Value of Waiving Coinsurance of Colorectal Cancer Screening in Medicare Beneficiaries

ABSTRACT

Financial barriers to colorectal cancer screening persist despite the Affordable Care Act (ACA). Medicare beneficiaries may face 20 percent coinsurance for a screening colonoscopy when the procedure includes the removal of polyps or follows a positive fecal screening test. Using an established microsimulation model, we estimated that waiving this coinsurance would result in 1.7 fewer colorectal cancer deaths (a decrease of 13 percent) and $17,000 higher colorectal cancer–related costs (an increase of 0.6 percent) for the Centers for Medicare and Medicaid Services per 1,000 sixty-five-year-olds, assuming a 10-percentage-point increase in the rates of first colonoscopy screening, follow-up, and surveillance. If the rates did not change, waiving coinsurance would increase total costs by $51,000 (1.9 percent) per 1,000 sixty-five-year-olds. Estimated screening benefits were comparable when fecal testing was assumed to be the primary screening method. Moreover, waiving coinsurance would be cost-effective if the screening rate increased by 0.6 percentage points, assuming a willingness-to-pay threshold of $50,000 per quality-adjusted life-year gained. Thus, the waiver is likely to have a favorable balance of health and cost impact.

INTRODUCTION

Colorectal cancer is the second leading cause of cancer death in the United States (US). It is estimated that in 2017, over 135,000 new cases will be diagnosed, and more than 50,000 deaths due to the disease will occur.[191] Screening may prevent such deaths and is therefore recommended for people ages 50-75 years by the US Preventive Services Task Force.[109] Despite the overwhelming evidence for the effectiveness of screening,[155] in 2015 only 61.1 percent of eligible people reported having received colorectal cancer testing consistent with current guidelines (Stacey Fedewa, director of screening and risk factor surveillance, American Cancer Society, personal communication, February 1, 2017). Removing financial barriers is an effective way to increase participation in colorectal cancer screening.[192, 193] Provisions of the Affordable Care Act (ACA) aimed to improve health care access and affordability of preventive services for all Americans[194] and eliminated cost sharing for services such as colorectal cancer screening that are recommended with by the task force a grade A or B.[195-199] Financial barriers for receipt of colorectal cancer screening persist despite the ACA. For Medicare beneficiaries, the group with the highest age-related disease risk, negative screening colonoscopy and fecal test such as fecal immunochemical test (FIT) are full covered–that is, the beneficiary has no deductible or coinsurance. However, beneficiaries without supplemental insurance face out-of-pocket spending when a polyp is detected and removed during the course of a screening colonoscopy, as the service is then classified by Medicare as diagnostic rather than preventive and is subject to a 20 percent coinsurance.[65] Beneficiaries are also responsible for both the part B deductible and the 20 percent coinsurance payment for colonoscopy when it is performed after a positive fecal test, regardless of the outcome. Since the 2011-2012 session of Congress, bills have been introduced to amend title XVIII of the Social Security Act to waive colonoscopy screening coinsurance for Medicare beneficiaries, regardless of the findings of the procedure. On the basis of Medicare claims, it has been estimated that the amendment increase Medicare spending on colonoscopies by US $48 million annually.[65] Because of the lack of studies on the potential impact of waiving the coinsurance on screening rates and the corresponding savings in colorectal cancer treatment, none of the introduced legislation has become law. To help inform future Medicare reimbursement policy, we estimated the potential impact of waiving Medicare coinsurance for screening colonoscopies with polyp removal and for diagnostic colonoscopies performed after a positive FIT. Using a well-established microsimulation model, we evaluated several scenarios for the effect of such a waiver on take-up of screening to determine whether, and under what circumstances, it could prove cost-effective.

STUDY DATA AND METHODS

The Microsimulation Screening Analysis-Colon model

We used the Microsimulation Screening Analysis-Colon model to estimate the cost-effectiveness of waiving coinsurance for every component of colorectal cancer screening from the prospective of the Centers for Medicare and Medicaid Services (CMS). The model was developed by the Department of Public Health in the Erasmus University Medical Center, and it has been described extensively elsewhere.[122, 200] It is part of the National Cancer Institute's Cancer intervention and Surveillance Modeling Network[201] and has been used to inform screening recommendations of the US Preventive Services Task Force.[69, 202] In brief, the model generates, with random variation, the life histories of people in a large cohort to simulate the US population in terms of life expectancy and cancer risk. Each simulated person ages over time and may develop one or more adenomas that can progress from small (no more than 5 mm), to medium (6-9 mm) to large size (10 mm or more). Some adenomas develop into preclinical cancer, which may progress through stages I to IV. At each disease transition point, colorectal cancer may be diagnosed because of symptoms. Survival after clinical diagnosis is determined by the stage at diagnosis, the location of the cancer, and the person's age. Some simulated life histories are altered by the effect of detecting and removing adenomas or diagnosing colorectal cancer at an earlier stage, which results in a better prognosis. Screening also results in overdiagnosis and overtreatment and may have several complications, which are considered in the modelling. The Microsimulation Screening Analysis-Colon model quantifies the effectiveness and associated costs of the screening by comparing outcomes with and without a specific screening intervention. Further details about the model and its natural history assumptions are described in the General Appendix.

Analysis

We simulated an average-risk Medicare-eligible US population cohort of sixty-five-year-olds, 60 percent of whom were then up-to-date with screening according to guidelines of the US Preventive Services Task Force (which recommend colonoscopy screening at ages fifty and sixty or annual FIT screening from age fifty to age sixty-four).[203-205] We then simulated potential increases in screening rates and benefits and costs due to waiving the Medicare coinsurance from age sixty-five over the patient's lifetime. We simulated screening until age seventy-five, following the task force's guidelines. Patients with a positive FIT result were referred to diagnostic colonoscopy. Detected adenomas were removed and followed by colonoscopy surveillance every three to five years, depending on the number and the size of adenomas detected, as recommended by current guidelines.[206] Test characteristics were based on a study by Amy Knudsen and coauthors.[69] We assumed a Medicare reimbursement of $21.65 per FIT.[207] Estimates of the costs of colonoscopy screening, follow-up, and surveillance without polyp removal and of colonoscopies with polyp removal were obtained from

an analysis of 2014 Medicare claims data from the Chronic Conditions Data Warehouse and updated to 2015US dollars using the Consumer Price Index (CPI). Costs of colorectal cancer care were obtained from an analysis of data for the period 1998–2003 that linked information from the Surveillance, Epidemiology, and End Results (SEER) database with data from Medicare claims,[208] updated to 2015 US dollars using the CPI. Detailed model assumptions regarding test characteristics, utility losses in terms of quality-adjusted life-years (QALYs), and costs are in **Supplementary Exhibit A6.1**. Five scenarios were simulated that differed with regard to coinsurance and screening rate— which were evaluated separately for FIT- and colonoscopy-based screening strategies. The first scenario was the current state, in which 70 percent of the total population ages 50–75 had received at least one screening, 60 percent adhered to screening recommendations,[203-205] 80 percent adhered to potential diagnostic and surveillance colonoscopy recommendations,[35, 209] and there was a 20 percent coinsurance for screening colonoscopy with polypectomy and colonoscopy after a positive FIT result (no supplemental insurance was taken into account) (for more details on adherence assumptions as applicable to each round, see **Supplementary Exhibit A6.1**). In the second scenario, coinsurance for all participants was waived, with no assumed effect on screening rates. In the third scenario, waiving coinsurance was assumed to lead to a 5-percentage-point increase in the rate of completion of a diagnostic colonoscopy and surveillance after a positive FIT result.

In the fourth scenario, waiving coinsurance produced a 5-percentage-point increase in the initial screening rate and in diagnostic follow-up and surveillance rates. In this scenario, the percentage of people up-to-date with screening and ever having been screened increased to 65 percent and 73.75 percent, respectively (for similar relative reductions in the number not current with screening and never screened). In the fifth scenario, we simulated a 10-percentage-point increase in the initial screening rate and diagnostic follow-up and surveillance rates, which resulted in 70 percent and 77.5 percent of people being up-to-date with screening and ever having been screened, respectively (see **Supplementary Exhibit A6.1**). The levels of increased screening participation simulated in the fourth and the fifth scenarios match the effect seen with the elimination of coinsurance for screening colonoscopies.[195, 196, 210] For all coinsurance and screening-rate scenarios, and for both the FIT- and colonoscopy-based screening regimens, our main outcomes were numbers of colorectal cancer cases and deaths, number of colonoscopies potentially subject to coinsurance, life-years and QALYs gained compared to no screening, and associated costs. We applied the conventional 3 percent annual discount rate to all outcomes except for the numbers of colorectal cancer cases and deaths and of colonoscopies with coinsurance requirements. In addition, because the true effect on screening participation of waiving coinsurance is unknown, we determined the threshold increase in screening rate at which full coverage of colonoscopy by CMS is cost-effective compared to the current state based on willingness-to-pay thresholds of $100,000 and $50,000 per QALY gained.[211]

Sensitivity Analyses

In sensitivity analyses, we used the following seven alternative assumptions to evaluate the robustness of our results: 60 percent of the cohort of sixty-five-year-olds had been screened once at age fifty-five using colonoscopy and received colonoscopy screening at ages sixty-five and seventy-five; none of the cohort of sixty-five-year-olds received screening before that age; the costs for colonoscopy were 10–75 percent higher (see **Supplementary Exhibit A6.1**); treatment costs for the initial phases of stage III and IV and the terminal phase of colorectal cancer care (at all stages) were 10–75 percent higher (see **Supplementary Exhibit A6.1**); the population that participated in screening only if coinsurance was waived (socio-economically disadvantaged people without supplemental insurance) and the population that never participated had a 1.2-fold higher incidence of colorectal cancer than the population that participated in screening regardless of the cost (based on a study by Raymond Oliphant and coauthors);[212] test sensitivities of FIT and colonoscopy were lower (worst case) or higher (best case) than our base-case analyses (see **Supplementary Exhibit A6.1**); and potential increases in screening rates, benefits, and costs were simulated from age fifty on.

Limitations

Our study had a few limitations. First, the effect of waiving coinsurance on participation is not well known because of the paucity of published studies. We therefore evaluated several scenarios based on estimates of the effect of the coinsurance waiver for screening colonoscopies, and we determined a threshold of increased screening at which waiving the coinsurance was cost-effective. Second, the costs of colorectal cancer treatment derived from SEER-Medicare linked data for 1998–2003 might be underestimates, as therapy with monoclonal antibodies received approval by the Food and Drug Administration after that period. Therefore, we underestimated cost savings due to averted treatment expenses for cancer cases in our base-case analyses, and we explored the impact of higher treatment costs in our sensitivity analyses. Third, no up-to-date information was available on the proportion of Medicare beneficiaries with supplemental insurance. Supplemental coverage may vary across packages and states. We assumed a 20 percent increase in costs for CMS for all colonoscopies with polypectomy and those performed after a positive FIT after waiving the coinsurance. Since for people with Medicare Advantage, the private plans that receive premiums from CMS may already cover expenses, this likely overestimated the increase in cost from CMS's perspective and therefore the cost-effectiveness threshold of waiving coinsurance. Likewise, the health impact of waiving coinsurance might mainly occur among people without supplemental coverage (an estimated 14 percent of Medicare beneficiaries in 2010),[213] given that those with additional insurance might not benefit financially from the coinsurance change.

STUDY RESULTS

Potential Benefits And Costs Of Waiving Coinsurance

We estimated that in the current state, using the colonoscopy regimen with coinsurance, 12.8 colorectal cancer deaths occurred and 124.1 QALYs were gained per 1,000 sixty-five-year-olds (**Exhibit 6.1**). The total number of procedures per 1,000 Medicare beneficiaries was 1,132, of which 410 (36 percent) were potentially subject to coinsurance requirements. We estimated the total lifetime costs for CMS, which included colorectal cancer screening, surveillance, and treatment, with coinsurance, to be $2.675 million per 1,000 sixty-five-year-olds (**Exhibit 6.1** and **Supplementary Exhibit A6.2**). The benefits of waiving coinsurance for a screening colonoscopy in which a polyp is removed varied with the assumed increase in participation. For the colonoscopy strategy, if there was no change in screening rate as a result of waiving the coinsurance, the benefits of screening would not change, but the total costs of screening and treatment would increase to $2.726 million (an increase of $51,000, or 1.9 percent) per 1,000 sixty-five-year-olds (**Exhibit 6.1**). In contrast, an assumed 5-percentagepoint increase in the rates of first colonoscopy screening and surveillance decreased the number of colorectal cancer deaths by 0.9 (6.4 percent), accompanied by an increase of $33,000 (1.2 percent) in total costs, with a cost per QALY gained (or cost-effectiveness ratio) of $4,086. A 10-percentage-point increase instead decreased deaths by 1.7 (13 percent) and increased costs by only $17,000 (0.6 percent), resulting in a cost- effectiveness ratio of $1,035. The potential benefits and costs of waiving all coinsurance for colorectal cancer screening were comparable using a FIT-based strategy (**Exhibit 6.1**). Of special interest is the scenario in which a 5-percentage-point increase in adherence to diagnostic follow-up and surveillance was assumed to be a consequence of waiving coinsurance. This resulted in a cost-effectiveness ratio of $48,606 compared to the current state, which suggests that even if only adherence to diagnostic follow-up and surveillance increased by this amount—with no increase in adherence to primary FIT screening—waiving the coinsurance would be cost-effective.

In the colonoscopy strategy, costs were higher at ages seventy, seventy-five, and eighty because of the increased costs for screening and surveillance colonoscopies, but costs were lower at the other ages if the waiver increased the screening rate (see **Supplementary Exhibit A6.3**). In the FIT strategy, waiving coinsurance was estimated to initially increase costs but to lead to cost savings after a decade because of averted cases of colorectal cancer. The estimated increase in per person costs was slightly higher for the colonoscopy strategy compared to the FIT strategy (see **Supplementary Exhibit A6.3**).

Cost-Effectiveness Threshold Determination

Assuming a willingness-to-pay threshold of $100,000 per QALY gained, we estimated that waiving all coinsurance would be cost-effective if it increased screening participation by

0.4 percentage points (from 60.0 percent to 60.4 percent) in a colonoscopy-based screening protocol and by 0.3 percentage points (from 60.0 percent to 60.3 percent) in a FIT-based screening protocol (**Exhibit 6.2**). When a willingness-to-pay threshold of $50,000 was applied, we estimated that in both protocols the screening rate would need to increase 0.6 percentage points, to 60.6 percent, for waiving coinsurance to be cost-effective.

EXHIBIT 6.1. Colorectal cancer (CRC) outcomes per 1,000 sixty-five-year-old Medicare beneficiaries, by screening category, coinsurance requirement, and change in adherence

Category Scenario[a]	**CRC Cases**[a]	**CRC Deaths**[a]	**Colonoscopies with coinsurance requirements**[a]	**LY gained**[b]	**QALY gained**[b]	**Total costs (million $)**[b]	**Incremental Costs/ QALY gained compared to the current state**[b]
No screening	60.1	26.6	60.1	0.0	0.0	3.276	-[c]
Colonoscopy							
With coinsurance							
Current state	34.2	12.8	410[d]	104.1	124.1	2.675	-[c]
Without coinsurance							
No impact on adherence	34.2	12.8	410	104.1	124.1	2.726	-[c]
With 5 percentage point increase in adherence diagnostic follow-up and surveillance.	34.1	12.7	411	104.1	124.1	2.728	$1,142,885
With 5 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	32.9	11.9	439	111.0	132.2	2.708	4,086
With 10 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	31.6	11.1	470	117.9	140.4	2.692	1,035
FIT							
With coinsurance							
Current state	39.5	14.0	357	99.4	115.9	2.743	-[c]
Without coinsurance							
No impact on adherence	39.5	14.0	357	99.4	115.9	2.785	-[c]
With 5 percentage point increase in adherence diagnostic follow-up and surveillance.	39.2	13.9	368	100.1	116.7	2.783	48,606
With 5 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	38.5	13.2	391	106.2	123.7	2.772	3,747
With 10 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	37.3	12.4	427	112.9	131.6	2.758	974

SOURCE Authors' analysis of data using the Microsimulation Screening Analysis–Colon model. NOTES Increases are compared to the current state (a 60 percent screening rate and 80 percent adherence rates to diagnostic follow-up and surveillance after a positive FIT). QALYs are quality-adjusted life-years. [a]Not discounted. [b]Discounted at the conventional 3 percent annual rate. [c]Not applicable. [d]Out of a total 1,132 colonoscopies.

Sensitivity Analyses

Several sensitivity analyses affected the percentage-point increase in screening rate required for waiving coinsurance to be cost-effective. First, in the sensitivity analysis that assumed one previous colonoscopy screening at age fifty-five or no screening before age sixty-five increased the thresholds at which waiving coinsurance was cost-effective from 0.6 to 0.9 and 1.8 percentage points, respectively, using a willingness-to-pay threshold of $50,000 per QALY gained (**Exhibit 6.3**). Second, in the sensitivity analysis that assumed higher colonoscopy costs, the threshold increased up to 1.3 percentage points.

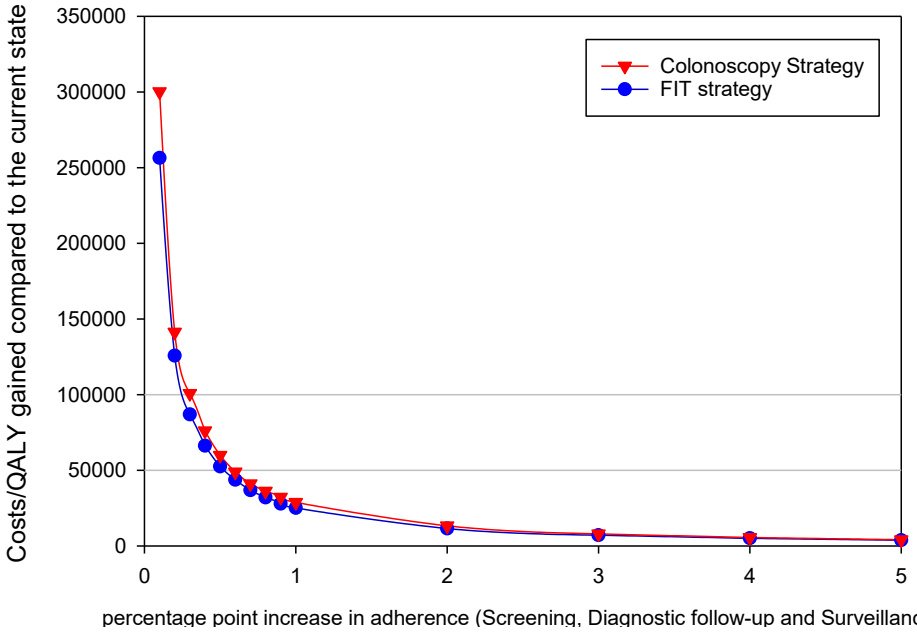


EXHIBIT 6.2. Predicted increases in costs per quality-adjusted life-year (QALY) gained if coinsurance for colorectal cancer screening were waived, by percentage-point increase in adherence to screening, diagnostic follow-up, and surveillance.

SOURCE Authors' analysis of data using the Microsimulation Screening Analysis–Colon model. NOTES Increases in costs and adherence are compared to the current state for sixty-five-year-old Medicare beneficiaries (who have a screening rate of 60 percent and an 80 percent adherence rate to diagnostic follow-up and surveillance), and are 3 percent discounted to the age of 65. With a willingness-to-pay threshold of $50,000 or even $100,000 per QALYgained, waiving coinsurance is cost-effective with even small increases in adherence. FIT is fecal immunochemical test.

Third, if we simulated potential increases in screening rates, benefits, and costs starting at age fifty rather than age sixty-five, the threshold more than doubled (increasing to 1.8 percentage points). Sensitivity analyses that evaluated the effect of alternative assumptions for treatment costs, higher colorectal cancer risk in additional participants, and test sensitivities demonstrated that these assumptions minimally affected the percentage-point increase

in screening rate needed to make waiving coinsurance cost-effective. The needed increase in screening rate did not exceeded 1.8 percentage points in any of the sensitivity analyses.

EXHIBIT 6.3. Percentage-point increases in screening rate for colorectal cancer (CRC), diagnostic follow-up, and surveillance needed for waiving coinsurance for Medicare beneficiaries to be cost-effective, by selected assumptions

	Colonoscopy		FIT	
Willingness to pay Threshold	*US $100,000*	*US $50,000*	*US $100,000*	*US $50,000*
Base-Case	0.4	0.6	0.3	0.6
One previous screening at age 55[a]	0.5	0.9	-[b]	-[b]
Without Previous Screening[a]	0.8	1.8	0.4	0.8
Higher Colonoscopy costs of:				
10%	0.4	0.7	0.3	0.6
25%	0.4	0.8	0.4	0.7
50%	0.5	1.0	0.5	0.9
75%	0.6	1.3	0.5	1.0
Higher Treatment costs[c] of:				
10%	0.4	0.6	0.3	0.6
25%	0.3	0.6	0.3	0.6
50%	0.3	0.6	0.3	0.5
75%	0.3	0.6	0.3	0.5
Higher CRC risk in additional participants	0.3	0.5	0.3	0.5
Worst-case test sensitivity	0.4	0.6	0.3	0.6
Best-case test sensitivity	0.3	0.6	0.3	0.6
Population of 50 year olds	0.8	1.8	0.5	1.0

SOURCE Authors' analysis of data using the Microsimulation Screening Analysis–Colon model. NOTES Increases are compared to the current state among sixty-five-year-old beneficiaries (a 60 percent screening rate and 80 percent adherence rates to diagnostic follow-up and surveillance after a positive fecal immunochemical test [FIT]). All costs were discounted at the conventional 3 percent annual rate. QALYs are quality-adjusted life-years. [a]Screenings at ages sixty-five and seventy-five. [b]Not applicable. [c]For initial phase stages III and IV and for terminal phase (all stages) CRC care.

Costs per QALY gained compared to the current state remained below $25,000 in every scenario if waiving coinsurance resulted in an increase in the screening rate (see **Supplementary Exhibit A6.4**). Strikingly, in the sensitivity analysis that assumed at least 25 percent higher costs of colorectal cancer care, the increase in costs of waiving coinsurance was totally offset by savings in the colorectal cancer care costs if the waiver resulted in a 10-percentage-point increase in the screening rate, which means that in this scenario, waiving coinsurance would be cost-saving (see **Supplementary Exhibits A6.4** and **A6.5**).

DISCUSSION

Colorectal cancer screening is an effective prevention method, and removing financial barriers has been identified as a promising intervention for enhancing participation in the screening.[192, 193] While we did not estimate the effect on participation of waiving coinsurance for screening colonoscopies with polyp removal or for colonoscopies performed after a positive FIT, we showed that the policy would be cost-effective if it increased the screening rate from 60.0 percent to 60.6 percent in Medicare beneficiaries, using a willingness-to-pay threshold of $50,000 per QALY gained. Even if waiving all coinsurance for colorectal cancer screening did not result in an increase in the screening rate, total costs for Medicare would increase by only 1.9 percent for the colonoscopy strategy and 1.5 percent for the FIT strategy (assuming that costs were discounted at the conventional 3 percent annual rate). Our sensitivity analyses demonstrated that if the actual costs were at least 25 percent higher than the current state for initial phases of care for stages III and IV colorectal cancer, and for terminal phases of care for all stages, waiving coinsurance would be cost-saving if it increased screening rates from 60 percent to 70 percent.

Literature On Cost And Health Impacts Of Waiving Coinsurance

We are aware of one previous study that examined the potential budget impact of waiving coinsurance for all screening related colonoscopies. David Howard and co-authors reported a 10 percent increase in total colonoscopy costs after coinsurance was waived for a diagnostic colonoscopy after a positive FIT and for a positive screening colonoscopy.[65] The increases in total colonoscopy costs in our analyses were 7.3 percent (the costs of screening, diagnostic follow-up, surveillance, and associated complications) in the colonoscopy strategy and 11.8 percent (the costs of diagnostic follow-up, surveillance, and associated complications) for the FIT strategy, if waiving coinsurance did not increase screening rate. However, the study by Howard and coauthors focused only on colonoscopy costs and did not consider cost savings from averted cases of colorectal cancer.[65] The strength of our study is that we also considered the potential impact of waiving coinsurance on screening behavior and estimated costs of the entire colorectal cancer screening process—including screening, diagnosis, surveillance, complications, and care—thereby placing the increase in costs from waiving coinsurance in a more complete context. To our knowledge, ours is the first study to explore the potential benefits of waiving coinsurance for a colonoscopy with polypectomy and for a follow-up colonoscopy after a positive FIT. The predicted health benefits of the waiver depend on its assumed impact on the screening rate. As a potential source of information for the expected impact, several studies have looked at the effect of similar legislation changes in which coinsurance was removed for screening colonoscopies. Shabnam Khatami and colleagues reported that waiving coinsurance for a negative screening colonoscopy resulted in an annual increase in colonoscopy use of 8.0–9.5 percent

among employees of the University of Texas System,[210] an increase of 18 percent. Mary Hamman and Kandice Kapinos found a 4-percentage-point increase in annual colonoscopy rates in men ages 66–75 within one year of the ACA's enactment. They found even larger increases among socioeconomically disadvantaged men.[196] Stacey Fedewa and coauthors compared data from the National Health Interview Survey for 2013 and 2008 and found a 9.8-percentage-point increase in colorectal cancer screening prevalence among Medicare beneficiaries after mandates on coverage of preventive care from the ACA took effect.[195] However, it is important to note that the ACA affected more factors than cost sharing that could have influenced screening participation, such as providing a free annual wellness visit and a temporary primary care bonus for physicians. In contrast, some studies found no effect of the elimination of cost sharing for screening colonoscopies on rates of colorectal cancer screening,[214-216] despite the fact that financial concerns constitute one of the most reported barriers to the screening. Substantial financial barriers may persist despite ACA provisions (for example, coinsurance requirements remain for an estimated 36 percent of the procedures), which reflects the complexity of the current reimbursement policy for both patients and providers. Other factors such as the need to take time off from work, family responsibilities, transportation, and fear of or other perceptions about the screening test also affect screening participation.[217, 218]

Policy Implications

We showed that waiving coinsurance would be cost-effective even with a modest increase of 0.6 percentage points in the screening rate, assuming a current rate of 60 percent. If all colonoscopies used in screening were fully reimbursed regardless of their findings or indications, a clear and consistent message could be communicated—which in itself might be a stimulus for screening participation in addition to reducing financial barriers. In general, FIT screening was associated with a lower number of procedures subject to coinsurance. If FIT screening becomes more popular in the United States, following trends observed in several settings,[219, 220] the costs of waiving the coinsurance would be even lower. It is likely that waiving coinsurance would primarily affect the out-of-pocket spending of Medicare beneficiaries of low socioeconomic status, who more often than other beneficiaries lack Medigap and supplemental insurance.[221] Beneficiaries of very low socioeconomic status are eligible for Medicaid and may be protected from coinsurance in the thirty-one states that, along with the District of Columbia, expanded eligibility for Medicaid under the ACA.[222] However, in the remaining nineteen states, people of low socioeconomic status neither are eligible for Medicaid as well as Medicare nor can afford supplemental insurance. This means that waiving coinsurance might also contribute to reducing disparities in colorectal cancer in the United States.[221] Health disparities are larger in the United States than in many other Western countries,[223] and reducing them is an important objective of Healthy People 2020.[224]

Conclusion

The results of our study can inform the public debate and policy related to the balance of costs and benefits of waiving Medicare beneficiaries' coinsurance for colonoscopy screening in instances where a polyp is removed or the procedure is a follow-up to a positive FIT result. We estimated that waiving coinsurance would be cost-effective if screening rates increased from 60.0 percent to 60.6 percent, assuming a willingness- to-pay threshold of $50,000 per QALY gained—which suggests that the waiver would likely have a very favorable balance of health and cost impact.

SUPPLEMENTARY METHODS

Supplementary Exhibit A6.1

TEST CHARACTERISTICS				
	Colonoscopy		*FIT*	
Specificity	86%[a]		96.4%	
Sensitivity[b] [Worst-Case –Best-Case][c]				
Adenoma 1-5 mm	75% [70.0-79.0%]		0.00% [0.00-0.00%][d]	
Adenoma 6-9 mm	85% [80.0-92.0%]		11.4% [8.30-15.2%]	
Adenoma 10+ mm	95% [93.1-99.5%]		15.9% [13.7-18.3%]	
Colorectal Cancer	95% [93.1-99.5%]		62.565/88.6% [48/81.1-75.3/93.4%][e]	
Reach	95% reaches the cecum			
Costs (2015 US$) [+10-75%]			21.65	
without polypectomy screening	699.41 [769.35-1049.12]			
without polypectomy diagnostic	591.42 [650.56-887.13] / 722.68 [794.95-1084.02][f]			
without polypectomy surveillance	682.06 [750.27-1023.09]			
with polypectomy	814.12 [895.53-1221.18]/ 982.40 [1080.64-1473.60][f]			
diagnosis of CRC by symptoms	814.12 [895.53-1221.18]			
Utility Loss (QALYs)	0.002 (1.5 day at 0.5 utility)		0	
COLORECTAL CANCER CARE				
Costs per LY CRC care[g] **(2015 US$)** [+10-75%]	*Initial care*	*Continuing care*	*Terminal care Death CRC*	*Terminal care Death other cause*
Stage I CRC	29,135	2,319	52,228 [57,451-91,399]	12,868
Stage II CRC	40,207	2,161	52,081 [57,289-91,141]	11,255
Stage III CRC	49,023 [53,925 – 85,790]	3,089	54,877 [60,365-96,035]	14,891
Stage IV CRC	64,015 [70,416 – 112,026]	9,573	73,649 [81,014-128,886]	39,980
Utility Losses per LY with CRC care[h]				
Stage I CRC	0.12	0.05	0.70	0.05
Stage II CRC	0.18	0.05	0.70	0.05
Stage III CRC	0.24	0.24	0.70	0.24
Stage IV CRC	0.70	0.70	0.70	0.70
COMPLICATIONS COLONOSCOPY				
	Costs (2015 US$)		*Utility losses*	
Serious gastrointestinal event[i]	6,665		0.0055 (4 days at 0.5 utility)	

Supplementary Exhibit A6.1 (*continued*)

TEST CHARACTERISTICS								
Other Gastrointestinal event[j]				4,749			0.0027 (2 days at 0.5 utility)	
Cardiovascular event[k]				5,205			0.0048 (3.5 days at 0.5 utility)	
ADHERENCES SIMULATED[l]								
Scenario	*Size stratum 1*	*Size stratum 2* [mn]	*Size stratum 3* [mn]	*Adh. scr.*	*Adh. next scr. if prev. adh.*[o]	*Adh. next scr. if prev. unadh.*[p]	*Adh. Diagnostic FU* [q] *& surv.*	*Adh.*
				----------*Stratum 1 and Stratum 2*---------				*Stratum3*
Current adherence	70%	0%	30%	85.71%[r]	90.00%	60.00%	80.00%	0
+5 %point FU and Surv.	70%	0%	30%	85.71%	90.00%	60.00%	85.00%	0
+5%point 1st Scr. FU and Surv.	70%	3.75%	26.25%	88.14%	91.25%	65.00%	85.00%	0
+10%point 1st Scr. FU and Surv	70%	7.5%	22.5%	90.32%	92.50%	70.00%	90.00%	0

CRC = colorectal cancer, Str. = Stratum, Adh = Adherence, Scr. = Screening, prev. = previously, FU = diagnostic follow-up, Surv. = Surveillance.

a. The lack of specificity with endoscopy reflects the detection of non-adenomatous lesions, where the non-adenomatous lesions are removed and therefore induce polypectomy and biopsy.

b. The sensitivity of colonoscopy for the detection of adenomas and CRC within the reach of the endoscope was obtained from a systematic review on miss rates observed in tandem colonoscopy studies [77] .We assumed the same test characteristics for diagnostic colonoscopy as for screening colonoscopy.

c. In the worst- and best-case test sensitivity FIT scenarios, the corresponding worst- and best-case values for colonoscopy were used.

d. We assumed that small adenomas do not bleed, and therefore cannot cause a positive stool test.

e. "Long" before clinical diagnosis / "Short" before clinical diagnosis.

f. CMS costs in the current state with coinsurance/ CMS costs if coinsurance is waived

g. CRC care costs were obtained from an analysis of 1998-2003 SEER-Medicare linked data [208] and updated to 2015 US dollars using the Consumer Price Index. CRC care was divided in three clinically relevant phases. The initial care phase was defined as the first 12 months after diagnosis, the terminal care phase as the final 12 months of life, and the continuing care phase as all months in between. For patients surviving less than 24 months, the last 12 months were allocated to the terminal care phase and the remaining months were allocated to the initial care phase. As these costs are derived from 2003 data, these costs exclude the potential use of expensive monoclonal antibodies cetuximab and bevacizumab as these received FDA approval for treatment of colorectal cancer in 2004. Therefore, we assumed 10%, 25%, 50% and 75% higher treatment costs for initial phase stage III and IV, and terminal care CRC death all stages.

h. Utility losses for LYs with initial care were derived from a study by Ness et al. [225]. For LYs with continuing care for stage I and II CRC, we assumed a utility loss of 0.05 QALYs; for LYs with continuing care for stage III and IV CRC, we assumed the corresponding utility losses for LYs with initial care. For LYs with terminal care for another cause, we assumed the corresponding utility losses for LYs with continuing care.

i. Serious gastrointestinal events are perforations, gastrointestinal bleeding, or transfusions. The rate depends on age, formula 1/[exp(9.27953 – 0.06105 x Age) + 1] – 1/[exp(10.78719 – 0.06105 x Age) + 1].

j. Other gastrointestinal events are paralytic ileus, nausea and vomiting, dehydration, or abdominal pain. The rate depends on age, formula 1/[exp(8.81404 – 0.05903 x Age) + 1] – 1/[exp(9.61197 – 0.05903 x Age) + 1].
k. Cardiovascular events are myocardial infarction or angina, arrhythmias, congestive heart failure, cardiac or respiratory arrest, syncope, hypotension, or shock. The rate depends on age, formula 1/[exp(9.09053 – 0.07056 x Age) + 1] – 1/[exp(9.38297 – 0.07056 x Age) + 1].
l. To reflect observed screening rates in the United States, the population of 10 million men and women was divided in three strata: stratum 1 (70%) contained current participants [226-228], stratum 2 (0-7.5%) contained additional participants, stratum 3 (30-22.5%) never attended screening.
m. In sensitivity analyses 5, we assumed that stratum 2 and stratum 3 have a relative risk of getting CRC of 1.2 compared to the population that attends irrespectively of costs, based on the study of Oliphant et al. [212].
n. We decreased the population that is never screened with the same proportion as the population that is currently not up to date with CRC screening by increasing the proportion of the population in stratum 2.
o. We assumed 90% adherence next screening if previously adherent [229, 230]. We decreased the population that not adheres to the next screening round if previously adherent by the same proportion as the population that is currently not up to date with CRC screening.
p. Calculated that overall adherence in next screening round remains the same.
q. Represents the adherence to a diagnostic colonoscopy after a positive FIT test.
r. Calculated as 60/70, which reflects the ratio up to date with screening compared to the people ever screened.

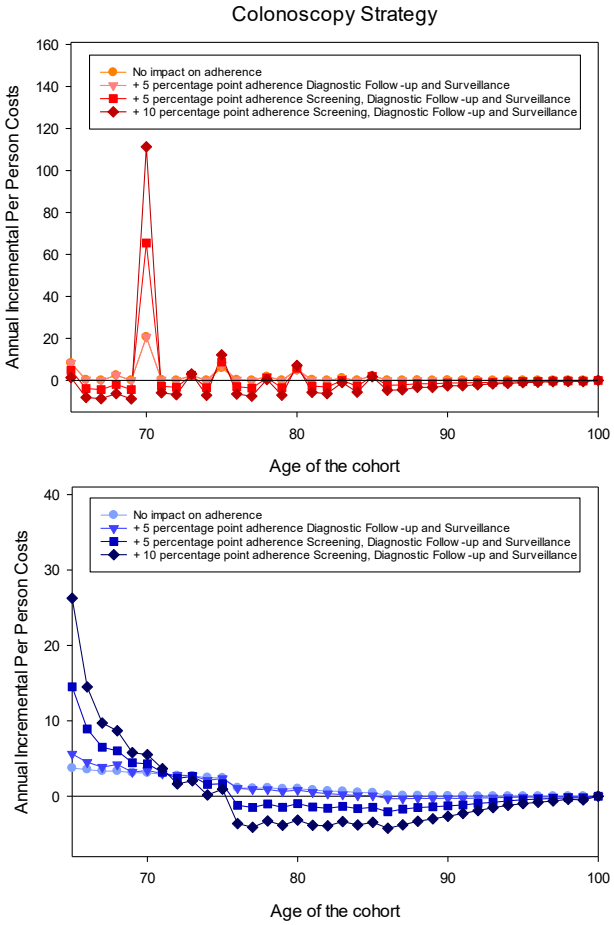
Supplementary Exhibit A6.2. Costs in million US dollars per 1,000 65-year-olds (3% discounted).

Category Scenario[a]	Screening costs	Diagnostic costs	Surveillance costs	Complications costs	CRC care costs	Total costs
No screening	0.000	0.034	0.000	0.005	3.236	3.276
Colonoscopy						
With coinsurance						
Current state	0.238	0.016	0.412	0.032	1.978	2.675
Without coinsurance						
No impact on adherence	0.252	0.016	0.449	0.032	1.978	2.726
With 5 percentage point increase in adherence diagnostic follow-up and surveillance.	0.252	0.016	0.452	0.032	1.977	2.728
With 5 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	0.283	0.014	0.468	0.034	1.910	2.708
With 10 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	0.314	0.013	0.488	0.036	1.840	2.692
FIT						
With coinsurance						
Current state	0.077	0.111	0.224	0.022	2.309	2.743
Without coinsurance						
No impact on adherence	0.077	0.131	0.246	0.022	2.309	2.785
With 5 percentage point increase in adherence diagnostic follow-up and surveillance.	0.076	0.136	0.253	0.023	2.296	2.783
With 5 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	0.083	0.148	0.263	0.024	2.255	2.772
With 10 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	0.089	0.166	0.281	0.025	2.196	2.758

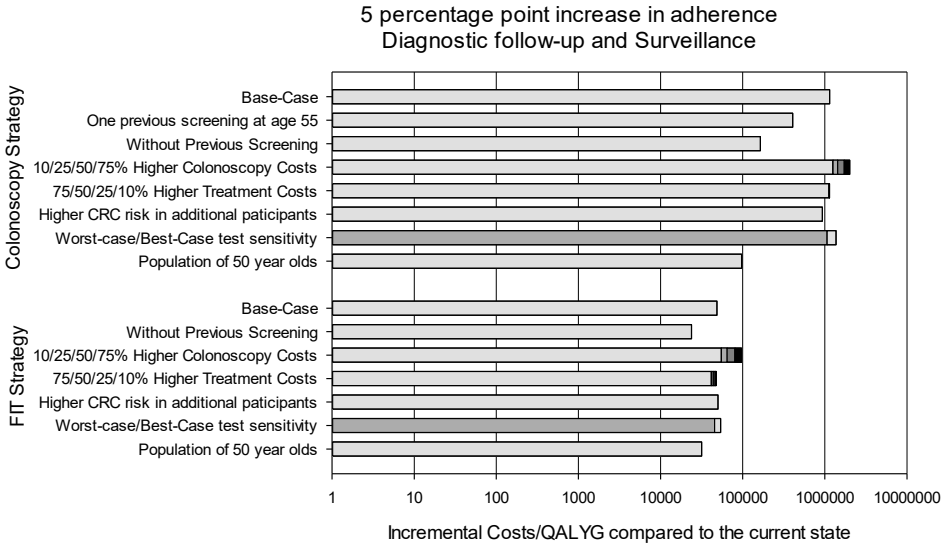
a. In the current state, we assumed a 60% adherence in first screening, an 80% adherence to diagnostic follow-up after a positive FIT, and an 80% adherence to surveillance. In the second scenario, coinsurance is waived without an effect on adherence. In the third scenario, waiving coinsurance is assumed to lead to a 5 percentage point increase in adherence to diagnostic follow-up and surveillance. In the fourth and the fifth scenario, we simulated a 5 percentage point and 10 percentage point increase in adherence to screening, diagnostic follow-up and surveillance as a consequence of coinsurance removal, respectively.

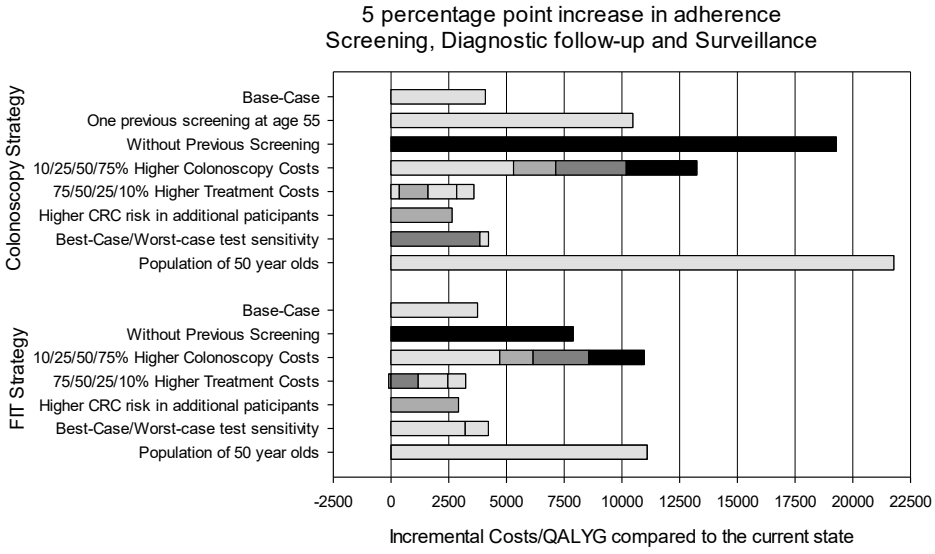
SUPPLEMENTARY EXHIBIT A6.3.

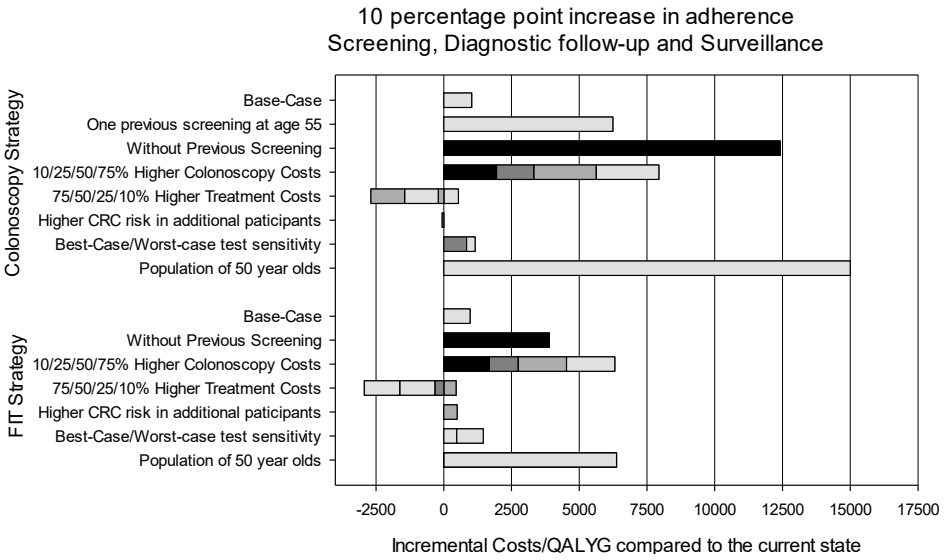
Annual incremental costs of waiving coinsurance from a CMS perspective (including costs of screening, diagnostic follow-up, and surveillance and savings of treatment, 3% discounted) compared to a situation without coinsurance removal by screening strategy and screening rate scenario. Most of the increase in costs would occur immediately upon waiving all coinsurance, while after a decade costs start to stabilize and decline due to costs savings in CRC treatment costs. In the graph of the colonoscopy strategy, the peaks reflect the screening and surveillance years.



SUPPLEMENTARY EXHIBIT A6.4.







Cost-effectiveness of waiving coinsurance for every component of CRC screening with alternative model assumptions if this coinsurance waiver would lead to a 5 percentage point increase in adherence diagnostic follow-up and Surveillance (top) or a 5 percentage point (middle) or a 10 percentage point (bottom) increase in adherence to screening, diagnostic follow-up and surveillance. The costs and QALY gained were compared to the current state, in which we assumed a 60% adherence in screening, an 80% adherence to diagnostic follow-up after a positive FIT, and an 80% adherence to surveillance. In the first sensitivity analysis, 60% of the cohort had one previous colonoscopy screening at the age of 55. We then simulated potential increases in screening uptake, benefits and costs due to waiving the Medicare coinsurance from age 65 years onward, implementing screening rounds at age 65 and 75. In the second sensitivity analyses, no screening before the age of 65 was assumed. In the third sensitivity analyses, we assumed 10-75% higher colonoscopy costs. The different shades of grey represent the cost-effectiveness of a 10%, 25%, 50% and 75% higher colonoscopy costs, respectively, where the results of assuming a 10% higher colonoscopy costs are shown in the lightest color, and the results of assuming a 75% higher colonoscopy costs are shown in black. In the fourth sensitivity analyses, 10-75% higher treatment cost for initial phase stage III and IV and for Terminal phase CRC care (all stages) were simulated. The different shades of grey represent the cost-effectiveness of a 75%, 50%, 25% and 10% higher treatment costs, respectively, where the results of assuming a 75% higher treatment costs is shown in the lightest color, and the results of assuming a 10% higher treatment costs are shown in black. In the fifth sensitivity analysis, we assumed that the population that only attends if coinsurance of every CRC screening component are fully waived and the population that never attends have a relative risk of getting CRC of 1.2 compared to the population that attends irrespectively of costs. In the sixth sensitivity analyses, we assumed Best-Case

(light grey) and Worst-Case (dark grey) test sensitivities. In the seventh sensitivity analysis, we simulated potential increases in screening rate, benefits and costs from age 50 onward.

SUPPLEMENTARY EXHIBIT A6.5.

Results sensitivity analyses: Quality-adjusted life-years gained and Total costs from a CMS perspective per 1,000 65-year-old Medicare Beneficiaries, by screening category, coinsurance requirement and screening rate scenario (3% discounted).

Category *Scenario*[a]	*Base-Case*		*One Previous Screening at age 55*		*Previously Unscreened*		*Higher colonoscopy costs (10-75%)*	
	QALY gained	**Total costs (million $)**	**QALY gained**	**Total costs (million $)**	**QALY gained**	**Total costs (million $)**	**QALY gained**	**Total costs (million $)**
No screening	0.0	3.276	0	3.211	0	2.832	0.0	3.279 – 3.302
Colonoscopy								
With coinsurance								
Current state	124.1	2.675	112.7	2.929	69.1	3.020	124.1	2.741 – 3.174
Without coinsurance								
No impact on adherence	124.1	2.726	112.7	2.996	69.1	3.105	124.1	2.798 – 3.263
With 5 percentage point increase in adherence diagnostic follow-up and surveillance.	124.1	2.728	112.9	3.000	69.7	3.114	124.1	2.800 –-3.268
With 5 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	132.2	2.708	120.6	3.012	75.2	3.138	132.2	2.785 – 3.281
With 10 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	140.4	2.692	128.6	3.028	81.4	3.172	140.4	2.773 – 3.303
FIT								
With coinsurance								
Current state	115.9	2.743	-	-	57.5	2.867	115.9	2.776 – 2.994
Without coinsurance								
No impact on adherence	115.9	2.785	-	-	57.5	2.913	115.9	2.822 – 3.068
With 5 percentage point increase in adherence diagnostic follow-up and surveillance.	116.7	2.783	-	-	59.2	2.909	116.7	2.822 – 3.075
With 5 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	123.7	2.772	-	-	63.2	2.912	123.7	2.813 – 3.080
With 10 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	131.6	2.758	-	-	68.9	2.912	131.6	2.803 – 3.093

Category *Scenario*[a]	*Higher Treatment costs (10-75%)b*		*Higher CRC Risk additional participantsc*		*Test Sensitivity (Worst-Case ; Best-Case)d*		*50-year-olds*	
	QALY gained	**Total costs (million $)**	**QALY gained**	**Total costs (million $)**	**QALY gained**	**Total costs (million $)**	**QALY gained**	**Total costs (million $)**
No screening	0.0	3.420 – 4.358	0	3.276	0	3.276	0	2.433
Colonoscopy								
With coinsurance								
Current state	124.1	2.745 – 3.201	116.8	2.731	120.8 ; 128.3	2.719 ; 2.628	75.4	2.835
Without coinsurance								
No impact on adherence	124.1	2.796 – 3.252	116.8	2.780	120.8 ; 128.3	2.770 ; 2.679	75.4	2.927
With 5 percentage point increase in adherence diagnostic follow-up and surveillance.	124.1	2.798 – 3.254	116.9	2.782	120.8 ; 128.3	2.772 ; 2.681	76.4	2.935
With 5 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	132.2	2.774 – 3.202	125.9	2.755	128.8 ; 136.5	2.753 ; 2.660	82.1	2.980
With 10 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	140.4	2.754 – 3.157	135.0	2.730	136.9 ; 144.8	2.737 ; 2.642	88.7	3.035
FIT								
With coinsurance								
Current state	115.9	2.817 – 3.301	109.5	2.779	106.5 ; 125.4	2.830 ; 2.644	70.8	2.491
Without coinsurance								
No impact on adherence	115.9	2.859 – 3.344	109.5	2.819	106.5 ; 125.4	2.871 ; 2.687	70.8	2.554
With 5 percentage point increase in adherence diagnostic follow-up and surveillance.	116.7	2.857 – 3.336	110.3	2.818	107.3 ; 126.1	2.871 ; 2.685	72.8	2.554

Category *Scenario*[a]	*Higher Treatment costs (10-75%)b*		*Higher CRC Risk additional participantsc*		*Test Sensitivity (Worst-Case ; Best-Case)d*		*50-year-olds*	
With 5 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	123.7	2.842 – 3.301	118.2	2.804	114.1 ; 133.5	2.862 ; 2.670	77.3	2.563
With 10 percentage point increase in adherence first screening, diagnostic follow-up and surveillance.	131.6	2.824 – 3.255	126.9	2.787	121.7 ; 141.7	2.852 ; 2.651	83.8	2.574

QALY = quality-adjusted life-years, gained compared to no screening; CRC= colorectal cancer

a. In the current state, we assumed a 60% adherence in first screening, an 80% adherence to diagnostic follow-up after a positive FIT, and an 80% adherence to surveillance. In the second scenario, coinsurance is waived without an effect on adherence. In the third scenario, waiving coinsurance is assumed to lead to a 5 percentage point increase in adherence to diagnostic follow-up and surveillance. In the fourth and the fifth scenario, we simulated a 5 percentage point and 10 percentage point increase in adherence, diagnostic follow-up and surveillance as a consequence of coinsurance removal, respectively.

b. In the fourth sensitivity analysis, we assumed a 10%, 25%, 50% and 75% higher treatment cost for initial phase stage III and IV and for Terminal phase CRC care (all stages) as the costs of CRC care were obtained from an analysis of 1998-2003 SEER-Medicare linked data which excludes costs for potential use of expensive monoclonal antibodies cetuximab and bevacizumab as these received FDA approval for treatment of colorectal cancer in 2004.

c. In the fifth sensitivity analysis, we assumed that the population that only attends if coinsurance of every CRC screening component is fully waived and the population that never attends have a relative risk of getting CRC of 1.2 compared to the population that attends irrespectively of costs.

d. We tested worst-case and best-case test sensitivity of FIT and colonoscopy. In the worst- and best-case test sensitivity FIT scenarios, the corresponding worst- and best-case values for colonoscopy were used.