception, all CRC screening and follow-up tests provided by the CRCCP have been tracked in the CDC's Colorectal Clinical Data Elements (CCDE) database [27, 28]. We used CCDE data, including screening modality and test results, for all first screening encounters occurring from January 2009 to October 2020 (study period). The CCDE data used were deidentified, and this analysis was exempt from review by the University of North Carolina at Chapel Hill Institutional Review Board.

Figure 2 displays the inclusion and exclusion criteria for our CRCCP study cohort. We included individuals ages 45–75 in our study population. While most individuals receiving screening through the program were aged 50–64, a small number outside of this age range also received services. The exclusion of individuals outside the 45–75 age range was to make the age eligibility compatible with the current USPSTF CRC screening recommendation. We included individuals who reported prior CRC screenings; however, we excluded those who had self-reported prior polyps or CRC or reported experiencing CRC symptoms (2.6% of our population and considered a high-risk group) because we did not have additional information on how they were initially screened, size of polyps removed, and other details of progression necessary to match them to simulated equivalents. We also excluded individuals who completed a surveillance exam as the first encounter, had initial screening modalities other than colonoscopy or FIT/FOBT, did not have final test results available, or had missing sex information since cancer risk is sex-specific [29, 30]. Our goal was to create a study sample similar to the population who are at average risk for CRC. However, we did not exclude individuals with family history of CRC – also considered a high-risk group, because the self-reports of familial history did not meet the criteria for an inherited genetic syndrome.

Simulation model

We previously developed the microsimulation model used in this analysis to estimate the relative effectiveness and cost-effectiveness of approaches intended to increase CRC screening in two diverse U.S. state contexts [18–25]. Details are also available in our supplemental model documentation. The model simulates individuals' "natural history" of CRC in terms of the growth from premalignant adenomatous polyps to CRC that is differentiated based on individuals' age, sex, and race. Parameters were estimated using prior literature and calibrated using screening, cancer registry, and census data in North Carolina. We modeled individuals' receipt of CRC screening, which affects their natural history of CRC by preventing or slowing cancer incidence and progression. For the current study, we re-calibrated the model to reflect the observed data for individuals who received colonoscopy screening through the CRCCP [18, 25]. Prior to re-calibration, the model

underestimated the prevalence of polyps and cancers detected in the CRCCP cohort, likely due to this cohort having a higher incidence of CRC and reporting less screening compared to the general North Carolina population [19].

Following re-calibration, we developed “simulated equivalents” for all individuals receiving the cycle of CRC screening/testing from the CRCCP. For each individual receiving screening through the program, we simulated many (1 million) potential simulated equivalents with the same sex and race through the age at which the intervention was received. We created a sample of simulated equivalents for each screened individual ($n = 450$) that matched their screening/follow-up test result: positive or negative FIT/FOBT and normal with no polyps detected, polyps detected with no cancer, or CRC cancer for those who either received a routine colonoscopy or a follow-up diagnostic colonoscopy after a positive FIT/FOBT. From this point on, simulated equivalents were duplicated with one receiving the CRCCP-supported screening cycle for sure (intervention) and the other only receiving it probabilistically based on assumptions about screening outside of the intervention (counterfactual). This process is described in more detail elsewhere [18, 25] and in our supplemental model documentation. Similar to a digital twin [31, 32], a simulated equivalent is a virtual representation of an actual person, however the match is only required at the point when CRC screening is provided by the CRCCP. The number of replications of each screened individual was determined to be high enough such that adding additional replications would not change life-course CRC cancer prevalence by more than 1%.

Intervention

In this analysis, we defined the intervention as the first cycle of CRC screening that each individual received through the CRCCP (referred to as the “CRCCP-provided screening” and including the routine screening and any follow-up testing provided). We focused on the first screening cycle for analytical simplicity since 95.8 percent of patients in the CRCCP cohort completed only a single screening cycle through this program. Patients’ initial screening modality (colonoscopy or FIT/FOBT), along with any associated follow-up (e.g., whether colonoscopy was completed after abnormal FIT/FOBT) were determined using observed CCDE data. Below, we describe the prior screening patterns for this cohort, and the multiple simulated scenarios used to estimate the health impact of various counterfactual and future screening assumptions.

Screening history

CCDE data provides information on CRC screening history pre-intervention. However, among those who did report prior CRC screening, little information is available, such as the number of screenings completed, screening dates, and modalities. Since we excluded people who reported ever having polyps removed or CRC detected in the past, the individuals included in this analysis with a self-reported screening history likely did not have a prior screening that changed their CRC natural history (for example, by having polyps removed during a previous colonoscopy), and, thus, their CRC risk or subsequent CRC screening patterns. As a result, we did not simulate any prior screening in these individuals.

Simulation analyses and scenarios

Screening receipt among the intervention group was informed by the CCDE data. Since we were interested in estimating the lifelong health impact and programmatic cost-effectiveness of the CRCCP-provided screening, we needed to make assumptions about the current CRC screening of the counterfactual group as well as the future CRC screening behavior of both the intervention and counterfactual groups. Given uncertainties, we conducted analyses of multiple scenarios with varied current and future screening assumptions, described below and in Appendix Table 4.

In our primary analysis, we estimated the health impact and programmatic cost-effectiveness of the intervention compared to no intervention in the CCDE cohort, assuming higher background screening (as described under the “Future screening assumptions” section below) in the intervention year and in future years. We reported on the higher background screening assumption in an attempt to be conservative with our estimates of health outcomes; that is, if CRC screening rates are higher in the background (i.e., in the absence of the CRCCP-provided screenings), then the value of the screening provided through the program would be lower. By assuming the same higher level of future screening in both the CRCCP cohort and the counterfactual cohort, we considered the health impact if (1) the only difference was this single CRC screening cycle *provided* through the program and (2) there was a relatively high prevalence of CRC screening during the intervention year and in the future.

Considering uncertainty in CRC screening among low-income, medically underserved populations, the first category of supplemental analyses explored different scenarios with varied assumptions about the prevalence of screening and usage of different screening modalities. Since there was relatively low screening prevalence in the population studied, we considered scenarios assuming lower background screening levels (described below).

Given suboptimal uptake of screening in low-income, medically underserved populations [6, 9, 33], it is likely that many patients in our cohort never were and rarely would screen for CRC throughout their lifetimes. We ran a final supplemental analysis assuming that the counterfactual cohort receives no screening – unless patients became symptomatic and received testing because of their symptoms. By doing so, we assumed that receiving screening through the CRCCP may encourage subsequent screenings among these individuals (for example, by helping them to understand the screening process and importance of screening) that may not otherwise occur. In this last analysis, we considered the health impact of the intervention both using lower and higher background levels of screening (for future screening in the intervention group and if symptoms were detected in the counterfactual group) and assuming both patterns of screening in the future after a positive FIT/FOBT leads to a diagnostic colonoscopy.

Future screening assumptions

Across analyses, we varied individuals' probability of completing additional CRC screening across two levels, defined as “lower background screening” and “higher background screening.” Background screening refers to screening that is happening outside of

the CRCCP, including individuals screening independently or with a clinic-provided screening. We used estimates from prior studies and existing datasets reporting CRC screening prevalence (see probabilities below and more details in the supplemental model documentation) [34–37]. We assumed that individuals' modality for screening in the future would remain the same as their routine test during their first CRCCP-provided screening (e.g., FIT/FOBT screeners continue to screen with stool tests), except when they had a positive FIT/FOBT and underwent a diagnostic colonoscopy. We tested the health impact of a screening modality change after diagnostic colonoscopy following a positive FIT/FOBT.

In our model, individuals who completed a colonoscopy as their routine screening modality during their CRCCP-provided screening were offered opportunities to complete repeat routine colonoscopies when they were due for screening after 10 years, consistent with current screening recommendations [4]. Follow-up colonoscopies were offered every five years, through age 75, until one was completed. We assumed individuals who used colonoscopy for routine screening would remain with this modality over time, and we varied their probability of completing future colonoscopy screenings at our lower and higher background screening levels, using average 10-year colonoscopy screening data from the Behavioral Risk Factor Surveillance System (BRFSS) from 2014, 2016, and 2018 [34]. Our calculations are described in more detail in the supplemental model documentation, but briefly, we calculated a weighted average across these years, based on expert opinion to account for two factors: (1) evidence that self-reported CRC screening is overestimated [38], and (2) the CRCCP supports individuals with a mix of insurance types (including none) while BRFSS estimates are provided conditional on insurance status (yes/no). After adjustment, we estimated a lower-level probability of completing screening colonoscopy offered every five years at 16.33% and a higher-level probability at 22.54%.

For those individuals with at least one polyp detected during screening colonoscopy, we varied their probability of completing subsequent surveillance colonoscopies across lower and higher levels with point estimates of 27% and 69%, respectively, based on prior research that included surveillance colonoscopy data among safety-net patients [35].

Among people whose initial screening test was FIT/FOBT, we assumed they would continue to screen by FIT/FOBT in the future if they had a negative result, or if they had a positive result but did not complete a follow-up colonoscopy. We used a similar process as above, in which we adjusted the mean annual probabilities of FOBT/FIT testing from BRFSS data, to estimate their annual probability of completing routine stool testing in the future at lower (6%) and higher (8%) background levels. For those with a positive FIT/FOBT, we assumed lower (20%) and higher (82%) probabilities of adherence to follow-up colonoscopy, informed by prior evidence [36, 37] and adjusted to allow for a broad range of possible estimates.

Since there are limited data on how the recommendation for a follow-up colonoscopy after abnormal FIT/FOBT may or may not impact subsequent modality choice, we explored two scenarios. In one scenario (and our primary analysis), we assumed individuals with an abnormal FIT/FOBT who completed a follow-up colonoscopy would permanently change their future screening modality to colonoscopy. In the second scenario, we assumed these

individuals would return to routine FIT/FOBT testing in the future when they become screening-eligible again (but if they ever completed a colonoscopy after a positive FIT/FOBT in the future where polyps were removed, they would enter surveillance and not return to stool testing). For both scenarios, we varied the probability of adherence to future FIT/FOBT or colonoscopy screenings at the aforementioned lower and higher background levels. Individuals with normal FIT/FOBT and colonoscopy results were assumed to not switch screening modalities.

Across all scenarios, individuals with a CRC diagnosis were assumed to be treated (outside of the CRCCP) and were no longer offered routine screenings. Details about how we modeled survival are in the supplemental model documentation.

Simulated outcomes

Using our CCDE-simulated equivalents projected forward through their remaining lifetimes in the intervention and counterfactual groups [18, 25], we compared the simulated CRC health outcomes associated with the CRCCP intervention to that of no such intervention across background screening scenarios. We report the number of CRC cases overall and by stage at diagnosis, CRC-attributable deaths, and life-years for both the intervention cohort and their counterfactuals, and calculated the incremental change associated with the CRCCP intervention. Means and uncertainty intervals are reported for each outcome overall and by screening modality (i.e., overall cohort, colonoscopy cohort, and FIT/FOBT cohort). We present the percent of adverse health outcomes averted across scenarios with the intervention compared to no intervention by cohort. We focus on sharing the results of our primary analysis (higher background screening and a modality change to colonoscopy following diagnostic colonoscopy after abnormal FIT/FOBT). Supplemental analysis findings are in the appendix. Health outcomes were simulated using AnyLogic, version 8.5.2.

Program costs

We included all program costs incurred by the CRCCP to provide CRC screening to individuals in this cohort. The program cost estimates are specific to whether screening was completed by a routine colonoscopy or FIT/FOBT and were previously reported for the CRCCP [26]. Across modalities, outreach (e.g., navigating patients to follow-up colonoscopy after a positive FIT/FOBT) accounted for approximately 26% of the total cost, while direct screening costs (i.e., actual CRC screening and required follow-up, including diagnostic colonoscopy after positive FIT/FOBT, provided by CRCCP) accounted for 39% and indirect costs (e.g., program management) accounted for 35% [26]. Cost inputs are reported in Table 3.

Our focus was on estimating the long-term health changes associated with the CDC's upfront spending on screening provided to this cohort. Our calculation of program costs was based on CDC's perspective, which may reflect the perspective of similar organizations and contexts considering one-cycle screening. We excluded downstream costs, such as future screenings and CRC treatment and survivorship costs. The CRCCP provided support to link any individuals diagnosed with CRC to cancer treatment, and the costs for connecting these patients are included in our cost estimates. However, the program did not pay for

treatment and our focus was estimating the costs incurred by the CRCCP. For each modality and scenario, we report the programmatic cost-effectiveness per additional year up-to-date with CRC screening, cancer case averted, cancer death averted, and life-year gained of the intervention (screening provided directly by the CRCCP) for that specific modality (colonoscopy or FIT/FOBT) compared to not having received that intervention screening in the CRCCP cohort.

Results

A total of 82,973 unique individuals completed 95,471 CRC screenings during the two CRCCP funding cycles between 2009 and 2020. From these 82,973 individuals, we excluded 4,288 (5.1%) after applying all exclusion criteria. Our remaining cohort size was 78,685 individuals; of these, 28,978 (37.8%) screened using colonoscopy and 49,707 (63.2%) screened using FIT/FOBT. Most were female (73%), White (72%), and non-Hispanic (62%) (Table 1). The routine intervention screening received was colonoscopy for approximately one-third (36.8%) and FIT/FOBT for 63.2%. Of those screened with colonoscopy, 42.1% had polyps found and 0.47% had CRC detected. Among FIT/FOBT screeners, 8.2% had an abnormal result, of whom 86.0% completed a follow-up colonoscopy, where 51.4% had polyps found and 2.56% had cancer detected.

In our primary analysis, the CRCCP-provided screening was found to improve CRC-related health outcomes, versus no intervention, in the overall, colonoscopy, and FIT/FOBT cohorts (Table 2). In the overall cohort ($n = 78,685$), our simulation found an average number of 3,924 CRC cases, 1,538 CRC deaths, and 19,465 life-years lost in the absence of the CRCCP-provided screening, with rates (per 100,000 population) reported. Assuming higher background future screening, diagnostic testing, and surveillance, and that FIT/FOBT screeners would switch to colonoscopy after completing a diagnostic colonoscopy following an abnormal FIT/FOBT – we estimate that the CRCCP intervention would avert 634 CRC cases and 308 CRC deaths and add 4,224 life-years.

In the absence of intervention, the colonoscopy cohort ($n = 28,978$) was estimated to have 1,177 CRC diagnoses and 502 CRC deaths across the lifespan, with a total of 6,700 life-years lost to CRC. The CRCCP-provided screening was found to reduce CRC cases by 487 and CRC deaths by 236, while adding 3,313 life-years.

Without intervention, the FIT/FOBT cohort ($n = 49,707$) would experience 2,747 CRC diagnoses, 1,036 CRC deaths, and 12,765 life-years lost to CRC. If individuals in this cohort are assumed to change modality to colonoscopy after abnormal test and diagnostic colonoscopy completion in the future is at higher background levels, the CRCCP-provided screening is expected to avert 147 CRC cases, 72 CRC deaths and add 911 life-years.

Figure 3 displays the percent of CRC cases averted, CRC deaths prevented, and life-years gained for each cohort. Under our primary analysis assumptions, the CRCCP intervention would avert approximately 16–22% of adverse health outcomes in the overall cohort, compared to 41–49% in the colonoscopy cohort and 5–7% in the FIT/FOBT cohort.

Appendix Tables 5, 6, 7 report the results of our supplemental analyses that assumed lower background screening and/or the FIT/FOBT cohort always remaining with stool testing (where the only difference between groups was the guaranteed CRCCP-provided screening). Appendix Tables 8, 9, 10 present results across simulated scenarios when the counterfactual was no CRC screening except in the case of developing symptoms. The same pattern as our primary analysis was observed across these analyses where the intervention was associated with health gains over the lifetime versus no intervention.

Table 3 reports the programmatic costs and cost-effectiveness of the CRCCP-provided screening, versus no intervention, by screening modality cohort. From the CRCCP perspective, the program cost per additional year up-to-date with CRC screening was \$315 for colonoscopy screeners and \$789 for FIT/FOBT screeners. In the colonoscopy cohort, the programmatic costs per life-year gained, per CRC case averted, and per CRC death averted were \$27,583, \$187,767, and \$386,496, respectively, assuming higher background screening. In the case of lower background screening, there is a lower program cost associated with averting each outcome; \$25,740 per life-year gained, \$170,844 per CRC case averted, and \$356,765 per CRC death averted. For the FIT/FOBT cohort, the programmatic cost per life-year gained ranged from \$70,410 (for higher background screening and switching modality with diagnostic colonoscopy) to \$75,979 (for lower background screening and remaining with FIT/FOBT), compared to no intervention (e.g., not having received the stool tests provided through the program). Under these same assumptions for the FIT/FOBT cohort, the programmatic cost per CRC case averted ranged from \$435,653 to \$502,126, and the programmatic cost per CRC death averted ranged from \$893,757 to \$996,456.

Discussion

This simulation study found that, even in one of our most conservative scenarios, the CRCCP's direct CRC screening provision intervention has substantial health benefits over the lifetime of individuals served by the program. In the overall cohort including both colonoscopy and FIT/FOBT screening modalities, the intervention was associated with reductions of 806 CRC cases (primarily late-stage cancers) and 392 CRC deaths, and 5,368 additional life-years, per 100,000 population, under more conservative assumptions including higher background screening. Of the 78,685 individuals in our CRCCP cohort, this translated to 308 CRC-specific deaths averted. Our study included patients who represent low-income, medically underserved populations, and are typically from clinics with low CRC screening prevalence and serving under-resourced communities.

Our analysis showed that, while more people completed screening through FIT/FOBT compared to colonoscopy, the colonoscopy screenings were associated with greater health improvements. For example, of the 78,685 individuals in our overall cohort, 63% initially screened by FIT/FOBT compared to 37% by colonoscopy, but there were more averted CRC cases in the colonoscopy cohort (487 cases averted among 28,978 individuals) than the FIT/FOBT cohort (147 cases averted among 49,707 individuals). This translated into rates per 100,000 population of 679 CRC cases averted for the colonoscopy cohort versus 296 for the FIT/FOBT cohort. This finding highlights an important tradeoff in the

CRCCP context given the typical low screening prevalence in the populations served and challenges in ensuring a continuity of future screenings. On the one hand, more people can be reached with a mailed or real-time provided FIT/FOBT because it is cheaper to provide and easier for individuals compared to colonoscopies. However, the benefits of a single colonoscopy are more substantial than FIT/FOBT. It is important to note that we compared the health outcomes of one-time screening with colonoscopy versus FIT/FOBT, whereas, in an ideal situation, there should be ten consecutive FIT/FOBTs completed over ten years for every colonoscopy. Additionally, FIT/FOBT screening is complete only when all abnormal results are followed up with colonoscopies. For this analysis, we focused on estimating the impact of what was actually provided by the CRCCP in terms of screenings (and the vast majority of people completed only a single cycle of screening/follow-up testing through the program). There is some evidence, albeit mixed [39–41], regarding the probability that individuals will screen again in the future by FIT/FOBT after completing an initial screening; if stool testing can be repeated year-to-year, the CRCCP's provision of screening will have an even more substantial impact on outcomes. Importantly, we believe it is critical to continue offering both screening modalities, as both are associated with considerable lifelong health benefits. For example, we found substantial improvements in long-term CRC health outcomes even with the provision of a single stool test offered by the program. In addition to the lower program cost of individual stool tests compared to colonoscopies, prior research has documented differences in predictors of and preferences for CRC screening modality across groups [42–45]. Additionally, access to endoscopy providers varies geographically, making it challenging for patients in some regions to access colonoscopy due to transportation and capacity challenges [46, 47]. Our results suggest that when people are open to both modalities, and when the community context is supportive of completing colonoscopies (e.g., colonoscopies are accessible), providing a single routine colonoscopy is more impactful on health and cost-effective than a single FIT/FOBT (with follow-up testing if abnormal) from the program perspective.

Recognizing that there are many uncertainties regarding future CRC screening patterns, we varied our assumptions and simulated multiple scenarios about future screening modalities and adherence levels. We found that different assumptions about the level of future screening, diagnostic testing, and surveillance (i.e., lower vs. higher) had a stronger impact on health outcomes than assumptions about future modality changes. The relatively small changes in health outcomes when allowing for modality change were due, in part, to the fact that only individuals who screened by FIT/FOBT and had an abnormal result were allowed to change modality in this analysis. Because the findings of large health gains over the lifetime were robust across all scenarios, there is strong evidence of the large health impact of the first CRC screening received in this population through CRCCP.

From the program perspective, the program cost per life-year gained for the colonoscopy cohort ranged from \$25,740 (lower background screening scenario) to \$27,583 (higher background screening scenario), compared to a range of \$70,410 to \$75,979 for the FIT/FOBT cohort. The magnitude of the difference in programmatic cost-effectiveness across the health outcomes assessed between the two cohorts was greatest per CRC death averted (\$386,000 for colonoscopy cohort and \$894,000 for FIT/FOBT cohort under equivalent assumptions). Given the CDC's organizational perspective and the context of providing

prevention screening to medically underserved individuals, the cost components included in the programmatic cost-effectiveness estimates are likely underestimated compared with payer, health system or societal perspectives. We did not account for the longer-term treatment and survivorship costs that are associated with CRC prevention and early detection and would be included in those perspectives [48–50]. For example, Mariotto and colleagues found annual CRC treatment costs to be over \$51,000 in the first year post-diagnosis, over \$3,100 for each subsequent year, and over \$84,000 for the last year of life [49]. We also did not account for the societal costs associated with having CRC, such as productivity losses and poor quality of life. Additionally, we expect these programmatic cost-effectiveness values to be higher in this CRCCP population compared to other cohorts because the majority of individuals were unscreened and found to have relatively higher polyp and cancer rates [18, 25].

The CRCCP also offers additional health gains, such as improved quality of life of survivors, not captured here. Additional research should include the change in health outcomes and program costs when accounting for subsequent routine CRC screenings received through this program among average-risk individuals. To understand the program's full effect, future work should also account for CRC screening provided to higher-risk populations, such as those with prior history of polyps or CRC, and those with genetic syndromes or familial risk of CRC. Analyses might also explore how to best spend limited funds—for example, whether to prioritize increasing the number of average-risk individuals who complete an initial screening versus increasing adherence to future CRC screenings among those who complete a first CRC screening through CRCCP.

This analysis has limitations. We made assumptions about subsequent screening patterns, such as lower versus higher background screening rates. While our results were insensitive to some of our assumptions, other scenarios and ranges of screening rates may better reflect true background screening patterns in our population though there was limited data available. Similarly, while we used routine screening estimates from BRFSS in our modeling assumptions, these estimates were based on self-reported data and not confirmed tests. Our study sample is not representative of the U.S. population who are at average risk of CRC. Although we included those ages 45–75 in this cohort, the sample predominantly included individuals who were 50–64. We excluded those who reported prior polyp removal because we were unable to match them to a simulated equivalent, but this was also a rare event (< 3% of patients). Additionally, we limited our cost analysis to include only implementation and screening costs, excluding the longer-term costs associated with future CRC screening, treatment and survivorship. Our goal was to focus on the programmatic costs directly incurred by the CDC in implementing the CRCCP. Because of statistical analysis used to understand the importance of different uncertain parameters in our prior work [18, 49], and given that it is very computationally expensive to run this model with the use of simulated equivalents, we did not conduct more extensive univariate or probabilistic sensitivity analyses. However, we believe this is reasonable because we had observed data (program costs, outcomes of screenings completed through the CRCCP) for some of our parameters and tested a variety of scenarios with different assumptions and estimates for those that are less certain. Finally, all the health gains or benefits from our analysis are potential.

Conclusion

The study findings underscore the substantial potential health benefits over individuals' lifetime associated with the direct CRC screenings provided through the CRCCP. Notably, the CRCCP health impact on the population served was more substantial compared to the general population, particularly since the vast majority of individuals received CRC screening for the first time in their lives, and these individuals presumably were less likely to undergo screening in the absence of the intervention. These findings suggest that, although in modest scale, the CRCCP played a pivotal role in addressing the disparities associated with CRC among the population served through direct screening service provision. The program's long-term cost-effectiveness can serve as a benchmark to which the health outcomes and costs of alternative interventions can be directly compared, providing robust tools to decision-makers who seek to determine the best strategies to achieve the desired goal.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Data availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

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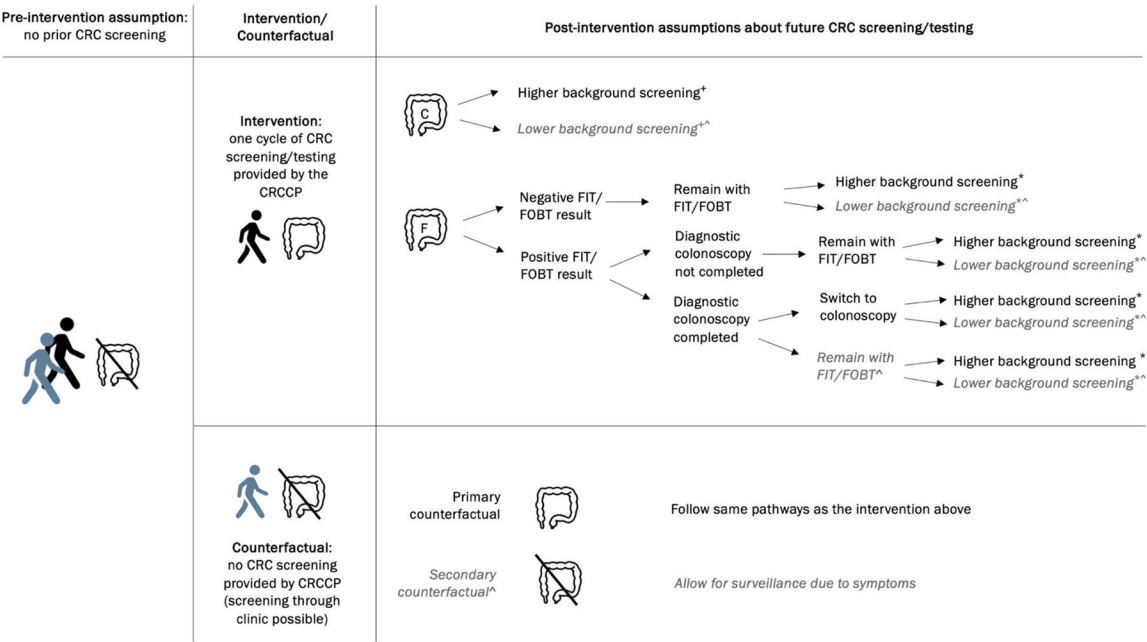


Fig. 1. Overview of modeled intervention, and the multiple future and counterfactual screening scenarios simulated. The figures of a person in black represent a member of the cohort who received a CRCCP-provided screening (the intervention). The type of modality (colonoscopy vs. FIT/FOBT) is based on the actual test received, with the number of individuals who completed each screening test reported in Fig. 2. The figures of a person in blue (lighter shading) represent the simulated equivalent of the individual in black who does not receive the intervention. See Appendix Table 4 for a written description of these assumptions. ⁺ Polyp removal triggers surveillance. ^{*}Positive FIT/FOBT result triggers a diagnostic colonoscopy. [^]Results for lower background screening and/or remain with FIT/FOBT scenarios, as well as the secondary counterfactual, are available in the Appendix

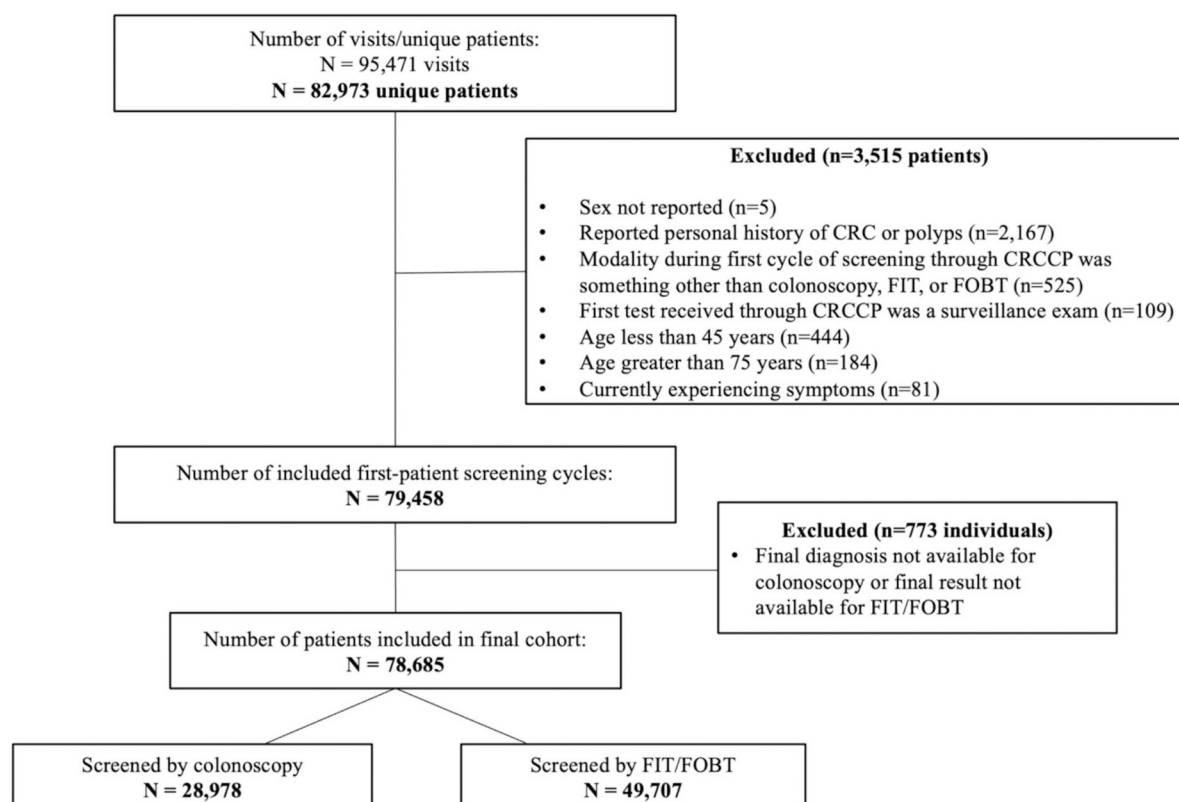
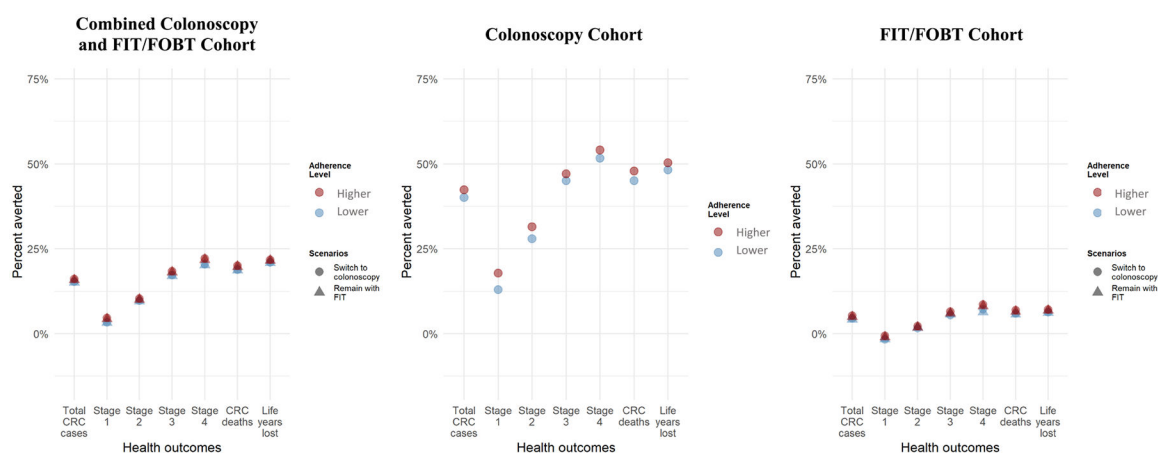


Fig. 2.

Inclusion/exclusion criteria to identify average-risk population receiving at least one routine colorectal cancer (CRC) screening through the Colorectal Cancer Control Program (CRCCP). Colorectal Clinical Data Elements (CCDE) for the CRCCP program were obtained for all encounters from January 2009 to October 2020. For each encounter, data included the type of CRC test completed, test indication (screening, diagnostic, surveillance), test result, complications occurring during colonoscopy, number (if any) of polyps removed, size of largest polyp, histology, recommended surveillance interval, and CRC stage (if diagnosed). In addition, de-identified individual-level data including age, sex, race, ethnicity, state of residence, self-reported CRC screening history (prior CRC screening; history of polyps or CRC; currently experiencing CRC symptoms), and self-reported family history of CRC were provided.

**Fig. 3.**

Percent of adverse colorectal cancer (CRC) related health outcomes averted with the Colorectal Cancer Control Program (CRCCP)-provided screening, compared to no intervention, by cohort. We present the percent of CRC-related health outcomes averted assuming higher versus lower background screening levels (i.e., adherence to recommended screening, diagnostic testing, and surveillance) for each cohort. In addition, for the combined and FIT/FOBT cohorts, we present the results under our two simulated scenarios for possible modality change after an abnormal FIT/FOBT followed by completion of a diagnostic colonoscopy (i.e., switch to colonoscopy or remain with FIT/FOBT thereafter)

Table 1

Characteristics of individuals who received at least one routine colorectal cancer (CRC) screening through the Colorectal Cancer Control Program (CRCCP), overall and by initial screening modality

Characteristic of CRCCP patients	Colonoscopy (n = 28,978)	FIT/FOBT (n = 49,707)	Overall (n = 78,685)
<i>Sex</i>			
Male	9,556 (33.0%)	11,554 (23.2%)	21,110 (26.8%)
Female	19,422 (67.0%)	38,153 (76.8%)	57,575 (73.2%)
<i>Race</i>			
White	18,921 (65.3%)	37,709 (75.9%)	56,630 (72.0%)
Black	5,488 (18.9%)	5,055 (10.2%)	10,543 (13.4%)
Other	4,569 (15.8%)	6,943 (14.0%)	11,512 (14.6%)
<i>Ethnicity</i>			
Hispanic	7,617 (26.3%)	22,499 (45.3%)	30,116 (38.3%)
Non-Hispanic	21,361 (73.7%)	27,208 (54.7%)	48,569 (61.7%)

Table 2

Simulated colorectal cancer (CRC) related health outcomes over the lifetime of the Colorectal Cancer Control Program (CRCCP) cohort, overall and by initial screening modality, with no intervention (primary counterfactual), and the incremental change in health outcomes with the CRCCP-provided screening (assuming higher background screening and switch to colonoscopy scenarios)*

Health Outcome, average (95% confidence interval)	Combined colonoscopy and FIT/FOBT cohorts (n = 78,685)			Colonoscopy cohort (n = 28,978)			FIT/FOBT cohort (n = 49,707)		
	No intervention	Incremental change with CRCCP-provided screening	No intervention	Incremental change with CRCCP-provided screening	No intervention	Incremental change with CRCCP-provided screening			
Absolute number by cohort									
Total CRC cases	3,923.7 (3,911.7, 3,935.7)	- 634.0 (- 639.1, - 628.9)	1,176.8 (1,170.4, 1,183.2)	- 486.6 (- 490.8, - 482.4)	2,746.9 (2,737.2, 2,756.6)	- 147.3 (- 150.0, - 144.6)			
Stage 1 cases	575.0 (570.0, 580.0)	- 26.9 (- 29.7, - 24.1)	170.3 (167.8, 172.8)	- 29.2 (- 31.5, - 26.9)	404.7 (400.6, 408.8)	+ 2.3 (+ 0.8, + 3.8)			
Stage 2 cases	661.7 (6,56.7, 666.7)	- 68.6 (- 71.5, - 65.7)	196.2 (193.7, 198.7)	- 58.2 (- 60.5, - 55.9)	465.5 (461.4, 469.6)	- 10.4 (- 12.1, - 8.7)			
Stage 3 cases	1,512.4 (1505.2, 1519.6)	- 278.9 (- 282.6, - 275.2)	454.0 (450.0, 458.0)	- 210.1 (- 213.4, - 206.8)	1,058.3 (1,051.8, 1,064.8)	- 68.8 (- 70.9, - 66.7)			
Stage 4 cases	1,174.6 (1,168.3, 1,180.9)	- 259.5 (- 263.1, - 255.9)	356.2 (352.7, 359.7)	- 189.0 (- 191.7, - 186.3)	818.4 (813.1, 823.7)	- 70.5 (- 72.3, - 68.7)			
CRC deaths	1,537.7 (1,530.7, 1,544.7)	- 308.1 (- 311.7, - 304.5)	501.9 (497.8, 506.0)	- 236.4 (- 239.5, - 233.3)	1,035.8 (1,030.3, 1,041.3)	- 71.8 (- 73.6, - 70.0)			
Life-years lost	19,465.0 (19,354.2, 19,575.8)	- 4,223.9 (- 4,280.4, - 4,167.4)	6,700.1 (6,627.3, 6,772.9)	- 3,312.5 (- 3,365.2, - 3,259.8)	12,764.9 (12,677.9, 12,851.9)	- 911.4 (- 937.5, - 885.3)			
Rate per 100,000 population									
Total CRC cases	4,986.6 (4,971.4, 5,001.8)	- 805.7 (- 812.2, - 799.2)	4,060.9 (4,038.9, 4,082.9)	- 1,679.3 (- 1,693.8, - 1,664.8)	5,526.2 (5,506.7, 5,545.7)	- 296.4 (- 301.9, - 290.9)			
Stage 1 cases	730.8 (724.4, 737.2)	- 34.2 (- 37.7, - 30.7)	587.7 (578.9, 596.5)	- 100.9 (- 108.9, - 92.9)	814.2 (805.9, 822.5)	+ 4.7 (+ 1.6, + 7.8)			
Stage 2 cases	840.9 (834.5, 847.3)	- 87.2 (- 90.9, - 83.5)	677.0 (668.5, 685.5)	- 201.0 (- 208.8, - 193.2)	936.5 (928.2, 944.8)	- 20.9 (- 24.3, - 17.5)			
Stage 3 cases	1,922.0 (1,912.9, 1,931.1)	- 354.4 (- 359.1, - 349.7)	1,566.8 (1,552.9, 1,580.7)	- 725.1 (- 736.6, - 713.6)	2,129.1 (2,116.0, 2,142.2)	- 138.4 (- 142.5, - 134.3)			
Stage 4 cases	1,492.8 (1,484.8, 1,500.8)	- 329.8 (- 334.4, - 325.2)	1,229.3 (1,217.2, 1,241.4)	- 652.3 (- 661.7, - 642.9)	1,646.4 (1,635.8, 1,657.0)	- 141.8 (- 145.4, - 138.2)			
CRC deaths	1,954.3 (1,945.5, 1,963.1)	- 391.6 (- 396.1, - 387.1)	1,732.0 (1,717.8, 1,746.2)	- 815.8 (- 826.4, - 805.2)	2,083.8 (2,072.7, 2,094.9)	- 144.4 (- 148.0, - 140.8)			
Life-years lost	24,737.8 (24,596.9, 24,878.7)	- 5,368.1 (- 5,439.9, - 5,296.3)	23,121.3 (22,870.0, 23,372.6)	- 11,431.1 (- 11,612.8, - 11,249.4)	25,680.2 (25,505.3, 25,855.1)	- 1,833.6 (- 1,886.1, - 1,781.1)			

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In this analysis, we assumed a higher background level of routine screening, diagnostic testing, and surveillance in the future (and during the year of intervention for the counterfactual). We also assumed that following a diagnostic colonoscopy after a positive FIT/FOBT, the routine screening modality will thereafter be colonoscopy

*

Table 3

Program cost-effectiveness per health outcome of the CRCCP intervention (CRC screening provided by the program by the modality used) compared to no intervention (not having received that known screening), in the CRCCP cohort from the program perspective

Program cost-effectiveness ⁺	Colonoscopy cohort (n = 28,978), as compared to not having received a routine colonoscopy through the CRCCP		FIT/FOBT cohort (n = 49,707), as compared to not having received a FIT/FOBT through the CRCCP			
	Lower background screening	Higher background screening	Lower background screening – switch with diagnostic colonoscopy	Lower background screening – remain with FIT/FOBT	Higher background screening – switch with diagnostic colonoscopy	Higher background screening – remain with FIT/FOBT
Average program cost per person incurred by CRCCP, including program implementation and direct clinical costs [*]	\$3,153	\$3,153	\$1,291	\$1,291	\$1,291	\$1,291
Per additional year up-to-date with CRC screening recommendations [*]	\$315	\$315	\$789	\$789	\$789	\$789
Per life year gained	\$25,740	\$27,583	\$73,965	\$75,979	\$70,410	\$72,864
Per CRC case averted	\$170,844	\$187,767	\$472,546	\$502,126	\$435,653	\$471,504
Per CRC death averted	\$356,765	\$386,496	\$957,787	\$996,456	\$893,757	\$942,316

⁺ In this analysis, we included only short-term program costs incurred by the CRCCP upfront. Longer-term costs, such as CRC treatment and survivorship, and possibly cost savings resulting from reduced CRC cases associated with the intervention, are excluded since they would likely be attributed to other payers

^{*} Average program cost per person was previously reported [26]. This cost includes program implementation (i.e., costs required to implement evidence-based interventions to promote screening) and direct clinical costs (i.e., costs of completed screenings)