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: Jan 21, 2020
To: "eva lathrop" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-2121

RE: Manuscript Number ONG-19-2121

The Zika Contraception Access Network: final program data and factors associated with LARC removal

Dear Dr. lathrop:

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 Feb 11, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Thank you for your report on contraceptive uptake and continuation during the Z-CAN time period. The difference in contraceptive use before and after is quite striking. Your attention to minimizing coercion is laudable and your addition for safety-net removals following the end of the program period is so important. I would like to see more specifics about how you trained your providers in shared-decision making, and how this translated into patient conversations, for example did you use a tool or a script or something similar?

Why do you think that college-educated women were more likely to seek removal? I know you adjusted for some variables, but perhaps this merely a substitute for another SES characteristic? Similarly, are there similar data regarding lower rates of removal in breastfeeding women? These are your main findings, so it is important to your readers to know if comparable data exists.

Reviewer #2: Excellent article- very well written. I have just 2 small edits to consider. In the Discussion section, the last paragraph starts has sentence that starts with: furthermore, strengths of the analysis included that we were able to "ascertained" (should be ascertain) information on contraceptive method mix before the program to allow us to compare (would insert the word 'it' here) with contraceptive method mix as part of Z-CAN.

Reviewer #3: Thank you for this report

Abstract: this is succinct and generally well written. Lines 18-20 could be re-written as it read as though all of these are factors that drove removal , also I would specify it is level of education of patient, not patient education at visit.

Introduction:
Page 7: the paragraph beginning in line 4 contains a lot of information more appropriate for methods than introduction.

Methods

Given that the program has been previously described this could be shortened to just basic details, or details specific to this study of LARC removal (the part in the introduction)

Page 10, your description of IRB exemption doesn't read correctly, should say did not require review or approval from IRB.

Results:

Succinctly described.
In table 1 given the amount of data I would make more obvious the few statistically significant findings

Discussion:
Page 14 the paragraph starting at line 13 again is not really discussion but description of the program. It should be in methods.

Page 15 paragraph starting line 22: I would discuss the strengths of the study and data, but not sure this is the place for discussing the program's strengths, similar comment for limitations

Your conclusion paragraph should be more focused on successes and lessons learned, as well as what the data tells up, not on re-describing the program details again.

STATISTICAL EDITOR'S COMMENTS:

1. Table 1: The cohorts should be compared statistically. Many differences are statistically different, eg, age, relationship status etc. Should enumerate all missing data.

2. Table 2: The sample sizes are large, but some subsets are modest. Likely the aPR for effectiveness of contraceptive method used before Z-CAN were too few to allow for adjustment for all the characteristics cited, ie, likely over fitted model.

3. For the column Copper IUD, the n = 79, so there is no basis for citing %s to nearest 0.1%, should round to nearest integer %.

4. General: Should include a flow diagram to show the exclusions and how many were in each final cohort analyzed.

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. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. 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.

3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained." *The manuscript's guarantor.

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.

4. Obstetrics & Gynecology follows the Good Publication Practice (GPP3)* guideline for manuscripts that report results that are supported or sponsored by pharmaceutical, medical device, diagnostics and biotechnology companies. The GPP3 is designed to help individuals and organization maintain ethical and transparent publication practices.

(1) Adherence to the GPP3 guideline should be noted in the cover letter.

(2) For publication purposes, the portions of particular importance to industry-sponsored research are below. In your cover letter, please indicate whether the following statements are true or false, and provide an explanation if necessary:

(2a) All authors had access to relevant aggregated study data and other information (for example, the study protocol) required to understand and report research findings.
(2b) All authors take responsibility for the way in which research findings are presented and published, were fully involved at all stages of publication and presentation development and are willing to take public responsibility for all aspects of the work.
(2c) The author list accurately reflects all substantial intellectual contributions to the research, data analyses, and publication or presentation development. Relevant contributions from persons who did not qualify as authors are disclosed in the acknowledgments.
(2d) The role of the sponsor in the design, execution, analysis, reporting, and funding (if applicable) of the research has been fully disclosed in all publications and presentations of the findings. Any involvement by persons or organizations with an interest (financial or nonfinancial) in the findings has also been disclosed.
(2e) All authors have disclosed any relationships or potential competing interests relating to the research and its publication or presentation.

(3) The abstract should contain an additional heading, "Funding Source," and should provide an abbreviated listing of the funder(s).

(4) In the manuscript, a new heading—"Role of the Funding Source"—should be inserted before the Methods and contain a detailed description of the sponsor's role as well as the following language:

"The authors had access to relevant aggregated study data and other information (such as study protocol, analytic plan and report, validated data table, and clinical study report) required to understand and report research findings. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data analysis, and publication or presentation development are listed appropriately. The role of the sponsor in the design, execution, analysis, reporting, and funding is fully disclosed. The authors' personal interests, financial or non-financial, relating to this research and its publication have been disclosed." Authors should only include the above statement if all of it is true, and they should attest to this in the cover letter (see #2, above).

*From Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, et al. Good publication practice for communicating company-sponsored medical research: GPP3. Ann Intern Med 2015;163:461-4.

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 authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

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 and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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.

8. 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).

9. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

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.

11. 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.

12. 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%").

13. 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 on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

14. 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.

15. 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 via the Clinical Guidance & Publications page at https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance.

16. 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 http://edmgr.ovid.com/acd/accounts/ifauth.htm.

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.

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 Feb 11, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2018 IMPACT FACTOR: 4.965
2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

_____

January 31, 2020

Dear *Obstetrics & Gynecology* Editors,

It is my pleasure to submit a revision of the original research manuscript entitled, "The Zika Contraception Access Network: final program data and factors associated with LARC removal" (ONG-19-2121) for consideration in *Obstetrics & Gynecology*. A point-by-point response to each of the reviewers' comments is provided in a table below. The paper is not under consideration elsewhere. None of the authors have any conflicts of interest to disclose.

As corresponding author, I had full access to all aspects of the writing process, and I take full responsibility for the paper. I affirm that this manuscript is an honest, accurate, and transparent account of the program being reported; that no important aspects of the program relevant to this analysis have been omitted; and that any discrepancies from the study as planned have been explained. Additionally, the Zika Contraception Access Network programmatic data was determined to be non-research public health practice thus did not require the Centers for Disease Control and Prevention Institutional Review Board nor necessitate Office of Management and Budget Paperwork Reduction Act approval. All persons listed in the acknowledgement section have consented to be included.

Furthermore, we have submitted a revised complementary current commentary entitled, "LARC removal-inclusive programming to safeguard reproductive autonomy: Lessons Learned from the Zika Contraception Access Network" (ONG -19-2118) also for consideration in *Obstetrics & Gynecology*. The 2 submissions have been reviewed together and any duplicative text has been struck and messages streamlined so that these papers are not repetitive but rather stand alone and complimentary. If both are accepted for publication and if feasible, we ask for consideration that they be published in the same issue.

Thank you for considering our paper.

Sincerely,

Eva Lathrop, MD, MPH
Adjunct Associate Professor
Emory University School of Medicine
Department of Gynecology and Obstetrics
[redacted]

Reviewer Comments	Response
Reviewer #1: Thank you for your report on contraceptive uptake and continuation during the Z-CAN time period. The difference in contraceptive use before and after is quite striking. Your attention to minimizing coercion is laudable and your addition for safety-net removals following the end of the program period is so important. I would like to see more specifics about how you trained your providers in shared-decision making, and how this translated into patient conversations, for example did you use a tool or a script or something similar?	*Thank you for the comment. In the introduction on page 7, line 12,I have added 2 references: one to our paper in the Lancet 2018 that describes Z-CAN program development, including the training component, in detail, and the second to the paper describing the training model we used, a program called Beyond the Pill that has been studied and validated and was also describe in Lancet. I have added references in lieu of repeating aspects that have already been published and to be in line with other reviewers' comments that we not repeat in methods information that has been published elsewhere.*
Reviewer #1: Why do you think that college-educated women were more likely to seek removal? I know you adjusted for some variables, but perhaps this merely a substitute for another SES characteristic? Similarly, are there similar data regarding lower rates of removal in breastfeeding women? These are your main findings, so it is important to your readers to know if comparable data exists.	*We have expanded the discussion section related to these findings, including a discussion of what other studies have found (if any). We have also postulated possible reasons for an association when data from other studies were not available. Please see page 14 lines 1-12.*
Reviewer #2: Excellent article- very well written. I have just 2 small edits to consider. In the Discussion section, the last paragraph starts has sentence that starts with: furthermore, strengths of the analysis included that we were able to "ascertained" (should be ascertain) information on contraceptive method mix before the program to allow us to compare (would insert the word 'it' here) with contraceptive method mix as part of Z-CAN.	*Thank you for catching this- this edit has been added. Please see page 16 lines 12-14.*
Reviewer #3: Thank you for this report Abstract: this is succinct and generally well	*Thank you for the comment. We have edited the results section of the abstract accordingly. Page 4 lines 17-19.*

Reviewer Comments	Response
written. Lines 18-20 could be re-written as it read as though all of these are factors that drove removal , also I would specify it is level of education of patient, not patient education at visit.	
Reviewer 3: Introduction: Page 7: the paragraph beginning in line 4 contains a lot of information more appropriate for methods than introduction.	*Thank you for the comment. We did go back and forth on putting this section in methods vs in the introduction and chose to have it in the introduction as background, given that details of program development and training have been published elsewhere and are not necessarily the core of this paper. We have added 2 references to this section to strengthen the placement in the introduction as background. Please see page 7 line 6.*
Reviewer 3: Methods Given that the program has been previously described this could be shortened to just basic details, or details specific to this study of LARC removal (the part in the introduction)	*Thank you for this comment. Several sections that describe the program development, training, and post-training activities have been removed.*
Reviewer 3: Methods Page 10, your description of IRB exemption doesn't read correctly, should say did not require review or approval from IRB.	*Thank you for catching this. The sentence should read correctly now. Please see page 10 line 2.*
Reviewer 3: Results Succinctly described. In table 1 given the amount of data I would make more obvious the few statistically significant findings	*The intent of Table 1 is simply to describe the characteristics of all women who participated in the Z-CAN program and those who chose and received a LARC method at the initial Z-CAN visit, not compare the two groups. Therefore, we did not conduct statistical testing. We have edited the results section to clarify that statistical testing was not conducted. Please see page11 line 8.* *However, we have previously reported on the factors associated with choosing and receiving a LARC method among program participants (see Lathrop et al, 2018, Lancet Public Health).*
Reviewer 3: Discussion: Page 14 the paragraph starting at line 13 again is not really discussion but description	*Thank you for the comment. The opening sentence of discussion paragraph 3 provides context for the reader of the informed-choice principles used in the*

Reviewer Comments	Response
of the program. It should be in methods.	*development of the Z-CAN program and respectfully we would like to keep this in the discussion for clarity and thorough understanding on the part of the reader.*
Reviewer 3: Discussion Page 15 paragraph starting line 22: I would discuss the strengths of the study and data, but not sure this is the place for discussing the program's strengths, similar comment for limitations	*Thank you for the comment. We have struck several areas in this paragraph that are not specific to this paper.*
Reviewer 3: Conclusion Your conclusion paragraph should be more focused on successes and lessons learned, as well as what the data tells up, not on re-describing the program details again.	*Thank you for the comment. The opening and closing sentences of the conclusion are program conclusion, but are also overarching conclusions of this paper. They also serve to ground the middle of the paragraph. We respectfully choose to keep the conclusion as originally submitted.*
Statistical Editor's Comments	
Table 1: The cohorts should be compared statistically. Many differences are statistically different, eg, age, relationship status etc. Should enumerate all missing data.	*Thank you for the comment. The intent of Table 1 is simply to describe the characteristics of all women who participated in the Z-CAN program and those who chose and received a LARC method at the initial Z-CAN visit, not compare the two groups. Therefore, we did not conduct statistical testing. We have edited the results section to clarify that statistical testing was not conducted.* *However, we have previously reported on the factors associated with choosing and receiving a LARC method among program participants (see Lathrop et al, 2018, Lancet Public Health).* *Since numerators and denominators are reported for each characteristic, one can calculate the number of missing values. If the editors wish, we can add this information to Table 1 as requested.*
Table 2: The sample sizes are large, but some subsets are modest. Likely the aPR for effectiveness of contraceptive method used before Z-CAN were too few to allow for adjustment for all the characteristics cited, ie, likely over fitted model.	*Thank you for this comment. We reexamined the log file to check for errors when running the adjusted model. The model ran with no errors reported. Also, it is reassuring that the interpretation of the unadjusted prevalence ratios matches that of the adjusted prevalence ratios. For example, in the unadjusted model examining effectiveness of the contraceptive*

Reviewer Comments	Response
	method used before Z-CAN (where there are no concerns about overfitting), women using a most effective method before Z-CAN were less likely to report a removal. This same finding is found after adjustment. Respectfully, we have kept Table 2 as originally submitted.
For the column Copper IUD, the n = 79, so there is no basis for citing %s to nearest 0.1%, should round to nearest integer %.	*Thank you for this comment. For consistency, all percentages in Table 3 (not just those in the copper IUD column) have been rounded to the nearest integer.*
General: Should include a flow diagram to show the exclusions and how many were in each final cohort analyzed.	*Thank you for this. A flow chart of exclusions for Table 3 has been developed (Figure 1). Reference to Figure 1 has been added to a Table 3 footnote.*
Editors' Comments	*All editor comments have been reviewed, adhered to and respected.*