Cost-Effectiveness of Waiving Coinsurance for Follow-Up Colonoscopy after a Positive Stool-Based Colorectal Screening Test in a Medicare Population

A. Mark Fendrick[1], David Lieberman[2], Vahab Vahdat[3], Jing Voon Chen[3], A. Burak Ozbay[3], and Paul J. Limburg[4]

ABSTRACT

Commercial insurance covers a follow-up colonoscopy after a positive colorectal cancer–screening test with no patient cost-sharing. Instituting a similar policy for Medicare beneficiaries may increase screening adherence and improve outcomes. The cost-effectiveness of stool-based colorectal cancer screening was compared across adherence scenarios that assumed Medicare coinsurance status quo (20% for follow-up colonoscopy) or waived coinsurance. The CRC-AIM model simulated previously unscreened eligible Medicare beneficiaries undergoing stool-based colorectal cancer screening at age 65 for 10 years. Medicare costs, colorectal cancer cases, colorectal cancer–related deaths, life-years gained (LYG), and quality-adjusted life-years (QALY) were estimated versus no screening. Scenario 1 (S1) assumed 20% coinsurance for follow-up colonoscopy. Scenario 2 (S2) assumed waived coinsurance without adherence changes. Scenarios 3–7 (S3–S7) assumed that waiving coinsurance increased real-world stool-based screening and/or follow-up colonoscopy adherence by 5% or 10%. Sensitivity analyses assumed 1%–4% increased adherence. Cost-effectiveness threshold was ≤$100,000/QALY. Waiving coinsurance without adherence changes (S2) did not affect outcomes versus S1. S3–S7 versus S1 over 10 years estimated up to 3.6 fewer colorectal cancer cases/1,000 individuals, up to 2.1 fewer colorectal cancer deaths, up to 20.7 more LYG, and had comparable total costs per-patient (≤$6,478 vs. $6,449, respectively) as reduced colorectal cancer medical costs offset increased screening and colonoscopy costs. In sensitivity analyses, any increase in adherence after waiving coinsurance was cost-effective and increased LYG. In simulated Medicare beneficiaries, waiving coinsurance for follow-up colonoscopy after a positive stool-based test improved outcomes and was cost-effective when assumed to modestly increase colorectal cancer screening and/or follow-up colonoscopy adherence.

Prevention Relevance: Follow-up colonoscopy after a positive stool-based test is necessary to complete the colorectal cancer-screening process. This analysis demonstrated that in a simulated Medicare population, waiving coinsurance for a follow-up colonoscopy improved estimated outcomes and was cost-effective when it was assumed that waiving the coinsurance modestly increased screening adherence.

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Introduction

Stool-based tests represent an effective, convenient colorectal cancer–screening option for average-risk individuals. Follow-up colonoscopy after a positive stool-based test is necessary to complete the screening process (1, 2). Screening colonoscopy reduces colorectal cancer incidence and mortality, but many exams do not reveal neoplasia. Follow-up colonoscopy after a positive stool-based test has at least a 2-fold higher yield of advanced neoplasia and cancer versus screening colonoscopy (3), resulting in an estimated 3-times higher life-year gained (LYG), prevention of 4-times more colorectal cancer cases, and prevention of 2-times more colorectal cancer–related deaths based on recent modeling analyses (4). Initial average-risk colorectal cancer screening with any of the United States Preventive Screening Task Force-recommended screening test options is fully covered by Medicare (1). As of January 1, 2023, commercial insurance plans in the US will be required to cover a follow-up colonoscopy with no patient cost-sharing (5). However, Medicare beneficiaries may still be responsible for cost-sharing, including 20% coinsurance, deductibles, and copayments for a follow-up colonoscopy. In a 2021 analysis (6), over three quarters of Medicare claims for follow-up colonoscopy after a stool-based colorectal

[1]Division of General Medicine, Departments of Internal Medicine and Health Management and Policy, University of Michigan, Ann Arbor, Michigan. [2]Division of Gastroenterology and Hepatology, School of Medicine, Oregon Health and Science University, Portland, Oregon. [3]Exact Sciences Corporation, Madison, Wisconsin. [4]Division of Gastroenterology and Hepatology, Mayo Clinic, Rochester, Minnesota.

Corresponding Author: A. Mark Fendrick, University of Michigan, North Campus Research Complex, 2800 Plymouth Rd, Building 16/4th floor, Ann Arbor, MI 48109. Phone: 734-647-9688; Fax: 734-936-8944; Email: amfen@med.umich.edu

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cancer–screening test had associated cost-sharing. Mean (SD) out-of-pocket costs ranged from $99 ($290) to $231 ($481) depending on the original screening test used. The out-of-pocket costs for follow-up colonoscopy were even higher when a polyp was found and removed. Therefore, the 20% coinsurance for a follow-up colonoscopy to complete the colorectal cancer–screening process may pose a financial hardship for some Medicare recipients.

Studies have shown that the elimination of patient cost-sharing increased the use of screening colonoscopy for Medicare beneficiaries who did not have supplemental insurance (7, 8). Similarly, removing the cost barrier for follow-up colonoscopy may increase total colorectal cancer–screening rates as well as screening completion, thereby improving outcomes (9–11). Accordingly, the objective of this analysis was to compare the cost-effectiveness of stool-based colorectal cancer screening using the status quo for follow-up colonoscopy coinsurance (20% coinsurance) with the scenarios that waived the coinsurance and had various impacts on total colorectal cancer–screening rates and adherence to follow-up colonoscopy in a simulated Medicare population.

Materials and Methods

Microsimulation model

The analyses were conducted using the Colorectal Cancer and Adenoma Incidence and Mortality (CRC-AIM) microsimulation model. Validation of the CRC-AIM model has been previously described (12, 13). Natural history modeling for colorectal cancer describes the adenomacarcinoma sequence in the absence of screening for a large population of individuals. The model simulates individuals with normal colorectal tissue with the risk of developing one or more precancerous adenomas that may transition to symptomatic cancer, replicating the US 1975–1979 colorectal cancer incidence. The model also simulates colorectal cancer–screening strategies where screening decreases the incidence and mortality of colorectal cancer by the detection and subsequent removal of adenomas and preclinical colorectal cancer during a screening colonoscopy or follow-up colonoscopy after a positive stool-based test. However, the effectiveness of the screening (either by colonoscopy or stool-based test) is affected by the test performance (sensitivity and specificity) and how often an individual is screened (adherence; refs. 12, 14). Thus, the screening component of the model contains assumptions about screening test performance and adherence. Details of the CRC-AIM natural history and screening components have been previously described (12, 13). Variations of the screening component assumptions used in the current analysis are described below.

Analysis

The model simulated a population of 2 million average-risk previously unscreened eligible US Medicare beneficiaries free of diagnosed colorectal cancer at age 40 who underwent triennial multitarget stool DNA (mt-sDNA), annual fecal immunochemical test (FIT), or annual high-sensitivity guaiac fecal occult blood test (FOBT) screening at age 65 years for 10 years. Sensitivity and specificity of the stool-based tests were identical to those used in the base case of a 2021 decision analysis for colorectal cancer screening prepared by the Cancer Intervention and Surveillance Modeling Network (Supplementary Table S1; ref. 14). Outcomes were calculated independently for mt-sDNA, FIT, and FOBT, and then the weighted average of the outcome was calculated, scaled by their proportional

Table 1. Estimated outcomes per 1,000, 65-year-old, previously unscreened Medicare patients over 10 years of screening by screening and follow-up scenarios.

Scenario	Coinsurance (%)	Screening adherence rate	Follow-up COL adherence rate	LYG vs. no screening[c]	CRC case[c]	CRC death[c]	Incremental Medicare costs per-patient vs. status quo[d]	Incremental QALYs per-patient vs. status quo[d]	ICER vs. status quo
S1 (status quo)	20	RW[a]	RW[b]	65.2	69.3	30.0	—	—	—
S2	0	RW	RW	65.2	69.3	30.0	$42.45	0	NA
S3	0	RW + 5%	RW	70.2	68.6	29.6	$29.71	0.0019	$15,294.61
S4	0	RW	RW + 5%	72.4	68.2	29.3	$5.18	0.0028	$1,845.87
S5	0	RW	RW + 10%	78.8	67.2	28.7	−$26.93	0.0051	Dominant
S6	0	RW + 5%	RW + 5%	75.8	67.4	29.0	−$9.26	0.0042	Dominant
S7	0	RW + 10%	RW + 10%	85.9	65.7	27.9	−$50.40	0.0081	Dominant

Abbreviations: CRC, colorectal cancer; COL, colonoscopy; ICER, incremental cost-effectiveness ratio; NA, not applicable; QALYs, quality-adjusted life years; RW, real-world; S1, 20% coinsurance for follow-up COL after a positive stool test and real-world adherence for the initial stool-based screening and the follow-up COL; S2, waived follow-up COL coinsurance and no impact on adherence rates for screening and follow-up COL; S3, waived follow-up COL coinsurance and 5% increase in real-world screening adherence; S4, waived follow-up COL coinsurance and 5% increase in real-world follow-up COL adherence; S5, waived follow-up COL coinsurance and 10% increase in real-world follow-up COL adherence; S6, waived follow-up COL coinsurance and 5% increase in both real-world screening and follow-up COL adherence; S7, waived follow-up COL coinsurance and 10% increase in both real-world screening and follow-up COL adherence.

[a]RW screening adherence was assumed to be 73.6% with multitarget stool DNA, 42.6% with fecal immunochemical test, and 33.4% with fecal occult blood test.

[b]RW follow-up COL adherence was assumed to be 71.5% with multitarget stool DNA, 46.7% with fecal immunochemical test, and 46.7% with fecal occult blood test.

[c]Per 1,000 individuals screened among previously unscreened 65-year-old over 10-year screening period.

[d]Over 10-year screening period.

estimated use in the US general population ages 65–75 years. Estimated use of each stool-test was based on 2018 National Health Interview Survey data (mt-sDNA, 26%; FIT, 54%; FOBT, 20%; refs. 15, 16).

In the primary analysis, 8 scenarios were modeled (**Table 1**). Scenario 1 (S1, the status quo) assumed 20% coinsurance for follow-up colonoscopy after a positive stool test and assumed real-world adherence for the initial stool-based screening and the follow-up colonoscopy. Real-world adherence was based on published literature and for initial screening was 73.6% for mt-sDNA (17), 42.6% for FIT (18), and 33.4% for FOBT (18) and for follow-up colonoscopy was 71.5% after positive mt-sDNA (19), 46.7% after positive FIT (19), and 46.7% after positive FOBT (assumed to be identical to FIT). Scenario 2 (S2) waived the follow-up colonoscopy 20% coinsurance and assumed no impact on adherence rates for screening and follow-up colonoscopy. Scenarios 3 through 7 waived the follow-up colonoscopy 20% coinsurance and assumed real-world screening and/or follow-up colonoscopy adherence rates used for the status quo increased by 5% or 10% in varying combinations (**Table 1**).

Outcomes

Outcomes estimated over the 10 year modeling period were costs [screening, colonoscopy (follow-up/surveillance/diagnostic), colonoscopy complications (serious gastrointestinal events, other gastrointestinal events, and cardiovascular events), colorectal cancer–related direct medical, and total costs], LYG, percentage reductions in colorectal cancer–related incidence and mortality, quality-adjusted life years (QALY), and incremental cost-effectiveness ratio (ICER; $/QALY). LYG, colorectal cancer cases, and colorectal cancer–related deaths were calculated per 1,000 individuals compared with no screening. Costs and QALYs were calculated per-patient. The willingness-to-pay threshold for cost-effectiveness was $100,000/QALY gained. All individuals were simulated until death, and a 3% discount rate was applied to both costs and QALYs.

Model inputs

The cost of a colonoscopy was assumed to be $1528 based on a published US claims database analysis (20). The costs of colonoscopy complications were assumed to be $9,069 for gastrointestinal, $25,855 for serious gastrointestinal, and $11,628 for cardiovascular based on a budget impact model of colorectal cancer screening (21). The costs of FIT ($18.05), FOBT ($4.38), and mt-sDNA ($508.87) were determined from the 2021 Centers for Medicare and Medicaid Services Clinical Laboratory Fee Schedule (22). Colorectal cancer–related direct medical costs [e.g., initial care, continuous care, and terminal care (death and non-death) for Stages I–IV] were the same as those used in a cost-effectiveness analysis of mt-sDNA for colorectal cancer screening (23). All costs were adjusted to November, 2021 US dollars using the Medical Care Services component of the Consumer Price Index (24).

Utility inputs for the model were based on a cost-effectiveness analysis of stool-based colorectal cancer screening (25), which included EQ-5D population norms for the general utility (26), −0.0055 for colonoscopy (27), and −0.0384 for colonoscopy complications (e.g., gastrointestinal, serious gastrointestinal, and cardiovascular; ref. 27). Colorectal cancer utility inputs were for Stage I–III initial care (−0.15), Stage I–III continuous care (−0.10), Stage I–III terminal care, colorectal cancer death (−0.29), Stage I–III terminal care, non-colorectal cancer death (−0.10), Stage IV initial care (−0.34), Stage IV continuous care (−0.29), Stage IV terminal care, colorectal cancer death (−0.29), and Stage IV terminal care, non-colorectal cancer death (−0.29; refs. 27, 28).

Sensitivity analyses

Sensitivity analyses were conducted assuming a waived follow-up colonoscopy 20% coinsurance and using absolute increases of 1%, 2%, 3%, 4% to real-world screening adherence rates, real-world follow-up colonoscopy adherence rates, or both. Results were presented alongside the assumed increases of 5%, and 10% used in the primary analyses. Outcomes were ICER ($/QALY) or LYG (per 1,000 individuals screened) for each percentage of increase in adherence versus the status quo.

Data availability

The data generated in this study are available within the article. CRC-AIM demonstrates the approach by which existing colorectal cancer models can be reproduced from publicly available information and provides a ready opportunity for interested researchers to leverage the model for future collaborative projects or further adaptation and testing. To promote transparency and credibility of this model, CRC-AIM's formulas and parameters are available on a public repository (https://github.com/CRCAIM/CRC-AIM-Public).

Results

Waiving coinsurance assuming no impact on adherence to screening or follow-up colonoscopy (S1 vs. S2)

In the scenario where waiving the 20% coinsurance for a follow-up colonoscopy was assumed to have no impact on screening and/or follow-up colonoscopy adherence (S2), the incremental Medicare cost per patient screened increased by $42.45 compared with the status quo (S1), with no additional clinical benefits (**Table 1**).

Waiving coinsurance assuming modest impact on adherence to screening or follow-up colonoscopy (S1 vs. S3–7)

In scenarios where waiving coinsurance was assumed to modestly increase screening and/or follow-up colonoscopy adherence (S3–S7), over the 10-year screening period up to 3.6 fewer colorectal cancer cases (range, 0.7–3.6) and up to 2.1 fewer colorectal cancer–related deaths (range, 0.4–2.1) per 1,000 individuals were observed versus the status quo, resulting in up to 20.7 more LYG (range, 5.0–20.7; **Table 1**). Total

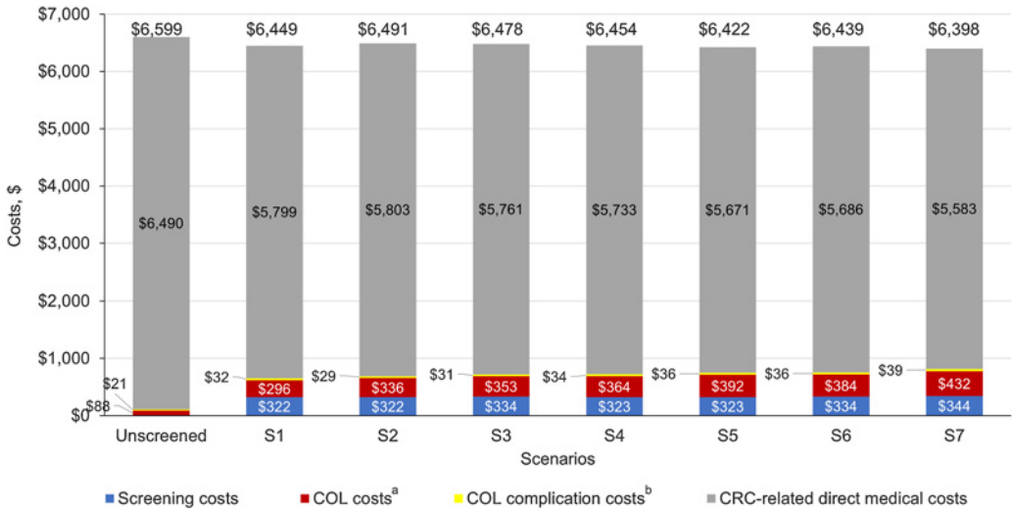

Figure 1.

Per-patient Medicare costs by screening and follow-up scenarios over 10 years of screening. [a]Includes costs of follow-up/surveillance/diagnostic colonoscopy. [b]Colonoscopy complications include serious gastrointestinal events, other gastrointestinal events, and cardiovascular events. COL, colonoscopy.

QALYs in scenarios S3–S7 (range, 9.3662–9.3724) were greater than the status quo (9.3643).

Ten-year, per-patient colorectal cancer–screening Medicare costs of $322 with the status quo increased in scenarios S3–S7 (range, $323–$344). Colonoscopy costs of $296 with the status quo also increased (range, $353–$432). However, colorectal cancer–related per-patient direct medical costs of $5,799 with the status quo decreased in scenarios S3–S7 (range, $5,583–$5,761), resulting in total Medicare costs in scenarios S3–S7 (**Fig. 1**; range, $6,398–$6,478) that were comparable with the status quo ($6,449). Stool-based testing in scenarios S3–S7 was either more effective and less costly or cost-effective compared with the status quo (**Table 1**).

In sensitivity analyses, any assumed increase in colorectal cancer–screening adherence and/or follow-up colonoscopy adherence of 1% or more as a consequence of waiving the follow-up colonoscopy coinsurance was cost-effective (ICER ≤$61,063; **Fig. 2A**). LYG increased by 2%–32% at any assumed increase in screening and/or follow-up colonoscopy adherence relative to no change in adherence (**Fig. 2B**).

Discussion

Average-risk colorectal cancer–screening guidelines clearly state that a positive on stool test results require a follow-up colonoscopy to complete the screening evaluation. The importance of a follow-up colonoscopy after a positive stool-based test was demonstrated in a retrospective cohort study of 111,423 patients with a positive FIT test in Italy, in which the 10-year cumulative mortality and risk of dying from colorectal cancer was found to be more than double in patients who did not have a follow-up colonoscopy than in those who did have a follow-up colonoscopy (29). Although there are many identified barriers to follow-up colonoscopy adherence (19, 30, 31), previous research has demonstrated that out-of-pocket costs for Medicare beneficiaries who undergo colonoscopy after a stool screening test are common and increase when additional endoscopic interventions such as polypectomy is performed (6), potentially decreasing patient participation with this potentially life-saving procedure or creating other financial hardship. Indeed, a February 2022 President Cancer Panel report states: "Since these colonoscopies are part of the screening process, they should be covered by insurance at no cost to patients" (32).

In this simulated average-risk Medicare population, a policy that removes patient coinsurance for follow-up colonoscopy was found to improve clinical outcomes and was also cost-effective (and often cost saving) when the analysis assumed that waiving coinsurance led to a minimum 1% increase in adherence. The increased adherence led to fewer colorectal cancer cases and deaths, which in turn led to cost-savings in colorectal cancer–related direct medical costs, lessening the overall costs.

If, and to what extent, colorectal cancer–screening completion would increase after removal of Medicare coinsurance for follow-up colonoscopy is unclear and the magnitude of increase differs widely based on the methodology used to estimate screening rates (33). In addition, changes in adherence after removing cost barriers likely will differ based on demographics and socioeconomic status. One study of Medicare-aged individuals found that removing the coinsurance for screening colonoscopy increased the probability of having a screening colonoscopy by 4% in men, with no increase seen in women (34). Two patient surveys indicated that removing patient cost-sharing significantly increased the use of screening colonoscopy by 9.8% to 12.0% in Medicare beneficiaries who did not have private insurance and by 5.7% in Medicare beneficiaries living in poverty (7, 8). In contrast, a Medicare

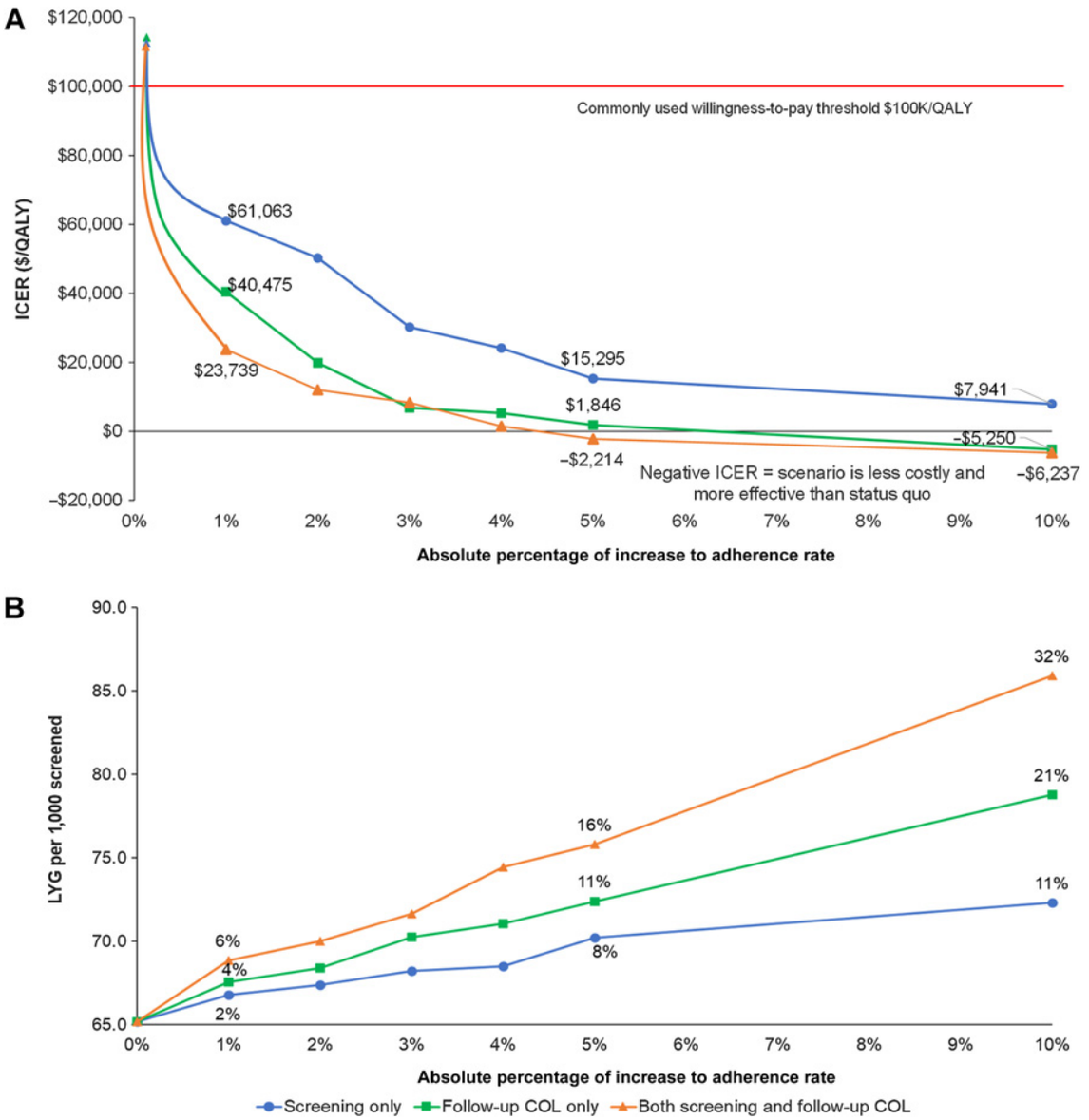

Figure 2.

A, Incremental cost-effectiveness ratio (ICER) and **B,** Life-years gained (LYG) per individual by absolute increases in adherence rates for colorectal cancer screening, follow-up colonoscopy (COL), or both. Adherence rates are assumed to increase as a consequence of waiving coinsurance for follow-up colonoscopy. **A,** ICER, theoretical ICER approaches infinity as adherence approaches 0% due to incremental QALYs approaching zero. **B,** LYG, data labels above each marker represent the percentage of increase in LYG relative to no change in adherence.

claims database analysis of high-risk individuals ≥70 years old and an analysis of Medicare Current Beneficiary Survey data linked to Medicare claims found that removing patient cost-sharing had no significant effect on the probability of receiving a screening or surveillance colonoscopy (35, 36). A 2022 study comparing colorectal cancer screening rates in states with and without cost-sharing found that full coverage significantly increased overall colorectal cancer screening and the use of non-invasive testing in one instance, but did not increase the utilization of colonoscopy for those who received an initial non-invasive screening test, indicating that factors other than cost can contribute to screening barriers (11).

Another recently published modeling analysis evaluated the impact of waiving follow-up colonoscopy coinsurance from a Medicare perspective (9). Assuming a 5% increase in adherence to both FIT-based screening (base case 60% adherence) and follow-up colonoscopy (base case 80% adherence) resulted in 106.2 LYG, prevented 1.0 colorectal cancer cases, prevented 0.8 deaths, and was cost-effective at $3,747/QALY gained per 1,000 65-year-old Medicare beneficiaries. Under the applied

assumptions, the previously reported analysis found that increasing adherence by as little as 0.3% to FIT-based initial screening was cost-effective at a threshold of $100,000/QALY. Together with the current analysis, available model simulations indicate that even very small increases in colorectal cancer–screening adherence resulting from removal of follow-up colonoscopy coinsurance would likely result in improved colorectal cancer outcomes and be cost-effective from a Medicare perspective.

A limitation of this analysis is that it did not include the costs of patient deductibles or copayments. These costs are difficult to model because they vary by patient depending on how much of the deductible has been met by payments for medical reasons other than colorectal cancer screening, and copayments depend on the Medicare plan and type of healthcare visit or service. Modeling waiving of deductibles and copayments would numerically increase the ICER but would not change the directionality of the current results.

Recently, President Biden reignited the Cancer Moonshot effort with the goal of reducing the cancer death rate by 50% over the next 25 years and recognized the role that cancer screening must play if these goals are to be achieved (37). More specifically, the Moonshot issued a call-to-action to leverage at-home screening tests for colorectal cancer as a way to help ensure equitable access to screening and prevention (37). In addition, the recently enacted Removal of Barriers to Colorectal Cancer Screening Act eliminates Medicare coinsurance for polyp removal performed during a screening colonoscopy over an 8-year period. Although an important step forward, this policy pertains only to screening colonoscopy and not to recommended non-invasive colorectal cancer–screening modalities. Given cancer prevention goals, existing disparities in colorectal cancer–screening use, and the current findings, Medicare policy changes to eliminate patient cost-sharing for a follow-up colonoscopy after a positive non-invasive colorectal cancer–screening test should be implemented without delay.

Authors' Disclosures

A.M. Fendrick reports personal fees from Exact Sciences outside the submitted work; and reports providing consulting services to AbbVie, Amgen, Bayer, California Health Care Foundation, CareFirst Blue Cross Blue Shield, Centivo, Community Oncology Association, Covered California, EmblemHealth, GRAIL, Harvard University, Health & Wellness Innovations Inc., Health[at]Scale Technologies, HealthCorum, Hygieia, Livongo, MedZed Inc., Merck & Co, Mercer, Montana Health Co-op, Mother Goose Health LLC, Pair Team, Penguin Pay, Phathom Pharmaceuticals, Risalto, Risk International, Sempre Health, Silver Fern Healthcare, the State of Minnesota, US Department of Defense, Virginia Center for Health Innovation, Wellth Inc., Wildflower Health Inc., Yale-New Haven Health System, Zansors; has equity interest in Health & Wellness Innovations, Health[at]Scale Technologies, Pair Team, Sempre Health, Wellth Inc., Zansors; receiving research support from the Agency for Healthcare Research and Quality, Boehringer Ingelheim, West Health Policy Center, Arnold Ventures LLC, National Pharmaceutical Council, Patient-Centered Outcomes Research Institute, Pharmaceutical Research and Manufacturers of America, the Robert Wood Johnson Foundation, the State of Michigan, and the Centers for Medicare & Medicaid Services; serving as coeditor for the American Journal of Managed Care and a member of the Medicare Evidence Development & Coverage Advisory Committee; and maintaining a partnership at VBID Health LLC. D. Lieberman reports other support from ColoWrap, other support from Geneoscopy, other support from Freenome, and other support from Ironwood outside the submitted work. V. Vahdat reports other support from Exact Sciences and other support from Exact Sciences during the conduct of the study; other support from Exact Sciences and Exact Sciences outside the submitted work. J.V. Chen reports other support from Exact Sciences Corporation and other support from Exact Sciences Corporation during the conduct of the study; other support from Exact Sciences Corporation and Exact Sciences Corporation outside the submitted work. A.B. Ozbay reports other support from Exact Sciences Inc. and other support from Exact Sciences Inc. during the conduct of the study. P.J. Limburg reports other support from Exact Sciences during the conduct of the study; other support from Exact Sciences outside the submitted work; and reports as a Chief Medical Officer for Screening at Exact Sciences through a contracted services agreement with Mayo Clinic as well as reports contractual rights to receive royalties through this agreement.

Authors' Contributions

A.M. Fendrick: Conceptualization, visualization, methodology, writing–review and editing. **D. Lieberman:** Conceptualization, visualization, methodology, writing–review and editing. **V. Vahdat:** Resources, software, formal analysis, methodology, writing–review and editing. **J.V. Chen:** Resources, software, formal analysis, validation, methodology, writing–review and editing. **A.B. Ozbay:** Conceptualization, supervision, methodology, project administration, writing–review and editing. **P.J. Limburg:** Conceptualization, visualization, methodology, writing–review and editing.

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Note

Supplementary data for this article are available at Cancer Prevention Research Online (http://cancerprevres.aacrjournals.org/).

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