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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.*

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Date: Jul 15, 2022
To: "Alexandra S. Bercow" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-1100

RE: Manuscript Number ONG-22-1100

Guideline-Discordant Care in Early-Stage Vulvar Cancer: A National Cancer Database Study

Dear Dr. Bercow:

Thank you for sending us your work for consideration for publication in Obstetrics & Gynecology. Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors would like to invite you to submit a revised version for further consideration.

If you wish to revise your manuscript, please read the following comments submitted by the reviewers and Editors. Each point raised requires a response, by either revising your manuscript or making a clear argument as to why no revision is needed in the cover letter.

To facilitate our review, we prefer that the cover letter you submit with your revised manuscript include each reviewer and Editor comment below, followed by your response. That is, a point-by-point response is required to each of the EDITOR COMMENTS (if applicable), REVIEWER COMMENTS, STATISTICAL EDITOR COMMENTS (if applicable), and EDITORIAL OFFICE COMMENTS below. Your manuscript will be returned to you if a point-by-point response to each of these sections is not included.

The revised manuscript should indicate the position of all changes made. Please use the "track changes" feature in your document (do not use strikethrough or underline formatting).

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REVIEWER COMMENTS:

Reviewer #1: I think the most important point of this paper is: Discrepancies in guideline concordant care in vulvar cancer in low-volume facilities and in black women. This has been shown in other cancer types, including ovarian cancer, but this is the first I am aware of authors showing this in vulvar cancer.
-It may not be possible to capture with the NCDB database, but I would be curious to see if there are differences in the method of LNE (sentinel vs dissection) in elderly women or black women and the performance of this based on center volume.
-I think the authors make a good point about the inability to capture data on 1) palliative vulvectomy vs with curative intent and 2) other factors influencing surgery (frailty, PS, etc). I agree that more research is needed evaluating these. That being said, the OS of older vulvar cancer patients with negative nodes is >5 years vs ~3 for patients with no LNE. It would be interesting to look at whether these patients died of vulvar cancer or other causes.

Minor Points:
-The authors do not specify what they mean by "older women" in the abstract, the introduction, the hypothesis or the objective. They do define "older women" as women diagnosed at 80 years or older in the methods but I think that it would be helpful to clarify/specify this earlier in the paper.
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Notably, the study captures a period of time where there may have been an active transition away from transitional lymph

node evaluation to sentinel nodes - the barriers to implementation of this novel technique and the stark differences in terms of surgical complexity and morbidity should be noted in this study. It would be helpful to see the number of patients who underwent lymphadenectomies compared with sentinel lymph node biopsies, and how that changed over the time period studied. Were sentinel lymph node procedures were equally performed when comparing with the older patient population?
Similarly, when assessing hospital level differences in volume, evaluating the number of inguinal lymph node dissections performed (rather than vulvectomies) may better capture high and low volume centers, particularly when considering comfort with a new procedure or considering patient outcomes for a more morbid traditional procedure.
The definition of older patients as >80 should be justified as well- if this was not based on published literature, or supported by a societal definition of older patients, consideration for outcomes by different age cut offs may be an interesting sensitivity analysis.
Is there a way of ensuring those patients who did not have a lymph node assessment in fact had positive nodes on imaging? perhaps the inclusion of data on the receipt of adjuvant therapy in those patients would clarify this population.
Finally, the authors should consider an alternative word to use over "defer" when describing those patients who did not undergo lymph node assessment, as this suggests this procedure was postponed to a later time and not omitted.

Reviewer #3: The authors present an analysis to evaluate what variables are associated with guideline concordant care for vulvar cancer. They found that the overall rate of concordance (specifically with LN evaluation) is lower than expected, and <50% in women over the age of 80. There are some important findings here, specifically looking to risk factors for discordant care. However, the main limitation of this study is that the authors cannot evaluate the exact reasons for discordance, LN evaluation is associated with significant morbidity, and patients may have been counseled appropriately but opted to not proceed with LN evaluation due to concerns about adverse events. Without information regarding how patients were counseled this study has limited utility.

Precis: please change "decreased odds" to "lower probability"

Abstract:
line 22: is "deferred" the correct phrasing here? it implies the patient themselves declined the LN evaluation; since this is a database, can you tell if the patient themselves deferred LN evaluation or is it more accurate to say that they "did not undergo" LN evaluation
I would also recommend putting the frequency of guideline concordant care in the results section

Introduction:
overall concise and well written

Methods:
line 65-67: While the logic of choosing a starting point of analysis around the time of new guidelines and safety recommendations is sound, I would recommend that the authors instead choose 2013 or even 2014 as their starting point as the adoption of such guidelines takes time, even at high volume centers with fellowship trained surgeons

line 74: why was age 80 chosen as the definition of "elderly" ? why not 75 or even 65?

81: please define what the Charlson-Deyo score is

98-100: on what basis are these distinctions (low, intermediate, high-volume made)? prior research (if so cite sources)? authors' own assumptions (if so please clarify rationale for these assumptions)?

line 108-122: was any information collected on complications related to LN evaluation? this would be an important variable to consider, since elderly people (in particular as defined here as >=80) may be less likely to want to undergo LN evaluation due to risk of complications such as edema (or they may be more likely to experience such complications)

line 123-133 : I would recommend the authors perform a propensity score matched analysis as well as there is likely significant selection bias, and while PSM analysis is not likely to ameliorate all selection bias, it can help better understand the results, particularly if PSM results are similar to the primary analysis

Results:
I am unable to find any references to Table 1 and 2 in the results section
line 163-170: is this after adjusting for confounding variables?
line 171-180: do you have absolute values for the number of people who did not undergo LN evaluation and experienced outcomes similar to those with positive nodes?

STATISTICAL EDITOR COMMENTS:

Table 1: Need units for age. In the analysis by ethnicity, the difference between cohorts is statistically significant due to the

differential distribution of "unknown". Comparison of Hispanic vs Non-Hispanic is NS. Same issue with Tumor size. Comparison of ≤ 4 cm vs > 4 cm is NS.

Table 3: Need units for age. Need to include a column of unadjusted ORs for contrast with aORs. Should omit the column of p-values, since CIs are included with ORs. Need to include in footnote to Table a list of all variables retained in final regression model. What tests were done to test for collinearity? For instance, age 80-90 y and either Medicare or comorbidities?

Table 4: It appears that these RRs are not adjusted for any baseline differences. Should include multivariable analysis, as in Table 3. Same issue with p-value column, since CIs are included. Need to include a footnote listing all variables retained in the multivariable regression analysis.

Fig 2: Need to include along the x-axes at the indicated time points, the counts of women remaining at risk. Need to somewhere in Tables/text the median (range) of follow-up times for each cohort. If there is evidence of difference in follow-up times, then should include hazard rate analysis with adjustment for relevant variables. Also, need to include either in figure or figure legend, a summary of the stats test for K-M and then possibly for aHR analyses. Also, in supplemental, should show in more detail, the data for Fig 2B. That is, a Table similar to Table 1, but only for the cohort age 80-90y.

EDITORIAL OFFICE COMMENTS:

1. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and at the end of the abstract. For industry-sponsored studies, describe on the title page how the funder was or was not involved in the study.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology's Copyright Transfer Agreement (CTA) must be completed by all authors. We have not received forms from:

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Alexander Melamed
Whitfield B. Growdon
Sara Bouberhan
Amy Bregar

When you uploaded your manuscript, each coauthor received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please ask your coauthor(s) to complete this form, and confirm the disclosures listed in their CTA are included on the manuscript's title page. If they did not receive the email, they should check their spam/junk folder. Requests to resend the CTA may be sent to em@greenjournal.org.

4. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, describe the reasons that race and ethnicity were assessed in the Methods section and/or in table footnotes. Race and ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories.

List racial and ethnic categories in tables in alphabetic order. Do not use "Other" as a category; use "None of the above" instead.

Please refer to "Reporting Race and Ethnicity in Obstetrics & Gynecology" at https://edmgr.ovid.com/ong/accounts/Race_and_Ethnicity.pdf.

5. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "People with disabilities" or "women with disabilities" instead of "disabled people" or "disabled women"; "patients with HIV" or "women with HIV" instead of "HIV-positive patients" or "HIV-positive women"; and "people

who are blind" or "women who are blind" instead of "blind people" or "blind women."

6. The journal follows ACOG's Statement of Policy on Inclusive Language (https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2022/inclusive-language). When possible, please avoid using gendered descriptors in your manuscript. Instead of "women" and "females," consider using the following: "individuals;" "patients;" "participants;" "people" (not "persons"); "women and transgender men;" "women and gender-expansive patients;" or "women and all those seeking gynecologic care."

7. 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.

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Original Research: 3,000 words

9. Specific rules govern the use of acknowledgments in the journal. Please review the following guidelines and edit your title page as needed:

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* 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 or indicate whether the meeting was held virtually).
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* Do not use only authors' initials in the acknowledgement or Financial Disclosure; spell out their names the way they appear in the byline.

10. Be sure that each statement and any data in the abstract are also stated in the body of your manuscript, tables, or figures. Statements and data that appear in the abstract must also appear in the body text for consistency. Make sure there are no inconsistencies between the abstract and the manuscript, and that the abstract has a clear conclusion statement based on the results found in the manuscript.

In addition, the abstract length should follow journal guidelines. Please provide a word count.

Original Research: 300 words

11. 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.

Do not use "LN" or "SCC" as abbreviations.

12. ACOG avoids using "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

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Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001").

Express all percentages to one decimal place (for example, 11.1%"). Do not use whole numbers for percentages.

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15. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available at http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

16. Please review examples of our current reference style at https://edmgr.ovid.com/ong/accounts/ifa_suppl_refstyle.pdf. 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 formal reference list. Please cite them on the line in parentheses.

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Please make sure your references are numbered in order of appearance in the text.

17. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

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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 a point-by-point response to each of the received comments in this letter. Do not omit your responses to the EDITOR COMMENTS (if applicable), the REVIEWER COMMENTS, the STATISTICAL EDITOR COMMENTS (if applicable), or the EDITORIAL OFFICE COMMENTS.

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

Again, your manuscript will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Aug 05, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

MASSACHUSETTS GENERAL HOSPITAL
OBSTETRICS & GYNECOLOGY

HARVARD MEDICAL SCHOOL

Department of Obstetrics and Gynecology
Division of Gynecologic Oncology
[redacted]

June 14th, 2022
Jason D. Wright, MD, Editor-in-Chief
Obstetrics & Gynecology

Dear Dr. Wright,

Thank you again for the opportunity to submit our manuscript: "Guideline-Discordant Care in Early-Stage Vulvar Cancer: A National Cancer Database Study." We presented the findings from our project as an oral presentation at the Dana Farber/Harvard Cancer Center Celebration of Early Career Investigators in Cancer Research (March 2022) and New England Association of Gynecologic Oncologists Annual Conference (June 2022). We also presented these findings as an abstract at Academy Health's Annual Research Meeting (June 6th, 2022). We are exclusively submitting this original, never-presented research exclusively for publication in Obstetrics & Gynecology. This was research was carried out during my time at the Center for Surgery and Public Health so it was deemed exempt by the institutional review board at Brigham and Women's Hospital.

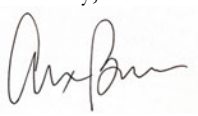
This project examines the use of National Comprehensive Cancer Network guideline-concordant inguinofemoral lymph node evaluation in women with early-stage vulvar cancer and to evaluate differences in guideline-concordant care for older women. This study demonstrates that older age, Black race, and treatment at a low-volume facility is associated with decreased odds of guideline-concordant lymph node evaluation among women with early-stage vulvar cancer. Additionally, both in the general cohort and in the elderly subgroup, women in whom lymph node evaluation was deferred had a poorer overall survival compared to those who underwent lymph node evaluation with pathologically negative nodes and had no difference in survival compared to those who underwent lymph node evaluation with pathologically positive nodes. This study is the first of its kind to examine patient and hospital-level characteristics associated with odds of receiving guideline-concordant lymph node evaluation in early-stage vulvar cancer.

I, Alexandra Bercow, affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant) have been explained. I, Alexandra Bercow, have reviewed and edited the submission to omit any identifying information. I hereby submit this self-blinded manuscript for consideration in Obstetrics & Gynecology. This work has not been funded. I am the corresponding author for this manuscript. Please find my contact information below.

We are grateful for all of the comments provided to improve the quality of this paper. Enclosed you will find point-by-point responses to reviewer, statistical editor, and editorial office comments. The new version of our manuscript is also submitted, with track changes.

Thank you again for your consideration.

Sincerely,



Alexandra Bercow, MD
Research and Clinical Fellow, Division of Gynecologic Oncology
Vincent Department of Obstetrics and Gynecology, Massachusetts General Hospital
[redacted]

RE: Manuscript Number ONG-22-1100

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-It may not be possible to capture with the NCDB database, but I would be curious to see if there are differences in the method of LNE (sentinel vs dissection) in elderly women or black women and the performance of this based on center volume.
Thank you for this suggestion. Given the word limit restrictions for this journal, we were unable to include all subgroup analyses but plan to present this data in a different paper that looks more closely at type of lymph node evaluation, rather than whether any type of lymph node evaluation was performed for patients in whom it was indicated, as this paper examines.

-I think the authors make a good point about the inability to capture data on 1) palliative vulvectomy vs with curative intent and 2) other factors influencing surgery (frailty, PS, etc). I agree that more research is needed evaluating these. That being said, the OS of older vulvar cancer patients with negative nodes is >5 years vs ~3 for patients with no LNE. It would be interesting to look at whether these patients died of vulvar cancer or other causes.
We completely agree with this point. Unfortunately, NCDB only records all-cause mortality and does not delineate cause of death or cancer-specific mortality rates. This limitation is now noted in the discussion section on lines 394-395.

Minor Points:
-The authors do not specify what they mean by "older women" in the abstract, the introduction, the hypothesis or the objective. They do define "older women" as women diagnosed at 80 years or older in the methods but I think that it would be helpful to clarify/specify this earlier in the paper.

Thank you for bringing this to our attention. Lines 17-18 of the abstract now read, “and a subgroup of older patients, defined as individuals ≥80 years-old.” Additionally, lines 60-64 in the introduction now read, “The objective of this study was to define current use of indicated lymph node evaluation in early-stage vulvar cancer and to evaluate differences in guideline-concordant care for individuals aged 80 years or older. We hypothesized that indicated lymph node evaluation in early-stage vulvar cancer is underutilized for the general population and even more so for patients aged 80 years or older.”

-A possible flaw in looking at adjuvant therapy is by consider +margin - an acceptable alternative is re-excision and this doesn't appear to be taken into account.
We completely agree that positive margin is not a perfect variable for indicating adjuvant therapy as patients can undergo re-excision instead of undergoing adjuvant radiation, chemo, or a combination of the two. Unfortunately, NCDB does not have data available on whether a patient underwent re-excision of their primary vulvar lesion to obtain better margins, so we use the positive margin variable as a proxy for indication of adjuvant treatment. We clarify this in lines 301-303 which now read, “Data regarding re-excision of the primary lesion in patients whose initial pathology displayed positive margins was not available in the NCDB.”

Reviewer #2: This retrospective cohort study using the National Cancer Database describes the application and patient and hospital factors associated with NCCN guideline-concordant surgery care in early stage vulvar cancer and seeks to determine differences in receipt of care and outcomes in older patients. Specifically, this paper examined nearly 5700 patients included in this database who would have otherwise had an indication lymph node assessment between the years 2012-2018; 2012 was chosen given this was the publication year of two practice changing trials supporting use of sentinel lymph node in early vulvar cancer. This study adds to the literature in that they identified volume-access differences in receipt of guideline-adherent care in vulvar cancer, and found lower rates of lymph node assessment and subsequent worse outcomes in older patients. This represents a leveraging of a large cancer dataset with thought-provoking findings about impacts of performance (or omission) of lymph node surgery in vulvar cancer.
Notably, the study captures a period of time where there may have been an active transition away from transitional lymph node evaluation to sentinel nodes - the barriers to implementation of this novel technique and the stark differences in terms of surgical complexity and morbidity should be noted in this study.
We are greatly appreciative of this comment. It should be mentioned that the adoption of the sentinel technique at some institutions and not others may have altered their rate lymph node evaluation. For example, if a patient who required lymph node evaluation was wary of lymphedema rates after complete lymphadenectomy, she may be more willing to undergo sentinel lymph node biopsy, but only if that was offered to her at the institution where she received care. Thus, lines 105-113 in the Methods section now read, “Importantly, the timeframe of this study includes a transition period where some institutions were beginning to incorporate sentinel lymph node biopsy for this cohort of patients. The uptake of this novel technique has been gradual given the barriers to implementation, namely surgeon skillset, operative resources, and access to lymphoscintigraphy. Sentinel lymph node biopsy had been shown to significantly decrease short-term and long-term surgical morbidity compared to complete lymphadenectomy.[19,20] Thus, in institutions where the sentinel technique was rapidly adopted, they may have had a higher rate of patients undergoing lymph node evaluation given the more favorable surgical outcomes associated with the new technique.”

It would be helpful to see the number of patients who underwent lymphadenectomies compared with sentinel lymph node biopsies, and how that changed over the time period studied. Were sentinel lymph node procedures were equally performed when comparing with the older patient population?
Thank you for this question. Due to word constraints, the decision was made to write a separate manuscript examining the trends of sentinel lymph node biopsy over time as well as hospital factors associated with increased utilization of the relatively new technique. Thus, the breakdown of type of lymph node evaluation over time is not within the scope of this paper.

Similarly, when assessing hospital level differences in volume, evaluating the number of inguinal lymph node dissections performed (rather than vulvectomies) may better capture high and low volume centers, particularly

when considering comfort with a new procedure or considering patient outcomes for a more morbid traditional procedure.
Thank you for this important point. Vulvectomies were chosen as the index procedure to base hospital volume on because of the rarity of inguinal lymph node evaluation. We felt that the number of vulvectomies performed at a hospital more accurately depicts the volume of vulvar cancer seen at any given institution. However, when we define case volume using number of lymph node evaluations performed per year, the findings are the same: patients seen at institutions with higher lymph node evaluation volume are more likely to undergo lymph node evaluation.

The definition of older patients as >80 should be justified as well- if this was not based on published literature, or supported by a societal definition of older patients, consideration for outcomes by different age cut offs may be an interesting sensitivity analysis.
This is a critical piece of feedback. There is no standardized definition for “older” or “elderly” patients. Some of the breast cancer literature uses 70 years old as the cut off and other literature uses greater than 65 years old. We used 80 years old as the cutoff as this is the oldest decade available in the NCDB and offers a “cleaner” subgroup since a healthy and active 65-year-old is quite different than a frail 85-year-old. However, in response to your comment, we performed a sensitivity analysis of the multivariable analysis and survival analysis using age 65 and then age 70 as the cutoff and had similar findings: patients in the older cohort with each cutoff were less likely to undergo lymph node evaluation and their survival patterns were similar to that of the 80 years and older cohort. This is now described in both the methods section (lines 186-189) and the results section (lines 331-335).

Is there a way of ensuring those patients who did not have a lymph node assessment in fact had positive nodes on imaging? Perhaps the inclusion of data on the receipt of adjuvant therapy in those patients would clarify this population.
These patients would be considered patients with “clinically positive nodes” or nodes that appeared to be positive prior to surgery, whether that was on physical exam or by imaging. Patients with “clinically positive nodes” were excluded from this study and therefore would not affect our results on adjuvant therapy in our cohort population.

Finally, the authors should consider an alternative word to use over “defer” when describing those patients who did not undergo lymph node assessment, as this suggests this procedure was postponed to a later time and not omitted.
You raise an important point. The word defer/deferred has been replaced throughout the paper with “omit/omitted” or “did not undergo.”

Reviewer #3: The authors present an analysis to evaluate what variables are associated with guideline concordant care for vulvar cancer. They found that the overall rate of concordance (specifically with LN evaluation) is lower than expected, and <50% in women over the age of 80. There are some important findings here, specifically looking to risk factors for discordant care. However, the main limitation of this study is that the authors cannot evaluate the exact reasons for discordance, LN evaluation is associated with significant morbidity, and patients may have been counseled appropriately but opted to not proceed with LN evaluation due to concerns about adverse events. Without information regarding how patients were counseled this study has limited utility.
We whole heartedly agree with your final comment. We acknowledge that this dataset has certain limitations, especially the granular patient-level data that would better inform us how patients were counseled and why they were counseled in that way. However, this paper justifies more in-depth and qualitative research to better understand and define the barriers to receiving guideline-concordant lymph node evaluation.

Precis: please change "decreased odds" to "lower probability"
This suggestion has been incorporated in the precis which now reads “Older age, black race, and treatment at a low-volume hospital are associated with lower probability of undergoing guideline-concordant lymph node evaluation for early-stage vulvar cancer.” (Lines 4-6).

Abstract:
line 22: is "deferred" the correct phrasing here? it implies the patient themselves declined the LN evaluation; since

this is a database, can you tell if the patient themselves deferred LN evaluation or is it more accurate to say that they "did not undergo" LN evaluation
This is now corrected and lines 23-24 now read, “Older individuals who did not undergo LN evaluation had significantly worse overall survival (OS)…”

I would also recommend putting the frequency of guideline concordant care in the results section
The first sentence states that 66.1% of patients underwent LN evaluation. It is now addended to read, “Of the 5,685 women with vulvar cancer, 3,756 (66.1%) underwent guideline-concordant LN evaluation” (lines 19-20).

Introduction:
overall concise and well written
Thank you!

Methods:
line 65-67: While the logic of choosing a starting point of analysis around the time of new guidelines and safety recommendations is sound, I would recommend that the authors instead choose 2013 or even 2014 as their starting point as the adoption of such guidelines takes time, even at high volume centers with fellowship trained surgeons
We appreciate this feedback. Because we incorporated both methods of lymph node evaluation, we wanted to see whether the performance of lymph node evaluation (full LND and/or SLNB) increased over time with the incorporation of SLNB into practice. Because of this, we wanted to include the years where SLNB was introduced to see if there was a change in rate of lymph evaluation over time. Interestingly, with the adoption of SLNB, the performance of lymph node evaluation did not increase over time. However, we did perform a sensitivity analysis and only included patients diagnosed from 2014-2018 and our main findings did not change: older and Black women as well as women at low volume hospitals were less likely to undergo guideline-concordant lymph node evaluation (Appendix 5, lines 178-186, 329-330)

line 74: why was age 80 chosen as the definition of "elderly" ? why not 75 or even 65?
We chose the narrowest definition of elderly by selecting only 80 years and older. Unfortunately, there is no standardized definition for “older” or “elderly” patients. Some of the breast cancer literature uses 70 years old as the cut off and other literature uses greater than 65 years old. We used 80 years old as the cutoff as this is the oldest decade available in the NCDB. We have also performed a sensitivity analysis using age 65 and then age 70 as the cutoff and had similar findings: patients in the older cohort with each cutoff were less likely to undergo lymph node evaluation and their survival patterns were similar to that of the 80 years and older cohort. This is now described in both the methods section (lines 186-189) and the results section (lines 331-335).

81: please define what the Charlson-Deyo score is
Lines 117-118 now read, “Charlson-Deyo Index score, which is a validated method of predicting mortality by weighting comorbidities”

98-100: on what basis are these distinctions (low, intermediate, high-volume made)? prior research (if so cite sources)? authors' own assumptions (if so please clarify rationale for these assumptions)?
These subcategories are based on the existing NCDB data that is used in this study. The number of vulvectomies per year was calculated for each NCDB institution and the institutions were then ranked in order of volume and divided into equal terciles. This method has been performed in other studies using NCDB, which are now cited on Line 144.

line 108-122: was any information collected on complications related to LN evaluation? this would be an important variable to consider, since elderly people (in particular as defined here as >=80) may be less likely to want to undergo LN evaluation due to risk of complications such as edema (or they may be more likely to experience such complications)
Thank you for this important question. Unfortunately, NCDB only collects a limited amount of post-operative data,

specifically, length of inpatient stay, readmission to the same hospital within 30 days, and 30- as well as 90-day mortality. This limitation is described in lines 392-397.

line 123-133: I would recommend the authors perform a propensity score matched analysis as well as there is likely significant selection bias, and while PSM analysis is not likely to ameliorate all selection bias, it can help better understand the results, particularly if PSM results are similar to the primary analysis
We appreciate this thoughtful comment. Propensity score matching analysis is for studies which intend to evaluate the causal effect of a single exposure of interest on a single outcome of interest (Pearl, J. "The Foundations of Causal Inference." *Sociological Methodology*, vol. 40, 2010, pp. 75–149). Our study, however, is an associative study meant to evaluate multiple exposures' association with one particular exposure of interest. It would not be clear which exposure of interest to use in a PSM analysis. Therefore, for this study, is best suited for a multivariable logistic regression.

Results:
I am unable to find any references to Table 1 and 2 in the results section
Thank you for noting this. Table 1 is now referenced on line 202. Table 2 is referenced on line 205.

line 163-170: is this after adjusting for confounding variables?
Yes, this is now adjusting for confounding variables and is clarified in lines 226-229 as well as in a footnote beneath table 4.

line 171-180: do you have absolute values for the number of people who did not undergo LN evaluation and experienced outcomes similar to those with positive nodes?
Thank you for this valuable question. The only outcome data that NCDB provides is all-cause mortality. We can report on the absolute number of individuals who died that that did not undergo LN evaluation compared to those who died that underwent LN evaluation, but those numbers in isolation would not necessarily contribute to the overall objective of the article.

STATISTICAL EDITOR COMMENTS:

Table 1: Need units for age. In the analysis by ethnicity, the difference between cohorts is statistically significant due to the differential distribution of "unknown". Comparison of Hispanic vs Non-Hispanic is NS. Same issue with Tumor size. Comparison of ≤ 4 cm vs > 4 cm is NS.
Years has been added as the unit for age. We have also made a note below the table of which variables are not considered significant on post hoc analysis when excluding the unknown variables.

Table 3: Need units for age. Need to include a column of unadjusted ORs for contrast with aORs. Should omit the column of p-values, since CIs are included with ORs. Need to include in footnote to Table a list of all variables retained in final regression model. What tests were done to test for collinearity? For instance, age 80-90 y and either Medicare or comorbidities?
Thank you for this feedback. Years has been added as the units for age. P values have been removed and unadjusted ORs have been added to the table. I have also included a footnote that lists all variables retained in the final regression model. Line 159-161 discuss that multicollinearity was assessed between covariates. This included age and Medicare as well as age and comorbidities. The only covariates found to be collinear were minority serving hospital status and Medicaid proportion, so Medicaid proportion was removed from the model to avoid overadjustment. Because of the word limit, we did not list all of the collinearity tests performed, but rather only the one where the covariates were found to be collinear as that affected the model.

Table 4: It appears that these RRs are not adjusted for any baseline differences. Should include multivariable analysis, as in Table 3. Same issue with p-value column, since CIs are included. Need to include a footnote listing all variables retained in the multivariable regression analysis.
Thank you for this note. We have now performed a regression analysis for postoperative outcomes and adjuvant treatment adjusted for age, comorbidities, insurance type, facility type, hospital volume, minority serving hospital

status, tumor size, tumor grade, margin status, lymph node status. This is now outlines in Table 4 and the variable retained in the analysis are listed in a footnote below the table.

Fig 2: Need to include along the x-axes at the indicated time points, the counts of women remaining at risk. Need to somewhere in Tables/text the median (range) of follow-up times for each cohort. If there is evidence of difference in follow-up times, then should include hazard rate analysis with adjustment for relevant variables. Also, need to include either in figure or figure legend, a summary of the stats test for K-M and then possibly for aHR analyses. Also, in supplemental, should show in more detail, the data for Fig 2B. That is, a Table similar to Table 1, but only for the cohort age 80-90y.
Number of women at risk for each group is now demonstrated below both survival curves. Appendix 2 shows the clinicopathologic characteristics of the older women subgroup, that is women ≥ 80yo. In the figure legend, it now reads "Cox regression models were used to adjust for factors associated with survival. Covariates included age, year of diagnosis, race, ethnicity, comorbidities, tumor size and grade, lymphovascular space invasion, margin status, insurance type, receipt of adjuvant radiation and chemotherapy." The adjusted hazard ratios for survival are now included within the figures themselves and median follow up times are mentioned in the manuscript text on lines 235-237 and 284-286.

EDITORIAL OFFICE COMMENTS:

1. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.

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There was no funding provided for this manuscript.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
This is not a clinical trial nor a systematic review so it is not registered as such.
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
The name of the IRB has now been included on line 81.
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.
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4. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, describe the reasons that race and ethnicity were assessed in the Methods section and/or in table footnotes. Race and ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases missing data may comprise a high enough proportion that it compromises

statistical precision and bias of analyses by race.
The paragraph starting on line 74 explains how race and ethnicity data were abstracted from patients' medical record and documented in the NCDB. The missing data on race and ethnicity are enumerated as "None of the Above."

Use "Black" and "White" (capitalized) when used to refer to racial categories.
Black and White are capitalized throughout the manuscript and tables.

List racial and ethnic categories in tables in alphabetic order. Do not use "Other" as a category; use "None of the above" instead.
"None of the above" has replaced "Other" as a category for race.

Please refer to "Reporting Race and Ethnicity in Obstetrics & Gynecology" at https://secure-web.cisco.com/1FGkxscPEXJIPy85wnBDcUbGGRkeSaqog2rW0MIaudlONNyOsSmkryccQ1Kh9RqIhiflfuQw8QBnsLPwwUqYxvu6XdsduhaKPq0nxcy6rl-b5BNh6aAZgZL44AmbJc0ui5pQeZrxwVVaqYwwIFlpBtmya_ertDI6v9iNJw5U9NyR_--HFXbzVMxnmM0xM91EG-ENIFHg4FqEfPxHqpVwSQTgYrDMiQiC2wpQKfkv6as3KEVunB8VGCDm7lTyReua0YYFeXyqTTzF5g72FgyJrgtAxuPA7McVou6wCeXKFoBDIaRGbRYrIpLbanjCYgjBE/https%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2FRace_and_Ethnicity.pdf
Of note, while use of the word "Minorities" is not used, we do use the term "Minority Serving Hospital," which is based off of previous literature that defines these facilities as the top decile of hospitals serving the highest proportion of Black and Hispanic patients.

5. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "People with disabilities" or "women with disabilities" instead of "disabled people" or "disabled women"; "patients with HIV" or "women with HIV" instead of "HIV-positive patients" or "HIV-positive women"; and "people who are blind" or "women who are blind" instead of "blind people" or "blind women."
N/A.

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The word "women" has been replaced with "individual" or "patient" throughout the manuscript.

7. 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://secure-web.cisco.com/1IfzeiWf4QQ-Mf8xesWTVVZcBCf35EgBgKMd157EZWhc1dg-FlcePDNaLblyT-Fvkvqq1yse5HrIgQuwb4SwEb9MNd99eTch6eOExS-mmn3qLYmi517E5qmxZzNxpb5-B8lVe0WwoOcpUqIH34eHi4HdbuCp82SRvvO0pyqKoMIKWwQbU7-w6GA-Jhf_SetGo-YKhbCWF1Y2cKej39tXJud_eehhk3qzltGhTKJdiy29hYlrd0s15pvW_bNuBbboghJkE9agccj9SAg7g8on4qvmRqvueVdbVuQ-X_u5NOpaP8PEINt2lYO_vfDNOAUQT/https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2Frevitalize-obstetrics-data-definitions and the gynecology data definitions at https://secure-

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Do not use "LN" or "SCC" as abbreviations.
I have replaced LN with lymph node and SCC with squamous cell carcinoma throughout the paper. When I emailed prior to submission, I was told the journal will allow abbreviations used in "Dorland's Illustrated Medical Dictionary and the American Medical Association Manual of Style, so if you find an abbreviation for "lymph node evaluation" in either of those sources, you are allowed to use it." Both LN (lymph node) and SCC (squamous cell carcinoma) can be found in the seventh edition of Dorland's Illustrated Medical Dictionary. Because of the word limit, I would like to change the words back to the abbreviations, if possible. Please let me know if it would be acceptable to do so.

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The has been corrected throughout the paper.

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Express all percentages to one decimal place (for example, 11.1%"). Do not use whole numbers for percentages.
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The statement has been rephrased and line 349-350 now reads: "However, the literature on the volume-access relationship in vulvar cancer is sparse and our study found that women treated at low-volume hospitals had significantly lower odds of undergoing lymph node evaluation compared to those treated at intermediate and high-volume hospitals"

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