To: Arpita B.
Research Integrity and Inclusion Associate Editor
SAGE Publications

From: James Studnicki, ScD, MPH, MBA
Vice President, Data Analytics
Charlotte Lozier Institute

Professor Emeritus, Public Health Sciences
University of North Carolina, Charlotte

Re: Studnicki J, Harrison DJ, Longbons T, et al. A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999–2015. Health Services Research and Managerial Epidemiology. 2021;8. doi:10.1177/23333928211053965

PE-1708 RESPONSE NEEDED: Your article 10.1177/23333928211053965

Dear Ms. Arpita B:

We have reviewed the email from you outlining concerns expressed about our publication. Following is our response.

1. Concern expressed: Figures 2 and 3 are "presented with dual y-axis with significant scale differences." Why was this method used? Comment on why the method may/may not have been a better choice?

Response:

Regarding concerns about our use of dual axis in Figures 2 and 3, it is first of prime importance to note that all the data represented in the graphs are provided in Table 1. This complete report of our findings was sufficient to allow the complaining reader(s) to construct alternative graphs with different axis choices. Any reader is therefore also enabled to regraph the data as they prefer. Therefore, it is obvious that we have fully provided our data in an easy to interpret manner.

Our choice to use the dual axis, in our opinion, provided sophisticated readers a faster way to visualize the degree of change in all three outcome variables over time. The complaining reader's alternative using a single y-axis compresses the visualization in a manner that, in our opinion, hides important variations over time. More specifically, Figures 2 and 3 displayed the growth in the counts of ER visits following surgical (Figure 2) and chemical (Figure 3) abortions 1999-2015. Each figure arrayed the yearly counts for three categorizations of ER visits: all-cause; abortion-related (ICD-9 630-639); and spontaneous abortion (ICD-634). Compared to the total ER visit count, the abortion-related and spontaneous abortion categories are relatively small numbers. We wanted to visually illustrate the variation in the two categories with lower counts over time and the differences between them. For example, between 2008-2015, the abortion-related visit count following chemical abortion increased from 50 to 790 or 14.8 times the 2008 count. The abortion-related visit count following surgical abortion increased from 313 to 651 for the same period, or an increase of 1.1 times the 2008 count. As demonstrated in the single y-axis version, these differences are not meaningfully discernible visually. The double axis Figures allow a diligent reader to discern the slope differences.

While the specific objection to the two-axis visualization was not made explicit in your expression of concern, it could allow a careless reader to mistakenly perceive abortion-related visits as a larger share of the all-cause visit count. This misunderstanding, however, would be corrected by the immediately following Figures 4 and 5 which directly illustrate the percentages that abortion-related and miscoded spontaneous abortions represent of all emergency room visits following chemical and surgical abortion. The two-axis Figures are appropriately labeled and convey important information that the single axis version does not.

2. Concern expressed: Indicate the rationale behind including all the codes (specifically the reason for including codes 630, 631, 632, 633, and 636). Share your inputs and data extraction.

Response: The rationale for our study approach and design is discussed in some detail in our paper Introduction. First, prior to our study there was no estimate of the total ER visit burden (incidence) of women following an abortion. Our longitudinal design enabled us to not only track the trajectory of total ER visit morbidity but to also discern the contribution to that morbidity represented by abortion related visits. Thus, there was a simple and persuasive epidemiological reason for tracking all ER visits for this population. Second, existing research on ER visits following abortion had likely underestimated their incidence for at least two reasons. ER secondary data may describe treatment for a problem (e.g. hemorrhage) which is not, for various reasons, attributed to a prior abortion. Therefore, the ER visit would not be identifiable as abortion related. Also, investigators may only count an ER visit if it meets certain criteria to be considered as urgent or major such as requiring hospitalization, surgery, or a blood transfusion (1). This approach would likely understate the full range of risks associated with abortion. Unlike most other complication studies, our more comprehensive examination of ER visits was predicated on the existence of a prior abortion confirmed by a paid claim. Our three code categories represent the total ER burden (all-cause), visits related to abnormal (ICD-9 630, 631, 632, 633) or abortive pregnancy outcomes (ICD-9 634, 635, 636, 637, 638), and complications following both (ICD-9 639). Our particular interest in spontaneous abortion (ICD-9 634) derived from statements by abortion providers which encouraged women to withhold information about their chemical abortion when seeking care in the ER (2,3), which could lead to misclassification of treatments as being related to a miscarriage rather than an induced abortion.

3. Concern expressed: “The nature of all ER visits in this study are not provided in the article.” How does this relate to study objective and results?

Response: All-cause ER visits is the measure for total ER visit morbidity for any reason occurring to women within 30 days of any induced abortion. Chemical abortion is more likely than surgical (OR 1.22) to result in any ER visit. The odds ratios were calculated for the entire 17-year study period, would be larger if calculated for a cross section of more recent years with disproportional chemical abortion growth, and therefore likely understate the current difference between chemical and surgical abortions. Perhaps the most notable finding regarding all-cause ER visits is that fully one-third of all induced abortions are followed by an ER visit by the year 2015. Whether related to the pregnancy outcome or not, the magnitude of ER use among Medicaid-eligible women in their reproductive years identified in this analysis should be viewed as a health crisis and cause for investigation. The question of “concern” shouldn’t be why we considered all-cause ER visits, but why they are so high! The rate of total ER visits per 1,000 surgical abortions increased 183% between 2002 and 2015. The increase following chemical abortion was even higher at 247%. The likelihood of a chemical rather than surgical abortion-related ER

visit (ICD-9, 630-639) during the entire study period is greater (OR 1.53) than for all-cause ER visits. In the period 2002-2015, abortion-related ER visits following surgical abortion per 1,000 abortions increased 315% while the increase following chemical abortion was 507%.

The finding that many ER visits following confirmed abortions are misclassified or miscoded (ICD-9 634) as spontaneous abortions is another seminal finding of this research. To our best knowledge, our paper is the first, and perhaps only reported research to document this serious issue. We found the widest difference between chemical and surgical abortions in their likelihood to be followed by a miscoded spontaneous abortion (OR 1.88). In a follow-up post hoc analysis of this finding, we demonstrated that the miscoded ER visit following chemical abortion represented a significantly increased risk of inpatient hospitalization (OR 2.18) for surgical removal of retained products of conception than did those without miscoding (4).

The tri-partite classification of emergency room visits which served as the study outcome variables are consistent with the study objectives and demonstrate significant findings consistent with the increased risk of chemical abortion, relative to surgical abortion, for all three types of ER utilization morbidity. As per the COPE guidelines, the design and conduct of the study emphasized its importance to existing knowledge in the domain, clarity in the methods, and originality and innovation in its results and implications. The history of the paper since its November 2021 publication demonstrates its scientific quality.

4. Concern expressed: Three papers (Mortensen et al.; Cheung; Sommers) are mentioned to make the point that Medicaid eligible patients may have poorer health and may have a financial incentive to use emergency rooms. The question is whether the behavior of Medicaid eligible women in our paper can be generalized.

Response: Of course, in the paper we are careful to note that “Medicaid eligible beneficiaries are by definition financially disadvantaged and are not representative of all women experiencing abortion.” We are also careful to identify other limitations of claims data including the fact that services provided to these women, but not paid for by Medicaid, are excluded from the Medicaid files. Coding practices by some providers, insurers and states could also result in undercounting of abortions. All of these facts are appropriately mentioned as limitations in the Discussion section of the paper.

5. Concern expressed: The suggestion is made that the affiliation of some of the authors with the Charlotte Lozier Institute “should have been” revealed considering the “topic of the article.”

Response: In fact, the affiliations of all authors are documented in the paper. In addition, a bio sketch for each author is included with the paper. Funding support for the research from CLI is also disclosed. Part of the COPE definition of conflict of interest describes “those which may not be fully apparent and which may influence the judgment of author, reviewers, and editors” and “which, when revealed later, would make a reasonable reader feel misled or deceived” (5). All relevant information was fully disclosed.

6. Concern expressed: “The corresponding author is an editorial board member of the journal.”

Response: publication by editorial board members is not considered a conflict of interest as long as the member is not involved in the review of his/her own paper. In fact, the practice is explicitly encouraged by most journals as a way to attract and publish high quality content. The SAGE policy: “Editorial board members should be encouraged to contribute articles to the journal, either by submitting their own

work (subject to rigorous peer review) or soliciting articles from their colleagues" (6). I have done both for *Health Services Research and Managerial Epidemiology.* BMC policy states: "Editorial Boards can be encouraged to recommend that their colleagues submit to the journal. They could also be encouraged to submit their own manuscripts, or recommend ideas for commissioned articles" (7). Appointment to the Editorial Board is often recognition that the appointee has a distinguished record of science.

In summary, the "issues" raised in your letter do not present any meaningful challenge to the accuracy or validity of the findings. Nor do the questions of data visual presentation or design represent any challenge to the methodology or analysis. No errors, miscalculations or deceptive practices are identified. Limitations related to the source of data and the selection of the study population are fully described. No potential conflicts of interest are undisclosed.

We are disappointed that this vague and insubstantial communication would result in the publication of an Expression of Concern *before* these issues have been fully investigated.

This paper is the single most read in the journal *Health Services Research and Managerial Epidemiology.* It has been repeatedly referenced in legal cases and legislative discourse in many states. It has enriched the scientific discourse on the relative safety of chemical induced abortion. Most importantly, it is excellent science, and the methods and findings are unchallenged. We respectfully ask that you not allow ideologically motivated and unsubstantiated "concerns" to damage the reputation of this work and its authors.

References

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