OBSTETRICS & GYNECOLOGY

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

Date: Apr 02, 2021
To: "Adam Schaffer"
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-161

RE: Manuscript Number ONG-21-161

The Effect of Simulation Training on Medical Malpractice Rates among Obstetrician-Gynecologists

Dear Dr. Schaffer:

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 Apr 23, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

The authors present and interesting study assessing the association between simulation and malpractice claims. This is a well written and thought out study and though retrospective in nature appears to be not too over reaching.

Line 37: You state that miscommunication is the root cause of issues in 72% of general cases and 36% of OB cases. Why is this so different? If there something different about OB?
Discussion section: this is overall way too long and technical and should be rewritten. Move most of this to supplemental materials.

Line 120: Given that 35% of you practitioners are in academic practice, does that not prejudice your data since most OBs do not practice in academic centers?

Line 130-131: I dont understand the time frame here. If your time frame for claims from 1976-2019 did not the training happen after potential litigation? Also including the period prior to the early 90s was a low malpractice time.

Line 178-180: This is far to technical and should be moved to supplemental materials.

Results: Please include odds ratios with p values as well as CIs for precision Significant figures should be standardized throughout this manuscript.

The conclusion is too verbose; please concentrate and an analysis of the data.

Reviewer #2:

ON-21-161: The Effect of Simulation Training on Medical Malpractice Rates among Obstetrician-Gynecologists

Lines 69-71: your sentences read "pre- and post-simulation" but your rates (in parenthesis) are list post- then pre-

simulation - recommend reordering your numbers to read pre then post to match the sentence structure.

Lines 97-99: would remove the sentence at the end of this paragraph "Another study…16% of claims." It lessens your previous 36% found and also reads as somewhat redundant. Could combine them to say "studies show anywhere from 16-36% of cases…"

Line 131-138: it sounds like you are counting coverage years for your denominator from 1976-2019? If so, this seems an odd choice rather than using the years actually applicable to your study which would start in 2000 (2 years before you first training). I'm confused as to why you would increase the denominator to coverage years beyond the time frame you are actually pulling malpractice cases from

Line 205-208: Why would 1 year periods not result in statistically significant changes but 2 years did - this is not addressed later in the discussion either. In the discussion you assert that the training does result in less claims and that your data is not likely skewed significantly by the general trend in decreased claims - I think your 1 year data might contradict this assertion that the overall decrease was not a significant confounder.

Line 243-252: I don't find this pharmacology analogy helpful - would edit this out and just explain, I feel this can be done without the analogy and result in less words and more focus on your study and data.

Line 246: insert "likely" before causal. You have not proven causality

Line 313-317: I don't understand the assertion that the fact that participants were spread over the whole time period of the study, 2002-2019, limits "the influence of the underlying temporal trend" of decreasing claims regardless and independent of training. If the rate were still going down throughout it doesn't matter when they participated, the two years after would always be steadily less even without training. The temporal trend holds throughout if the decline was steady.

Overall:
* It sounds like simulation was for obstetrical situations - did you consider only assessing obstetrics claims?
* Was there data available for physicians in the same area that did not participate in simulation? If so, why not compare this group to the physicians who participated and the respective claims rates differences between the groups? This would be an even better control and remove the confounder of decrease in claims overall over time that you discuss (Line 304-306)
* Grammatically, when you reference "1- and 2-year periods" throughout this article the numbers should be spelled out. Numbers under 10 are conventionally spelled out unless they are statistics being reported in papers.
* I think the topic of this article is interesting and shows encouraging data for why simulation training is valuable and should be funded by institutions. I would love to see a comparison to a cohort that did not participate in trainings to see if their rates remained higher to further prove the likely causal relationship and value of training.

Reviewer #3:

Schaffer and colleagues present a retrospective analysis of claims rate before/after simulation training at one simulation center.

Intro - well-written and referenced.
(minor) - the sentence in 105 (among the goals of team training using simulation are) is a bit awkward and can be rewritten for improved clarity
(moderate) - Would add additional references and language in Para 3 of the Intro re: simulations improving outcomes (forceps, shoulder dystocia, etc). Then have a "gap" sentence. e.g. However it is unknown whether simulation impacts malpractice. . .

Methods -
well done

Results
(minor) what percentage of area ob-gyns participated in the study? That is, what is the total number of ob-gyns at these 9 centers? Any area centers that do not participate?
(minor) was there anything clinically/demographically different about those physicians that attending >= 3 sessions?

Discussion
(minor) would revise the first two paragraph. They are duplicative of text earlier in the manuscript (methods and results).

Would focus on the take-home points and explanation of study findings.
(moderate) some of the material in paragraphs 4/5 could be brought to the introduction and then the differences/information added in this study focused on for the discussion
(moderate) I am not sure that one can definitively infer that simulation training is a causal factor from this methodology.

STATISTICS EDITOR COMMENTS:

Table 1: The mean number of years of practice was 11.6. What were the median and range of years of practice and how did those measures compare for (1) the cohort with 1 year pre and post (2) the cohort with 2 years pre and post and (3) the entire cohort. Also, were there any other characteristics that would have made the cohort with longer pre and post intervention data more likely to be involved in a claim? Were those in the 1 or 2 year cohorts (thus duration of 2 or 4 years) over a different calendar year distribution than the entire cohort? In other words, could the differences be attributed to variation in claim rates that were independent of the duration of analysis?

Table 2: Need to provide CIs for the rates of claims/100 physician years. Based on the rates provided and the number of physician coverage years, the counts for number of claims was 144 vs 119 for the full study period, yet the number of claims cited in Table 3 were 131 and 90. Need to clarify. Also, should include in Table 2 the number of claims along with the number of physician coverage years for each entry.

Fig 1: Need to include CIs for the three histograms.

General: The main issue with the analysis is that there is no control group to compare vs the intervention. By design, this study cannot assign causation, but simply association. Thus, cannot investigate an effect, as cited on lines 56-57.

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
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*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.

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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 data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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 print appendixes) but exclude references.

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* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

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In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words;

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17. Figure 1: okay

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* A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Apr 23, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,
Dwight J. Rouse, MD
Editor-in-Chief

2019 IMPACT FACTOR: 5.524
2019 IMPACT FACTOR RANKING: 6th out of 82 ob/gyn journals

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