

Joint Statement on Chu *et al.* Lancet article on physical distancing, face masks, and eye protection and Mandavilli New York Times article

June 22 2020

Re: Chu, D. *et al.* Physical Distancing, face masks, and eye protection to prevent person-to-person transmission of SARS-CoV-2 and COVID-19: a systematic review and meta-analysis. Lancet 2020. DOI:[https://doi.org/10.1016/S0140-6736\(20\)31142-9](https://doi.org/10.1016/S0140-6736(20)31142-9)

Re: Mandavilli, A. (2020 June 1). *Medical Workers Should Use Respirator Masks, Not Surgical Masks*. The New York Times. <https://www.nytimes.com/2020/06/01/health/masks-surgical-N95-coronavirus.html?referringSource=articleShare> accessed 2 June 2020.

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Introduction

A systematic review and meta-analysis assessing factors influencing the person-to-person transmission of COVID-19 was published on June 1, 2020, in The Lancet. This study by Chu *et al.* was commissioned by the World Health Organization to inform their guidance documents, and it has generated media attention, including a New York Times article, around the use of N95 respirators in particular. The Ministry of Health in British Columbia (BC), Provincial Infection Control Network of BC, and Regional Health Authorities refer to scientific literature to support the development of evidence-based guidelines to protect healthcare workers (HCWs), patients, and the public from infectious diseases. As such, this article was reviewed to determine whether updates to provincial guidance on the use of physical distancing, respiratory protection (including N95 respirators and surgical/procedure masks) and eye protection in healthcare and community settings were necessary.

Chu *et al.* study search strategy and reported objectives and results

In their study, Chu *et al.* searched 21 databases for studies evaluating the roles of physical distancing, respiratory protection (both face masks and respirators), and eye protection in preventing transmission of COVID-19 (i.e. SARS-coV-2) and related viral pathogens (i.e. Severe Acute Respiratory Syndrome coronavirus [SARS-coV] and Middle Eastern Respiratory Syndrome coronavirus [MERS-coV]) between infected individuals and people close to them (e.g., household members, and HCWs). The authors assessed studies of any design available until May 3, 2020, and a total of 172 articles were included in the systematic review, with 44 studies contributing to the meta-analysis. The stated objective of the article was to systematically review the effect of physical distance, face masks, and eye protection on transmission of SARS-CoV-2, SARS-CoV, and MERS-CoV.

The main conclusions reported in the study (along with authors rating of the finding) are: (1) increasing physical distance probably lowers the risk of transmission (moderate certainty); (2) any type of N95 respirator and other face masks might provide better protection than no mask (low certainty); and (3) eye protection might provide better protection than no eye protection (low certainty).

Strengths of the Study

The authors are world leaders in the performance of systematic reviews of the literature and meta-analyses. The study is well-researched, and the approach to the meta-analysis (e.g. Cochrane methods and GRADE approach) and statistical techniques are sound. It has also successfully undergone the peer-review process required for publication in *The Lancet*.

Challenges with Study Design and Methods

One significant challenge in interpreting the authors' findings, particularly in terms of COVID-19, stems from the articles on which the systematic review and meta-analysis are based. The inclusion/exclusion criteria for the studies analyzed is not clearly stated, and the decision to include "studies of any design" results in a very heterogeneous evidence base, both in terms of population and intervention.

The majority of the cited studies specifically focus on SARS-coV (26 of 44 studies) and MERS (11 of 44 studies); only seven articles relate to COVID-19. Of these seven, the majority are descriptive (including one letter to the editor) and have not been published in peer-reviewed journals to date. Furthermore, several articles included – both those applying to COVID-19 and those referring to SARS or MERS – do not directly evaluate the effects of physical distancing or personal protective equipment (PPE) on prevention of disease transmission.

Regarding the effects of respirator use specifically, there were no direct comparisons of the use of N95 respirators versus surgical/procedure masks in prevention of COVID-19 included in their cited work. The studies included also did not take into consideration numerous potential confounding variables - hand hygiene, type of HCW, presence of aerosol-generating medical procedures (AGMPs), duration of exposure, access to PPE, doffing proficiency, engineering controls, environmental contamination, hospital capacity, and potential acquisition of infection in the community – all of which independently affect the transmission of COVID-19.

While the study aims to control for the significant heterogeneity of this data with a variety of statistical methods, the indirect and disparate nature of the source material makes it impossible to draw any reliable conclusions from this article regarding the relative protectiveness of N95 respirators versus surgical/procedure masks outside the setting of AGMPs. At best, conclusions are based on inference from a highly variable, uncontrolled data set.

Challenges with interpretation of results and conclusions

As detailed above, interpreting the findings of the meta-analysis is challenging given the quality of the source data. For example, in the assessment of mask use, the study combines results from cloth masks, surgical masks, multi-layer cotton masks, and potentially others with no reported proportion of each type. There are efforts to distinguish among the various types of masks in the subgroup analyses, however, these comparisons are again indirect and are potentially subject to major confounders. These challenges likely contribute to the large confidence intervals in the reported results.

Of important note, there have been several improvements in the quality of surgical/procedural masks that occurred following the SARS epidemic to comply with updated minimum standards

for filtration efficiency. As such, the results from the SARS epidemic in 2003, on which this publication is heavily based, may not be directly applicable to prevention of COVID-19 in 2020.

Finally, it is important to acknowledge the existence of multiple international N95 respirator and surgical/procedure mask performance standards. The performance attributes and qualification thresholds are different when comparing North American, European, and Asian standards. The article does not address these differences, and how variability in performance standards may influence the validity of compiling studies across international boundaries.

Our Appraisal and Analysis

The objective of our appraisal and analysis of this article was to assess the evidence and findings from the article regarding the effect of physical distancing, mask use, and eye protection use on the transmission of COVID-19. While looking for evidence to inform our provincial guidance, our review has kept in mind: (1) the quality of the research papers included in the meta-analysis; (2) the heterogeneity of the populations and interventions; and (3) the strength of the conclusions the authors themselves draw.

Physical Distancing

The authors report a strong association between proximity of an exposed individual and the risk of infection, with risk decreasing as distance increases. They attempt to quantify this for three different baseline levels of risk for infection, as displayed in Figure 3. For all levels, the association was found to decrease in variability with increased distance. On average, they report a risk reduction of 2.02 for every 1m further away (i.e. risk of transmission decreases approximately 2-fold with every 1 metre of increased distance). The authors note significant variability in this estimate, with the 95% confidence interval for the risk reduction between 1.08 and 3.76 for each metre of increased distance. This variability is reflected in the “moderate certainty” they attribute to this finding.

Given the inability to control for other contributing factors and to account for the effect of bundled infection prevention and control interventions, it is challenging to precisely estimate the independent effect of spatial distancing from this article. That said, the study shows a clear decrease in transmission with increased spatial separation, and a logarithmic decrease in transmission with increased distance up to 3 metres. This is consistent with the provincial and local recommendations from Public Health and Infection Prevention and Control for spatial distancing.

Eye Protection

The authors report that eye protection might result in a large reduction in transmission of COVID-19/SARS/MERS infection, however they rate this finding as “low certainty”. Their meta-analysis shows a high variability in the studies included in their analysis (see Figure 6), with only one study specific for patients with COVID-19. Similar to above, the nature of the sources underlying this assessment does not allow for control of other contributing factors and bundled interventions. This makes it challenging to draw any quantitative conclusions from the results they present. Overall, the study shows that the use of eye protection likely decreases the risk of transmission. This supports the idea that COVID-19 is predominantly spread by large respiratory droplets, and it is consistent with the recommendations by B.C. Public Health and Infection Prevention and Control for the use of eye protection in the care of patients with suspected or confirmed COVID-19.

Face Masks and N95 Respirators

A significant portion of the article is dedicated to attempts at evaluating and quantifying the protection offered by different forms of face masks and N95 respirators. The most robust finding is that the use of N95 (or equivalent) respirators or facemasks (specifically surgical masks or reusable 12-16 layer cotton masks) is strongly associated with a large reduction in the risk of infection compared to the use of no respiratory protection. This association was found to be stronger in healthcare settings than in non-healthcare settings (See Figure 4).

The authors then compare the use of N95 or equivalent respirators alone to the use of no respiratory protection. Unsurprisingly, use of the N95 respirators is strongly associated with a significant reduction in the risk of infection (Figure 5). Of note, this comparison was made using the results of four studies, only two of which identified when AGMPs were present, and only one of which was specific to COVID-19. Interestingly, the COVID-19 study did not specify whether AGMPs were present.

Next, there is a comparison of the use of surgical masks or multi-layer cotton face masks to the use of no respiratory protection. This comparison is made using the results from six studies on SARS, four of which were in healthcare settings, and all of which were from China and Vietnam. Only one study specifies if AGMPs were used, and there are no studies specific to COVID-19 included in this assessment. Multiple analyses show an association between the use of face masks and decreased transmission which persists through multiple statistical tests of robustness.

Of note, there are no direct claims in this study that N95 respirators are more protective than face masks for preventing transmission of COVID-19, SARS, or MERS. The article shows that the use of face masks and N95 respirators both showed statistically significant associations with decreased infection when separately compared to the use of no respiratory protection at all. The authors note that the association of decreased infection with respirator use was statistically stronger than with face masks, but the direct comparison they make between respirator use and face mask use is not statistically significant. They assert that this stronger association does not rule out the possibility that the use of respirators could be more protective than face masks, but that they could not rate this finding as “high” certainty. Importantly, they note that more robust and direct comparisons are needed to accurately answer this question.

Final Thoughts

This study suggests that physical distancing, eye protection, and respiratory protection (face masks or N95 respirators) all act to decrease the transmission of COVID-19, SARS, and MERS as a group. The degree to which each factor independently decreases transmission is not reliably determinable, and the quantitative estimates are broad.

This article clearly demonstrates that the use of respiratory protection in healthcare settings, whether surgical/procedure mask or N95 respirator, provides significant protection against HCW infection when compared to the use of no respiratory protection at all. The use of masks outside of healthcare settings is not adequately addressed in this study to make clear recommendations; only two studies of non-healthcare mask use were included, and both were specific to SARS.

The conclusion that N95s provide superior protection to HCWs versus surgical masks at all times is not a valid interpretation. The findings in this study neither address this question directly nor support this inference in their findings; their direct comparison was not statistically significant. Furthermore, multiple major issues - the vast heterogeneity of the data set, the lack of controls for confounding variables (e.g. hand hygiene), the improvement of mask quality since the SARS epidemic, and the lack of data specific to COVID-19 in the comparison of masks to N95 respirators – make the findings of a “stronger association” very difficult to interpret.

In summary there is no conclusive evidence to warrant changes to the provincial guidelines for respirator, face mask, or eye protection use in healthcare settings. This study supports the current recommendations regarding the use of respiratory protection and eye protection for direct care of patients with, WHO-defined, confirmed or probable cases of COVID-19. Current physical distancing measures in BC are also aligned with the suggestions by Chu *et al.*

Importantly, the use of a single specific PPE item is only one of many aspects important to the prevention of COVID-19 transmission. Point of Care Risk Assessments, hand hygiene, proper donning and doffing techniques, identification and isolation of potential cases via screening, as well as proper cleaning and disinfection all play important roles. We are dedicated to actively monitoring published literature in order to update guidelines as necessary.
