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Questions about these materials may be directed to the Obstetrics & Gynecology editorial office: obgyn@greenjournal.org.
RE: Manuscript Number ONG-20-2219

Outpatient Penicillin Allergy Testing in Pregnant Women with Self-Reported Allergy

Dear Dr. Desravines:

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 14 days from the date of this letter. If we have not heard from you by Oct 08, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Dr. Desravines and colleagues report the results of a prospective cohort study that sought to address the feasibility and safety of penicillin allergy testing in an outpatient setting. Although a relatively small cohort (n=50), this study supports the safety and ease of outpatient allergy testing and highlights the rare occurrence of true penicillin allergy in those with reported allergy. The strengths, limitations and generalizability of this study to our practice are nicely reviewed. Likely an error but recommend removing the word skin in line 32 of the abstract.

Reviewer #2: Our aim was to estimate the feasibility, acceptability and safety of penicillin allergy testing in the pregnant population in the outpatient setting.

A prospective cohort study evaluating the feasibility, acceptability and safety of penicillin allergy testing among pregnant women with a self-reported penicillin allergy

Overall nicely written, easy to follow and understand each step of the allergy protocol and treatment plan

Methods: Very well done, nicely described step by step outpatient protocol during pregnancy

Discussion: I have to say that 0.5-15% (large CI because of small sample size.) but 3 women needed treatment so the proper setting with appropriate treatment facilities is absolutely necessary and this should be stressed/ Perhaps Allergy testing should become part of a public health effort before pregnancy? How about a few sentences on the Public Health perspective

Since the 4% is higher than the non pregnant state? (understand the small sample size) This is important regarding safety

I disagree and challenge the last sentence "In light of the potential to increase antibiotic stewardship and demonstrated acceptability and feasibility of testing, women with a reported penicillin allergy should undergo allergy testing in pregnancy." I would argue that they should undergo allergy testing preconception or around the time they report a reaction to confirm if it is indeed a penicillin allergy. It is all of our responsibility
Reviewer #3: The authors report the results of a prospective analysis of the feasibility and results of penicillin allergy testing in pregnant women in a single academic institution. These are important results, but the manuscript is full of grammatical and typographical errors and is somewhat disorganized in its structure, making it difficult to understand at times.

Introduction
Please expand on this statement and provide a reference: "drug provocation challenge is the gold standard for determining tolerance versus true drug hypersensitivity". (lines 75-76)

Methods
1. The methods are reasonably clear, although how subjects were identified is not clear (see comments on Results section)
2. I would argue against calling the group who declined or failed to get testing "the standard of care" group. Perhaps label them as the "No testing" group? "Standard of care" is a legal definition.
3. On p. 7 and elsewhere, the drug challenge is referred to by two different names - please standardize.
4. Is PCN-allergy testing covered by public health insurance in North Carolina?

Results
1. lines 145-151 are very confusing regarding how "screening" was defined and done, and how the authors arrived at 74 subjects. 152 subjects were "identified" yet 176 subjects were "screened"? How were the 176 subjects who were "screened" identified?
2. Is it really legitimate to include the 4 subjects who "planned" to get tested but were thwarted by the coronavirus pandemic in the "tested" group? Is there really a difference between the 24 subjects who accepted testing and failed to get it and the 4 who "intended" to get tested and weren't? Was the PCN allergy clinic shut down? What was the time period between their enrollment and the clinic closure? Perhaps it would make more sense to eliminate these 4 from the analysis altogether if they were recruited just prior to the clinic closure?
3. Please use a clearer term than "clinically delabeled". I don't think delabeled is even a word.
4. There is what probably is a typo in Figure 1 - was it really 53 women who declined participation?
5. The table and figure captions need to be more succinct.
6. Please include both N and % in Table 1.
7. Why is gestational age presented as a range in Table 2? Wasn't allergy testing done in a single session?
8. Why was cefazolin given as GBS prophylaxis to a woman who was found to have anaphylaxis at PCN allergy testing? (Table 2) What was her response?

Discussion
The reasons for declined testing are first mentioned in the discussion section. If there are data regarding the reasons for which PCN allergy testing was declined, this should be presented in the results section.

STATISTICAL EDITOR COMMENTS:

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

Table 1: The format should be n(%) rather than as % alone. If there are any missing data, should enumerate.

line 40-41: The ratio is based on small counts of (+) rxn and should not assume normal distribution. The correct CI is 68% to 100%.

lines 43-45: In methods, need to state which variables were included in the final aOR model.

lines 224-225, 285-287: Regarding safety, although 46 tests were done and only three had any reaction and those were successfully treated, 46 is a small number from which to generalize safety. For instance, there were no deaths among 46 women, but that 0% has 95% CI = 0 to 8%. Is one willing from these data to generalize that up to a mortality of 8% would be acceptable?
EDITOR COMMENTS:

1. 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. 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). 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. Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

3. 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.

4. Please include the DOI with each of your References. It should appear at the end of the citation with no period following the DOI number.

5. For studies that report on the topic of race, 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, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes).

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

The category of "Other" is a grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

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 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.

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. 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 limit for Original Research articles is 300 words. Please provide a word count.

10. 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.

11. 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.

12. ACOG is moving toward discontinuing the use of "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.

13. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%).

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. 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 reference you are citing is still current and available. If the reference you are citing has been updated (ie, 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 (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found at the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top).

16. Figures

Figure 1: Please check n values for those who declined participation (127-56=71). Please upload as a figure file on Editorial Manager.

Figure 2: Please upload as a figure file on Editorial Manager.

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  * 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.

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 14 days from the date of this letter. If we have not heard from you by Oct 08, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Dwight J. Rouse, MD, MSPH

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2019 IMPACT FACTOR RANKING: 6th out of 82 ob/gyn journals

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