Reviewer’s report

Title: Effect of External Airflow Resistive Load on Postural and Exercise-associated Cardiovascular and Pulmonary Responses in Pregnancy

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Reviewer: Philip Harber

Reviewer’s report:

MAJOR

The paper addresses a very relevant topic since many filtering facepiece respirator users are women. The results provide reassuring insight into the very limited adverse impact of respirator use.

Several aspects of the manuscript might be clarified so that readers without detailed knowledge of respirators would optimally benefit:

General Comments:

The paper provides very useful data about the potential impact of respirator use upon workers who might be pregnant. The data are generally reassuring. The entire discussion and introduction focus on resistance of the respirator. However, respirators also add dead space, thermal loading, and other effects. Thermal and moisture affects are generally particularly prominent for the class of respirators they studied here. The investigators have previously published several very insightful reviews of the physiologic impact of respirators, and they have been extremely useful when considering pregnant users. While they certainly should not repeat their entire previous publication, general readers would benefit from an explanation that resistance is not the only important fact.

Similarly, they use a single subjective factor, the relative perceived exertion (RPE). Aspects other than perceived exertion may also be important to respirator users. Perhaps they should mention other possible subjective factors of importance.

81: They used two distinct models of N95 respirators. It appears that each subject only used a single type. While they indicate that the resistance of the two models was comparable, the functional dead space may become quite different with a flat fold and a cup type device. This would in turn significantly affect ventilation. The authors should indicate how many used each device and if there were differences depending upon the device type (even if not statistically significant because of the small sample size using each one).

85: The investigators performed a quantitative fit test and excluded subjects with a fit factor <100. Since they mention numerous types of head coverings in their general comments, can they indicate which if any of the non-respirator head
coverings could actually be considered in any way comparable to a respirator? (They reference a study done by their colleagues that investigated this specific topic). If the alternative forms of cloth devices did not achieve appropriate fits, do they believe the devices would impose any resistance or dead space comparable to the actual filtering facepiece respirators?

112: The results might be more easily understood by the reader if a table of the results were presented. Since they used an analysis of variance approach, such a table should include the estimate for each factor as well as its DF.

112: if they actually analyzed each minute rather than just the end of each activity time, a model other than ANOVA would seem appropriate since there is such a high correlation between results at time t and time (t-1)

The figure shows that there were apparent changes over time within each of the activity types (e.g., heart rate and relative perceived exertion to progressively increase within exercise time, and there were progressive declines while sitting). If so, this may violate the assumption of a steady-state or pseudo-steady-state condition for which the last minute of each exercise type can be chosen to be indicative. (If they are predominantly concerned about health care workers, many of the respirator use durations are less than 15 min. when nurses enter/leave patient rooms).

The authors may wish to discuss whether they considered alternative statistical analyses (e.g., including every data point rather than just three for each subject, using time since initiating an activity type as a variable). The results may also be subject to an autoregressive component (results at one time may depend very heavily upon results upon the immediately preceding time).

Since the graphs seem to suggest that several physiologic variables have continued to change, the authors may wish to expand their excellent discussion section to indicate whether their results are applicable only for very short times or may be relevant to more prolonged use.

MINOR

Abstract: The authors describe this as a "case-control" study. However, they did not actually match participants on an individual basis as is typically done in a case-control design. Rather, they compared a group of pregnant and nonpregnant volunteers. Comparing the same subjects with/without a respirator does not constitute a typical case-control study.

47: “Face coverings” versus “respirator”: The introduction includes an innovative mention that face coverings are widely used for religious/cultural reasons as well as protection against inhaled materials, the relevance is uncertain since most of the women’s head coverings are to prevent seeing the face rather than having a tight seal. Their study is narrowly focused on one particular type of standard clinical respiratory protective device. It is not clear from their references that these extended uses impose resistive or dead space loads since they are not
tightly worn. Perhaps the authors could express this potential limitation.

77: The research methods might be described in some more detail. Specifically, was the order of assignment to exercise with/without respirator randomly assigned to the subjects or did all complete one phase initially?

90: The measurements of stroke volume and total peripheral resistance were made using a technique that estimates these noninvasively rather than by direct measurement. Since this method differs from the typical invasive (and therefore infeasible for studies such as this) approach, the authors may describe its mechanism and its strength/limitations in some more detail. For example, is it affected by the blood volume (which in turn is impacted by pregnancy)? Is the accuracy of the indirect estimation of stroke volume and resistance impacted by body position? (E.g., standing may lead to reduced venous return). Or, by the authors confident that the stroke volume and TPR would not be affected by the exercise your body position, so that any differences would only reflect use of the respirator?

111: Statistical methods: They collected a great deal of data with minute by minute measurements and 10 min. aggregates. Readers would benefit from a more clear explanation of the statistical approaches. It seems that they actually only used a single point from each of the exercise regimens (the last minute).

158: For clarity, the major heading “vascular” might be better described as “cardiovascular” since most of the variables referred to the heart.

188: The Results section includes only a brief summary of the actual findings. The reader is referred to the figures for many details. However, the figures do not include any symbols showing statistical significance test results, confidence intervals, etc. Since the ANOVA they performed presumably gave estimates for it the effect of each of their variables (pregnancy status, activity type, and respirator condition), these estimates and their associated statistical significance and confidence intervals could easily be presented in a table.

188 FF: Including a table of results would also help the reader ascertained the effects of pregnancy per se. While physiologic impact of pregnancy is not the focus of the paper, it would put the respirator and activity related changes in perspective.

231: The conclusions focus only on resistance, but there may have been effects of temperature, dead space, or other factors as well. Please see general comments above

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.
Declaration of competing interests:

I have received funding from the federal agency for which the authors work.