Government of Canada,
Responsible Conduct of Research,
Tri-council Federal Office Panel on the responsible conduct of research,
The Secretariat on Responsible Conduct of Research (SRCR)
secretariat@srcr-scrr.gc.ca
19 April 2021

Dear Secretariat,

We write to bring to your attention a multi-centre randomized controlled trial which unnecessarily puts the safety of front-line healthcare workers at significant risk of contracting COVID-19.

The "Study" in question is by Principal Investigator: Mark B Loeb, and is entitled, *"Medical Masks versus N95 Respirators to Prevent 2019 Novel Coronavirus Disease (COVID-19) in Healthcare Workers: A Randomized Trial".*

> Abstract*: A randomized controlled trial in which nurses will be randomized to either medical masks or N95 respirators when providing medical care to patients with COVID-19. This Canadian multi-centre randomized controlled trial will assess whether medical masks are non-inferior to N95 respirators when nurses provide care involving non-aerosol generating procedures. Nurses will be randomized to either use of a medical mask or to a fit-tested N95 respirator when providing care for patients with febrile respiratory illness. The primary outcome is laboratory confirmed COVID-19 among nurse participants.*
> URL: https://www.smartpatients.com/trials/NCT04296643
> https://www.clinicaltrials.gov/ct2/show/NCT04296643
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> **Actual Study Start Date**: April 1, 2020
> **Estimated Primary Completion Date**: February 1, 2021
> **Estimated Study Completion Date**: April 1, 2021

Our fundamental concern about the ethics of this study is that it exposes healthcare workers to COVID-19 infection by allowing them to wear surgical masks when engaged in patient care versus the respirators to which they would otherwise be entitled.

There is ample research to support the premise that COVID-19 is an infectious disease transmitted "via aerosols" which can be inhaled, and therefore requires respiratory protection as the minimum line of safety protection for at-risk workers. Since the infectious dose of SARS-CoV-2 is unknown, all health care workers working in proximity to patients who may have COVID-19, must be assumed to be working in high-risk situations. Therefore, there is an obligation to protect workers with the highest level of respiratory protection, not the minimum. Respirators protect the wearer by filtering harmful contaminants from the air that might otherwise be inhaled (Council of Canadian Academies, 2007).

Respirators are now recommended widely because of the strong evidence for aerosol transmission of SARS-CoV-2 (Morawska et al. 2020, Greenhalgh et al. 2021). Transmission through inhalation of small aerosol particles is an important and significant mode of SARS-CoV-2 virus transmission (Morawska et al. 2020, AIHA 2021).

The Government of Canada (2020), Public Health Agency of Canada (PHAC), Nov. 6 2020, has acknowledged the aerosol role in SARS-CoV-2 infection transmission. Emerging experimental evidence indicates aerosols containing SARS-CoV-2 virus can be dispersed beyond two metres and can remain suspended in air for prolonged periods (PHAC, 2020).

> **Our primary concern is that the methodology puts health care workers at risk of becoming infected with SARS-Co-V-2.**
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> **Secondly, it supports health care workers wearing surgical masks which do not provide effective personal protection against highly infectious aerosols, whereas properly fit tested filtering face-piece respirators do** (Oksanen et al. 202, Douglas et. al., 2020, MacIntyre et. al., 2011, 2013, 2020b, Goldberg et al. 2021).
>
> **Thirdly, we have significant concerns about the questionable study design. The likelihood of flawed findings is high. Flawed findings are often used to justify inadequate safety protections for health care workers.**

We ask for the study to be decoded immediately and formal letters of apology sent to participants by the investigator.

For many months it has been clear that transmission through inhalation of small aerosol particles is an important and significant mode of SARS-CoV-2 virus transmission (Morawska et al. 2020).

Human-generated aerosols have been well-studied; people generate many small infectious particles that can remain suspended in air for long periods of time. With 30-40% of infected people being asymptomatic and people being infectious 2-5 days before (and up to 10 days after) symptom onset, there has been significant household and workplace transmission. The risk factors – close contact, many contacts, enclosed spaces and poor ventilation – point to infectious particle inhalation as a significant mode of transmission.

In addition, the concept of “equipoise” or the “uncertainty principle”, a central ethical principal in randomized control trials (RCT), is flawed in this case. A subject should be enrolled in an RCT only if there is true uncertainty about which of the trial arms is likely to benefit the participants (Fries & Krishan 2004), which clearly is not the case when applying Selection, use and care of respirators (CAN/CSA-Z94.4-18), figures 1 – 4 (pp 21 – 25). We make reference to a most recent study (Goldberg et al. 2021) which describes COVID-19 infections in a pediatric ward. Overall, 6 health care workers were infected, of whom, at least 3 did not have direct contact with those who were first infected. In addition, 3 of the health care workers did not perform any aerosol generating medical procedure (AGMP) or other procedures involving mucosal membranes, despite adhering to guidelines for physical distancing and wearing surgical masks. They were still infected despite wearing surgical masks which will not protect the wearer against inhalable bio-aerosols.

Thus, any study (i.e. randomized control trial RCT), that attempts to compare surgical mask to respirator use when doing non AGMPs clearly does not align with the principle of “equipoise” as there is now clear evidence that N95s are far superior to surgical masks when comparing efficacy for HCW doing non-AGMPs (Oksanen et al. 2021, Wilson et al 2021).

The study design does not distinguish between aerosol generating medical procedures (AGMPs) which are clinical procedures that are considered as generating aerosols (e.g. intubation) and non-AGMPs (i.e. other ward activities). There are a wide range of healthcare occupations within the study group, which do not appear to be sorted into groups doing similar tasks / activities. This introduces significant variability. With only 576 participants, the error is likely to be compounded. Therefore, providing surgical masks to health care workers (HCW) doing non-AGMPs leaves them vulnerable to infection for inhalable SARS-CoV-2.

Plus, each of these occupations spends differing amounts of time performing a variety of tasks with different patients. There is no provision in the study design to account for, and track, the range of activities which will have varying (and dynamic) exposure and infection risks. Validation of the occupational data will be very difficult due to multiple sources of error.

The primary concern is that a flawed finding may be used to justify inadequate safety protections for health care workers.

Flaws in the Study Design

It is plausible, based on the study design, that the study may find no significant difference in efficacy between surgical masks and respirators. Confounding factors are many and include:

- Unknown inconsistent use of eye protection;
- only 576 participants across 13 facilities and innumerable work environments;
- uncertain and unknown workplace airflow and ventilation effectiveness;
- inconsistent fit-testing, allowing fit-test records up to 24-months old, and not for the specific type of respirator supplied for use;
- allowing the extended and potentially inconsistent use and re-use of N95 respirators;
- unclear requirements for training in the use of respiratory protection (CAN/CSA-Z94.4-18); and
- no processes in place to ensure that respiratory protection provided in the study meets approved standards for use (CAN/CSA-Z94.4-18, IRSST 2021, CDC 2021, Health Canada 2021)
- “without a control arm, the absence of difference between arms could reflect equal efficacy or inefficacy, and it is not possible to draw any conclusions about efficacy” (MacIntyre, 2020b, p.4).

The study fails to consider the findings of the Toronto SARS Commission (Campell A, 2006), which recommended using the precautionary principle to protect health workers during a serious emerging infection epidemic. During the SARS epidemic in Toronto in 2003, the very same arguments and denial of airborne precautions to health workers occurred, resulting in over 300 infections and many deaths that could have been prevented. (Campell A, 2006).

In Ontario, the latest WSIB (Workplace Safety and Insurance Board) data ranks "Nursing and residential care facilities" and "Hospitals" as number 1 and 2 respectively for the number of COVID-19 worker compensation claims. These claims to date are 7668 and 2772 respectively and only reflect submitted and allowed claims.

In contrast, an analysis of SARS-CoV-2 infection rate and the secondary attack rate among healthcare workers (HCWs) in Quebec, from an analysis of HCWs and infections between 1st March and 14th June 2020, is provided by Carazo et al. (2021). HCWs represented 25% (13,726/54,005) of all reported COVID-19 cases in Quebec and had an 11-times greater rate than non-HCWs. Most affected occupations were healthcare support workers, nurses and nurse assistants (Carazo et al. 2021).

The current level of protection especially for those doing non-AGMPs is clearly inadequate.

The Government of Canada now requires long-term care homes (LTCH) to be prepared to identify and manage residents who are considered exposed to, or suspected or confirmed to have, COVID-19. Policies and procedures must include N95s or better protection along with respirator fit testing. In acute care settings "*an N95 or equivalent respirator in place of a medical mask may occur based on a HCW's point-of-care risk assessment*" (PCRA) (Government of Canada, 2021).

Healthcare workers in non-COVID-19 patient care and support positions are at high risk of infection (Karlsson and Fraenkel 2021, Goldberg et al. 2021, Nguyen et al. 2021, Lan et. al 2021) and should be wearing respirators.

Several studies of healthcare worker seropositivity clearly demonstrate that there are significant risks for COVID-19 transmission and infection in many areas of a healthcare organization. For example, healthcare worker seropositivity in a UK hospital ranged from 24-34% in housekeeping, admissions, and general internal medicine, OBGYN, outpatient and support services personnel. Seropositivity rates were much lower (13-15%) in general surgery, emergency department and ICU personnel, all of whom wore respirators rather than surgical masks (Shields et al. 2020). Infection rates among healthcare workers in a Finland hospital were 15 times greater than in the community. Half of cases were found to be work-related, with 30% of those from co-workers. Half of the work-related cases were only wearing surgical masks; there were no cases in healthcare professionals wearing respirators (Oksanen et al. 2020).

Prevalence of infection for healthcare workers in a US hospital was 15 times greater than in the community. The highest positivity rates (8-11%) were in nurses and emergency department and operating room personnel. Lowest rates (2%) were in attending physicians and the ICU (Barrett et al. 202). A meta-analysis of 97 healthcare worker studies showed highest rates of PCR positivity and antibodies in nurses and personnel in non-emergency departments (Gómez-Ochoa et al. 2020). A study in four US healthcare systems found 3-11 times greater seropositivity rates in healthcare workers compared to the community. The highest prevalence of seropositivity occurred in environmental services, patient care technicians, nursing assistants, nurse technicians, phlebotomists, dialysis assistants, radiology, nurses and respiratory therapists (Jacob et al. 2020).

There is ample evidence from fit testing and workplace studies that respirators provide high levels of protection from hazardous aerosols. Surgical masks, on the other hand, provide little to no protection from inhalation of small infectious particles. A recent study in a Boston Hospital using genomic

epidemiology found two clear cases of COVID-19 transmission from patients to healthcare workers who were wearing only a surgical mask (Klompas et al. 2021).

Wilson et al. (2021) has demonstrated that aerosols generated during aerosol generating medical procedures (AGMPS), which routinely require an N95 respirator, are at least an order of magnitude lower than those generated during talking and coughing. Non-AGMPs are seen by this Study, and continued practice to only require a surgical mask, which, although counter intuitive, needs to be reversed based on the results from Wilson et al. (2021).

An update on the study from Finland, reported by Oksanen et al. (2021), noted as the first study to analyse the source of infection and impact of using surgical masks compared to filtering face-piece respirators (FFP2 or FFP3), in a region of low population density which increased the reliability in the analysis of workplace related infection. This recent international study has demonstrated that "occupational infections occurred while using a surgical mask, and all infections originating from patients occurred while using a surgical mask or no mask at all. Whereas no occupational infections were found while using an FFP2/3 respirator and following aerosol precautions" (Oksanen et al. 2021).

Given the very high likelihood of aerosol transmission, ALL healthcare workers – not just those caring for suspected or confirmed COVID-19 patients – need: fit-tested respiratory protection (which face masks are not); to be part of a respiratory protection program (CAN/CSA-Z94.4-18); plus good ventilation and administrative controls to limit their risk of exposure to infected co-workers and patients. Besides protecting individuals, every healthcare worker infection prevented lowers the risk of work overload, moral injury and household and community transmission.

As Ontario's "Directive 5" (October, 2020) notes: If a HCW is at risk based, on their professional and clinical judgement and proximity to the patient or resident, an N-95 respirator may be required (Ontario Ministry of Health 2020). Allowing nurses to opt for a lesser level of personal protection than they could obtain pursuant to Directive 5 is unacceptable. FFP respirators are designed to protect the wearer, whereas, surgical masks are designed to protect the patient (CDC 2020).Manitoba now requires health system operators, including health regions as well as hospitals, personal care homes and home care providers, to ensure that staff working with COVID-positive and suspect patients, residents and/or clients in environments where the risk of exposure to COVID-19 is higher are able to access an N95 respirator (Manitoba Shared Health 2021). In Alberta "all healthcare workers regardless of classification, across the care continuum and in all clinical settings, who are within two metres of patients suspected, presumed or confirmed to have COVID- 19 shall have access to requested PPE. Workers will have access to a fit-tested and seal-checked N95 or equivalent respirator if required based upon their own point of care risk assessment (PCRA), even in non-AGMP situations" (Alberta Health Services, 2021).

Finally, Justice Philippe Bouvier has noted the significant risk of airborne transmission in a court decision. Quebec's court decision ensures that all health-care professionals are provided an N95 respirator immediately when a resident or patient is suspected to be infected with COVID-19.

"Justice Philippe Bouvier recognized that one of the modes of transmission of COVID-19 is via aerosols and that medical masks are not a sufficient protection for health care workers in hot or warm zones"[1].

The Commission des normes, de l'équité, de la santé et de la sécurité du travail (CNESST) now requires all health care workers who work in a health care setting in warm and hot zones to wear an N95 respirator or respiratory protective equipment (RPE) that provides superior protection (CNESST 2021).

In closing, the weight of historic and contemporary evidence, along with provincial requirements for PPE, leads us to conclude that underlying premise and voluntary or optional methods of this study put Health Care Workers at high risk of developing COVID-19. The results of such a study are indefensible, and **we therefore ask for the study to be decoded immediately and formal letters of apology to be sent to participants by the investigator.**

Respectfully yours,

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[1] (Paragraph 16 of Décision 735965 (N95) of the TRIBUNAL ADMINISTRATIF DU TRAVAIL (Division de la santé et de la sécurité du travail) of March 23, 2021).([16] Par ailleurs, le Tribunal retient que l'un des modes de transmission du virus duSRAS-CoV-2 est la voie aérienne ou par inhalation. Dans cette perspective, les masquesmédicaux, qu'ils soient qualifiés de chirurgical ou de procédure, ne représentent pas une protection efficace pour les travailleurs affectés aux zones chaudes et tièdes. Le Tribunaljuge également que les Employeurs ne se sont pas acquittés de leurs obligations en matière de santé et sécurité du travail dans la détermination des zones à risque et de la création des équipes dédiées).

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