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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)*

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Date: Sep 02, 2022
To: "Ramen Chmait" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-1334

RE: Manuscript Number ONG-22-1334

Advances in prenatal management of open spina bifida

Dear Dr. Chmait:

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

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

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

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

Your submission will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Sep 23, 2022, we will assume you wish to withdraw the manuscript from further consideration.

EDITOR COMMENTS:
Thank you again for writing this excellent review. In terms of suggestions for paring down length, the ultrasound diagnosis section and the prevention in future pregnancies section could be pared down a bit to make them a little bit tighter. For the title, we suggest "Advances in Fetal Surgical Repair of Open Spina Bifida" (or something else that emphasizes the focus on repair of this defect).

REVIEWER COMMENTS:

Reviewer #1: In this review, the authors describe the evidence and advances in care for patients with open spina bifida. The authors provide an excellent summary of NTDs, risks, pathophysiology, diagnosis, the manners of repair, and delivery and postnatal management. In particular, I applaud the authors for writing their review to be easily understandable and applicable for a general OBGYN audience, instead of just MFM specialists. There are only a handful of minor comments to note below.

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Reviewer #2: This is a systematic review of contemporary antepartum management of spina bifida. Historical perspective, pathophysiology, antepartum screening, and fetal closure of spina bifida lesions are discussed. The authors are to be congratulated for a complete review of the subject manner and the paper is well referenced.

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EDITORIAL OFFICE COMMENTS:

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

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* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology's Copyright Transfer Agreement (CTA) must be completed by all authors. We have not received the form from Andrew H. Chon (chona@ohsu.edu). When you uploaded your manuscript, each coauthor received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please ask your coauthor(s) to complete this form, and confirm the disclosures listed in their CTA are included on the manuscript's title page. If they did not receive the email, they should check their spam/junk folder. Requests to resend the CTA may be sent to em@greenjournal.org.

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

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

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

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

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

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

7. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry

Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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

* 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 or indicate whether the meeting was held virtually).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."
* Do not use only authors' initials in the acknowledgement or Financial Disclosure; spell out their names the way they appear in the byline.

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

11. Please review examples of our current reference style at https://edmgr.ovid.com/ong/accounts/ifa_suppl_refstyle.pdf. Include the digital object identifier (DOI) with any journal article references and an accessed date with website references.

Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the formal reference list. Please cite them on the line in parentheses.

If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document. In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

12. Figures 1-5: Please confirm that these are original to the manuscript.

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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 as a Microsoft Word document. Your revision's cover letter should include a point-by-point response to each of the received comments in this letter. Do not omit your responses to the EDITOR COMMENTS (if applicable), the REVIEWER COMMENTS, the STATISTICAL EDITOR COMMENTS (if applicable), or the EDITORIAL OFFICE COMMENTS.

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

Again, your manuscript will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Sep 23, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

September 6, 2022

Re: ONG-22-1334

Dear Reviewers,

Thank you for the opportunity to revise our manuscript. Below you will find a detailed response to your comments and questions.

EDITOR COMMENTS:
Thank you again for writing this excellent review.
-*Thank you.*

In terms of suggestions for paring down length, the ultrasound diagnosis section and the prevention in future pregnancies section could be pared down a bit to make them a little bit tighter.
-*Agreed. Both sections have been pared down. The word length of the ultrasound diagnosis section was decreased from 1507 to 1304, and the prevention section was decreased from 500 to 273 words.*

For the title, we suggest "Advances in Fetal Surgical Repair of Open Spina Bifida" (or something else that emphasizes the focus on repair of this defect).
-*Agreed. Title changed as suggested.*

REVIEWER COMMENTS:

Reviewer #1: In this review, the authors describe the evidence and advances in care for patients with open spina bifida. The authors provide an excellent summary of NTDs, risks, pathophysiology, diagnosis, the manners of repair, and delivery and postnatal management. In particular, I applaud the authors for writing their review to be easily understandable and applicable for a general OBGYN audience, instead of just MFM specialists.
-*Thank you.*

There are only a handful of minor comments to note below.

Abstract: excellently written and salient
-*Thank you*.

- Line 29 Please clarify if the AFP the authors report to is general AFP, maternal serum AFP, or amniotic AFP.
-*In this manuscript, we have clarified "AFP" with the letters "ms" in front of the AFP to inform the reader that we are referring to "maternal serum AFP".*

- Line 77: cranioschisis appears to be misspelled
-*Agreed. This was fixed as suggested.*

- Risk Factors: Perhaps this section may be summarized in a table to reduce the length of this review
-*We have shortened this section from 314 words to 192 words*.

- Line 115: We should be cautious about discussing mode of delivery and I might remove this from the sentence, especially as various modes of delivery are concerned in the Antepartum and Delivery sections
-*Agreed. This section was removed.*

- One suggestion might be the natural history section to follow the prenatal screening section
-*Our preference is to keep the natural history section in its current location.*

- Line 173-176: I'm not sure if this statement applies considering new limitations across this country. In most of those states with 18-20 week restrictions, not there are total bans. I might just remove it altogether since it refers to dated policies.
-*Agreed. This section was removed.*

- Lines 598-604: It might be helpful to add after the section on sexual dysfunction if there is any data on reproductive outcomes of individuals who themselves had NTD (specifically pregnancies where the mother had NTD as a child).
-*Due to the excessive length of this manuscript, we have elected not to add this information.*

- Lines 606-624: I might integrate this into the section about delivery as opposed to after discussing postnatal evaluation and transition to adult care.
-*We elected to maintain the Future Pregnancies section as its own stand-alone section, as we feel that the sub-header will direct the interested reader to this important section. Otherwise this section will be swallowed up in the middle of another lengthy section.*

Reviewer #2: This is a systematic review of contemporary antepartum management of spina bifida. Historical perspective, pathophysiology, antepartum screening, and fetal closure of spina bifida lesions are discussed. The authors are to be congratulated for a complete review of the subject manner and the paper is well referenced.
-*Thank you.*

With reference to laparoscopic fetal repair there are some issues for discussion. It would appear that a randomized prospective clinical trial was never performed comparing laparoscopic repair with a non-repaired control group as was done in the MOMS study. It is assumed that such a study would like be deemed unethical as it would withhold fetal repair from the control group. However, has there been any randomized trial comparing open hysterotomy repair to laparoscopic repair?
-*No. There are no randomized trial comparing open hysterotomy repair to laparoscopic repair.*

In addition, did any of the studies concerning fetal outcome with laparoscopic repair utilize an historical control group of open hysterotomy repair in the same institution?

-Yes. This information is detailed at length in the manuscript. This section has been copied and pasted here:

"A 2021 publication by the Fetoscopic MMC Consortium described both pregnancy and postnatal short-term neurologic outcomes at 12 months of age in a cohort of 300 patients post prenatal fetoscopic repair.(122) With respect to gestational age at delivery, fetoscopic repair patients as a whole delivered at an average gestational age of 34.3 weeks, similar to the average delivery gestational ages for the MOMS and post-MOMS open fetal surgery patients (34.1 and 34.3 weeks, respectively).(106, 162) While gestational age at delivery appeared similar, fetoscopic repair patients demonstrated a higher rate of PPROM (54.6%) compared to patients undergoing open repair (32-46% in the original MOMS trial and post-MOMS experience publication).(106, 122, 162) Short-term neurologic outcomes by 12 months of life were similar, where 43.8% of fetoscopic repair patients required a ventriculoperitoneal shunt insertion or other cerebrospinal fluid diversion procedure compared to 40.8% for patients in the original MOMS trial.(106, 122) Recently, several collaborating centers have published long-term neurologic outcomes at 30-months of life, demonstrating a 46-54% independent ambulation rate in prenatal fetoscopic repair patients(167, 168) compared to the 42% independent ambulation rate at 30-months of life observed in the original MOMS trial.(106) In addition, 61% of fetoscopic repair patients demonstrated independent voiding without clean intermittent catheter use at 30-months of life,(167) compared to 38% of patients following open prenatal repair patients at long-term follow up (mean age 7.4 years).(169)"

Finally have there been any meta-analysis studies comparing open repair to hysterotomy repair, principally with reference to fetal-neonatal outcome?
-As far as we know, there have been no meta-analysis published with this comparison yet.

EDITORIAL OFFICE COMMENTS:

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

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
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-N/A
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
-N/A
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
-N/A
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.
-N/A

3. Obstetrics & Gynecology's Copyright Transfer Agreement (CTA) must be completed by all authors. We have not received the form from Andrew H. Chon (chona@ohsu.edu). When you uploaded your manuscript, each coauthor received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please ask your coauthor(s) to complete this form, and confirm the disclosures listed in their CTA are included on the manuscript's title page. If they did not receive the email, they should check their spam/junk folder. Requests to resend the CTA may be sent to em@greenjournal.org.
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-*N/A*

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

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

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-*Agreed.*

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7. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://urldefense.com/v3/__https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions__;!!LIr3w8kk_Xxm!tgWVgC9QI1YUIHlhGPiJRe2l_AXbP2-_3FbnmRjGuxD1qIIVttE10smm6AJmavXMq-K-lUfS5TMXIA$ and the gynecology data definitions at https://urldefense.com/v3/__https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions__;!!LIr3w8kk_Xxm!tgWVgC9QI1YUIHlhGPiJRe2l_AXbP2-_3FbnmRjGuxD1qIIVttE10smm6AJmavXMq-K-lUfIuBQq-w$. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

-Agreed.

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* All financial support of the study must be acknowledged.
-No financial support.
* 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.
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-N/A

11. Please review examples of our current reference style at https://urldefense.com/v3/__https://edmgr.ovid.com/ong/accounts/ifa_suppl_refstyle.pdf__;!!LIr3w8kk_Xxm!tgWVgC9QI1YUIHlhGPiJRe2l_AXbP2-

_3FbnmRjGuxD1qIIVttE10smm6AJmavXMq-K-lUeVsNPxzw$. Include the digital object identifier (DOI) with any journal article references and an accessed date with website references.

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12. Figures 1-5: Please confirm that these are original to the manuscript.
-*Originals*.

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