

# OBSTETRICS & GYNECOLOGY



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[obgyn@greenjournal.org](mailto:obgyn@greenjournal.org).

**Date:** Aug 05, 2019  
**To:** "Arden McAllister" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-19-1306

RE: Manuscript Number ONG-19-1306

The patient experience with miscarriage management in the emergency and ambulatory settings.

Dear Dr. McAllister:

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 26, 2019, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

Reviewer #1:

Thank you for submitting your work on important topic.

In this manuscript, the authors present a prospective cohort study, which is follow up paper on sub-analysis of preceding O&G publication (Miscarriage Management Choice Study published in 2016 and supported by RO1 grant), which utilized mixed methods to look at decision-making around treatment decisions. 2 cohorts were compared: patients cared for in ED and in clinic. Parameters described were clinical workflow (number of teams involved, interaction with hospital system) and time to resolution along with interviews. Like preceding publication it focused on patient experience and found that time to resolution was the same (those who went to ED were not more likely to miscarry faster) but there was more provider exposure and less satisfaction with care. Non-white patients and underinsured were more likely to go to ED. Sample size was a convenience sample.

The subject matter is very important-how to deliver compassionate and appropriate care to women with miscarriages, and it is concerning that they don't get it in ED, esp. in underserved areas where private insurance does not give patients access to providers easily. It is well designed and written.

Intro:

Nice summary of issues at stake.

1. From references cited, it looks like most prior publications focused on phone interviews, which is different from this paper which had objective measures. This makes it novel. If so, please highlight that.

Methods:

Described in Reference 9 previously published in here. Well-thought out and executed.

2. Was this a convenience sample (one year interval)? If so, what was this based on? Funding? Other factors?

3. Were there any barriers to patient recruitment identified? Any potential for bias here?

Results:

5. Tables 2 and 3 highlight patient experiences in a vivid way.

Discussion:

6. It seems that prior studies focused on patient interviews, and your metrics are more objective in addition to interview data. I would highlight that in your discussion.

7. Would results presented in figure 1 reach significance with larger sample size? What would effect of larger sample size be?

8. lines 236-243

To the point description of importance of the findings and next steps to improve miscarriage care in ED.

9. Could you briefly explain how early pregnancy assessment units function? Is there programs/resources for miscarriage ED care aside from those units? If ED provider/unit decided they wanted to improve their skills, what should they be considering? What might be generalizable and implementable in low and high resources settings?

Reviewer #2: Title: The patient experience with miscarriage management in the emergency and ambulatory settings

Précis: succinctly summarizes the study

Purpose of the study: noted both in abstract as the Objective (lines 43-46) and in the Introduction (lines 86-88). Hypothesis also clearly stated that the duration between symptoms and miscarriage resolution would be shorter for patients who access miscarriage care via the Emergency Department. This could be clarified further by adding the comparison to the ambulatory-only setting.

Study design and analysis:

Study design is described as a secondary analysis of a prior convergent exploratory mixed-method study, the Miscarriage Management Choice Study, which examined factors influencing miscarriage treatment decision makers among clinically stable patients undergoing first trimester miscarriages. This study instead looked at the study sample from where patients received care, in the emergency department or in the ambulatory-only setting. This sets up two cohorts of patients whose data is then reviewed. The criteria for recruitment for study participants are defined. Validated baseline questionnaires for demographics and psychometric measures and open-ended, semi-structured interviews were performed and analyzed to obtain quantitative and qualitative measures, which are also described.

Results:

Lines 151-154 are helpful in describing some of the characteristics that were different between the two cohorts of patients. Lines 156-163 give the quantitative major points that answer the study question. Lines 164-173 are helpful in looking at all of the patients in this study with the qualitative analysis, while lines 174-189 discuss the difference between the ED and ambulatory-only patients. Within this, lines 185-189 are helpful for summarizing the differences in qualitative experiences.

Conclusions:

The different demographic profiles of the two cohorts is interesting as the patients in the ED were more likely to be young, Black, under/not insured, and to meet PTSD criteria (lines 197-198); it is helpful to have the qualitative data from the PCLC in lines 206-208 to note that patients did not differ in the measurements of acute stress but likely due to chronic stress. In describing the limitations of the study inlines 222-225, it is possible that adding a larger and more diverse socioeconomic/linguistic population might widen the demographic differences between the two groups as access becomes more of a factor limiting who is able to obtain strictly ambulatory care, especially in underserved populations or where ambulatory access is less available. Both the quantitative data re: time to completion of pregnancy and the overall experience of patients undergoing miscarriages help guide possible ways to better serve patients and allocate resources, education, and counseling.

Comments:

1) There are some significant non-random differences between the two cohorts studied, in particular in terms of access. It also is interesting as many Emergency Departments will refer to the ambulatory clinics for follow-up, so ED-only patients in particular may have reasons not described (financial constraints, time of day, childcare responsibilities, work responsibilities, ambulatory physician availability) for not being followed in the ambulatory setting.

2) Clarifying the setting of the ambulatory clinic and the teams there would be helpful as not all ambulatory clinics have multiple teams assigned and thus this would affect the assessed quantitative number of health care team interactions. Continuity of care within the ED seems difficult to expect due to the nature of shift changes and various departments being involved, especially if requiring several visits.

3) It would be helpful to look at if medical/surgical/expectant management were involved as that affects time to resolution, one of the other quantitative variables discussed (and the primary variable in the hypothesis). Time to resolution is

defined as the days from initial patient contact regarding early pregnancy concern to final health care system interaction during the observed pregnancy in lines 123-125. That definition is difficult to assess; does it also count ultrasound or laboratory followup after medical management or postoperative followup after D+C? Is there a difference between which method (D+C or medical management/expectant management) a patient would choose that would not be captured in this analysis, such as cost, privacy, access? This did not appear to be addressed. Were all patients followed to completion of their miscarriages (empty uterine stripe on ultrasound, negative laboratory testing) or only to their last health care interaction specific to the miscarriage itself? The choice of management might also affect number of health care interactions (particularly if surgical management) and time to resolution.

4) This is an interesting secondary analysis describing some of the differences between ED-only and ambulatory-only miscarriage care, both in quantitative and qualitative terms. It could help improve care for patients experiencing miscarriage. The secondary analysis is different in its focus than the original study by looking at location of care.

Reviewer #3:

Overall: Thank you for the opportunity to review this well-written manuscript. This is a secondary analysis of a mixed methods prospective study on the relationship between the location of miscarriage care (emergency department or ambulatory only) and the patient experience. This is a relevant topic to the journal audience given the prevalence of first trimester pregnancy loss. The authors examine interesting outcomes between the 2 study groups: time to miscarriage resolution (days), number of health system interactions, number of provider care teams in addition to in-depth narrative interviews. The authors found that patients who had an ED encounter during their miscarriage care did not have a shorter time to pregnancy resolution, saw more care teams and described less positive experiences/lower satisfaction compared to those who only had ambulatory care for their miscarriage. However, its small sample size and single-institution design limits its generalizability. The authors provide the STROBE checklist with their submission and overall followed the STROBE guidelines when designing their study and writing the manuscript.

1. In the first trimester, the terms miscarriage, spontaneous abortion, and early pregnancy loss are used interchangeably and there's no consensus on terminology in the literature. However, the term pregnancy loss is the term that is used in ACOG Practice Bulletin No. 200. Recommend considering the use of that term or at least mentioning there is no consensus.

2. Introduction (line 73-74): Change to "present for care in emergency departments at 500,000 visits each year." The reference Wittels et al refers to ED visits only and not combined ambulatory/ED visits. Also, it was published in AJOG and not Obstetrics and Gynecology.

3. Methods:

- I understand that the full methods from the initial study conducted by Schreiber et al in 2014-2015 are described in a different publication. However, I would recommend adding some additional information to this manuscript on how participants were recruited: 1) location of recruitment (both ED and ambulatory settings); 2) if participants initiated care outside of the study institution and then referred to study site. I would also clearly state that ED group included participants who received care in ED only and combined ED/ambulatory setting.

- Definition of primary outcome (lines 123-125): For your outcome "time to miscarriage resolution," consider specifying that it is starting from initial patient contact regarding early pregnancy concern at study institution, since participants could have initiated care at outside institutions and have longer "time to miscarriage resolution" than you are able to data abstract. Also, I am uncertain about how miscarriage resolution is defined - someone who opts for expectant or medical management would likely have longer time to resolution than someone who opts for surgical management. Were any of these participants LTFU after expectant or medical management? I would add more details to how the primary outcome is defined.

4. Results:

- Recommend adding a flow chart starting with study population (n=55) and how you get to final analysis population (ideally separated out into ED and ambulatory groups with n's in each group for who contributed quantitative only and quantitative/qualitative data).

- Recommend adding information on miscarriage management choice in the 2 study groups.

- Consider adding gestational age or date from LMP until miscarriage diagnosis - it's implied that all participants had first trimester losses but not clearly stated.

- If available, would include data on type of ambulatory-only setting (internal medicine, family medicine, ob/gyn clinics) as there may be different patient satisfaction depending on where they received ambulatory care.

- If available, for ED group, may be informative to list number or % of care received in ED vs ambulatory setting. I know the study sample is small but there may be difference between those who exclusively get care in ED vs those who had 1 ED visit.

5. Tables/Figures:

- Table 1: Would define how insurance is categorized in a footnote. In text, it appears "other/none" is Medicaid/none.

Were there no other public insurance types (eg Medicare, Tricare) in the study population?

- Table 1: Consider adding footnotes for "timeline", "number of touches," and "number of care teams" as it's not understood from table alone without reading the manuscript what these terms are.
- Table 1: Would consider using using different wording for "number of touches" as that is not used in the manuscript. Maybe "number of health care system interaction?"

6. Discussion:

- Line 217: may want to mention the different terms used - miscarriage, threatened abortion, incomplete abortion, spontaneous abortion, early pregnancy loss/failure etc.

#### STATISTICAL EDITOR COMMENTS:

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

lines 58-59: Should state whether the times were formatted as median or mean # of days.

lines 125-126: Need to cite the proposed SD of times for the two cohorts, citing the difference alone is not sufficient for the reader. Also, the power is cited, but not the p-value, nor whether a one or two sided test was used. Need to more completely justify this power calculation vs the samples at hand.

lines 136-138: Did the timing of the events conform to the assumptions of a proportional hazards model?

Table 1: The cohorts are relatively modest in size. Were continuous variables normally distributed? If not, should format as median(range or IQR) and test non-parametrically. The N for each group (25 and 29) do not allow precision to nearest 0.1% for proportions. Need to round to nearest integer %. The sample sizes limit power to discern differences, so the NS findings cannot be generalized. However, the baseline differences in age, race, insurance along with the cohorts not being randomized makes interpretation of the results difficult.

Fig 1: Need to include the N for women remaining at risk for miscarriage at the indicated time increments along the x-axis. The curves appear to be a Kaplan Meier plot and the difference does not appear to be significant by log-rank. Should so state. Also, the aHR needs CIs, which will include aHR = 1.0, that is, NS.

The qualitative analysis is accurate, but the study was not randomized, the groups differed in multiple factors at baseline that might have affected interactions and the primary outcome (time to resolution) was NS different.

#### 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. These comments should be included in your point-by-point response cover letter.

\*\*\*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.\*\*\*

- We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues, and other things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting.

For instance, the précis is a single sentence of no more than 25 words, written in the present tense and stating the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstracts conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Précis should be the "hook" for people who scan the Table of Contents to see what to read.

--Given the relative small size of your sample populations and the differences in the two groups at baseline, your results are best presented using descriptive statistics, rather than comparative statistics. Please on revision convert to a descriptive paper.

Please also review the standards for reporting qualitative research (Standards for Reporting Qualitative Research : A Synthesis of Recommendations. O'Brien, Bridget C. PhD; Harris, Ilene B. PhD; Beckman, Thomas J. MD; Reed, Darcy A.

MD, MPH; Cook, David A. MD, MHPE. Academic Medicine doi: 10.1097/ACM.000000000000388). While it is not required for the GJ, it does provide some important information and guidance for papers of this type.

For instance, its not clear to me if you have defined the qualitative approach or paradigm, as suggested by the guideline.

- Please avoid causal language throughout your manuscript. Your study can identify and quantify associations, but not causation. Language should be changed in the precis, abstract, and manuscript, if causal language is used in those sites.

- How do you know they are novel? Also, don't start a sentence w/ a numeral. Either spell out "54" or rearrange your sentence to avoid starting w/ a number.

- do you mean they already met these criteria when they first got to the ED (Pre-existing disorder) or that they had developed it since their experience with the miscarriage?

- The conclusion as written restates your results (except in results, you didn't provide satisfaction information). Rather, what do you conclude about your findings?

- maybe "and potentially before the usual time of the first prenatal visit"?

- why did you think this would be the case? Its not intuitive.

- this should perhaps be clarified in abstract. I though this was referring to shift-changes with new teams at change of shift when I read it in the abstract.

- Did you collect time of day and day of week information?

- same clarification as asked for in abstract.

- Please provide some sort of data to support statements like sentence starting line 184 that one setting had more or less of some aspect of their care.

- One thing that is not clear to me is whether the women in the ED group got ALL of their care over the up to 57 days in the ED or was follow up in the ambulatory setting for some? This is another characteristic that could alter patient's perception and quality of care.

- not sure "but" is very clear here. It makes intuitive sense if you have more teams involved it would not be expedited care--it would add to time. in results, please list the different care teams people saw.

- what is a "number of touches"?

2. Please consider adding a discussion about how disjointed the care of patients with early pregnancy loss can become, no matter what the setting. From a "systems based" approach, this seems to be one problem institutions and departments can begin to address.

3. 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.

4. 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.

5. 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.

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. Provide a précis on the second page, for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

10. 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.

11. 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.

12. 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.

13. 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%).

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](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

15. Figure 1 should be uploaded as a Figure file with the revision, in Editorial Manager.

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/ifaauth.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.

17. 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 Aug 26, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD  
Editor-in-Chief

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

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