

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: Apr 30, 2020
To: "Mariam Naqvi" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-1058

RE: Manuscript Number ONG-20-1058

SARS-CoV-2 universal testing experience on a Los Angeles labor and delivery unit

Dear Dr. Naqvi:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Dr. Chescheir is interested in potentially publishing your revised manuscript in a timely manner. In order to have this considered quickly, we need to have your revision documents submitted to us as soon as you are able. I am tentatively setting your due date to May 4, 2020, but please let me know if you need additional time.

The standard revision letter text follows.

REVIEWER COMMENTS:

Reviewer #1: The authors have submitted Research Letter on a timely topic as L&D units across the country struggle with how to deal with pandemic

Intro

1 - Line 42 do the authors mean to say 'asymptomatic' here?

Methods

2 - How long does it take to get test result?

Results

3 - Does it really matter how many were admitted to antepartum v L&D (line 57)? This could be omitted without loss of content & just leave it in the table.

Discussion

4 - It would be more forceful here to acknowledge that while universal testing in a low-incidence area appears pointless and just wastes PPE, this is a very fluid situation and will be revisited regularly with dept/hospital leadership

Table

5 - Unnecessary data provided here as this report is not about how many c-sections were performed, etc

Figure

6 - Excellent visual, adds value to the submission

Reviewer #2: Well done and thank you for the brevity which is refreshing.

Line 59: Please give a 95% confidence interval;

Line 76: Data are plural

Line 80: Would drop "dramatically";

Table 1 seems of very little value and I would suggest deleting it.

STATISTICAL EDITOR COMMENTS:

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

lines 48-49: Should either cite or cite a reference for which symptoms were included in the screening. What is the sensitivity and specificity (with CIs) for the test kit cited?

lines 59-61: The occurrence of 0 (+) cases out of 80 tests has a CI, namely the estimate is 0%, with 95% CI = 0-5%. The estimate should include its CI to put it in context, especially since the sample was $n = 80$.

Table 1: Since the $N=80$, the $n(\%)$ entries should be formatted with % rounded to the nearest integer, not to 0.1% level of precision. Need units for age, GA, BMI and length of stay. LOS typically has a non-normal distribution. If so in this case, should cite as median (Range or IQR). Were the two cases with a history of exposure to Covid-19 the same two patients who were symptomatic (lines 58-59)? If so, should clarify for the reader. If not, why were those not included in the initial screening protocol?

Fig 1, lines 107-108: Although it seems obvious that the rates of (+) test were different, should include a stats test to demonstrate the difference in proportions.

EDITOR COMMENTS:

Thank you for this submission; I agree with the comments by the other reviews. I agree with Reviewers 1 and 2 that the Table is not necessary.

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. All studies should follow the principles set forth in the Helsinki Declaration of 1975, as revised in 2013, and manuscripts should be approved by the necessary authority before submission. Applicable original research studies should be reviewed by an institutional review board (IRB) or ethics committee. This review should be documented in your cover letter as well in the Methods section of the body text, with an explanation if the study was considered exempt. If your research is based on a publicly available data set approved by your IRB for exemption, please provide documentation of this in your cover letter by submitting the URL of the IRB website outlining the exempt data sets or a letter from a representative of the IRB. In addition, insert a sentence in the Methods section stating that the study was approved or exempt from approval. In all cases, the complete name of the IRB should be provided in the manuscript.

5. 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.

6. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Research Letters articles should not exceed 2.5 pages (600 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.

7. 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).

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

9. Provide a précis on the second page, for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

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. 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.

13. Figure 1: Please upload as a separate figure file on Editorial Manager. Please add a y-axis line and tick marks along both axes. Also, please provide a figure key.

14. 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 <http://edmgr.ovid.com/acd/accounts/ifauth.htm>.

Please note that 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 to revise your manuscript, please submit your revision through Editorial Manager at <http://ong.editorialmanager.com>. Your manuscript should be uploaded in a word processing format such as Microsoft Word. 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.

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.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2018 IMPACT FACTOR: 4.965

2018 IMPACT FACTOR RANKING: 7th 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.

May 1, 2020

Re: Manuscript # ONG-20-1058R1 [Revisions]

Dear Editor,

Thank you for your interest in our original research letter entitled “SARS-CoV-2 universal testing experience on a Los Angeles labor and delivery unit” for consideration by *Obstetrics & Gynecology*.

We greatly appreciate the thoughtful comments from the reviewers and have edited our manuscript to reflect this feedback. Please see our point-by-point responses attached with this letter, and do not hesitate to reach out to us if any other modifications or revisions are needed. Of note, we included two versions of Figure 1 (one with the key inset, and one separate) to allow for some flexibility in formatting.

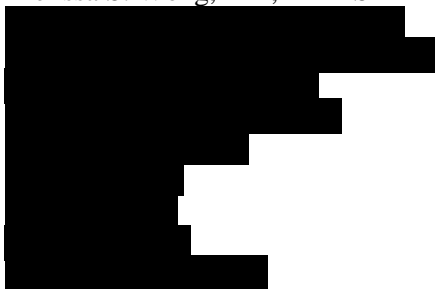
We again confirm that this work is original and has not been published, nor it is under consideration for publication elsewhere. As the lead author, I confirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained. Our study was approved by the Cedars-Sinai Institutional Review Board.

Thank you for allowing us to submit our research and for considering it for publication. We look forward to hearing your thoughts.

Sincerely,



Mariam Naqvi, MD
John A. Ozimek, DO
Richard M. Burwick, MD, MPH
Naomi H. Greene, PhD
Sarah J. Kilpatrick, MD, PhD
Melissa S. Wong, MD, MHDS



Responses to individual responses are highlighted with bold text.

REVIEWER COMMENTS:

Reviewer #1: The authors have submitted Research Letter on a timely topic as L&D units across the country struggle with how to deal with pandemic

Intro

1 - Line 42 do the authors mean to say 'asymptomatic' here?

We did mean to refer to symptomatic women, not asymptomatic women, in Line 42. Prior to instituting universal testing for all women admitted to our labor and delivery unit, we were only testing women with symptoms or relevant exposures and found relatively few positive cases. We have changed the verbiage of this sentence to make this clearer.

Methods

2 - How long does it take to get test result?

Test results were available within 20 hours, and this has been added to the manuscript.

Results

3 - Does it really matter how many were admitted to antepartum v L&D (line 57)? This could be omitted without loss of content & just leave it in the table.

We agree this information is redundant and have decided to remove Table 1 from the manuscript in light of comments from the reviewers and the Editor. We have summarized basic demographic information into the Results section.

Discussion

4 - It would be more forceful here to acknowledge that while universal testing in a low-incidence area appears pointless and just wastes PPE, this is a very fluid situation and will be revisited regularly with dept/hospital leadership

We agree with this point and have strengthened this point in our discussion.

Table

5 - Unnecessary data provided here as this report is not about how many c-sections were performed, etc

We agree and removed the Table as described above.

Figure
6 - Excellent visual, adds value to the submission

Thank you for this feedback.

Reviewer #2: Well done and thank you for the brevity which is refreshing.

Line 59: Please give a 95% confidence interval;

We have added this to the manuscript.

Line 76: Data are plural

We have made this change to the manuscript.

Line 80: Would drop "dramatically";

We have made this change to the manuscript.

Table 1 seems of very little value and I would suggest deleting it.

We agree with this comment, and have deleted Table 1 as stated above.

STATISTICAL EDITOR COMMENTS:

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

lines 48-49: Should either cite or cite a reference for which symptoms were included in the screening. What is the sensitivity and specificity (with CIs) for the test kit cited?

Patients were screened for symptoms of fever, cough and shortness of breath, and this was updated in Methods section. The sensitivity of the test kit was 100% at 250 copies/reaction and 95% at 25 copies/reaction (lower limit of detection). The specificity was 100%, with no cross-reactivity with other common respiratory viruses (Influenza, RSV and Seasonal Coronavirus). This has been added to the methods section.

lines 59-61: The occurrence of 0 (+) cases out of 80 tests has a CI, namely the estimate is 0%, with 95% CI = 0-5%. The estimate should include its CI to put it in context, especially since the sample was $n = 80$.

Thank you for the comment. Since we had 0 positive cases, we agree with a one-sided confidence interval, and we have added this to the text.

Table 1: Since the $N=80$, the $n(\%)$ entries should be formatted with % rounded to the nearest integer, not to 0.1% level of precision. Need units for age, GA, BMI and length of stay. LOS

typically has a non-normal distribution. If so in this case, should cite as median (Range or IQR). Were the two cases with a history of exposure to Covid-19 the same two patients who were symptomatic (lines 58-59)? If so, should clarify for the reader. If not, why were those not included in the initial screening protocol?

Table 1 was removed from the manuscript based on recommendations from the other reviewers and the Editor.

Fig 1, lines 107-108: Although it seems obvious that the rates of (+) test were different, should include a stats test to demonstrate the difference in proportions.

Thank you for this comment. We did internally perform a chi-square to compare our proportion of positive tests among asymptomatic women to that reported by our colleagues in New York ($p=0.0005$). After careful consideration, we decided to omit this from the manuscript as our principal conclusion was that the decision for universal testing should be made based on local rates of infection, rather than our finding of significant differences between rates of asymptomatic infection between Los Angeles and New York City. As such, we have removed the word “significantly” from the figure caption.

EDITOR COMMENTS:

Thank you for this submission; I agree with the comments by the other reviews. I agree with Reviewers 1 and 2 that the Table is not necessary.

Thank you for the prompt and thorough review of our manuscript. We have removed Table 1 based on all of your suggestions.

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:

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We will opt-in.

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

I have confirmed that all co-authors have no financial disclosures and ensured this is stated on the 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.

This statement has been added to the cover letter.

4. All studies should follow the principles set forth in the Helsinki Declaration of 1975, as revised in 2013, and manuscripts should be approved by the necessary authority before submission. Applicable original research studies should be reviewed by an institutional review board (IRB) or ethics committee. This review should be documented in your cover letter as well in the Methods section of the body text, with an explanation if the study was considered exempt. If your research is based on a publicly available data set approved by your IRB for exemption, please provide documentation of this in your cover letter by submitting the URL of the IRB website outlining the exempt data sets or a letter from a representative of the IRB. In addition, insert a sentence in the Methods section stating that the study was approved or exempt from approval. In all cases, the complete name of the IRB should be provided in the manuscript.

Our study was approved by the Cedars-Sinai IRB, and this was added to the manuscript.

5. 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.

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- * 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).

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This has been added.

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A precis has been added.

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13. Figure 1: Please upload as a separate figure file on Editorial Manager. Please add a y-axis line and tick marks along both axes. Also, please provide a figure key.

A y-axis line and tick marks have been added. A figure key has been added. For ease of formatting for the *Journal*, we have included two versions of the figure – one with the Figure Key inset, and one with them separated (the latter are two separate files).

14. 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 <http://edmgr.ovid.com/acd/accounts/ifaauth.htm>.