

OBSTETRICS & GYNECOLOGY



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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

**The corresponding author has opted to make this information publicly available.*

Personal or nonessential information may be redacted at the editor's discretion.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office:
obgyn@greenjournal.org.

Date: Jul 23, 2021
To: "A. Mark Fendrick" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-1359

RE: Manuscript Number ONG-21-1359

Out-of-Pocket Costs for Colposcopy Among Commercially Insured Women from 2006-2019

Dear Dr. Fendrick:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

Please be sure to address the Editor comments (see "EDITOR COMMENTS" below) in your point-by-point response.

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Aug 13, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

The article by Fendrick et al shows that cost-sharing for patients with health insurance for colposcopy continues to increase. The authors suggest that this cost may be a barrier in patients obtaining the procedure. I have the following observations.

1. Most patients undergoing colposcopy will get a biopsy at that time or at least an endocervical curettage. It is a little unclear to me if the "colposcopy without biopsy" group were those with an ecc tissue sample or not. In figure 2, is the "colposcopy with additional services" a group with any tissue sampling, whether biopsy and/or ecc, or just a subsequent LEEP or other procedure? The difference between the groups in Figure 2 is relatively small (\$10-20) so I am unclear what elements of the process receive a cost sharing (pathologist?). These issues are important in developing meaningful health policies.

2. The number of colposcopies performed continues to decrease due to changes in recommendations by the ASCCP and other bodies. Currently patients under 25 with ASCUS are returning for follow-up paps, for example. This has changed during the period of this study. Additionally, patient with HGSIL are now referred directly for LEEP, which eliminates them from initial colposcopy. The number of colposcopies will continue to decline as the HPV-based testing beginning at age 25 becomes the norm and improvements in the process of reflex pap smear interpretation.

3. Regarding plan benefit design, co-pays with private and employer insurance continue to increase for procedures and even office visits. This is driven by costs. The issue is one of trying to control health care costs in general.

4. If insurers payed this co-pay, the cost would be passed on to the employees of these plans.

5. I suggest the discussion be expanded to include these issues plus: what percentage of women are now covered on employer insurance? Are there co-pays for Medicaid/Medicare in any states? The underserved population has probably the highest incidence of abnormal pap smears and need for colposcopy. What is the extent of this problem (or not) in other populations?

6. The median co-pay (\$80.40) may not dissuade many from having colposcopy. Given the level of anxiety of this issue with women, it's unclear that in this procedure the standard assumptions about co-pays impacting follow-up holds up.

7. Figure 2 reports the mean out of pocket costs, but the median is more revealing.

Reviewer #2: Thank you for the opportunity to review your work.

I am very grateful for the work authors did on this topic. As a gynecologist who does colposcopy often, I am facing this challenge of what we call "cost-sharing" in the trenches, which basically prevents women from getting the care they need.

The strengths of this paper are:

- well-written
- relevant topic to the audience
- large N
- calls for advocacy by presenting numbers, which speak louder than words

My comments are below

1. Out-of-pocket costs: Figure 2 is very impressive. I am wondering if the same trend was noted in other procedures within and outside of gyn (ex. endometrial biopsies, prostate biopsies)?
2. Figure 1-interesting trend seen as a number of colposcopies with biopsies went up. This was outside of the scope of your paper, but I am wondering that was the diffusion of 2012 guidelines into practice?
3. Lines 51-52. Are there any publications to show this for colposcopy? How about for other procedures?
4. Line 51. Would it possible to add a little more info about this database? Approx. how many members does this cover? % Of US population?
5. Line 63. Why 30-day cut-off was used? I am thinking that sometimes it takes more than 30 days to schedule a CKC after colposcopy. Why not 60 days for example?
6. Lines 68-71. I could not tell from figure 1 how many women received add'l services.
7. I am wondering if replacing "non-trivial" with "significant" would be possible. \$127 is a lot for most.
8. Line 78. Is the word "screening" appropriate? By default, post-colpo is not "screening" it is "surveillance"
9. Lines 93-94 are great. I suggest adding "cancer" in front of "screening"
10. I am wondering if ref below is relevant (along with 14 references that quoted it)
<https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1467-842X.1996.tb01027.x>

Predicting nonattendance for colposcopy clinic follow-up after referral for an abnormal Pap smear

Anne M. Kavanagh, Judy M. Simpson

First published: June 1996

<https://doi.org/10.1111/j.1467-842X.1996.tb01027.x>

Reviewer #3: This is a research letter outlining the out-of-pocket costs associated with colposcopy and associated services for commercially insured women. The authors identified an important gap in coverage that impacts a substantial segment of the population and describe the problem. This topic is quite novel and should be of interest to anyone performing cervical cancer screening. Also, the study has public health implications since the cost burden associated with follow up studies is likely to undermine screening efforts by prolonging time to treatment. To strengthen their work further, the authors may consider the following suggestions:

1. It is implied in the introduction and stated in the discussion that a significant number of women require a colposcopy and additional clinical interventions. However, readers are not given any objective measure of how significant a proportion this is. If the authors were to include some numbers (an estimate of the number of women who undergo these procedures annually or a percentage of women who undergo them at some point in their lifetime), this would help to support their claim.
2. In lines 81 through 83, the authors point out their inability to distinguish between colposcopies indicated based on an abnormal pap smear as part of routine screening or performed for diagnostic purposes when a lesion is discovered. Though I appreciate the clinical importance of making this distinction, it would improve the paper if they provided further

explanation of how this bears out in the context of their study, especially given that they list it as their most significant limitation.

3. For Figure 1, do the authors have any explanation to give in the discussion as to why there was such a staggering increase in colposcopies with out of pocket cost between 2014 and 2018, relative to colposcopies without biopsies?

4. For lines 84 through 86, the authors state they were likely underestimating out-of-pocket costs as a limitation of their study. I don't think this is actually a limitation, and would propose that if they bring this up, they instead use this point to further underscore the financial burden on patients. However, generally colposcopies are billed as "procedure only" visits and I am therefore unsure of whether there are significant office visit bills that contribute to the out-of-pocket costs; if there are indeed extra costs not accounted for and authors could clarify this, it would strengthen their argument.

5. At our institution, cold knife cone biopsies are generally performed in the operating room at a relative premium to what an in-office colposcopy would cost. It may be too far afield of their study to include, but if the authors have information about out-of-pocket expenses associated with this type of follow-up procedure, it may greatly help to demonstrate their point.

6. Do the authors have data on whether there are disparities in out of pocket costs by race / ethnicity / geographic region? This would be worth reporting, if so.

7. Is there variation in costs based on insurance product? This would also be interesting to know, if available.

8. The first line of the discussion (77-79) could be removed; the authors have adequately outlined the issue in the introduction.

9. In line 70, please provide the percentage of women who received additional services such as biopsy or conization.

10. In line 74, please provide the mean, median, and IQR for colposcopy with additional services including biopsies, if possible.

11. In line 46, please provide a definition for the acronym "CC".

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Methods: Should include as on-line supplemental, the ICD codes used to generate the data and should provide a Table with yearly entries corresponding to Figs 1, 2.

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

- A. OPT-IN: Yes, please publish my point-by-point response letter.
- B. OPT-OUT: No, please do not publish my point-by-point response letter.

2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

3. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations

of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at <http://ong.editorialmanager.com>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions> and the gynecology data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Research Letters should not exceed 600 words and may include no more than two figures and/or tables (2 items total). Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

6. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

- * All financial support of the study must be acknowledged.
- * Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
- * All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
- * If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).
- * If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

7. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmgr.ovid.com/ong/accounts/abbreviations.pdf>. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

8. Please review examples of our current reference style at <http://ong.editorialmanager.com> (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources"). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document.

If the reference you are citing has been updated and replaced by a newer version, please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

9. Figures 1-2: Please add tick marks along the x-axes. Please upload as figure files on Editorial Manager.

10. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at <http://links.lww.com/LWW-ES/A48>. The cost for publishing an article as open access can be found at <https://wkauthorservices.editage.com/open-access/hybrid.html>.

If your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

If you choose open access, you will receive an Open Access Publication Charge letter from the Journal's Publisher, Wolters Kluwer, and instructions on how to submit any open access charges. The email will be from publicationservices@copyright.com with the subject line, "Please Submit Your Open Access Article Publication Charge(s)." Please complete payment of the Open Access charges within 48 hours of receipt.

If you choose to revise your manuscript, please submit your revision through Editorial Manager at <http://ong.editorialmanager.com>. Your manuscript should be uploaded as a Microsoft Word document. Your revision's cover letter should include the following:

- * A confirmation that you have read the Instructions for Authors (<http://edmgr.ovid.com/ong/accounts/authors.pdf>), and

- * A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Aug 13, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Dwight J. Rouse, MD, MSPH
Editor-in-Chief

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: <https://www.editorialmanager.com/ong/login.asp?a=r>). Please contact the publication office if you have any questions.



August 11, 2021

Dwight J. Rouse, MD, MSPH
Editor-in-Chief
Obstetrics and Gynecology

Dear Dr. Rouse,

Please accept our revised manuscript titled “Out-of-Pocket Costs for Colposcopy Among Commercially Insured Women from 2006-2019” (ONG-21-1359) to be further considered for publication in *Obstetrics and Gynecology* as a Research Letter.

We appreciate the thoughtful comments from the reviewers and have responded to each in the attached document. Line numbers refer to the clean version of the revised manuscript. If our manuscript is accepted, we choose to **opt-in** to the publication of our point-by-point response to the revision letter.

Thank you for your continued consideration of our work for publication in *Obstetrics and Gynecology*.

Sincerely,

A handwritten signature in black ink, appearing to read 'A. Mark Fendrick'.

*A. Mark Fendrick, MD

Response to Reviewers (ONG-21-1359)

Reviewer #1:

The article by Fendrick et al shows that cost-sharing for patients with health insurance for colposcopy continues to increase. The authors suggest that this cost may be a barrier in patients obtaining the procedure. I have the following observations.

1. Most patients undergoing colposcopy will get a biopsy at that time or at least an endocervical curettage. It is a little unclear to me if the "colposcopy without biopsy" group were those with an ecc tissue sample or not. In figure 2, is the "colposcopy with additional services" a group with any tissue sampling, whether biopsy and/or ecc, or just a subsequent LEEP or other procedure? The difference between the groups in Figure 2 is relatively small (\$10-20) so I am unclear what elements of the process receive a cost sharing (pathologist?). These issues are important in developing meaningful health policies.

Response: Thank you for these great insights. We agree that these nuances are important to identifying appropriate corresponding policy levers.

We have updated the analysis to better understand differences in cost sharing across types of colposcopy episodes. We now categorize all colposcopy episodes into one of three groups:

- Colposcopy procedures alone (i.e., no tissue sampling)
- Colposcopy procedures with associated tissue biopsy (e.g., cervical biopsy, ECC, endometrial biopsy)
- Colposcopy procedures with additional services (i.e., LEEP, conization)

We created these groups by identifying the presence of any colposcopy code and looking forward 60 days for evidence of a) codes associated with additional services like LEEP or conization, and b) codes suggestive of biopsy (e.g., cervical tissue biopsy, ECC, endometrial biopsy). The colposcopy episode was assigned to the "colposcopy with additional services" group, if any relevant codes were present. Remaining colposcopy episodes with evidence of tissue sampling, but not excisional or conization procedures, were assigned to group 2. The remaining colposcopy episodes, with no evidence of codes associated with tissue sampling of any kind, were assigned to the "colposcopy alone" group. We describe this process in detail in the appendix. We have updated our Methods section to describe these groups and added a footnote to both Figures to enhance clarity.

In the current Research Letter, we did not examine the drivers of out-of-pocket spending for these services. Understanding the relative contributions of charges related to the colposcopy itself vs. those related to surgical pathology-related services is an important area for future work.

2. The number of colposcopies performed continues to decrease due to changes in recommendations by the ASCCP and other bodies. Currently patients under 25 with ASCUS are returning for follow-up paps, for example. This has changed during the period of this study. Additionally, patients with HGSIL are now referred directly for LEEP, which eliminates them from initial colposcopy. The number of colposcopies will continue to decline as the HPV-based testing beginning at age 25 becomes the norm and improvements in the process of reflex pap smear interpretation.

Response: During the study period in our study cohort of commercially-insured women, the number of individuals receiving colposcopies rose over time:

	Group 1		Group 2		Group 3	
year	Frequency	Percent	Frequency	Percent	Frequency	Percent
2006	1292	10.85	9199	77.26	1415	11.88
2007	1431	10.22	11156	79.68	1414	10.10
2008	1503	9.60	12758	81.46	1400	8.94
2009	1653	9.36	14572	82.52	1434	8.12
2010	1669	8.64	16315	84.46	1333	6.90
2011	1937	8.77	18671	84.50	1488	6.73
2012	2002	8.43	20062	84.46	1690	7.11
2013	2174	8.04	23033	85.20	1826	6.75
2014	2329	7.82	25522	85.66	1943	6.52
2015	2562	7.25	30495	86.32	2272	6.43
2016	3318	7.02	40688	86.12	3237	6.85
2017	4547	6.86	56935	85.86	4832	7.29
2018	5797	6.76	73625	85.85	6342	7.39
2019	4204	6.15	59250	86.74	4852	7.10

This likely reflects the rise in number of women with commercial insurance and the changing demographics of the population of commercially-insured women, as the ACA was implemented. We agree with the reviewer that this number may decrease over time due to evolving guidelines. However, the key message of our study is that the majority of women who receive a colposcopy are facing an out-of-pocket cost for that care. This is an important finding, independent of the counts of women receiving colposcopy.

3. Regarding plan benefit design, co-pays with private and employer insurance continue to increase for procedures and even office visits. This is driven by costs. The issue is one of trying to control health care costs in general.

Response: Based on findings from the landmark RAND Health Insurance experiment,¹ cost sharing is a commonly used and effective strategy to reduce overall healthcare costs. Yet, while cost sharing may reduce the use of clinically inappropriate healthcare, it may also inadvertently reduce the use of recommended preventive care. In other words, current cost sharing strategies are 'blunt' in that they require consumers to pay for both high- and low-value services. A longstanding goal of our team's research agenda is to quantify high out-of-pocket costs for essential, recommended clinical services. It is our hope that research findings such as this will inform the policy debate and ultimately lead to the implementation benefit designs that remove or reduce cost sharing for evidence-based care, such as colposcopy and associated services.

4. If insurers paid this co-pay, the cost would be passed on to the employees of these plans.

Response: Reviewer 1 raises an insightful question: if health plans were to eliminate cost sharing for colposcopy and associated services, how would the health plan defray these costs? Our prior work suggests that plans do not have to transfer these costs to all plan enrollees (i.e., via premiums). In fact, the economic consequences of eliminating cost sharing for HIGH-value care is often easily offset by imposing cost sharing for LOW-value care and reducing utilization of these services. For example, the economic impact of removing cost sharing for colposcopy could easily be paid for by the reduction of unnecessary utilization of cervical cancer screenings (e.g., under age 21, too-frequent intervals, over age 65). This concept is a foundational principle of value-based insurance design (V-BID), a term coined by study first author Dr. Fendrick and implemented in many recent health policies, such as the Affordable Care Act. We have added the following to the discussion:

Reducing utilization of unnecessary cervical cancer screening (e.g., under age 21, too frequent intervals, over age 65) is one strategy for offsetting the health plan's expense for eliminating cost sharing for colposcopy and associated services. (Lines 95-98)

5. I suggest the discussion be expanded to include these issues plus: what percentage of women are now covered on employer insurance? Are there co-pays for Medicaid/Medicare in any states? The underserved population has probably the highest incidence of abnormal pap smears and need for colposcopy. What is the extent of this problem (or not) in other populations?

Response: Approximately 59 million women ages 19-64 (61%) received their health coverage from employer-sponsored insurance in 2019.²

¹RAND Corporation. *RAND's Health Insurance Experiment (HIE)*. Retrieved July 23, 2021 from <https://www.rand.org/health-care/projects/hie.html>. Accessed July 23, 2021.

²Kaiser Family Foundation. Women's Health Insurance Coverage. Available at: [https://www.kff.org/womens-health-policy/fact-sheet/womens-health-insurance-coverage/#:~:text=Approximately%2059%20million%20women%20ages,in%202019%20\(Figure%201\)](https://www.kff.org/womens-health-policy/fact-sheet/womens-health-insurance-coverage/#:~:text=Approximately%2059%20million%20women%20ages,in%202019%20(Figure%201)). Accessed July 23, 2021

Medicaid programs³ are allowed to impose cost sharing. The amount varies by state and by Medicaid plan, but limits on annual out-of-pocket maximums for Medicaid enrollees mean that cost sharing is almost exclusively a problem of the commercially-insured.

The commercially-insured population includes many individuals traditionally classified as “underserved” or “marginalized.” For example, more than a quarter of individuals with income 100%-200% of the federal poverty level (FPL) and more than half of individuals with income 200%-400% FPL have employer-sponsored coverage.⁴ These individuals are expected to be highly vulnerable to out-of-pocket costs for medical care.

We added the following sentence to our Discussion:

Approximately 59 million women ages 19-64 (61%) received their health coverage from employer-sponsored insurance in 2019, including more than a quarter with income 100%-200% of the federal poverty level and more than half with income 200%-400% of the federal poverty level, who may be highly sensitive to out-of-pocket costs for medical care.³ (Lines 82-85)

Additional details are included in the Appendix.

6. The median co-pay (\$80.40) may not dissuade many from having colposcopy. Given the level of anxiety of this issue with women, it's unclear that in this procedure the standard assumptions about co-pays impacting follow-up holds up.

Response: This is an excellent observation. A robust body of evidence suggests that even small dollar amounts deter use of high value drugs.⁵ Similarly, \$80 is a known “walk away price” for high value vaccines.⁶ We agree that it is unclear whether the general associations between cost sharing and utilization will apply to colposcopy utilization. This is an empirical question that we plan to answer in future work.

7. Figure 2 reports the mean out of pocket costs, but the median is more revealing.

Response: We have updated this Figure to now report the median. Additionally, our Appendix provides a table with mean and SD and median and IQR amounts for all groups, for all years.

³Centers for Medicare and Medicaid Services. Cost Sharing. Available at: <https://www.medicaid.gov/medicaid/cost-sharing/index.html>. Accessed July 23, 2021.

⁴Tax Policy Center. Briefing Book. Available at: <https://www.taxpolicycenter.org/briefing-book/who-has-health-insurance-coverage>. Accessed July 23, 2021

⁵Goldman DP, Joyce GF, Zheng Y. Prescription Drug Cost Sharing: Associations With Medication and Medical Utilization and Spending and Health. JAMA 2007;298(1):61–69.

⁶Tao Z, Li Y, Stemkowski S, Johnson KD, et al. Impact of Out-of-Pocket Cost on Herpes Zoster Vaccine Uptake: An Observational Study in a Medicare Managed Care Population. Vaccines 2018;6(4):78.

Reviewer #2:

Thank you for the opportunity to review your work. I am very grateful for the work authors did on this topic. As a gynecologist who does colposcopy often, I am facing this challenge of what we call "cost-sharing" in the trenches, which basically prevents women from getting the care they need. The strengths of this paper are:

- well-written
- relevant topic to the audience
- large N
- calls for advocacy by presenting numbers, which speak louder than words

My comments are below

1. Out-of-pocket costs: Figure 2 is very impressive. I am wondering if the same trend was noted in other procedures within and outside of gyn (ex. endometrial biopsies, prostate biopsies)?

Response: Our broader research group is studying this same phenomenon in breast, colorectal, and lung cancer screening and have found similar trends in out-of-pocket costs. The first of these papers, addressing out-of-pocket costs after mammography, will be published in JAMA Network Open in August 2021.

2. Figure 1-interesting trend seen as a number of colposcopies with biopsies went up. This was outside of the scope of your paper, but I am wondering that was the diffusion of 2012 guidelines into practice?

Response: The counts of all colposcopy episode types (colposcopy alone, colposcopy with biopsy, and colposcopy with additional procedures) rose across our study period, with counts of colposcopy with biopsy rising particularly precipitously. Our current analysis cannot empirically answer why these trends were observed. We do know that the sample population changed over time, due to implementation of various ACA policies (e.g., ACA policies made it easier for young women to acquire insurance as dependents on their parents' plans up to age 26; the ACA abolished gender rating and coverage due to pre-existing conditions, increasing access to coverage). It is also possible that ASCCP guideline changes led to less frequent Pap/HPV testing, which led to colposcopies being done once disease was slightly more advanced—thus prompting clinicians to collect biopsies, which may explain the particularly precipitous rise in this type of colposcopy episode. Understanding the mechanisms of these trends is an important area for future research. We have not alluded to these considerations in the Discussion, due to the 600-word limit, but we would be happy to add this if the Editors wish.

3. Lines 51-52. Are there any publications to show this for colposcopy? How about for other procedures?

Response: We are unaware of contemporary studies demonstrating that cost sharing for colposcopy impedes use. This is an important area of inquiry in our ongoing work, as a follow-up to the findings of this Research Letter. However, there is a decades-long literature suggesting that cost sharing impedes

utilization of other preventive services, including the landmark RAND Health Insurance Experiment, which we do cite in the manuscript.

4. Line 51. Would it be possible to add a little more info about this database? Approx. how many members does this cover? % Of US population?

Response: We have added additional details about the data set to the Appendix.

5. Line 63. Why 30-day cut-off was used? I am thinking that sometimes it takes more than 30 days to schedule a CKC after colposcopy. Why not 60 days for example?

Response: This is an excellent point. We increased the time window to 60 days in the revised analysis, to ensure full capture of additional services like conization.

6. Lines 68-71. I could not tell from figure 1 how many women received add'l services.

Response: We have updated this figure to enhance clarity. Please see detailed response to Reviewer #1's first comment.

7. I am wondering if replacing "non-trivial" with "significant" would be possible. \$127 is a lot for most.

Response: We are happy to make this change.

8. Line 78. Is the word "screening" appropriate? By default, post-colpo is not "screening" it is "surveillance"

Response: Thanks for this comment. We have removed this sentence based on Reviewer #3's comment #8.

9. Lines 93-94 are great. I suggest adding "cancer" in front of "screening"

Response: Thank you for the compliment. We have adjusted this sentence to read:

Plan benefit design must better take into account that cervical cancer screening often requires multiple steps and should remove financial barriers for patients to complete the entire process. (Lines 93-95)

10. I am wondering if ref below is relevant (along with 14 references that quoted it)
<https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1467-842X.1996.tb01027.x>

Predicting nonattendance for colposcopy clinic follow-up after referral for an abnormal Pap smear

Anne M. Kavanagh, Judy M. Simpson

First published: June 1996

<https://doi.org/10.1111/j.1467-842X.1996.tb01027.x>

Response: Thanks for this reference. We reviewed this manuscript, and the other 14 references citing it. Much of this literature is 10-15+ years old, and these papers do not address the central topic of this study: out-of-pocket costs for colposcopy and associated services. We do not believe any of these references need to be included.

Reviewer #3:

This is a research letter outlining the out-of-pocket costs associated with colposcopy and associated services for commercially insured women. The authors identified an important gap in coverage that impacts a substantial segment of the population and describe the problem. This topic is quite novel and should be of interest to anyone performing cervical cancer screening. Also, the study has public health implications since the cost burden associated with follow up studies is likely to undermine screening efforts by prolonging time to treatment. To strengthen their work further, the authors may consider the following suggestions:

1. It is implied in the introduction and stated in the discussion that a significant number of women require a colposcopy and additional clinical interventions. However, readers are not given any objective measure of how significant a proportion this is. If the authors were to include some numbers (an estimate of the number of women who undergo these procedures annually or a percentage of women who undergo them at some point in their lifetime), this would help to support their claim.

Response: As others have observed,⁷ the number of colposcopies performed annually in the US is unknown. Because the United States has neither a nationally, integrated healthcare system nor an organized screening system for cervical cancer that might permit tracking of abnormal results, it is very difficult to generate accurate, contemporary estimates of the frequency of colposcopy.

⁷Huh WK, Papagiannakis E, Gold MA. Observed Colposcopy Practice in US Community-Based Clinics: The Retrospective Control Arm of the IMPROVE-COLPO Study. J Low Genit Tract Dis 2019;23(2):110-115.

2. In lines 81 through 83, the authors point out their inability to distinguish between colposcopies indicated based on an abnormal pap smear as part of routine screening or performed for diagnostic purposes when a lesion is discovered. Though I appreciate the clinical importance of making this distinction, it would improve the paper if they provided further explanation of how this bears out in the context of their study, especially given that they list it as their most significant limitation.

Response: Thank you for raising this consideration. Upon reflection, we believe that this sentence should be removed from the manuscript. This is not actually a limitation, as it does not affect the validity or generalizability of the analysis. Rather, we intended to convey that if this analysis were to prompt policy changes, some women might continue to have costs for colposcopies conducted for visible lesions. However, this clinical scenario is quite rare (the vast majority of colposcopies are conducted in asymptomatic individuals). Additionally, one could argue that even these colposcopies conducted for a visible lesion are expediting diagnosis and treatment of cervical cancer, and thus should be covered first-dollar in the spirit of the ACA's Section 2713 preventive services provision. We therefore recommend removing this sentence.

Relatedly, we also recommend noting a different choice made in this analysis to include a range of colposcopy episode types. Section 2713, the preventive services clause of the ACA, set out to eliminate cost sharing for preventive services, with lofty goals of ensuring universal access, promoting equity, and optimizing outcomes. The spirit of Section 2713 was to improve access to all preventive healthcare--not "screening" services alone. In fact, policymakers have interpreted Section 2713 quite broadly. For example, recent guidance from the Department of Treasury⁸ allows high-deductible health plans to classify certain chronic disease management services as preventive and thereby cover them without cost sharing. Such services are not "screening" for a disease, but do prevent disease prevention and complications. Similar logic could be applied to policies regulating cost sharing for colposcopy and associated services. Preventive care for cervical cancer doesn't include simply a pap and an HPV test, or even the first colposcopy after an abnormal Pap/HPV test, but rather, all colposcopies and associated procedures prior to the diagnosis of cancer. All colposcopies, including those associated with procedures like a LEEP or a conization that are both diagnostic and therapeutic, are aimed at preventing development of cancer and shortening time to diagnosis and treatment of cancers and are thus "preventive." With these considerations in mind, we decided to include all colposcopy procedures in the current analysis, even those that might clinically be considered "surveillance," and not initial screening as clinically defined. Based on these considerations, we have added the following to the Methods:

We included colposcopy episodes associated with excisional procedures that are both diagnostic and therapeutic, since all colposcopies are aimed at cancer prevention and shortening time to diagnosis and treatment of cancer. (Lines 63-65)

⁸Internal Revenue Service. Additional preventive care benefits permitted to be provided by a high deductible health plan under § 223. Available at: www.irs.gov/pub/irs-drop/n-19-45.pdf. Accessed February 6, 2021.

3. For Figure 1, do the authors have any explanation to give in the discussion as to why there was such a staggering increase in colposcopies with out-of-pocket cost between 2014 and 2018, relative to colposcopies without biopsies?

Response: Please see response to Reviewer 2's comment #2.

4. For lines 84 through 86, the authors state they were likely underestimating out-of-pocket costs as a limitation of their study. I don't think this is actually a limitation, and would propose that if they bring this up, they instead use this point to further underscore the financial burden on patients. However, generally colposcopies are billed as "procedure only" visits and I am therefore unsure of whether there are significant office visit bills that contribute to the out-of-pocket costs; if there are indeed extra costs not accounted for and authors could clarify this, it would strengthen their argument.

Response: We agree with the suggestion to reframe to emphasize the financial burden for patients. Because we did not empirically evaluate the frequency of billing for colposcopy-related visits vs. "procedure only" visits, we removed the claim about "likely" overestimating costs. This sentence now reads:

Notably, the reported out-of-pocket costs for cervical cancer screening-related care, such as office visits, were not included; our findings may thus underestimate patients' total financial burden. (Lines 85-87)

5. At our institution, cold knife cone biopsies are generally performed in the operating room at a relative premium to what an in-office colposcopy would cost. It may be too far afield of their study to include, but if the authors have information about out-of-pocket expenses associated with this type of follow-up procedure, it may greatly help to demonstrate their point.

Response: We do include conization procedures in the "colposcopy with additional procedures" group (Group 3). As Figure 2 demonstrates, cost sharing for these procedures is generally higher than for colposcopies alone or colposcopies with simple biopsies. In the current Research Letter, we do not examine the relative contribution of procedure setting (operating room vs. office) to total out-of-pocket costs, but this would be an interesting area for future study.

6. Do the authors have data on whether there are disparities in out of pocket costs by race / ethnicity / geographic region? This would be worth reporting, if so.

Response: This is a very interesting question. This is beyond the scope of this Research Letter, but we are including this line of inquiry in our future work in this area.

7. Is there variation in costs based on insurance product? This would also be interesting to know, if available.

Response: Yes, out-of-pocket costs will vary across a population based on plan benefit designs (e.g., deductible amount, co-payment levels) and whether or not an individual has met their individual or family deductible for the year. Investigating plan-level and patient-level (i.e., race-ethnicity) predictors of high cost sharing for preventive services like colposcopy is an important line of inquiry in our ongoing work, but beyond the scope of this Research Letter.

8. The first line of the discussion (77-79) could be removed; the authors have adequately outlined the issue in the introduction.

Response: Thanks. We have removed this sentence.

9. In line 70, please provide the percentage of women who received additional services such as biopsy or conization.

Response: In this updated manuscript, the unit of analysis is the colposcopy episode. We now report the percentage of colposcopy episodes in each group:

A substantial percentage of colposcopy episodes were associated with biopsies (79.71%; Group 2) or additional procedures (7.23%; Group 3) (Figure 1). (Lines 72-74)

10. In line 74, please provide the mean, median, and IQR for colposcopy with additional services including biopsies, if possible.

Response: We have added the following:

Out-of-pocket costs (Figure 2) were non-trivial, increased throughout the study period, and were higher when a biopsy or additional procedure was performed (2019, colposcopy alone: median \$135.53, IQR 216.19; colposcopy with biopsy: median \$152.03, IQR 261.46; colposcopy with additional procedure: median \$701.82, IQR 1,279.18; Appendix). (Lines 75-78)

11. In line 46, please provide a definition for the acronym "CC".

Response: We have deleted this abbreviation as it was not used again.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

Methods: Should include as on-line supplemental, the ICD codes used to generate the data and should provide a Table with yearly entries corresponding to Figs 1, 2.

Response: We have added these as a supplemental file (Appendix) as requested.

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

A. OPT-IN: Yes, please publish my point-by-point response letter.

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2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

Response: We will do this.

3. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and

systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at <http://ong.editorialmanager.com>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

Response: We have completed and uploaded the RECORD checklist.

4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions> and the gynecology data definitions at <https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

Response: N/A

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Research Letters should not exceed 600 words and may include no more than two figures and/or tables (2 items total). Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

Response: We have adhered to the limits.

6. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

* All financial support of the study must be acknowledged.

* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.

* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.

* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

Response: We have acknowledged funding sources and assistance with manuscript preparation. We did not previously present this work at a national meeting or deposit findings in a preprint service.

7. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmgr.ovid.com/ong/accounts/abbreviations.pdf>. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

Response: We have used only standard abbreviations.

8. Please review examples of our current reference style at <http://ong.editorialmanager.com> (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources"). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document. If the reference you are citing has been updated and replaced by a newer version, please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

Response: We have followed these guidelines.

9. Figures 1-2: Please add tick marks along the x-axes. Please upload as figure files on Editorial Manager.

Response: We have done so.

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