OBSTETRICS & GYNECOLOGY

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Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office: obgyn@greenjournal.org.

Date: Feb 07, 2019
To: "Lorinda Wells Anderson" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-2390

RE: Manuscript Number ONG-18-2390

Pharmacist Provision of Hormonal Contraception in the Oregon Medicaid Population

Dear Dr. Anderson:

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 28, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The purpose of the paper was the assess the trends related to pharmacist dispensed oral contraception and the demographic characteristics of the population accessing the new services. The topic discussed in the paper is relevant and innovative in addressing access related disparities. Overall, the paper is written well and is concise in providing the data and summarizing the results. There are a couple of areas that I identified that need clarification.

Introduction: The introduction could be strengthened by including a brief historical assessment of Pharmacist and there work in clinical practice. It is a new avenue of research, therefore, giving brief context on the role that pharmacist have played in relation to other health concerns may help. Also, in the introduction, there is mention of seven other states who have implemented a similar program. My question is...is there data or are there published studies giving information about their experience thus far. How about governmental reports that give background information. Again, this goes to the basis of getting a broader understanding of the literature to really see the relevance and the placement of this timely study. In finding those other assessments, share what was discovered, what barriers were addressed and what are the outcomes now.

Methods: for objective one, you state you are characterize the trends. However, I disagree. There is not really trends data that is being presented, but more so just a reporting of the status quo. You don't have enough information or comparison to actually make any statements regarding trends. Also, while appendix A and B are helpful, I don't know how they are actually adding to the larger study.

Results: Line 157 - could you give some information about why so many prescriptions or how the number of prescriptions line up with the regular amount that women get dispensed.
Line 158-160 - this line is very confusing. In the end, I get it - you are comparing to the larger total of that same period of time, but I think you need to be a lot more clear. Maybe say, all providers including ...
Line 165-166 - is there a reason for the increase in July/August. Are you able to say anything regarding this.

Discussion: I would delete the first sentence as it is about inconsistent and incorrect use of contraception. Your study is about access to contraception, so that one statement does not help.

In the conclusion, I think you need to build the case for additional qualitative studies with pharmacists and the patients to understand why this one avenue is the best. Additionally, in the introduction, I think you need to be a bit more clear about exactly how this program was rolled out, how did the pharmacist advertise the service, what public level awareness raising was done, etc. Right now, you share that Oregon did it. But I am interested in knowing the how to then connect it with the outcome.

Reviewer #2:

Summary: Descriptive study using claims data from Oregon Medicaid to look at monthly trends in pharmacist prescribing of short-acting hormonal contraception and characterize the women using this route to obtain contraception.

Overall impression: A good study. The conclusions need to be more nuanced. I don't think that we can conclusively say that all patients without an Rx in the preceding 180 days are "new" users. I think some may be relapsed, may have been pregnant, may have had a LARC, may have had Title X funding. There is a missed opportunity for hypothesis generation here.

Line 15: This short title might be too general.

Lines 39-48: It is stated in the Methods (main body and abstract) that the first objective is to quantify monthly trends in pharmacist prescribing, but this is entirely left out of the Abstract Results. Please add here for consistency in reporting.

Line 59: There are newer references for this.

Lines 75 and 109-110: This is inconsistent. Please specify which methods may be pharmacist-prescribed in Oregon in particular in line 75.

Lines 123-4: "Consequently, …" belongs in the results section.

Lines 135-138: Did you include codes for LARC and LARC removals? Pregnancies and deliveries, miscarriages and abortions? Please clarify whether or not these other possibilities were explored, as they affect the use/need for contraception in the preceding 180 days.

Lines 159-160: I would clarify the language here. "Among women using short-acting hormonal contraception…" LNG-IUDs and Etonorgestrel implants are hormonal, too.

Lines 161-168: A summary of this should be in the results section of the abstract.

Lines 173-174: This is where the 30% unknown race should be placed.

Line 180-183: I don't think we can definitively conclude that all of these women were "new" users. There is a possibility that they are returning users. Even in the women with 180 days lead time, pregnancy is a possibility. And I think it highly likely that some unknown subset of the 61% of women without an Rx in that time had been prescribed contraception prior to that time frame. There is an opportunity here for hypothesis generation and further studies to both quantify which of these women are new versus returning users and to qualify reasons for the gap in those returning.

Lines 184-187: The math here doesn't add up. Line 184 says 12 women, but 8+5+3 = 16. Did some women have more than one of these diagnostic codes? Please clarify.

Lines 194-197: Move these two sentences to the introduction as a transition. Start the Discussion section with the third sentence (line 197).

Line 198: Rephrase this sentence. The denominator is wrong. Talk about the percentage of patients getting Rx from provider who are new (or returning - see prior comments) users, not the percentage of new users getting Rx for contraception who get it from pharmacists (that number is much lower, as you state at the beginning that only 10% of total users get Rx from pharmacists).

Line 203: Inconsistent. Check your rounding. In line 183 you state 61%, here it is 62%.

Line 204: initiating or re-initiating

Line 208: This is inconsistent. Line 184 states that 5% (12) women had contraindications. Here it is 2 (1%). If this means that <1% had MEC cat 3 or 4, move this result to the paragraph beginning on line 184 and then discuss what a low number that is here at line 208.

Line 218: new or returning/relapsed users

Line 264: new or returning/relapsed users

Reviewer #3: The authors aim to describe the utilization and demographics of women receiving hormonal contraception prescribed by pharmacists enrolled in Oregon's Medicaid program. Globally I wonder if the authors considered making comparisons between women who received a prescription from the pharmacist to women who received a contraceptive prescription from another type of provider. It seems like that may allow them to draw more conclusions about the group of women that this policy change will affect the most, and strengthen the paper. I have the following additional comments regarding the manuscript:

Intro
1. Line 85-86. In this part of the manuscript the authors state that they want to look at utilization patterns of women prescribed contraception by a pharmacist. Would specify that you were only seeking this information in the Medicaid population.

Methods
1. It is not until the second paragraph that the reader realizes these are only Medicaid data. It would be nice if statewide data for all payors were available. Is there a way to know at least what proportion of the pharmacist prescriptions were for patients with Medicaid as the payor?
2. Line 106-107. Is it possible that the pharmacist changed the Rx of a prescribing provider in some small way and then gets identified as the prescriber? Or is this not allowed?
3. Line 109. Were there pharmacy NPI numbers associated with other methods of contraception that they should not be prescribing? This may be a way to demonstrate validity of the dataset.
4. Line 129-38. I read this paragraph several times and still am having a hard time sorting out why you are looking at a 30-day period, and why there is also information about an 180 day period. Can this be better clarified?
5. Line 151. Why was breastfeeding considered a contraindication to hormonal contraception? Also it seems like diagnostic codes are a weak way to capture breastfeeding data.
6. There is no statistical analysis plan described in the Methods section. Would recommend adding one.

Results
1. Line 160. It seems like it would be valuable to compare women who received a prescription from a pharmacist to those who received it from another provider, rather than just describing the women who got a prescription from a pharmacist.
2. Line 161. The methods section does not describe looking at trends in prescriptions over time but it is presented in the results. This needs to be added to the methods.

Discussion
1. Line 198. The authors state that pharmacist prescriptions were reaching "a majority" of new contraceptive users among Medicaid enrollees. But the results state that only 10% of the contraceptive users obtained their prescription from a pharmacist. What result are the authors referencing here?

Reviewer #4:

Title:
Pharmacist Provision of Hormonal Contraception in the Oregon Medicaid Population

Abstract:
Overall good - I would want to know which contraindications were tracked here (short list)

Intro:
It would be nice to include the Standard Procedures Algorithm as an attachment or figure if possible to help demonstrate best practice for other states considering Pharmacist provision of contraception. It would also be nice in the intro to have a breakdown of utilization of Medicaid in Oregon vs other insurance models.

Sources of Study:
Robust system for tracking claims data. Reliable source. If possible it would be nice to know the limitations of the data (what is the suspected Medicaid fraud use in Oregon) - I would assume not enough to impact the data but important to know.

Inclusion/Exclusion/Data Analysis:
It would be nice to have some information on the contraception provision in non-medicaid women in Oregon for comparison.
It clearly seems like it increased access for the 10% of women that utilized this but was provision different between pharmacists and other providers? It would be very interesting to see the comparison data on number of days provided and incidence of contraindications.
It would also be nice to see the total % of women utilizing contraception before pharmacist provision compared to after.

Conclusions:

While the new provision of birth control is important it would also be nice to see if you can use this data to comment on continued provision (non-interruption) of contraception.

Overall:
Good job. I just want to see a little more comparison info to other providers and to explore the data on continuation of prescriptions as well.

STATISTICAL EDITOR COMMENTS:

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

lines 26-27: Where is the evidence of a control group or before and after groups that demonstrates the improvement in contraception initiation among women enrolled in Medicaid in Oregon?

lines 39-48, Table 1 and 169-174: Need to make clearer the distinctions made between the total cohort (367 women) vs those with 180-day continuous coverage (252 women).

lines 40-43 and 53: How is no prior contraception within the past 30 days equivalent to initiating contraception? Perhaps contraceptive use was interrupted for > 30 days.

lines 43-45: How does the age distribution compare with other groups and how does the geographic origin of these women compare to Oregon generally? That is, is the observation meant to state that rural or urban women in this series were differentially served or proportionate to their population distributions?

Fig 1, 2: These figures show the total numbers of claims on a monthly basis, but since on average, each women had > 3 claims, should also show figures with the number of new claims (in other words), not counting women with a prior claim. I presume these are based on the larger cohort of 367 women, rather than 252 women, but need to clarify. Need legends for the figures.

EDITOR COMMENTS:

1. Thank you for your submission to Obstetrics & Gynecology. In addition to the comments from the reviewers above, you are being sent a notated PDF that contains the Editor's specific comments. Please review and consider the comments in this file prior to submitting your revised manuscript.

The notated PDF is uploaded to this submission's record in Editorial Manager. If you cannot locate the file, contact Randi Zung and she will send it by email - rzung@greenjournal.org.

- visit from a clinician implies something like a home visit. Perhaps: "without a visit with a clinician"?

- Your paper isn't exploring the differences between states' laws, so this sentence isn't necessary.

- Full name is Centers for Disease Control and Prevention

- The Journal style doesn't not use the virgule (/) except in numeric expressions. Please edit here and in all instances.

- The College of Pharmacy isn't a "who" its "what'. Perhaps ...College of Pharmacy which has developed....

- on line 75 you indicate that Pharmacists can also prescribed the hormonal ring and injectable progesterone.
Did you include these? If not, why not?

- replace with a comma.

- As noted by some of your reviewers, there are multiple reasons why someone would not have filled a prescription for a hormonal contraceptive in the prior 30 news sho was not a new user. You had 180 days of data on these women. Why did you use this definition?

- On average, how many women in the included age range were enrolled in Medicaid during your study period? This would give us a sense of over all use. 3614 women seems like a really low number, unless the population is small.

- To make this paragraph flow a bit easier please organize: Average # of women in age range on Medicaid during time period. Total number of hormonal scrips for Medicaid pop. The Number of women and scrips by pharmacists % by pharmacists. You mention ring and injectables here again. You need to be really clear about what you are studying. At this point, I'm not sure.

- In order to put this in context, what % of pharmacies in the state are chain pharmacies and what % are urban?

- On line 157, you indicate your n=367 women. Why 252 here? I suspect it is because of the 180 days of coverage, but you need to be clear about this. Perhaps, start this paragraph. "This study is limited to the 252/367 (x%) of women who were prescribed hormonal contraception by a pharmacists and who had 180 days of enrollment preceding their index contraceptive prescription."

- please report denominators in data presented

- is this for the 252 only?

- in the other manuscript, did you use the 30 day definition of "new user" or the 180 day definition?

- you used antibiotics before; please be consistent.

- you haven't told us the % of new contraceptive users were by pharmacists. Also, you listed your first objective to be to describe the trend of pharmacist's prescribing. Please report that first in your discussion. In fact, you don't ever mention that in your discussion. Also when you says women were new contraceptive users, its really "new" (as you have defined it) hormonal contraceptive users. They may have been using other types of contraception.
Do you have data on how many women who had an index prescription of < 364 days refilled during the time period?

- interesting decline in prescriptions here. Is this significant?

2. 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:
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3. 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.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

4. 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.

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 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.

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 26 typed, double-spaced pages (6,500 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.

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* 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).

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 commercial name (with the generic name in parentheses) may be used once in the body of the manuscript. Use the generic name at each mention thereafter. Commercial names should not be used in the title, précis, or abstract.

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. 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.

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14. Figures 1 and 2: Please upload the original source files. Please do not copy and paste into MS Word.

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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 28, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

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

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