

Reallocating Cervical Cancer Preventive Service Spending from Low to High-Value Clinical Scenarios

Running Title: Cervical Cancer Screening/ Follow-up Care Policy

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CONFLICT OF INTEREST DECLARATION: J.N. Mafi reported grants from the National Institute on Aging (NIA) during the conduct of the study, as well as non-financial support from Milliman MedInsight and grants from Arnold Ventures. J.N. Mafi was also supported by a NIH/NIA Beeson Emerging Leaders in Aging Research Career Development Award (grant K76AG064392-01A1). S.D. Armbruster was an iTHRIV Scholar during the study period. The iTHRIV Scholars Program is supported in part by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Numbers UL1TR003015 and KL2TR003016. A.M. Fendrick reports other support and has been a consultant for AbbVie, Amgen, Bayer, Centivo, Community Oncology Association, Covered California, EmblemHealth, Exact Sciences, Freedman, Health, GRAIL, Harvard University, Health and Wellness, Innovations, Health at Scale Technologies, HealthCorum, Hygieia, MedZed, Merck, Montana, Health Cooperative, Pair Team, Penguin Pay, Phathom Pharmaceuticals, Rialto, Risk International, Sempre Health, State of Minnesota, U.S., Department of Defense, Virginia Center for Health Innovation, Wellth, Wildflower Health, Yale-New Haven Health System, Zansors, as well as equity interest research: AHRQ, Boehringer-Ingelheim, Gary and Mary West Health Policy Center, Arnold Ventures, National Pharmaceutical Council, PCORI, PhRMA, RWJ Foundation, State of Michigan/CMS. M.S. Rockwell, J.N. Mafi, and A.M. Fendrick, J.C. Capucão (funded author), and K.B. Russell (funded author) worked on the Smarter Care Virginia initiative (Virginia Health Innovation), which is funded by Arnold Ventures, during the conduct of this study.

ABSTRACT

Timely follow-up care after an abnormal cervical cancer screening test result is critical to the prevention and early diagnosis of cervical cancer. The current inadequate and inequitable delivery of these potentially life-saving services is attributed to several factors, including patient out-of-pocket costs. Waiving of consumer cost-sharing for follow-up testing (e.g., colposcopy and related cervical services) is likely to improve access and uptake, especially among underserved populations. One approach to defray the incremental costs of providing more generous coverage for follow-up testing is reducing expenditures on 'low value' cervical cancer screening services. To explore the potential fiscal implications of a policy that redirects cervical cancer screening resources from potentially low to high-value clinical scenarios, we analyzed 2019 claims from the Virginia All-Payer Claims Database to quantify: 1) total spending on low-value cervical cancer screening and 2) out-of-pocket costs associated with colposcopy and related cervical services among commercially-insured Virginians. In a cohort of 1,806,921 female patients (aged 48.1 ± 24.8 years), 295,193 claims for cervical cancer screening were reported, 100,567 (34.0%) of which were determined to be low-value (\$4,394,361 total; \$4,172,777 for payers and \$221,584 out-of-pocket [\$2/patient]). Claims for 52,369 colposcopy and related cervical services were reported (\$40,994,016 total; \$33,457,518 for payers and \$7,536,498 out-of-pocket [\$144/patient]). These findings suggest that reallocating savings incurred from unnecessary spending to fund more generous coverage of necessary follow-up care is a feasible approach to enhancing cervical cancer prevention equity and outcomes.

PREVENTION RELEVANCE

Out-of-pocket fees are a barrier to follow-up care after an abnormal cervical cancer screening test. Among commercially-insured Virginians, out-of-pocket costs for follow-up services averaged \$144/patient; 34% of cervical cancer screenings were classified as low-value. Reallocating low-value cervical cancer screening expenditures to enhance coverage for follow-up care can improve screening outcomes.

2507 words

INTRODUCTION

In 2022, the Biden Administration relaunched the ‘Cancer Moonshot’, a national effort to reduce the cancer death rate by 50% within 25 years.¹ In support of this endeavor, the 2022 report of the President’s Cancer Panel focuses on effective and equitable implementation of cancer prevention services, explicitly recommending that “*access to cancer screening, follow-up testing, and treatment should not depend on a patient’s ability to pay*”.² Section 2713 (2011) of the Patient Protection and Affordable Care Act (ACA) requires full payer coverage with no patient out-of-pocket costs (i.e.: copays, deductibles, coinsurance) for preventive services receiving a Grade A or B rating from the U.S. Preventive Services Task Force (USPSTF) (e.g., breast, cervical, colorectal, and lung cancer screening).³ This preventive care mandate has led to important clinical, equity, and cost implications. In their recent rapid review, Norris et al.⁴ concluded that the elimination of patient cost-sharing has increased uptake of preventive services, particularly among financially vulnerable populations. Overall, the U.S. Department of Health and Human Services estimated that in 2020, 151.6 million people accessed free preventive care under the ACA.⁵

The ACA provision, however, is not without limitations. One important shortcoming is that “full coverage” often includes only the *initial* screening test. This limitation is especially germane to cancer screening since abnormal initial screening results necessitate additional testing to determine the presence of malignancy. For example, most insurers cover 100% of costs for initial cervical cancer screening tests (cervical cytology, human papillomavirus (HPV), or cervical cytology/HPV cotesting) (TABLE 1) regardless of appropriateness, but often do not fully cover high-value, guideline-concordant follow-up care (e.g., colposcopy and related services). Fendrick et al.⁶ found that nearly 80% of colposcopy and related cervical services incurred by commercially-insured patients were associated with out-of-pocket costs (range: \$20 to \$1499) and that patient cost-sharing for these services increased over time. Presently, less than 50% of patients with abnormal cervical cancer screening tests receive appropriate follow-up care, with lowest rates among racial/ethnic minorities and those living in poverty.^{7–9} As “*lack of timely follow-up care after an abnormal screening test result undermines the effectiveness of screening*” (2022 Report of the President’s Cancer Panel)² and financial concerns are commonly cited barriers to cervical cancer screening and follow-up care,¹⁰ elimination of out-of-pocket costs for colposcopy and related cervical services is essential to enhancing the effectiveness and equity of cervical cancer prevention.

Recent federal policy changes related to colorectal cancer screening require that most private insurers, as well as the Medicare program, cover follow-up colonoscopy after a positive stool-based test without patient cost-sharing beginning in January 2023.¹¹ No similar federal policy exists for breast, cervical, and lung cancer screening. More generous coverage of colposcopy and other clinically-indicated follow-up testing is likely to improve outcomes, increase efficiency, and reduce disparities. Removal of out-of-pocket-costs for follow up care also has economic implications. Treatment costs for cancers detected at earlier stages are substantially lower than costs of treatment for more advanced cancer.^{12,13} However, short-term costs would likely increase

with the removal of patient cost barriers, resulting from a predicted increase in total screening rates (as has been demonstrated with colorectal cancer¹⁴), and a rising proportion of patients receiving appropriate follow-up care. One potential strategy for defraying these increased costs is to redirect funds presently spent on low-value cervical cancer screening (inconsistent with professional guidelines) (TABLE 1). In the U.S., up to 65% of cervical cancer screening tests have been classified as low-value.^{15,16} In addition to potentially wasteful expenditures, consequences of low-value cervical cancer screening may include patient distress and care cascades (i.e.: unnecessary follow-up procedures).^{17,18} Moreover, reallocating low-value expenditures to more generous coverage (reduced patient out-of-pocket-costs) for high-value preventive healthcare represents an important opportunity to improve outcomes while reducing potential harm.

The purpose of this study was to quantify expenditures dedicated to cervical cancer preventive care and to explore the potential fiscal implications of a policy that redirects cervical cancer screening resources from low to high-value clinical scenarios. Using insurance claims data, we quantified 1) total spending on low-value cervical cancer screening tests and 2) out-of-pocket costs associated with colposcopy and related cervical services among commercially-insured Virginians in 2019.

MATERIALS AND METHODS

This cross sectional, observational study involved the analysis of insurance claims from the Virginia All-Payer Claims Database (APCD). The APCD collects medical and pharmaceutical claims for 5.5 million Virginians insured by public and private payers. We limited this analysis to adult (aged ≥ 18 years) females (APCD data include only “male” and “female” sex data) who were continuously-enrolled with a commercial payer for >12 months in 2019. We selected 2019 for the focus of our study since it occurred before the COVID-19 pandemic, during which cancer screening declined.¹⁹ The Institutional Review Board of Carilion Clinic determined that this study does not meet the definition of human subjects research as outlined in 45 CFR 46.102(d) and therefore did not require IRB oversight or approval.

Cervical Cancer Screening Tests

From the APCD, we extracted all claims for cervical cytology, HPV, or cervical cytology/HPV co-testing occurring in 2019 (see Supplementary Table S1 for codes). We used the Milliman Medinsight Health Waste Calculator, proprietary algorithm-driven software applied broadly in research and practice,^{20–23} to classify these claims as high or low-value based on guidelines outlined in TABLE 1. All analyses included patients for whom at least 5 years of data were available since the look-back period for the cervical cancer screening measure is 5 years. We analyzed all available historical data (even beyond 5 years, when available). Detailed criteria for claims classification are included in Supplementary Table S2. Patients’ age, medical history, and cervical cancer screening test information available within claims data were used to classify high and low-value care. For example, a claim for CPT 87624 (*infectious agent detection by nucleic acid: HPV*) for a 40-year-old patient

with no history of abnormal screening or high-risk medical conditions, and whose most recent cervical cytology test occurred more than three years ago, would also be classified as high-value. A similar claim would be classified as potentially low-value had it been submitted for a 19-year-old average-risk patient, as guidelines recommend that screening begin at age 21.²⁴

Total costs, payer costs, and patient out-of-pocket costs were obtained from claim line data in the APCD. We verified that APCD data was comparable to costs reported in the literature^{6,25} and those reported by a local health system in terms of total costs and patient cost-sharing.

Colposcopy and Related Cervical Services

From the APCD, we extracted all claims for colposcopy-related encounters in 2019. We excluded claims for patients who were not continuously-enrolled for one year following the initial colposcopy. Informed by the methods of Fendrick et al.,⁶ colposcopy and related cervical services were categorized into one of three groups: **1)** colposcopy without biopsy or cervical procedure, **2)** colposcopy with biopsy within 60 days of initial colposcopy, and **3)** colposcopy with loop electrode biopsy or conization within 60 days of initial colposcopy (see Supplementary Table S3 for codes).⁶ Total costs, payer costs, and patient out-of-pocket costs were obtained and verified as described above.

Statistical Analysis

Rate of utilization was expressed as annual service use per 1000 patients. Cost rate (total, payer, and patient out-of-pocket costs) was reported as annual dollars per 1000 patients. Descriptive statistics (i.e. frequencies, means, standard deviations) were calculated at the direction of study co-authors using Statistical Package for the Social Sciences (SPSS, RRID:SCR_002865) v.28.0 (IBM, Chicago, IL).

Data Availability

The data analyzed in this study were obtained from the Virginia APCD, which is generated under authority of the Virginia Department of Health (<http://www.vhi.org/APCD/>).

RESULTS

The study cohort was comprised of 1,806,921 female patients (aged 48.1 + 24.8 years) (TABLE 2). Of the 295,193 cervical cancer screening claims reported in 2019, 100,567 (34.0%) were classified as potentially low-value (TABLE 3). The cost of potentially low-value screenings was \$4,394,361: \$4,172,777 for payers and \$221,584 for patients. (TABLE 3). The average out-of-pocket cost for potentially low-value screenings was \$2 overall. Only 4 of 15 parent payers reported out-of-pocket costs, so the majority of potentially low-value screenings were associated with \$0 of patient cost sharing.

After excluding the 6,773 claims for patients not enrolled for >12 months following the initial colposcopy, there were 52,369 claims for colposcopy and related cervical services reported in 2019. The majority of claims included a colposcopy and an additional service (e.g., biopsy, LEEP, etc.) within 60 days of the initial colposcopy. Patient out-of-pocket costs for colposcopy and related cervical services totaled \$7,536,498, with an average out of pocket cost of \$144 (mean: colposcopy only-\$98; colposcopy + biopsy-\$108; colposcopy + other procedures-\$300) (TABLE 4).

DISCUSSION

In the U.S., cervical cancer screening rates remain below national targets, less than half of patients with an abnormal screening test result receive appropriate follow-up care, and disparities in screening and outcomes persist.^{7,8,26} At the same time, delivery of unnecessary cervical cancer screening services is prevalent. This misallocation of resources compelled our exploration of the fiscal feasibility of a policy that redirects cervical cancer prevention dollars from low to high-value clinical scenarios. We found that one-third of commercial cervical cancer screening claims reported to the Virginia APCD in 2019 – a total cost of more than \$4 million per year – were not concordant with evidence-based guidelines. Meanwhile, patients undergoing high-value cervical cancer screening follow-up testing were required to pay substantial out-of-pocket costs (\$7.5 million, mean \$144 per patient). The savings incurred through a reduction in potentially low-value screening could fund a substantial proportion of the patient out-of-pocket costs associated with follow-up care subsequent to an initial abnormal cervical cancer screening test result.

The USPSTF, American Society for Colposcopy and Cervical Pathology (ASCCP), American College of Obstetricians and Gynecologists (ACOG), and Women's Preventive Services Initiative recommend that most abnormal cervical cancer screening tests be followed-up with colposcopy.^{2,24,27} Presently, the rate of follow-up after abnormal initial screening tests is inadequate, with significantly lower rates in low-income individuals, those living in rural regions, and racial/ethnic minorities, – populations with higher incidence of cervical cancer and related mortality.^{2,7,8} The COVID-19 pandemic exacerbated these disparities.¹⁹ Lack of timely follow-up care – perpetuated by non-trivial out of pocket costs - undermines the effectiveness of cervical cancer screening programs. In alignment with the Biden Cancer Moonshot and 2022 President's Cancer Panel, innovative approaches to improving access to screening and uptake of colposcopy and related cervical services are needed.² Elimination of out of pocket costs for follow-up care is one such approach.

We report that in 2019, the average out-of-pocket cost for colposcopy and related cervical services was \$144 per patient (higher for patients who needed more complex testing), similar to previous research.⁶ With 50% of Americans reporting difficulty affording healthcare and 40% delaying medical care due to costs,²⁸ it is understandable that these non-trivial follow-up costs would be prohibitive. Costs, perceived costs, and concerns about costs have been identified as critical barriers to completion of the cervical cancer diagnostic

process.^{9,10} The incremental expense may worsen emotional stress experienced during the period between the initial abnormal test result and the establishment of a definitive diagnosis - recently referred to as “cancer screening purgatory”.¹⁸ Further, in addition to the burden of not knowing whether or not cancer is present, those who forgo recommended follow-up care often are diagnosed at later stages that require more invasive and costly treatment. Importantly, beginning in January 2023, federal policy requires many payers to fully cover the costs of required follow-up care after an initial abnormal colorectal cancer screening result.^{11,29} A similar state-level policy resulted in a modest uptake in screening rates.¹⁴ Policy reform to support more generous coverage for cervical cancer screening and follow-up care would offer comparable benefits, particularly for patients at greatest risk for poor outcomes.

More than one-third of cervical cancer screening tests delivered to commercially-insured Virginians in 2019 were classified as potentially low-value. This rate is lower than the 65% low-value rate previously identified within a commercially-insured population, likely due to variation in age of inclusion.¹⁶ Low-value cervical cancer screening exists among publicly-insured patients as well; a recent report described 1.3 million Medicare fee-for-service patients receiving >\$83 million of potentially low-value cervical cancer screening services in 2019.³⁰ Multiple drivers of low-value cervical cancer screening have been described in the literature, including patient request, clinician disagreement with recommendations, concerns about missing a diagnosis, lack of time to discuss with patients, and opposing health system goals.^{16,31} Considering the potential psychological, physical, and financial harms associated with low-value cervical cancer screening, provider- and patient-facing approaches to de-implementation are needed. Changes in payer coverage have proven effective in the reduction of low-value care.³² As such, reallocation of expenditures from low-value screening to high-value follow-up care after an abnormal cervical cancer screening test result could be dually beneficial to improving the quality, equity and efficiency of women’s healthcare. It is unclear whether the four parent payers who reported patient cost-sharing for low-value cervical cancer screening in the present study provided lower coverage due to the unnecessary nature of the service or if cost-sharing was in place for all screenings, which continues in a small percentage of cases despite ACA provisions.²⁵

We acknowledge several study limitations. First, we only analyzed commercial claims reported in Virginia in 2019. Although our cohort included representation from each Virginia region and was comprised of urban and rural-residing patients, future studies should incorporate public payers and a nationally-representative cohort to assure generalizability of findings. Second, our analysis was limited to de-identified, population-level, aggregated data available from the APCD. Thus, our study lacks detail and nuance that may be ascertained from individual and/or medical chart data (e.g. history of hysterectomy may be difficult to ascertain, history of in utero DES exposure was not considered in the analysis). Third, the Milliman Health Waste calculator algorithms are based on claims data, which are similarly limited by lack of detailed information and may result in misclassification of claims as high or low-value. Additionally, for analyses of colposcopy and related

procedures, we generally reproduced the methodology of Fendrick et al.,⁶ making analytical decisions to err in the direction of overinclusion of data as opposed to undercounting follow-up care after abnormal cervical cancer screening. This potential overinclusion reflects <11% of claims analyzed. Fourth, our analysis of low-value cervical cancer screening services included costs for the tests themselves, but not the associated downstream care cascades, which add substantial costs. For example, Kim et al.³³ reported that for every \$1 spent on low value prostate cancer screening, \$6 was spent on resultant care cascades. Therefore, our findings likely underrepresent actual costs of low-value care. It is also possible that our findings overrepresent the actual costs of colposcopy and related care since we were unable to evaluate diagnosis codes associated with these services and a minority may not have been associated with cancer prevention/follow-up. Fifth, the analysis did not account for potential increases in initial screening and follow-up care (and the associated costs) that may result from proposed policy changes. Finally, cervical cancer screening guidelines have changed and continue to evolve. Our analysis used data from 2019, just one year after the USPSTF released updated screening recommendations.²⁴

CONCLUSIONS

The ACA provision that requires elimination of out-of-pocket costs for preventive services does not currently extend to follow-up care after an abnormal initial screening exam. Lack of timely follow-up care undermines the effectiveness of cervical cancer screening programs. The preponderance of underinsurance for follow-up care coupled with the high prevalence of potentially low-value cervical cancer screening warrants the consideration of payment reform and benefit design initiatives that incentivize the delivery of fewer screening tests not supported by evidence-based guidelines. The savings incurred could be redirected to pay for more generous coverage for potentially life-saving colposcopy and related cervical services, a reallocation that stands to improve patient-centered outcomes and enhance health equity.

ACKNOWLEDGEMENTS

FUNDING STATEMENT

This study was supported, in part, by a grant from Arnold Ventures (Smarter Care Virginia). J.C. Capucio and K.B. Russell were partially funded by Arnold Ventures. Publication fees were covered by the Virginia Tech Open Access Subvention Fund.

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TABLE 1. Recommendations for Routine Cervical Cancer Screening in Average-Risk Women (High-Value vs. Low-Value)

HIGH-VALUE SCREENING
<p>Average-risk women aged 21 to 29 years:</p> <ul style="list-style-type: none"> -cervical cytology[†] every 3 years (USPSTF, Grade A) <p>Average-risk women aged 30 to 65 years:</p> <p><i>One of the following-</i></p> <ul style="list-style-type: none"> -cervical cytology every 3 years -high-risk human papillomavirus (hrHPV) testing every 5 years -combination cervical cytology/hrHPV testing (cotesting) every 5 years (USPSTF, Grade A)
LOW-VALUE SCREENING
<p>Any screening in women aged <21 years. (USPSTF, Grade D)</p> <p>Any screening in women aged >65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer. (USPSTF, Grade D)</p> <p>Screening in women who have had a hysterectomy (with removal of the cervix) and do not have a history of cervical cancer or high-grade precancerous lesion. (USPSTF, Grade D)</p> <p>Screening at more frequent intervals than recommended above in HIGH-VALUE SCREENING.</p>

[†]cervical cytology is also known as Papanicolaou testing (or Pap test/Pap smear)

Recommendations from the US Preventive Services Task Force (2018), endorsed by the American Society for Colposcopy and Cervical Pathology (ASCCP), American College of Obstetricians and Gynecologists (ACOG), and Women's Preventive Services Initiative.

These recommendations apply to individuals with a cervix who do not have signs or symptoms of cervical cancer (regardless of sexual history and HPV vaccination status) and are not identified as high-risk (e.g., history of cervical cancer or high-grade precancerous lesion, in utero exposure to diethylstilbestrol, HIV infection, or a compromised immune system).

TABLE 2. Demographics of commercially-insured female patient cohort from the Virginia All-Payer Claims Database (N=1,806,921)

	n (%)
Age	18 to 39: 1,468,534 (44.7) 40 to 64: 1,639,370 (49.9) 65 to 79: 144,554 (4.4) >80: 32,853 (1.0)
Virginia Region	Central: 620,924 (18.9) Eastern: 60,203 (20.4) Northern: 841,040 (25.6) Northwest: 361,384 (17.1) Southwest: 624,209 (19.0)

TABLE 3. Utilization and Costs associated with High and Low-value Cervical Cancer Screening Tests among Commercially Insured Patients in Virginia in 2019

<i>Screening Test</i>	High-value screenings total utilization	Low-value screenings total utilization	Low-value screenings total costs	Low-value screenings payer costs	Low-value screenings patient costs
<i>Cervical cytology alone</i>	49,462	20,559	\$417,900	\$409,471	\$8,429
<i>HPV alone</i>	30,131	31,487	\$1,271,276	\$1,196,506	\$74,770
<i>Cytology/HPV co-testing</i>	117,754	55,800	\$2,705,184	\$2,566,800	\$138,384
Overall	194,626 (66.0% of screenings)	100,567 (34.0% of screenings)	\$4,394,361	\$4,172,777 (99.5% of total costs)	\$221,584 (.05% of total costs)
Overall Rate (per 1000 patients)	107.7	55.6	\$2432	\$2309	\$123
Mean cost per service			\$43	\$41	\$2

Codes used in the analysis and criteria for high and low-value screenings can be found in Supplementary Table S2.

TABLE 4. Utilization and Costs of Colposcopy and Related Cervical Services among Commercially Insured Patients in Virginia in 2019

<i>Colposcopy or Cervical Service</i>	utilization	total costs	payer costs	patient costs
<i>colposcopy</i>	7,117 (13.6% of overall utilization)	\$3,647,630	\$2,949,452	\$698,178
<i>colposcopy with biopsy</i>	32,347 (61.8% of overall utilization)	\$14,804,796	\$11,841,202	\$2,963,594
<i>Colposcopy with other procedure</i>	12,905 (24.6% of overall utilization)	\$24,880,840	\$18,666,834	\$3,874,726
Overall	52,369	\$40,994,016	\$33,457,518 (81.6% of total costs)	\$7,536,498 (18.4% of total costs)
Overall Rate (per 1000 patients)	28.9	\$22,687	\$18,516	\$4,170
Mean cost per service		\$783	\$639	\$144

This table depicts the utilization and costs (total, payer, and patient) for colposcopy and related cervical services in Virginia in 2019. Colposcopy and related cervical services are divided into colposcopy without biopsy or cervical procedure, colposcopy with biopsy within 60 days of initial colposcopy; and colposcopy with loop electrode biopsy or conization within 60 days of initial colposcopy. See Supplementary Table S3 for codes.⁶