Date: Oct 12, 2018
To: "Erin E. Burke" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1674

RE: Manuscript Number ONG-18-1674

Evaluation of a Novel, Minimally Invasive Test for Fertility Hormones

Dear Dr. Burke:

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 Nov 02, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: There is no doubt that low cost screening tests have multiple advantages, and have shown their relevance with the use of over the counter pregnancy tests. The authors mention convenience because the tests described herein do not require a phlebotomist. However, this is an advantage more restricted to the USA, because in many other countries, physicians and nurses are well trained in venipuncture. The authors highlight the convenience of using a fingerstick for sample collection, and although it is obviously less invasive than venipuncture, it is still an invasive procedure, that may not appeal to some patients.

The study itself is well designed, proving that the analysis of filter paper stored fingerstick samples provided data that was quite similar to that obtained from conventionally obtained venipuncture serum samples. They did so for a multitude of relevant hormone, including gonadotropins, anti-Müllerian hormone, estradiol, testosterone, thyrotropin and free thyroxine.

The authors do make a point of highlighting a limitation that this type of assay has, specifically, that it is intended to be a screening tool, that would inform a woman about her need to seek the advice of a physician in order to undergo more comprehensive examinations.

A limitation that is not mentioned by the authors is that with regards to steroid immunoassays are no longer the gold standard. High-performance liquid chromatography/tandem mass spectrometry is what should be used as a comparator for any assay measuring steroids. One might argue that the analysis of both types of samples was done using the same immunoassay, but it was done in the same laboratory. The biggest limitations of steroid immunoassays are the inter-operator and inter-laboratory variations, which can yield several fold differences. This has led NIH and CDC to require that high-performance liquid chromatography/tandem mass spectrometry becomes the method of choice.

Overall, the authors make a good set of disclaimers, as well recommendations for future studies. It will be interesting to see if the test will gain FDA/EMA approval, as well as good reviews from NIH and CDC.

Reviewer #2: Overall: The authors present a report of using fingerstick instead of phlebotomy to collect a blood sample to analyze frequently measured hormones associated with infertility visits. There are some major weaknesses. The authors do not explain what Modern Fertility is in their disclosure. Is this a company that would benefit financially from this approach?

The target audience for the Green Journal are practicing clinicians. The paper is written for a statistical or laboratory science audience, not a general practicing clinician.

Reviewer #3: This is an interesting report, but I think that there are areas where additional detail would provide clarity for other reviewers.

1. Methods: Additional detail is needed about how the study was carried out. The authors note that 706 women expressed interest and 130 women were prospectively enrolled. How did you select the 130 women and why 130? The authors provide some inclusion/exclusion criteria, but how did you define "good general health" and "started their menses within the months of enrollment". Western IRB is listed - how are they associated with the authors affiliations? Were all participants asked to come to a central location to do the blood draws? It is unclear whether they were given the fingerstick materials and did it at home or if it was all done in one central location with careful supervision.

2. Table 1: The only information about study participants was their age and their race/ethnicity. Did the authors have any other information about the participating women? Is race/ethnicity only shown in comment to the 'diversity of the sample population'?

3. Discussion: The conclusions drawn in the discussion seem too strong given the research performed. How would this work in real life? It is very unclear how a woman would be able to use this in her home and how everything would be coordinated. Would it be an out of pocket cost? How would a physician be linked to provide counseling to women before and after? These are all questions that came up as I read page 10.

4. There are some areas where the authors did not follow the instructions for authors for a "Procedures and Instruments" report. The suggested maximum number of references is 10. The authors have 26. It is unclear whether this type of article will support 7 tables and 'one' figure that includes 8 smaller figures. Also the Journal encourages videos to accompany these reports.

STATISTICAL EDITOR'S COMMENTS:

1. Since ultimately the finger stick method may be used in place of venipuncture, it is important to demonstrate the variability of FS assay. Should include Bland-Altman or some other graphical display of variability of FS method assay. Another useful metric would be what were the largest differences observed for each of the assays when comparing paired FS samples. Given the large sample from 130 women, this would assure the reader in the worst case scenario, what difference was observed. The correlations cited do not convey to the average reader what variation might be encountered.

Much improved version since the prior submission. For the figures A-H which demonstrate the correlation between the venipuncture and FS samples, should include the 95% CI for individual estimates (not the 95% CI for the regression line) to give the reader an appreciation for the potential variability of individual measurements.

ASSOCIATE EDITOR - GYN:

Please note Rev#2 last comment. We appreciate the submission, but the writing is not currently in alignment with journal expectations for what our readership would expect. When revising, please try to target towards the 'general practicing clinician'.

EDITORIAL OFFICE 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, 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:
   1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
   2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

2. 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), and quality improvement in health care (ie, SQUIRE 2.0). 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, or SQUIRE 2.0 guidelines, as appropriate.

3. 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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at http://links.lww.com/AOG/A515, and the gynecology data definitions are available at http://links.lww.com/AOG/A935.

4. 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 appendixes).

Please limit your Introduction to 250 words and your Discussion to 750 words.

5. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with 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 signature on the journal's author agreement 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).

6. 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.

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

8. 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.

9. 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.

10. The American College of Obstetricians and Gynecologists' (College) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite College 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. 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 a College document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All College documents (eg, Committee Opinions and Practice Bulletins) may be found via the Resources and Publications page at http://www.acog.org/Resources-And-Publications.

***

If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at http://ong.editorialmanager.com. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors, that each author

has given approval to the final form of the revision, and that the agreement form signed by each author and submitted with the initial version remains valid.

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 Nov 02, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

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

November 2, 2018

Nancy C. Chescheir, MD
Editor-in-Chief, *Obstetrics & Gynecology*

Dear Dr. Chescheir,

Thank you for the opportunity to revise and resubmit our manuscript entitled "Evaluation of a Novel, Minimally Invasive Test for Fertility Hormones." This manuscript describes the validation of an at-home, self-collection method for measuring reproductive hormones. We show that fingerstick sampling on filter paper can be used interchangeably with traditional venipuncture sampling for measuring anti-Müllerian hormone, estradiol, follicle-stimulating hormone, luteinizing hormone, prolactin, testosterone, thyroid-stimulating hormone and free thyroxine.

The additional reviewers' comprehensive and insightful comments have significantly improved our manuscript, particularly in aligning our focus with the interests of a practicing clinician. Notably, we streamlined the Discussion section to underline the importance of hormone tests for screening common gynecological and fertility disorders, how these tests can be incorporated into an obstetrician's workflow, and how they represent a patient-centered approach to healthcare. We also moved our laboratory and statistical methods to appendices.

Enclosed, we provide a point-by-point response to address the critiques of each reviewer and the comments of the Statistical and Associate Editors. We also highlighted all changes in the revised manuscript.

Thank you in advance for your continued consideration.

Sincerely,

Erin E. Burke, PhD
Modern Fertility

Safedin H. Beqaj, PhD
Universal Diagnostic Laboratories, Modern Fertility

Nataki Douglas, MD, PhD
Rutgers-New Jersey Medical School, Modern Fertility

Robert Luo, MD, MPH
Modern Fertility

Enclosures

Evaluation of a Novel, Minimally Invasive Test for Fertility Hormones
Response to Reviewers

Reviewer #1:
The authors mention convenience because the tests described herein do not require a phlebotomist. However, this is an advantage more restricted to the USA, because in many other countries, physicians and nurses are well trained in venipuncture. The authors highlight the convenience of using a fingerstick for sample collection, and although it is obviously less invasive than venipuncture, it is still an invasive procedure, that may not appeal to some patients.

> Response: Thank you for raising this concern. We altered our text to highlight that venipuncture requires the time of a medical professional and often travel to a clinic, hospital, or other medical office. The convenience of fingersticks lies in the ability to self-administer blood sampling, reducing the associated time and expense of this procedure. We have added more explicit language around this distinction in lines 58 to 59 and 148 to 151. We have also added language around the limitation that some patients may prefer venipuncture in the Discussion, line 156.

A limitation that is not mentioned by the authors is that with regards to steroid immunoassays are no longer the gold standard. High-performance liquid chromatography/tandem mass spectrometry is what should be used as a comparator for any assay measuring steroids. One might argue that the analysis of both types of samples was done using the same immunoassay, but it was done in the same laboratory. The biggest limitations of steroid immunoassays are the inter-operator and inter-laboratory variations, which can yield several fold differences. This has led NIH and CDC to require that high-performance liquid chromatography/tandem mass spectrometry becomes the method of choice.

> Response: Thank you for this suggestion. While we agree that LC-MS is the methodology of choice for quantifying steroid concentrations, there are currently no FDA cleared LC-MS assays for steroid testing and many labs still use immunoassays, particularly for estradiol. Additionally, we believe our accuracy data (the agreement between measured quantities and the true values) for testosterone and estradiol demonstrate more than acceptable "trueness." Percent recovery was 95.5% for testosterone and 96.3% for estradiol, well within the +-20% guidelines from the FDA. (Please note, we had previously cited the 2013 FDA guidelines, which is 15%. We changed this to the newest guidelines of 20%, published in 2018, reference 6). Additionally, steroid hormones were measured in the same laboratory on the same equipment, using the same assays to ensure that other sources of variability, such as those mentioned by the reviewer, did not impact the comparison of fingerstick to venipuncture testing. In the future, we may look into validating fingersticks for LC-MS measurement of testosterone, but that is beyond the scope of the current manuscript.

Reviewer #2:
The authors do not explain what Modern Fertility is in their disclosure. Is this a company that would benefit financially from this approach?

> Response: Thank you for pointing out this oversight. Modern Fertility is a fertility testing company that offers the fingerstick test described in this manuscript. We have added this information to the title page and the "Disclosure of Potential Conflicts of Interest."

The target audience for the Green Journal are practicing clinicians. The paper is written for a statistical or laboratory science audience, not a general practicing clinician.

Response: Thank you for this comment. Although this manuscript is targeted for the "Procedures and Instruments" section of the Green Journal, we have improved our manuscript to also target the general readership of the Green Journal. We have moved the detailed explanations of our laboratory and statistical methods to Appendices A and B, respectively, and expanded our focus on the benefits of testing at home to providers and patients (lines 52 to 55, 130 to 134, and 145 to 148).

Reviewer #3:

The authors note that 706 women expressed interest and 130 women were prospectively enrolled. How did you select the 130 women and why 130? The authors provide some inclusion/exclusion criteria, but how did you define "good general health" and "started their menses within the months of enrollment".

Response: Thank you for this comment. We have added details about our screening methods to lines 77 to 82. In short, 706 women emailed us requesting to join the study. However, of those 706 women, only 478 completed the screening survey. Of those, 331 either did not pass the screening or could not be reached to set up an appointment for a blood draw. The main reasons why women did not pass the screening were because 1) they were on hormonal birth control, 2) did not have their period in the timeframe (February to early March) of the study or 3) were not available for a blood draw on day three of their period. Our protocol stipulates that we sample women on the third day of their menstrual cycle because we are measuring hormones that fluctuate throughout the cycle. This left us with 147 enrolled women, of whom 17 did not have adequate sample volume available for testing. We had a final enrollment of 130 women.

We have added additional language to line 77 explaining that 478 women completed the screening survey (as opposed to the original language about 706 women expressing interest) as this better reflects the actual screening numbers.

Western IRB is listed - how are they associated with the authors affiliations?

Response: Thank you for bringing this to our attention. Western IRB (WIRB) is a third party institutional review board. It is accredited by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). Their IRB registration number is IRB00000533, parent organization number is IORG0000432. The authors are not affiliated with WIRB beyond the fact that Modern Fertility, Inc. has contracted WIRB for their review of this study. We have added clarification of what WIRB is to lines 83 to 84.

Were all participants asked to come to a central location to do the blood draws? It is unclear whether they were given the fingerstick materials and did it at home or if it was all done in one central location with careful supervision.

Response: Thank you for bring this oversight to our attention. We have added details about the location and administration of the blood draws to lines 86 and 89. Participants were given the option of coming to our central lab or having a mobile phlebotomist come to their home for the blood draw. The phlebotomist performed both the venipuncture and the fingerstick. Lack of participant self-testing does represent a limitation of this study. However, having now measured hormones from the self-administered fingersticks of several hundred women, we have a sample success rate comparable to the rate of the trained phlebotomist. We have added discussion to this potential limitation in the discussion section, lines 155 to 159.

Table 1: The only information about study participants was their age and their race/ethnicity. Did the authors have any other information about the participating women? Is race/ethnicity only shown in comment to the 'diversity of the sample population'?

Response: Thank you for this comment. Race/ethnicty is shown to comment on the diversity of our sample population. We do not have any more demographic-specific data to report, other than general health status for which we screened.

Discussion: The conclusions drawn in the discussion seem too strong given the research performed. How would this work in real life? It is very unclear how a woman would be able to use this in her home and how everything would be coordinated. Would it be an out of pocket cost? How would a physician be linked to provide counseling to women before and after? These are all questions that came up as I read page 10.

Response: Thank you for this question. Initially, we did not provide much detail regarding the testing workflow, but as we have discussed clinician use of FS sampling, we have addressed potential workflow in the manuscript in lines 145 to 148.

There are some areas where the authors did not follow the instructions for authors for a "Procedures and Instruments" report. The suggested maximum number of references is 10. The authors have 26. It is unclear whether this type of article will support 7 tables and 'one' figure that includes 8 smaller figures. Also the Journal encourages videos to accompany these reports.

Response: To be more in line with a *Procedures and Instruments* submission, we removed 12 references. At the combined request of the first and second reviewers for additional clarification of our statistical methods and expansion of the discussion of benefits to practicing clinicians, we now include 14 references. We deleted Table 2 and combined Tables 3 and 4, bringing the total number of tables to five. We also streamlined the Introduction and Discussion sections, reducing the length of the manuscript by approximately 780 words.

Statistical Editor's Comments:
Since ultimately the finger stick method may be used in place of venipuncture, it is important to demonstrate the variability of FS assay. Should include Bland-Altman or some other graphical display of variability of FS method assay. Another useful metric would be what were the largest differences observed for each of the assays when comparing paired FS samples. Given the large sample from 130 women, this would assure the reader in the worst case scenario, what difference was observed. The correlations cited do not convey to the average reader what variation might be encountered. For the figures A-H which demonstrate the correlation between the venipuncture and FS samples, should include the 95% CI for individual estimates (not the 95% CI for the regression line) to give the reader an appreciation for the potential variability of individual measurements.

Response: Thank you for this feedback. Because of the constraints of the Procedures and Instruments submission, we chose to display the Deming Regression graphs instead of the Bland Altman graphs**.** The variation is captured in the bias measure. Bias measures the difference between each pair of matched samples and thus captures systematic measurement error. We have added 95% confidence intervals for the bias to Table 2 to further elucidate the variation in sample measurements. It is also possible to view the variation of individual measurement on the scatterplots (Figure 1) by comparing to the line of identity to the individual points. Additionally, the precision data (Table 4) shows the variability seen on repeat testing of the same sample.

For TSH and fT4, we mistakenly reported the biases as absolute values instead of as percentages. We have changed these to percentages (-0.95% and -1.77%, respectively) so that they are consistent with our other bias measures (Table 2). We apologize for this error.

Associate Editor - Gyn:
Please note Rev#2 last comment. We appreciate the submission, but the writing is not currently in alignment with journal expectations for what our readership would expect. When revising, please try to target towards the 'general practicing clinician'.

Response: Thank you for this comment. We changed the focus of the manuscript to address the benefits of reproductive hormone testing for both patients and gynecologists and how this testing can be seamlessly integrated into the normal workflow of the practicing clinician. To this end, we moved the laboratory and statistical methods to appendices, shortened the manuscript by approximately 780 words, removed 12 references and condensed the tables.

From: [redacted]
To: Denise Shields
Subject: Re: Manuscript Revisions: ONG-18-1674R1
Date: Friday, November 16, 2018 2:28:38 PM
Attachments: 18-1674R1 ms (11-9-18v3) EEB 11.16.18.docx
Burke_Appendixes_EEB 11.16.18.docx

Dear Denise,

Such great news about the acceptance.

Thank you for catching the reference mistake. The 7 in the discussion should be 6, and the 14 in the appendix becomes the new 7. I have attached updated manuscript and appendix docs that have the correct numbers changed and noted.

We opt-in to publish the response letter.

Thank you and have a happy Thanksgiving.

Erin\

On Fri, Nov 16, 2018 at 9:09 AM, Denise Shields <DShields@greenjournal.org> wrote:

> Hi Erin,
>
> I noticed that you deleted reference 7, but it's cited in the Discussion section. I deleted the references you marked for deletion from the References list. Would you take a look and make sure the edited list matches your in-text citations?
>
> Also, there is one other item that I need to ask about:
>
> 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. 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 with one of two responses:
>
> 1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
> 2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.
>
> Thank you,
> Denise
>
> -----Original Message-----
> From: Denise Shields
> Sent: Friday, November 9, 2018 2:01 PM
> To: 'Erin Burke' [redacted]
> Subject: RE: Manuscript Revisions: ONG-18-1674R1

You do the same!

-----Original Message-----
From: Erin Burke [redacted]
Sent: Friday, November 9, 2018 1:45 PM
To: Denise Shields <DShields@greenjournal.org>
Subject: Re: Manuscript Revisions: ONG-18-1674R1

Thank you Denise! Have a great weekend.

On Fri, Nov 9, 2018 at 10:39 AM, Denise Shields <DShields@greenjournal.org> wrote:
> Hi Erin,
>
> I like your suggested title, thank you for including it. No need to accept all the changes in the document.
>
> There were no changes to the appendixes, but I have attached the
> latest file in case you want to make some edits. (I need to update the
> title in the footer.)
>
> Regards,
> Denise
>
>
> -----Original Message-----
> From: Erin Burke [redacted]
> Sent: Friday, November 9, 2018 1:29 PM
> To: Denise Shields <DShields@greenjournal.org>
> Subject: Re: Manuscript Revisions: ONG-18-1674R1
>
> Dear Denise,
>
> Please find attached the manuscript. I have made a few tracked edits and comments, but overall we agree with all of your changes (though I have changed the suggested title). Would you like me to accept changes in the document?
>
> Also, were there any changes to the text in the Appendices?
>
> Thank you!
>
> Erin
>
> On Thu, Nov 8, 2018 at 10:44 AM, Denise Shields <DShields@greenjournal.org> wrote:
>> Dear Dr. Burke,
>>
>> I am assisting Daniel while he is out of the office for the next few days. Please see responses below:
>>
>> 1. In the Introduction, the author would like for you to clarify the term, "cold-chain transportation."

>> 6. In the current version of the manuscript (attached), this query is in the "Experience" section of the abstract.
>> 7. I would suggest, "The authors, who are employees of Modern Fertility, were involved in the study design, analysis, interpretation of the data, writing of the report and decision to submit the report for publication." Please change "The authors" as appropriate.
>>
>> No worries about what time you return the manuscript. We will work on it when you send it to us.
>>
>> Regards,
>> Denise
>>
>>
>> Denise Shields
>> Senior Manuscript Editor
>> Obstetrics & Gynecology
>> www.greenjournal.org
>> Find us social media:
>> Twitter (https://twitter.com/greenjrnl) Facebook
>> (https://www.facebook.com/greenjournal/)
>> Instagram (https://www.instagram.com/greenjrnl/)
>> LinkedIn (https://www.linkedin.com/groups/4058408)
>>
>>
>>
>> -----Original Message-----
>> From: Erin Burke [redacted]
>> Sent: Thursday, November 8, 2018 1:19 PM
>> To: Daniel Mosier <dmosier@greenjournal.org>
>> Cc: [redacted]; Denise Shields <DShields@greenjournal.org>
>> Subject: Re: Manuscript Revisions: ONG-18-1674R1
>>
>> Dear Daniel,
>>
>> Thank you for your email. The line numbers in your email do not seem to match up to the line numbers in the attached manuscript. I just wanted to confirm the following before sending back the manuscript:
>>
>> 6. Line 53: do you mean line 67?
>> 7. Do you have any examples of similar statements of how funders are
>> involved in the study? I am a full time employee (not a paid
>> consultant, as was added to the manuscript by the editors. I have
>> updated) of Modern Fertility and as stated in the author agreement, I was involved in the study design, analysis, interpretation of the data, writing of the report and decision to submit the report for publication (so pretty much I ran the study in my role at the company). I just want to make sure that this is properly conveyed.
>> 1. Which term in line 70 requires clarification (Accuracy? Percent recovery?)? Or so you mean line 95?
>>
>> Once these are confirmed I will return the manuscript with the requested changes. We

are on the west coast, so I wanted to confirm what time you would like the revisions as we have different COB times.
>> In the meantime, I have attached the signed transparency declaration statement.
>>
>> Thank you in advance,
>>
>> -Erin
>>
>> On Thu, Nov 8, 2018 at 6:04 AM, Daniel Mosier <dmosier@greenjournal.org> wrote:
>>> Dr. Burke,
>>>
>>>
>>> I'm very sorry, but I attached the wrong version of the manuscript
>>> to my previous message. Please use the version of the manuscript in
>>> this message when making your revision. Additionally, there is one
>>> additional query I did not include in my last message:
>>>
>>>
>>> LINE 70: Please clarify or revise this term as the readership would
>>> be unfamiliar.
>>>
>>>
>>> Please contact our office if you have any other questions or concerns.
>>>
>>> Sincerely,
>>> -Daniel Mosier
>>> _____
>>> From: Daniel Mosier
>>> Sent: Thursday, November 8, 2018 8:57:09 AM
>>> To: [redacted]
>>> Cc: Denise Shields
>>> Subject: Manuscript Revisions: ONG-18-1674R1
>>>
>>>
>>> Dear Dr. Burke,
>>>
>>>
>>>
>>> Thank you for submitting your revised manuscript. It has been
>>> reviewed by the editor, and there are a few issues that must be
>>> addressed before we can consider your manuscript further:
>>>
>>>
>>>
>>> Please note the minor edits and deletions throughout. Please let us
>>> know if you disagree with any of these changes.
>>> Given that your manuscript is over our word count limit, the Editors
>>> will ask that you shorten the Discussion section of your paper by
>>> roughly 350 words.
>>> LINE 1: This edit to your title will make it more specific. Do you

>>> agree with the edits?
>>> LINE 9: 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. Please
>>> provide a signed version of this statement.
>>> LINE 38: We prefer to state the "bottom line" in your precis. Please
>>> be sure this is correct.
>>> LINE 53: Please be sure this is stated in the body of your paper.
>>> Statements and data that appear in the Abstract must also appear in
>>> the body text for consistency.
>>> LINE 85: Besides the authors' involvement, would you describe how
>>> the funder was involved in the study?
>>> TABLE 3: Please express this p-value and all the p-values in your
>>> paper to no more than three decimal places.
>>>
>>>
>>>
>>>
>>> Please let me know if you have any questions. Your prompt response
>>> to these queries will be appreciated; please respond no later than
>>> COB on Friday, November 9th.
>>>
>>>
>>>
>>> Sincerely,
>>>
>>> -Daniel Mosier
>>>
>>>
>>>
>>>
>>>
>>> Daniel Mosier
>>>
>>> Editorial Assistant
>>>
>>> Obstetrics & Gynecology
>>>
>>> The American College of Obstetricians and Gynecologists
>>>
>>> 409 12th Street, SW
>>>
>>> Washington, DC 20024
>>>
>>> Tel: 202-314-2342

>>>
>>> Fax: 202-479-0830
>>>
>>> E-mail: dmosier@greenjournal.org
>>>
>>> Web: http://www.greenjournal.org
>>>
>>>

From: [redacted]
To: Stephanie Casway
Cc: [redacted]
Subject: Re: O&G Figure Revision: 18-1674
Date: Tuesday, November 6, 2018 1:06:37 PM

Dear Ms. Casway,

The figure and the legend both look perfect. Thank you.

Erin Burke, PhD
[redacted]

On Tue, Nov 6, 2018 at 4:23 AM, Stephanie Casway <SCasway@greenjournal.org> wrote:

> Good Morning Dr. Burke,
>
> Your figure has been edited, and PDFs of the figure and legend are attached for your review. Please review the figure and legend CAREFULLY for any mistakes.
>
> PLEASE NOTE: Any changes to the figures must be made now. Changes made at later stages are expensive and time-consuming and may result in the delay of your article's publication.
>
> To avoid a delay, I would be grateful to receive a reply no later than Thursday, 11/8. Thank you for your help.
>
> Best wishes,
>
> Stephanie Casway, MA
> Production Editor
>
> *Obstetrics & Gynecology*
> American College of Obstetricians and Gynecologists
> 409 12th St, SW
> Washington, DC 20024
> Ph: (202) 314-2339
>
> Fax: (202) 479-0830

scasway@greenjournal.org