COVID-19 Scientific Advisory Group Rapid Response Report

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 April 20, 2020]

Context

- After further review of the evidence (as of April 6, 2020), the World Health Organization continues to not recommend the use of masks by healthy individuals.
- On April 3, 2020 the CDC recommended the use of cloth face-coverings in the community
- On April 6, 2020, PHAC made a "permissive statement" suggesting that cloth masks could be used in the community, but they emphasized the need for ongoing social distancing, hand hygiene, and strict adherence to mask "etiquette" (ie. not touching face, regular laundering). A similar statement was endorsed by Alberta Health Services.
- Community mask use is now either encouraged or mandatory in an increasing number of countries, with many countries encouraging use of cloth masks
- Shortages of medical (procedure, surgical masks) masks and N95 masks for health care workers persist globally and nationally

Key Messages from the Evidence Summary

- Partly related to the fact that masks are often bundled with other interventions (ie. hand hygiene) and have variable compliance, clinical studies on the effectiveness of medical masks have been challenging. Despite methodological flaws and small underpowered studies, systematic reviews of low-quality studies in health care settings suggest a reduction in acute respiratory infections (ARIs) and ILIs with medical mask use. Similarly, there is a paucity of clinical evidence in favor of using medical masks in the community, with multiple inconclusive randomized trials. There are lower quality studies showing a reduction in viral infection rates in households with symptomatic ILI patients, and in transmission of viral respiratory infections in the context of mass gatherings.
- Laboratory studies investigating the efficacy of masks in filtering viral particles as well as studies in medical settings with laboratory based endpoints for respiratory pathogens (*Pseudomonas aeruginosa and Mycobacterium tuberculosis*) point to a theoretical benefit to medical mask use, particularly as a form of source control (protecting others from the wearer). Data for SARS-CoV-2 (or coronaviruses in general) are much more limited.
- There is also some modelling, ecological, and anecdotal data suggesting benefit to medical mask use in the community.
- There is limited evidence of any harms related to community mask wearing, specifically, as it relates to any behavioral modifications that may ensue or non-adherence to other protective interventions such as social distancing or optimal hand hygiene practices. However, concern



regarding unintended negative consequences with promotion of masks persists.

- The only clinical study to examine cloth masks was in a healthcare setting, and had significant methodological issues and suggested that they conferred less benefit and potentially harm when compared with the use of standard practice. While the comparator (usual practice) was somewhat unclear, a large percentage of individuals in the comparison group used medical masks. Based on lab-based bioaerosol studies, medical masks are consistently superior to homemade cloth masks, but homemade masks do offer some protection.
- There is currently very limited data on optimal filtration properties of various fabrics and construction techniques to inform cloth mask use and standardization requirements.
- There is evidence of pre-symptomatic and asymptomatic transmission of COVID-19, although varied estimates of the degree to which this could impact community transmission. 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 might be useful in reducing transmission from community based infected persons. One member was very concerned, and there was some agreement, that a focus on mask use poses a risk in the form of a reduced sense of personal risk potentially leading to less attention to social distancing and hand hygiene as the mainstays of prevention in a community setting. One member also felt that while there is evidence that medical masks can reduce ARIs and ILIs in health care settings, that there is no evidence that use of medical masks in the community reduces viral transmission.

With respect to home-made masks, there was agreement that there is insufficient information to make a firm recommendation on the use of home-made masks in the community, and it was acknowledged that there may be further developments in that regard with a need to re-evaluate this topic. 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 can not be maintained (as masks protect other people). To account for these controversies, which were mostly based on uncertainties in the evidence, a Research Gaps section has been added.

Recommendations

- 1. Given that there is a strong consensus for the use of medical masks in healthcare settings and for symptomatic ILI and COVID-19 specific patients, the threshold of evidence for recommending community-use of face masks should not be onerously high.
- 2. Given that there are limitations in maintaining optimal levels of social distancing when moving in and out of different health care settings and in households with symptomatic individuals; a lower threshold for wider use of medical masks for those with symptoms of URTI/ILI and for immunocompromised individuals (who are at greater risk of complications if they might contract COVID-19) in these settings might be warranted.

- 3. In light of concerns around PPE shortages, medical masks should be prioritized for HCWs in direct patient care roles and then for immunocompromised and medically complex patients when appropriate social distancing is not possible.
- 4. Given the relative absence of demonstrable harms and the potential benefit in preventing the possibility of transmission from asymptomatic, presymptomatic and paucisymptomatic individuals, use of medical masks could be reconsidered for wider use in the community in the context of future changes to social distancing measures and with assurances that the supply of medical masks can be maintained for the needs of the HCW's taking part in direct patient care for the duration of the pandemic.
- 5. Based on current evidence, including a consideration of harms, and the lack of standardization and research addressing the physical properties of mask construction and mask fit, we cannot recommend for or against the use of home-made masks. For those who choose to use these, it is important to note this does 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 moist and ensure appropriate laundering. Further instructions for those choosing to use home-made masks are available at https://www.albertahealthservices.ca/topics/Page16997.aspx#prev

Research Gaps:

- 1. There is currently no evidence supporting the optimal construction and fabric composition in home-made masks to meet desired filtration properties for protection against viral transmission or acquisition.
- 2. There is currently no evidence of efficacy of cloth masks for reducing population viral transmission outside the setting of community observational studies during the SARS-CoV outbreak in 2003, and evolving observations of SARS-CoV-2 in which shelter in place and community hygienic measures are also recommended. Currently, we only have theoretic benefit in lab studies of the filtration capabilities of cloth masks using heterogeneous materials and approaches. Further studies assessing population benefits or harms of home-made masks are urgently required.

Summary of Evidence

Guidelines for use of masks in the community setting:

Table 1 in the Appendix outlines the recommendations from various jurisdictions.

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

No clinical studies have examined mask use for prevention of COVID-19 transmission, but inferences can be made from evidence about masks and the prevention of other respiratory viruses.

Clinical evidence for the use of masks in mixed settings (clinical and community) 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. 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 nonstatistically 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 metaanalysis 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 recent systematic reviews by **Brainard et al**, **2020 (preprint)**, **MacIntyre et la**, **2015**, **and Barasheed et al**, **2016**. Brainard et al, 2020 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" 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). The results were inconclusive. A copy of the table summarizing these 9 articles is provided in the **Appendix**. In general the RCT's 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 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).

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.

One small study has looked specifically at SARS-CoV-2. **Bae et al. 2020**, compared medical and cotton masks to no mask. 4 patients with COVID-19 coughed into a petri dish held at 20cm. There was minimal difference in the viral load on the petri dish when comparing medical masks, cotton masks, and no masks. No virus could be detected on the *inside* of the masks while the *outside* of the masks were contaminated. The authors hypothesized both medical and cotton masks were ineffective at filtering COVID-19. However, interpretation of the study is limited by its small size and the artificial nature of coughing into a petri dish held so close to the face. In the only other study to look at coronaviruses, **Leung et al, April 2020** found that coronaviruses could be detected in respiratory droplets and aerosols in 3/10 (30%) and 4/10 (40%) of samples collected without face 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 aereginosa* 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. **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. That is, the public would be protected from the mask wearer.

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

Brienen et al, 2010 developed a population transmission model to explore the impact of populationwide 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). 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%. 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). 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). These studies do not allow the effect of face masks to be separated by other community measures in place at the time, including school closure, public space closure, hand hygiene and household hygiene campaigns.

There are also two case cluster reports outlining the benefits of community facemask use. **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.

Studies of home-made masks:

Several studies have looked at whether homemade masks are able to reduce 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. **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.

These studies, while showing the relative filtration inefficiency of homemade masks over medical masks, also suggested that non-medical masks may filter some droplets and therefore may offer *some* protection as compared to no face masks.

By contrast, a cluster randomized trial of cloth masks vs medical masks vs a standard practice arm in Vietnam (Macintyre et al, 2015) has raised concern about cloth masks and deserves detailed assessment. 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. 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, thus rendering the comparison to have—in effect been—cloth masks to cloth masks in preventing infection acquisition in a health-care setting, it cannot 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.

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

It is accepted that SARS-CoV-2 is transmitted via droplets expelled when a patient sneezes or coughs. However, the exact distance droplets emitted via a sneeze, for instance, 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 presymptomatic, pauci-symptomatic, or 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 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.

From a sociologic perspective, others 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**).

There are also several theoretical harms associated with widespread mask use. There is some concern that moisture retention could increase risk of infection. 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. The importance of risk-compensation in population-level health interventions has been debated **(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 stressed by the World Health Organization in their guidance issued on April 6, 2020 **(WHO, 2020).**

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 banning or threatening to ban export of medical masks (<u>https://www.cnbc.com/2020/04/03/coronavirus-trump-to-ban-export-of-protective-gear-after-slamming-3m.html</u>), and with reports of hoarding and price gouging.

Some jurisdictions, such as Taiwan, were able to foresee impending medical mask shortages and 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).

However, given the reality of medical masks shortages in most countries, including Canada, there is widespread agreement that medical masks should be reserved for HCWs and attention has been focused exclusively on the use of cloth masks for the public until shortages are resolved.

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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, and Nathan Zelyas.

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Appendix

The literature search was conducted by Lauren Seal from the AHS Knowledge Resource Service.

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 SarsCov-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)



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CINAHL

S1	(MH "Coronavirus+")				
S2	(MH "Coronavirus Infections+")				
S3	coronaviru*				
S4	"corona virus"				
S5	ncov*				
S6	n-cov*				
S7	COVID-19 OR COV	ID19 OR COVID-2019 OR COVID2019			
S8 SARS-COV-19 OR SARSCOV	SARS-COV-2 OR S -19 OR SARSCOV2	ARSCOV-2 OR SARSCOV2 OR SARSCOV19 OR 019 OR SARS-COV-2019 OR SARSCOV-2019			
S9 syndrome coronavirus*"	"severe acute respir	atory syndrome cov 2" OR "severe acute respiratory			
S10	"2019 ncov" OR 20 ²	19ncov OR Hcov*			
S11	S1 OR S2 OR S3 O	R S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10			
S12	(MH "Masks")	2,140			
S13 medical N2 mask OR face N2 of	mask OR masks OF cover*10,693	R facemask OR face-mask OR face N2 mask OR			
S14	S12 OR S1310,693				
S15 made OR "hand made" OR ha	homemade OR hom ndcraft* OR hand-cra	ne-made OR "home made" OR handmade OR hand- aft* OR "hand craft*" 2,013			
S16	S14 AND S15	10			
S17	S14 OR S1610,693				
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 "hand-crafted 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 "hand-crafted mask" OR "hand-crafted mask")

mask

facemask

face covering

Evidence Synthesis

What is the effectiveness of wearing medical masks, including home-made masks, to reduce the spread of COVID-19 in the community?

While there are no clinical studies examining mask use for prevention of SARS-CoV-2 transmission, inferences can be drawn from evidence about masks and the prevention of other respiratory viruses, particularly, SARS-COV-1 and influenza.

At least three separate reviews (Jefferson et al. 2011, Offeddu et al. 2017 and Saunders-Hastings et al, 2017), have examined this question. A Cochrane systematic review and meta-analysis by Jefferson et al, 2011 looked at physical interventions to prevent transmission of respiratory viruses in a variety of settings (hospitals, households, and community-living centers). The authors found inconsistent results and classified the evidence as very low certainty. Nevertheless, of the physical interventions examined (including but not limited to hand hygiene, gowns, gloves), masks were the best performing intervention across populations, settings, and pathogens. Owing to the heterogeneity and methodological concerns around the RCTs, no meta-analyses of the RCTs were performed and the evidence was deemed to be of low to very low certainty. However, a meta-analysis was carried out on seven case control studies, with 3216 participants total, and found a reduction of acquisition of an ARI when a medical mask was used, OR 0.32, 95% CI 0.26 to 0.39. That is, 315 per 1000 people (95% CI 273 to 359) who contracted an ARI wore masks compared with 588 per 1000 people who did not contract an ARI (calculated using median event rate).

Another systematic review and meta-analysis looking at mask use for prevention of respiratory viruses was undertaken by **Offeddu et al, 2017.** While this study was only focused on the health-care setting, it included three newer RCTs and undertook slightly different methods of analysis than Jefferson et al, 2011. When comparing the effectiveness to masks to no-masks in RCTs, the mask comparison group included both medical masks and N95 respirators. They found that wearing a medical mask or N95 respirator throughout the work shift conferred significant protection against self-reported clinical respiratory illness (CRI) (RR = 0.59; 95% CI: 0.46-0.77) and influenza-like illness (ILI) (RR = 0.34; 95%

CI: 0.14-0.82). Meta-analysis suggested a protective, but nonstatistically significant, effect against laboratory-confirmed viral infections (VRI) (RR = 0.70; 95% CI: 0.47-1.03). In meta-analyses combining 6 case-control and 3 cohort, there was a protective effect of medical masks vs. no mask (OR = 0.13; 95% CI: 0.03-0.62) against SARS. Interestingly, no clear benefit could be documented with use of masks and protecting against pandemic H1N1 infection. However, the authors cautioned that, "overall, the evidence to inform policies on mask use in HCWs is poor, with a small number of studies that is prone to reporting biases and lack of statistical power." **Saunders-Hastings et al, 2017** looked specifically at the effective of PPE during a pandemic influenza season. They included studies distinct from those included in the previously mentioned analyses. Again, results related to facemask use and respiratory virus protection were mixed but a meta-analysis of three case-control studies suggested that facemask use provided a non-significant protective effect (OR = 0.53; 95% CI 0.16-1.71; I 2 = 48%)

There are considerable challenges related to clinical studies of mask use (even within the relatively controlled environments of hospital as compared to the community). These challenges including contamination of the intervention with other methods of personal protection, variable compliance rates, and the challenge of reliably recording compliance. There is marked heterogeneity in study locations and interventions further complicating meta-analyses.

Another approach has been to directly measure the efficacy of facemasks in filtering respiratory viruses (and reducing viral release) or in providing a barrier to entrance of pathogens. Milton et al, 2013 collected samples of exhaled particles in volunteers with seasonal influenza, measured viral copy number using quantitative RT-PCR, and tested the fine-particle fraction for culturable virus. Medical masks reduced viral copy numbers in the fine fraction by 2.8 fold (95% CI 1.5 to 5.2) and in the coarse fraction by 25 fold (95% CI 3.5 to 180). Overall, masks produced a 3.4 fold (95% CI 1.8 to 6.3) reduction in viral aerosol shedding. Johnson et al, 2009 assessed for the presence of influenza on influenza sample plates (ISP) held 20cm in front of infected participant's mouths. Nine participants were asked to cough, with and without masks (both medical and N95), and the ISP was assessed by RT-PCR for influenza A and B. Influenza could be detected in all samples where a mask was not worn whereas no influenza was detected with either medical or N95 masks were used. The only study to look specifically at the efficacy of facemasks in controlling coronaviruses is a pre-print of a publication by Leung et al, March 2020. In this study, participants with respiratory viruses (including coronaviruses NL63, OC43, 229E and HKU, influenza A and B, and rhinoviruses were randomly assigned to breath into a bioaerosol collecting device, the Gesundheit-II (G-II), for 30 minutes, with or without a mask. For coronavirus, they detected virus in respiratory droplets and aerosols in 3/10 (30%) and 4/10 (40%) of the samples collected without face masks, respectively, but did not detect any virus in respiratory droplets or aerosols collected from participants wearing face masks.

Two studies have examined the effectiveness of medical masks to protect the wearer, as a barrier against viral bioaerosol. Ma et al, 2020 compared the efficacy of a one-layer polyester cloth homemade masks to an N95 mask, a medical mask, and a homemade mask made of one polyester layer and 4 layers of kitchen paper. They then challenged the masks with avian influenza virus. They found that compared with one-layer of polyester, the N95 masked blocked 99.98% of viral particles, the medical masks blocked 97.15% and the 4-layer homemade mask blocked 95.15%. There was no statistically significant difference in the Ct value of the medical masks vs the 4-layer medical masks. The high efficacy rates of all the masks may have been related to the unrealistically tight seals that may have been present. **Makison-Booth et al, 2013** tested the efficacy of five different surgical masks against attenuated vaccine strain influenza A type virus. Mask were realistically adhered to the face of a

mannequin and quantitative assays was used to measure the amount of viable live virus from the air in front and behind of the mask. The influenza plaque reduction was anywhere between 1.1 to 55, depending on the type of mask. On average, medical masks reduced exposure to aerosolized influenza virus, approximately 6-fold,.

Based on systematic reviews of clinical data—primarily in the health care setting—the quality of the randomized controlled trial evidence in support of masks to prevent respiratory virus transmission is poor. If observational and case-control studies are used; however, there does seem to be more evidence in support of the use of masks. The clinical data is enhanced by the evidence showing efficacy in facemasks in filtering respiratory viruses in exhaled breaths (or cough). This corresponds with the guidelines of all major bodies recommending mask use in health care settings, in the event of that an individual is ill with COVID-19, or is caring for a household contact with COVID-19 (WHO, CDC, European CDC, AHS).

The question of spread in the community is more challenging to study. **Mcintyre et al. 2015**, looked specifically at the question of facemask use in the community setting. They identified 9 RCTs of facemasks in various household and community settings. In all but one they were used to protect well individuals from acquisition of infection, as opposed to a method of source control to prevent the spread of infections from the wearer. These RCTs had diverse settings, designs, and interventions— many of which were mixed, such as hand washing and facemasks. The results were inconclusive and there were methodological flaws amongst the RCT, often, lack of power. The most concise review of RCTs of masks in the community (up-to-date to 2015) can be found in **figure 3 of this review** (<u>https://www-bmj-com.login.ezproxy.library.ualberta.ca/content/bmj/350/bmj.h694/F3.large.jpg</u>).

Beyond clinical studies, **Brienen et al, 2010** developed a population transmission model to explore the impact of population-wide mask use on an influenza pandemic. The many assumptions regarding transmission potential of influenza A virus notwithstanding, they concluded that masks could lower the basic reproduction number, at least delaying, if not containing, an influenza outbreak. In an ecologic study, **Lo JY et al, 2005** examined the role of "community hygienic measures" during the 2003 SARS epidemic in Hong Kong in reducing transmission of other respiratory viruses. It was estimated that ~75% of the population used face masks and ~75% used soap when washing their hands and covered their mouths with sneezing or coughing. By comparing the proportion of positive specimens of various respiratory viruses from 2003 with those from 1998 to 2002, they showed that "community hygienic measures" significantly reduced the incidence of various respiratory viral infections.

There are also two case reports outlining the benefits of community facemask use. After multiple passengers developed influenza, **Zhang et al, 2013** assessed transmission of influenza A virus on two flights from New York, USA to Hong Kong to Fuzhou, China. They compared exposures of 9 case-passengers with those of 32 asymptomatic control-passengers. None of the 9 case-passengers, compared with 47% (15/32) of control-passengers, wore a face mask for the entire flight (odds ratio 0, 95% CI 0–0.71). 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 of the 39 other passengers were infected. By contrast, on his second ride, a 50-minute ride, he wore a mask that he had purchased in the interim and 0/14 other passengers were infected.

Despite the strong recommendations for health care workers, given the lack of clear benefit in the community, many jurisdictions do not recommend use of facemasks in the community. As of March 31, 2020, masks were mandated in two provinces in China (**Feng et al, 2020**) and it is recommended for almost everyone to wear them. And though not mandated, it is recommended in Japan and Hong Kong to anyone entering crowded places. It has recently become mandated in the Czech Republic, Slovakia, a province in Germany and in crowded places (ie. grocery stores) in Austria (<u>https://www.theguardian.com/world/2020/mar/31/calls-grow-for-germany-wide-use-of-face-masks-covid-19</u>).

The arguments in opposition to mask use include: a "false sense of security" (WHO, Canadian guidelines) and presumably, the consequent behavioural modification. There is also major concern about shortages (in particular for health care workers) and price gouging.

Several studies now suggest COVID19 transmission potential from asymptomatic patients (can refer to asymptomatic transmission brief as well). And, while isolation of the virus does not mean necessarily mean capability to transmit, ie. without sneezing or coughing, it does markedly increase concerns for asymptomatic transmission. Thus, if guidelines are recommending use of masks if an individual is symptomatic and must have contact with others (for instance, while seeking health care), then it becomes increasingly compelling to also recommend masks for asymptomatic but potentially infectious individuals who similarly must be in contact with others (for instance, to obtain groceries).

There is little high-quality evidence to support the use of masks in the community but given the real concern for asymptomatic transmission, and the absence of evidence that behavioral modification will result in a "false sense of security", face masks should be recommended in the community. The major limitation; however, is the shortage of masks. Therefore, non-medical (or "homemade" masks) need to be examined. If these non-medical masks are not harmful, then it may be sufficient evidence for masks to be recommended.

Davies et al, 2013 examined a variety of household material derived homemade masks as an alternative to commercial face masks. Their home-made mask was made from cotton t-shirt fabric and its filtration efficiency of viral particles was ~50% as compared to 90% for medical masks. When the effectiveness of the mask in preventing dispersal of droplets and aerosol was measured, both masks significantly reduced the number of microorganisms expelled by volunteers, although the medical mask was 3 times more effective in blocking transmission than the homemade mask. Thus, the authors concluded that while a cotton home-made mask would be preferable to no mask, it should only be used as a last resort. Another group (van der Sande et al, 2008) also compared homemade masks to medical masks and respirators. They found that medical masks provided about twice as much protection as homemade masks against particles to which the volunteers were exposed. They found minimal benefit in the mask's ability to prevent outward dispersal. Thus, they concluded that while inferior and complicated by poor fit, homemade masks would provide some protection from viral exposures. A cluster randomized trial of cloth masks vs medical masks in Vietnam (Macintyre et al, 2015); however, raised concern because cloth mask wearers had higher rates of ILI compared with the control arm, RR=6.64, 95% CI 1.45 to 28.65, and laboratory-confirmed virus, RR=1.72, 95% CI 1.01 to 2.94. A possible hypothesis for the worse outcome with cloth masks is that in the process of becoming wet with exhaled breaths, they are more likely to trap viral particles. Alternatively, there was inadequate

washing of the masks. Another possibility for these findings is more methodological in nature. That is, the control arm "usual care" consisted of a high-rate of mask use, thus, the comparison may in effect have been cloth masks vs medical masks. 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 mask, thorough and daily disinfection is required to prevent potential harms.

Critical Appraisal

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

				Mixed M Appraisa Criteria:	ethods al Tool
	Reference	Peer reviewed?	Type of evidence	Are there clear resear ch questio ns or a clearly identifi ed issue?	Is the collecte d data or present ed evidenc e appropri ate to address the researc h question s 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	⊠ Yes	Systematic review and	⊠ Yes	⊠ Yes

	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.		meta- analysis		
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: <u>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 .</u>		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. <i>et</i> <i>al.</i> Respiratory virus shedding in exhaled breath and efficacy of face masks. <i>Nat</i>	⊠ Yes	Randomzie d lab-based trial	⊠ Yes	⊠ Yes

	<i>Med</i> (2020). https://doi.org/10.1038/s41591- 020-0843-2				
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
1 0	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: International recommendations regarding mask use in the community

Jurisdiction	Recommendations			
Canada	On April 6, 2020, the Chief Public Health Officer of Canada			
	said that in a "permissive statement", cloth masks could be			
	used to reduce COVID19 transmission, particularly in setting			
	where social distancing may be difficult.			
	https://www.canada.ca/en/health-canada/services/drugs-			
	health-products/medical-			
	devices/activities/announcements/covid19-notice-home-			
	made-masks.html			
WHO ¹	If you are healthy, you only need to wear a mask if you are			
	taking care of a person with suspected SARS-CoV-2			
	infection.			
	Updated on April 6, 2020: "The wide use of masks by healthy			
	people in the community setting is not supported by current			
	evidence and carries uncertainties and critical risks"			
United States	As of April 3 rd , 2020 the CDC recommended the use of cloth			
	masks in the community			

	(https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-		
	sick/diy-cloth-face-coverings.html)		
China ²	People at moderate risk* of infection: medical or disposable		
	mask for medical use.		
	• People at low risk† of infection: disposable mask for medical		
	USE. • Deenle et vers leur riekt of infections de net heve te weer e		
	• People at very low lisk of infection, do not have to wear a		
Hong Kong ³	Medical masks can provent transmission of respiratory		
	viruses from people who are ill. It is essential for people who		
	are symptomatic (even if they have mild symptoms) to wear a		
	medical mask		
	Wear a medical mask when taking public transport or		
	staying in crowded places. It is important to wear a mask		
	properly and practice good hand hygiene before wearing and		
	after removing a mask.		
Singapore	• As of April 13 th , masks became mandatory in public spaces		
	with strict financial penalties for non-adherence		
	(https://www.scmp.com/week-asia/health-		
	environment/article/3079889/coronavirus-singapore-makes-		
	face-masks-compulsory)		
Japan	As of April 2 nd , the Japanese governments was providing		
	each nousenoid with 2 cloth masks per nousenoid		
	(<u>nilps://www.scmp.com/news/asia/easi-</u>		
	asia/article/3070115/c0101avirus-japari-pin-gets-social-media-		
Germany	. The city of Jena (pop. 110,000) has mandated use of		
	facemasks when shopping and on public transit		
	ntips://nationalpost.com/pmn/nealtn-pmn/german-city-		
	\leq On April 1 st the Robert Koch Institute stated that widespread		
	mask use could help reduce transmission particularly from		
	asymptomatic individuals		
	(https://www.thelocal.de/20200402/latest-face-masks-in-		
	public-could-help-to-reduce-spread-of-coronavirus-says-		
	germanys-robert-koch-institute)		
Austria Austria has mandated use of masks in supermarke			
	they are given free of charge upon arrival to the store) and		
	recommends it for general use.		
	(https://www.reuters.com/article/us-health-coronavirus-		
	austria/austria-to-make-basic-face-masks-compulsory-in-		
Poopia and Horzagovnia	Supermarkets-IdUSKBNZTHT0A)		
Doshia and Herzegovnia	https://www.businessinsider.com/coropovirus.countries		
	rethink-advice-masks-facial-coverings 2020 4		
	10011111-201105-1112313-120121-0010111143-2020-4		

Czech Republic	Mandatory use of masks in all public (interior) spaces. ?Use			
	in the streets			
	(https://www.praguemorning.cz/face-masks-now-mandatory-			
	in-all-prague-shops-and-offices/)			
Slovakia	Mandatory mask use in all public spaces			
	(https://spectator.sme.sk/c/22366501/masks-will-be-			
	obligatory-new-measures-mainly-aimed-at-the-elderly.html)			
Taiwan	State controlled production and distribution of medical			
	masks with daily individual, name-based rations of			
	masks (at modest cost), and free provision of masks			
	for school-aged children.			
	Strict controls and financial penalties for hoarding and			
	price gouging.			
	 Masks now mandatory on public transportation 			
	(https://www.taiwannews.com.tw/en/news/3908366)			
Indonesia	As of April 5 th , compulsory mask use in public places, with a			
	focus on preserving medical masks and N95 for health care			
	workers.			
	https://www.straitstimes.com/asia/se-asia/coronavirus-			
	indonesia-orders-citizens-to-wear-masks-as-infections-rise)			
Israel	As of April 12 th , mandatory mask use in public spaces			
	(https://www.haaretz.com/israel-news/.premium-face-masks-			
	become-mandatory-for-israelis-on-sunday-here-s-what-you-			
	need-to-know-1.8759337)			
Morocco	Mandatory public mask use with subsidized, state-			
	manufactured masks.			
	(https://www.bbc.com/news/uk-52197747)			
Vietnam	Masks required in public spaces			
	(http://www.xinhuanet.com/english/2020-			
	<u>03/16/c 138883155.htm</u>)			
Ukraine	Masks required in public spaces			
United Kingdom	The United Kingdom is re-examining the evidence around			
	face masks			
	(https://www.telegraph.co.uk/news/2020/04/13/now-official-			
	advice-may-wear-face-masks-public-fight-coronavirus/)			

*People at moderate risk of infection include those working in areas of high population density (eg, hospitals, train stations), those have been or live with somebody who is quarantined, and administrative staff, police, security, and couriers whose work is related to COVID-19. †People at low risk of infection include those staying in areas of high population density (eg, supermarket, shopping mall), who work indoors, who seek health care in medical institutions (other than fever clinics), and gatherings of children aged 3–6 years and school students. ‡People at very low risk of infection include those who mostly stay at home, who do outdoor activities, and who work or study in well-ventilated areas

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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 0.877) Hand hygiene alone was not 	 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
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 (0R 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
Aielio 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.

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