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Commentary

Coverage for the Entire Cervical Cancer Screening Process Without Cost-Sharing: Lessons From Colorectal Cancer Screening

Allison Ruff, MD, MPHE [a,*], Diane M. Harper, MD, MPH [b,c,d], Vanessa Dalton, MD [c], A. Mark Fendrick, MD, MPH [a]

[a] *Department of Internal Medicine, University of Michigan, Ann Arbor, Michigan*
[b] *Department of Family Medicine, University of Michigan, Ann Arbor, Michigan*
[c] *Department of Obstetrics and Gynecology, University of Michigan, Ann Arbor, Michigan*
[d] *Department of Women and Gender Studies, University of Michigan, Ann Arbor, Michigan*

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Section 2713 of the Patient Protection and Affordable Care Act (ACA) includes provisions requiring that all ACA Marketplace and non-grandfathered private health plans eliminate cost-sharing (i.e., avoid charging copayments or coinsurance, regardless of whether the plan deductible has been met) for specific preventive health services, including screening for four common cancers: breast, cervical, colorectal, and lung. The primary motivation for removing consumer cost-sharing was to enhance access and reduce well-documented disparities in preventive care use. The U.S. Department of Health and Human Services has estimated that in 2020, 151.6 million people had access to free preventive care under the ACA (Office of the Assistant Secretary for Planning and Evaluation, 2022). A recent review reported that removing cost-sharing boosts the use of preventive services, which helps to decrease disparities and save lives (Norris et al., 2022).

This popular ACA provision is not without its limitations. One important shortcoming is that "full coverage" often includes only the initial screening test used to determine the presence or absence of a disease. This limitation is especially germane to cancer screening, because the completion of the cancer screening process may necessitate multiple additional tests to determine if malignancy is present (or not). Thus, in many cases, after receiving an abnormal initial test result, patients are often faced with a substantial financial barrier to completing the diagnostic process for breast, cervical, colorectal, and lung cancers (Institute of Healthcare Policy and Innovation, 2022). This incremental expense may worsen the emotional stress experienced during the period between the initial abnormal test result and the establishment of a definitive diagnosis—recently referred to as "the cancer screening purgatory" (Tradeoffs Podcast, 2022). Unified processes and advocacy are needed to bring about true full coverage for the entire cancer screening process. In this article, we recommend steps for achieving such full coverage of the cervical cancer screening process, based on successful efforts regarding colorectal cancer.

The American Medical Association criteria are that a screening test must be safe to administer, reasonably priced, able to detect a high percentage of disease, lead to improvement in health outcomes, and be widely available, as must be any downstream interventions that are required after a positive test (Herman, 2006). This explicit mention of downstream interventions is important, because it is rare for a single cancer screening test to determine the presence of malignancy.

Consumer cost-sharing is associated with decreased use of evidence-based health care services and has been shown to worsen health disparities (Norris et al., 2022). The requirement that patients pay substantial amounts out of pocket to complete

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* Corresponding author. Allison Ruff, MD, MPHE, Department of Internal Medicine, University of Michigan, 1500 E Medical Center Dr, Ann Arbor, MI 48103. Phone: (734) 998-2020.

E-mail address: alliruff@med.umich.edu (A. Ruff).

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the screening process is likely a contributor to the suboptimal screening follow-up rates for breast, cervical, colorectal, and lung cancers, for which early detection has been established to improve patient-centered outcomes.

Take breast cancer screening as an example. Screening mammography is mandated by the ACA to be fully covered without cost-sharing by insurance plans. However, necessary diagnostic testing after the initial screening can come with out-of-pocket charges to patients. A study published in *JAMA* in 2021 reported that, among commercially insured women aged 40–64 years, the out-of-pocket costs for additional breast imaging evaluations and procedures after screening were common, nontrivial, and increasing over time (Lowry, Bell, Fendrick, & Carlos, 2021).

It is possible that even the limited existing protection against cost-sharing for preventive screening services will disappear given the recent federal judicial opinion in *Braidwood Management v Beccera* (Hughes, Chappel, & Walters, 2022). Specifically, the decision refers to the ACA preventive care mandate, which requires that services receiving an A or B recommendation from the U.S. Preventive Services Task Force (USPSTF) be covered without consumer cost-sharing. The judge ruled that recommendations from the USPSTF are unconstitutional because the Task Force—authorized by the U.S. Congress to convene since 1998—is an independent, volunteer panel of national experts in prevention and evidence-based medicine and is not appointed by the president and confirmed by the senate. This ruling has potentially important clinical, equity, and cost implications, because preventive care is important for individuals and public health. If this impactful and popular ACA provision survives litigation, USPSTF and U.S. Department of Health and Human Services should act to ensure it covers the full range of screening services.

The Elimination of Cost-sharing Improved the Entire Colorectal Cancer Screening Process

In response to a well-organized, multistakeholder campaign that incorporated scientific evidence, policy change for colorectal cancer screening ensued. The evidence presented included 1) underserved populations and Black Americans are disproportionately impacted by colorectal cancer (Siegal, DeSantis, & Jemal, 2014); 2) missed screenings, later colorectal cancer presentation, and worsened disparities in screening have been caused by the coronavirus disease 2019 pandemic (Balzora, Issaka, Anyane-Yeboa, Gray II, & May, 2020); 3) cost-sharing for follow-up diagnostic colonoscopy after an initial test was common (Fendrick, Princic, Miller-Wilson, Wilson, & Limburg, 2021); 4) cost-sharing for preventive services causes negative health and equity impacts (Norris et al., 2022); and 5) the elimination of cost-sharing for cancer screening tests increases the use of preventive services and decreases disparities (Norris et al., 2022).

In January 2022, the Biden Administration issued new guidance released as part of the "FAQs about Affordable Care Act Implementation Part 51" (FAQs) requiring that commercial insurers eliminate cost-sharing for diagnostic colonoscopy following an abnormal noninvasive colorectal cancer screening test (Departments of Labor, Health and Human Services, and the Treasury, 2022). The Medicare program followed suit several months later by including a similar policy in the 2023 Centers for Medicare and Medicaid Services payment rule, stating that effective January 1, 2023, a follow-on screening colonoscopy after a noninvasive stool-based test returns a positive result will be covered without patient cost-sharing (Centers for Medicaid and Medicare Services, 2022).

This feasible, low-cost policy will likely increase colorectal cancer screening uptake, enhance equity, and ultimately reduce colorectal cancer morbidity and mortality, especially for patient groups that underuse these potentially life-saving interventions. Similar policies that remove financial barriers to completing the screening process for cervical, breast, and lung cancers are warranted.

The Case to Remove Cost-sharing for the Entire Cervical Cancer Screening Process

Despite highly effective screening methodologies, cervical cancer remains a cause of significant morbidity and mortality. Disparities remain in screening, follow-up, and treatment. Black women are more likely to be diagnosed with late-stage cervical cancer, even after receipt of appropriate screening (Francoeur et al., 2022). White women diagnosed with cervical cancer have a 5-year survival rate of 71%, whereas for Black women it is 58%. For Black women over the age of 65, the 5-year survival rate is only 39%. Contributing factors include differences in tumor histology and stage at diagnosis as well as access to screening programs and follow-up care (Perkins et al., 2021).

A recent analysis of claims data reported that 8 out of 10 commercially insured women 21–65 years old who required a diagnostic workup for an abnormal cervical cytology and/or human papillomavirus (HPV) test (e.g., colposcopy and biopsy) incurred nontrivial out-of-pocket costs (Fendrick, Dalton, Tilea, Malone, & Moniz, 2022). Moreover, the out-of-pocket cost burden increased over the past 20 years (Centers for Medicaid and Medicare Services, 2022). It is possible that the financial burden associated with cost-sharing contributes to the sobering statistic that 51% of women with abnormal cervical cancer screening do not complete a recommended colposcopy (Perkins et al., 2021).

This suboptimal follow-up rate has important equity implications, as incompletion rates were substantially worse for Black and older women (Tsui, Llanos, Doose, Rotter, & Stroup, 2019). Given the clear clinical parallels between the multistep colorectal and cervical cancer screening processes, federal policymakers should extend the recent national guidance eliminating cost-sharing for the entire colorectal cancer screening process to cervical cancer screening.

Replicating the Colorectal Cancer Advocacy Process

Step 1: Establish Regulatory Authority

Because the ACA relies on the USPSTF to implement a national coverage policy, explicit language regarding screening follow-up in the USPSTF recommendation is required.

For example, the ACA FAQ document that mandates that commercial plans fully cover follow-up diagnostic colonoscopy quoted the following statement from the 2021 update of the USPSTF colorectal cancer screening guidelines: "Positive results on stool-based screening tests require follow-up with colonoscopy for the screening benefits to be achieved" (Departments of Labor, Health and Human Services, and the Treasury, 2022). Additionally, the final recommendation statement includes: "Abnormal findings identified by flexible sigmoidoscopy or [computed tomography] colonography screening require follow-

up colonoscopy for screening benefits to be achieved" (USPSTF, 2021).

Consistent with the colorectal cancer example, the 2018 USPSTF guidelines for cervical cancer screening includes a similar statement about need for follow-up: "Strategies that aim to ensure that all women are appropriately screened and receive adequate follow-up are most likely to succeed in further reducing cervical cancer incidence and mortality in the United States" (USPSTF, 2018). Future USPSTF cervical cancer screening updates, including the update currently in process, should further emphasize the importance of follow-up testing.

Analogous reasoning implies that the Biden Administration has the regulatory authority to implement a requirement that commercial plans eliminate out-of-pocket costs for needed follow-up testing after an initial abnormal screening test to confirm the diagnosis of cervical cancer.

Step 2: Provide Data to Support the Policy Change

As noted elsewhere in this article, an analysis of commercially insured women between 21 and 65 years of age reported that out-of-pocket costs for women who underwent colposcopy—the most common diagnostic procedure after an initial abnormal test—are common and significant and have increased between 2006 and 2019(Fendrick, Dalton, Tilea, Malone, & Moniz, 2022).

Over this period, at least 79% of colposcopy episodes had some patient cost-sharing. This very high likelihood of cost-sharing for cervical cancer diagnostic testing was substantially greater than the 48% of commercially insured patients who paid out-of-pocket for a diagnostic colonoscopy after a noninvasive colorectal cancer screening test. In both studies, out-of-pocket costs increased as the number of interventions needed to complete the diagnostic process (e.g., polypectomy, cervical biopsy) grew.

The fiscal implications of removing consumer cost-sharing are important to policymakers. In the colorectal cancer screening example, published modeling studies concluded that waiving cost-sharing for follow-up colonoscopy after a positive stool-based test improved patient outcomes and was cost-effective—and potentially cost-saving—when colorectal screening and/or follow-up colonoscopy adherence modestly increased (Francoeur et al., 2022; Fendrick, Lieberman, et al., 2022).

Similar modeling studies are underway to estimate the clinical and economic impact of a policy that would eliminate out-of-pocket costs for cervical cancer diagnostic testing. Preliminary results suggest that the cost savings incurred from earlier cancer detection, a shift in screening modality toward primary HPV testing and away from cytology, and reduction in unnecessary (i.e., too frequent) cervical cancer screening would cover the added costs required to fully cover necessary diagnostic testing.

A growing body of clinical and economic evidence supports the implementation of a national policy to eliminate out-of-pocket costs for necessary follow-up testing after an initial abnormal screening test to confirm the diagnosis of cervical cancer.

Step 3: Engage and Align with Federal Policymakers

The Biden–Harris Administration recently relaunched the Cancer Moonshot, setting ambitious goals to cut the rate of cancer deaths by one-half over the next 25 years and to improve the clinical experience for individuals diagnosed with cancer (White House, 2022). An important component of this far-reaching initiative is a strong recommitment to decreasing the well-documented disparities in the prevention, diagnosis, and treatment of cancer.

This version of the Moonshot pays careful attention to cancer screening and early detection, calling for solutions that support patients through the entire cancer screening process until a diagnosis of cancer is made (or not).

In addition, the President's Cancer Panel Report (2022) highlights access to cancer screening and explicitly addresses coverage for follow-up care, stating

> Cancer screening effectiveness depends on timely follow-up care and diagnostic resolution after an abnormal screening test result. There currently are insufficient data on follow-up for abnormal lung cancer screening results, but gaps in follow-up have been documented for mammography, cervical cytology and HPV tests, and stool-based tests.

There is significant alignment between the removal of cost-sharing for cervical cancer diagnostic testing with federal policy goals related to cancer care and equity given that, as noted elsewhere in this article, Black Americans are disproportionately impacted by cervical cancer, and there is ample evidence that the coronavirus disease 2019 pandemic has worsened these disparities.

Step 4: Build a Multistakeholder Coalition of Patient Advocates and Key Professional Societies

The American Cancer Society, American College of Radiology, National Colorectal Cancer Roundtable, and American Gastroenterological Association all made formal statements endorsing follow-up colonoscopy as an integral part of the screening process that should be covered with no patient cost. A comparable group of professional societies that address cervical cancer screening has begun an advocacy campaign to bring attention to this issue.

Currently, the National Women's Health Network and the American Cancer Society Cancer Action Network are advocating that follow-up colposcopy is a necessary part of the screening process, and other large organizations—including the American Society for Colposcopy and Cervical Pathology, American College of Obstetricians and Gynecologists, and American Academy of Family Physicians—should do the same. A broad coalition of stakeholders who support the elimination out-of-pocket costs for necessary follow-on testing after an initial abnormal screening test to confirm the diagnosis of cervical cancer can sound the alarm for change.

Step 5: Communicate with Decision-Makers

The coalition is embarking on a communication campaign like those colorectal cancer advocacy groups used to reach to congressional and administration leaders. The campaign proposes an expansion of the regulatory definition of cervical cancer screening to include follow-up after a covered initial cervical cancer screening test returns a positive result.

Closing Arguments

The substantial morbidity from cervical cancer in the United States is largely preventable. In addition to HPV vaccination,

evidence-based screening is a cornerstone of prevention efforts that requires more than one procedure for many of those who receive it. Although a single screening test can usually rule out this disease, 3 million women yearly in the United States undergo a colposcopy procedure (Wentzensen et al., 2015). At least another 3 million have abnormal cervical cancer screening tests and have not returned for follow-up (Tsui et al., 2019; Perkins et al., 2020).

To achieve the ambitious goal of eliminating cervical cancer, or at least decreasing the well-known disparities in care, policies should incorporate well-established evidence, including following. 1) Patients of color and those with fewer financial resources are less likely to be screened and receive follow-up for an initial positive screening test, and therefore are more likely to be diagnosed with, and die of, cervical cancer. 2) Eliminating out-of-pocket cost increases the chances that a patient will receive a timely diagnosis and needed care. 3) Finally, the positive health and economic effects of policies that improve screening and follow-up rates will disproportionally benefit underserved populations.

Now that federal guidance requires private and public payers to eliminate cost-sharing for the complete colorectal cancer screening and diagnostic process, a similar policy to decrease the health, emotional, and financial burden of completion of the entire cervical cancer screening process is warranted. Free cervical cancer screening should include primary HPV screening, cytology screening, HPV genotyping, biomarker triage, colposcopy, and associated pathology costs of biopsy and endocervical curetting, all of which are needed in informing the best treatment.

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Author Descriptions

Allison Ruff, MD, MHPE, is a Clinical Associate Professor in Internal Medicine at the University of Michigan. Research interests include women's health, preventative care, and medical education.

Diane M. Harper, MD, MPH, MS, is a tenured Professor of Family Medicine, Obstetrics and Gynecology, and Women's and Gender Studies at the University of Michigan. She is an internationally renowned physician-scientist improving cervical cancer prevention at all stages.

Vanessa Dalton is the Timothy R B Johnson M. D. Collegiate Professor of Global Women's Health and Associate Chair in the Department of Obstetrics and Gynecology at the University of Michigan.

A. Mark Fendrick is a Professor of Internal Medicine in the School of Medicine and a Professor of Health Management and Policy in the School of Public Health at the University of Michigan, where he directs the Center for Value Based Insurance Design.