OBSTETRICS & GYNECOLOGY

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

Date: Mar 21, 2019
To: "Jason D. Wright" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-329

RE: Manuscript Number ONG-19-329

Prognostic Performance of the 2018 FIGO Cervical Cancer Staging Guidelines

Dear Dr. Wright:

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).

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 Apr 11, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Overall this is a well written manuscript with an interesting approach to examining the prognostic implications of staging guideline changes in cervical cancer. In light of recent data suggesting mode of surgery impacts outcome for surgically managed early stage disease, re-examining the modalities we use to prognosticate and treat cervical cancer is timely. The inclusion of this manuscript in Obstetrics and Gynecology would be appropriate given the topic of diagnosis and initial management of cervical cancer is often the purview of the general gynecologist.

Would advise the following clarifications:

1) Multiple places in the manuscript the term "discriminatory ability" was used. Would recommend this be changed or defined as it's vague- It may be worthwhile in the intro to explain the purpose of staging to prognosticate and define treatment. Then instead of discriminatory ability you could use a term like more discrete staging.

2) Pg 3 Abstract- Line 100 typo at the end. Line 104 Last sentence of the line should be corrected

3) Line 265 refers to"clinically positive nodes" can you define this term in the methods section where you discuss the changes in the FIGO 2018 staging criteria to include addition of imaging

4) Line 247, sentence starting at the end the line is confusing, the percentages listed for 5-year survival seem to refer to discriminatory ability instead of 5-year survival.

5) In your discussion section, the issue of inconsistent capture of nodal stage and other factors included in the new staging criteria. How/why did you decide to include patients all the way back to 2004?

Reviewer #2:

1. The authors use 5-year mortality synonymously with discriminatory ability, as in line 247-251, and lines 275- 277 but this could be clarified for the reader to make be consistent throughout the manuscript. Can the authors describe what improved discriminatory ability means? Figures 1 and 2 are intended to illustrate this point, but further detail as to how these figures support the conclusion would be helpful.

2. Did positive nodes mandate some pathologic confirmation (lines 195-197), or was PET activity and or CT enlargement considered as positive? Do the authors have any information about whether positive lymph nodes were resected or simply biopsied in the surgically staged women? Similarly did ant women with clinically (radiographically noted) positive nodes have a lymph node dissection (ie extraperitoneal lymph node removal)? Could this explain the slightly better survival seen in these women in Table 4 among pathologically positive nodes?

3. The authors provide no information the potential impact, and variation in, treatment for lymph node positive patents compared to lymph node negative patients within stage or substage exploratory analysis. Understandably, the superiority of one treatment to another was not the aim of the manuscript, but the potential impact of different, and notably more, treatment for node positive women deserves some mention in the discussion given the primary study outcome of 5-year survival.

Reviewer #3: For the manuscript titled "Prognostic performance of the 2018 FIGO cervical cancer staging guidelines", I have the following comments and queries:

1. Thanks for submission of your work to the Green Journal.

2. The manuscript is succinctly written, the analysis is rigorously done, and the conclusions are appropriate and of clinical value.

3. This manuscript is well-suited and will be very informative for the practicing OB/GYNs. The Tables will be excellent tools for clinicians to use for prognosis counseling.

4. The authors describe the potential limitations of using data from these databases including the accuracy of staging and the inability to capture cancer-specific survival. However, all-cause mortality is important as well.

5. Figure 2 is a bit difficult to read.

6. Line 299 has a typo (stage IIIIC2).

STATISTICAL EDITOR COMMENTS:

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

lines 276-277: This section should be expanded and perhaps clarified in the introduction. That is, how does the new staging scheme improve discriminatory ability? (It appears to offer more differentiation in terms of prognosis for 5 yr survival)

Table 2: Need units for age.

General: Is there any information re: the number of LN evaluated in each subset?

Table 4: It is not clear to me how the clinical diagnosis of positive nodes was made. Could this be clarified? Were there differences in these cohorts in other clinical or demographic characteristics that might account for the worse 5-yr survival among the clinical nodes (+) groups?

Figs 1 and 2: Need to cite the number of women remaining at risk in each of the cohorts at the indicated time points. If visually unattractive, could cite as supplemental table.

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript. These comments should be included in your point-by-point response cover letter.

The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.

- The précis is a single sentence of no more than 25 words, written in the present tense and stating the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstracts conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Precis should be the "hook" for people who scan the Table of Contents to see what to read. It shouldn't not include statements like "in this study" or "we found". Just state what you found.

- The objective for the abstract should be a simple "to" statement without background.

- Please consult the Instructions for Authors regarding the use of abbreviations, and what constitutes an acceptable abbreviation. This is not an acceptable abbreviation. Please spell out all abbreviations on first use. It is reasonable to not use abbreviations for words that are seldom used in the paper. We try to limit “unique” abbreviations so that readers don’t have to frequently refer back to the first notation of the abbreviation to remember its meaning. We realize that this may affect word count but believe it makes it easier in most cases for the reader.

- is this a typo?

- I'm not sure your data has shown this. FIGO 2018 FIGO Stage IIIC1 (+ pelvic nodes) have a CI that is only 59-63% for 5 year survival. That seems rather narrow. For the IIIC2 are the ones with + para aortics and that does have a 9 point percentage spread,which is pretty broad.

- abbreviation should be spelled out

- state why exempt, and add a "period".

- The Journal style doesn’t not use the virgule (/) except in numeric expressions. Please edit here and in all instances.

2. The Editors of Obstetrics & Gynecology are seeking to increase 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, as well as subsequent author queries. 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:
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3. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

4. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms 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, registered) have been explained." *The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

5. Please submit a completed STROBE checklist.

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), 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, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

6. 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 and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

8. 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).

9. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

10. The most common deficiency in revised manuscripts involves the abstract. Be 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 paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

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.

12. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

13. Please make sure "pathologically" and "radiologically-detected" are defined in your manuscript. These terms currently appear in the abstract.

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

15. Figures may be resubmitted as-is.

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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 Apr 11, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

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