OBSTETRICS & GYNECOLOGY

NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

- 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: Sep 29, 2020
To: "Henriette Svarre Nielsen" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-2537

RE: Manuscript Number ONG-20-2537

Impact of SARS-CoV-2 antibodies at delivery in women, partners and newborns

Dear Dr. Nielsen:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors are 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 October 2, 2020, but please let me know if you need additional time.

The standard revision letter text follows.

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).

REVIEWER COMMENTS:

Reviewer #1:

The authors report a study on outcomes corresponding with serologic testing for COVID 19 of women admitted to a maternity hospital in Denmark.

1. Since women were invited to participate in this study, what is the percent of women who accepted? Ah! This is delineated on line 173: please move to your abstract to demonstrate that 75% of women participated.

2. Line 112: you describe this as project as "unselected serological testing:, but the women were approached during a specific timeframe. Were all women approached and did they have to deliver to be included?

3. Line 133: the method you use for testing has a relatively low sensitivity for IgM but good sensitivity for IgG antibodies: how does that affect your data?

4. Line 147: who performed the review of the electronic health records and how was that data verified?

5. Consider writing something about the significance of antibodies with COVID-19 and what is known and not known about finding antibodies in patients.

Reviewer #2: This is a report from Denmark of 1361 parturients who agreed to participate in what is essentially a seroprevalence study. Questions for the authors include:

1.Is this essentially a study of COVID positivity in asymptomatic individuals? Only 4 of your study patients had previously been diagnosed with COVID (for moderate to severe symptoms. I presume?). The rest did not have that diagnosis. You state on Line 266 that your patients were asymptomatic or had "mild" symptoms- please elaborate. In retrospect, would any of these mild symptoms have raised the suspicion of COVID 19? If symptoms were so mild as to not lead to a doctor visit or work up, this study would provide new (reassuring) information on the risk to pregnant women of asymptomatic or unrecognized COVID 19.

2.When you say "other chronic diseases" - other than asthma- does that include autoimmune or other immune dysfunction

disorders? Please specify, since individuals with these kinds of medical problems are presumed to be at higher risk of infection.

3.In line 214 you refer to families with complete serologic data. Are you referring to the triads in your study (mother, father, infant) or additional family members? Please clarify

Reviewer #3:

Thank you for your submission. This is a relatively large cohort study of women, their partners and newborns virological and serological status from a single, large hospital in a 3month period in Denmark. My main concern is the conclusion that SARS CoV-2 infection does not have any association with perinatal outcomes requires a more full evaluation than you have provided. Please provide a secondary analysis of outcomes based on maternal symptoms, virological and serologic status. We cannot differentiate outcomes based on maternal symptoms at all here as you have reported them only by serological/PCR results. Additionally, you really have very few individuals who were antibody positive, even fewer with positive PCR results. I suspect your results are under powered to be able to assert a lack of an association with poor outcomes. Please address.
Numbers below refer to line numbers.

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

It's not clear from the precis what you mean. You were studying antibodies to SARS CoV2 not COVID 19 infection. Your precis should reflect this.

72. The objective of the abstract should be a simple "To" statement without background information.

74. It is an idiosyncratic fact that at the Journal we tend to avoid the use of the word impact to imply the result of a change, preferring to limit "impact" to mean a physical blow. Please edit here and throughout your paper. As well please careful of causal language. Yours is an observational study so you can report on associations, not causation.

77. Please make sure in the paper itself you address the sensitivity of. Pharyngeal vs nasopharyngeal swabs for detecting SARS CoV 2.

90. It seems rational and you have the opportunity to report it, that there may be a difference in perinatal outcomes between those who are symptomatic (55% in your study) and those were not. Please report this comparison. (Antibodies in patients, partners and newborns as well out perinatal outcomes).

93. Increased risk of what? Again, the conclusion needs to be reconsidered once you've analyzed by whether women were symptomatic or not.

108. Please edit out the "to our knowledge" or similar wording. As the readers cannot gauge the depth and breadth of your knowledge, this phrase does not add significant meaning. You can either reference your literature search details (database searched and search terms used) that informed your knowledge, or you could say something noting that your cited references provide limited information about this point.

112-115: Delete as these are either methods or results and should be reported in the appropriate section.

119. Was this a time of significant COVID 19 infection in Denmark? Please explain why you chose these dates.

141. This would be premature prelabor rupture of membranes. By GBS in urine, does that mean you do not do 3rd trimester anal/vaginal swabs as is done in the US?

143. cesarean delivery, not section.

173. "of whom" not "of which".

181. Could you split out the issue of blood type and symptoms? I don't really know what your p value on 182 is referring to. Also, these are really different things (blood type, symptoms). Reading further, I see you do discuss these separately. I would just end the sentence starting on line 180 after "antibodies" on line 181. Then, start sentence that now reads "Nonetheless,…." With "Only 52%....".

185. I would move the "only one woman had a positive pharyngeal swab" to follow sentence ending on line 177. Would clarify that "Four women in the antibody positive group…".

189. Please provide denominators so we know which population you are dealing with. I think you are meaning " Fourteen of the 29 women with SARS-CoV-2 antibodies (63.6%) had IgG antibodies, and 3/1,332 women without SARS COV-2 antibodies (3%) had IgG antibodies (Wouldn't this be 0.2%?)

191. You can exclude the p values since you provide 95% CI's which we prefer. Not sure we need information on line 192 since your RR is so high on line 1919.

196 -199. Please provide the absolute values, and RR, not just the p values here.
I would rewrite: More men in the antibody positive group aa%(xx/34) compared to the antibody negative group bb%(yy/1197) had a prior positive SARS-CoV-2 swab (RR, 95% CI). Sixty one percent of partners with SARS-CoV-2 antibodies reported symptoms. [is this any symptoms at the time they were completing the questionnaire or in the past?]

202, 185. Please co-locate the information about the newborns, rather than reporting information in 2 separate places.

One concern is your power for reporting a lack of difference. You have really very few women, partners or newborns with antibodies. Please consider a post hoc power analysis for all of the outcomes of mothers and babies.

214. Could you report the concordance rates for mothers/partners/infants? This section is rather confusing. How many women were neg if dad is positive and vice versa?

224. Just say:" if the partner had anti-SARS-CoV-2 antibodies, the woman had a 37% risk of infection."

244. Can't you say more strongly "is likely passive transfer from the mother and not evidence of vertical transmission". In limitations, please note that essentially all of these patients were likely infected in the late second or 3rd trimester given your 3 month period of data collection and average EGA at birth of 41 weeks; thus, vertical transmission rates if maternal infection occurs earlier in pregnancy cannot be addressed with this study.

252. I don't know what this sentence means. What do you mean by "age appropriate women in the community"? I think you could delete lines 251-262 as it is content not directly applicable to your study. You could include information lines 254-256

274. You include 3 groups, so "both" should be deleted,as it refers to 2.

STATISTICAL EDITOR COMMENTS:

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

Table 1: The cohort with (+) Ab has N = 29, so the entries in that column should have %s rounded to nearest integer %, not cited to nearest 0.1% precision. lines 180-182: The stats test comparing blood type prevalence did not specifically test one blood type, but rather whether the distribution of blood types differed in the two cohorts. Need to specifically test type A to conclude a statistical difference is present. Many of the adverse events were infrequent, so there was limited power to discern a difference and thus many NS findings cannot be generalized.

lines 173-174: Need to compare the demographic/clinical characteristics of those who consented vs those who did not consent to address issue of possible bias.

Table 2: Same issue with %s rounded to nearest integer % in column with N = 34. Also, comparisons re: Asthma, other chronic diseases, smoking were each underpowered, so cannot generalize the NS findings.

Table 3: Same issue with %s rounded to nearest integer % in column with N = 17. Insufficient power for $Apgar_5 < 7$, art pH < 7.0, NICU admit etc.

Should summarize prevalences with CIs.

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. 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.

The following co-authors will need to complete our electronic Copyright Transfer Agreement, which was sent to them by email through Editorial Manager. Please note their email addresses and make sure they are correct. Once the form is complete, please add their disclosures to the "Financial Disclosure" section.

Line Fich Olsen (line.fich.olsen@regionh.dk)
Lisbeth Prætorius (Lisbeth.Praetorius@regionh.dk)
Henrik Westh (Henrik.Torkil.Westh@regionh.dk)
Nina la Cour Freiesleben (nina.la.cour.freiesleben@regionh.dk)

3. Use only these headings in the body text and remove any subheadings: Introduction, Methods, Results, Discussion.

4. Do not use "impact" to mention anything other than "to strike." Use "effect" or "affect" instead. In your title, change "Impact" to "Effects."

Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

5. Shorten your Precis to read, "Serological testing of parturient women, partners, and newborns found no association between coronavirus disease 2019 (COVID-19) and obstetric or neonatal complications."

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."

6. This is a preprint on https://www.medrxiv.org/content/10.1101/2020.09.14.20191106v1. This needs to be noted on title page.

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. 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.

9. 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).

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

11. 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.

12. 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.

13. 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.

14. 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%").

15. Line 273: Your manuscript contains a priority claim. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

16. 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.

17. Figures

Figure 1: Please upload as a figure file on Editorial Manager. Are there any exclusions that need to be added?

Figure 2: Please upload as a figure file on Editorial Manager. Where is the clip art from? By chance is it from the Noun Project?

18. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

19. 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 https://wkauthorservices.editage.com/open-access/hybrid.html.

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,

Dwight J. Rouse, MD, MSPH
Associate Editor for Obstetrics

2019 IMPACT FACTOR: 5.524
2019 IMPACT FACTOR RANKING: 6th out of 82 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.

Hvidovre Hospital

Department of Obstetrics and Gynecology

[redacted]

Obstetrics and Gynecology

Editor-in-chief Dr. Nancy C. Chescheir

Date: 2 October 2020

SARS-CoV-2 antibodies at delivery in women, partners and newborns

We are pleased to be afforded the opportunity to submit a revised manuscript and for the timely process. Enclosed, please find our manuscript *"SARS-CoV-2 antibodies at delivery in women, partners and newborns"*.

Thank you for your positive reply and the constructive comments from the reviewers, which provided insight for our revision of the manuscript. We have added some changes to accommodate the reviewer's comments, and we believe the revised manuscript is improved. We hope that you find our revision of the manuscript appropriate for publication in Obstetrics and Gynecology.

In the following you will find the reviewers' comments, followed by our reply (formatted in regular, blue-colored font). Changes made to the manuscript are also clearly marked with track changes.

I confirm that we have read and followed the Instructions for Authors. All authors have read and approved the revised version of the manuscript.

We look forward to hearing from you. On behalf of all authors with my kindest regards.

Yours sincerely,

Henriette Svarre Nielsen
Professor, Chief Physician
Department of Obstetrics and Gynecology
[redacted]

UNIVERSITY OF COPENHAGEN

Impact of SARS-CoV-2 antibodies at delivery in women, partners and newborns

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REVIEWER COMMENTS:

Reviewer #1:

The authors report a study on outcomes corresponding with serologic testing for COVID 19 of women admitted to a maternity hospital in Denmark.

Thank you for your thorough review of our manuscript.

1.Since women were invited to participate in this study, what is the percent of women who accepted? Ah! This is delineated on line 173: please move to your abstract to demonstrate that 75% of women participated.
Comment: Information on the proportion of participating women has now been added to the abstract.

Point of action: The following has now been added to the abstract (line 90-91): *“A total of 1,361 parturient women (75.1% of all women admitted for delivery at the hospital in the study period), 1,236 partners and 1,342 newborns participated in the study.”*

2.Line 112: you describe this as project as "unselected serological testing:, but the women were approached during a specific timeframe. Were all women approached and did they have to deliver to be included?
Comment: By “unselected” we mean that all women admitted for delivery were approached and invited to participate in the study. However, we concur with the confusing statement, which is now deleted.

Point of action: The following has now been clarified in the manuscript (line 133-134): *”..all women giving birth at the department, their partners and newborns were approached and invited to participate in the study”.*

3.Line 133: the method you use for testing has a relatively low sensitivity for IgM but good sensitivity for IgG antibodies: how does that affect your data?
Comment: This is an interesting point raised by the reviewer. The low(er) sensitivity may lead to a higher than expected prevalence. However, in this case, the vast majority of all cases (N=63) with antibodies were identified by elevated levels of the IgG antibodies and only 15 presented strictly with IgM antibodies. We therefore see it as unlikely to have influenced the results. We further show this in the subgroup analysis where we include only mothers with no antibodies or IgG antibodies (Appendix 4).

Point of action: The following has now been added to the manuscript (line 213-214): *“Furthermore, an analysis including only mothers with IgG antibodies indicated that the low sensitivity of IgM did not disrupt results (Appendix 4).”*

4.Line 147: who performed the review of the electronic health records and how was that data verified?
Comment: Pregnancy related coding in the Danish universal health care system is verified by specially trained midwife at the time of discharge and before reporting to national health registries. The information from the electronic health records was extracted by members of the research group after standardized training.

Point of action: The following has now been added to the manuscript (line 150-151): *“Verified information from the electronic health records*

were extracted by members of the research group after standardized training."

5.Consider writing something about the significance of antibodies with COVID-19 and what is known and not known about finding antibodies in patients.
Comment: We have now added the information suggested by the reviewer.

Point of action: The following has now been added to the manuscript (line 291-295): "*The course of development and duration of antibody responses in patients infected with SARS-CoV-2 is still unclear. Studies have shown that the majority (>95%) of confirmed PCR SARS-CoV-2 patients develop IgG and/or IgM antibodies after infection even in mild or asymptomatic cases, though depending on time of blood sample collection and with a difference in titer-strength.[13-15]"*

Reviewer #2: This is a report from Denmark of 1361 parturients who agreed to participate in what is essentially a seroprevalence study. Questions for the authors include:

1.Is this essentially a study of COVID positivity in asymptomatic individuals? Only 4 of your study patients had previously been diagnosed with COVID (for moderate to severe symptoms. I presume?). The rest did not have that diagnosis. You state on Line 266 that your patients were asymptomatic or had "mild" symptoms- please elaborate. In retrospect, would any of these mild symptoms have raised the suspicion of COVID 19? If symptoms were so mild as to not lead to a doctor visit or work up, this study would provide new (reassuring) information on the risk to pregnant women of asymptomatic or unrecognized COVID 19.

Comment: Thank you for your thorough review of our manuscript. We have now elaborated the argument for mild/asymptomatic patients in our cohort. We concur with the reviewer that our study is reassuring information to the pregnant women of asymptomatic SARS-CoV-2 infection.

Point of action: The following has now been added to the manuscript (line 307-314): *"Only 3 women and 2 partners with SARS-CoV-2 antibodies had previously had a positive PCR swab indicating that our study primarily represents asymptomatic or mild cases of SARS-CoV-2 infection. In the beginning of the epidemic, people in Denmark were only tested if they had severe symptoms with need of clinical examination[18]. From April testing of mild cases was implemented[18] and from the end of May all people in Denmark could be tested, also if they were*

asymptomatic[19]. Since only 5 women and 94 partners in the positive group had a previously PCR swab test, we assume that the rest of the positive only had mild symptoms or were asymptomatic."

2.When you say "other chronic diseases" - other than asthma- does that include autoimmune or other immune dysfunction disorders? Please specify, since individuals with these kinds of medical problems are presumed to be at higher risk of infection.
Comment: Other chronic diseases include all other chronic diseases than asthma so autoimmune diseases are also included in this category. For the included women a medical doctor from the research group has extracted information from the electronic health records ensuring that the chronic disease is validated by a medical doctor. For the partners the information about chronic diseases were in the first manuscript recorded from their personal questionnaire. In order to ensure sufficient quality of the information and similarity, researchers from the research group had to this revision extracted data concerning chronic diseases from the partners medical files (similar procedure as for the included women).

In accordance with validation of chronic diseases we additionally validated all SARS-CoV-2 positive women and partners. On this note, one partner was removed to the negative group (previous positive PCR swab one day before delivery but negative antibodies), one partner were excluded (previous positive PCR swab but no serological test) and one women were removed to the negative group (previous positive PCR swab but negative antibodies). This resulted in minor changes throughout the text, but did not alter the main findings or conclusion.

Point of action: The following has been added as foot notes to Table 1 and 2: *"Information about asthma was extracted from the personal questionnaire and information about other chronic diseases was extracted from the electronic health record."*

3.In line 214 you refer to families with complete serologic data. Are you referring to the triads in your study (mother, father, infant) or additional family members? Please clarify

Comment: Yes, with "complete serologic data" we mean full serologic data from the trio mother, partner and newborn. This has now been clarified in the manuscript.

Point of action: The following has now been added to the manuscript (line 246-248): *"Looking at family patterns of infection across 1,051 families with complete serological data (in trios of mother, partner and newborn)...."*

Reviewer #3:

Thank you for your submission. This is a relatively large cohort study of women, their partners and newborns virological and serological status from a single, large hospital in a 3month period in Denmark. My main concern is the conclusion that SARS CoV-2 infection does not have any association with perinatal outcomes requires a more full evaluation than you have provided. Please provide a secondary analysis of outcomes based on maternal symptoms, virological and serologic status. We cannot differentiate outcomes based on maternal symptoms at all here as you have reported them only by serological/PCR results. Additionally, you really have very few individuals who were antibody positive, even fewer with positive PCR results. I suspect your results are under powered to be able to assert a lack of an association with poor outcomes. Please address.
Numbers below refer to line numbers.

We thank the reviewer for the extensive comments.

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

It's not clear from the precis what you mean. You were studying antibodies to SARS CoV2 not COVID 19 infection. Your precis should reflect this.

Comment: The précis has now been corrected. We concur with the reviewer that our study focused on SARS-CoV-2 antibodies and not COVID-19 infection. This has been clarified throughout the manuscript.

Point of action: The précis is now: *"Serological testing of parturient women, partners, and newborns found no association between SARS-CoV-2 antibodies and obstetric or neonatal complications."*

72. The objective of the abstract should be a simple "To" statement without background information.

Comment: The objective of the abstract has now been modified,

Point of action: Objective (line 82-83): *"To investigate the frequency of SARS-CoV-2 antibodies in parturient women, their partners and newborns and the association to obstetric outcomes."*

74. It is an idiosyncratic fact that at the Journal we tend to avoid the use of the word impact to imply the result of a change, preferring to limit "impact" to mean a physical blow. Please edit here and throughout your paper. As well please careful of causal language. Yours is an observational study so you can report on associations, not causation.
Comment: "Impact" has now been changed to "association" throughout the paper.

77. Please make sure in the paper itself you address the sensitivity of. Pharyngeal vs nasopharyngeal swabs for detecting SARS CoV 2.
Comment: Pharyngeal swabs for SARS-CoV-2 are implemented as standard in Denmark. The sensitivity is 90-95% in symptomatic individuals. However, as the majority of individuals included in this study are asymptomatic, the sensitivity is likely lower. We have added a sentence reflecting this in the Discussion. We note that this does not alter the results, as we compare individuals based on antibody levels.

Point of Action: The following has been added to the manuscript (line 335-338): *"Pharyngeal swabs for SARS-CoV-2 are implemented as standard in Denmark, and has a sensitivity of 90-95% in symptomatic individuals[20]. However, the sensitivity is likely lower in asymptomatic individuals leading to an increased false negative rate".*

90. It seems rational and you have the opportunity to report it, that there may be a difference in perinatal outcomes between those who are symptomatic (55% in your study) and those were not. Please report this comparison. (Antibodies in patients, partners and newborns as well out perinatal outcomes).
Comment: We hope we have understood the issue raised by the reviewer correctly. We have added comparisons of women without antibodies to positive symptomatic women (Appendix 2), symptomatic versus asymptomatic women (Appendix 3), newborns born to mothers with and without antibodies (Appendix 5) and newborns born to parents with and without antibodies (Appendix 6).

Point of action: The following has been added to the Result section (line 210-214): *"This was further confirmed in a sub-group analysis of symptomatic mothers versus mothers with no antibodies, and an analysis of*

only mothers with antibodies stratified by symptoms (Appendix 2 and Appendix 3).”
Line 244-245: *“Perinatal outcomes were also not affected by the antibody status of the parents (Appendix 5 and Appendix 6).*

93. Increased risk of what? Again, the conclusion needs to be reconsidered once you've analyzed by whether women were symptomatic or not.
Comment: Line 93 has now been elaborated. The new subgroups analysis according to symptoms confirmed our previous results so the conclusion has not been changed.

Point of action: The following has been added to the manuscript (line 102-103): *“The family pattern showed a substantial higher incidence of infection for women living with a partner with antibodies.”*

108. Please edit out the "to our knowledge" or similar wording. As the readers cannot gauge the depth and breadth of your knowledge, this phrase does not add significant meaning. You can either reference your literature search details (database searched and search terms used) that informed your knowledge, or you could say something noting that your cited references provide limited information about this point.
Comment: We have now added information on our litterature search in the Appendix.

Point of action: The following has been added to the introduction (line 119): *“Our literature search (Appendix 1) found no previous study that has investigated the frequency of SARS-CoV-2 in partners of pregnant women.”*

112-115: Delete as these are either methods or results and should be reported in the appropriate section.
This has been corrected.

119. Was this a time of significant COVID 19 infection in Denmark? Please explain why you chose these dates.
Comment: The study period reflects the first epidemic wawe in Denmark.

Point of action: The following has been added to the manuscript (line 133): *“From April 4th, 2020 to July 3rd, 2020, (3 months), at the first epidemic wave in Denmark, all women giving birth at the department, their partners and newborns were invited to participate in the study.”*

141. This would be premature prelabor rupture of membranes. By GBS in urine, does that mean you do not do 3rd trimester anal/vaginal swabs as is done in the US?
Comment: The definition of PPROM has now been corrected. In Denmark we do not perform anal/vaginal swabs in the 3rd trimester.

143. cesarean delivery, not section.
Comment: This has now been corrected.

173. "of whom" not "of which".
Comment: This has now been corrected.

181. Could you split out the issue of blood type and symptoms? I don't really know what your p value on 182 is referring to. Also, these are really different things (blood type, symptoms). Reading further, I see you do discuss these separately. I would just end the sentence starting on line 180 after "antibodies" on line 181. Then, start sentence that now reads "Nonetheless,…." With "Only 52%....".
Comment: A p-value for both blood type and symptoms has now been added. We have otherwise retained the sentence as it is related to the first part of the sentence.

Point of action: The following has been changed in the manuscript (196-199): "*There was no significant difference between pre-pregnancy characteristics in relation to SARS-CoV-2 antibodies, except blood type (p=0.034) and that women with antibodies reported more COVID-19-like symptoms (p=0.04). Only 50%...*"

185. I would move the "only one woman had a positive pharyngeal swab" to follow sentence ending on line 177. Would clarify that "Four women in the antibody positive group…".
Comment: "only one woman had a positive pharyngeal swab" is now moved as suggested. The sentence "Four women in the antibody positive group…" has now been clarified.

Point of action: The following has been added to the manuscript (line 205): *"Three women in the positive group had previously been diagnosed with SARS-CoV-2 with a positive PCR swab."*

189. Please provide denominators so we know which population you are dealing with. I think you are meaning " Fourteen of the 29 women with SARS-CoV-2 antibodies (63.6%) had IgG antibodies, and 3/1,332 women without SARS COV-2 antibodies (3%) had IgG antibodies (Wouldn't this be 0.2%?)
Comment: The population has now been clarified with denominators.

Point of action: The following is now clarified in the manuscript (line 214-216): *"A total of 14 newborns with serological test (14/21) (67%) had positive SARS-CoV-2 antibodies in the group of positive mothers, and three newborns (3/1131) (0.3%) in the negative group."*

191. You can exclude the p values since you provide 95% CI's which we prefer. Not sure we need information on line 192 since your RR is so high on line 1919.
Comment: This has now been corrected.

196 -199. Please provide the absolute values, and RR, not just the p values here.
I would rewrite: More men in the antibody positive group 12%(xx/34) compared to the antibody negative group bb%(yy/1197) had a prior positive SARS-CoV-2 swab (RR, 95% CI). Sixty one percent of partners with SARS-CoV-2 antibodies reported symptoms. [is this any symptoms at the time they were completing the questionnaire or in the past?]
Comment: We have replaced the text in the Results section with the suggested text. The symptoms are covid-like symptoms since December 2019, this is now stated in the manuscript.

Point of action: The following has been added to the manuscript (line 225-228): *"More men in the antibody positive group 6% (2/32) compared to the antibody negative group 0% (1/1156) had a prior positive SARS-CoV-2 swab (OR=77, 95%CI 6.8-872.6). Sixty five percent (95%CI 42%-77%) of partners with SARS-CoV-2 antibodies reported symptoms since December 2019."*

202, 185. Please co-locate the information about the newborns, rather than reporting information in 2 separate places.
Comment: Unfortunately, we are not sure that we understand this comment. Line 185 says *"Four women in the positive group had previously been diagnosed with COVID-19"?* Do you mean the sentence concerning gestational age (previous line 189)? In the first section we briefly report the number of patients and in the later section we report the results (prevalence of newborns with antibodies).

One concern is your power for reporting a lack of difference. You have really very few women, partners or newborns with antibodies. Please consider a post hoc power analysis for all of the outcomes of mothers and babies.
Comment: We understand the reviewers' caution due to the low prevalence, but a post hoc power analysis is generally discouraged for a number of reasons. A post hoc power analysis is merely another way of presenting the p-value, and does not add any information. This is well described in simulation studies

(https://stat.uiowa.edu/sites/stat.uiowa.edu/files/techrep/tr378.pdf, Table 1. Notice how the post-hoc power is directly correlated with the p-value), a more formal Discussion published by the American Statistical Association (https://www.vims.edu/people/hoenig_jm/pubs/hoenig2.pdf), and through commentaries (https://www.journalofsurgicalresearch.com/article/S0022-4804(20)30502-3/fulltext).

214. Could you report the concordance rates for mothers/partners/infants? This section is rather confusing. How many women were neg if dad is positive and vice versa?
Comment: We have inserted a table of concordance between mother-partners, mothers-babies, and partners-babies (Appendix 8), as well as a reference in the text.

Point of action: We have added the following text to the Results section (line 252-53): *"There was a significantly positive concordance between infection in family members (Appendix 8)".*

224. Just say:" if the partner had anti-SARS-CoV-2 antibodies, the woman had a 37% risk of infection."
Comment: This is now corrected.

244. Can't you say more strongly "is likely passive transfer from the mother and not evidence of vertical transmission". In limitations, please note that essentially all of these patients were likely infected in the late second or 3rd trimester given your 3 month period of data collection and average EGA at birth of 41 weeks; thus, vertical transmission rates if maternal infection occurs earlier in pregnancy cannot be addressed with this study.
Comment: We have stated more strongly concerning maternal transmission of antibodies. We concur with the reviewer that the COVID-19 infection in our population was in the late second or 3rd trimester. We have now stated this in the discussion section.

Point of action: The following has been added to the manuscript (line 281): *"The presence of IgG antibodies but not IgM antibodies in the newborns is most likely passive transfer from the mother and not evidence of vertical transmission"*.
And in the discussion (line 331-334): *"Additionally, the parturient women in our cohort have most likely been infected in the late second or 3rd trimester of pregnancy (due to the time period and due to the time of the first confirmed SARS-Cov-2 positive patient in Denmark). Future studies are thus needed to assess the risk for vertical transmission in the first trimester."*

252. I don't know what this sentence means. What do you mean by "age appropriate women in the community"? I think you could delete lines 251-262 as it is content not directly applicable to your study. You could include information lines 254-256
Comment: With age-appropriate women we mean women with the same age. We have now retained line 254-256 and deleted line 251-262 as suggested by the reviewer.

274. You include 3 groups, so "both" should be deleted,as it refers to 2.
Comment: This has been corrected.
STATISTICAL EDITOR COMMENTS:

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

Table 1: The cohort with (+) Ab has N = 29, so the entries in that column should have %s rounded to nearest integer %, not cited to nearest 0.1% precision. lines 180-182: The stats test comparing blood type prevalence did not specifically test one blood type, but rather whether the distribution of blood types differed in the two cohorts. Need to specifically test type A to conclude a statistical difference is present. Many of the adverse events were infrequent, so there was limited power to discern a difference and thus many NS findings cannot be generalized.
Comment: We agree with the reviewer and have revised the tables accordingly. We also performed the suggested test of blood type A versus the rest. We have further grouped some of the outcomes into three categories (pregnancy complications, obstetric complication, and perinatal complications). This should have additional power, but did also not demonstrate any significant difference. We have further added a sentence in the Discussion highlighting the possibility that the results may not generalize.

Point of action: The following has been added to the manuscript (340-342) *"Due to the low prevalence of SARS-CoV-2 antibodies and event rate, we cannot rule out that some of the non significant findings may not generalize to other populations."*

lines 173-174: Need to compare the demographic/clinical characteristics of those who consented vs those who did not consent to address issue of possible bias.
Comment: We agree with the editor that the characteristics of the non-participating women could be interesting to include. We are, however, not allowed to extract data from their personal electronic health records

as they have not consented. The study has in general a high participating rate which minimizes bias. Additionally, the public hospitals in Denmark serve predefined admission areas. Therefore, regarding the demographic area the patients who participated and those who did not participate are from the same admission area for the hospital, which is Copenhagen South and West. To minimize the risk of inclusion bias the participant information was available in Danish, English, Turkish, Polish, Arabic, Urdu and Farsi for patients who preferred to read it in one of these languages.

Table 2: Same issue with %s rounded to nearest integer % in column with N = 34. Also, comparisons re: Asthma, other chronic diseases, smoking were each underpowered, so cannot generalize the NS findings.
Comment: We have rounded to nearest integer, and as stated have added a sentence in the limitation section.

Point of action: The following has been added to the discussion (340-342): "*Due to the low prevalence of SARS-CoV-2 antibodies and event rate, we cannot rule out that some of the non significant findings may not generalize to other populations."*

Table 3: Same issue with %s rounded to nearest integer % in column with N = 17. Insufficient power for $Apgar_5$ < 7, art pH < 7.0, NICU admit etc.
Comment: We have rounded to nearest integer, and as stated have added a sentence in the limitation section (please see above point of action).

Should summarize prevalences with CIs.
Comment: We are unsure which prevalences the reviewer refers to. The adjusted prevalence that we report is reported alongside CIs in the Results section (line 194 and line 222).

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. 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.
Comment: A.OPT-IN - yes, please 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.

The following co-authors will need to complete our electronic Copyright Transfer Agreement, which was sent to them by email through Editorial Manager. Please note their email addresses and make sure they are correct. Once the form is complete, please add their disclosures to the “Financial Disclosure” section.

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Comment: All authors have now completed their electronic copyright transfer agreement.

3.Use only these headings in the body text and remove any subheadings: Introduction, Methods, Results, Discussion.
Comment: The subheadings are now removed.

4.Do not use “impact” to mention anything other than “to strike.” Use “effect” or “affect” instead. In your title, change “Impact” to “Effects.”
Comment: This has now been corrected.

Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review,"

as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.
Comment: Our title is now *"SARS-CoV-2 antibodies at delivery in women, partners and newborns"* (65 chatacters including spaces).

5.Shorten your Precis to read, "Serological testing of parturient women, partners, and newborns found no association between coronavirus disease 2019 (COVID-19) and obstetric or neonatal complications."
Comment: The precis is now corrected.

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."

6. This is a preprint on https://www.medrxiv.org/content/10.1101/2020.09.14.20191106v1. This needs to be noted on title page.
Comment: The information on preprint is now added on the title page.

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.
Comment: This in now ensured.

8. 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.
Comment: The word count in our revised manuscript is 4,636 (including title page, précis, abstract, text, tables and figure legends).

9. 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).
Comment: The manuscript is in accordance with the above guidelines.

10. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.
Comment: Thor title/running foot is noted on the title page (*SARS-Cov-2 antibodies at delivery*, 33 characters including spaces)

11. 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.

Comment: The abstract is consistent with the manuscript. The word count is 272.

12. 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.
Comment: This has been ensured.

13. 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.
Comment: This has been corrected.

14. 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%").
Comment: This has been corrected.

15. Line 273: Your manuscript contains a priority claim. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.
Comment: We have now changed the wording to *“The present study is a prospective cohort study from the largest obstetric department in Denmark including trio of, parturient women, partners and newborns.“*

16. 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.
Comment: This has been ensured.

17. Figures

Figure 1: Please upload as a figure file on Editorial Manager. Are there any exclusions that need to be added?

Comment: The figure has been uploaded as a separate file. No exclusions need to be added.

Figure 2: Please upload as a figure file on Editorial Manager. Where is the clip art from? By chance is it from the Noun Project?
Comment: Figure 2 is made in powerpoint. The clip art is from powerpoint.

18. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.
Comment: We have now numbered the appendix as described above.

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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.

Sincerely,

Dwight J. Rouse, MD, MSPH
Associate Editor for Obstetrics

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