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Is there equipoise and according to who?

Many professionals, including those who have expertise in aerosol science and respiratory protection, have expressed concern about the “ethical nature” of this study. Many will state that there is, in fact, no equipoise.

A [letter](#)¹ (April 2021) sent to the Canadian Government, Responsible Conduct of Research, Tri-council Federal Office from occupational health and safety professionals from around the world, noted:

- Our primary concern is that the methodology puts health care workers at risk of becoming infected with SARS-CoV-2.
- Secondly, it supports health care workers wearing surgical masks which do not provide effective personal protection against highly infectious aerosols. Such protection can be provided by properly fit-tested filtering face-piece respirators, used in accordance with a respiratory protection program.
- Thirdly, we have significant concerns about the questionable study design, which call the findings and conclusions of the study into question. Such flawed findings and conclusions may have global implications if they are used to justify inadequate safety protections for health care workers.

Unfortunately, the published “comments section” is limited in the word count of 400 words. To elaborate on this comment, reference is made to a follow up [letter](#)² sent to the Editor in Chief of *Annals of Internal Medicine* with the support of 33 professionals, along with extensive information / references, to support that there was no equipoise.

We believe that the study violated the principle of equipoise, which requires that a subject be enrolled in a trial only if there is true uncertainty about which of the trial arms is likely to benefit the participants^{1,2,3}. Without equipoise, a study is unethical. In this case, there was, at the time of the study, sufficient evidence, amplified since that time, to demonstrate that N95 respirators are superior to surgical masks for protection from inhalable aerosol transmissible diseases.

Therefore, we challenge whether a randomized controlled trial (RCT) was necessary^{4,5} to prove whether filtering face piece respirators provide more protection against inhalable infectious aerosols when compared to a surgical mask. Sharing a conclusion that there is “no statistical difference”, will lead to misinterpretation and will threaten the lives of health care workers around the world.

References

1. Letter to the Government of Canada, Responsible Conduct of Research, Tri-council Federal Office Panel on the responsible conduct of research, The Secretariat on Responsible Conduct of

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2. Letter to Editor in Chief of *Annals of Internal Medicine*.
<https://www.aerosoltransmissioncoalition.ca/>
https://www.aerosoltransmissioncoalition.ca/_files/ugd/cdec4_79fc29c516734009bbdb1c0be0a5bcfd.pdf
3. Alexander, JH, 2022, Equipose in Clinical Trials: “Enough Uncertainty in Whose Opinion?”, *Circulation*. 2022;145:943–945.
<https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.057201>
4. Greenhalgh, T, Fisman, D, Cane D J, Oliver, M, McIntyre, CR “Adapt or die: how the pandemic made the shift from EBM to EBM+ more urgent”, *BMJ Evidence Based Medicine*.
<https://ebm.bmj.com/content/27/5/253>
5. *BMJ Evidence Based Medicine* response, Hedges, K 2022, “Equipose, or not, when comparing filtering face piece respirators to surgical (medical) masks, and the futility of using a randomized control trial (RCT) for comparison. The need for evidence-based medicine+ - a paradigm shift”.
<https://ebm.bmj.com/content/27/5/253.responses>

Disclosures:

Dr. Kevin Hedges is a Certified Occupational Hygienist with the [Occupational Health Clinics for Ontario Workers](#) (OHCOW), where he has delivered presentations to the Ontario Nurses Association (ONA) on “respiratory protection for an inhalable virus”. Through OHCOW he has facilitated and presented webinars on airborne precautions for COVID-19 as well as being included as an expert on a panel at a Lancaster House - Law conference. He is also former international president of a non-profit volunteer organisation, [Workplace Health Without Borders](#) (WHWB) International and current board member of WHWB, as well as a member of the [Canadian Aerosol Transmission Coalition](#), a multi-disciplinary volunteer group focused on stopping COVID-19 with ethical policy and practical, scientifically based solutions to the issue of airborne / aerosol virus transmission.

Marianne Levitsky is a Certified Industrial Hygienist, Registered Occupational Hygienist and a Fellow of the American Industrial Hygiene Association. She is an adjunct lecturer at the University of Toronto, Dalla Lana School of Public Health and was the founding President of Workplace Health Without Borders. She is a member of the Canadian Aerosol Transmission Coalition and a consultant with ECOH Management in Mississauga, Ontario.

Dr. Genevieve Marchand is one of the authors of the IRSST control banding webtool helping select the proper respirator for respiratory protection to prevent the inhalation of bioaerosols. She has presented conferences on bioaerosol exposition in occupational settings and airborne precautions against infectious agents. She was also appointed as an expert by Judge Bouvier in a case regarding the respirators in healthcare settings and by Geahan Kamel, coroner for the inquiry of elderly deaths in Québec during the first COVID wave.

Professor Lidia Morawska – No disclosure.

Dr. Luc Bh  rer has facilitated and presented webinars on airborne precautions for COVID-19 as well as being appointed as an expert witness by Judge Bouvier and participated on IRSST’s and CSA’s committees on control banding for bioaerosols.

Dr. Marie-Claude Letellier has facilitated and presented webinars on airborne precautions for COVID-19 and participated on CSA committee on control banding for bioaerosols. She also produced reports on COVID-19 cases for court. She provided advocacy for health workers during pandemic. Actions were presented at American Public Health Association 2022 annual meeting <https://apha2022sessions.hubb.me/AbstractDetail.aspx?id=928824>.