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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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<sup>\*</sup>The corresponding author has opted to make this information publicly available.

Date: May 03, 2021
To: "Sarita Sonalkar"

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

**Subject:** Your Submission ONG-21-676

RE: Manuscript Number ONG-21-676

The role of subcutaneous depot medroxyprogesterone acetate in reducing health disparities: A lesson of the COVID 19 pandemic

## Dear Dr. Sonalkar:

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 May 24, 2021, we will assume you wish to withdraw the manuscript from further consideration.

### **REVIEWER COMMENTS:**

#### Reviewer #1:

The manuscript is a commentary on the role of self-administered Subcutaneous DMPA in reducing health disparities, particularly during the COVID-19 pandemic.

- 1. Line 23: Please complete the disclosures section.
- 2. Line 88: Is there a difference in cost between SQ and IM formulations?
- 3. Lines 94-96: Please provide more information on why only 58% of those interested in DMPA-SQ actually received an injection.
- 4. I would recommend placing section #2 (Safety, acceptability, and continuation of DMPA-SQ) to #1 ahead of DMPA prescription during the COVID-19 pandemic).
- 5. Lines 105-106: It would help your argument to discuss here the overall high discontinuation rates for DMPA-IM as an issue that the self-administered SQ version helps to mitigate.
- 6. Line 107: Please briefly describe any considerations for storage of this medication in between doses. Or does the patient go back to the pharmacy for each dose?
- 7. Lines 113-114: is there data to support that patients of color are more likely to be prescribed IM DMPA over SC in practices which are able to supply both?
- 8. Provide reference for LARC methods in racially motivated reproductive coercion as reference #13 does not discuss this.
- 9. Line 132: Though one may extrapolate, the data in reference #18 showed that Medicaid-insured women and Black women were more likely to use DMPA, not necessarily Medicaid-insured Black women.
- 10. Line 154: While Medicaid covers at least one form of the injection, plans may not cover both formulations (ref #18).
- 11. I cannot find ref #1; is there a link that could be included?

## Reviewer #2:

This is an insightful article on the role of subcutaneous depot medroxyprogesterone acetate (DMPA-SC) in reducing health

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disparities based on experiences in the COVID-19 pandemic.

Very important points have been raised including the fact that DMPA-SC is not commonly prescribed despite FDA approval for contraception in 2004 and current coverage by both state Medicaid providers and many private insurers. In contrast to intramuscular depot medroxyprogesterone acetate (DMPA-IM) which is commonly prescribed and administered in the office, DMPA-SC may be self-administered though not FDA approved for that use.

The authors rightly advise to consider sources of implicit bias that may impede prescription of DMPA-SC. Indeed, there is no reason not to offer DMPA-SC as a contraceptive option where DMPA-IM is also offered. However just offering DMPA-SC does not guarantee successful follow-through as already noted in the paper with challenges from insurance coverage, high out-of-pocket costs, and supply issues. The authors' also described the successful public health program in California made possible by rapid policy change and dedicated efforts by personnel to navigate hurdles with patients.

Knowing that many institutions, offices, and individual prescribers do not have that level of staff support used in the successful examples in the paper, the authors may consider practical suggestions and more detailed steps for individual offices and family planning institutions for successful patient self-administration of DMPA-SC.

#### Reviewer #3:

The article is a timely and an important review of the underused option of subcutaneous depo-provera contraception. The submission is both well written and easy to read. Althought it focuses on contraceptive options and equality, the basis of the commentary is applicable across the medical system. The pandemic has further highlighted racial and gender inequalities within the system as well as the need for flexibility in care. The article provides overview of the challenges met with providing fair and timely contraceptive options during the pandemic. The authors highlight the need to review all options with the patient and partner with them to choose the best method for their current needs and situation. The submission includes a clinical scenario to center the discussion around the unique needs of the patient instead of reviewing what is the most efficacious method. It is not a research study and therefore I cannot comment on methodology or statistics. However it is thoughtful, invokes the reader to review their own current practices and challenges them to find alternative options to provide their patients.

## **EDITOR COMMENTS:**

Please revise to take out the (fictitious?) patient vignette and the digression into racial disparities. The importance to the readership consists of knowing this medication exists, yet is not widely used even during pandemic times.

# EDITOR 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:
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coauthors received an email from the system, titled "Please verify your authorship for a submission to Obstetrics & Gynecology." Each author should complete the eCTA if they have no yet done so.

3. 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, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/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. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

- 4. 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.
- 5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Current Commentary articles should not exceed 3,000 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.
- 6. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:
- \* All financial support of the study must be acknowledged.
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- \* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).
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- 7. 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 Current Commentary articles is 250 words. Please provide a word count.

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- 8. 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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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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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. 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 May 24, 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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Hospital of the University of Pennsylvania

PEACE

7 June 2021

Editor-in-Chief Obstetrics and Gynecology

Dear Editor,

Thank you for your consideration of our revision of our submission of our Current Commentary, "The role of subcutaneous depot medroxyprogesterone acetate in equitable contraceptive care: A lesson of the COVID-19 pandemic" to the journal *Obstetrics and Gynecology*.

All authors contributed to drafting and revising the manuscript for intellectual content. All authors have approved the final version of the manuscript.

The authors do not report potential conflicts of interest.

The paper is not under consideration at any other journal.

Below, we have included a point-by-point response to reviewers.

Best wishes,

Sarita Sonalkar, M.D., M.P.H.

Perelman School of Medicine at the University of Pennsylvania

Point-by-point response to reviewers:

# Reviewer #1:

The manuscript is a commentary on the role of self-administered Subcutaneous DMPA in reducing health disparities, particularly during the COVID-19 pandemic.

1. Line 23: Please complete the disclosures section.

Response: We have now completed the disclosures section.

2. Line 88: Is there a difference in cost between SQ and IM formulations?

Response: There is a difference in cost between the two formulations: the average retail cost for is \$219.63 for DMPA SC, and \$95.56 for DMPA IM (www.goodrx.com). We have included an indication of this in line 90.

3. Lines 94-96: Please provide more information on why only 58% of those interested in DMPA-SQ actually received an injection.

Response: We have included additional information about why many who desired DMPA-SC did not receive their injection based on information from reference 11. The reasons were varied, including changing their mind, moving home locations, desiring to stop contraception, as well as clinic miscommunication and pharmacy and insurance delays.

4. I would recommend placing section #2 (Safety, acceptability, and continuation of DMPA-SQ) to #1 ahead of DMPA prescription during the COVID-19 pandemic).

Response: Thank you for this suggestion. We have moved "Safety, acceptability, and continuation of DMPA-SC" earlier in the manuscript.

5. Lines 105-106: It would help your argument to discuss here the overall high discontinuation rates for DMPA-IM as an issue that the self-administered SQ version helps to mitigate.

Response: Thank you for this suggestion. We have now included information on high 12-month discontinuation rates of DMPA-IM.

6. Line 107: Please briefly describe any considerations for storage of this medication in between doses. Or does the patient go back to the pharmacy for each dose?

Response: Thank you for this suggestion. We now include information about prescribing and storage in lines 80-83.

7. Lines 113-114: Is there data to support that patients of color are more likely to be prescribed IM DMPA over SC in practices which are able to supply both?

Response: Thank you for bringing up this point. We do not know of research that compares prescription of DMPA-SC between white and non-white patients. However, all practices have the

ability to prescribe both DMPA-IM and DMPA-SC, DMPA-IM is disproportionately used by Black patients, and practices currently are rarely prescribing DMPA-SC.

8. Provide reference for LARC methods in racially motivated reproductive coercion as reference #13 does not discuss this.

Response: Thank you for this comment. We have corrected the reference.

9. Line 132: Though one may extrapolate, the data in reference #18 showed that Medicaid-insured women and Black women were more likely to use DMPA, not necessarily Medicaid-insured Black women.

Response: Thank you for this point. We have edited the sentence for accuracy.

10. Line 154: While Medicaid covers at least one form of the injection, plans may not cover both formulations (ref #18).

Response: Thank you for the detailed review. Reference 22 specifically identifies Medicaid coverage of DMPA SC in addition to coverage of DMPA IM.

11. I cannot find ref #1; is there a link that could be included?

Response: Thank you for this comment. We have now included the link in the citation. https://www.nationalfamilyplanning.org/file/documents---service-delivery-tools/NFPRHA---Depo-SQ-Resource-guide---FINAL-FOR-DISTRIBUTION.pdf

# Reviewer #2:

This is an insightful article on the role of subcutaneous depot medroxyprogesterone acetate (DMPA-SC) in reducing health disparities based on experiences in the COVID-19 pandemic. Very important points have been raised including the fact that DMPA-SC is not commonly prescribed despite FDA approval for contraception in 2004 and current coverage by both state Medicaid providers and many private insurers. In contrast to intramuscular depot medroxyprogesterone acetate (DMPA-IM) which is commonly prescribed and administered in the office, DMPA-SC may be self-administered though not FDA approved for that use.

The authors rightly advise to consider sources of implicit bias that may impede prescription of DMPA-SC. Indeed, there is no reason not to offer DMPA-SC as a contraceptive option where DMPA-IM is also offered. However just offering DMPA-SC does not guarantee successful follow-through as already noted in the paper with challenges from insurance coverage, high out-of-pocket costs, and supply issues. The authors' also described the successful public health program in California made possible by rapid policy change and dedicated efforts by personnel to navigate hurdles with patients.

Knowing that many institutions, offices, and individual prescribers do not have that level of staff support used in the successful examples in the paper, the authors may consider practical suggestions and more detailed steps for individual offices and family planning institutions for successful patient self-administration of DMPA-SC.

Response: Thank you for this suggestion. We appreciate the comment that implicit bias is an important barrier to provision of DMPA-SC. We have now included a dedicated section on implementation of

DMPA-SC prescribing and use and edited this section to provide detailed steps for providers and offices.

## Reviewer #3:

The article is a timely and an important review of the underused option of subcutaneous depo-provera contraception. The submission is both well written and easy to read. Althought it focuses on contraceptive options and equality, the basis of the commentary is applicable across the medical system. The pandemic has further highlighted racial and gender inequalities within the system as well as the need for flexibility in care. The article provides overview of the challenges met with providing fair and timely contraceptive options during the pandemic. The authors highlight the need to review all options with the patient and partner with them to choose the best method for their current needs and situation. The submission includes a clinical scenario to center the discussion around the unique needs of the patient instead of reviewing what is the most efficacious method. It is not a research study and therefore I cannot comment on methodology or statistics. However it is thoughtful, invokes the reader to review their own current practices and challenges them to find alternative options to provide their patients.

Response: Thank you for these comments.

## **EDITOR COMMENTS:**

Please revise to take out the (fictitious?) patient vignette and the digression into racial disparities. The importance to the readership consists of knowing this medication exists, yet is not widely used even during pandemic times.

Thank you for your comments and for your review. The patient vignette was based on an actual patient case that inspired the commentary, and we have removed it as requested. We have significantly shortened the section on racial disparities in order to balance it with the other sections. Given that DMPA is a method that is disproportionately used by Black patients, we feel that the discussion regarding equity in contraceptive care is relevant. Advocacy to provide DMPA-SC in our healthcare system requires a commitment to Black patients, whose reproductive autonomy has been historically breached and underprioritized. We hope our commentary will help providers and practices examine the systemic and programmatic reasons as well as individual biases that create a barrier to DMPA-SC provision.