COVID-19 Scientific Advisory Group Rapid Response Report

Since completion of this report, additional potentially relevant papers have come to attention, to be reviewed for inclusion in any possible future update of this literature synthesis (added September 3, 2021):

Abaluck, J., Kwong, L.H., Styczynski, A., Haque, A., Kabir, A., et al. (preprint). The impact of community masking on COVID-19: A cluster-randomized trial in Bangladesh. https://www.poverty-action.org/publication/impact-community-masking-covid-19-cluster-randomized-trial-bangladesh

Bundgaard H, Bundgaard JS, Raaschou-Pedersen DET, et al. Effectiveness of adding a mask recommendation to other public health measures to prevent SARS-CoV-2 infection in Danish mask wearers. Ann Intern Med. 2020; 18:M20-6817. https://www.acpjournals.org/doi/10.7326/m20-6817

Key Research Question: What is the effectiveness of wearing medical masks, including home-made masks, to reduce the spread of COVID-19 in the community? [Updated June 19, 2020]

Context

- On June 5th, 2020, the WHO, despite a limited evidence base, provided guidance on the continuous use of medical masks by health workers and caregivers in areas of known or suspected community transmission regardless of whether direct care to COVID-19 patients is being provided. In addition they provided guidance to decision makers using a risk based approach for the use of masks in areas with community transmission of COVID-19 when physical distancing is difficult (ie. public transit, shops, or other confined or crowded spaces).
- On May 20, 2020, the Public Health Agency of Canada recommended that non-medical masks be used in settings where it is not possible to maintain a 2-metre physical distance. The federal transportation minister then mandated mask use on planes, rail transport, and ships.
- The government of Alberta has initiated distribution of 20 million, single-use non-medical masks to the community which appear to be of high grade (with a 3 layer design, purporting a 96% filtration rate for particles up to 3 um and Delta-R 1.7 which would meet FFP2 requirements).
- Community mask use is now either encouraged or mandatory in over 80 countries, with many jurisdictions encouraging but not mandating the use of cloth masks; however, some countries such as Australia and New Zealand continue to not recommend community masking and have achieved low rates of COVID activity despite the lack of this particular intervention.
- Shortages of medical (procedure, surgical masks) masks and N95 masks for health care workers persist globally and nationally.
- With a focus on recovery and relaxation of social distancing in the context of the stabilization of the initial wave of the pandemic, the general population is returning to community and workplace settings where social distancing will not always be possible, which is driving interest in, and controversies around the use of cloth and home-made masks.

Key Messages from the Evidence Summary

- As medical masks are often bundled with other IPC interventions and have variable compliance, clinical trials on the effectiveness of medical masks have been challenging. Systematic reviews of randomized controlled trials in health care settings have not demonstrated a significant reduction in acute respiratory infections, (ARIs), ILIs or laboratory confirmed viral infections with medical mask use although it is acknowledged there were methodological flaws and smaller underpowered studies in the data analyzed.
- There is a paucity of clinical evidence in favor of using medical masks in the community, with multiple randomized trials demonstrating mixed results which when pooled demonstrate no significant reduction in acute respiratory infections (ARIs), ILIs or laboratory confirmed viral infections. There are some lower quality studies showing a reduction in viral infection rates in households, in transmission of viral respiratory infections in the context of mass gatherings, and in university residences when combined with hand hygiene interventions.
- However, while systematic reviews of randomized clinical trials fail to show significant benefit with medical mask use in community settings, more observational and case-control studies (both at higher risk of bias), have suggested that masks are protective.
- The reasons for the lack of significant reduction for ARIs in the randomized trials is complex and may include: study design, setting, and human factors associated with wearing masks including low compliance with mask wearing, lack of concomitant hand hygiene, inoculation via the conjunctiva, frequent facial touching and mask adjustment leading to inoculation events, risk compensation behaviours, and self-contamination with inappropriate mask doffing. These possibilities have not been rigorously assessed.
- Laboratory studies investigating the efficacy of masks in filtering viral particles as well as studies in medical settings with laboratory based endpoints for bacterial respiratory pathogens (*Pseudomonas aeruginosa and Mycobacterium tuberculosis*) point to a theoretical benefit to medical mask use as a form of source control (protecting others from the wearer). There are no laboratory studies with SARS-CoV-2 and only one looking at other human coronaviruses.
- There are modelling studies and ecological data suggesting a benefit to medical mask use in the community via a reduction in viral transmission rates (R0) across wide ranges of community transmission levels. While these models are suggestive, they have significant inherent bias based on multiple assumptions including assumptions around mask efficacy in preventing transmission, and bundled interventions.
- Based on lab-based bioaerosol and NaCl aerosol studies, medical masks are superior to homemade cloth masks, but non-medical masks and optimally constructed home-made masks may offer some protection in reducing dispersion of droplets. Laboratory-based studies are of highly variable quality, with only a few studies using industry approved filtration efficiency testing methods.
- The newly released guidance from the World Health Organization suggests decision makers advising on non-medical mask use should take into consideration features of filtration efficiency (FE), breathability, number (and combination) of materials used, shape, coating and maintenance of cloth masks. The WHO suggests minimum Q (filter quality factor) score of the material chosen of 3 (three) based on expert consensus and engineering science and industry standards. They further suggest an optimal combination of material for non-medical masks should include three layers:

    1) an innermost layer of a hydrophilic material (e.g. cotton or cotton blends);

2), an outermost layer made of hydrophobic material (e.g., polypropylene, polyester, or their blends) and

3) a middle hydrophobic layer of synthetic non-woven material such as polypropylene, or a cotton layer which may enhance filtration or retain droplets

- There is limited evidence of harms related to community mask wearing with no studies identified that have systematically looked at potential harms. Such harms could include behavioral modifications such as risk compensation/non-adherence to social distancing or optimal hand hygiene practices, self-contamination, induction of facial rashes, and increasing real or perceived breathing difficulties. There are also concerns about poor compliance or tolerance of masks in children or those with cognitive challenges and communication difficulties.
- The only clinical study to examine cloth mask efficacy in preventing repiratory virus transmission was in a healthcare setting, comparing continuous cloth or medical masks use to usual practice. Among the comparator (usual practice) group, a large percentage of individuals used medical masks for part of the time. The study had significant methodological issues but did demonstrate a significantly higher respiratory viral infection event rate of HCW using a 2-ply cotton cloth masks when compared with the use of standard practice. (Macintyre et al, 2015)
- Pre-symptomatic transmission and asymptomatic transmission of SARS-CoV-2 have been described but the degree to which they contribute to community spread is unclear, At this point, there is no direct evidence that the use of a medical or homemade cloth mask or the wider use of masks in the community significantly reduces this risk. For more information, refer to the Asymptomatic Transmission of SARS-CoV-2 rapid review.

Committee Discussion

There was agreement that although the evidence base is poor, the use of masks in the community is likely to be useful in reducing transmission from community based infected persons, particularly those with symptomatic illness. One member was very concerned, and there was some agreement, that a focus on mask-use could lead to a reduced sense of personal risk, i.e. risk compensation. There is some evidence demonstrating less attention to social distancing and hand hygiene as the mainstays of prevention in a community setting. It was noted that while there is evidence from observational studies that medical masks may reduce ARIs and ILIs in health care settings, that there is no clinical trial evidence that use of non-medical or medical masks in the community reduces viral transmission.

There was agreement that there is insufficient information to make a firm recommendation for the use of home-made (non-medical) masks in the community. In the face of difficulties in quantifying risk of asymptomatic transmission and potential benefit outweighing the harms of wider use of home-made masks in the community, several committee members felt strongly that we should carefully balance the recommendation for community use to reflect the precautionary principle as well as evidence gaps. One member felt that to achieve the maximum population benefit, the majority of people should be wearing masks in settings where physical distancing cannot be maintained. To account for these controversies, which were mostly based on uncertainties in the evidence, a Research Gaps section has been added.

There was concern that we may be over-emphasizing the potential harm associated with the use of non-medical masks in the community, and there was general but not unanimous agreement to reduce this emphasis and focus on the need for systematic research looking at benefits and harms with clinical outcomes.

This update was predominantly based on the WHO revised advice, but it was noted that there is little new evidence aside from information on filtration efficiency of different home-made masks since our last update. There remains a lack of data demonstrating benefit of cloth masks as currently used in the community, beyond lab based filtration studies. There remains a significant disconnect between RCTs and observational study results of community mask use, and significant confounding and bias in ecologic trials. Since the last version of this review, there is very little new data except new syntheses of previous studies, new modeling studies, and some new collations of cloth filtration characteristics. One reviewer commented on the system level issues with supporting medical and non-medical mask use in the community as important elements in addition to the patient level harms.

One reviewer highlighted the importance of identifying specific level of guidance and evidence provided by the updated advice from the WHO. As little additional evidence was highlighted in this review, the emphasis of the WHO report was discussed: "the process of interim guidance development during emergencies consists of a transparent and robust process of evaluation of the available evidence on benefits and harms, synthesized through expedited systematic reviews and expert consensus-building facilitated by methodologists. This process also considers, as much as possible, potential resource implications, values and preferences, feasibility, equity, ethics and research gaps" (WHO, June 5, 2020). Therefore more specific description of the document, recommendations and the risk-based approach to community mask use with consideration of local epidemiology has been incorporated. (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)

Lastly, committee members felt that the research gaps section should better highlight the remaining uncertainties regarding mask use in the community, and how they might be addressed. This would include better information about optimal mask construction, as well as more robust evidence about their impact on clinically relevant measures of benefit and harm. Finally, additional details about compliance with medical and non-medical mask use in the community would be helpful.

Recommendations

1. In light of concerns around PPE shortages, medical masks should continue to be prioritized for HCWs in direct patient care roles. HCWs should continue to wear medical masks whenever providing direct patient care and whenever social distancing is not possible in health care settings.
2. In the community, medical mask use should be prioritized for those with any symptoms suggestive of COVID-19, as a form of source control. Community caregivers of potentially infectious COVID-19 patients and care providers for those who are more vulnerable to severe infection in the household setting should also wear medical or well-constructed non-medical masks as a form of protection.
3. In settings where social distancing cannot be maintained, medical masks or high-quality non-medical masks should be encouraged as a form of protection for those vulnerable to severe COVID-19 infection outcomes. Vulnerable populations include those over 60 and those with comorbidities or immunosuppression.
4. Evaluation of the extent of community transmission of SARS-CoV-2 is required to continually assess the risks and benefits of community mask use in various situations, although there is insufficient evidence to recommend specific epidemiologic thresholds for this purpose. This is consistent with WHO guidance which advises decision makers to apply a risk-based approach focusing on specific criteria when considering or encouraging the use of masks for the general public that incorporates consideration of local epidemiology. The WHO encourages use of a well-constructed non-medical mask, designed according to the available evidence from

materials engineering science, as a possible method of reducing risk of transmission of COVID-19 when social distancing is not possible. Situations where this may be particularly relevant include: on public transportation, workplaces necessitating close proximity to other workers or the public, or when entering and exiting public buildings.

5. In light of widespread interest in masks and anecdotal evidence of potentially harmful, inappropriate use by the public, health officials should widely communicate the need for both optimal mask construction and mask “etiquette”. It is important to strengthen the messaging that their use not replace the need for maintaining social distancing and hand hygiene as more important strategies to prevent transmission of COVID-19; and the need to not touch the mask, to replace when soiled or wet and ensure appropriate laundering. Current advice on when and how to wear home-made or non-medical masks is available at: https://www.albertahealthservices.ca/topics/Page16997.aspx#prev

Research Gaps

1. While there is some additional evidence, there is a need for further research into the optimal construction and fabric composition of home-made or non-medical masks and their efficacy in protection against transmission or acquisition of SARS-CoV-2.
2. Currently, we only have theoretical benefit demonstrated in laboratory studies of the filtration capabilities of cloth masks. Further studies assessing population benefits and harms of home-made (non-medical) masks are urgently required. These studies should include RCTs that assess clinical outcomes.
3. Studies evaluating the frequency and compliance of mask use by individuals in clinical and community settings, potentially using longitudinal surveys and/or contact tracing data would be of benefit while awaiting more rigorous trial results.

Summary of Evidence

Since the last update on April 21, 2020, the World Health Organization has provided new guidance on the use of masks in the community. There has also been a significant number of new studies examining their use. However, there is only one new clinical study. The remainder of the studies have been multiple new systematic reviews and meta-analyses of previously published clinical studies, modelling studies, and laboratory-based studies of various homemade materials.

International guidelines and practices for use of masks in the community setting:

World Health Organization guidance on the use of masks in the community

On June 5th, the WHO provided an update to prior guidance from April 6th. 2020.
The process of interim guidance development during emergencies consists of a transparent and robust process of evaluation of the available evidence on benefits and harms, synthetized through expedited systematic reviews and expert consensus-building facilitated by methodologists. This process also considers, as much as possible, potential resource implications, values and preferences, feasibility, equity, ethics and research gaps (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).

The primary differences with this update included:
Updated information on transmission from symptomatic, pre-symptomatic and asymptomatic people infected with COVID-19, as well as an update of the evidence of all sections of this document;

• New guidance on the targeted continuous use of medical masks by health workers working in clinical areas in health facilities in geographical areas with community transmission1 of COVID-19;
• Updated guidance and practical advice for decision-makers on the use of medical and non-medical masks by the general public using a risk-based approach;
• New guidance on non-medical mask features and characteristics, including choice of fabric, number and combination of layers, shape, coating and maintenance. (**WHO, June 2020)**
(see Table 1 in the Appendix).

As it relates to the: Targeted continuous medical mask use by health workers in areas of known or suspected COVID-19 community transmission, the updated WHO guidance document suggests the following guidance: (WHO, June 5, 2020)

In the context of locations/areas with known or suspected community transmission or intense outbreaks of COVID-19, WHO provides the following guidance:
• Health workers, including community health workers and caregivers, who work in clinical areas should continuously wear a medical mask during their routine activities throughout the entire shift; apart from when eating and drinking and changing their medical mask after caring for a patient who requires droplet/contact precautions for other reasons;
• According to expert opinion, it is particularly important to adopt the continuous use of masks in potential higher transmission risk areas including triage, family physician/GP practices, outpatient departments, emergency rooms, COVID-19 specified units, haematological, cancer, transplant units, long-term health and residential facilities;
• When using medical masks throughout the entire shift, health workers should make sure that:

- the medical mask is changed when wet, soiled, or damaged;
- the medical mask is not touched to adjust it or displaced from the face for any reason; if this happens, the mask should be safely removed and replaced; and hand hygiene performed;
- the medical mask (as well as other personal protective equipment) is discarded and changed after caring for any patient on contact/droplet precautions for other pathogens;

• Staff who do not work in clinical areas do not need to use a medical mask during routine activities (e.g., administrative staff);
• Masks should not be shared between health workers and should be appropriately disposed of whenever removed and not reused;
• A particulate respirator at least as protective as a US National Institute for Occupational Safety and Health-certified N95, N99, US FDA surgical N95, European Union standard FFP2 or FFP3, or equivalent, should be worn in settings for COVID-19 patients where AGPs are performed (see WHO recommendations above). In these settings, this includes its continuous use by health workers throughout the entire shift, when this policy is implemented.

To be fully effective, continuous wearing of a medical mask by health workers, throughout their entire shift, should be implemented along with other measures to reinforce frequent hand hygiene and physical distancing among health workers in shared and crowded places where mask use may be unfeasible such as cafeterias, dressing rooms, etc.

The following potential harms and risks should be carefully taken into account when adopting this approach of targeted continuous medical mask use, including:
• self-contamination due to the manipulation of the mask by contaminated hands;
• potential self-contamination that can occur if medical masks are not changed when wet, soiled or damaged;

• possible development of facial skin lesions, irritant dermatitis or worsening acne, when used frequently for long hours
• masks may be uncomfortable to wear;
• false sense of security, leading to potentially less adherence to well recognized preventive measures such as physical distancing and hand hygiene;
• risk of droplet transmission and of splashes to the eyes, if mask wearing is not combined with eye protection;
• disadvantages for or difficulty wearing them by specific vulnerable populations such as those with mental health disorders, developmental disabilities, the deaf and hard of hearing community, and children;
• difficulty wearing them in hot and humid environments.(**WHO, June 5, 2020)**

As it relates to the WHO updated Advice to decision makers on the use of masks for the general public

WHO advises decision makers to apply a risk-based approach focusing on the following criteria when considering or encouraging the use of masks for the general public:

Taking into account the available studies evaluating pre- and asymptomatic transmission, a growing compendium of observational evidence on the use of masks by the general public in several countries, individual values and preferences, as well as the difficulty of physical distancing in many contexts, WHO has updated its guidance to advise that to prevent COVID-19 transmission effectively in areas of community transmission, governments should encourage the general public to wear masks in specific situations and settings as part of a comprehensive approach to suppress SARS-CoV-2 transmission . WHO advises decision makers to apply a risk-based approach focusing on the following criteria when considering or encouraging the use of masks for the general public:

1. Purpose of mask use: if the intention is preventing the infected wearer transmitting the virus to others (that is, source control) and/or to offer protection to the healthy wearer against infection (that is, prevention).
2. Risk of exposure to the COVID-19 virus:
- due to epidemiology and intensity of transmission in the population: if there is community transmission and there is limited or no capacity to implement other containment measures such as contact tracing, ability to carry out testing and isolate and care for suspected and confirmed cases.
- depending on occupation: e.g., individuals working in close contact with the public (e.g., social workers, personal support workers, cashiers).
3. Vulnerability of the mask wearer/population: for example, medical masks could be used by older people, immunocompromised patients and people with comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer and cerebrovascular disease.
4. Setting in which the population lives: settings with high population density (e.g. refugee camps, camp-like settings, those living in cramped conditions) and settings where individuals are unable to keep a physical distance of at least 1 metre (3.3 feet) (e.g. public transportation).
5. Feasibility: availability and costs of masks, access to clean water to wash non-medical masks, and ability of mask wearers to tolerate adverse effects of wearing a mask.
6. Type of mask: medical mask versus non-medical mask

Based on these criteria, (Table 1 in appendix) provides practical examples of situations where the general public should be encouraged to wear a mask and it indicates specific target populations and the type of mask to be used according to its purpose. The decision of governments and local jurisdictions whether to recommend or make mandatory the use of masks should be based on the above criteria, and on the local context, culture, availability of masks, resources required, and preferences of the population.

Masking recommendations
The following link provides a list of countries recommending or requiring community use of masks: https://masks4all.co/what-countries-require-masks-in-public/
It is updated daily.

Mask provision
Foreseeing impending medical mask shortages, Taiwan enlisted multiple interventions to try to prevent them. These included: state-controlled production and distribution of medical masks with daily, individual, name-based rations of masks (at modest cost) distributed at local drugstore and free provision of masks for school-aged children. South Korea also implemented state control over manufacturing and now provides a weekly ration of two masks (https://www.nytimes.com/2020/04/01/opinion/covid-face-mask-shortage.html).

In Japan (https://english.kyodonews.net/news/2020/04/67ad0dfcd954-delivery-of-cloth-masks-from-govt-starts.html), Hong Kong (https://www.qmask.gov.hk/about/), and Singapore (https://www.gov.sg/article/when-should-i-wear-a-mask) mass-manufactured, re-usable, cloth masks are being provided to citizens. In Hong Kong, pre-registered, low-income families may also receive 5 disposable medical masks per week for 10 weeks at vending machine dispensers (https://finance.yahoo.com/news/world-development-mask-dispensers-live-133000505.html).

The city of Los Angeles is providing garment manufacturers with crude guidelines on sewing non-medical masks (https://www.dropbox.com/s/x9myr2t9mhxd4zo/COVID_Mask-Manufacturer-Packet.pdf?dl=0) that can then be sold to the public.

Current evidence on COVID-19 Transmission:
It is accepted that SARS-CoV-2 is transmitted via droplets (<5 μm) expelled when a patient sneezes or coughs. However, the exact distance droplets can travel has been called into question **(Bourouiba, 2020)**. Others have also posited the possibility of SARS-CoV-2 transmission through ordinary speech (**Asadi S et al, 2020)**. There is also increasing concern regarding pre-symptomatic, pauci-symptomatic, or rarely, asymptomatic transmission of COVID-19, wherein individuals have RT-PCR detectable SARS-CoV-2 from nasal or throat swabs prior to or without development of symptoms **(Bai et al. 2020, Chan et al. 2020, Pan et al. 2020, Kimball et al. 2020, Wei et al. 2020,** and **Li et al. 2020)**. It also appears that viral loads are highest during the early symptomatic phase **(To et al. 2002, Wolfel et al. 2020,** and **Bai et al. 2020**) or even the pre-symptomatic stage. Indeed, **He et al. 2020** infer that infectiousness may peak on or before symptom onset and through modelling, estimate that up to 44% of secondary cases were infected during the index cases' pre-symptomatic stage. Therefore, the main theoretical benefit of masks during the COVID-19 pandemic would be as a form of source control to minimize dispersion of the expelled viral particles from individuals unknowingly transmitting disease.

For more information, refer to the Asymptomatic Transmission of SARS-CoV-2 Rapid Review.

Clinical studies and systematic reviews examining use of medical masks to prevent transmission of COVID-19:

One new clinical study has examined masks for prevention of COVID-19 transmission in the community, specifically, in the household setting. **Wang Y et al, 2020** undertook a retrospective study of 335 people (124 families) to determine characteristics and practices of both the source case and their contacts that were predictors of secondary transmission. They determined that if one or more members of the household (either the primary case or their contacts) wore a mask *before* development of symptoms, there was a 79% reduction in transmission (OR=0.21, 95% CI: 0.06 to 0.79). In another study of 105 cases (imported from Wuhan to other centres) and 392 household contacts, the overall attack rate in households was 16.9%, but was 0% in households of 14 index patients who reportedly self isolated (used masks, dining separately, and residing alone within the home) upon (not before) symptom development (Wei Li et al, 2020).

Clinical evidence for the use of medical masks in mixed settings (clinical and community) prior to COVID-19 has been well summarized in three separate systematic reviews and meta-analyses (**Jefferson et al. 2011, Offeddu et al. 2017, Saunders-Hastings et al, 2017)**. Offeddu et al. focused only on health-care settings, Jefferson et al. 2011 and Saunders-Hasting et al. 2017 looked at mixed settings. All three reviews reported methodologic concerns related to the randomized trials that were often under-powered and prone to reporting biases. Offeddu et al, did a meta-analysis of RCTs comparing any mask (medical or N95) to no masks. They found that masks conferred significant protection against self-reported clinical respiratory illness (RR = 0.59; 95% CI: 0.46–0.77) and influenza-like illness (RR = 0.34; 95% CI: 0.14–0.82) but only a non-statistically significant effect against laboratory-confirmed viral infections. A meta-analysis of observational studies noted a protective effect of medical masks vs. no mask (OR = 0.13; 95% CI: 0.03–0.62) against SARS. Jefferson et al, 2011 undertook a meta-analysis of seven case-control studies (~50% of participants were not health care workers) with 3216 participants and found fewer acute respiratory infections with medical mask use, OR 0.32, 95% CI 0.26 to 0.39. Of all physical interventions (including hand hygiene, gowns and gloves), masks were the most effective. In a meta-analysis of three case-control studies (19% of the participants being in a household setting), Saunders-Hastings et al. found that medical masks provided a non-significant protective effect against pandemic influenza (OR = 0.53; 95% CI 0.16–1.71; I 2 = 48%).

Clinical evidence for the use of masks in the community setting (only) has also been examined, with three systematic reviews by **Brainard et al, 2020 (preprint), MacIntyre et al, 2015, and Barasheed et al, 2016.** Brainard et al, 2020 identified 31 different studies (including pre-post, cross-sectional, case-control, observational, and randomized controlled trials). 12 studies were RCTs. These authors found the evidence to be of low to very low certainty and concluded that "the evidence is not sufficiently strong to support widespread use of facemasks as a protective measure against COVID-19. However, there is enough evidence to support the use of facemasks for short periods of time by particularly vulnerable individuals when in transient higher risk situations**."** MacIntyre et al. 2015, identified 9 RCTs of facemasks in diverse settings (households and community), and with varied designs and interventions (ie. combination hand washing and facemasks). Due to the heterogeneity, no meta-analysis was undertaken. The results were inconclusive. A copy of the table summarizing these 9 articles is provided in **Table 2** of the **Appendix**. In general, the RCTs included use of a surgical grade facemask but the observational studies did not provide adequate description of the types of masks used.

Barasheed et al. 2016**,** pooled the results of 13 heterogeneously designed studies examining the effectiveness of medical masks at preventing variably defined acute respiratory infection endpoints arising during the Hajj pilgrimage. Based on studies which the authors deemed to be of “average” quality, they found a small, statistically significant benefit (RR 0.89, 95% CI 0.84-0.94). However, pooling of studies of vastly different design may be considered inappropriate from an analytic perspective and it is possible this small difference disappears when a more appropriate pooling is done.

Since the completion of the last review, multiple new systematic reviews, with or without meta-analyses, have been completed. They almost exclusively re-examined the studies already included in the reviews mentioned above.

Any setting:

- **Chu et al, 2020** did a systematic review and meta-analysis **of observational studies** (using frequentist, Bayesian meta-analysis, and random effects meta-regressions) to look at the impact of physical distancing, masks, and eye protection. Their analysis was limited to studies of coronaviruses (SARS-CoV-2, SARS-CoV, and MERS-CoV). They did not identify any randomized controlled trials. They found any masks (N95, medical mask, or 12-16 layer cotton) reduced risk of infection (unadjusted n=10,170, RR 0.34, 95% CI 0.26-0.45; adjusted studied n=2647, aOR 0.15, 95% CI 0.07-0.34) when compared to no mask. When only medical *or* 12-16 layer cotton masks were compared with no mask, the protective effect was diminished but persisted (aOR 0·33, 95% CI 0·17–0·61). There was no comparison of medical masks to cotton masks. When only the 3 community-based studies were included, masks remained protective (RR 0.56, 95% CI 0.40-0.79). Using the GRADE category of evidence, the findings were deemed to be of low certainty. This study was limited by the observational nature of the studies included which are subject to significant bias.
- **Jefferson et al, 2020** (pre-print) updated their previous review looking at physical interventions to stop the spread of respiratory viruses, this time focusing only on **randomized and cluster randomized trials**. 14 trials assessed the impact of mask wearing. Looking at general population, there was no reduction in ILI cases (RR 0.93, 9% CI 0.83 to 1.05) nor in laboratory-confirmed influenza (RR 0.84, 95% CI 0.61-1.17). No benefit was identified in health care workers either.
- **Liang et al. (pre-print)** examined use of any type of mask in any setting in preventing respiratory virus transmission. In the subgroup of non-HCW, a protective effect was found with a pooled OR of 0.53 (95% CI=0.36 - 0.79), this effect persisted in both household (OR=0.60, 95% CI=0.37-0.97) and the non-household settings (OR=0.44, 95% CI=0.33-0.59). The RCTs included in this study scored 3 or 4/5 on the Jadad scale, but it should be noted that this a quality assessment tool whose use is discouraged by the Cochrane Collaboration with concerns of its ability to detect bias.
- **MacIntyre R and Chughtai AA, 2020** looked only at randomized controlled trials. Including eight trials in community settings, and concluded that when masks were used by ill individuals, their well contacts were protected. Of note, these findings were dissimilar from many others in that among health care workers in clinical settings, they found that only continual use of respirators was beneficial, with medical masks found to be less effective and cloth masks were even less effective than medical masks.

Community settings only:

- **Wei et al. (pre-print)** did a systematic review and meta-analysis of 8 RCTs examining any type of mask in the community setting. Masks lowered the risk of developing ILI (pooled RR=0.81, 95% CI: 0.70-0.95).
- In a pre-registered, rapid review using Bayseian analysis, **Pereski et al. (pre-print)** identified 21 studies examining incidence of ILI (variably reported) in the community. All masks types were considered. 1/11 RCTs and 6/10 observational studies found that masks reduced incidence of

ILI. They found that while RCTs showed a moderate likelihood of a *small* effect of wearing medical masks in the community to reduce self-reported ILI, the risk of reporting bias was high. The evidence for reduction of clinically or lab-confirmed infection was equivocal. By contrast, observational studies showed that masks reduced incidence of ILI but there was a high risk of confounding and reporting bias. The difference in the findings between RCTs and observational studies was also noted previously by **Brainard et al.**

Cloth masks only:

- **Mondal et al. (pre-print)** looked at the utility of cloth masks in any setting. They included both clinical and non-clinical studies, in what can be more accurately described as a scoping review. They found two clinical studies, only one of which assessed the clinical effectiveness of cloth masks. This was the study by **MacIntyre et al, 2015** which is discussed later in this review. In the laboratory studies, cloth mask filtration efficiency was highly variable, between 3-95%, likely reflecting the highly variable materials and measurement techniques.

Laboratory based studies examining use of medical masks to prevent transmission of COVID-19:

Given the challenges of clinical studies, another approach has been to directly measure the efficacy of medical masks in both filtering exhaled respiratory viruses and in providing a barrier to entrance of pathogens.

In the only laboratory study to look at coronaviruses, **Leung et al, April 2020** found that coronaviruses could be detected in respiratory droplets (>5um) and aerosols (<5 uM) in 3/10 (30%) and 4/10 (40%) of samples collected without medical masks, respectively. They did not detect any virus in respiratory droplets or aerosols collected from participants wearing medical masks.

Multiple other studies have examined the use of masks for preventing spread of other respiratory pathogens. **Milton et al, 2013** found that medical masks reduced influenza viral copy numbers in exhaled samples by ~3-25 fold (depending on the size of the particle). **Johnson et al, 2009** could detect influenza in all samples of exhaled breath where a mask was not worn but detected no influenza virus by RT-PCR with medical masks. In two separate studies medical masks reduced the release of *Pseudomonas aeruginosa* in patients with cystic fibrosis both when worn for short **(Stockwell et al, 2018)** and longer durations **(Stockwell et al, 2018). Dharmadhikari et al, 2012**, examined the benefit of medical masks as a form of source control on a multi-drug resistant tuberculosis ward where exhaust air from patients is delivered to guinea pig exposure chambers. Compared to patients who did not wear a masks, patients who did wear a mask infected 56% fewer guinea-pigs (36/90 vs 69/90 infected guinea pigs).

Two studies have examined the effectiveness of medical masks to protect the wearer, as a barrier against viral bioaerosols. Ma et al, 2020 found that compared with one-layer of polyester, medical masks blocked 97.15% of avian influenza viral bioaerosols while a 4-layer homemade mask blocked 95.15%. The high efficacy rates of the masks may have been related to the unrealistically tight seals in the model used. **Makison-Booth et al, 2013** realistically adhered masks to the face of a mannequin and then measured the amount of viable live influenza virus from the air in front and behind of five different types of surgical masks. They found that medical masks reduced exposure to aerosolized influenza virus by approximately 6-fold.

Thus, the preponderance of lab-based studies (Milton et al 2013, Johnson et al, 2009, Stockwell et al. 2018, Stockwell et al. 2018, Dharmadhikari et al, 2012, and Leung et al, 2020) suggest the benefit of a mask is as a method of source control with reduction of the amount of respiratory virus released by exhaled particles. That is, the public would be protected from respiratory spread of infection from the mask wearer.

Other studies (modelling, ecological, anecdotal, etc) examining use of medical masks to prevent transmission of COVID-19:

Influenza transmission models:
Brienen et al, 2010 developed a population transmission model to explore the impact of population-wide mask use on an influenza pandemic. They assumed that the reduction in infection risk would be proportional to the reduction in exposure to the virus based on particle retention by the mask and mask coverage (number of people appropriately wearing masks). It is unknown if this assumption is valid. They concluded that masks could lower the basic reproduction number, at least delaying, if not containing, an influenza outbreak. A detailed transmission model by **Trachet et al, 2009;** however was less optimistic, concluding that while 10% of the population using N95 masks could result in a 20% reduction in H1N1, even 50% of the population wearing medical masks would only results in a 6% reduction in number of cumulative cases. In their model, **Yan et al, 2019,** found that at a population-level compliance of 50%, all types of masks—except low-filtration surgical mask—could reduce prevalence of influenza outbreak to <5%. At a compliance rate of 80%, low-filtration surgical masks (not otherwise defined) could reduce prevalence by 50%.

COVID-19 models: In a model assessing various local interventions, **Tian et al, 2020 (preprint)** estimated reductions in the basic reproduction number $R0$ of SARS-CoV-2 with different interventions. Assuming masks reduce $R0$ by a factor $(1 - epm)^2$, where e is the efficacy of trapping viral particles inside the mask, and pm is the percentage of the population that wears masks – for example, if 50% of the population wears a mask and the mask has a 50% efficacy at trapping particles, $R0$ could drop to 1.35 (down from ~2.4). It is unknown if this assumption is valid.

Eikenberry et al. 2020 developed a mathematical model that adapted the SEIR model of Breinen et al. and Trachet et al. to the COVID19 pandemic epidemiologic parameters and then looked at the impact of varying mask efficacy and compliance rates on transmissions and epidemiologic outcomes (death, hospitalizations). They found that 80% coverage of masks that are only 20% effective could still reduce the effective transmission rate by 1/3. Applied to a case study of Washington state, this could translate into a reduction in mortality of 24-65%. **Javid et al, 2020 (pre-print)** created a simple, proof of principle, SIR model, assuming that masks reduced transmission by 8-16%. Like Eikenberry et al. where there was more mortality benefit seen in areas of lower transmission, Javid et al. noted a more substantial reduction on deaths when the effective R approached 1. Finally, **Worby et al, 2020 (pre-print)** created a SEIRD model to test various strategies for mask allocation (ie. different percentage of allocation to symptomatic vs asymptomatic individuals; or to the elderly population). First, they found that the more effective the mask, the lower the population uptake required. That is, deaths could be reduced by 65% with 15% coverage of a highly effective mask (75%) whereas they would be reduced by only 10% with 30% coverage with a low effectiveness mask (25% containment). In terms of mask allocation, they identified that prioritizing the elderly and maintaining a supply for identified infectious cases is a superior strategy to random distribution.

It should be noted that all the modelling studies listed vary the effectiveness of masks in the model; however, they do not assume that masks can carry harms that could outweigh benefits.

In an ecologic study, **Lo JY et al, 2005** found that in the setting of “community hygienic measures” promotion during the SARS 2003 epidemic in Hong Kong, where ~76% of individuals were wearing masks, the proportion of positive specimens of other respiratory viruses dropped significantly in 2003. A similar finding has been noted in Hong Kong since February 2020, where again mask use has increased with the COVID19 outbreak **(Leung et al, 2020). Kenyon et al. (pre-print)** compared countries who had implemented mask use vs no-mask use (as a binary outcome). At the time of the analysis, 8/49 countries promoted universal mask use. After adjusting for date of the first COVID-19 diagnosis in the country and testing intensity, they found that masking resulted in an average decrease of 326 cases per 1,000,000 inhabitants (linear coefficient -326, -601 to -51, p=0.021). These studies do not allow the effect of masks to be separated from other community measures, including social distancing with school closure, public space closures, hand hygiene, and household hygiene campaigns. When undertaking ecological comparisons, it should be noted that countries such as New Zealand, Australia, Denmark, and Switzerland have had success at containment of their epidemics without the use of universal masking.

There are also two case cluster reports outlining the benefits of community mask use. It is unclear if medical or non-medical masks were used. **Zhang et al, 2013** assessed transmission of influenza A virus on two flights from the United States to China. None of the 9 influenza-infected passengers, compared with 47% (15/32) of control-passengers wore a face mask. Unfortunately, this report does not include any information regarding the location of the other passenger relative to the index case. **Liu et al, 2020** report a case of a SARS-CoV-2 infected male who took two separate buses to return to his hometown. On the first 2-hour bus ride, he did not wear a mask and 5/39 passengers were infected. By contrast, on his second ride, a 50-minute ride, he wore a mask and 0/14 passengers were infected. While **Schwartz et al. 2020** do not focus on the use of a mask by the source case, the source case was masked during a flight from China to Toronto where no SARS-CoV-2 transmissions were identified.

<u>Studies of cloth masks:</u>

Clinical studies

The only clinical study of cloth masks is a cluster randomized trial of cloth masks at all times vs medical masks at all times (2 masks/8h) vs a standard practice arm in hospitals in Vietnam **(Macintyre et al, 2015)**. In this study, cloth mask users had higher rates of ILI compared with the control arm, RR=6.64, 95% CI 1.45 to 28.65 and more laboratory-confirmed virus, RR=1.72, 95% CI 1.01 to 2.94. Compared to medical masks, the RR for ILI was 13.25 in the cloth mask arm and 3.8 in the control (mixed) arm. A possible hypothesis for the worse outcome with cloth masks is that when they become wet, they are more likely to trap viral particles. Alternatively, there may be inadequate washing of the masks.

However, a methodologic concern was that the control arm consisted of high rates of mask wear. Specifically, in the control arm, (170/458) 37% used medical masks and (245/458) 53% used a combination of medical masks and cloth masks, with 24% of control arm participants wearing masks for more than 70% of working hours (versus 57% of participants in the other 2 arms adherent to masks for >70% of working hours). This renders the comparison to have been consistent cloth mask use, to consistent medical mask use, to inconsistent use of any mask type. Therefore, while the study may have conclusively shown the superiority of medical masks to cloth masks in preventing infection acquisition in a health-care setting, it cannot be used to reliably evaluate cloth masks to no masks in a community setting. Given the sudden interest in cloth-mask use, the authors published a response to their own article on March 30, 2020 **(MacIntyre et al. 2020)** wherein they state that HCW should not work without adequate PPE but if they choose to work with a cloth masks, thorough and daily disinfection is required to prevent potential harms. In another commentary, the same author (**MacIntyre CR and Hasanain SJ, 2020)** supports universal masking, stating “There is more evidence supporting face mask use in the community than hand hygiene including in RCTs which compare both interventions directly, so it is inconsistent to advocate hand hygiene as a sound principle but not masks."

Laboratory based studies
Several contemporary and historical studies have looked at whether homemade masks are able to reduce the physical spread of droplets by the mask wearer. In a laser-light scattering experiment, **Anfinrud et al. 2020**, qualitatively showed that while regular speech resulted in droplets ranging in size from 20 to 500 μm, a slightly damp washcloth over the mouth could decrease these forward moving particles. After assessing the filtration performance of a variety of household fabrics (using NaCl aerosols of smaller size than droplets), **Rangesamy et al, 2010** concluded that while markedly inferior to N95 respirators, the filtration rate of some household materials was comparable to surgical masks. **Davies et al, 2013** found that masks made from cotton t-shirt fabric had a filtration efficiency of viral particles of ~50% as compared to ~90% for medical masks and that medical masks were 3 times more effective in blocking transmission than homemade masks. **Dato et al. 2006,** also found some protection against an aerosol challenge with the use of a homemade cotton mask.

We identified two studies examining the theoretical benefit of homemade masks in reducing personal risk of exposure to particles. As previously noted**, Ma et al. 2020,** found a homemade mask of one polyester cloth layer and 4 layers of kitchen paper to be as effective as medical masks in providing protection against avian influenza virus bioaerosols. However, an artificially tight seal may have been present in this model. **van der Sande et al, 2008** found that medical masks provided about twice as much protection as homemade masks against the entrance of particles. Notably and unlike other groups, they did not find that masks significantly prevented outward dispersal.

Since the last update, we identified multiple other laboratory-based studies investigating filtration efficiency, 3 of which were completed since the last update.
Historical studies

- **Greene et al, 1961** had volunteers wear muslin and flannel masks (the standard for medical masks at the time) in a contained chamber. Bacterial recovery on agar sedimentation plates was dramatically reduced (by 88% to >99% depending on the particle size).
- **Quesnel et al, 1975** used a similar chamber to Green et al. and volunteers were asked to try 4 disposable medical masks and one cotton mask. The filtration efficiency of the cotton mask (after 30 minutes of wear) for larger droplets (>3 *μ*m) >99%.

***Air pollution and fine particulate matter (aerosol) studies* (<2.5 *μ*m)**

- A study by **Shakya et al. 2017**, that was assessing filtration potential of cloth masks for fine particulate matter (air pollution related study) noted that the filtration efficiency of three particle sizes (30, 100, and 500 nm) ranged from 15% to 57%, thus they felt that cloth masks would be of limited utility for particles<2.5 *μ*m.
- **Jung et al, 2014**, also assessed a variety of masks for protection against aerosols. Their testing adhered to the Korean Food and Drug Administration (KFDA) [similar to the European Union (EU) protocol] and the National Institute for Occupational Safety and Health (NIOSH) protocols. 44 different types of masks were tested. On average, the aerosols used for testing were less than 2.5 ***μ*m.** The filtration efficiency of medical masks was only about 60% and only in the 2-12% range for cloth handkerchiefs. Pressure drop was also measured. They found that "general masks" and handkerchiefs provided little protection against aerosols.

- **Jang et al, 2015 [only available in Korean; abstract was reviewed],** using polydisperse NaCl aerosols (0.3~10 μm), compared five commercial cloth masks vs. a respirator. The filtration efficiencies varied from 9.5-28.5% as compared with 91% by the respirator but increased by 1.7-6.8 times after folding to create multiple layers. Washing once reduced filtration efficiency. The authors warned that cloth masks were inadequate in protecting against particulate matter.

Bioaerosol and polydisperse NaCl aerosol studies

- **Rodriguez-Palacios et al, 2020 (pre-print)** used household spray bottles filled with a bacterial suspension to see whether various textiles could prevent dispersion of the bacterial solution (which they said mimicked a sneeze) onto agar containing Petri dishes. All the fabrics used, even in one layer, reduced droplet dispersion to <30cm. As a double layer, they were as effective as medical masks and reduced droplet dispersion to <10cm. The relevance of this model is questionable.
- **Wang et al, 2020 (pre-print)** used industry approved standardized tests to compare 17 different fabrics against approved medical masks. Testing pressure difference (breathability), particle filtration efficiency, bacterial filtration efficiency, and resistance to surface wetting, they found that only 3 materials would pass industry standards. The results showed that three double-layer materials including double-layer medical non-woven fabric (example, polypropylene) medical non-woven fabric plus non-woven shopping bag, and medical non-woven fabric plus granular tea towel could meet all the standards of breathability, particle filtration efficiency (>30%), and resistance to surface wetting, and were close to the standard of the bacterial filtration efficiency (>95%).
- **Aydin et al, 2020 (preprint)** compared one brand of medical mask to a variety of homemade fabrics to assess for: efficiency of blocking droplets, breathability, weight, hydrophilicity, and texture. To measure droplet blockage (or filtration) efficiency, they used a metered-dose inhaler (MDI) loaded with fluorescent beads, of similar size to SARS-CoV-2 virus (70-100nm). A petri dish covered with the various materials was then held 36mm and 300mm away from the MDI and the number of fluorescent beads penetrating through to the petri dish were measured. In this study, even one layer of a 100% cotton t-shirt had 91% efficiency. And while a blend of cotton and polyester had only 40% efficiency, this increased to 99.98% with 3 layers. They concluded that multiple fabrics were comparable to a medical mask in terms of filtration and breathability. However, a 2-3 layer cotton/polyester blend was the closest; despite being far less hydrophobic. Of note, the materials appear to have been tightly adhered to the petri dish.
- **Konda et al, 2020** also tested a variety of household materials. They introduced a polydisperse NaCl aerosol into a mixing chamber, where it passed through the material being tested (held down tightly by a clamp). They analyzed particle size with two different particle analyzers and followed the protocol used for testing face respirators in compliance with the NIOSH 42 CFR Part 84 test protocol. For droplets >300nm, several materials had filtration efficiency equivalent to a medical mask (>95% efficiency), including even one layer of a high thread count cotton. However, the authors recommended a hybrid fabric (cotton + silk) that could leverage both mechanical and electrostatic properties. Furthermore, the authors found that even small gaps (hole of 1% surface area) could reduce filtration efficiency by 60%, highlighting the importance of a tight fit
- **Zhao et al, 2020** evaluated common materials using a modified version of the NIOSH standard test procedure for N95 respirator approval. They used NaCl aerosols (0.075 ± 0.02 μm), without taking real-world leakage from around the mask into account, to identify the material with the highest filtration quality factor (Q) – a metric that results from a high filtration efficiency (low penetration) with low pressure drop. They identified that polypropylene spunbound, a material

commonly found in reusable bags, had the optimal *Q*. While the filtration efficiency was ~6-10% (which was similar to the other fabrics tested), if it were triboelectrically charged or multiple layers were added, its filtration efficiency improved without a concomitant increase in pressure. In fact, as compared with the medical masks they tested (~19-33% filtration efficiency), the five-layer polypropylene had a filtration efficiency of ~50% with a lower pressure drop.

Though there are now many different laboratory studies to draw from, the variability of the methodology of the studies and the variability in their findings make their interpretation challenging. Taken together, these studies suggest that non-medical masks can act as a barrier to outward dispersion of droplets (but not particles <2.5 μm). For that reason, WHO states that non-medical masks “should only be considered for source control (used by infected persons) in community settings and not for prevention”.

Despite the challenges of interpreting non-medical mask studies, a non-medical mask standard has been developed by the French Standardization Association (AFNOR Group) (https://www.afnor.org/en/faq-barrier-masks/). AFNOR Group defines minimum performance in terms of filtration (minimum 70% solid particle filtration or droplet filtration) and breathability (maximum pressure difference of 0.6 mbar/cm2 or maximum inhalation resistance of 2.4 mbar and maximum exhalation resistance of 3 mbar).

In addition, in its latest interim guidance report (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), WHO has now provided guidance on the optimal composition and construction of non-medical masks. They advise that when decision-makers are providing recommendations on masks, they should take filtration efficiency, breathability, number and combination of materials used, shape, coating and maintenance into account. Using the filter quality factor “Q” metric, which is a function of filtration efficiency and breathability (with higher values being better), they advise the following mask composition:

a) Inner layer of a hydrophilic material (cotton or cotton blend)
b) Outer layer of a hydrophilic material (ie. polypropylene, polyester or blend)
c) Middle hydrophobic layer of a synthetic non-material such as polypropylene or a cotton layer

Table 3 in the **Appendix** provides a list of different materials with their corresponding filter quality factor as well as filtration efficiency and breathability.

In terms of fit, they also recommend a tightly-fitted flat-fold or duckbill shape.
(WHO, June 5, 2020)

Theoretical sociological benefits and harms of mask use in COVID-19:

From a sociologic perspective, some have noted that if mask wearing were widespread and not just limited to those who are feeling ill, it would reduce the stigma associated with their use and increase the likelihood of their use in ill individuals. Similarly, mask use may act as a visual cue reminding individuals to maintain physical distance and act as visible signal of social solidarity (preprint, **Howard et al. 2020**). In terms of acting as a visual cue, **Seres et al, 2020** undertook a field experiment where they randomized 300 individuals to “exposure” to an individual wearing a mask vs no-mask. Specifically, the *experimenter* was randomly assigned to wear a mask or not. Then, they took the last position in line-ups (ie. a supermarket, store) and noted the distance with which the subsequent customer would stand. Individuals kept a statistically significantly further distance when someone was wearing a mask.

Subsequent survey data suggested this was because it was perceived that a masked person preferred more distance.

Finally, it is becoming increasingly clear that racial minorities are disproportionately impacted by COVID-19 (**Hooper et al, 2020)**. In addition to underlying co-morbidities and structural inequalities (ie. lack of access to healthcare), this discrepancy may be attributed to living conditions and employment. As **Yang, 2020** stated "social distancing is a privilege". For instance, outside of LTC outbreaks, most outbreaks in Calgary, Alberta are occurring at warehouses and workplaces (https://www.alberta.ca/covid-19-alberta-data.aspx#toc-1) where social distancing either cannot be or is not being enforced. Mandatory masking, with provision of masks and targeted education about mask hygiene, may be particularly helpful in such settings.

There are also several possible harms associated with widespread mask use. There is concern that moisture retention could increase the risk of infection which is one possible interpretation of the McIntyre study. Masks may also increase the frequency with which individuals touch their face. There is also concern regarding self-contamination of the hands or face with improper donning and doffing technique. In an observational study of ~10,000 pedestrians in Hong Kong in February 2020, 94% of individuals wore masks (84% of which were medical masks). However, 13% of individuals wore them incorrectly, with 5% wearing them inside out or upside-own and 5% wearing them too low **(Tam et al, 2020).**

The importance of risk-compensation in population-level health interventions has been called into question **(B Pless, 2016).** However, the potential harms of masks in creating a false sense of security and consequent neglect of physical distancing or hand hygiene is raised by the World Health Organization **(WHO, 2020).** A recent study by **Yan et al, 2020 (pre-print)** used smart device location data to determine the time spent at home and at various public locations before and after mask mandates were implemented in 36 different states. They accounted for weather patterns, re-openings orders, and time since stay-at-home orders were implemented. They found that masks mandates were associated with an increase of 4% (20-30 minutes) of time outside the home per day and they specifically noted more trips to restaurants. This suggests that for mask to be beneficial, their efficacy in reducing transmission needs to exceed the increased risk associated with a 4% increase in time away from home.

Another concern is related to the environmental impact of mass use of medical masks. For instance, the sheer numbers of disposable masks that would be required in China would be around 900 million daily and would pose significant disposal challenges **(Wang MW et al, 2020).** Safe disposal concern are already arising throughout Asia (https://www.bangkokpost.com/opinion/opinion/1924908/face-mask-crisis-of-another-design)

Another major concern is the risk of PPE shortages for HCW who are more frequently exposed to SARS-CoV-2 than the general public. Indeed, there have been shortages globally, with some countries

Date question received by advisory group: March 31, 2020

Date report submitted to committee: April 2, 2020

Date of first assessment: April 3, 2020

(If applicable) Date of re-assessment: June 19, 2020 banning or threatening to ban export of medical masks (https://www.cnbc.com/2020/04/03/coronavirus-trump-to-ban-export-of-protective-gear-after-slamming-3m.html), and with reports of hoarding and price gouging.

Authorship and Committee Members

This report was written and updated by Leyla Asadi and scientifically reviewed by Elizabeth Mackay (primary reviewer), Lynora Saxinger (co-chair), and Nelson Lee. The full Scientific Advisory Group was involved in discussion and revision of the document: Braden Manns (co-chair), John Conly, Alexander Doroshenko, Shelley Duggan, Andrew McRae, Jeremy Slobodan, James Talbot, Brandie Walker, and Nathan Zelyas.

Appendix

The literature search was conducted by Lauren Seal from the AHS Knowledge Resource Service. The literature search was last updated on May 14, 2020.

Medline/PubMed

1 exp Coronavirus/ or exp Coronavirus Infections/ or coronaviru*.mp. or "corona virus*".mp. or ncov*.mp. or n-cov*.mp. or COVID-19.mp. or COVID19.mp. or COVID-2019.mp. or COVID2019.mp. or SARS-COV-2.mp. or SARSCOV-2.mp. or SARSCOV2.mp. or SARSCOV19.mp. or Sars-Cov-19.mp. or SarsCov-19.mp. or SARSCOV2019.mp. or Sars-Cov-2019.mp. or SarsCov-2019.mp. or "severe acute respiratory syndrome cov 2".mp. or "2019 ncov".mp. or "2019ncov".mp. (18987)

2 Masks/ (4203)

3 mask.mp. (28586)

4 masks.mp. (15768)

5 facemask.mp. (1101)

6 "face-mask".mp. (2557)

7 (face adj2 mask*).mp. (3254)

8 2 or 3 or 4 or 5 or 6 or 7 (37583)

9 homemade.mp. (2899)

10 home-made.mp. (2094)

11 "home made".mp. (2094)

12 handmade.mp. (505)

13 "hand made".mp. (346)

14 hand-made.mp. (346)

15 handcraft*.mp. (335)

16 hand-craft*.mp. (321)

17 "hand craft*".mp. (321)

18 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 (6424)

19 8 and 18 (32)

20 8 or 19 (37583)

21 1 and 20 (140)

22 limit 21 to last year (19)

CINAHL

S1 (MH "Coronavirus+")

S2 (MH "Coronavirus Infections+")

S3 coronaviru*

S4 "corona virus"

S5 ncov*

S6 n-cov*

S7 COVID-19 OR COVID19 OR COVID-2019 OR COVID2019

S8 SARS-COV-2 OR SARSCOV-2 OR SARSCOV2 OR SARSCOV19 OR SARS-COV-19 OR SARSCOV-19 OR SARSCOV2019 OR SARS-COV-2019 OR SARSCOV-2019

S9 "severe acute respiratory syndrome cov 2" OR "severe acute respiratory syndrome coronavirus*"

S10 "2019 ncov" OR 2019ncov OR Hcov*

S11 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10

S12 (MH "Masks") 2,140

S13 mask OR masks OR facemask OR face-mask OR face N2 mask OR medical N2 mask OR face N2 cover* 10,693

S14 S12 OR S13 10,693

S15 homemade OR home-made OR "home made" OR handmade OR hand-made OR "hand made" OR handcraft* OR hand-craft* OR "hand craft*" 2,013

S16 S14 AND S15 10

S17 S14 OR S16 10,693

S18 S11 AND S17 87

S19 S11 AND S17 Limiters - Published Date: 20190101-20201231

12

TRIP Pro/Google Scholar/Google/ LitCovid/CEBM/ /Twitter/WHO/Stanford Medicine/REACTing/Nebraska Medicine COVID-19 resources/CAIC-RT – COVID-19 Capacity Tool/NEJM/ The Oakes Academy Coronavirus Clinical Collaboration/CochraneLibrary

("covid-19" OR coronavirus OR COVID19 OR “corona virus” OR ncov OR “n-cov” OR “covid-2019” OR covid2019 OR “SARS-COV-2” OR “sarscov-2” OR sarscov2 OR sarscov19 OR “sars-cov-19” or “sarscov-19” OR sarscov2019 OR “sars-cov-2019” OR “severe acute respiratory syndrome”) AND (mask OR facemask OR “face-mask” OR “face mask” OR “face cover” OR “face covering” OR “homemade mask” OR “home-made mask” OR “handmade mask” OR “hand-made mask” OR “handcrafted mask” OR “hand-crafted mask”)

(mask OR facemask OR “face-mask” OR “face mask” OR “face cover” OR “face covering” OR “homemade mask” OR “home-made mask” OR “handmade mask” OR “hand-made mask” OR “handcrafted mask” OR “hand-crafted mask”)

mask

facemask

face covering

Critical Appraisal

Table 2. Summary of quality assessment results for articles included in this review

				Mixed Methods Appraisal Tool Criteria:	
	Reference	Peer reviewed?	Type of evidence	Are there clear research questions or a clearly identified issue?	Is the collected data or presented evidence appropriate to address the research questions or issue?
1.	Jefferson T, Del Mar CB, Dooley L, Ferroni E, Al-Ansary LA, Bawazeer GA, van Driel ML, Nair S, Jones MA, Thorning S, et al. 2011. Physical interventions to interrupt or reduce the spread of respiratory viruses. The Cochrane Database of Systematic Reviews. 2011(7):CD006207.	☒ Yes	Systematic review and meta-analysis	☒ Yes	☒ Yes

2.	Offeddu V, Yung CF, Low MSF, Tam CC. 2017. Effectiveness of masks and respirators against respiratory infections in healthcare workers: A systematic review and meta-analysis. Clinical Infectious Diseases : An Official Publication of the Infectious Diseases Society of America. 65(11):1934-42.	☒ Yes	Systematic review and meta-analysis	☒ Yes	☒ Yes
3	Saunders-Hastings P, Crispo JAG, Sikora L, Krewski D. 2017. Effectiveness of personal protective measures in reducing pandemic influenza transmission: A systematic review and meta-analysis. Epidemics. 20(C):1-20.	☒ Yes	Systematic review and meta-analysis	☒ Yes	☒ Yes
4	Brainard J ea. 2020. Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review.	☐ No (pre-print)	Systematic review and meta-analysis	☒ Yes	☒ Yes
5	WHO. Advice on the use of masks in the context of COVID19. Available at: https://www.who.int/publications-detail/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 .		WHO guidelines		
6	MacIntyre CR, Chughtai AA. 2015. Facemasks for the prevention of infection in healthcare and community settings. BMJ : British Medical Journal. 350(apr09 1):h694.	☒ Yes	Review article	☒ Yes	☒ Yes
7	MacIntyre CR, Seale H, Dung TC, Hien NT, Nga PT, Chughtai AA, Rahman B, Dwyer DE, Wang Q. 2015. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers. BMJ Open. 5(4):e006577.	☒ Yes	Cluster randomzied trial	☒ Yes	☒ Yes
8	Leung, N.H.L., Chu, D.K.W., Shiu, E.Y.C. *et al.* Respiratory virus shedding in exhaled breath and efficacy of face masks. *Nat Med* (2020). https://doi.org/10.1038/s41591-020-0843-2	☒ Yes	Randomzied lab-based trial	☒ Yes	☒ Yes
9	Davies A, Thompson K, Giri K, Kafatos G, Walker J, Bennett A. 2013. Testing the efficacy of homemade masks: Would they protect in an influenza pandemic? Disaster Medicine and Public Health Preparedness. 7(4):413-8.	☒ Yes	Laboratory	☒ Yes	☒ Yes
10	Makison Booth C, Clayton M, Crook B, Gawn JM. 2013. Effectiveness of surgical masks against influenza bioaerosols. Journal of Hospital Infection. 84(1):22-6.	☒ Yes	Laboratory	☒ Yes	☒ Yes

APPENDIX

Table 1: Situations and types of masks recommended for use in the community (from the World Health Organization, June 2020 interim guidance "Advise on the use of masks in the context of COVID-19")

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

Situations/settings	Population	Purpose of mask use	Type of mask to consider wearing if recommended locally
Areas with known or suspected widespread transmission and limited or no capacity to implement other containment measures such as physical distancing, contact tracing, appropriate testing, isolation and care for suspected and confirmed cases.	General population in public settings, such as grocery stores, at work, social gatherings, mass gatherings, closed settings, including schools, churches, mosques, etc.	Potential benefit for source control	Non-medical mask
Settings with high population density where physical distancing cannot be achieved; surveillance and testing capacity, and isolation and quarantine facilities are limited	People living in cramped conditions, and specific settings such as refugee camps, camp-like settings, slums	Potential benefit for source control	Non-medical mask
Settings where a physical distancing cannot be achieved (close contact)	General public on transportation (e.g., on a bus, plane, trains) Specific working conditions which places the employee in close contact or potential close contact with others e.g., social workers, cashiers, servers	Potential benefit for source control	Non-medical mask
Settings where physical distancing cannot be achieved and increased risk of infection and/or negative outcomes	Vulnerable populations: • People aged ≥60 years • People with underlying comorbidities, such as cardiovascular disease or diabetes mellitus, chronic lung disease, cancer, cerebrovascular disease, immunosuppression	Protection	Medical mask
Any setting in the community*	Persons with any symptoms suggestive of COVID-19	Source control	Medical mask

*This applies to any transmission scenario

Table 2. Summary of high level evidence (GRADE guidelines) on facemasks in the household setting (from: Raina MacIntyre, and Abrar Ahmad Chughtai BMJ 2015;350:bmj.h694)

Study, year of publication	Design, participants	Mask type, intervention	Outcome	Results	Comments, limitations, biases
Cowling[11] 2008	• Cluster RCT • 198 index cases and household contacts • Hong Kong	• Medical masks • Hand hygiene • Control	• Self reported influenza symptoms • Laboratory confirmed influenza (by culture or RT-PCR) in household	• No significant difference in rates of laboratory confirmed influenza (OR 1.16, 95% CI 0.31 to 4.34) and ILI (0.88, 0.34 to 2.27) in the medical masks arm versus control arm	• Both index cases and household contacts used medical masks • This pilot study was small and underpowered • Compliance 45% in index cases and 21% in household contacts • Compliance data showed that some index cases in the control and hand hygiene arms used medical masks
Cowling[12] 2009	• Cluster RCT • 407 index cases and 794 household contacts • Hong Kong	• Hand hygiene • Masks + hand hygiene • Control (education)	• Self reported influenza symptoms • Laboratory confirmed influenza (by RT-PCR) in household	• No significant difference in rate of laboratory confirmed influenza in three arms • Significant difference if masks + hand hygiene together applied within 36 hours of illness (OR 0.33, 0.13 to 0.87) • Hand hygiene alone was not significant	• No separate medical mask arm, making it difficult to evaluate the efficacy of masks • Both index cases and household contacts used masks • Compliance 49% in index cases and 26% in household contacts using masks • Compliance data showed that some index cases in the control and hand hygiene arms used medical masks
MacIntyre[13] 2009	• Cluster RCT • 145 child index cases and well adult household contacts • Australia	• Medical masks for contacts • P2 respirators (equivalent to N95) for contacts • Control	• Self reported ILI • Laboratory confirmed respiratory infection	• No significant difference in ILI and laboratory confirmed respiratory infections in all three arms • Adherent use of P2 or medical masks significantly reduced the risk of ILI (HR 0.26, 0.09 to 0.77)	• Only household contacts used medical masks • Low compliance: 21% of household contacts wore masks often/always
Aiello[14] 2010	• Cluster RCT • 1437 well university residents • Michigan, USA	• Medical masks • Medical masks + hand hygiene • Control	• Self reported ILI • Laboratory confirmed influenza (by culture or RT-PCR)	• No significant difference in ILI in three arms • Significant reduction in ILI in the medical masks + hand hygiene arm over 4-6 weeks ($P<0.05$)	• Self reported ILI • Not all ILI cases (n=368) were laboratory tested (n=94) • No data on compliance
Larson[15] 2010	• Block RCT • 617 households • Manhattan, USA	• HE • HE + hand sanitiser • HE + hand sanitiser + medical masks	• Self reported ILI • Self reported URI • Laboratory confirmed influenza through culture	• No significant difference in rates of URI, ILI, or laboratory confirmed influenza between the three arms • Significantly lower secondary attack rates of URI/ILI/influenza in the HE	• No separate medical masks group • Household contacts used medical masks • Low compliance and around half of household in the masks arm used
Canini[16] 2010	• Cluster RCT • 105 index cases and 306 households • France	• Medical mask (as source control to be used by index case) • Control	• Self reported ILI in household	• No significant difference in the rates of ILI between the two arms (OR 0.95, 0.44 to 2.05)	• Trial stopped early owing to low recruitment and influenza A/H1N1-pdm09 in subsequent year
Simmerman[17] 2011	• Cluster RCT • 465 index patients and their families • Thailand	• Hand hygiene • Hand hygiene + medical masks • Control	• Self reported ILI • Laboratory confirmed influenza by PCR and serology in family members	• No significant difference in secondary influenza infection rates between hand hygiene arm (OR 1.20, 0.76 to 1.88) and hand hygiene plus medial masks arm (1.16, 0.74 to 1.82)	• No separate medical mask group • Owing to H1N1 pandemic, hand and respiratory hygiene campaigns and mask use substantially increased among the index cases (from 4% to 52%) and families (from 17.6% to 67.7%) in control arm
Aiello[18] 2012	• Cluster RCT • 1178 university residents • Michigan, USA	• Medical masks • Medical masks + hand hygiene • Control	• Clinically diagnosed and laboratory confirmed influenza (by RT-PCR)	• No overall difference in ILI and laboratory confirmed influenza in three arms • Significant reduction in ILI in the medical masks + hand hygiene arm over 3-6 weeks ($P<0.05$)	• Good compliance: medical mask + hand hygiene group used masks for 5.08 h/day (SD 2.23) and medical mask group used masks for 5.04 h/day (SD 2.20) • Self reported ILI • Effect may have been due to hand hygiene because medical masks alone not significant
Suess[19] 2012	• Cluster RCT • 84 index cases and 218 household contacts • Berlin, Germany	• Masks • Masks + hand hygiene • Control	• Laboratory confirmed influenza infection and ILI	• No significant difference in rates of laboratory confirmed influenza and ILI in all arms by intention to treat analysis • The risk of influenza was significantly lower if data from two intervention arms (masks and masks + hand hygiene) were pooled and intervention was applied within 36 hours of the onset of symptoms (OR 0.16, 0.03 to 0.92)	• Around 50% participants wore masks "mostly" or "always" • Participants paid to provide respiratory samples

CI=confidence interval; CRI=clinical respiratory infection; HCW=healthcare worker; HE=health education; HR=hazard ratio; ILI=influenza-like illness; OR=odds ratio; PCR=polymerase chain reaction; RCT=randomised controlled trial; RR=relative risk. RT=reverse transcriptase; SD=standard deviation; URI=upper respiratory tract infection.

Table 3. Non-medical mask filtration efficiency, pressure drop and filter quality factor* (from the World Health Organization, June 2020 interim guidance "Advise on the use of masks in the context of COVID-19" Adapted from Jung et al, 2014 and Zhao et al, 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

Table 3. Non-medical mask filtration efficiency, pressure drop and filter quality factor*

Material	Source	Structure	Initial Filtration Efficiency (%)	Initial Pressure drop (Pa)	Filter quality factor, Q ** (kPa^{-1})
Polypropylene	Interfacing material, purchased as-is	Spunbond (Nonwoven)	6	1.6	16.9
Cotton 1	Clothing (T-shirt)	Woven	5	4.5	5.4
Cotton 2	Clothing (T-shirt)	Knit	21	14.5	7.4
Cotton 3	Clothing (Sweater)	Knit	26	17	7.6
Polyester	Clothing (Toddler wrap)	Knit	17	12.3	6.8
Cellulose	Tissue paper	Bonded	20	19	5.1
Cellulose	Paper towel	Bonded	10	11	4.3
Silk	Napkin	Woven	4	7.3	2.8
Cotton, gauze	N/A	Woven	0.7	6.5	0.47
Cotton, handkerchief	N/A	Woven	1.1	9.8	0.48
Nylon	Clothing (Exercise pants)	Woven	23	244	0.4

* This table refers only to materials reported in experimental peer-reviewed studies. The filtration efficiency, pressure drop and Q factor are dependent on flow rate. ** According to expert consensus, three (3) is the minimum Q factor recommended.

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