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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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^{*}The corresponding author has opted to make this information publicly available.

Date: Mar 15, 2021

To: "Kavita Shah Arora"

From: "The Green Journal" em@greenjournal.org

Subject: Your Submission ONG-21-384

RE: Manuscript Number ONG-21-384

Postpartum Sterilization Without A Valid Medicaid Consent Form - A Qualitative Study of Obstetrician-Gynecologists

Dear Dr. Arora:

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 Apr 05, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

The primary objective of this manuscript was to explore the behaviors of US OB-GYNs surrounding postpartum sterilization when the Medicaid sterilization consent form (SCF) was not valid. It explored the reasons or workarounds that some physician might still proceed with the sterilization in certain circumstances, and why others would never go ahead without the signed Medicaid SCF. I felt that this was a very clear and well-written paper, and it was both interesting and easy to read. I think that many other OB-Gyns would be interested in reading the results of this manuscript as it is a situation that most practicing OBs have probably had to deal with in their careers. I have just a few minor comments.

- 1) There were a number of quotes in Table 2 that I found interesting, but weren't explored in the Results or Discussion section, perhaps because of word count limits.
- a. The first, was the comment that a hospital had re-interpreted that the SCF only needs to be signed "30 days before the due date" rather than before the actual procedure. It would be helpful to mention this quote in the Results and whether or not that is a valid interpretation in the Discussion.
- b. The second quote noted that "my biggest concern would be in terms of litigation from that regard." It wasn't clear to me if the fear of litigation was because of Medicaid fraud or if it was because if the patient later regretted the procedure, if the patient would then try to sue the doctor for performing it? Again, I thought it would be helpful to highlight this quote in the Results and mention whether or not concerns about legal repercussions (not just financial ones) are legitimate in the Discussion section.
- 2) On a somewhat related note, in the Discussion (Lines 243-246), you mention that federal policy states that "loss of funding is for the procedure itself only, studies of state Medicaid officials corroborate the confusion on the part of ob-gyns given the variability in practice at the level of individual state Medicaid offices." It would be helpful for you to elaborate a bit more about this "variability", ie, whether a hospital really could lose the entire pregnancy global fee, delivery hospitalization fee, or Medicaid contract in certain states. I was not aware of these concerns and variability, and now I (and perhaps other readers) am left wondering if there should be such concerns in some states, besides the known repercussion of losing funding for the procedure itself.

Reviewer #2:

Review of Manuscript ONG-21-384 "Postpartum sterilization without a valid Medicaid consent form - a qualitative study of Obstetricians-Gynecologists"

Arora and colleagues have submitted a qualitative study of 30 OB/GYN providers utilizing an ACOG database from representative states that perform a large number of Medicaid deliveries in the hopes of determining the impact of a lack of a "valid" Medicaid sterilization consent form and the operationalization of this in clinical practice. As noted, the authors used a survey to collect this information and standard techniques to further assess themes in order to assure adequate representation of results. I have the following questions and comments.

Title - Can you include a qualifier about the area of the study noting that this represents high areas of Medicaid deliveries?

Précis - While this may be true how about something along the lines of Ongoing assessment of the Medicaid consent process and regulations is needed to ensure reproductive equity?

Abstract - Line 41 - Is it behaviors or decisions?

Introduction - Line 69 - Would it be informative to lists reasons why this does not occur?

Methods - Line 82 - Was there data to predict how many providers would need to be interviewed?

Line 86 - how did you actually randomly select the providers for interviews?

Results - How many providers did you have to contact to get the sample size of 30?

Discussion - Line 239 - Isn't this an area to perhaps focus on? Education and ways to improve the performance of the requested procedure.

Line 266 - How concerned are you about this limiting generalizability?

Tables - Table 1 - No comments

Table 2 - No comments

Figures - Figure 1 is a bit blurry when I tried to zoom in to evaluate some of the numbers.

Reviewer #3:

Thank you for the opportunity to review this manuscript. The authors report on the results of qualitative interviews where obstetric providers discussed their care for patients who desire postpartum sterilization but are lacking a valid Medicaid consent form. This paper is well-written and the methods seem appropriate. I have a few comments about the tone of the manuscript and suggestions to improve its clarity.

Major Comments:

- 1. It is not clear what is meant by the phrase "autonomously desired postpartum sterilization" and its variations. In some parts of the paper, it is difficult to discern whether this refers to the provider or the patient. For example, in Results, page 7, line 115, is "autonomously sterilizations" a typo? Please consider different language or defining this phrase early in the text.
- 2. The paper, particularly the Discussion section, is written from the viewpoint that the Medicaid policy is a hindrance to what is appropriate care. Because of this, the paper reads more like an opinion piece than a research manuscript. I would suggest softening this language so the message is more impartial, but defer to the editors.

Minor Comments:

- 1. Abstract, lines 56-57. It is unclear what direction is implied by "not functioning to protect reproductive autonomy."
- 2. Results, page 7, lines 113-114. I believe that Figure 1 should be referenced here (instead of Table 1), as that is where the states of the participating physicians are shown.
- 3. Results, page 8, lines 133-136. I know you can't change the quotes, but it is unclear if one of these situations is where the doctor would do the sterilization and one is where they would not, or if both are examples of when the doctor would do the sterilization.
- 4. Results, page 11, line 215. Is "valid" supposed to be :invalid?"
- 5. Figure 1 legend has a typo: 201612

EDITORIAL OFFICE COMMENTS:

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If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

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- 6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.
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In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

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

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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%").

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In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found at the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top).

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black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

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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. Do not omit your responses to the Editorial Office or Editors' comments.

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Apr 05, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

John O. Schorge, MD Associate Editor, Gynecology

2019 IMPACT FACTOR: 5.524

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

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REVIEWER COMMENTS:

Reviewer #1:

The primary objective of this manuscript was to explore the behaviors of US OB-GYNs surrounding postpartum sterilization when the Medicaid sterilization consent form (SCF) was not valid. It explored the reasons or workarounds that some physician might still proceed with the sterilization in certain circumstances, and why others would never go ahead without the signed Medicaid SCF. I felt that this was a very clear and well-written paper, and it was both interesting and easy to read. I think that many other OB-Gyns would be interested in reading the results of this manuscript as it is a situation that most practicing OBs have probably had to deal with in their careers. I have just a few minor comments.

Thank you for your time and thoughtful review.

- 1) There were a number of quotes in Table 2 that I found interesting, but weren't explored in the Results or Discussion section, perhaps because of word count limits.
- a. The first, was the comment that a hospital had re-interpreted that the SCF only needs to be signed "30 days before the due date" rather than before the actual procedure. It would be helpful to mention this quote in the Results and whether or not that is a valid interpretation in the Discussion.

We have moved this quotation to the Results section (lines 177-180). We have added some additional language in the Discussion as well (lines 258-259) but note that we are unable to confirm whether that is a valid interpretation, at least not in every state. As noted in our prior work (References 18-20), different states define premature delivery differently – thus leading to confusion regarding these exemptions.

New language in Discussion – While the federal policy specifically states that loss of funding is for the procedure itself only, studies of state Medicaid officials corroborate the confusion on the part of ob-gyns given the variability in practice at the level of individual state Medicaid offices with some states denying payment for the procedure itself whereas others deny payment for the entire pregnancy global fee and hospitalization.

b. The second quote noted that "my biggest concern would be in terms of litigation from that regard." It wasn't clear to me if the fear of litigation was because of Medicaid fraud or if it was because if the patient later regretted the procedure, if the patient would then try to sue the doctor for performing it? Again, I thought it would be helpful to highlight this quote in the Results and mention whether or not concerns about legal repercussions (not just financial ones) are legitimate in the Discussion section.

We have clarified this quotation in the Table (to balance word limitation considerations with the need to expand on this issue). We have added additional text in the Results (Lines 228) and Discussion (lines 251-253).

New language in the Discussion - Additionally, the possible legal repercussions of proceeding without a valid SCF are also unclear and could potentially range from insurance fraud to performing surgery without adequate consent.

2) On a somewhat related note, in the Discussion (Lines 243-246), you mention that federal policy states that "loss of funding is for the procedure itself only, studies of state Medicaid officials corroborate the confusion on the part of ob-gyns given the variability in practice at the level of individual state Medicaid offices." It would be helpful for you to elaborate a bit more about this "variability", ie, whether a hospital really could lose the entire pregnancy global fee, delivery hospitalization fee, or Medicaid contract in certain states. I was not aware of these concerns and variability, and now I (and perhaps other readers) am left wondering if there should be such concerns in some states, besides the known repercussion of losing funding for the procedure itself.

Thank you for this point. We have clarified the degree of variability. Some states deny payment simply for the procedure whereas others for the entire global fee, which is counter to the federal policy (now lines 253-261).

Edited language in Discussion - While the federal policy specifically states that loss of funding is for the procedure itself only, studies of state Medicaid officials corroborate the confusion on the part of ob-gyns given the variability in practice at the level of individual state Medicaid offices with some states denying payment for the procedure itself whereas others deny payment for the entire pregnancy global fee and hospitalization.18,19 Additionally, the possible legal repercussions of proceeding without a valid SCF are also unclear and could potentially range from insurance fraud to performing surgery without adequate consent. Increased education as well as transparency, clarity, and uniformity regarding the repercussions are important so that ob-gyns and institutions are able to offer comprehensive patient-centered contraceptive options without unnecessary barriers.

Reviewer #2:

Review of Manuscript ONG-21-384 "Postpartum sterilization without a valid Medicaid consent form - a qualitative study of Obstetricians-Gynecologists"

Arora and colleagues have submitted a qualitative study of 30 OB/GYN providers utilizing an ACOG database from representative states that perform a large number of Medicaid deliveries in the hopes of determining the impact of a lack of a "valid" Medicaid sterilization consent form and the operationalization of this in clinical practice. As noted, the authors used a survey to collect this information and standard techniques to further assess themes in order to assure adequate representation of results. I have the following questions and comments.

Thank you for your time and thoughtful review.

Title - Can you include a qualifier about the area of the study noting that this represents high areas of Medicaid deliveries?

This has been added. The new title is now: Postpartum Sterilization Without A Valid Medicaid Consent Form – A Qualitative Study of Obstetrician-Gynecologists Practicing in States with the Highest Percentages of Medicaid Births

Précis - While this may be true how about something along the lines of Ongoing assessment of the Medicaid consent process and regulations is needed to ensure reproductive equity?

We have blended both sentiments to ensure specificity to this research paper, as well as the overall conclusion of this body of literature. The new Précis is: As obstetrician-gynecologists feel occasionally perform desired postpartum sterilizations without valid Medicaid consent forms for ethical reasons, revision of the policy is necessary to ensure reproductive equity.

Abstract - Line 41 - Is it behaviors or decisions?

We have edited to "practices" to mirror the Title.

Introduction - Line 69 - Would it be informative to lists reasons why this does not occur?

We have added text to clarify that these barriers occur at the patient-, clinician-, and hospital-levels.

Edited language to clarify - Given this policy barrier and other barriers at the patient-, clinician-, and hospital-level, it is estimated that only approximately 50 percent of women with Medicaid who desire sterilization postpartum actually have their request fulfilled.

Methods - Line 82 - Was there data to predict how many providers would need to be interviewed?

In general, 5-12 interviews are typically needed per theme to achieve theoretical saturation. Therefore, given our interview guide and our knowledge of the literature, we proposed to begin with 30 interviews (a robust number for qualitative methodology) and then continue to interview additional clinicians if thematic saturation had not been reached.

Line 86 - how did you actually randomly select the providers for interviews?

Given the word limit considerations, we have referenced our previously published paper using this dataset (reference #15). Details from that manuscript are pasted below. We have added additional methodological details to this manuscript in Line 91-92.

"We identified potential participants using the American College of Obstetricians and Gynecologists' (ACOG) online physician directory, which is searchable by state and lists members in each state by city. To identify ob–gyns, we first randomly selected ten cities per state and imported the names of ob–gyns in these ten cities into Excel. Junior Fellows

in Practice, Fellow Senior Status, and Life Fellow or Founding Life Fellows were excluded as we sought to focus on Fellows with active clinical practices. We then randomized these names within the sheet."

New language in this manuscript - We randomly selected potential participants from the American College of Obstetricians and Gynecologists' (ACOG) online physician directory by first, randomly selecting at the level of city of practice and then at the level of individual name.

Results - How many providers did you have to contact to get the sample size of 30?

Including email messages, voicemails, and faxed information sent, we had to contact approximately 30-50 physicians for each interview conducted. We mention this limitation of participation bias in the Discussion (line 278).

Discussion - Line 239 - Isn't this an area to perhaps focus on? Education and ways to improve the performance of the requested procedure.

Thank you for this important point. We have added education to this paragraph of the Discussion in Line 258.

New language - Increased education as well as transparency, clarity, and uniformity regarding the repercussions are important so that ob-gyns and institutions are able to offer comprehensive patient-centered contraceptive options without unnecessary barriers.

Line 266 - How concerned are you about this limiting generalizability?

We have edited from "generalizability" to "impact" as this is more accurate.

Tables - Table 1 - No comments
Table 2 - No comments

Figures - Figure 1 is a bit blurry when I tried to zoom in to evaluate some of the numbers.

We have removed Figure 1 completely given it has previously been published in another journal. The specific states included are secondary to the fact that clinicians practiced in states with a high number of Medicaid-covered births.

Reviewer #3:

Thank you for the opportunity to review this manuscript. The authors report on the results of qualitative interviews where obstetric providers discussed their care for patients who desire postpartum sterilization but are lacking a valid Medicaid consent form. This paper is well-written and the methods seem appropriate. I have a few comments about the tone of the manuscript and suggestions to improve its clarity.

Thank you for your time and thoughtful review.

Major Comments:

1. It is not clear what is meant by the phrase "autonomously desired postpartum sterilization" and its variations. In some parts of the paper, it is difficult to discern whether this refers to the provider or the patient. For example, in Results, page 7, line 115, is "autonomously sterilizations" a typo? Please consider different language or defining this phrase early in the text.

We have removed this phrase and corrected the typographical error. We wanted to clarify that these sterilizations are desired by the patient. They are not procedures done without a patient's consent but rather solely without a valid consent form. However we feel, "desired sterilization" conveys that point adequately.

2. The paper, particularly the Discussion section, is written from the viewpoint that the Medicaid policy is a hindrance to what is appropriate care. Because of this, the paper reads more like an opinion piece than a research manuscript. I would suggest softening this language so the message is more impartial, but defer to the editors.

We too will defer to the Editors and are open to further revision. However, given the number of research papers on this topic, we feel it is no longer editorial to state the Medicaid policy can function as a barrier to care (indeed, it is mentioned in our Introduction as one barrier – among others). We feel we have appropriately discussed the important context of continuing to protect against coercion and identified areas for revision – rather than recommending complete removal of the policy.

Minor Comments:

1. Abstract, lines 56-57. It is unclear what direction is implied by "not functioning to protect reproductive autonomy."

We have edited this phrase.

New language - Physicians' varied behaviors related to providing postpartum sterilization without a valid Medicaid sterilization consent form demonstrate that the policy is in need of revision.

2. Results, page 7, lines 113-114. I believe that Figure 1 should be referenced here (instead of Table 1), as that is where the states of the participating physicians are shown.

We agree the reference was in the incorrect section but have removed the Figure completely as it has been published previously and is not integral to the Results of this paper. Full study methodology is referenced in the Methods section.

3. Results, page 8, lines 133-136. I know you can't change the quotes, but it is unclear if one of these situations is where the doctor would do the sterilization and one is where they would not, or if both are examples of when the doctor would do the sterilization.

Both are examples of when the doctor would do the sterilization. This has been clarified for the second quotation (line 141).

4. Results, page 11, line 215. Is "valid" supposed to be :invalid?"

We have chosen to use with/without a valid SCF rather than valid/invalid throughout the manuscript. We did so to convey that the form may not be valid, but the procedure may still be so.

5. Figure 1 legend has a typo: 201612

Thank you for noting this. The Figure and legend have been removed.

EDITORIAL OFFICE COMMENTS:

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We have removed the Figure entirely. It is already published in Contraception and the full study methodology (including location of subjects) is referenced in the Methods section. More importantly, we feel the distribution of the physicians interviewed is secondary to the fact that there was geographic variation and that all clinicians practiced in states with a high percentage of Medicaid births.

5. 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

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There are no specific guidelines listed for qualitative research though we feel our methodology is rigorous and adheres to qualitative methodology norms.

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

We have used standard definitions.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

Our revised manuscript is 21 pages (including references).

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- * All financial support of the study must be acknowledged.
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We confirm our acknowledgements are complete and accurate.

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In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

The abstract has been carefully revised and is 212 words.

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

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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%").

Our methodology is qualitative.

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We have edited accordingly.

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