Subject: Fwd: Anaesthesia | Your submission ANAE.2020.01192 has been provisionally accepted
From: David Clinkard <dclinkard@qmed.ca>
Date: 2020-10-05, 11:03 a.m.
To: ludwikfedorko@gmail.com, Azad Mashari <azad.mashari@mail.utoronto.ca>, azad.mashari@uhn.ca, keyvan.karkouti@uhn.ca

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Date: Mon., Oct. 5, 2020, 11:01 a.m.
Subject: Fwd: Anaesthesia | Your submission ANAE.2020.01192 has been provisionally accepted
To: dclinkard@qmed.ca <dclinkard@qmed.ca>

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Date: Oct. 5, 2020 10:52 a.m.
Subject: Anaesthesia | Your submission ANAE.2020.01192 has been provisionally accepted
To: David Clinkard <david.clinkard@mail.utoronto.ca>
Cc:

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CC: anaesthesia@aagbi.org, editor-kariem@anaesthetists.org, "Keyvan Karkouti" keyvan.karkouti@uhn.ca, "Azad Mashari" azad.mashari@mail.utoronto.ca, "Ludwik Fedorko" ludwik.fedorko@uhn.ca

Anaesthesia
Peri-operative medicine, critical care and pain
Association of Anaesthetists

Re: ANAE.2020.01192 – Evaluation and comparison of N95 masks with Modified Snorkel Masks and Positive Air Pressure Respirators (PAPR) in Healthcare Workers

Dear Dr Clinkard

Thank you for submitting this paper to *Anaesthesia*. It has been reviewed by members of the Editorial Board and I am pleased to inform you it has provisionally been accepted for publication, subject to you satisfactorily addressing each of the following points.

Reviewer 1

- Thank you for the opportunity to review this manuscript. Provision of adequate PPE for HCWs during this pandemic is important and objective assessments of mask performance vital. Please find below comments/suggestions:
- General comments - I found the heavy use of acronyms difficult to follow and detracted from the readability of the manuscript
- **Introduction**
  - I understand that aerosolised spread is now recognised as the primary mode of COVID transmission - the authors may wish to update this section accordingly.
- **Methods**
  - The methods described will be unfamiliar to the majority of the readership, I would be reassured if the authors would describe in more detail and set these in context with international standards
  - I think the authors essentially describe a new medical device (Figure 1). Adoption of such a device would require more rigorous testing to achieve a CE mark or North American equivalent.
  - I think the authors need to be clearer about these obligatory steps and describe where they are up to on this pathway. They would also have to discuss this in the limitations section.
  - Whilst the authors have made licensing details available, we need more information about IP and potential conflict of interest.
  - We need more explanation of the SWPF metric - figure 2 scale goes up to 100,000. We know that <100 is failure but what is considered good/excellent etc.
  - I understand from the methods that each individual underwent paired assessment for each type of mask - Kruskall Wallis is not a pairwise test.
- **Results**
  - Heavy use of acronyms makes this very difficult to follow
  - Brevity is, in general, to be encouraged but we need more context to understand the steps taken in mask assessment
  - Would Figure 2 be better on a logarithmic scale?
  - The resolution of the figures is in general poor
  - Figure 3 doesn't seem to add much without further comment. Failures in the SM group seemed clustered around 4 individuals - were there particular features that contributed to this - I wonder if the mask was not fitted properly.
- **Discussion**
  - There is an extensive literature on the limitations of N95 masks, I do not feel that this finding is particularly novel or new
  - The cost data should be included within the results section
  - High costs for the device. I think this needs further exploration as limits wider generalisability of findings. In which circumstances do the authors consider it would be reasonable to use this?
  - The authors make no recommendations on what additional steps are required to advance their findings
  - Diverse ethnic sample described but we do not know what this was.

Reviewer 2

- **Title page**

- The fact that this occurred in healthcare workers is somewhat irrelevant. The study was evaluating the masks, not the participants. Therefore, I would propose the title be changed to: “Evaluation of N95 respirators, modified snorkel masks and low-cost powered air-purifying respirators: a prospective observational cohort study”
- Please provide the job title of each of the authors
- Please provide a short title and provide 3–5 keywords

- **Summary**
  - The aim of the Summary was “to determine if N95s and Snorkel Masks (SM) equipped with filters provide consistent protection levels in healthcare workers and if the addition of positive pressure via an inexpensive powered air purifier respirator (PAPR) to the SM can enhance protection”. However, the conclusion was “These findings suggest that qualitative N95 testing may overestimate respiratory protection, and that a quantitative assessment of N95 fit significantly improves the consistency of respiratory protection.” There is a discrepancy in your aims and in your conclusion. Please consider harmonising these.
- **Introduction**
  - There are different standards for respirators. N95 is one standard, but in Europe, many adhere to FFP3/FFP2 standards, which account not just for filtration capacity, but adequacy of fit. This needs to be justified, and the generalisability of this manuscript will be improved by highlighting that similar principles apply to FFP2/3 respirators. Similarly, readers may wish to have the naming of these respirators clarified, as what you describe as an N95 respirator is a half-mask respirator, while the snorkel mask is a full-face mask, which becomes a PAPR when a positive pressure pump is applied to it through a filter.
  - “Overall the currently available data suggests that either SARS-CoV 2 has other significant routes of transmission, in addition to droplets and aerosols, against which HCWs are not adequately protected, or that N95 respirators do not provide adequate, consistent protection against droplets and close-range aerosols.” – this sentence is both unclear and also not supported with any objective data. Please reference this, but also clarify whether there truly are data that respirators (e.g. N95) do not provide adequate protection.
  - “Unfortunately, limited supply of N95 respirators…” – it is respirators in general, not just N95 respirators. Again, in Europe, N95 are not used unless FFP3 are unavailable.
  - PAPR stands for powered air-purifying respirator not positive air pressure respirator. Please amend.
  - “PAPRs are considered gold standard when dealing with virulent airborne pathogens” – Defining a device as a gold standard warrants a reference supporting this statement.
  - The transition to the aims of this manuscript are unclear. This is because you did not highlight that, given the limitations of PAPRs, inexpensive designs are warranted, and therefore you designed your own. You wished to objectively assess the suitability of currently used half-mask respirators (i.e. your N95), filter-fitted snorkel masks and your customised PAPR.
- **Methods**
  - This is an observational cohort study, and should be reported as such, adhering to the STROBE reporting checklist.
  - The exact N95 masks used need to be defined. Was it a single mask, or were different masks used for different participants?
  - How were the participants recruited?
  - What qualitative fit-testing standards were used to fit-test on the disposable N95s before enrolment into this study? Who performed these tests and were they either certified or accredited fit-testers?
  - How were the particle concentrations measured within the snorkel masks? With the AccuFIT device, either a puncture in disposable devices with an adaptor is inserted, or a specific adaptor that is placed through the filter diaphragm of exhalation ports in reusable respirators. How was this handled with the snorkel mask? A photograph would be useful.
  - There are no details about the filter used in the PAPR snorkel mask. While the snorkel mask used an AirGuard filter (filtration capacity should be stated), the PAPR uses what seems to be a high-efficiency filter in the pump according to Figure 1, but this is not discussed in the methods. More details about the motor that is used (manufacturer, specifications) and the high-efficiency filter are required.
  - What was the primary outcome of this study? How was the study powered? What were the secondary outcomes?
  - Who performed the fit-testing? Were they certified, trained or accredited fit-testers? How much experience did they have?
  - Was the order of testing standardised (i.e. N95 then snorkel mask then PAPR?), or was this randomised?
  - In the methods, please state how you will be reporting your data. Mean (SD) for parametric data.
  - Kruskal-Wallis, not Kruski-Wallis
  - The statistical methodology is insufficient. Were the data assessed for parametricity? If the data are parametric, a paired 3 group test should be used such as the one-way repeated measures ANOVA, or if non-parametric then a Friedman test. Please carefully review and consider.
  - How was ‘practicality’ and ‘usability’ defined to the participants?
  -
- **Results**
  - Was participant ethnicity collected? This matters as there is increasingly evidence that failure of respirator fit-testing is associated with body habitus, sex as well as ethnicity. A table with the demographics of the participants is required.
- **Discussion**
  - Given that there is a poorly defined primary outcome, the first paragraph is unclear as the fundamental message of the study is unclear. I am unsure if this study is designed to assess qualitative fit-testing or the respirators themselves.
  - You provide estimated costs for different respirators, but do not provide the manufacturer details for the costs. There are far cheaper purpose-built PAPRs than those suggested, and it may be worth providing a range of costs.
  - There has been little to no mention of re-usable half-masks (e.g. N95 reusables). They have been shown to have a higher pass rate than disposables, and the authors need to provide some context on this.
  - A major limitation is the assumption that a snorkel mask that has been designed to work under water and has not been validated nor rigorously tested in this setting may be suitable simply by adding a filter. Several authors have criticised this approach. Moreover, the material used for 3D printing of adaptors is very important, as the porosity of the material matters. It has been suggested that this material requires fluid-resistant paint to be used on top of it to deal with the issue of porosity, and this may also be responsible for failures.
  - The authors must be careful about making recommendations for using off-label products such as this for respiratory protection of healthcare workers. They must not recommend the use of products without prior approvals, registration, certification and rigorous testing procedures used nationally and internationally.
  - The conclusion needs to be more developed. What are the primary and secondary findings of this study and what needs to be done now, what will it change, what are the benefits? It is also confusing because the conclusion focuses on N95 respirators, but if this study was simply about qualitative vs quantitative fit-testing, why include snorkel masks?
- **Figures**
  - Figure 2. Please remove the labels (Mean (SD)) from the figure and the legend as well. Please carefully review author guidelines for this.
  - Figure 3. Please provide a higher resolution version of this figure. It is unclear what this figure adds, but it may be worth moving it to a supplementary appendix.
- **General**
  - Fundamentally, there needs to be much more clarity in the message of this manuscript. It is currently unclear whether this was designed to test the reliability of a qualitative fit-testing protocol vs. quantitative fit-testing, or to assess the suitability of the snorkel respirators and PAPR snorkel respirators vs. rigorously designed, tested and certified N95 respirators. The manuscript needs to have much more clarity on the research question of interest.
  - The terminology here needs to be standardised. The N95 respirator should be named as such throughout, the snorkel mask, and the PAPR snorkel mask.
  - There are too many abbreviations throughout. Please minimise the use of abbreviations such as HCW, SM, SWP, SWPF.
  - Please use UK English throughout. Thus, anaesthetists, not anesthesiologists, aerosolisation not aerosolization, etc.

- Pre-operative, not preoperative; intra-operative not intraoperative; postoperative not post-operative; peri-operative not perioperative.
- Your references are not in keeping with Journal style. Please pay particular attention to the formatting and style of references and any figures or tables. The link to the journal author guidelines is below.

Revising the manuscript

- Please send a **covering letter** addressing each of the comments above, confirming you have made the changes or explaining why you have decided against them. Please make revisions obvious either by tracking changes or highlighting in yellow or a different coloured font.
- Please go through each of the references you have cited and check they have not been retracted, unless you did this at your first submission. Please confirm this. Please also ensure that none of your references are published only on preprint servers – all journal references must be peer-reviewed and published online/in print.
- Please ensure you have declared any conflicts of interest – failure to do so is a serious breach of publication ethics. Please refer to the COPE website for more information and this resource from our publishers.
- Please ensure all parts of your submission conform to *Anaesthesia* author guidelines – www.anaesthesia-journal.org/guidance

As a guide, your revised article is due by **02/11/2020** or before, but if you need more time than that, please do just let us know.

To submit a revision, please go to Editorial Manager and log in as an Author. You will see a menu item called Submission Needing Revision. You will find your submission record there. Click the "Revise Submission" action link to begin editing your files.

Once we have ensured the revised manuscript conforms to *Anaesthesia* formatting and style, we will continue the editing process. I will be able to give you a final verdict on acceptance when I have reviewed your revised manuscript. If you are able to address the points made in the above letter, it is highly likely we will accept your paper for publication; however, very rarely, serious and unaddressed flaws may result in rejection.

If you have any problems with submitting a revised manuscript or any queries, please contact Rona Gloag, Editorial Co-ordinator, anaesthesia@anaesthetists.org

Yours sincerely

Dr Kariem El-Boghdadly, MBBS, BSc, FRCA, EDRA, MSc
Editor, *Anaesthesia*

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