

SYNTHESIS

(ARCHIVED) Wearing Masks in Public and COVID-19 – What We Know So Far

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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"What We Know So Far" documents are intended to provide an overview of some of the published and unpublished reports related to emerging issues with respect to Coronavirus Disease 2019 (COVID-19).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 information specialists at Public Health Ontario searched Ovid MEDLINE, Embase, PsycINFO, EBSCOhost, CINAHL, and Scopus from January 1, 2000 to August 31, 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.
- Mandatory public mask policies have been associated with a decrease in new COVID-19 cases compared to regions without such policies.
- Studies evaluating masking in children are limited and have demonstrated variable results with respect to their effectiveness for source control. However, studies have consistently shown lower adherence, especially in younger children.
- 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**.

 There are theoretical risks of harms from public mask use including self-contamination from improper use and facial dermatitis or discomfort. Children may experience more discomfort from wearing a mask compared to adults. Though there are studies that observe subtle physiologic changes caused by N95 use, there is currently **no evidence that surgical or cloth masks exacerbate respiratory diseases**.

Background

Masks have two potential functions. They may protect the wearer of the mask from exposure (personal protective equipment), 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 coverings 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 asymptomatic transmission and the potential benefit for source control</u>.^{5,6} As part of <u>Ontario's school re-opening plans</u>, masks are recommended for children in junior kindergarten (JK) to grade 3 and mandatory for grades 4-12.⁷ This *What We Know So Far* was updated on September 8, 2020 and reviews the available evidence for wearing a mask to prevent respiratory viral infections in non-healthcare settings including evidence surrounding homemade masks and evidence specific to children.

Mask-wearing in Non-Healthcare Settings: COVID-19 Studies

No randomized trials have been published so far on mask use by the public during the COVID-19 pandemic. However, observational and ecological studies suggest that mask-wearing provides source control and public mask-wearing mandates have led to reduced daily COVID-19 growth rates.⁸⁻¹¹

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.¹⁰ 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.¹⁰

- Lyu et al. 2020 performed an observational event analysis, similar to a difference-in-differences design, which provides evidence that states in the United States (US) mandating face mask use in public had a greater decline in daily COVID-19 cases compared to states that did not issue mandates.¹¹ Sixteen regions issued mask mandates between April 8th and May 15th. Compared to states without mandates, daily COVID-19 growth rates significantly declined by 0.9%, 1.1%, 1.4%, 1.7%, and 2.0% at 1-5, 6-10, 11-15, 16-20, and 21 or more days following the state mandate, respectively. In another analysis, the authors evaluated the impact of employee-only mandates (no public community requirement) and did not find a significant impact from those more targeted mask mandates. While the authors attempted to adjust for other public health measures in their models, residual confounding is possible. This study was unable to assess masking adherence by the public, but provides supporting evidence that state-level mask mandates may have been effective in reducing COVID-19 case numbers.¹¹
- Xu et al. 2020 conducted an interrupted time series evaluating trends in new COVID-19 cases and deaths in the US.¹² The authors report slope changes which they attribute to stay-at-home orders on March 23rd (slope change: -0.18, 95% CI: -0.22 to -0.14) and face mask recommendations by the US Centers for Disease Control and Prevention (CDC) on April 3rd (slope change: -0.10, 95% CI: -0.18 to -0.08). Two delayed slope changes were also identified in new deaths on April 9th (slope change: -0.17, 95% CI: -0.21 to -0.14) and April 19th (slope change: -0.13, 95% CI: -0.25 to -0.07). There is a high risk of residual confounding in this study. The attribution of the initial slope change to these two policy interventions is very close together and it is unlikely that the CDC recommendation on April 3rd would result in an immediate change in incidence of new cases. Furthermore, this observational study was unable to account for the multiple simultaneous public health interventions occurring.¹²
- <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).¹³ 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.¹³
- <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.⁹ 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
- <u>Hong et al. 2020</u> conducted contact tracing of 197 residents in Taizhou, China exposed to 41 presymptomatic COVID-19 positive cases who returned from Wuhan in January 2020.⁸ The secondary attack rates from 28 mask-wearing presymptomatic cases was 8.1% (10/123) compared to 19.0% (14/74) from 13 non-mask-wearing presymptomatic cases (p<0.001).⁸
- A contact investigation of <u>two hairstylists</u> with respiratory symptoms and confirmed COVID-19 who wore cloth face masks during close contact with 139 clients did not result in any secondary transmissions (67 of whom tested negative for SARS-CoV-2 by RT-PCR).¹⁴

- Two case reports describe no in-flight transmission aboard an airplane with symptomatic COVID-19 cases who wore masks during the flight.^{15,16}
- <u>Chou et al. 2020</u> are conducting a living rapid systematic review on the effectiveness of mask use in both healthcare and community settings.¹⁷ As of their most recent update on September 1st, 2020, they have identified one study by Wang et al., discussed above. Updates are expected every 1-2 months.¹⁷

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/droplet 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.¹⁸ 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.¹⁸
- <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.¹⁹ 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.¹⁹
- <u>MacIntyre et al. 2016</u> performed a cluster randomized controlled trial (RCT) of surgical masks for patients with ILI (n=123) compared to controls (n=122) evaluating the risk of secondary cases in household contacts.²⁰ 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.²⁰
- <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.²¹ The results were similar for surgical masks and N95 respirators.²¹
- <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.²²
- <u>Dharmadhikari et al. 2012</u> studied patients with multidrug-resistant tuberculosis and demonstrated that surgical mask-wearing significantly reduced transmission in experimental conditions.²³
- <u>Leung et al. 2020</u> studied surgical mask-wearing in 246 symptomatic individuals with influenza, rhinovirus, and seasonal coronaviruses.²⁴ 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.²⁴

Evidence for Mask Use in Children

There have been no studies evaluating mask use for COVID-19 source control in children. However, there have been 4 cluster RCTs evaluating mask use for influenza prevention in the community that included children as the index cases. Two studies found a possible protective effect for masking and hand hygiene (HH) together, particularly if the intervention was implemented within 36 hours of symptom-onset in the index case,^{25,26} while two studies found no apparent protective effect.^{27,28} However, in all studies, mask-adherence when reported was generally poor and the effects may have been related to adults in the study wearing masks, children wearing masks for source control, or a combination thereof. The one study which evaluated masking alone for source control (33% of the index cases were children) did not demonstrate any benefit.²⁷ One observational study in Japan found a small reduction in influenza infections from self-reported mask-wearing in schools.²⁹

- <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. This study included 35 (33%) children <15 years as the index case. The analysis was not stratified by age; however, children were significantly more likely to report mask discomfort (i.e., reported feeling pain), compared to adults (3/12 [25%] vs. 1/39 [2.6%], p=0.036).²⁷
- <u>Suess et al. 2012</u> conducted a cluster RCT comparing masking, masking + HH, or control in 84 households, including index cases, with influenza infection in the 2009/10 and 2010/11 seasons.²⁵ There was no significant effect from either intervention in the primary analysis. Almost all index cases were children <14 years (81/84 [96%]). The average daily adherence to masking by index patients ranged from 40-60% and decreased over time. There was a potential effect observed in the subgroup that implemented masking + HH within 36 hours of symptomonset of the index case (adjusted odds ratio (OR): 0.16, 95% CI: 0.03-0.92).²⁵
- <u>Simmerman et al. 2011</u> performed a cluster RCT of 442 households 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.²⁸ 50% (221/442) of the index patients were <6 years of age. There were no differences in clinical or laboratory-confirmed influenza in either intervention arm (HH + mask compared to control; OR: 1.16; 95% CI: 0.74-1.82). Adults wore their masks for a median of 153 (IQR: 40-411) minutes per day compared to 35 (IQR: 4-197) minutes in the child index cases.²⁸
- Larson et al. 2010 conducted a cluster RCT in 509 households and 2,788 individuals (47.3% children ≤ 17 years) 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.²⁶ 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 and while index cases were encouraged to wear masks in the masking group, adherence to mask use was reported as poor by the authors.²⁶
- Uchida et al. 2017 conducted an observational questionnaire-based study with 10,524 school-aged children in Japan, of whom 5,474 (52.0%) reported wearing masks.²⁹ In the multivariable logistic regression model, wearing a mask was associated with reduced risk of influenza infection (OR: 0.86; 95% CI: 0.78-0.95). 21.5% of non-mask-wearing children in grades 4-6 were diagnosed with influenza compared to 18.9% of mask-wearing children (relative effectiveness 12.0%, absolute risk reduction 2.6%). 21.3% of non-mask-wearing children in grades 1-3 were diagnosed

with influenza, compared to 20.2% of mask-wearing children (relative effectiveness 5.3%, absolute risk reduction 1.1%). No statistical analysis was performed on the subgroups by age.²⁹

- <u>Chen et al. 2020</u> conducted a survey of 3,649 school-aged children 6-13 years of age about mask use.³⁰ 51.6% reported good mask-wearing behaviour, with older children (grades 5-6 compared to grades 1-2; OR 1.21, 95% CI; 1.03-1.43), and parental educational level, being associated with better reported mask-wearing behaviour.³⁰
- <u>Allison et al. 2010</u> conducted a survey of teachers after distributing masks to both teachers and students for 4 weeks.³¹ Teachers reported that 39% of them thought mask use was not disruptive and 35% reported they would use masks again the following winter. However, 97% reported they would use masks during a pandemic. By direct observation only 30% of students wore masks in week 1 of the study, which decreased to 15% in week 2.³¹
- <u>Stebbins et al. 2009</u> conducted a parent and teacher survey on nonpharmaceutical interventions to prevent influenza in schools.³² Student mask-wearing was among the lowest acceptable interventions by both parents and teachers.³²
- <u>Van der Sande et al. 2008</u>, discussed further in the next section, compared homemade tea cloth masks, surgical masks, and FFP-2 (European equivalent of N95 respirators) in 28 healthy adult volunteers and 11 children between the ages of 5-11 years performing various physical maneuvers and measured quantitative differences in particles with a Portacount[®].³³ There were no differences in median protection factors between adults and children.³³

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 RCTs 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 (NCT04337541).³⁴

- Dugre et al. 2020 performed an umbrella systematic review of masks in healthcare workers and the public.³⁵ They identified 11 systematic reviews, with 18 RCTs, of which 12 were in the community. In their meta-analysis, mask-wearing by the public did not reduce clinical respiratory infection (RR=1.06, 95% Cl; 0.82-1.36; l²=0%) or confirmed influenza or other viral respiratory infection.³⁵ The authors pooled the two studies below by Aiello from 2010 and 2012 and identified a significant protective effect on mask-wearing in university dormitories for ILI (RR=0.83, 95% Cl; 0.69-0.99; l²=0%; NNT=24).^{36,37}
- <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 HH versus control (6 studies, pES -0.09, 95%CI -0.58 to 0.40), in reducing ILI in household and university settings.³⁸

- <u>Aiello et al. 2012</u> conducted a cluster RCT in university residents comparing three arms: HH + masking, masking alone, or control. They found no effect in the primary analysis of 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.³⁷
- <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).³⁶
- <u>Cowling et al. 2009</u> performed a cluster RCT of 259 households with confirmed influenza patients.³⁹ Households (≥3 people) were randomized to either HE (control), HH, or HH + masking with surgical masks. The study included 189 (73%) index cases <16 years. There was no statistically significant difference in either laboratory-confirmed or clinical influenza infection between the 3 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. Self-reported mask adherence + HH for index cases and contacts was 49% and 26%, respectively. The authors conclude that if applied early, masks + HH for household contacts of influenza-infected individuals may be effective.³⁹
- <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.⁴⁰

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.

- Liang et al. 2020 performed a systematic review and meta-analysis of mask effectiveness. Of the 21 identified studies for inclusion, 8 were in non-healthcare workers.⁴¹ The pooled results of these 8 studies published from 2004-2014 showed a significant protective effect from mask-wearing (OR: 0.53; 95% CI; 0.36-0.79, I²=45%). However, a number of trials were not included and the observed effect was predominately driven by observational studies (not RCTs).⁴¹
- <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.⁴² 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.⁴²

- <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.⁴³ The meta-analysis found regular HH 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).⁴³
- 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.⁴⁴ 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).⁴⁴
- <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.⁴⁵ 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.⁴⁵

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 nonhealthcare settings. Broadly speaking, there are two types of studies on the effectiveness of cloth masks: studies that evaluate filter efficiency in a laboratory setting, and studies 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 observed some evidence for reduction of viral respiratory transmission at the population level, although have not proven such masks effective at an individual level. Overall, the evidence suggests there is variability in the effectiveness of cloth 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.⁴⁶ 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. With respect to the materials used in cloth masks, a few studies looked at filtration efficiency in a lab setting, and generally agreed that cotton materials with high thread count were more efficient than other materials. There was some variability in findings of filtration efficiency with respect to layered designs and combining materials. Adding electrostatic charge was also noted to improve filtration efficiency.

- <u>Ho et al. 2020</u> compared a 3-layer 100% cotton mask versus surgical mask and found 86.4% and 99.9% filtration efficiency, respectively.⁴⁷ 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.⁴⁷
- <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.⁴⁸ They found that the masks blocked 99.9%, 97.1%, and 95.2% of aerosols, respectively.⁴⁸

- <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.⁴⁹ Both masks blocked microorganisms expelled; however, surgical masks were three times more effective.⁴⁹
- <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.⁵⁰ Note that National Institute for Occupational Safety and Health (NIOSH)-approved N95 respirators are required to have a fit factor of 100.⁵⁰
- Rengasamy et al. 2010 similarly found in experimental conditions that cloth masks and various fabric materials were much less efficient than N95 respirators at filtering various size aerosols.⁵¹ Sodium chloride (NaCl) aerosol penetration tests were run at face velocities of 5.5 and 16.5 cm/s 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."⁵¹
- <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.⁴⁶ The primary outcomes were rates of ILI or laboratory-confirmed respiratory viral infection. Infection rates were highest in the cloth mask group, with an RR for ILI of 13 compared to the medical mask arm, an RR for ILI of 6.6 compared to the control arm, and an 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.⁴⁶
- <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[®].³³ 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.³³
- Konda et al. 2020 evaluated filtration efficiency for particle sizes in the 10nm to 10µm range for 15 different cloth types (e.g. cotton, silk, flannel, etc.).⁵² 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.⁵²

- <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).⁵³
 Filtration efficiency for polypropylene in N95 masks was >95%, whereas for 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.⁵³
- <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.⁵⁴ Combinations of materials with hydrophilic, hydrophobic, and absorbent layers were most efficient, and were comparable to materials in N95 respirators in this laboratory setting.⁵⁴
- <u>Zangmeister et al. 2020</u> evaluated 32 different cloth materials and combinations of materials using NaCl aerosols of diameters of 50-825nm, and found that 3 of 5 top performing materials were high thread-count cottons.⁵⁵

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.⁵⁶ Continuous mask use may be associated with facial skin lesions, irritant dermatitis, impaired vision in those wearing glasses, or worsening acne.^{4,57,58} One study <u>observed physiologic respiratory changes</u> from the use of N95 respirators in healthcare workers (with prolonged use), these finding were subtle and not considered clinically relevant.⁵⁹ <u>Another study in healthcare workers</u> reported various subjective complaints (e.g. headache, impaired cognition); however, only skin effects (e.g. irritation, acne) were consistently noted.⁶⁰ The Canadian Thoracic Society <u>position statement</u> on mask use for the public states, "There is NO evidence that wearing a face mask will exacerbate (cause a 'flare up' of) an underlying lung condition."⁶¹ Studies in children have identified low adherence to proper use in school settings.³⁰⁻³² No study has evaluated the impact of mask use on children's education quality. Further studies are needed on optimal methods for optimizing mask use in children.

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