



06/17/2020

COVID-19 – What We Know So Far About...Wearing Masks in Public

Introduction

"What We Know So Far" documents are intended to provide an overview of some of the published and unpublished reports related to emerging issues with respect to coronavirus disease 2019 (COVID-19). The reports are found through ongoing scanning of the published literature and scientific grey literature (e.g., <u>ProMed</u>, <u>CIDRAP</u>, <u>Johns Hopkins Situation Reports</u>), as well as media reports. For this report library staff at Public Health Ontario searched Ovid MEDLINE, Embase, PsycINFO, EBSCOhost CINAHL, and Scopus from January 1, 2000 to June 10, 2020 (search strategy available upon request). It is recognized that there may be additional information not captured in this document. As this is a rapidly evolving outbreak, the information will only be current as of the date the document was written.

Key Points

- Public mask wearing is **likely beneficial as source control** when worn by persons shedding infectious SARS-CoV-2 virus when physical distancing is not possible in public spaces (e.g. public transit, visiting grocery store).
- There is emerging data from ecological studies showing a decrease in new COVID-19 cases in regions where mandatory public mask policies were implemented compared to regions where such policies were delayed. However, there may be confounding by other public health measures.
- Masking to **protect the wearer is unlikely to be effective in non-healthcare settings**. Existing evidence demonstrates that wearing a mask within households after an illness begins is not effective at preventing secondary respiratory infections.
- There is variability in the effectiveness of homemade and cloth masks. Some materials adequately filter the expulsion of viral droplets from the wearer making them theoretically suitable for **source control**. Medical masks should not be used by the public to avoid shortages in personal protective equipment for healthcare workers.
- There are theoretical risks of harms from public mask use including self-contamination from improper use, reduction in physical distancing, and facial dermatitis. These risks may be mitigated by **clear and consistent messaging** on the importance of hand hygiene as well as the intended purpose of masking and proper use.

Background

Masks have two potential functions. They may protect the wearer of the mask from exposure, or protect individuals from exposure to respiratory aerosols/droplets from the mask wearer, referred to as **source**

control. The use of masks for the general public has been recommended as one of several COVID-19 pandemic mitigation strategies. The Canadian and Ontario governments are currently recommending non-medical face masks or homemade face covering to be worn by the public when physical distancing cannot be maintained.^{1,2} The <u>World Health Organization</u> revised their guidance on June 5, 2020 that "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".^{3,4} These recommendations have been made largely due to the increasing recognition of the importance of <u>pre-symptomatic and</u> <u>asymptomatic transmission and the potential benefit for source control</u>.^{5,6} This *What We Know So Far* was updated on June 17, 2020 and reviews the available evidence for wearing a mask to prevent respiratory viral infections in non-healthcare settings including evidence surrounding homemade masks.

Mask Wearing in Non-Healthcare Settings - COVID-19 Studies

No randomized trials have been published so far on mask use by the public in the COVID-19 era. However, observational and ecological studies support a protective effect on wide-spread mask use by the well general public as source control.

- An ecological report from Germany released in June 2020 utilized Synthetic Control Methodology (SCM) to evaluate the impact of mandatory mask use on public transportation and in sales shops in the city of Jena. On March 30th the local government in Jena announced that masks would be mandatory starting April 6th 2020. Masks became mandatory in the rest of Germany between April 20 and 29th, 2020. SCM involves identifying synthetic control groups which were following the same COVID-19 trend as Jena prior to April 6th. The weighted average of this synthetic control group of regions where masks did not become mandatory on April 6th were used as a counterfactual to evaluate the causal effect of mandatory masking. The authors concluded that mandatory masking reduced the daily growth rate of COVID-19 in Jena by 40%. It is not known from this ecological analysis the extent and quality of uptake of mask wearing, the type of masks worn, and if the demonstrated benefit is related to source control, protecting the wearer, or a combination thereof. It is possible there were other public health measures taken in Jena at this time that confound this finding (i.e. physical distancing), and the impact of behavioural change due to mandatory masking was not addressed. However, the authors do note that the timing of the introduction of face masks was not affected by other overlapping public health measures as a general "lock down" had been in place for two weeks. This report has not been peer-reviewed, however it is the best evidence to date on the potential impact of mask policy.⁷
- <u>Cheng et al. 2020</u> report COVID-19 data from Hong Kong with 11 clusters (113 cases) from "mask-off" settings (dining, karaoke, fitness clubs) compared to 3 clusters (11 cases) from "mask-on" settings in workplaces (p=0.036). However, this study cannot differentiate if the differences are related to masks versus physical distancing and increased expulsion of droplets (i.e., singing, exercising) in these settings. They also describe COVID-19 epidemiology in Hong Kong, which had a daily mask compliance of >95%, compared to representative countries in North America, Europe, and Asia and describe significantly lower COVID-19 incidence in Hong Kong. These findings also have potential confounding from broad public health measures of strict quarantine and physical distancing guidance early on in the pandemic in Hong Kong.⁸

• <u>Wang et al. 2020</u> conducted a retrospective cohort study of household contacts of COVID-19 cases for predictors of secondary transmission in Beijing, China. The overall secondary attack rate was 23% and they found that if it was reported that one or more family members (primary case or family contacts) wore face masks **prior to the development of symptoms**, then there was a 79% reduction in transmission (OR=0.21, 95%CI: 0.06-0.79). Of note in this study was no protective effect of mask wearing by household contacts if initiated after symptom onset in the primary case. The findings are associated with the inherent limitations with telephone interview including recall bias.⁹

Mask Wearing as Source Control – Non-COVID-19 studies

Studies to date have found that the use of medical masks may reduce the amount of aerosol shedding of some bacteria and viruses from symptomatic individuals, but have inconsistently demonstrated a reduction in secondary cases in household or other close contact studies.

- <u>MacIntyre et al. 2020</u> re-analyzed data from a previous clinical trial using only seasonal coronavirus data. They identified 10 index cases in the mask group and 9 controls. There was no secondary transmission in either group, although 5/9 control index cases reported wearing a mask.^{10,11}
- <u>Barasheed et al. 2014</u> conducted a pilot study randomizing tents at the Hajj to 'supervised mask use' (mask use 76%) or 'no supervised mask use' (mask use 12%) for both individuals with influenza-like illness (ILI) and their contacts who slept within 2 meters. They found less ILI among contacts in the mask group (31% versus 53%, p=0.04), however there were no differences in laboratory confirmed respiratory virus detections.¹²
- <u>Canini et al. 2010</u> performed a cluster RCT of masking the index patient for five days after testing positive for influenza on a rapid test to prevent secondary household transmission. ILI was reported in 16.2% of contacts where the index case was masked, and 15.8% when the index case was not masked; there were no significant differences between surgical mask and control groups.¹³
- <u>MacIntyre et al. 2016</u> performed a cluster RCT of surgical masks for patients with ILI (n=123) compared to controls (n=122) evaluating the risk of secondary cases in household contacts.¹¹ There were no statistically significant differences in clinical respiratory illness (relative risk (RR) 0.61, 95% CI 0.18 to 2.13), ILI (RR 0.32, 95% CI 0.03 to 3.13) or laboratory-confirmed viral infections (RR 0.97, 95% CI 0.06 to 15.54). As one third of controls wore masks, the authors conducted a post-hoc per protocol analysis and there was a statistically significant protective effect in clinical respiratory infections (RR 0.22, 95% CI 0.06 to 0.86), but not laboratory confirmed respiratory infections.¹¹
- <u>Stockwell et al. 2018</u> found that mask wearing significantly reduced the release of Pseudomonas aeruginosa aerosols during coughing in people with cystic fibrosis compared to uncovered coughing. The results were similar for surgical masks and N95 respirators.¹⁴
- <u>Milton et al. 2013</u> examined exhaled breath samples from symptomatic people infected with seasonal influenza viruses and found that surgical masks reduced the amount of viral aerosol shedding by 3.4 fold overall, ranging from 2.8 to 25 fold depending on particle size.¹⁵
- <u>Dharmadhikari et al. 2012</u> studied patients with multidrug-resistant tuberculosis and demonstrated that surgical mask wearing significantly reduced transmission in experimental conditions.¹⁶

• <u>Leung et al. 2020</u> studied surgical mask wearing in 246 symptomatic individuals with influenza, rhinovirus, and seasonal coronaviruses. They found a significant reduction in virus by polymerase chain reaction testing of exhaled breath droplets and aerosols in the 124 individuals randomized to wearing masks (4/10 versus 0/11, p=0.04). This study did not confirm if the quantity of virus was infectious.¹⁷

Protective Effects to the Mask Wearer in Non-Healthcare Settings - Non-COVID-19 Viral Respiratory Infections

Randomized Trials

There have been several cluster randomized studies on the use of medical masks outside of the hospital setting. These studies have evaluated the effectiveness of masking household members and individuals in other confined spaces (e.g. university residences, airplanes) to prevent acquisition of respiratory infections. In the majority of studies, **no significant benefit** from wearing masks was identified. Studies that demonstrated a benefit were associated with **enhanced hand hygiene** measures. No randomized controlled trials evaluating the effectiveness of mask use by the public to decrease COVID-19 infections have been completed, however there is a trial in Denmark under way (<u>NCT04337541</u>).¹⁸

- <u>Aiello et al. 2012</u> conducted a cluster randomized controlled trial (RCT) in university residents comparing three arms: hand hygiene (HH) + masking, masking alone, or control. They found no effect in the primary analysis of influenza-like illness (ILI) or laboratory-confirmed respiratory infections. However, there was a significant effect on ILI in weeks 3-6 of the study in the mask + HH arm (RR=0.25, 95% CI, 0.07 to 0.87), but not in the mask-only arm, suggesting the effect may have been due to HH.¹⁹
- <u>Suess et al. 2012</u> conducted a cluster RCT comparing masking, masking + HH, or control in 84 households with influenza infection in the 2009/10 and 2010/11 seasons. There was no significant effect from either intervention in the primary analysis. There was a potential effect observed in the subgroup that implemented masking + HH within 36 hours of symptom onset of the index case (adjusted odds ratio (OR) 0.16, 95% CI, 0.03-0.92).²⁰
- <u>Aiello et al. 2010</u> performed a cluster RCT in university residence halls with 3 arms; masking with surgical masks, masking + HH, or no intervention. In the primary adjusted analysis there were no significant differences in the mask only group (relative risk (RR) 0.90, 95% confidence interval (CI) 0.77-1.05) or mask + HH group (RR 0.87, 95% CI 0.73-1.02).²¹
- <u>Simmerman et al. 2011</u> performed a cluster RCT of families in Thailand during the influenza H1N1 pandemic comparing HH, HH + masking with surgical masks, or control to prevent influenza transmission in households with an influenza-positive child. There were no differences in clinical or laboratory-confirmed influenza in either intervention arm. However, due to the H1N1 pandemic, mask use and HH substantially increased amongst control participants during the study period.²²
- <u>Larson et al. 2010</u> conducted a cluster RCT in households comparing health education (HE), HE + HH, or HE + HH + masking with surgical masks on incidence and secondary transmission of upper respiratory tract infections and influenza. There was a significant decrease in secondary respiratory infections in the HE + HH + mask group compared to HE alone (OR 0.82, 95% CI 0.70-0.97). This study did not evaluate a masking-only group.²³

- <u>Cowling et al. 2009</u> performed a cluster RCT of households with confirmed influenza patients.²⁴ Households (≥3 people) were randomized to either HE (control), HH, or HH + masking with surgical masks. There was no statistically significant difference in either laboratory confirmed or clinical influenza infection between the three groups. In a post-hoc analysis limited to those that applied the intervention within 36 hours of symptom onset in the index case, mask + HH reduced laboratory-confirmed influenza infections (OR 0.33, 95% CI 0.13-0.87), but not clinically defined influenza. The authors conclude that if applied early, masks + HH for household contacts of influenza infected individuals may be effective.²⁴
- <u>MacIntyre et al. 2009</u> performed a cluster RCT of adult household members masking after a child was diagnosed with a respiratory illness. They compared surgical mask, N95 respirator, or control. There were no significant differences between either type of mask and control, however mask adherence was low.²⁵
- <u>Aggarwal et al. 2020</u> pooled controlled trials and did not identify a significant effect for either mask use alone versus control (5 studies, pooled effect size (pES) -0.17, 95%CI -0.43 to 0.10) or mask use with hand hygiene versus control (6 studies, pES -0.09, 95%CI -0.58 to 0.40), in reducing ILIs in household and university settings.²⁶

Non-randomized Studies

Systematic reviews and meta-analyses of observational studies for non-COVID infections have found protective effects from mask wearing. In contrast to the largely negative randomized trials above, the results of these studies should be interpreted cautiously considering the substantial biases present from the original studies used in these meta-analyses.

- <u>Chu et al</u> performed a systematic review and meta-analysis utilizing observational data from Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS), and COVID-19 health-care and non-health care studies to evaluate the protective effects of physical distancing, mask use, and eye protection. Overall, mask use (non-medical, medical or respirator) was effective (unadjusted studies OR 0.34, 95%CI 0.26-0.45; adjusted studies OR 0.15, 95%CI 0.07-0.34); however, from the three included non-healthcare settings (all patients with SARS) masks were significantly less protective compared to healthcare settings (OR 0.56, 95%CI 0.40-0.79, p_{intereraction}=0.049). The applicability of these studies to non-healthcare transmission of COVID-19 are questionable.²⁷
- <u>Saunders-Hastings et al. 2017</u> conducted a systematic review and meta-analysis on the effect of personal protective measures on pandemic influenza transmission. The meta-analysis found regular hand hygiene provided a significant protective effect against pandemic viral transmission (OR = 0.62; 95% CI 0.52–0.73), but the effect of facemask use was not statistically significant (OR = 0.53; 95% CI 0.16–1.71).²⁸
- There is a body of literature on wearing masks at mass gatherings (e.g. Hajj). <u>Barasheed et al.</u> <u>2016</u> performed a systematic review of 25 studies. The studies were heterogeneous and generally of poor quality; however, the authors pooled results from 13 studies of masking involving 7,652 participants and found a small but significant protective effect against respiratory infections (RR 0.89 95% CI 0.84-0.94).²⁹
- <u>Zhang et al. 2013</u> conducted an observational study that evaluated the risk of influenza pH1N1 on two flights, after several passengers developed infections. They found that on one flight from New York to Hong Kong there were 9 infections in passengers compared to 32 asymptomatic controls. None of the infected passengers wore masks compared to 15 (47%) of the controls

who did wear masks. The index case was never identified. The authors concluded that wearing a mask on this flight was potentially protective.³⁰

 Modelling studies have estimated variable but substantial population level effects from mask use by the general public. However, these models are highly sensitive to the inputs of mask effectiveness and are based on data summarized in this review.^{31,32} <u>Stutt et al. 2020</u> incorporated modelling assumptions of risks associated with public mask use.³³ These included impacts on less physical distancing, as well as varying degrees of increased infection risk to the wearer through self-contamination. Overall population level benefits were attenuated but persisted.³³

Homemade and Cloth Masks

Given the challenges in maintaining personal protective equipment supply during the COVID-19 pandemic, the use of **homemade and/or cloth masks is the recommended mask type for use in non-healthcare settings**. Broadly speaking, there are two types of studies on effectiveness of cloth masks: ones that evaluate filter efficiency in a laboratory setting, and ones that evaluate infection risk to the wearer and those around them. There are more of the former studies which generally agree that at least some filtration occurs under certain conditions; the latter have not proven such masks effective in real-world settings. Overall, the evidence suggests there is variability in the effectiveness of cotton masks and that they are generally inferior to medical masks. One study in a healthcare setting demonstrated that cloth masks were associated with an increased risk of infection and they should not be used to protect healthcare workers.³⁴ However, the body of evidence supports that certain cloth materials provide sufficient filtration to be a suitable option for **source control** in non-healthcare settings.

- <u>Ho et al. 2020</u> compared a 3-layer 100% cotton mask versus surgical masks and found 86.4% and 99.9% filtration efficiency, respectively. They recruited 211 infected adult volunteers (205 influenza, 6 suspected COVID-19) and compared particle concentrations without masks, with medical masks, and with cotton masks. Both surgical and cotton masks significantly reduced (p=0.03) filtered particles, compared to no mask, with no significant differences between mask types.³⁵
- <u>Ma et al. 2020</u> conducted an experiment, using an avian influenza virus, on the comparable efficiency between N95, surgical masks, and homemade masks (made from 4 layers of "kitchen paper" plus 1 layer of polyester cloth) to block nebulizer-produced aerosols. They found that the masks blocked 99.9%, 97.1%, and 95.2% of aerosols, respectively.³⁶
- <u>Davies et al. 2013</u> in an experimental study found that masks made from 100% cotton t-shirts had about 50% the median-fit factor of surgical masks. Both masks blocked microorganisms expelled; however, surgical masks were three times more effective.³⁷
- <u>Dato et al. 2006</u> fashioned a nine-ply (one outer layer and eight inner layers) face mask out of heavy-weight 100% cotton T-shirt material, and achieved a maximum fit factor of 67 using quantitative measurements (a Portacount Fit Tester), with minimal discomfort or difficulty breathing reported in the three test subjects. Note that National Institute for Occupational Safety and Health (NIOSH)-approved N95 respirators are required to have a fit factor of 100.³⁸
- <u>Rengasamy et al. 2010</u> similarly found in experimental conditions that cloth masks and various fabric materials were much less efficient than N95 respirators at filtering various size aerosols.³⁹ NaCl aerosol penetration tests were run at face velocities of 5.5 and 16.5cm s⁻¹ flow rates, using a NIOSH particulate respirator certification method for polydisperse (various size) NaCl aerosol and a TSI 3160 Fractional Efficiency Tester for monodisperse (specific size) NaCl aerosol.

Percentage penetration (ratio of downstream to upstream concentration) for cloth masks and fabric ranged from 40-90% for polydisperse aerosols, compared to N95 penetrations of 0.12% and <5% at the lower and higher velocities, respectively. For monodisperse aerosols penetration varied by particle size and fabric type in the 20-1000 nm range. Certain fabrics (e.g., towels and scarves) had slightly lower penetration (around 20-80% for towels, increasing with particle diameter), which was noted by the authors to be comparable to other studies of surgical mask penetration levels (measured in cited studies ranging from 51-89%). They conclude that fabric materials provide minimal respiratory protection to the wearer from aerosol sized particles, but that "the use of improvised fabric materials may be of some value compared to no protection at all when respirators are not available."³⁹

- <u>MacIntyre et al. 2015</u> conducted a cluster RCT (N=1,607) on the effectiveness of cloth or surgical masks, compared to routine practices (personal protective equipment as needed), in hospital healthcare workers.³⁴ The primary outcomes were rates of ILI or laboratory-confirmed respiratory viral infection. Infection rates were highest in the cloth mask group, with a RR for ILI of 13 compared to the medical mask arm, a RR for ILI of 6.6 compared to the control arm, and a RR for laboratory confirmed virus of 1.7 compared to the medical mask group. Penetration of particles in cloth masks was 97%, compared to 44% in the medical masks.³⁴
- <u>Van der Sande et al. 2008</u> compared homemade tea cloth masks, surgical masks, and FFP-2 (European equivalent of N95 respirators) in healthy volunteers performing various physical maneuvers and measured quantitative differences in particles with a Portacount[®].⁴⁰ They calculated median protection factors (or PFs, the ratio of particle concentrations sized 0.02-1 μm outside to inside the mask) of 2.2-3.2 for cloth masks, 4.1-5.3 for surgical masks, and 66-113 for FFP-2 respirators among the adult volunteers. Marginal protection was seen for all mask types when testing for reduction in outgoing transmission of respiratory particles.⁴⁰
- <u>Konda et al. 2020</u> evaluated filtration efficiency for particle sizes in the 10nm to 10µm range for 15 different cloth types (e.g. cotton, silk, flannel, etc.). These were evaluated in different configurations (e.g. layers, combinations, and with simulated "gaps" in seal as may be expected in real-world use), and compared to N95 and surgical masks, using an aerosol generator. They observed that combinations of materials (e.g. high threads-per-inch cotton along with silk, chiffon, or flannel) filtered particles across the tested size spectrum (<300nm-6um), and that was likely due to the combined effects of electrostatic and physical filtering, with efficiencies that were generally >80%. They also noted a significant drop in filter efficiency with simulated gaps, 60% drop in the >300 nm range, and this was observed for all materials including N95 and surgical masks.⁴¹
- <u>Zhao et al., 2020</u> evaluated filtration efficiency for various common household materials (e.g. cotton, silk, nylon) as well as materials used in N95 and surgical masks (i.e. polypropylene). Filtration efficiency for polypropylene in N95 masks was >95%, whereas and most other materials (including polypropylene from surgical masks) ranged from 5-30%. The authors noted that the testing did not account for leakage that would be expected in real-world settings, which would reduce efficiency further.⁴²
- <u>Lustig et al., 2020</u> evaluated filtration efficiency using simulated cough/sneeze-generated aerosols comprised of fluorescent aqueous droplets (intended to simulate viruses), testing over 70 different common fabric combinations. Combinations of materials with hydrophilic, hydrophobic, and absorbent layers were most efficient, and were comparable to materials in N95 respirators in this laboratory setting.⁴³

Risks Associated with Wearing Masks

Mask use by the general public could be associated with a theoretical elevated risk of COVID-19 through decreased physical distancing and self-contamination. The external surface of the mask may become contaminated and touching one's face is a common practice. Continuous mask use may be associated with facial skin lesions, irritant dermatitis or worsening acne.⁴ It is important to incorporate hand hygiene with appropriate mask use to reduce the risk of self-contamination.

- <u>Kovacs et al. 2020</u> used Google COVID-19 Community Mobility Reports in Germany, taking advantage of the staggered mandatory mask policies across German states (mandatory for public transit and stores), and found no sustained impact from mandatory masking policy on mobility or amount of time outside the home.⁴⁴
- Yan et al. 2020 (pre-print, not peer-reviewed) used location data in the United States to demonstrate an association between states that mandated mask use (initially business use and then all individuals in public) and increased mobility. The authors found that persons in states which mandated mask use spent an average of 20-30 minutes less time at home with increased visits to commercial locations (i.e. restaurants). The authors did not assess temporal association of lifting of lockdown measures on restaurants, or changing weather patterns at time of policy introduction, that may have influenced mobility data.⁴⁵
- <u>MacIntyre et al. 2015</u> found that healthcare workers who wore cloth masks on a continuous basis compared to medical masks had higher ILI (RR=13.00, 95% CI 1.69 to 100.07). They cautioned that factors such as moisture retention, reuse of cloth masks, and poor filtration may result in increased risk of infection.³⁴
- <u>Kwok et al. 2015</u> found face touching is a frequent behaviour in their observational study of medical students. Although this study was not specific to mask wearing, face touching happens at an average of 23 times an hour, with almost half involving mucous membrane contact. The mouth was touched most often, followed by nose, eyes and a combination thereof.⁴⁷
- Surveys of the public have noted that mask use is associated with itchiness, skin irritation, and misting of glasses impairing vision.^{47, 48}

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Citation

Ontario Agency for Health Protection and Promotion (Public Health Ontario). COVID-19 – What we know so far about...wearing masks in public. Toronto, ON: Queen's Printer for Ontario; 2020.

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