Scientific Advisory Group

COVID-19 Scientific Advisory Group Rapid Evidence Report

Double Masking & Improved Mask Fit

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Lay Summary

- Masks are one of the tools for reducing COVID-19 transmission risk.
- In France, Germany and Austria, medical masks have been recommended instead of cloth or homemade masks. In the United States, the CDC released a guidance document offering suggestions for improving mask fit such as: “double masking” (cloth mask overtop of a medical mask) or knotting/tucking of medical masks.
- These developments as well as questions about the higher transmissibility of variants of concern (VoC) led local policy makers to ask whether Alberta should be advising these other techniques. That is, could double masking (or other techniques for making masks fit better) make masks work more effectively?
- Our review of the literature did not find any clinical studies to answer this question. We did, however, identify public health guidelines and recent laboratory studies that provide some guidance about improving masking.
- Firstly, if a cloth mask is used, it should consist of 3-layers (the characteristics of which are described in detail in a variety of documents).
- Public health guidelines note the importance of a well-fitted mask and recent laboratory studies further highlight the value of a tightly-fitted mask.
- In one laboratory experiment done at the CDC, two mannequins were placed in a small chamber where one mannequin was made to artificially “cough”. Noting that is unclear how filtration efficiency in these types of studies correlate with viral transmission, the study noted that as compared to when just one of them was wearing a medical mask, if both mannequins wore a medical mask (without modification), then there was a significant decrease in exposure to the particles produced from the cough. This reduction in exposure to artificial particles was further improved with double masking or with knotting/tucking.
- While more tightly fitted masks appear to provide a better barrier against both inward and outward penetrating particles in lab-based studies, we do not know how that translates into real-life differences in transmission of the SARS-CoV-2 virus.
- Both mask composition and mask fit are important. If there is concern about air leakage from mask edges, modifications can include double masking, knotting/tucking, or mask braces. However, given the overall limited data, no specific mask modification can be recommended.

Authorship and Committee Members

Name	Contribution
Leyla Asadi	Writing – original draft preparation, evidence extraction
Elizabeth MacKay	Primary scientific reviewer
John Conly	Secondary scientific reviewer
Braden Manns & Lynora Saxinger	Scientific Advisory Group chairs (oversight and leadership responsibility, editing and review)
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Topic: **In the community setting where nonmedical masks are used, what is the evidence (effectiveness, safety and filtration properties) for the use of two non-medical masks (or non-medical masks with multiple layers) to prevent COVID-19 transmission? Are there ways to optimize fit to improve filterability and reduce transmission? Do these findings have implications for healthcare settings?**

Context

- Due to concerns regarding the increased transmissibility of variants of concern, (VoC) there have been questions raised about currently recommended mask practices.
- A CDC document from February 2021 suggested that mask fit could be improved by either wearing two masks (non-medical mask overtop a medical mask) or by knotting/tucking medical masks. They also state that KN95 masks may be preferable in some higher risk settings or for some higher-risk individuals.
- Germany, Austria and France now recommend or mandate medical masks in lieu of non-medical or homemade masks in public spaces. In the states of Schleswig-Holstein and Bavaria only FFP2 (N95 equivalent) masks are permitted.
- The WHO has maintained current advice regarding masking.
- The variability of these approaches reflects the varied interpretation of data underpinning mask policy changes.
- Local policy makers have raised questions about whether “fit optimization” practices should be recommended for use in the community, and whether this has any implications for health care settings (hospitals and LTC).

Key Messages from the Evidence Summary

- To optimize effectiveness of masks, both the filtration properties of the materials and mask fit need to be considered.
- There is consensus among public health agencies (PHAC, WHO, CDC, AHS) that the optimal face mask construction should include 3 layers—a hydrophobic outer layer, blended non-woven fabric middle layer and a hydrophilic interior.
- Standard lab testing suggests that masks have variable filtration efficiency (FE), with the highest usually a fit tested N95 mask followed by a surgical (procedural) mask or well fit medical mask and then a variety of cloth masks. Limited data suggest that an optimized cloth mask may approach medical mask FE, and non-fit tested N95 masks may have a poor FE.
- Laboratory testing of standard medical or cloth masks, along with head or body movements simulating moderate work suggests there may be increase in droplet exposure potential which might be mitigated by the improved fit, which in one study was created by the addition of a second tight fitting layer. Other devices (“mask fitters”) and maneuvers to improve the fit to the face have been suggested.
- To reduce leakage, a tight mask fit is essential. A recent small laboratory-based study by CDC using mannequins and a simulated cough procedure suggested

that either improving the fit of medical masks by knotting the ear loops and tucking the extra material or double-masking with a 3 ply cloth mask over top of a medical mask reduced mean cumulative aerosol exposure by over 90%. These used a single example of each mask type, and a standardized headform so it is noted that individualized assessment of whether these maneuvers are acceptable from a comfort viewpoint and actually function to reduce the side gaps remains important.

- In the same laboratory based simulated cough study, the use of a standard medical mask by both the source and exposed mannequin reduced the mean cumulative aerosol exposure by the same proportion as double masking the source or receiving mannequin. This laboratory testing thus also highlights the combined importance of both the “source” and “exposed” individuals wearing a well fit mask in providing the largest reduction in exposure.
- No studies have examined the use of two non-medical masks. The layering of two medical masks is explicitly discouraged as it would not improve fit. The “double masking” examined has been limited to the use of a non-medical mask overtop of a medical mask. However, having three layers of fabric rather than a single layer has been a feature of guidelines so >1 single layer mask might accomplish that goal.
- There is no data on the harms associated with the wearing of double masks and no data on the real or perceived risk:benefit ratio.
- There is no data correlating the filtration efficiency to degree of viral transmission. That is, we do not know the extent of filtration efficiency required to ensure minimal viral transmission, nor are there any robust clinical studies.
- There is no published data suggesting that variants are more readily transmitted when good masking practice and hand hygiene are used. Of note, despite the B.1.1.17 variant of concern epidemic in the United Kingdom, their mask guidelines [1] remained unchanged and there has been a major decline in the variant cases which has been seen in South Africa as well. COVID-END is currently doing a rapid review on use of personal protective equipment in the context of variants so this was not considered in this report.

Committee Discussion

Committee members were in agreement that the evidence supporting the use of double masking was lacking and that an emphasis on the bundle of interventions required to minimize risk of transmission of COVID-19 would include a focus on optimization of mask fit. A number of committee members felt that despite the low quality and predominantly lab based data on mask fit, that the public would benefit from understanding the nature of the role that the type of mask and mask filtration may play on mask effectiveness. The committee felt more comfortable with keeping the recommendations around the more practical promotion of a public campaign and increased awareness of the importance of optimized mask use by both the source and exposed person rather than improvement in fit that might accompany the use of a double mask. Lastly, a committee member emphasized the potential risks of double masking which remain unexplored and the need for more rigorous research on mask use and its impact on real world viral transmission and not more laboratory studies.

Recommendation

Public Health guidance around mask use (in combination with other public health measures) should further emphasize the importance of mask quality and fit, with use of a well-fitting medical or 3-layer non-medical mask in recommended settings.
Rationale: Recent laboratory based data supports that filtration efficiency of masks can be potentially optimized by more attention to mask fit and quality, although “double masking” (using a cloth and surgical mask together) is only one maneuver individuals may assess to improve fit. There is no epidemiological or clinical trial evidence to support the need for double masking. Studies guiding recommendations regarding double masking or mask-fit optimization techniques are based on small laboratory studies. Optimal mask fit has been emphasized in previous AHS, PHAC, and WHO mask guidance documents

Practical Considerations

Guidance around mask use should include information around assessing mask fit (closeness to face, airflow through the filtering material versus around edges of masks) and possible ways to improve fit (including but not limited to adjusting ear loops and sides of the masks (“knot and tuck”), using devices that pull the mask closer to the face (braces and ear protectors), and proper use of nose wires. It is noted that variability in mask shape and face shape precludes standard recommendations.
Rationale: The importance of mask fit has been emphasized in previous AHS, PHAC, and WHO mask guidelines

Strength of Evidence

The body of evidence is very limited. Only a small number of laboratory-based experiments could be identified.

Limitations of this review

There is a continued paucity of clinical data regarding masks and prevention of SARS-Cov-2 transmission.

While there is now an abundance of laboratory data, providing mechanistic insights around the filtration properties of different materials, this data is limited by marked heterogeneity (both in terms of the variety of materials tested and the testing methodologies). There is very limited laboratory data on mask “fit” and mask fit optimization.

Summary of Evidence

Research Question 1

In the community setting where nonmedical masks are used, what is the evidence (effectiveness, safety and filtration properties) for the use of two non-medical masks (or non-medical masks with multiple layers) to prevent COVID-19 transmission? Are there ways to optimize fit to improve filterability and reduce transmission?

Numerous guidelines now exist regarding the effectiveness, safety and filtration properties of non-medical masks [2-5]. A consistent finding across the various guidelines is that the filtration efficiency of non-medical masks is highly dependent upon the materials used in the mask, with filtration efficiency ranging from (<10% to >95%) [2,3]. AHS, PHAC and WHO suggest that 3 layers are optimal— with a hydrophobic outer layer, blended non-woven fabric middle layer and a hydrophilic interior. On February 15, 2021, the American Society for Testing Material (ASTM) released the "Standard Specification for Barrier Face Coverings" to provide a certification (performance) standards for non-medical masks [6]. The goal of the specifications provided in the standards is to allow for direct comparison of mask products. To date, non-medical masks that comply with these standards are not yet widely available.

In addition to filtration properties of non-medical masks, guidelines [3,7] also stress the importance of the fit of masks. The CDC's latest guidance on masks[7](updated Feb 23, 2021) suggest the use of multi-layered cloth masks, medical procedure masks, or even KN95 respirators in certain situations. To improve fit, they advise the use of masks with nose-wires, the addition of mask fitters/braces, or knotting/tucking of medical masks. To improve both fit and filtration, they recommend layering a non-medical mask overtop of a medical mask. The guidance further clarifies that individuals may choose to adjust their mask based on the exposure risk. That is, if a higher risk exposure, then an option such as "double masking" may be appropriate.

To date, the only guidelines that suggest "double masking" or the layering of a non-medical mask overtop a medical mask are the CDC recommendations [7]. To assess the fit of a mask, the following suggestions are made: "Check for gaps by cupping your hands around the outside edges of the mask. Make sure no air is flowing from the area near your eyes or from the sides of the mask. If the mask has a good fit, you will feel warm air come through the front of the mask and may be able to see the mask material move in and out with each breath."

Evidence from the primary literature

A previous AHS reviews has summarized the primary literature related to non-medical masks up to June 2020 [2]. The PHAC mask review is updated to January 2021 [3]. While the filtration efficiency of some non-medical masks approach medical masks, the results from laboratory studies are highly heterogenous and dependent upon the particular materials used. As other reviews have closely examined material filtration properties [8], this review will instead focus on studies examining the impact of mask fit on filtration efficiency and mask effectiveness.

The importance of mask fit has been explored in several studies that show that even small leaks can markedly impact filtration efficiency [9-11] and in studies which have attempted to visualize[12] or quantify the extent of leakage[13].

To optimize mask fit, several different techniques have been explored: mask-braces [11], hosiery [14], knotting techniques [14,15] and layering a non-medical mask on a medical mask

[15]. No studies examine layering two non-medical masks. The layering of two medical masks for improved fit is explicitly discouraged by the CDC [7].

The latest CDC recommendations [7] on double masking and mask knotting/tucking are based primarily on experiments conducted at the CDC in January 2021, the results of which were published in February 2021 [15]**.** In this study, two mannequin head-forms were placed in a 10x10X7ft chamber. The source mannequin emitted simulated coughs (0.1-7μm potassium chloride aerosol). Two modifications were made to improve mask fit. As it pertains to non-medical masks, the intervention was layering a non-medical mask on top of the medical mask. When source control was assessed at baseline, the cloth mask blocked 51.4% (SD 7.1) of particles emitted and the medical mask blocked 56.1% (SD 5.8). When the mannequin was double masked, 85.4% (SD 2.4) of the cough particles were blocked. When a medical mask was knotted and tucked, 77% (SD 3.1) blockage occurred. In terms of exposure assessment, if *both* mannequins wore medical masks (without modification), the cumulative aerosol exposure was reduced by 84.3%. If only the receiver mannequin was masked (no modification), exposure was reduced by 7.5%. If only the source was masked (no modification), exposure was reduced by 41.3%. If only the receiver mannequin was double-masked, exposure was reduced by 83%, if only the source mannequin was double-masked the exposure was reduced by 82.2% and if both were double masked, exposure by reduced by 96.4%. A similar marked reduction was seen if both head-forms wore knotted/tucked medical masks.

Two other studies [14,16] have looked at the impact of nylon hosiery overlays and other methods of fit modifications. One study assessed the fitted filtration efficiency (concentration of particles behind the mask expressed as a percentage of the particle concentration in the chamber) or FFE of a series of masks worn by a volunteer exposed to sodium chloride particles (0.02-0.60 μm) in an exposure chamber. For cloth masks, FFE varied from: 26.5% (3-layer cotton mask) to 79% (2-layer nylon mask with ear loop, aluminum nose bridge, washed). A procedure mask with ear loops had an FFE of only 38.5% but this was improved to 60% with knotting/tucking, 62% with an ear guard, 65% with a claw hair clip, 78% with the “fix the mask” 3 rubber band method, and 80% with a nylon hosiery sleeve overtop. These modifications were not tested on the non-medical masks. For comparison, a medical mask with ties had an FFE of 72% and an n95 mask had a FFE of 98%. Mueller et al. undertook a similar study comparing a variety of medical masks and non-medical masks with and without a nylon overlay worn by a volunteer [16]. They found that medical masks had filtration efficiencies of 53% to 75%, which could be improved to 90% when a nylon layer was worn on top. In this experiment, cloth masks again had widely varying filtration efficiencies (<30% to 91%) but their fit and subsequent filtration efficiency was consistently improved with a nylon stocking over lay. Of note, the practice of using nylon hosiery overlays to decrease leakage from non-medical and medical masks has been known for many years [17].

Two studies explored the use of mask braces [11,18]. Runde et al. assessed a “double eights mask brace” (made of rubber bands) to improve the seal on ASTM level 1 surgical masks [18]. These authors found that when the “mask brace” was affixed with a

paperclip or on a face shield, 100% of the 11 individuals passed the quantitative fit test (at the level of N95 respirator fit test standards, using standardized OSHA practices). Rothamer et al. (pre-print) undertook a series of tests wherein they placed 15 mannequins in a simulated classroom setting where NaCl was aerosolized as a surrogate for SARS-CoV-2 bioaerosols [11]. They then tested the impact of ventilation as well as the effective filtration efficiency of different masks—with and without mask fitters. Their findings corroborated previous studies. Specifically, the non-medical mask had the lowest filtration efficiency and the medical mask the highest. Regardless of the mask type, mask braces improved the fit of the mask, reduced leakage, and thereby increased the filtration efficiency of the masks. For instance, medical masks used with mask fitters were able to achieve 95% effective filtration efficiency.

Evolving Evidence

Just as laboratory research on filtration properties of non-medical masks increased substantially since January 2020, it is likely that the laboratory data on fit optimization techniques will also continue to increase.

Methods

Appendix

Literature Search

A literature search was conducted by Joycelyn Jaca from Knowledge Resources Services (KRS) within the Knowledge Management Department of Alberta Health Services. KRS searched databases for articles published from 1946 to February 22, 2021, and included: Medline, CINAHL, Google Scholar, TRIP, PubMed. Briefly, the search strategy involved combinations of keywords and subject headings including:

For double masking:

1 exp COVID-19/pc, tm [Prevention & Control, Transmission] (3927)
2 exp SARS-CoV-2/ (46491)
3 exp Coronavirus Infections/pc, tm [Prevention & Control, Transmission] (16540)
4 or/1-3 (52958)
5 exp Masks/ (10310)
6 exp Personal Protective Equipment/ (32491)
7 "face mask*".ti. (940)
8 or/5-7 (32756)
9 effectiveness.ti. (99517)
10 efficacy.ti. (163843)
11 exp Safety/ (82911)
12 filtration.mp. (158659)
13 filterability.mp. (902)
14 multiple-layers.mp. (2027)
15 fit.mp. (127746)
16 or/9-15 (626061)
17 4 and 8 and 16 (273)
18 limit 17 to (english language and yr="2020 -Current") (180)

For variants of concern and masking:

1 exp COVID-19/ (58942)
2 exp Coronavirus Infections/ (69295)
3 exp SARS-CoV-2/ (46698)
4 or/1-3 (69757)

5 variant*.ti. (86594)
6 "variant strain*".ti. (149)
7 or/5-6 (86594)
8 4 and 7 (202)
9 exp Masks/ (10313)
10 facemask*.mp. (1424)
11 "Face mask".mp. (2972)
12 or/9-11 (13280)
13 8 and 12 (0)

References

1. SAGE-EMG. Application of physical distancing and fabric face coverings in mitigating the B117 variant SARS-CoV-2 virus in public, workplace and community settings. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/957010/s1029-emg-face-coverings-distancing.pdf. Updated 2020.

2. Alberta Health Services. Mask use in the community rapid review . https://www.albertahealthservices.ca/assets/info/ppih/if-ppih-covid-19-sag-mask-use-in-community-rapid-review.pdf. Updated 2020.

3. Public Health Agency Canada. Rapid review on the characteristics of effective non-medical face masks in reducing the risk of SARS-CoV-2. . 2021. https://www.nccmt.ca/covid-19/covid-19-evidence-reviews/261.

4. European Centre for Disease Prevention and Control. Using face masks in the community: First update - effectiveness in reducing transmission of COVID-19. . 2021(Stockholm). https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-face-masks-community-first-update.pdf.

5. World Health Organization. Mask use in the context of COVID-19 - interim guidance. . 2020. https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak.

6. American Society for Testing Material, (ASTM). Standard specification for barrier face coverings. https://www.astm.org/READINGLIBRARY/VIEW/F3502.pdf. Updated 2021.

7. Centers for Disease Control and Prevention. Improve the fit and filtration of your mask to reduce the spread of COVID-19. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/mask-fit-and-filtration.html. Updated 2021.

8. Clase CM, Fu EL, Ashur A, et al. Forgotten technology in the COVID-19 pandemic: Filtration properties of cloth and cloth Masks—A narrative review. *Mayo Clinic proceedings*. 2020;95(10):2204-2224. http://dx.doi.org/10.1016/j.mayocp.2020.07.020. doi: 10.1016/j.mayocp.2020.07.020.

9. Konda A, Prakash A, Moss GA, Schmoldt M, Grant GD, Guha S. Aerosol filtration efficiency of common fabrics used in respiratory cloth masks. *ACS nano*. 2020. https://www.ncbi.nlm.nih.gov/pubmed/32329337. doi: 10.1021/acsnano.0c03252.

10. Drewnick F. Aerosol filtration efficiency of household materials for homemade face masks: Influence of material properties, particle size, particle electrical charge, face velocity, and leaks. .

11. Rothamer DA. Strategies to minimize SARS-CoV-2 transmission in classroom settings: Combined impacts of ventilation and mask effective filtration efficiency. . 2021. https://www.medrxiv.org/content/10.1101/2020.12.31.20249101v1.full.pdf.

12. Darby S. COVID-19: Mask efficacy is dependent on both fabric and fit. . 2020. https://www.futuremedicine.com/doi/10.2217/fmb-2020-0292.

13. Kolewe EL, Stillman Z, Woodward IR, Fromen CA. Check the gap: Facemask performance and exhaled aerosol distributions around the wearer. *PloS one*. 2020;15(12):e0243885. https://www.ncbi.nlm.nih.gov/pubmed/33326449. doi: 10.1371/journal.pone.0243885.

14. Clapp PW, Sickbert-Bennett EE, Samet JM, et al. Evaluation of cloth masks and modified procedure masks as personal protective equipment for the public during the COVID-19 pandemic. *JAMA internal medicine*. 2020. http://dx.doi.org/10.1001/jamainternmed.2020.8168. doi: 10.1001/jamainternmed.2020.8168.

15. Brooks JT, Beezhold DH, Noti JD, et al. Maximizing fit for cloth and medical procedure masks to improve performance and reduce SARS-CoV-2 transmission and exposure, 2021. *MMWR. Morbidity and mortality weekly report*. 2021;70(7):254-257. https://www.ncbi.nlm.nih.gov/pubmed/33600386. doi: 10.15585/mmwr.mm7007e1.

16. Mueller AV, Eden MJ, Oakes JM, Bellini C, Fernandez LA. Quantitative method for comparative assessment of particle removal efficiency of fabric masks as alternatives to standard surgical masks for PPE. *Matter*. 2020;3(3):950-962. http://dx.doi.org/10.1016/j.matt.2020.07.006. doi: 10.1016/j.matt.2020.07.006.

17. Cooper, D W, Hinds, W C, Price, J M, Weker, R, and Yee, H S. Expedient methods of respiratory protection. II. leakage tests. final report. 1983(United States).

18. Runde DP, Harland KK, Van Heukelom P, Faine B, O'Shaughnessy P, Mohr NM. The “double eights mask brace” improves the fit and protection of a basic surgical mask amidst COVID-19 pandemic. *Journal of the American College of Emergency Physicians Open*. 2021;2(1):e12335-n/a. https://onlinelibrary.wiley.com/doi/abs/10.1002/emp2.12335. doi: 10.1002/emp2.12335.