Date: Aug 02, 2018
To: "Oskari Heikinheimo" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1317

RE: Manuscript Number ONG-18-1317

Unintended Pregnancy in a Population entitled to Free-of-Charge Long-Acting Reversible Contraception

Dear Dr. Heikinheimo:

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 Aug 23, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

REVIEWER #1:

This is a cohort study to assess the abortion rate in women initiating LARC compared to women visiting the same family planning clinic not choosing LARC.

1. For the Precis, the Abstract, and the paper, this study is measuring abortion rates, NOT unintended pregnancy, and all terminology should be changed to reflect that. Using the abortion rate as a proxy for unintended pregnancy is not accurate as women can have unintended pregnancies, yet continue them. The authors state this in the introduction as well that they did not measure the "intendedness" of pregnancies.

2. Methods: I am not clear on Cohort 2, women who attended the family planning clinics but did not choose LARC...what method of contraception did they choose? Is this data available? Or were they there for other reasons e.g. STD testing or well women care. It seems like we would want to compare 2 populations: women who were having heterosexual sex and at risk of pregnancy and either were on LARC or a non-LARC method of contraception. Why are we comparing the LARC group to a heterogenous group of other patients who attended the family planning clinic for a variety of reasons. Why not then use Cohort 2 as the control group? Indeed, the LARC vs. non LARC comparison is very similar to the LARC vs. non service user comparison. Why are Cohort 3 and 4 needed? Similar questions as to why 2 control groups are necessary if both controls groups never went to the family planning clinic. How do we know that the control groups were at risk of pregnancy?

3. Methods: I don't see that end of follow up included LARC removal....do we know duration of use?

REVIEWER #2:

Thank you for submitting this manuscript examining the unintended pregnancy rate among no-cost Long-Acting Reversible Contraception (LARC) users in Finland vs. adopters of non-LARC methods. This prospective cohort study followed women in Vantaa, Finland, who used family planning clinics where first time LARC users received the method free of charge. The no-charge LARC and non-LARC users from the family planning clinics were matched with controls who did not receive contraception from the family planning clinics, both LARC and non-LARC users. Subsequent abortion rates for the 4 groups were determined over an average follow-up of 2 years through national registry data. These data are important because they confirm the findings of the CHOICE study in the US that cost is a barrier to use of the most effective contraceptive methods (LARC) and removal of cost results in higher initiation of LARC methods as well as lower abortion rates. This study also adds new data comparing the no-cost LARC and non-LARC users to population matched controls who were not able to

access LARC free of charge.

1. General comment: The use of abortion rate as a proxy for unintended pregnancy rate in this study may be grossly underestimating the unintended pregnancy rate. In the US, for example, the unintended pregnancy rate is approximately 50%, but only half of unintended pregnancies go on to have abortions. Without access to the pregnancy intentions of the study participants, it is not possible to say what the unintended pregnancy rate might be. If there are some national data available for Finland, perhaps an estimate could be made, but otherwise, please limit the discussion to the data available and do not assume the abortion rate = the unintended pregnancy rate.

2. Title: As per general comment above, title needs to be changed if pregnancy intention data are not available

3, Precis: As per general comment, would need to risk of abortion vs risk of unintended pregnancy. Also, not sure who no-cost LARC users are being compared to - non-LARC users at same clinics, population control LARC or non-LARC users; please clarify.

4. Abstract: consider changing unintended pregnancy to abortion throughout unless these data are available and can be referenced in the manuscript. In the results section, it is not clear if the No-LARC group had to pay or not. In addition, it is unclear who the "74% lower than matched Non-service group user cohort is - does this include LARC and non-LARC users or both? Conclusion is good and does not reference unintended pregnancy rate.

5. Introduction: primary outcome is correct for the data: abortion rate.

Materials and Methods:

6- Please clarify - are all contraceptive methods free of charge at the family planning clinics all of the time or were the LARC methods free of charge only during 2013-2014?

7- The paragraph on the Finnish national registers could be omitted or moved to supplemental data for those who are interested and a sentence included stating the data were collected from available national registries.

8- The statistical methods and development of regression models section could be shortened. Also, do not include the information on which variables were used in the final model; that information should be reported in the results section instead. In the M&M section, state your intent to examine the risk factors for abortion through univariate and multivariate analysis including age, marital status, socio-economic status, etc. and the statistical methods you plan to use. In the results section, discuss which variables were significant and included in the final model.

9. Results: good overall. Please move the final model discussion from M&M to results section.

10. Discussion: Not sure what the concluding line of the paragraph staring "Notably... " and ending " choosing a LARC and non-service users may be more incidental" means. Please clarify your intent regarding the non-LARC users.

11- last sentence: likely an effective means to decrease the abortion rate (and probably unintended pregnancy as well, but again, these data do not support that conclusion.

Thank you for providing these data to further support the removal of cost as a barrier for LARC initiation. It is very clear that cost is an inhibiting factor. Making the most effective contraceptives available at not cost clearly lowers the abortion rate; these data show how much more it is reduced when cost is not a factor.

REVIEWER #3:

This is an important study evaluating the impact of LARC provided through publicly funded family planning clinics in Finland. The authors clearly define the research gap and the unique attributes of the study location. I have a few methodological concerns that I would recommend revisiting in the manuscript with further explanation:

1- Unintended pregnancy is not equivalent to unwanted pregnancy nor abortion rate. In the introduction, authors explain that abortion rate was used as these other two rates are not measured in the population. I would re-frame the entire wording of the manuscript around this point- that risk of induced abortion is lower among women choosing LARD when offered free-of-charge as this is still an important finding.

2- Lines 126-8 describes that if a woman was pregnant at the "start date" her follow-up was set to 30 days after the pregnancy ended. This does not take into about breastfeeding for those women whose pregnancies result in birth and choose to breastfeed. I recognize that this may be a limitation in the dataset however, it is a limitation that should be discussed.

3- How were clinically recognized pregnancies that end in miscarriage or ectopic handled? This is not discussed in the methods.

Smaller issue

4- Line 183: Define AIC prior to using in the manuscript.

STATISTICAL EDITOR'S COMMENTS:

1. lines 41-43: Should state the number of abortions among the "population controls" group (I assume 996-16-243=737) and the number of WY for that group.

2. Table 1: Should provide some stats analysis of differences in baseline characteristics among the groups.

3. Need to include a Table, rather than including information within Fig 2 of : number of abortions, number of women years (the figure does not state that these are 1,000 WY and incidence rates (should state that they are also rates per 1,000 WY).

4. Fig 2 is based on survival analysis method, but the y-axis should not be labelled as "survival probability", but e.g., as "probability without abortion". The x-axis should include the number remaining in each cohort at the designated time increments. There should be an overall statistical summary of whether the curves differed. E.g., log-rank test.

5. Table 2: The number of abortions in the LARC cohort was 16, a number too few to allow for adjustment with 5 covariates. The comparisons of LARC vs other are therefore likely over fitted. Should have used a matched control group to avoid this issue.

6. Methods: Did the model include competing risks? That is, were the rates of stillbirths included in the analysis?

7. The title and precis are based on unintended pregnancy, while the outcomes measured were rates of abortion. What other measures for an unintended pregnancy were considered? The rate of abortion only seems like one manifestation of an unwanted pregnancy.

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, as well as subsequent author queries. 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:
   1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
   2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

2. Based on the forms that have been submitted, Dr. But has not met the criteria for authorship. On the third page of the form, under the section labeled "Authorship," items #2-4, in addition to either #1a or 1b, MUST be checked off in order to qualify for authorship. Dr. But should be moved to the acknowledgments, or they could resubmit a revised author agreement form if they filled it out erroneously the first time. All updated and missing forms should be uploaded with the revision in Editorial Manager.

3. All studies should follow the principles set forth in the Helsinki Declaration of 1975, as revised in 2013, and manuscripts should be approved by the necessary authority before submission. Applicable original research studies should be reviewed by an institutional review board (IRB) or ethics committee. This review should be documented in your cover letter as well in the Materials and Methods section, with an explanation if the study was considered exempt. If your research is based on a publicly available data set approved by your IRB for exemption, please provide documentation of this in your cover letter by submitting the URL of the IRB web site outlining the exempt data sets or a letter from a representative of the IRB. In addition, insert a sentence in the Materials and Methods section stating that the study was approved or exempt from approval. In all cases, the complete name of the IRB should be provided in the manuscript.

4. 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), and quality improvement in health care (ie, SQUIRE 2.0). 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, or SQUIRE 2.0 guidelines, as appropriate.

5. 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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at http://links.lww.com/AOG/A515, and the gynecology data definitions are available at http://links.lww.com/AOG/A935.

6. 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 appendixes).

Please limit your Introduction to 250 words and your Discussion to 750 words.

7. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with 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 signature on the journal's author agreement 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).

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. The Journal's Production Editor had the following to say about the figures in your manuscript:

"Figure 2: Please move the legend and text inside the figure to below the figure. "

When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.

Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

Figures should be no smaller than the journal column size of 3 1/4 inches. Art that is low resolution, digitized, adapted from slides, or downloaded from the Internet may not reproduce. Refer to the journal printer's web site (http://cjs.cadmus.com/da/index.asp) for more direction on digital art preparation.

***

If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at http://ong.editorialmanager.com. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

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

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 Aug 23, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982
2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

If you would like your personal information to be removed from the database, please contact the publication office.

Response to Reviewers

REVIEWER #1:

This is a cohort study to assess the abortion rate in women initiating LARC compared to women visiting the same family planning clinic not choosing LARC.

1. For the Precis, the Abstract, and the paper, this study is measuring abortion rates, NOT unintended pregnancy, and all terminology should be changed to reflect that. Using the abortion rate as a proxy for unintended pregnancy is not accurate as women can have unintended pregnancies, yet continue them. The authors state this in the introduction as well that they did not measure the "intendedness" of pregnancies.

We received several comments on this matter, and agree with the reviewers. Instead of using abortion as a proxy for unintended pregnancy, we have changed the terminology throughout the revised manuscript to explicitly measure the abortion rate.

2. Methods: I am not clear on Cohort 2, women who attended the family planning clinics but did not choose LARC...what method of contraception did they choose? Is this data available? Or were they there for other reasons e.g. STD testing or well women care. It seems like we would want to compare 2 populations: women who were having heterosexual sex and at risk of pregnancy and either were on LARC or a non-LARC method of contraception. Why are we comparing the LARC group to a heterogenous group of other patients who attended the family planning clinic for a variety of reasons. Why not then use Cohort 2 as the control group? Indeed, the LARC vs. non LARC comparison is very similar to the LARC vs. non service user comparison. Why are Cohort 3 and 4 needed? Similar questions as to why 2 control groups are necessary if both controls groups never went to the family planning clinic. How do we know that the control groups were at risk of pregnancy?

We thank the reviewer for these valuable comments. Cohort 2 consists of women using the public family planning clinic services, and being eligible for a LARC method free-of-charge. All visits at the family planning clinic are linked to fertility and the need of contraception. If a woman has e.g. gynecological symptoms but does not use a contraceptive method she would attend a GP at the regular clinic instead. Thus, among all service users – i.e. LARC and No-LARC cohorts – there will be only a few women attending for other reasons than initiating or switching of contraceptive method. Anyhow, they are all in need of family planning services.

In this study, we aim at investigating the effects of a public free-of-charge LARC program. The four cohorts together represent the target population of the free-of-charge LARC intervention, i.e. women of fertile age, living in Vantaa, and being eligible to a free-of-charge LARC method. We chose to compare both LARC and No-LARC cohorts, as well as comparing both cohorts with their own, age-matched population controls, as an effort to make sure that the differences in abortion rate are not due to differences of baseline characteristics alone. The fact that the abortion rate in Cohorts 3 and 4 are much higher than in the LARC cohort shows that also these women are at risk of pregnancy.

In the revised manuscript, we have clarified the description of the family planning clinic services, to describe the service users and Cohort 2 more precisely.

Revised sentence starting at line 114, page 6: *The clinics provide counselling for residents in need of family planning services, including initiation and follow-up of hormonal contraceptives, initiation and removal of LARC methods, diagnostics and treatment of sexually transmitted infections among contraception users, counselling on fertility and sexual health, as well as referrals for and follow-up visits after induced abortion.*

3. Methods: I don't see that end of follow up included LARC removal....do we know duration of use?

Our key research interest lies on whether it is effective to provide LARC methods at no-cost – not if it is efficient to use them, which we already know e.g. from the CHOICE study. Thus, we did not include removal of LARC methods as end of follow-up. As the rates and reasons of LARC removals are very interesting study questions, we plan to assess this topic in a separate study.

REVIEWER #2:

Thank you for submitting this manuscript examining the unintended pregnancy rate among no-cost Long-Acting Reversible Contraception (LARC) users in Finland vs. adopters of non-LARC methods. This prospective cohort study followed women in Vantaa, Finland, who used family planning clinics where first time LARC users received the method free of charge. The no-charge LARC and non-LARC users from the family planning clinics were matched with controls who did not receive contraception from the family planning clinics, both LARC and non-LARC users. Subsequent abortion rates for the 4 groups were determined over an average follow-up of 2 years through national registry data. These data are important because they confirm the findings of the CHOICE study in the US that cost is a barrier to use of the most effective contraceptive methods (LARC) and removal of cost results in higher initiation of LARC methods as well as lower abortion rates. This study also adds new data comparing the no-cost LARC and non-LARC users to population matched controls who were not able to access LARC free of charge.

Thank you for these kind comments.

1. General comment: The use of abortion rate as a proxy for unintended pregnancy rate in this study may be grossly underestimating the unintended pregnancy rate. In the US, for example, the unintended pregnancy rate is approximately 50%, but only half of unintended pregnancies go on to have abortions. Without access to the pregnancy intentions of the study participants, it is not possible to say what the unintended pregnancy rate might be. If there are some national data available for Finland, perhaps an estimate could be made, but otherwise, please limit the discussion to the data available and do not assume the abortion rate = the unintended pregnancy rate.

We have changed the terminology throughout the manuscript to explicitly measure the abortion rate. Please see also our reply to Reviewer #1, point 1.

2. Title: As per general comment above, title needs to be changed if pregnancy intention data are not available

The Title has been changed to '*Induced abortion in a Population entitled to Free-of-Charge Long-Acting Reversible Contraception*'

3, Precis: As per general comment, would need to risk of abortion vs risk of unintended pregnancy. Also, not sure who no-cost LARC users are being compared to - non-LARC users at same clinics, population control LARC or non-LARC users; please clarify.

Thank you for this valuable comment, we have revised the Precis according to this and other comments: *Risk of induced abortion is markedly lower among women initiating free-of-charge Long-Acting Reversible Contraception, compared to women using family-planning services but not initiating such methods.*

4. Abstract: consider changing unintended pregnancy to abortion throughout unless these data are available and can be referenced in the manuscript.

The abstract is revised according to this and other comments, please also see our reply to Reviewer#1, point 1.

In the results section, it is not clear if the No-LARC group had to pay or not.

Thank you for pointing this out, the abstract has been revised to clarify that all women in the cohorts were eligible for free-of-charge LARC contraception, but only those in the LARC cohort chose to initiate such a method free-of-charge.

Line 34: *We assessed the risk of abortion among women entitled to LARC methods free-of-charge by survival analysis in four cohorts: women visiting public family planning clinics and initiating free-of-charge LARC methods during 2013 – 2014 ([LARC cohort] n=2035); women visiting public family planning clinics, not choosing LARC methods ([No-LARC cohort] n=7634); and three age-matched controls for every LARC and No-LARC participant, from the general population not using the services ([Non-service users] n=5981 and 22748).*

In addition, it is unclear who the "74% lower than matched Non-service group user cohort is - does this include LARC and non-LARC users or both?

Thank you for this comment, the sentence has been revised. Moreover, we found a typo concerning the adjusted rate ration for the LARC vs No-LARC comparison, which has now been corrected.

Line 45: *The adjusted abortion rate in the LARC cohort was 80% lower than in the No-LARC cohort (risk ratio [RR0.20, 95% CI 0.11 – 0.32), and 74% lower than among their matched population controls (RR 0.26, 95% CI 0.15 – 0.43).*

Conclusion is good and does not reference unintended pregnancy rate.

5. Introduction: primary outcome is correct for the data: abortion rate.

Thank you.

Materials and Methods:

6- Please clarify - are all contraceptive methods free of charge at the family planning clinics all of the time or were the LARC methods free of charge only during 2013-2014?

We have revised and clarified the sentences on this topic.

New sentence on line 118, page 6: *As of January 2013, every woman in Vantaa has also been eligible to one LARC method free-of-charge at these clinics.*

7- The paragraph on the Finnish national registers could be omitted or moved to supplemental data for those who are interested and a sentence included stating the data were collected from available national registries.

Finnish health registers are unique in their accuracy and national coverage. These reliable data sources form the basis for the study and hence, if acceptable, we would prefer to keep this paragraph in the manuscript.

8- The statistical methods and development of regression models section could be shortened. Also, do not include the information on which variables were used in the final model; that information should be reported in the results section instead. In the M&M section, state your intent to examine the risk factors for abortion through univariate and multivariate analysis including age, marital status, socio-economic status, etc. and the statistical methods you plan to use. In the results section, discuss which variables were significant and included in the final model.

We have revised the paragraph on statistical analysis according to this comment and others. Please see also our reply to the Statistical Editor, point 5 for details. The information of final variables has been moved to the results section, beginning on line 297, page 12.

9. Results: good overall. Please move the final model discussion from M&M to results section.

Yes, this has now been done.

10. Discussion: Not sure what the concluding line of the paragraph staring "Notably... " and ending " choosing a LARC and non-service users may be more incidental" means. Please clarify your intent regarding the non-LARC users.

Thank you for this comment, we have revised the paragraph.

Line 341, page 14: *We found no difference in abortion rates in the No-LARC versus control group comparison, suggesting that women using family planning services are sexually active and fertile. Thus, service use without initiation of a LARC method did not decrease the risk of abortion among these women.*

11- last sentence: likely an effective means to decrease the abortion rate (and probably unintended pregnancy as well, but again, these data do not support that conclusion.

We have revised the sentence on line 411, page 16 as suggested: *We conclude that providing the population with the option of free-of-charge LARC methods, is likely an effective means to decrease the abortion rate.*

Thank you for providing these data to further support the removal of cost as a barrier for LARC initiation. It is very clear that cost is an inhibiting factor. Making the most effective contraceptives available at not cost clearly lowers the abortion rate; these data show how much more it is reduced when cost is not a factor.

Thank you very much for this comment – we fully agree!

REVIEWER #3:

This is an important study evaluating the impact of LARC provided through publicly funded family planning clinics in Finland. The authors clearly define the research gap and the unique attributes of the study location. I have a few methodological concerns that I would recommend revisiting in the manuscript with further explanation:

1- Unintended pregnancy is not equivalent to unwanted pregnancy nor abortion rate. In the introduction, authors explain that abortion rate was used as these other two rates are not measured in the population. I would re-frame the entire wording of the manuscript around this point- that risk of induced abortion is lower among women choosing LARD when offered free-of-charge as this is still an important finding.

We have changed the terminology throughout the manuscript to explicitly measure the abortion rate. Please see also our replies above.

2- Lines 126-8 describes that if a woman was pregnant at the "start date" her follow-up was set to 30 days after the pregnancy ended. This does not take into about breastfeeding for those women whose pregnancies result in birth and choose to breastfeed. I recognize that this may be a limitation in the dataset however, it is a limitation that should be discussed.

Unfortunately, we do not have data on breastfeeding among women in Vantaa. In Finland, less than 10% of babies are exclusively breastfed until 6 month's age (THL, https://thl.fi/documents/10531/1449887/Imevaisikaisten+ruokinta.pdf/543a559d-32f7-4db0-9e47-c5285f873a9d), and use of LAM as a contraceptive is seldom recommended (Sannisto, T. & Kosunen, E. (2009). Initiation of postpartum contraception: a survey among health centre

physicians and nurses in Finland. Scand J Prim Health Care 27, 244-9.) Nevertheless, as the reviewer points out, this is a limitation of data which is now discussed in the sentence starting on line 375, page 15: *Information on breastfeeding was not available, and could hence not be accounted for.*

3- How were clinically recognized pregnancies that end in miscarriage or ectopic handled? This is not discussed in the methods.

Thank you for pointing out that this was not highlighted enough. All pregnancies reaching at least 22 weeks of gestation are registered in the Medical Birth Register, and all pregnancies ending in abortion are registered in the Register on Induced Abortions. Thus, ectopic pregnancies and pregnancies ending in a miscarriage are not identified and not included as an end of follow-up date in this study. This is now pointed out more clearly, beginning at line 184, page 8: *The Medical Birth Register was established in 1987 and includes data on both mothers and foetuses, including stillbirths if the gestational age is at least 22 weeks. It does not include information on pregnancies ending before the 22nd week, e.g. miscarriages and ectopic pregnancies.*

Smaller issue

4- Line 183: Define AIC prior to using in the manuscript.

We have revised the statistical analysis paragraph to include the definition of AIC.

Revised sentence starting on line 230, page 10: *Selection of covariates was guided by the statistical significance of their effect on the outcome variable ($p < 0.05$), and with information loss measured by the difference in Akaike information criterion (AIC) (i.e. decreasing AIC for the improved model).*

STATISTICAL EDITOR'S COMMENTS:

1. lines 41-43: Should state the number of abortions among the "population controls" group (I assume 996-16-243=737) and the number of WY for that group.

The sentence has been revised according to this comment. Also, we found and corrected the incorrectly calculated incidence rate for the LARC cohort.

New sentence starting at line 45: *Of these, 16 abortions occurred in the LARC cohort (3.9/1000, 95% CI 2.4 – 6.0), 243 in the No-LARC cohort (15.3/1000, 95% CI 13.5 – 17.2), and 737 (12.6/1000, 95% CI 11.7 – 13.5) among matched Non-service users.*

The number of women-years for each cohort is not spelled out in the abstract due to space limitations, but can be found in the new Table 2. We hope this is acceptable.

2. Table 1: Should provide some stats analysis of differences in baseline characteristics among the groups.

We tested for differences in baseline characteristics between the Service user cohort and non-service user cohort, as well as between the LARC cohort and No-LARC cohort, with chi-square test for categorical variables and with Wilcoxon rank sum test for continuous variables. All tests showed p-values <.001. We have now added this as a footnote to Table 1.
All comparisons between Service user cohort and Non-service user cohort, and between LARC cohort and No-LARC cohort, were significant at P <.001, using chi-square test for categorical variables and with Wilcoxon rank sum test for continuous variables.

3. Need to include a Table, rather than including information within Fig 2 of : number of abortions, number of women years (the figure does not state that these are 1,000 WY and incidence rates (should state that they are also rates per 1,000 WY).

The information in Figure 2 is now split up in one figure and one table, based on this comment and the comment in point 4. The new table is now called Table 2 and the regression estimate results table is called Table 3. Also, we corrected the incorrectly calculated incidence rate for the LARC cohort (please see above).

4. Fig 2 is based on survival analysis method, but the y-axis should not be labelled as "survival probability", but e.g., as "probability without abortion". The x-axis should include the number remaining in each cohort at the designated time increments. There should be an overall statistical summary of whether the curves differed. E.g., log-rank test.

Thank you, Figure 2 and the Figure legend are revised and the p-value from log-rank test is included.

5. Table 2: The number of abortions in the LARC cohort was 16, a number too few to allow for adjustment with 5 covariates. The comparisons of LARC vs other are therefore likely over fitted. Should have used a matched control group to avoid this issue.

Thank you for this comment. Indeed, the number of abortions in the LARC cohort is small compared to the number of variables we used in the multivariate model. Given the differences in the baseline variables between the cohorts, we still found it important to control for the effect of potential confounders through adjustment. Due to the risk of overfitting, we continued to make fully matched control groups for the LARC group (matched by all covariates included in the full model) and thereafter computed a crude poisson regression. There were only small differences in estimates and confidence intervals compared to the main models.

We have now added sentences on this matter to the manuscript in Material and methods, Results and Discussion.
Line 241, page 10: *Further, as the number of events in the LARC cohort was small compared to the number of covariates, we computed additional analyses for the LARC cohort comparisons with fully matched controls cohorts (1:1 matching by age, socioeconomic status, marital status, previous pregnancy, and previous abortion).*
Line 310, page 13: *The additional analysis of LARC cohort compared to fully matched control cohorts yielded similar results for both the No-LARC comparison (RR 0.19, 95% CI 0.10 – 0.31) and the Non-Service user comparison (RR 0.28, 95% CI 0.16 – 0.48).*

Line 398, page 16: *Given the low number of abortions in the LARC group, the full model with five covariates might be over fitted. Therefore, we repeated the crude comparison of no-cost LARC users with two fully matched control cohorts. This did not change the results.*

6. Methods: Did the model include competing risks? That is, were the rates of stillbirths included in the analysis?

No, we did not conduct a competing risk analysis. However, stillbirths were included as a censoring event, together with all pregnancies lasting at least 22 weeks (please also see our reply to Reviewer #3, point 3). In the perspective of our study question, pregnancies not ending in abortion are not relevant, as we aim to conclude whether such a no-cost LARC program decreases the risk of abortion in a population.

7. The title and precis are based on unintended pregnancy, while the outcomes measured were rates of abortion. What other measures for an unintended pregnancy were considered? The rate of abortion only seems like one manifestation of an unwanted pregnancy.

We have changed the terminology throughout the manuscript to explicitly measure the abortion rate, not the rate of unintended pregnancy.

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, as well as subsequent author queries. 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:

1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.

2. Based on the forms that have been submitted, Dr. But has not met the criteria for authorship. On the third page of the form, under the section labeled "Authorship," items #2-4, in addition to either #1a or 1b, MUST be checked off in order to qualify for authorship. Dr. But should be moved to the acknowledgments, or they could resubmit a revised author agreement form if they filled it out erroneously the first time. All updated and missing forms should be uploaded with the revision in Editorial Manager.

A new appropriately filled author agreement from Dr. But has been uploaded.

3. All studies should follow the principles set forth in the Helsinki Declaration of 1975, as revised in 2013, and manuscripts should be approved by the necessary authority before submission.

Applicable original research studies should be reviewed by an institutional review board (IRB) or ethics committee. This review should be documented in your cover letter as well in the Materials and Methods section, with an explanation if the study was considered exempt. If your research is based on a publicly available data set approved by your IRB for exemption, please provide documentation of this in your cover letter by submitting the URL of the IRB web site outlining the exempt data sets or a letter from a representative of the IRB. In addition, insert a sentence in the Materials and Methods section stating that the study was approved or exempt from approval. In all cases, the complete name of the IRB should be provided in the manuscript.

The study has been approved by the ethics committee at the Hospital District of Helsinki and Uusimaa, Finland, please see the cover letter for details. The approval is acknowledged in the manuscript, together with the name of the ethics committee and the diary number of the approval, starting on line 256, page 11.

4. 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), and quality improvement in health care (ie, SQUIRE 2.0). 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, or SQUIRE 2.0 guidelines, as appropriate.

A filled STROBE-checklist was included in the initial submission.

5. 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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at http://links.lww.com/AOG/A515, and the gynecology data definitions are available at http://links.lww.com/AOG/A935.

6. 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 appendixes).

Please limit your Introduction to 250 words and your Discussion to 750 words.

7. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with 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 signature on the journal's author agreement 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).

We have revised the acknowledgements according to these instructions.

8. 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.

The word count for the abstract is 300.

9. 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.

All abbreviations are in line with the guidelines.

10. 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.

We have no virgule symbol in sentences with words, only to express rates.

11. 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.

We have revised the sentence starting on line 331, page 14 in the Discussion section: *This study provides further evidence of the effect size of providing free-of-charge LARC methods, compared to matched cohorts in the general population.*

12. 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.

The tables are formatted according to the Table Checklist.

13. The Journal's Production Editor had the following to say about the figures in your manuscript:

"Figure 2: Please move the legend and text inside the figure to below the figure. "

The information in Figure 2 is now split up in one figure and one table, according to the Statistical Editor's comments.

Daniel Mosier

From: Oskari Heikinheimo [redacted]
Sent: Thursday, September 6, 2018 3:04 PM
To: Daniel Mosier
Cc: Gyllenberg, Frida K
Subject: Re: Manuscript Revisions: ONG-18-1317R1
Attachments: 18-1317R1 ms (9-5-18v2)_revised.docx

Dear Daniel Mosier,

Thank you for your kind email. Please find below our answers to each of your questions, together with the manuscript with the requested changes.

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.

Reply: Thank you, we have noted the edits and are happy with those.

2. LINE 4:

a. Please list each author's name in this way: First name, middle initial, last name, degrees

Reply: The names of the authors are now listed as required.

b. Please ask Anna But to respond to her authorship confirmation email. We emailed her at [redacted] The email contains a link that needs to be clicked on. The sender of the email isEM@greenjournal.org.

Reply: Anna But has replied to your email.

3. LINE 16: Please add the date in 2018 that the meeting took place, if known.

Reply: The date of the Budapest meeting is added. Also, after the initial submission, author FG has been given the opportunity to give an oral presentation at the FIAPAC conference in Nantes, France, on September 14th 2018. The details of this presentation are now included.

4. LINE 37: ACOG refers to patients of mixed ages (adolescents and adults) as "females." We have changed this to either "females" or "patients" throughout your paper.

Reply: Thank you, we have noted and approve these edits.

5. LINE 42: Did the 'No-LARC cohort' select a contraceptive other than LARC, or no contraceptive at all?

Reply: The LARC Cohort is identified as family planning clinic service users who initiated a LARC method free of charge during 2013-2014. As follows, the No-LARC Cohort is identified as family planning clinic service users, entitled to a LARC method free of charge, but not initiating such a method during 2013-2014. We do not know in detail which contraceptive method these women used. The service provided at the family planning clinics is being described in the materials and methods section starting on line 151, and further discussed starting on line 402.

6. LINE 47: Please be sure this is stated in the body of your paper.

Reply: The total number of women years accumulated is stated in the results section, in the sentence starting on line 330. However, we noticed a typo in the abstract, the correct number of total WYs is 78500 and is now corrected.

7. LINE 48: Where are these data stated in the body of your paper? If the data are not contained in the text, tables, or figures, please add them.

Reply: We have revised the sentence starting on line 331 to include the incidence rate for the total population: *During the follow-up period between 1st January 2013 and 28th February 2016, 78500 women-years (WYs) accumulated, with a mean follow-up time of 2.0 years (SD = 0.7), and a crude incidence rate of pregnancy ending in abortion of 12.3 abortions per 1000 WY (95% CI 11.6 – 13.1).*

8. LINE 54: Table 3 says 0.14. Which is correct?

Reply: We apologize for this typo, the correct confidence interval is 0.14 – 0.43.

9. LINE 305: If you are discussing those under the age of 18 here, please use "patients" or "females."

Reply: Yes, we mean women aged 15-24, and now use the word "females".

10. LINE 325: Please re-word this sentence for clarity.

Reply: We have revised the sentences starting from line 440 as follows: *Also, the Finnish national registers only contain information on education, reproductive and work-related history obtained from Finnish institutions. This may cause missing information especially among immigrant women.*

11. LINE 327: If you are discussing those under the age of 18 here, please use "patients" or "females."

Reply: Yes, we mean women of all ages, and now use the word "females".

12. TABLE 3: The abstract says 0.15.

Reply: We apologize for this typo, the correct confidence interval is 0.14 – 0.43.

13. FIGURE 2: Please cite this figure within the text of your main manuscript.

Reply: We have added a sentence starting on line 342 to include a citation to Figure 2: *The probability of not having a pregnancy ending in abortion during follow-up in each of the four cohorts is presented in Figure 2.*

Further, we noticed a comment regarding the sentences on line 227 – 231; "Is this necessary to include?". These sentences were revised based on comments by Reviewer #3, but can be deleted if regarded unnecessary.

Thank you for you help with our manuscript. We trust everything is now in good order!

Kindest regards,

Oskari Heikinheimo

Professor, Department of Obstetrics & Gynecology, University of Helsinki
Physician in-chief, Helsinki University Hospital
[redacted]

Daniel Mosier <dmosier@greenjournal.org> kirjoitti 5.9.2018 kello 21.21:

Dear Dr. Heikinheimo,

Thank you for submitting your revised manuscript. It has been reviewed by the editor, and there are a few issues that must be addressed before we can consider your manuscript further:

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.
2. LINE 4:
    a. Please list each author's name in this way: First name, middle initial, last name, degrees
    b. Please ask Anna But to respond to her authorship confirmation email. We emailed her at [redacted] The email contains a link that needs to be clicked on. The sender of the email is EM@greenjournal.org.
3. LINE 16: Please add the date in 2018 that the meeting took place, if known.
4. LINE 37: ACOG refers to patients of mixed ages (adolescents and adults) as "females." We have changed this to either "females" or "patients" throughout your paper.
5. LINE 42: Did the 'No-LARC cohort' select a contraceptive other than LARC, or no contraceptive at all?
6. LINE 47: Please be sure this is stated in the body of your paper.
7. LINE 48: Where are these data stated in the body of your paper? If the data are not contained in the text, tables, or figures, please add them.
8. LINE 54: Table 3 says 0.14. Which is correct?

9. LINE 305: If you are discussing those under the age of 18 here, please use “patients” or “females.”
10. LINE 325: Please re-word this sentence for clarity.
11. LINE 327: If you are discussing those under the age of 18 here, please use “patients” or “females.”
12. TABLE 3: The abstract says 0.15.
13. FIGURE 2: Please cite this figure within the text of your main manuscript.

Each of these points are marked in the attached manuscript. Please respond point-by-point to these queries in a return email, and make the requested changes to the manuscript. When revising, please leave the track changes on, and do not use the “Accept all Changes” function in Microsoft Word.

Please let me know if you have any questions. Your prompt response to these queries will be appreciated; please respond no later than COB on **Friday, September 7th.**

Sincerely,
-Daniel Mosier

Daniel Mosier
Editorial Assistant
Obstetrics & Gynecology
The American College of Obstetricians and Gynecologists
409 12th Street, SW
Washington, DC 20024
Tel: 202-314-2342
Fax: 202-479-0830
E-mail: dmosier@greenjournal.org
Web: http://www.greenjournal.org

<18-1317R1 ms (9-5-18v2).docx>

From: Stephanie Casway
To: [redacted]
Subject: RE: O&G Figure Revision: 18-1317
Date: Thursday, August 30, 2018 8:57:00 AM
Attachments: 18-1317 Fig 1 (8-30-18 v3).pdf
18-1317 Fig 2 (8-30-18 v2).pdf

Good Morning,

Thank you so much for your review and edits. We have updated Figure 1 per your suggestion. Additionally, we have updated Figure 2 to include "No LARC." I did speak with our manuscript editor regarding the hyphen, and that will be removed from the manuscript. Updated PDFs are attached for your records. If you have any questions or concerns, please let me know.

Have a great day!

From: Gyllenberg, Frida K [redacted]
Sent: Wednesday, August 29, 2018 11:58 PM
To: Stephanie Casway <SCasway@greenjournal.org>
Cc: Heikinheimo, M A Oskari [redacted]
Subject: Re: O&G Figure Revision: 18-1317

Dear Stephanie Casway,
Thank you for your email, I was asked to answer on Dr Heikinhiemo's behalf.
Our only comment regards Figure 2; Legend Box and Number at risk table. We would prefer to use *Population controls (No LARC)*, with a capital N to describe the population controls matched to the No LARC cohort instead of *Population controls (no LARC).* Also, if the name of the cohort No-LARC is changed to No LARC, we wish that this change is made consistently throughout the manuscript.
Further, I noticed that we have described the population controls in Figure 1 in an inconsistent way : Matched nonservice users of *service users* initiating a free-of-charge LARC *vs.* Matched nonservice users of *women* not choosing LARC.
If you wish, the later could be changed to Matched nonservice users of *service users* not choosing LARC, for clarity.

Best regards,
Frida Gyllenberg

Lähettäjä: Stephanie Casway <SCasway@greenjournal.org>
Aihe: O&G Figure Revision: 18-1317

Päivämäärä: 29. elokuuta 2018 klo 15.51.27 UTC+3
Vastaanottaja: [redacted]

Good Morning Dr. Heikinheimo,

Your figures and legend have been edited, and PDFs of the figures and legend are attached for your review. Please review the figures CAREFULLY for any mistakes. In addition, please see our query below.

AQ1: Note that we edited the *P* value in Figure 2 to 3 decimals per journal style.

PLEASE NOTE: Any changes to the figures must be made now. Changes at later stages are expensive and time-consuming and may result in the delay of your article's publication.

To avoid a delay, I would be grateful to receive a reply no later than Friday, 8/31. Thank you for your help.

Best wishes,

Stephanie Casway, MA
Production Editor
Obstetrics & Gynecology
American College of Obstetricians and Gynecologists
409 12th St, SW
Washington, DC 20024
Ph: (202) 314-2339
Fax: (202) 479-0830
scasway@greenjournal.org

<18-1317 Legend.pdf><18-1317 Fig 1 (8-29-18 v2).pdf><18-1317 Fig 2 (8-28-18 v1).pdf>