COVID-19 Living Evidence Synthesis 14.1a:
Effectiveness of masks for reducing transmission of COVID-19 in non-healthcare community-based settings

Executive summary

Question

What is the best-available evidence about the effectiveness of masks in reducing transmission of COVID-19 in non-health care community-based settings?

Sub-questions:

1. What is the best-available evidence about which types of masks are the most effective at reducing transmission of COVID-19 in non-health care community-based settings?
2. What is the best-available evidence about the effectiveness of mask mandates in reducing transmission of COVID-19 in non-health care community-based settings?
3. In studies about the effectiveness of masks in reducing transmission of COVID-19, was there evidence about the effectiveness of masks in reducing transmission of other respiratory infections?
4. What knowledge gaps and/or methodological gaps exist in the scientific literature related to masks for COVID-19?

Background

- This living evidence synthesis (LES) focused on the impact of masking is one of a suite of eight LESs aiming to describe the effectiveness of, and adherence to, public health and social measures (PHSMs) for reducing transmission of COVID-19 and other respiratory infections in non-health care community-based settings. The suite also aims to identify knowledge gaps in the scientific literature and potential negative outcomes associated with these PHSMs.
- Recommendations and mandates to use masks, respirators, and other facial coverings have been common PHSMs during the pandemic. Through a lens of the hierarchy of evidence, the initial version of this report focused on studies of randomized controlled trials (RCTs) of mask use. This version adds summaries of studies lower in the hierarchy, including observational studies with comparison groups about the effectiveness of masks (including different types of masks) and mask mandates in reducing transmission of COVID-19 in community settings.
- Face coverings of variable filtration efficiency are implemented in these studies. In this review "medical masks" refer to multilayer polypropylene masks as used in medical and surgical health care settings, cloth masks are face coverings of variable manufacture that cover the mouth and nose, and respirator masks refer to polypropylene masks manufactured for higher filtration efficiency which are usually intended to be fit tested to the wearer.

Key points

- **Majority of studies favoured masks.** Observational studies were the most common design contributing evidence to this question (n=32/35; 91%). Overall, there were more studies favouring masks (n=21/24; 85%) and mask mandates (n=9/10; 90%) to reduce transmission than those that found no effect (n=2/34; 6%) or favoured controls (n=1/34; 3%). However, study design, effect size, sample size, outcome measures, and intervention characteristics varied greatly across studies.
- **Few studies compared types of masks.** Two studies (one RCT, one observational) found that surgical masks were more effective than cloth masks, one RCT found that surgical masks plus face shields were non-inferior to surgical masks alone, and one observational study found that the type of mask (medical vs. non-medical) was not significantly associated with infection risk.
- **Randomized controlled trials (RCTs) were rare and had a high risk of bias.** RCTs about the effectiveness of masks in reducing transmission of COVID-19 in the community are limited in number with only three in community-based settings currently published. All three RCTs were assessed to have high risk of bias, and all took place before the more highly transmissible Omicron variant became prevalent.

- **Effect size was smaller in RCTs than observational studies.** In studies evaluating the effects of masks in general, RCTs had smaller odds ratios than observational studies presenting comparable data.
- **Almost all observational studies were at critical risk of bias (ROB) in at least one domain.** Method for assessing ROB in this review included a 'stop' decision when one criterion was identified as critical. ROB was assessed to be critical in at least one domain of almost all observational studies (n=29/32; 91%). Confounding in many studies (n=12/35; 34%) limited relating outcomes directly to masks or mask mandates alone, but it is challenging to design studies that reduce such biases. See Box 1 for more context about designing studies of PHSMs.
- **Masking most often assessed by self-report.** Observational studies of the effectiveness of masks in general or types of masks relied on self-reported mask-wearing behaviour collected via questionnaire (n=11/22; 50%), contact tracing (6/22; 27%), or interview (5/22; 23%). These studies are therefore subject to recall and social desirability bias. 90% of mask mandate studies (n=9/10) relied on publicly available information about what requirements were in effect; the remaining study used contact tracing. No included studies involved active observation of mask use.
- **The method for confirming COVID-19 status varied across studies.** PCR was the most common testing method (n=18/35; 51%), followed by serology (n=10/35; 29%). Nine studies (26%) did not specify the testing method used. Enzyme-linked immunosorbent assay (ELISA) was the most common immunoassay used (n=4). 22 studies using self-reported COVID-19 status were excluded from this review.
- **Adherence was rarely measured.** In addition to mask type and quality, adherence is likely to influence the protective effects of masking and is therefore an important factor to consider in this literature. Assessing and reporting of adherence was rare and varied across included studies.
- **Schools were most common setting for mask mandate studies.** The majority (n=6/10; 60%) of observational studies examining mask mandates have been conducted in school settings.
- **Overall, the existing body of literature examining effectiveness of masks and mask mandates in the community setting is trending in favour of the use of masks. However, the quality of evidence informing this trend has been assessed as critical ROB.** The studies included in this review may serve as a valuable source for hypothesis generation.

Patient-identified key messages

Patients and families, particularly those with compromised health, worry about how the limited number of RCTs and studies with a low ROB supporting the use of masks to reduce transmission of COVID-19 will impact adherence in community settings.

Overview of evidence and knowledge gaps

- As with many PHSMs for reducing transmission of COVID-19, there is a paucity of RCTs about effectiveness.
- Modelling and mechanical studies were the most common study design excluded from this LES. Study designs that measure real-world human response to complex natural, political, and social phenomena are needed to explain human behaviour related to masking in community settings as a PHSM, and how that impacts effectiveness of this intervention.
- Standardized strategies for recording and reporting adherence to masking are needed.

Date of last literature search: 3 March 2023

Suggested citation: Curran J, Boulos L, Gallant A, Johnson C, Delahunty-Pike A, Wong H, Dye C, Saxinger L, Chu D, Comeau J, Flynn T, Clegg J, COVID-END PHSM LES Working Group. COVID-19 Living Evidence Synthesis 14.1a: Effectiveness of masks for reducing transmission of COVID-19 in non-healthcare community-based settings Dalhousie University, 24 March 2023.

Please note: This living evidence synthesis (LESs) is part of a suite of LESs of the best-available evidence about the effectiveness of six PHSMs (masks, quarantine and isolation, ventilation, physical distancing and reduction of contacts, hand hygiene and respiratory etiquette, cleaning, and disinfecting), as well as combinations of and adherence to these measures, in preventing transmission of COVID-19 and other respiratory infectious diseases in non-health care community- based setting. This first full version was developed after two interim versions, which are available upon request. The next update to this and other LESs in the series is to be determined, but the most up-to-date versions in the suite are available on the COVID-END website. We provide context for synthesizing evidence about public health and social measures in Box 1 and an overview of our approach in Box 2.

Box 1: Context for synthesizing evidence about public health and social measures (PHSMs)

This series of living evidence syntheses was commissioned to understand the effects of PHSMs during a global pandemic to inform current and future use of PHSMs.

General considerations for identifying, appraising and synthesizing evidence about PHSMs

- PHSMs are population-level interventions and typically evaluated in observational studies.
  - Many PHSMs are interventions implemented at a population level, rather than at the level of individuals or clusters of individuals such as in clinical interventions.
  - Since it is typically not feasible and/or ethical to randomly allocate entire populations to different interventions, the effects of PHSMs are commonly evaluated using observational study designs that evaluate PHSMs in real-word settings.
  - As a result, a lack of evidence from RCTs does not necessarily mean the available evidence in this series of LESs is weak.
- Instruments for appraising the risk of bias in observational studies have been developed; however, rigorously tested and validated instruments are only available for clinical interventions.
  - Such instruments generally indicate that a study has less risk of bias when it was possible to directly assess outcomes and control for potential confounders for individual study participants.
  - Studies assessing PHSMs at the population level are not able to provide such assessments for all relevant individual-level variables that could affect outcomes, and therefore cannot be classified as low risk of bias.
- Given feasibility considerations related to synthesizing evidence in a timely manner to inform decision-making for PHSMs during a global pandemic, highly focused research questions and inclusion criteria for literature searches were required.
  - As a result, we acknowledge that this series of living evidence syntheses – about the effectiveness of specific PHSMs (i.e., quarantine and isolation; mask use, including unintended consequences; ventilation, reduction of contacts, physical distancing, hand hygiene and cleaning and disinfecting measures), interventions that promote adherence to PHSMs, and the effectiveness of combinations of PHSMs – does not incorporate all existing relevant evidence on PHSMs.
  - Ongoing work on this suite of products will allow us to broaden the scope of this review for a more comprehensive understanding of the effectiveness of PHSMs.
  - Decision-making with the best available evidence requires synthesizing findings from studies conducted in real-world settings (e.g., with people affected by misinformation, different levels of adherence to an intervention, different definitions and uses of the interventions, and in different stages of the pandemic, such as before and after availability of COVID-19 vaccines).

Our approach to presenting findings with an appraisal of risk of bias (ROB) of included studies

To ensure we used robust methods to identify, appraise and synthesize findings and to provide clear messages about the effects of different PHSMs, we:

- acknowledge that a lack of evidence from RCTs does not mean the evidence available is weak
- assessed included studies for ROB using the approach described in the methods box
- typically introduce the ROB assessments only once early in the document if they are consistent across sub-questions, sub-groups and outcomes, and provide insight about the reasons for the ROB assessment findings (e.g., confounding

with other complementary PHSMs) and sources of additional insights (e.g., findings from LES 20 in this series that evaluates combinations of PHSMs)
- note where there are lower levels of ROB where appropriate
- note where it is likely that risk of bias (e.g., confounding variables) may reduce the strength of association with a PHSM and an outcome from the included studies
- identify when little evidence was found and when it was likely due to literature search criteria that prioritized RCTs over observational studies.

Implications for synthesizing evidence about PHSMs
Despite the ROB for studies conducted at the population level that are identified in studies in this LES and others in the series, they provide the best-available evidence about the effects of interventions in real life. Moreover, ROB (and GRADE, which was not used for this series of LESs) were designed for clinical programs, services and products, and there is an ongoing need to identify whether and how such assessments and the communication of such assessments, need to be adjusted for public-health programs, services and measures and for health-system arrangements.

Findings

- 35 studies (3 RCTs and 32 observational studies) are included in this LES.
- 1 RCT reports on the effectiveness of masks in general in reducing transmission, 1 RCT reports on different types of masks, and 1 cluster RCT reports on both.
- 22 observational studies report on the effectiveness of masks in reducing transmission.
- 2 observational studies report on different types of masks.
- 10 observational studies report on mask mandates.
- 1 RCT reports on masks to reduce other respiratory infections as a secondary outcome.
- All RCTs were assessed to have high risk of bias.
- Among observational studies, all except three (one at moderate risk, two at serious risk) were assessed to have critical risk of bias in at least one domain. Box 1 provides more context about designing studies of PHSMs.
- A PRISMA 2020 flow diagram of the screening process is shown in Figure 1.

Box 2: Our approach

We retrieved candidate studies by searching: 1) PubMed; 2) the iCite pre-print server; 3) Embase; 4) CINAHL; and 5) ERIC. Searches were conducted for studies reported in English, conducted with humans and published since 1 January 2020 (to coincide with the emergence of COVID-19 as a global pandemic). Our detailed search strategy is included in **Appendix 1**.

Studies that report on empirical data with a comparator were considered for inclusion, with modelling studies, simulation studies, cross-sectional studies, case reports, case series, and press releases excluded. Other study designs may be considered for future versions in the absence of other forms of evidence. A full list of included studies is provided in **Tables 2-5**. Studies excluded at the last stages of reviewing are provided in **Appendix 2.**

Population of interest: All population groups that report data related to all COVID-19 variants and sub-variants.

Intervention and control/comparator: Any device that covers the nose and mouth and that may reduce the risk of spreading or becoming infected with an infectious pathogen. May include non-medical masks, medical masks, and/or respirators.

Primary outcome: Reduction in transmission of COVID-19; **Secondary outcomes**: Reduction in COVID-19 associated deaths, and transmission of other respiratory infections.

Data extraction: Data extraction was conducted by one team member and checked for accuracy and consistency by another using the template provided in **Appendix 3**.

Critical appraisal: Risk of Bias (ROB) of individual studies was assessed using validated ROB tools. For RCTs we used ROB-2, and for observational studies, we used a modified version of ROBINS-I. Judgements for the domains within these tools were decided by consensus of the synthesis team and underwent revision with subsequent iterations of the LES as needed. Once a study was seemed to meet one criterion that made it "critical" risk of bias, it was dropped without completing the full ROB assessment. Our detailed approach to critical appraisal is provided in **Appendix 4** and described here.

Summaries: We summarized the evidence by presenting narrative evidence profiles across studies by outcome measure. Results were not pooled, but figures were created to visualize odds ratios and 95% confidence intervals of eligible studies.

The next update to this document is to be determined.

Figure 1: PRISMA 2020 Flow Diagram

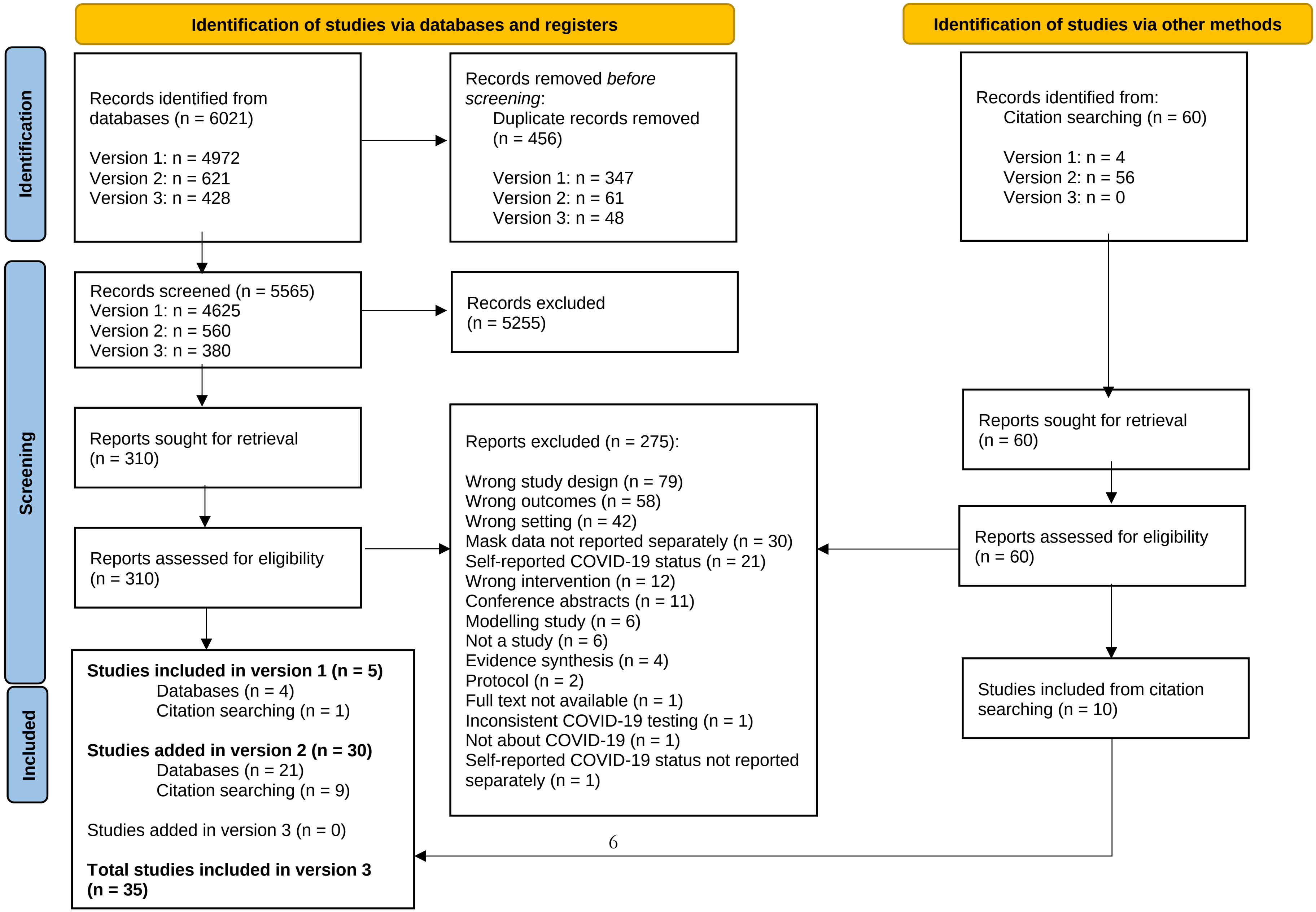


Table 1: High-level characteristics of included studies

Study	Design	Country	Phenomenon of interest	Outcome measure	Mask-wearing measure
Abaluck et al., 2022	Cluster RCT	Bangladesh	Masks for reducing transmission; types of masks	Serology (ELISA)	Direct observation (weekly)
Andrejko et al., 2022a	Observational	USA	Masks for reducing transmission; types of masks	Molecular test (non-specific)	Questionnaire
Andrejko et al., 2022b	Observational	USA	Masks for reducing transmission	Molecular test (non-specific)	Interview
Areekal et al., 2021	Observational	India	Masks for reducing transmission	Testing (method not specified)	Contact tracing
Baig et al., 2021*	Observational	Pakistan	Masks for reducing transmission	Serology (CLIA or ELISA)	Questionnaire
Boutzoukas et al., 2022	Observational	USA	Mask mandates for reducing transmission	Testing (method not specified)	Mandate data
Bundgaard et al., 2021	RCT	Denmark	Masks for reducing transmission	PCR or serology (LFIA)	Questionnaire
Cheng et al., 2020	Observational	Hong Kong	Masks for reducing transmission	PCR	Interview
DeJonge et al., 2022	Observational	USA	Mask mandates for reducing transmission	Testing (method not specified)	Mandate data
Doung-Ngern et al., 2020	Observational	Thailand	Masks for reducing transmission; types of masks	RT-PCR	Contact tracing
Doyle et al., 2021	Observational	USA	Mask mandates for reducing transmission	Nucleic acid or antigen	Mandate data
Gigot et al., 2022	Observational	USA	Masks for reducing transmission	Saliva antibody testing	Questionnaire
Goncalves et al., 2021	Observational	Brazil	Masks for reducing transmission	RT-PCR or antibody testing (non-specific)	Interview
Hast et al., 2022	Observational	USA	Masks for reducing transmission	RT-PCR	Contact tracing
Herstein et al., 2021	Observational	USA	Mask mandates for reducing transmission	Testing (method not specified)	Mandate data
Hobbs et al., 2020	Observational	USA	Masks for reducing transmission	RT-PCR	Interview

Islam et al., 2022	Observational	USA	Mask mandates for reducing transmission	Testing (method not specified)	Mandate data
Jehn et al., 2021	Observational	USA	Mask mandates for reducing transmission	RT-PCR or NAAT or antigen	Mandate data
Li et al., 2021	Observational	USA	Mask mandates for reducing transmission	Testing (method not specified)	Mandate data
Lio et al., 2021	Observational	Macao	Masks for reducing transmission	Testing (method not specified)	Questionnaire
Liu et al., 2021	Observational	USA	Masks for reducing transmission	RT-PCR (self-collected nasal)	Questionnaire
Moek et al., 2022	Observational	Germany	Mask mandates for reducing transmission	RT-PCR	Contact tracing
Nelson et al., 2021*	Observational	USA	Masks for reducing transmission	Testing (method not specified)	Contact tracing
Pauser et al., 2021	Observational	Germany	Masks for reducing transmission	PCR	Contact tracing
Payne et al., 2020	Observational	USA	Masks for reducing transmission	RT-PCR or seropositivity (ELISA)	Questionnaire
Rebmann et al., 2021	Observational	USA	Masks for reducing transmission	RT-PCR (saliva)	Contact tracing
Riley et al., 2022	Observational	USA	Masks for reducing transmission	Testing (method not specified)	Questionnaire
Shaweno et al., 2021	Observational	Ethiopia	Masks for reducing transmission	Serology (chemiluminescent microparticle immunoassay (CMIA))	Questionnaire
Sombetzki et al., 2021	Observational	Germany	Mask mandates for reducing transmission	PCR	Mandate data
Sugimura et al., 2021	Observational	Japan	Masks for reducing transmission	PCR	Interview
Theuring et al., 2021	Observational	Germany	Masks for reducing transmission	RT-PCR or serology (ELISA)	Questionnaire
Ulyte et al., 2021	Observational	Switzerland	Mask mandates for reducing transmission	Serology (multifactorial seroprofiling (ABCORA))	Questionnaire
van den Broek-Altenburg et al., 2021	Observational	USA	Masks for reducing transmission	PCR	Questionnaire

Varela et al., 2022	RCT	Colombia	Types of masks	RT-PCR or serology (rapid antibody test)	Photograph confirmation of mask use; questionnaire; interview
Wang et al., 2020a	Observational	China	Masks for reducing transmission	RT-PCR or serology (non-specific)	Questionnaire

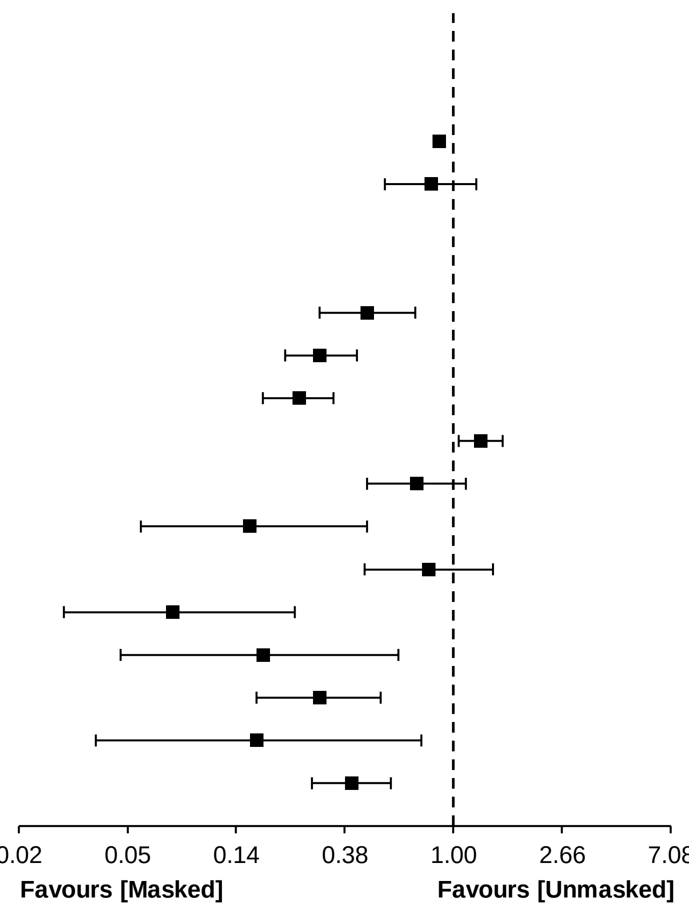
*Non-peer-reviewed preprint

Data visualizations of a subset of studies

A subset of 14 studies (2 RCTs, 12 observational) reported the number of COVID-19 infection events in those who wore a mask vs. those who were unmasked. The unpooled odds ratios and 95% confidence intervals of these studies are visualized in Figure 2. A subset of four studies (all observational) additionally reported the number of COVID-19 infection events in those who self-reported wearing a mask *sometimes* vs. those who were unmasked. The unpooled odds ratios and 95% confidence intervals of these studies are visualized in Figure 3.

Figure 2: Odds ratios and 95% confidence intervals of a subset of eligible included studies comparing masked vs. unmasked

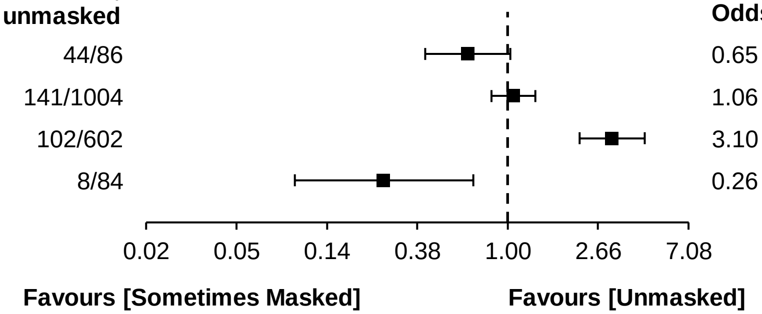
Study	Events, masked	Events, unmasked	Odds Ratio [95%CI]
RCTs			
Abaluck et al. 2022*	12784/178322	13287/163861	0.88 [0.85, 0.90]
Bundgaard et al. 2021	42/2392	53/2470	0.82 [0.54, 1.23]
Observational studies			
Andrejko et al. 2022a	393/1212	44/86	0.46 [0.30, 0.71]
Andrejko et al. 2022b	101/188	648/816	0.30 [0.22, 0.42]
Areekal et al. 2021	57/520	254/766	0.25 [0.18, 0.34]
Baig et al. 2021	716/4139	141/1004	1.28 [1.05, 1.56]
Doung-Ngern et al. 2020	29/227	102/602	0.72 [0.46, 1.12]
Goncalves et al. 2021	184/589	14/19	0.16 [0.06, 0.46]
Hast et al. 2022	22/259	30/289	0.80 [0.45, 1.43]
Lio et al. 2021	6/713	8/84	0.08 [0.03, 0.24]
Pauser et al. 2021	12/26	24/29	0.18 [0.05, 0.61]
Payne et al. 2020	158/283	80/99	0.30 [0.17, 0.52]
Rebmann et al. 2021	2/26	114/352	0.17 [0.04, 0.75]
Riley et al. 2022	47/376	131/495	0.40 [0.28, 0.57]



*Although Abaluck et al. 2022 is a cluster RCT, the sample sizes presented in this figure represent events at the individual level.

Figure 3: Odds ratios and 95% confidence intervals of a subset of eligible included studies comparing sometimes masked vs. unmasked

Study	Events, sometimes masked	Events, unmasked	Odds Ratio [95%CI]
Andrejko et al. 2022a	215/530	44/86	0.65 [0.41, 1.03]
Baig et al. 2021	176/1190	141/1004	1.06 [0.84, 1.35]
Doung-Ngern et al. 2020	79/204	102/602	3.10 [2.18, 4.41]
Lio et al. 2021	9/339	8/84	0.26 [0.10, 0.69]



Box 3: Summary of findings about the primary outcome: Masks for reducing transmission of COVID-19

24 studies (2 RCTs, 22 observational) were included that report on masks for reducing transmission of COVID-19. The characteristics, findings and assessment of risk of bias for each study are presented in Table 2.

The body of RCT related to the effectiveness of masks in reducing transmission of COVID-19 is sparse and inconclusive. While a community-based implementation cluster RCT **(Abaluck et al., 2022)** found a 9.5% reduction in symptomatic seroprevalence and an estimated 11.6% reduction in proportion of individuals with COVID-19-like symptoms in those who used masks versus those who did not, the other RCT **(Bundgaard et al., 2021)** found no statistically significant difference (1.8% versus 2.1% incidence, compared with a 46% reduction to 23% increase in infection) in reduction of SARS-CoV-2 infection transmission between the intervention group (medical masking recommendation) and control group. Both RCTs were assessed to have a high risk of bias.

The only observational study with a moderate risk of bias was **Andrejko et al. (2022b)**, a case-control study that controlled for all important confounding factors and matched cases with controls. They found that mask usage was protective when both parties reported mask usage, when exposures took place outside the household, when exposures involved no physical contact, and when exposures were indoors.

The remaining 21 studies in this section, all at critical risk of bias in at least one domain, have wide variation in study design, intervention characteristics, and outcome measures. Two are preprints that have not been subject to peer review.

Summaries of studies of masks for reducing transmission of COVID-19

Randomized controlled trials

Both studies in this section have a ***high*** *risk of bias*

In a cluster RCT involving adults living in rural villages dispersed throughout Bangladesh, **Abaluck et al. (2022)** examined the community-level impact of a range of mask promotion strategies including free masks, information on the importance of masking, role modeling by community leaders and reminders for 8 weeks, versus no intervention, on SARS-CoV-2 seroprevalence. Mask-wearing was assessed at community locations through direct observation at least weekly. Blood samples were collected at 10-12 week follow ups for symptomatic individuals. Findings estimate 11.6% reduction in COVID-19 symptoms and 9.5% reduction in symptomatic seroprevalence between intervention and control arms after adjusting for baseline covariates. Of note, proper mask wearing increased from 13.3% in control villages to 42.3% in intervention villages.

In another RCT involving adults in Denmark, **Bundgaard et al. (2021)** evaluated the impact on SARS-CoV-2 infection of receiving recommendations to wear a mask while outside of the home and providing 50 disposable masks. At the time of this study mask wearing was uncommon and not a recommended PHSM in Denmark. Participants were randomized to intervention (n=3,030) and control (n=2,994) groups at two time periods (April 12, 2020 and April 24, 2020) and were followed for 4 weeks after randomization. SARS-CoV-2 infection was determined by a positive result with either a self-administered oropharyngeal/nasal swab test, a positive SARS-COV-2 antibody test or a hospital-based diagnosis. Infections occurred in 42 participants (1.8%) in the mask group and 53 (2.1%) in the control group. Following an intention-to-treat analysis the between group difference favored the mask group but did not reach statistical significance –0.3 (95%CI: -1.2–0.4); p=0.38 (OR, 0.82 [95%CI: 0.54–1.23]; p=0.33). At follow-up, less than half (46%) of participants in the intervention group reported wearing masks as recommended and 7% reported nonadherence. Further, in three unplanned, post hoc analyses accounting for only those participants reporting wearing masks "exactly as instructed", excluding participants who did not provide antibody tests at baseline, and different constellations of patient characteristics, investigators did not find a subgroup where masks were effective at conventional levels of statistical significance.

Observational studies

Moderate *risk of bias*

Andrejko et al. (2022b) conducted a case-control study of 1,006 California residents to identify predictors of SARS-CoV-2 infection following high-risk exposures. Participants (n=1,448) with positive COVID-19 test results reported to the California Department of Public Health were matched with 1,443 COVID-19-negative controls. Cases and controls were contacted at random within 48 hours of their test results and administered a standardized phone-based questionnaire about their exposures over the 14 days preceding their tests, including whether they or their contacts had worn masks. Findings indicated that 52% of cases (n=751/1,448) and 18% of controls (n=255/1,443) reported high-risk exposures; among these participants, 14% of cases (n=101) and 34% of controls (n=87) reported mask usage during these exposures. Mask usage was protective when both parties reported mask usage (aOR=0.50; 95%CI: 0.26–0.96), when exposures took place outside the household (aOR=0.39; 95%CI: 0.22–0.70), when exposures involved no physical contact (aOR=0.37; 95%CI: 0.20–0.69), and when exposures were indoors (aOR=0.51; 95%CI: 0.28–0.93). Mask usage was not protective when exposures happened within the household, involved physical contact, or occurred outdoors. Notably, the benefits of mask-wearing were found to be highest in unvaccinated and partially vaccinated participants.

This study was assessed to have a **moderate** risk of bias. The authors adjusted for all important confounding factors, demographics, calendar time, and matched cases with controls. However, they did not account for mask mandates in effect at the time of the study.

Critical *risk of bias in at least one domain*

In North Carolina, **Gigot et al. (2022)** conducted a prospective cohort study of industrial livestock operation (ILO) workers, their families, and their neighbours from February 2021 to July 2022. The objective was to ascertain SARS-CoV-2 IgG antibody prevalence among participants via self-collected saliva samples, and to gather data on participant demographics, preventive behaviours including masking, and health history via a phone-based questionnaire. ILO workers and their families were compared to their neighbours and to non-ILO participants living in metropolitan areas of North Carolina. Among all 279 participants, not wearing a mask in public during the previous two weeks was associated with higher IgG prevalence (78.6%) compared to wearing a mask (49.3%; PR=1.59; 95%CI: 1.19-2.13). However, no comparison in mask-wearing was made between any of the groups, making it impossible to ascertain if masks were preventive in ILO vs. non-ILO settings. **As a preprint, this study has not undergone peer review.**

In a case-control involving residents in California (n=1,828), **Andrejko et al. (2022a)** examined the effectiveness of masks and respirators (NN95/KN95) against COVID-19 transmission over a 10-month span in 2021. Mask use and type of mask used were compared via self-report between identified test-positive cases and test-negative controls. Acquisition of COVID-19 was measured with a positive molecular test result for SARS-CoV-2. Odds ratio calculations were used to calculate COVID-19 risk. Self-reported use of any mask in indoor settings was associated with a significantly lower risk of contracting the virus (aOR= 0.51; 95%CI: 0.29–0.93). Self-reported data on face mask use identified those who always wore a mask had significantly lower odds of a positive COVID-19 test compared to those who never masked (aOR= 0.44; 95%CI: 0.24–0.82). Reductions in positive tests were also noted among those who masked most (aOR= 0.55; 95%CI: 0.29–1.05) or sometimes (aOR = 0.71; 95%CI: 0.35–1.46) compared to those who never masked. The author noted potential limitations of the study, primarily that other prevention measures may have been used with masks, which could also reduce COVID-19 transmission.

In a secondary analysis of case control data, involving students and staff from Georgia, USA, **Hast et al. (2022)** sought to evaluate transmission of COVID-19 between positive staff and students and contacts at school. Data was collected between December 2020 and January 2021. Mandatory mask use was in place in schools and on the school bus, among other public health measures. COVID-19 transmission was measured using RT-PCR tests. Transmission of COVID-19 and characteristics were assessed using descriptive statistics and logistic regressions. 628 students and staff completed the survey and COVID-19 testing. Among study findings, elementary aged students had a positivity rate of 44% (n=4/9) among unmasked students who played sports compared to 8% among other students (n=28/344; OR=9.0, 95%CI: 2.3-35.5; p<0.005). Among middle/high school students, COVID-19 positive rate was 18% (n=15/85) among students who played sports compared to 6% in other students (n=7/121; OR=3.5, 95%CI: 1.4-9.0). Positive rate increased to 20% (n=15/74) among sports-playing students who reported unmasked sport playing time compared to 6% among masked sports-playing students (OR=4.3, 95%CI: 1.7-11.3; p<0.001).

In a retrospective study of 21 basketball players and 48 staff at a professional basketball sporting event in November 2020 in Germany, **Pauser et al. (2021)** studied mask use for the length of the sporting event in three different zones. Community masks, surgical masks, and particle filtering masks (FFP2, FFP3, and KN95) masks were used. COVID-19 cases post-sporting event were measured using PCR testing. Participants were contacted about PCR testing after the event, testing was performed in approximately 90% of the participants. Using statistical methods, it was shown that self-reported wearing of masks (medical face mask - community masks and/or surgical masks) or particle filter masks (FFP2, FFP3 or KN95) was associated with a reduced risk of SARS-CoV-2 transmission from 83% to 46%.

In a case-control study involving residents of Iowa, USA, **Riley et al. (2022)** examined the effects of masks on secondary attack rates of COVID-19 between October 2020 and February 2021. COVID-19 rates were assessed using laboratory-confirmed tests. Using logic regressions, the authors found a secondary attack rate of 12.5% when it was self-reported that both parties were masked (n= 47/376; 95%CI: 9.6-16.3%). Most contacts were exposed when it was self-reported that at least one person was not wearing a mask, resulting in an overall infection rate in this group of 25.6% (n=151/590; 95%CI: 22.3-29.4%); this rate varied if the COVID-19 positive person was masked (29.1%; 95%CI: 19.3-43.9%) or if the contact was the masked person (10%; 95%CI: 4-25.3%). When all parties were not masked, the rates were 26.4% (95%CI: 22.9-30.7). Among contacts who were school-aged children (n=426; aged 5-18 years), 53 tested positive when at least one person was not masked (5.2%; 95%CI: 20.1-32.0%) and increased to 12% when both people were masked (95%CI: 8.4-17.2%).

In a survey of residents of Islamabad, Pakistan, **Baig et al. (2021)** examined the association between SARS-CoV-2 seropositivity and preventive behaviours such as mask-wearing. After administering a survey of 6,333 individuals who provided blood samples in June 2020, the authors concluded that a Chi-Square test indicated that self-reported regular mask use was correlated with lower seroprevalence ($\chi2 = 8.6$; $p<0.05$) than occasionally or never wearing a mask. However, calculations of the study's raw data show an OR of 1.28 (95%CI: 1.05-1.56) associated with always wearing a mask and 1.06 (95%CI: 0.84-1.35) associated with sometimes wearing mask, overall favouring the unmasked group. **The paper also presents several other quality concerns, and as a preprint, it has not undergone peer review.**

In a cohort study of staff and students in 70 Massachusetts K-12 schools, **Nelson et al. (2021)** examined SARS-CoV-2 secondary attack rate and factor associated with transmission risk. Index cases and their close contacts were questioned about whether both parties were masked or unmasked during their encounter. The secondary attack rate was significantly higher if both reported being unmasked vs. both masked (RR=6.98; 95%CI: 3.09-15.77; $p<0.001$). Although there were three incidences of exposures in which one party was masked and the other unmasked, these data were excluded from the analysis. This study is a preprint and has not been subject to peer review.

In a case control study involving students at St. Louis University (265 positive cases and 378 close contacts), in St. Louis USA, **Rebmann et al., (2021)** examined how a modified quarantine procedure at the university affected COVID-19 transmission between cases and close contacts during the spring 2021 semester (January-May 2021). COVID-19 transmission to close contacts was monitored through saliva-based PCR tests 5-7 days after exposure. Using t-tests and logistic regression analyses methods, the authors identified 116/378 (30.7%) of close contacts tested positive for COVID-19. Rates of positive results were significantly higher among self-reported unmasked contact with the initial positive cases (unmasked: n=114/352; 32.4 vs masked: n=2/26; 7.7%; aOR: 5.4, 95%CI: 1.5–36.5; $p = 0.008$).

In an epidemiological surveillance study conducted in Hiroshima Prefecture, Japan, **Sugimura et al. (2021)** evaluated mask-wearing among 820 close contacts of patients with COVID-19. In comparison to self-reported non-mask wearers who had a positive rate of 16.4% for COVID-19, individuals who reported wearing masks possessed a positive rate of 7.1%. A significant relationship between mask use and COVID-19 infections were observed in those who were men, involved in cluster cases, were in contact with the patient at the welfare facility, and worked with the patient.

In a cross-sectional longitudinal study involving 1,119 primary students, secondary students, staff and household members in Berlin, Germany in November 2020, **Theuring et al. (2021)** examined SARS-CoV-2 transmission and IgG antibodies and associations with individual and institutional prevention measures. SARS-CoV-2 infections and seroreactivity were measured using oral-nasopharyngeal swabs and blood samples, a questionnaire about individual prevention measures was administered, and school-related implementation of government infection was documented. Almost 9 in 10 index participants stated they often or always wore a mask at school, and their infection prevalence was 1.4%. Of those who wore masks never to sometimes, 14.3% tested positive (OR= 11.38; 95%CI: 2.28−59.64). 8 of 16 non-affected classes required masking in the classroom, while only 1 of 8 affected classes required masking.

In a prospective case-ascertained transmission study involving 15 index cases and 50 household contacts in Los Angeles County households, **Liu et al. (2021)** examined the effect of index case masking vs. not masking on secondary attack rates of household contacts from December 2020 to February 2021. Secondary attack rates were measured using self-collected nasal midturbinate swab specimens in which SARS-CoV-2 positivity was determined using the Swab Seq protocol. Demographics, medical history, household characteristics and control measures were captured via a Qualtrics survey completed by household contacts. Using $\chi 2$ test of proportions, it was found that transmission was significantly lower in households in which the index patient reported being masked compared with those who were unmasked.

In a cross-sectional survey consisting of 684 individuals aged 15 and older living in congregate households within Dire Dawa city administration, Ethiopia, **Shaweno et al. (2021)** examined self-reported mask-wearing practices while away from home. Blood samples were collected by the Ethiopian Public Health Institute (EPHI) to estimate SAR-CoV-2 antibody seroprevalence. In conducting multivariate logistic regression analyses, SARS-CoV-2 seroprevalence was found to be significantly associated with face mask usage outside of the home. In comparison to individuals who reported mask-wearing, the odds of SARS-CoV-2 antibody seroprevalence was found to be higher for those who did not use masks when away from home.

In a case-control study involving residents of Brazil, **Goncalves et al. (2020)** studied mask use and COVID-19 transmission between April-June 2020. Mandates were in place during the study period, however the authors note there was limited compliance with public health measures, including masking, as a result of influential sources in the country who discredited the pandemic control measures. Self-reported mask use and COVID-19 positive test rates were compared between case patients (n=229) and a subset of controls (n=464/1,396) as mask data was not consistently collected during data collection. From this analysis, mask use was associated with a decrease in COVID-19 cases (OR= 0.12; 95%CI: 0.04-0.30). When data from participants who stayed home at all times were removed from the sample, the trend in decreased COVID-19 cases as a result of mask use was maintained (OR=0.13; 95%CI: 0.04-0.36). When those who never and sometimes masked were grouped and compared with those who always masked, COVID-19 cases remained low (OR: 0.36; 95%CI: 0.17-0.74).

Lio et al. (2021) administered a cross-sectional survey to 24 hospitalized COVID-19 patients and 1,113 controls in Macao between March-April 2020. The objective was to evaluate risk and protective factors for COVID-19 infection, including self-reported mask-wearing behaviour. 25% of infected participants reported wearing a mask whenever outdoors vs. 63.5% of controls ($p < 0.001$), and those who wore masks whenever outdoors had a risk reduction of 80.9% (OR: 0.191; 95%CI:

0.075–0.486; p< 0.005) compared with those who did not. However, the sample size of COVID-19 infected participants (n=24) was very small.

In a retrospective cohort study consisting of close contacts of patients with COVID-19 in Thrissur, Kerala, **Areekal et al. (2021)** assessed secondary cases of infection. Contact tracing and telephone interviews for data collection were completed by a dedicated team at the Government Medical College, where the COVID infected patients were admitted. From the 267 admitted patients with COVID-19, 1,286 close contacts were identified, with 311 contacts subsequently testing positive. Results from binary logistic regression analyses suggested that self-reported mask use was associated with a statistically significant reduction of odds of COVID-19 infection (aOR=0.570; 95%CI: 0.461-0.704 p=0.001).

In a survey study involving 454 community dwelling adults in Vermont, **van den Broek-Altenburg et al. (2021)** measured the prevalence and incidence of COVID-19 and identified masking behaviours outside of work over 2 months. Prevalence of SARS-CoV-2 in the community was measured using PCR testing on nasopharyngeal swabs, while incidence rate was tested using two different serologic assays performed on patient-matched blood samples. Using multivariate analysis, it was found that there was no significant difference between those who tested positive and those who did not, on self-reported mask wearing outside of work. However, statistical analyses were not performed on the PCR test results because only one positive test was found, thus analyses were based only on patient-matched blood samples.

In a case-control, test-negative study involving 357 children and adolescents aged <18 years in Mississippi, **Hobbs et al. (2020)** examined the association between positive SARS-CoV-2 infection with parent or guardian reported exposures and mask use over 1 month, with the exposure history of RT-PCR positive participants compared to RT-PCR negative participants. Demographics and other information about exposures were collected using structured telephone interviews with parents or guardians. Children and adolescents who received a positive RT-PCR test were less likely to have a parent/guardian report consistent mask use. However, the sample included children and adolescents who received testing with health care facilities associated with one large academic medical center in Mississippi and might not be representative of children and adolescents in other geographic areas.

In a retrospective case-control study involving 211 cases who tested positive for SARS-CoV-2 and 839 controls with negative results in Thailand, **Doung-Ngern et al. (2020)** examined self-report of types of masks used and mask-wearing compliance during interaction with a person with COVID-19 ("index patient"). Cloth face masks were recommended for the public on March 3rd and data used for identifying sample population were gathered during March 1st to 31st, 2020. Comparisons were made across the usage of no masks, nonmedical masks only, medical masks only, and both types of masks. Mask-wearing compliance was rated as "not", "sometimes", or "always" wearing a mask. SARS-CoV-2 cases were confirmed using RT-PCR results. The Thailand Surveillance and Rapid Response Teams provided data for identification of study sample and telephone interviews were used to collect mask-wearing practices. The variable on mask usage of the index patient was not included in the final analyses because it comprised of 27% missing values. Assuming that all other missing values were occurring at random, authors applied the chain equation method to generate imputed datasets. Using multivariable analyses on the imputed datasets, wearing a mask during the entire contact time with a person with COVID-19 was negatively associated with risk for SARS-CoV-2 infection (aOR 0.23; 95% CI 0.09-0.60). Type of masks was not significantly associated with

COVID-19 risk (p=0.54). In comparison to those who did not wear a mask, individuals who always wore a mask while in contact with a person with COVID-19 also reported being more likely to have shorter contact duration and practice frequent hand washing.

In a survey study involving 382 military service members at a base in Guam, **Payne et al. (2020)** studied the self-reported use of facemasks compared to no facemask use on the risk of SARS-CoV-2 infection. SARS-CoV-2 infection was measured using serum specimens tested for antibody reactivity and RT-PCR nasopharyngeal tests. Participants voluntarily completed a questionnaire which captured demographics, exposure, and preventative measure information at the time of specimen collection. Data from the questionnaire was compared to SARS-CoV-2 infection data and ORs were calculated, which found that lower odds of infection were independently associated with use of face coverings (OR:0.3; 95%CI: 0.2-0.5; p-value: <0.005). Of note, authors used RT-PCR and ELISA tests to determine current or past SARS-CoV-2 infection in the study population.

In a retrospective cohort study involving 124 households in Beijing, China, **Wang et al. (2020)** used a questionnaire to examine the self-reported practices (mask wearing, social distancing, living arrangements) of family members 4 days before and 24 hours after another family in the home developed an illness with laboratory confirmed COVID-19. Interview subjects (n=124) ranged in age from 18 years to >60 years and included the primary case and other members of the household. When comparing self-reported mask wearing behaviour of families with and without secondary transmission, 19.5% of households with secondary transmission reported wearing masks all of the time versus 45.8% of households without secondary transmission (OR=0.03; 95%CI: 0.11-0.82). However, households reported other protective behaviours including eating separately and self-isolation after illness onset.

Cheng et al. (2020) conducted a study to evaluate the impact of mask usage within the community in managing the COVID-19 pandemic within Hong Kong Special Administrative Region (HKSAR). Between April 6 to 8, 2020, 67 employees from the Infection Control Unit and the Department of Microbiology within Queen Mary Hospital documented whether the first 50 people that they encountered on their way to work were wearing a mask. All SARS-CoV-2 were confirmed according to a screening protocol and daily cases were reported each day by the Center for Health Protection of the Department of Health and Hospital Authority. During the three consecutive days of assessment, masking behaviour was noted in 10,050 individuals, where 337 (3.4%) people were not using a mask. Within the first 100 days of the pandemic, there were 961 confirmed COVID-19 cases in HKSAR. In examining the 961 cases in clusters involving self-reported masked (e.g., people at work) and unmasked (e.g., dining in restaurants, exercising at the gym) activities, there was significantly greater unmasked COVID-19 cluster settings than the equal number of masked and unmasked clusters predicted by the null hypothesis (p=0.036).

Box 4. <u>Summary of findings about primary outcome: *Types* of masks for reducing transmission of COVID-19</u>

4 studies (2 RCTs, 2 observational) were included that compare the effectiveness of different types of masks in reducing transmission of COVID-19. The characteristics, findings and assessment of risk of bias for each study is presented in Table 3.

2 RCTs compared different types of masks in community settings. In one **(Abaluck et al., 2022)**, surgical masks outperformed cloth masks when compared with the control group without masks. In the other **(Varela et al., 2022)**, use of a closed face shield with surgical face mask was non-inferior to using surgical mask alone to prevent SARS-CoV-2 infection but adherence was lower in the intervention group. Both studies were at high risk of bias.

One observational study **(Andrejko et al., 2022a)** found that N95/KN95 masks and surgical masks were effective while cloth masks were not, but the other **(Doung-Ngern et al., 2020)** found that type of mask (medical vs. non-medical) was not significantly associated with infection risk. Both studies were at critical risk of bias.

Summaries of studies of types of masks for reducing transmission of COVID-19

Randomized controlled trials

Both studies in this section have a ***high*** *risk of bias*

Varela et al. (2022) conducted a non-inferiority RCT in Bogota, Colombia to determine the effectiveness of closed face shields with surgical masks compared with using only surgical masks to prevent SARS-CoV-2 transmission. Following randomization to one of two groups, packages containing masks, recorded educational materials about COVID-19 prevention measures, guidance to ensure adherence and appropriate handling of the assigned personal protective equipment (PPE) were mailed to participants. Follow up was conducted twice a week by phone and the primary outcome was the composite of positive RT-PCR or seroconversion during follow-up. A non-inferiority limit of –5% was established based on previous literature examining other respiratory devices. In the intention-to-treat analysis, the absolute risk difference was –1.40 % (95%CI: -4.14%-1.33%; p=0.31). Of note, adherence played an important role in study findings with high adherence to the assigned intervention noted by only 27.4% of the face shield plus surgical mask group compared with 88.6% of the surgical mask comparison group.

In a cluster RCT examining the impact of mask wearing on symptomatic SARS-CoV-2 in Bangladesh, **Abaluck et al. (2022)**, cross-randomized villages in the intervention group to receive either a cloth mask or a surgical mask. The control group did not receive any intervention. Mask wearing was assessed through direct observation at least weekly. Blood samples were collected at 10-12 week follow ups for symptomatic individuals. Findings indicate surgical masks lead to a relative reduction in symptomatic seroprevalence of 11.1% (adjusted prevalence ratio =0.89 (95%CI: 0.78–1.00; control prevalence =0.81%; treatment prevalence = 0.72%) and outperform cloth masks compared with control (adjusted prevalence ratio = 0.94 (95%CI: 0.78–1.10; control=0.67%; treatment=0.61%). The authors note that the statistical significance of the impact of cloth masks varied depending on whether they impute missing values for nonconsenting adults. Further, precision of the results may be impacted by the number of villages assigned to cloth masks (100) versus surgical masks (200). However, there was no significant difference in the rate of mask-wearing between surgical mask villages and cloth mask villages.

Observational studies

Both studies in this section have a ***critical*** *risk of bias in at least one domain*

In a case-control involving n=1,828 residents in California, **Andrejko et al. (2022a)** examined the effectiveness of masks and respirators (NN95/KN95) against COVID-19 transmission over a 10-month span in 2021. Self-reported mask use and type of mask used were compared between cases and controls. Transmission of COVID-19 was measured with a positive molecular test result for SARS-CoV-2 . Odds ratio calculations were used to calculate COVID-19 transmission and identified use of any mask in indoor settings was associated with a significantly lower risk of contracting the virus (aOR = 0.51; 95%CI: 0.29–0.93). Analysis of mask type identified wearing a N95/KN95 respirator (aOR = 0.17; 95%CI: 0.05–0.64) or surgical mask (aOR = 0.34; 95%CI: 0.13–0.90) were associated with lower positive test rates compared to no mask wearing. Cloth masks also had a lower positive rate when compared to non-masking, however it was not significant (aOR= 0.44; 95%CI: 0.17-1.17). The authors note potential limitations of the study, primarily that other prevention measures may have been used with masks, which could also reduce COVID-19 transmission.

In a retrospective case-control study involving 211 cases who tested positive for SARS-CoV-2 and 839 controls with negative results in Thailand, **Doung-Ngern et al. (2020)** examined self-report of types of masks used and mask-wearing compliance during interaction with a person with COVID-19 ("index patient"). Cloth face masks were recommended for the public on March 3rd and data used for identifying sample population were gathered during March 1st to 31st, 2020. Comparisons were made across the usage of no masks, nonmedical masks only, medical masks only, and both types of masks. Mask-wearing compliance was rated as "not", "sometimes", or "always" wearing a mask. SARS-CoV-2 cases were confirmed using RT-PCR results. The Thailand Surveillance and Rapid Response Teams provided data for identification of study sample and telephone interviews were used to collect mask-wearing practices. The variable on mask usage of the index patient was not included in the final analyses because it comprised of 27% missing values. Assuming that all other missing values were occurring at random, authors applied the chain equation method to generate imputed datasets. Using multivariable analyses on the imputed datasets, wearing a mask during the entire contact time with a person with COVID-19 was negatively associated with risk for SARS-CoV-2 infection (aOR 0.23; 95% CI 0.09-0.60). Type of masks was not significantly associated with COVID-19 risk (p=0.54). In comparison to those who did not wear a mask, individuals who always wore a mask while in contact with a person with COVID-19 also reported being more likely to have shorter contact duration and practice frequent hand washing.

Box 5. <u>Summary of findings about primary outcome and secondary outcome 1: *Mask mandates* for reducing transmission of COVID-19 and COVID-19 related deaths</u>

10 studies (all observational) are included that report on the effectiveness of mask mandates in reducing transmission of COVID-19, of which 1 also reported on reduction in deaths. The characteristics, findings and assessment of risk of bias for each study are presented in Table 4.

High-quality evidence relating to mask mandates for reducing transmission of COVID-19 in community settings is lacking, with few studies utilizing comparator groups or controlling for many possible confounders, given that mask mandates generally have been implemented as part of a suite of public health actions and in the context of altered community behaviours, and different levels of community level immune protection from infection and/or vaccination. Studies were limited in accounting for major confounders such as population mobility, distribution of infection risk factors in the population, concurrent public health restrictions, and level of population immunity.

The majority (n=6/10; 60%) of observational studies examining mask mandates have been conducted in school settings.

All studies were determined to be at critical risk of bias.

Summaries of studies of mask mandates for reducing transmission of COVID-19 and COVID-19 related deaths

Observational studies

Serious *risk of bias*

Islam et al. (2022) conducted a case-control study involving 38 counties across 4 USA states with populations from 40,000 to 105,000 to examine the effectiveness of mask mandates. 19 test counties were followed for 30 days after implementing their mask mandates. The 19 control counties, without mask mandates, were followed for the same period as their matched test county. Daily COVID-19 transmission data per county was collected using USAfacts.org. Difference-in-difference analysis revealed similar COVID-19 case rates between groups 10 days before the mask mandates were implemented. After 30 days, a difference-in-difference analysis indicated the average treatment effect reduced COVID-19 cases by 4.22 cases per day, or 16.9% (p=0.01). Compliance with mask mandates was not recorded in test counties and it is unknown if other factors such as lockdowns or social distancing were implemented during the study period.

In a comparative interrupted time series, **Li et al. (2021)** studied the impact of a mask mandate requiring face masks in public settings on COVID-19 cases and mortality. Data collection was carried out from March 25 to May 6, 2020 in New York (NY; intervention state) and Massachusetts (MA; comparison state). Facemask policy was implemented in NY on April 17, 2020. Data on daily COVID-19 cases for both states were accessed via the COVID Tracking Project and data on daily COVID-19 deaths were extracted from the *New York Times*, based on reports from state and local health agencies. Comparison between the two states reveal significant differences in both the level of change (2,686, 95%CI: 412-4961) and the trend change (223, 95%CI: 80-366) in the daily number of confirmed cases from pre-intervention to post-intervention. Compliance with mask mandate was not recorded and the effect of inter-state migration between 2 states that share a border was not included in the analysis.

***Critical** risk of bias in at least one domain*

In a cohort study of K-12 school districts in Wisconsin, **DeJonge et al. (2022)** examined the association of COVID-19 prevention policies (including masking obligations) within schools and COVID-19 cases among educators. Information about school COVID-19 prevention policies were collected via telephone surveys and information about COVID-19 cases were gathered from the Wisconsin Electronic Disease Surveillance System (WEDSS). The final study sample included 51,997 educators from 307 school districts, whereby 2,828 (5.5%) educators were infected with COVID-19 during September 2 to November 24, 2021. Seventy-three school districts reported having a robust masking policy that required masking in both educators and students. Authors conducted analyses using several data sets: (1) a completed data set with no missing data for any of the prevention policies, (2) an imputed data set that filled in missing policy data from available district-level information, and (3) other data sets that assumed missing policy data were "absent" or "robust". Using the completed data set (no missing policy information) to compare school districts with and without a robust masking policy, those who worked in districts with such masking requirements had an overall 19% reduced COVID-19 hazard during the study period (HR=0.81; 95% CI = 0.67, 0.98). Similar results were observed within other data sets involving imputed data for missing policy information.

Moek et al. (2022) conducted a retrospective cross-sectional study of in-flight transmission of COVID-19. Ninety-five close flight contacts of cases identified in Berlin, Germany were contacted by public health officials to confirm SARS-CoV-2 testing results. The time period of the study, from January to August 2020, occurred both before (Jan-Jun) and after (Jun-Aug) the implementation of mandatory in-flight masking. Four instances of probable in-flight transmission occurred, whereby two were before the implementation of mandatory masking, and two after. This would suggest that the mask mandate did not affect in-flight transmission. However, the researchers were unable to report data about actual mask usage in these cases, and assumed that passengers generally did not wear masks before the mask mandate was enforced.

In a prospective observational study comprised of children and staff within schools and pre-schools settings in Mecklenburg-Western Pomerania, Germany, **Sombetzki et al. (2021)** examined mask mandates from August 2020 to May 2021. While masking requirements changes throughout the study period for staff and school-aged students, children who attended pre-school were never required to wear a mask during this timeframe. COVID-19 positive cases were measured using RT-PCR testing. All study data was provided by the State Office for Health and Social Affairs Mecklenburg-Western Pomerania. Using multivariate regression model analyses, mask mandates for children and adults within school and pre-school settings were reported to significantly decrease the likelihood of secondary SARS-CoV-2 infections.

In a retrospective observational study involving 59,561 students and 11,854 staff at 783 schools in North Carolina, **Boutzoukas et al. (2022)** examined rates of primary (community-acquired) and secondary (school-acquired) transmissions of COVID-19. All sample schools implemented universal masking policies during the study period from August to November 2021. All staff and students, grades K-12, were required to wear a mask regardless of their vaccination status. The community-acquired to school-acquired infection ratio was calculated by diving the number of primary infections by that of secondary infections, whereby the latter figure was estimated by dividing the total number of within-school infections by the number of exposures requiring quarantine. The ratio of community-acquired to school-acquired infections was about 12.4 (808:64), and the estimated secondary attack rate was 2.6%, suggesting that the in-school mask mandate was associated with a low rate of secondary infection.

In a longitudinal cohort study involving 2,487 children in 55 different schools, in the Canton of Zurich, Switzerland, **Ulyte et al. (2021)** examined the effects of masking on seropositivity over three, one-month periods. Masks were mandated for adults, secondary school children and primary school children at varied time points. Clusters of seropositive children were measured with blood samples that underwent serological testing. Sociodemographic and health information was collected from parents using an online questionnaire. Using Bayesian logistic regression to estimate the proportion of seropositive children, and a difference-in-differences model, it was found that there was evidence to support the preventative effects of masking on seropositivity rates.

In a study involving students and staff as 1,020 K-12 schools in Arizona, **Jehn et al. (2021)** examined the association between school mask policies and school-associated COVID-19 outbreaks during in-person learning July-August 2021. Masks were required in schools at different stages throughout the year (early and late requirements) and some schools did not have mask requirements. School masking policies were drawn from publicly available mitigation plans, and outbreak data were obtained from Arizona's Medical Electronic Disease Surveillance Intelligence System. Schools enacting late (i.e., reactive) masking policies were excluded from the analysis due to potential confounding from existing outbreaks. Using crude analysis, the odds of a school-associated outbreak in schools with no mask requirement was 3.7 times higher than those in schools with an early (i.e., proactive) mask requirement.

In a descriptive study of schools in Florida, Doyle et al. (2021) examined mask mandates outlined in the reopening plans of each school district during August to December 2020. Data on positive COVID-19 cases were supplied by the county health department. Overall, higher student incidences of COVID-19 were reported in school districts without mask mandates than those with mask mandates.

In a study involving approximately 26,000 meat processing workers in Nebraska, **Herstein et al. (2021)** examined the effectiveness of masking and physical barriers over a 4-month period (April - July 2020). Facility masking policies were brought into effect with cloth and surgical masks used. SARS-CoV-2 incidence rates were measured with testing. Using confirmed case data, incidence of SARS-CoV-2 infection before and after the date the last intervention was initiated (e.g., physical barriers were installed if universal mask policy began first) was reported. Ten days after the last intervention was initiated, 8 facilities (62%) showed a statistically significant decrease in incidence and 3 showed a non-significant decrease, while 1 facility showed a statistically significant increase in incidence and 1 showed a non-significant increase in incidence.

Box 6. Summary of findings about secondary outcome 2: Masks to reduce transmission of *other respiratory infections*

1 RCT was included reporting on effectiveness of masks in reducing transmission of other respiratory infections as an outcome. The characteristics, findings and assessment of risk of bias for this study is presented in Table 5.

Summary of studies of masks to reduce transmission of other respiratory infections (secondary outcome)

Randomized controlled trial

Bundgaard et al. (2021) conducted an RCT involving adults in Denmark comparing mask recommendations with no mask recommendation. Findings suggest no significant difference between the mask group (0.5% positive) for 1 or more of 11 respiratory viruses other than SARS-CoV-2 compared with the control group (0.6% positive). Between-group difference was determined as -0.1% (95%CI: -0.6–0.4); p=0.87, OR, 0.84 (95%CI: 0.35–2.04); p=0.71.

This study was assessed to have a **high** risk of bias.

Box 7. Knowledge gaps and/or methodological gaps in the scientific literature related to masks for COVID-19

- Strategies that promote masking behaviour (e.g., educational, policy, distribution of supplies, modeling) are not well-described in the literature.
- Standardized strategies for recording and reporting adherence to masking are needed.

Table 2: Summary of studies reporting on effectiveness of masks in reducing transmission of COVID-19 (presented from most to least recent release date)

Reference	Date released	Setting and time covered	Study characteristics	Summary of key findings in relation to the outcome	Risk of Bias
Gigot, C., Pisanic, N., Kruczynski, K., Gregory Rivera, M., Spicer, K., Kurowski, K. M., Randad, P., Koehler, K., Clarke, W. A., Holmes, P., Hall, D. J., Jr, Hall, D. J., & Heaney, C. D. (2023). SARS-CoV-2 Antibody Prevalence among Industrial Livestock Operation Workers and Nearby Community Residents, North Carolina, 2021 to 2022. mSphere, e0052222. Advance online publication. https://doi.org/10.1128/msphere.00522-22	19-Jan-2023	North Carolina, USA Feb 2021 - Jul 2022	**Design**: Prospective cohort study **Intervention**: Wearing a mask vs. not wearing a mask **Sample**: 279 individuals from 240 households (80 industrial livestock operation (ILO) workers and their family members, 80 neighbours of ILO (ILON), 80 participants living in metropolitan areas of North Carolina (Metro) **Key outcomes**: SARS-CoV-2 IgG prevalence **VOCs assessed**: None	Participants who reported not wearing a mask in public during the previous two weeks had significantly higher infection-induced IgG prevalence (78.6%) compared to those who reported wearing a mask (49.3%) (PR=1.59; 95%CI: 1.19–2.13)	**Critical in at least one domain**

Andrejko, K. L., Pry, J. M., Myers, J. F., Fukui, N., DeGuzman, J. L., Openshaw, J., Watt, J. P., Lewnard, J. A., Jain, S., & California COVID-19 Case-Control Study Team (2022). Effectiveness of Face Mask or Respirator Use in Indoor Public Settings for Prevention of SARS-CoV-2 Infection - California, February-December 2021. MMWR. Morbidity and mortality weekly report, 71(6), 212–216. https://doi.org/10.15585/mmwr.mm7106e1	11-Feb-2022	California, USA Feb 18 – Dec 1, 2021	**Design**: Test-negative design case-control study **Intervention**: Mask use and type of mask **Sample**: n=1,828 California residents (cases: n=652; controls: n=1176) **Key outcomes**: COVID-19 positive test result **VOCs assessed**: None	Self-reported data on face mask use identified those who always wore a mask had significantly lower odds of a positive COVID-19 test compared to those who never masked (aOR = 0.44; 95%CI: 0.24–0.82). Reductions in positive tests were also noted among those who masked most (aOR = 0.55; 95%CI: 0.29–1.05) or some times (aOR = 0.71; 95%CI: 0.35–1.46) compared to those who never masked. For comparison of mask types, see Table 2	**Critical in at least one domain**
Hast, M., Swanson, M., Scott, C., Oraka, E., Espinosa, C., Burnett, E., Kukielka, E. A., Rice, M. E., Mehari, L., McCloud, J., Miller, D., Franklin, R., Tate, J. E., Kirking, H. L., & Morris, E. (2022). Prevalence of risk behaviors and correlates of SARS-CoV-2 positivity among in-school contacts of confirmed cases in a Georgia school district in the pre-vaccine era, December 2020-January 2021. BMC public health, 22(1), 101. https://doi.org/10.1186/s12889-021-12347-7	14-Jan-2022	Georgia, USA Dec 1, 2020 – Jan 26, 2021	**Design**: Secondary analysis of case control study data **Intervention**: All COVID-19 risk behaviours, including masks **Sample**: n=796 students and education staff participated in first survey, 628 completed survey and COVID-19 testing and were eligible for bivariate comparisons **Key outcomes**: COVID-19 transmission between positive cases in student and their close contacts **VOCs assessed**: None	Among study findings, elementary aged students had a positivity rate of 44% (n=4/9) among unmasked students who played sports compared to 8% among other students (n=28/344; OR=9.0, 95%CI: 2.3-35.5; p<0.005). Among middle/high school students, COVID-19 positive rate was 18% (n=15/85) among students who played sports compared to 6% in other students (n=7/121; OR=3.5, 95%CI: 1.4-9.0). Positive rate increased to 20% (n=15/74) among sports-playing students who reported unmasked sport playing time compared to 6% among masked sports-playing students (OR=4.3, 95%CI: 1.7-11.3; p<0.001).	**Critical in at least one domain**

Abaluck, J., Kwong, L. H., Styczynski, A., Haque, A., Kabir, M. A., Bates-Jefferys, E., Crawford, E., Benjamin-Chung, J., Raihan, S., Rahman, S., Benhachmi, S., Bintee, N. Z., Winch, P. J., Hossain, M., Reza, H. M., Jaber, A. A., Momen, S. G., Rahman, A., Banti, F. L., Huq, T. S., … Mobarak, A. M. (2022). Impact of community masking on COVID-19: A cluster-randomized trial in Bangladesh. Science (New York, N.Y.), 375(6577), eabi9069. https://doi.org/10.1126/science.abi9069	14 January 2022	Bangladesh Nov 2020 – Apr 2021	**Design**: Cluster-randomized controlled trial **Intervention**: Free masks (cloth or surgical); information on the importance of masking; role modeling by community leaders; and in-person reminders; vs. no interventions in the control group **Sample**: 342,183 adults (at baseline) from 572 villages: 178,322 in intervention group vs. 163,861 in control group; 336,010 provided symptom data; 10,790 consented to blood collection **Key outcomes**: Primary: symptomatic seroprevalence of SARS-CoV-2; Secondary: prevalence of proper mask-wearing, physical distancing, and symptoms consistent with COVID-19 **VOCs assessed**: None	• Reduction in transmission: 9.5% reduction in symptomatic seroprevalence (IG prevalence = 0.68%, control prevalence = 0.76%); estimated 11.6% reduction in proportion of individuals with COVID-19-like symptoms (IG=7.63%, Control=8.6%) • Other outcomes: Proper mask-wearing was 42.3% in IG vs. 13.3% in CG (adjusted % point difference = 0.29 (95%CI: 0.26–0.31); physical distancing was 29.2% in IG vs. 24.1% in CG (0.05 [0.05, 0.06]); no change in social distancing • For comparison of mask types (surgical vs. cloth), see Table 2	**High**

Andrejko, K. L., Pry, J., Myers, J. F., Openshaw, J., Watt, J., Birkett, N., DeGuzman, J. L., Barbaduomo, C. M., Dong, Z. N., Fang, A. T., Frost, P. M., Ho, T., Javadi, M. H., Li, S. S., Tran, V. H., Wan, C., Jain, S., Lewnard, J. A., & California COVID-19 Case-Control Study Team (2022). Predictors of Severe Acute Respiratory Syndrome Coronavirus 2 Infection Following High-Risk Exposure. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America, 75(1), e276–e288. https://doi.org/10.1093/cid/ciab1040	21-Dec-2021	California, USA Feb 24 - Nov 12, 2021	**Design**: Case-control study (test-negative design) **Intervention**: Mask usage during high-risk exposures **Sample**: 1,006 California residents reporting high-risk exposures ≤14 days before testing: 751 of 1,448 COVID-19 cases vs. 255 of 1,443 COVID-19 negative controls **Key outcomes**: Predictors of SARS-CoV-2 infection among participants reporting high-risk exposures **VOCs assessed**: None	52% of cases (n=751 of 1,448) and 18% of controls (n=255 of 1,443) reported high-risk exposures; among these participants, 14% of cases (n=101) and 34% of controls (n=87) reported mask usage during these exposures. Mask usage was protective when both parties reported mask usage (aOR = 0.50; 95%CI: 0.26–0.96), when exposures took place outside the household (aOR = 0.39; 95%CI: 0.22–0.70), when exposures occurred without physical contact (aOR = 0.37; 95%CI: 0.20–0.69), and when exposures were indoors (aOR = 0.51; 95%CI: 0.28–0.93). Mask usage was not protective when exposures occurred within the household, involved physical contact, or occurred outdoors. Notably, the benefits of mask-wearing were found to be highest in unvaccinated and partially vaccinated participants.	Moderate
Pauser, J., Schwarz, C., Morgan, J., Jantsch, J., & Brem, M. (2021). SARS-CoV-2 transmission during an indoor professional sporting event. Scientific reports, 11(1), 20723. https://doi.org/10.1038/s41598-021-99997-0	20-Oct-2021	Germany Date range not reported	**Design**: Retrospective study **Intervention**: Mask use **Sample**: 21 players and 48 staff/assistants **Key outcomes**: COVID-19 cases post-sporting event **VOCs assessed**: None	Self-reported wearing of masks (medical face mask - community masks and/or surgical masks) or particle filter masks (FFP2, FFP3 or KN95) was associated with a reduced risk of SARS-CoV-2 transmission from 83% to 46%.	**Critical in at least one domain**

Riley, J., Huntley, J. M., Miller, J. A., Slaichert, A. L. B., & Brown, G. D. (2022). Mask Effectiveness for Preventing Secondary Cases of COVID-19, Johnson County, Iowa, USA. Emerging infectious diseases, 28(1), 69–75. https://doi.org/10.3201/eid2801.211591	12-Oct-2021	Iowa, USA Oct 23, 2020 - Feb 29, 2021	**Design**: Case-control **Intervention**: Mask use **Sample**: n=1,400 community residents (431 cases and 969 contacts) **Key outcomes**: Secondary COVID-19 attack rates **VOCs assessed**: None	Using logic regressions, the authors found a secondary attack rate of 12.5% when both parties were masked (n= 47/376; 95%CI: 9.6-16.3%). Most contacts were exposed when at least one person was not wearing a mask, resulting in an overall infection rate in this group of 25.6% (n=151/590; 95%CI: 22.3-29.4%); this rate varied if the COVID-19 positive person was masked (29.1%; 95%CI: 19.3-43.9%) or if the contact was the masked person (10%; 95%CI: 4-25.3%). When all parties were not masked, the rates were 26.4% (95%CI: 22.9-30.7). Among contacts who were school-aged children (n=426; aged 5-18 years), 53 tested positive when at least one person was not masked (5.2%; 95%CI: 20.1-32.0%) and increased to 12% when both people were masked (95%CI: 8.4-17.2%).	**Critical in at least one domain**
Baig, M. A., Ansari, J. A., Ikram, A., Khan, M. A., Salman, M., Hussain, Z., Baig, M. Z. I., Chaudhry, A., Malik, M. W., Akram, K. S., Saeed, A., Ranjha, M. A., Sultan, F., & Sabir, S. (2021). Prevalence of SARS-CoV-2: An age-stratified, population-based, sero-epidemiological survey in Islamabad, Pakistan. medRxiv 2021.09.27.21264003; doi: https://doi.org/10.1101/2021.09.27.21264003	29-Sep-2021	Islamabad, Pakistan June 2020	**Design**: Survey **Intervention**: Wearing a mask regularly vs. occasionally vs. never **Sample**: 6,333 individuals **Key outcomes**: SARS-CoV-2 seropositivity **VOCs assessed**: None	A Chi-Square test indicated that regular mask use was correlated with lower seroprevalence ($\chi2 = 8.6$; $p<0.05$) than occasionally or never wearing a mask. However, calculations of the study's raw data show an OR of 1.28 (95%CI: 1.05-1.56) associated with always wearing a mask and 1.06 (95%CI: 0.84-1.35) associated with sometimes wearing mask, overall favouring the unmasked group. The paper also presents several other quality concerns, and as a preprint, it has not undergone peer review.	**Critical in at least one domain**

Nelson, S. B., Dugdale, C. M., Bilinski, A., Cosar, D., Pollock, N. R., & Ciaranello, A. (2021). Prevalence and risk factors for in-school transmission of SARS-CoV-2 in Massachusetts K-12 public schools, 2020-2021. medRxiv 2021.09.22.21263900; doi: https://doi.org/10.1101/2021.09.22.21263900.	26-Sep-2021	Massachusetts, USA 2020-2021 (months not specified)	**Design**: Prospective cohort study **Intervention**: Both parties unmasked vs. both masked **Sample**: 70 schools with ~33,000 enrolled students **Key outcomes**: SARS-CoV-2 secondary attack rate and factors associated with transmission risk **VOCs assessed**: None	The secondary attack rate was significantly higher if both were unmasked vs. both masked (RR 6.98, 95%CI: 3.09-15.77; p<0.001). Although, there were three incidences of exposures in which one party was masked and the other unmasked, these data were excluded from the analysis.	**Critical in at least one domain**
Rebmann, T., Loux, T. M., Arnold, L. D., Charney, R., Horton, D., & Gomel, A. (2021). SARS-CoV-2 Transmission to Masked and Unmasked Close Contacts of University Students with COVID-19 - St. Louis, Missouri, January-May 2021. MMWR. Morbidity and mortality weekly report, 70(36), 1245–1248. https://doi.org/10.15585/mmwr.mm7036a3	10-Sep-2021	St. Louis, Missouri, USA Jan - May 2021	**Design**: Case-control **Intervention**: Mask-wearing in context of mask mandate **Sample**: 9,335 students tested for COVID-19 (n=265 positive cases and 378 close contacts identified) **Key outcomes**: COVID-19 transmission between positive cases in student and their close contacts **VOCs assessed**: None	Rates of positive results were significantly higher among unmasked contact with the initial positive cases (unmasked: n=114/352; 32.4 vs masked: n=2/26; 7.7%; aOR: 5.4, 95%CI: 1.5–36.5; p = 0.008).	**Critical in at least one domain**

Sugimura, M., Chimed-Ochir, O., Yumiya, Y., Ohge, H., Shime, N., Sakaguchi, T., Tanaka, J., Takafuta, T., Mimori, M., Kuwabara, M., Asahara, T., Kishita, E., & Kubo, T. (2021). The Association between Wearing a Mask and COVID-19. International journal of environmental research and public health, 18(17), 9131. https://doi.org/10.3390/ijerph18179131	30-Aug-2021	Hiroshima Prefecture, Japan Mar 6 – May 31, 2020	**Design**: Epidemiological surveillance **Intervention**: Mask use vs. no mask use **Sample**: 820 people out of 1,434 interviewees in the analysis who provided answers regarding mask use and had a PCR test **Key outcomes**: COVID-19 infection **VOCs assessed**: None	In comparison to non-mask wearers who had a positive rate of 16.4% for COVID-19, individuals who reported wearing masks possessed a positive rate of 7.1%. A significant relationship between mask use and COVID-19 infections were observed in those who were men, involved in cluster cases, were in contact with the patient at the welfare facility, and worked with the patient.	**Critical in at least one domain**
Theuring, S., Thielecke, M., van Loon, W., Hommes, F., Hülso, C., von der Haar, A., Körner, J., Schmidt, M., Böhringer, F., Mall, M. A., Rosen, A., von Kalle, C., Kirchberger, V., Kurth, T., Seybold, J., Mockenhaupt, F. P., & BECOSS Study Group (2021). SARS-CoV-2 infection and transmission in school settings during the second COVID-19 wave: a cross-sectional study, Berlin, Germany, November 2020. Euro surveillance : bulletin Europeen sur les maladies transmissibles = European communicable disease bulletin, 26(34), 2100184. https://doi.org/10.2807/1560-7917.ES.2021.26.34.2100184	26-Aug-2021	Berlin, Germany 2-16 Nov, 2020	**Design**: Cross-sectional longitudinal **Intervention**: Individual and institutional prevention measures **Sample**: 1,119 participants total including 117 primary students, 175 secondary, 142 staff, 625 household members **Key outcomes**: SARS-CoV-2 infections and seroreactivity **VOCs assessed**: None	Almost 9 in 10 index participants stated they often or always wore a mask at school, and their infection prevalence was 1.4%. Of those who wore masks never to sometimes, 14.3% tested positive (OR = 11.38; 95%CI: 2.28−59.64). 8 of 16 non-affected classes required masking in the classroom, while only 1 of 8 affected classes required masking.	**Critical in at least one domain**

Liu, P. Y., Gragnani, C. M., Timmerman, J., Newhouse, C. N., Soto, G., Lopez, L., Spronz, R., Mhaskar, A., Yeganeh, N., Fernandes, P., & Kuo, A. A. (2021). Pediatric Household Transmission of Severe Acute Respiratory Coronavirus-2 Infection-Los Angeles County, December 2020 to February 2021. The Pediatric infectious disease journal, 40(10), e379–e381. https://doi-org.ezproxy.library.dal.ca/10.1097/INF.0000000000003251	12-Aug-2021	Los Angeles County, California, USA Dec 2020 - Feb 2021	**Design**: Prospective case-ascertained transmission study **Intervention**: Masked vs. unmasked index cases **Sample**: 15 index cases and 50 household contacts **Key outcomes**: Secondary attack rates from pediatric primary index case to household contacts **VOCs assessed**: None	Using $\chi 2$ test of proportions, it was found that transmission was significantly lower in households in which the index patient was masked compared with those who were unmasked.	**Critical in at least one domain**
Shaweno, T., Abdulhamid, I., Bezabih, L., Teshome, D., Derese, B., Tafesse, H., & Shaweno, D. (2021). Seroprevalence of SARS-CoV-2 antibody among individuals aged above 15 years and residing in congregate settings in Dire Dawa city administration, Ethiopia. Tropical medicine and health, 49(1), 55. https://doi.org/10.1186/s41182-021-00347-7	10-Jul-2021	Dire Dawa City Administration, Ethiopia Jun 15 - Jul 30, 2020	**Design**: Cross-sectional survey (SARS-CoV-2 serosurvey) **Intervention**: Practice of preventive measures (including mask wearing practice). Compared use of face covering while leaving home (yes/no) **Sample**: Data were analyzed for a total of 684 (91.2%) study participants living in congregate settings **Key outcomes**: SARS-CoV-2 seroprevalence **VOCs assessed**: None	In conducting multivariate logistic regression analyses, SARS-CoV-2 seroprevalence was found to be significantly associated with face mask usage outside of the home. In comparison to individuals who reported mask-wearing, the odds of SARS-CoV-2 antibody seroprevalence was found to be higher for those who did not use masks when away from home.	**Critical in at least one domain**

Gonçalves, M. R., Dos Reis, R. C. P., Tólio, R. P., Pellanda, L. C., Schmidt, M. I., Katz, N., Mengue, S. S., Hallal, P. C., Horta, B. L., Silveira, M. F., Umpierre, R. N., Bastos-Molina, C. G., Souza da Silva, R., & Duncan, B. B. (2021). Social Distancing, Mask Use, and Transmission of Severe Acute Respiratory Syndrome Coronavirus 2, Brazil, April-June 2020. Emerging infectious diseases, 27(8), 2135–2143. https://doi.org/10.3201/eid2708.204757	4-Jun-2021	Porto Alegre, Rio Grande do Sul, Brazil Apr – Jun 2020	**Design**: Case-control **Intervention**: Mask use **Sample**: n=1,667 community residents (cases: n=291; controls: n=1,396); Mask use and COVID-19 positive test rates were compared between n=229 case patients and a subset of controls (n=464/1,396) as mask data was not consistently collected during data collection **Key outcomes**: COVID-19 cases **VOCs assessed**: None	Mask use was associated with a decrease in COVID-19 cases (OR: 0.12; 95%CI: 0.04-0.30). When data from participants who stayed home at all times were removed from the sample, the trend in decreased COVID-19 cases as a result of mask use was maintained (OR:0.13; 95%CI: 0.04-0.36). When those who never and sometimes masked were grouped and compared with those who always masked, COVID-19 cases remained low (OR: 0.36; 95%CI: 0.17-0.74).	**Critical in at least one domain**
Lio, C. F., Cheong, H. H., Lei, C. I., Lo, I. L., Yao, L., Lam, C., & Leong, I. H. (2021). Effectiveness of personal protective health behaviour against COVID-19. BMC public health, 21(1), 827. https://doi.org/10.1186/s12889-021-10680-5	29-Apr-2021	Macao Mar 17 - Apr 15, 2020	**Design**: Cross-sectional survey **Intervention**: Personal protective behaviours including masking vs. none **Sample**: 24 COVID-19 patients vs. 1,113 controls **Key outcomes**: Risk and protective factors for COVID-19 at the individual level **VOCs assessed**: None	25% of infected participants wore a mask whenever outdoors vs. 63.5% of controls ($P < 0.001$), and those who wore masks whenever outdoors had a risk reduction of 80.9% (crude OR, 0.191 [95%CI: 0.075–0.486], $P < 0.005$) compared with those who did not.	**Critical in at least one domain**

Areekal, B., Vijayan, S. M., Suseela, M. S., Andrews, M., Ravi, R. K., Sukumaran, S. T., et al. (2021). Risk Factors, Epidemiological and Clinical Outcome of Close Contacts of COVID-19 Cases in a Tertiary Hospital in Southern India. JCDR, 15(3), LC34-LC37. 10.7860/JCDR/2021/48059.14664	Mar-2021	Thrissur, Kerala, India June 2020 - July 2020	**Design**: Retrospective cohort study **Intervention**: Various risk factors (including mask use: nil; cloth mask; surgical; N95) **Sample**: 1,286 close contacts of COVID- 19 patients admitted to Government Medical College **Key outcomes**: COVID-19 transmission from close contacts **VOCs assessed**: None	Results from binary logistic regression analyses suggested that self-reported mask use was associated with a statistically significant reduction of odds of COVID-19 infection (adjusted odds ratio of 0.570; p=0.001).	**Critical in at least one domain**
van den Broek-Altenburg, E. M., Atherly, A. J., Diehl, S. A., Gleason, K. M., Hart, V. C., MacLean, C. D., Barkhuff, D. A., Levine, M. A., & Carney, J. K. (2021). Jobs, Housing, and Mask Wearing: Cross-Sectional Study of Risk Factors for COVID-19. JMIR public health and surveillance, 7(1), e24320. https://doi-org.ezproxy.library.dal.ca/10.2196/24320	11-Jan-2021	Vermont, USA Apr 30 - Jun 28, 2020	**Design**: Survey **Intervention**: Wearing a mask outside of work vs. not wearing a mask outside of work **Sample**: 1,694 survey respondents, 26.8% (n=454) of participants provided samples **Key outcomes**: Prevalence of SARS-CoV-2 in community-dwelling adults **VOCs assessed**: None	Using multivariate analysis, it was found that there was no significant difference between those who tested positive and those who did not, on mask wearing outside of work. However, statistical analyses were not performed on the PCR test results because only one positive test was found, thus analyses were based only on patient-matched blood samples.	**Critical in at least one domain**

Hobbs, C. V., Martin, L. M., Kim, S. S., Kirmse, B. M., Haynie, L., McGraw, S., Byers, P., Taylor, K. G., Patel, M. M., Flannery, B., & CDC COVID-19 Response Team (2020). Factors Associated with Positive SARS-CoV-2 Test Results in Outpatient Health Facilities and Emergency Departments Among Children and Adolescents Aged <18 Years - Mississippi, September-November 2020. MMWR. Morbidity and mortality weekly report, 69(50), 1925–1929. https://doi.org/10.15585/mmwr.mm6950e3	18-Dec-2020	Mississippi, USA Sep 1 – Nov 5, 2020	**Design**: Case-control **Intervention**: Mask use **Sample**: 397 children and adolescents, including 154 case-patients (positive SARS-CoV-2 test results) and 243 control participants (negative SARS-CoV-2 test results) **Key outcomes**: Compare exposures of RT-PCR positive vs. negative participants **VOCs assessed**: None	Children and adolescents who received a positive RT-PCR test were less likely to to have a parent/guardian report consistent mask use. However, the sample included children and adolescents who received testing with health care facilities associated with one large academic medical center in Mississippi and might not be representative of children and adolescents in other geographic areas	**Critical in at least one domain**

Bundgaard, H., Bundgaard, J. S., Raaschou-Pedersen, D. E. T., von Buchwald, C., Todsen, T., Norsk, J. B., Pries-Heje, M. M., Vissing, C. R., Nielsen, P. B., Winsløw, U. C., Fogh, K., Hasselbalch, R., Kristensen, J. H., Ringgaard, A., Porsborg Andersen, M., Goecke, N. B., Trebbien, R., Skovgaard, K., Benfield, T., Ullum, H., … Iversen, K. (2021). Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers : A Randomized Controlled Trial. Annals of internal medicine, 174(3), 335–343. https://doi.org/10.7326/M20-6817	18 November 2020	Denmark Apr – Jun 2020	**Design:** Randomized controlled trial **Intervention:** Instruction to wear a mask when outside the home; 50 surgical masks were provided to intervention group participants; written instructions and instructional videos guided proper use of masks; help line was available to participants **Sample:** 3,030 participants in intervention group vs. 2,994 in control group; 4,862 completed the study **Key outcomes:** Primary: SARS-CoV-2 infection; Secondary: infection with other respiratory viruses **VOCs assessed:** None	• Primary outcome: Infection with SARS-CoV2 occurred in 42 participants recommended masks (1.8%) and 53 control participants (2.1%). The between-group difference was 0.3 percentage point (95%CI: 1.2–0.4; P= 0.38) (odds ratio, 0.82 [CI, 0.54 to 1.23]; P= 0.33). Multiple imputation accounting for loss to follow-up yielded similar results. Although the difference observed was not statistically significant, the 95%CIs are compatible with a 46% reduction to a 23% increase in infection. • Secondary outcome: see Table 4	**High**

Doung-Ngern, P., Suphanchaimat, R., Panjangampatthana, A., Janekrongtham, C., Ruampoom, D., Daochaeng, N., Eungkanit, N., Pisitpayat, N., Srisong, N., Yasopa, O., Plernprom, P., Promduangsi, P., Kumphon, P., Suangtho, P., Watakulsin, P., Chaiya, S., Kripattanapong, S., Chantian, T., Bloss, E., Namwat, C., … Limmathurotsakul, D. (2020). Case-Control Study of Use of Personal Protective Measures and Risk for SARS-CoV 2 Infection, Thailand. Emerging infectious diseases, 26(11), 2607–2616. https://doi.org/10.3201/eid2611.203003	15-Sep-2020	Thailand Apr 30 – May 27, 2020	**Design:** Retrospective case-control study **Intervention:** Personal protective measures including types of mask (none - referent; nonmedical masks only; nonmedical and medical; medical mask only) and compliance with mask-wearing (not wearing a mask - referent; wearing a mask; wearing a mask sometimes; always wearing a mask) **Sample:** COVID-19 case group = 211 persons who tested positive for SAR-CoV-2 by 2020 Apr 21; Control group = 839 persons who were negative for COVID-19 as of 2020 Apr 21 **Key outcomes:** SARS-CoV-2 infection: Cases were defined as asymptomatic contacts of COVID-19 patients who later tested positive for SARS-CoV-2; controls were asymptomatic contacts who never tested positive **VOCs assessed:** None	Using multivariable analyses, wearing a mask during the entire contact time with a person with COVID-19 was associated with decreased risk for SARS-CoV-2 infection. However, authors did report that they were unable to assess whether the person with COVID-19 wore a mask due missing data and not all controls within the study received a RT-PCR test. For results relating to mask types, see Table 2	**Critical in at least one domain**

Payne, D. C., Smith-Jeffcoat, S. E., Nowak, G., Chukwuma, U., Geibe, J. R., Hawkins, R. J., Johnson, J. A., Thornburg, N. J., Schiffer, J., Weiner, Z., Bankamp, B., Bowen, M. D., MacNeil, A., Patel, M. R., Deussing, E., CDC COVID-19 Surge Laboratory Group, & Gillingham, B. L. (2020). SARS-CoV-2 Infections and Serologic Responses from a Sample of U.S. Navy Service Members - USS Theodore Roosevelt, April 2020. MMWR. Morbidity and mortality weekly report, 69(23), 714–721. https://doi-org.ezproxy.library.dal.ca/10.15585/mmwr.mm6923e4	12-Jun-2020	Guam (U.S Military) Apr 20- 24, 2020	**Design:** Survey **Intervention:** Face covering use vs. not **Sample:** 382 service members (a convenience sample comprising 27% of 1,417 service members staying at the base on Guam or on the ship) **Key outcomes:** SARS-CoV-2 infection, use of preventative measures to lower risk of infection **VOCs assessed:** None	Data from the questionnaire was compared to SARS-CoV-2 infection data and odds ratios were calculated, which found that lower odds of infection were independently associated with use of face coverings.	**Critical in at least one domain**
Wang, Y., Tian, H., Zhang, L., Zhang, M., Guo, D., Wu, W., Zhang, X., Kan, G. L., Jia, L., Huo, D., Liu, B., Wang, X., Sun, Y., Wang, Q., Yang, P., & MacIntyre, C. R. (2020). Reduction of secondary transmission of SARS-CoV-2 in households by face mask use, disinfection and social distancing: a cohort study in Beijing, China. BMJ global health, 5(5), e002794. https://doi.org/10.1136/bmjgh-2020-002794	28-May-2020	Beijing, China Feb 28 - Mar 8, 2020	**Design:** Questionnaire **Intervention:** Mask use (never vs. sometimes vs. all the time) **Sample:** 124 individual family members (83 in households without transmission, 41 in households with transmission) **Key outcomes:** SARS-CoV-2 secondary attack rate and factors associated with transmission risk **VOCs assessed:** None	When comparing self-report mask wearing behaviour of families with and without secondary transmission, 19.5% of households with secondary transmission reported wearing masks all of the time versus 45.8% of households without secondary transmission (OR, 0.03; CI: 0.11–0.82).	**Critical in at least one domain**

Cheng, V. C., Wong, S. C., Chuang, V. W., So, S. Y., Chen, J. H., Sridhar, S., To, K. K., Chan, J. F., Hung, I. F., Ho, P. L., & Yuen, K. Y. (2020). The role of community-wide wearing of face mask for control of coronavirus disease 2019 (COVID-19) epidemic due to SARS-CoV-2. The Journal of infection, 81(1), 107–114. https://doi.org/10.1016/j.jinf.2020.04.024	23-Apr-2020	Hong Kong Special Administrative Region (HKSAR) Apr 6-8, 2020	**Design:** Observational **Intervention:** Community-wide mask usage (mask-on vs mask off activities) **Sample:** 10,050 persons were observed **Key outcomes:** People infected with COVID-19 **VOCs assessed:** None	During the three consecutive days of assessment, masking behaviour was noted in 10,050 individuals, where 337 (3.4%) people were not using a mask. Within the first 100 days of the pandemic, there were 961 confirmed COVID-19 cases in HKSAR. In examining the 961 cases in clusters involving masked (e.g., people at work) and unmasked (e.g., dining in restaurants, exercising at the gym) activities, there was significantly greater unmasked COVID-19 cluster settings than the equal number of masked and unmasked clusters predicted by the null hypothesis (p=0.036).	**Critical in at least one domain**

Table 3: Summary of studies reporting on effectiveness of different types of masks in reducing transmission of COVID-19

Reference	Date released	Setting and time covered	Study characteristics	Summary of key findings in relation to the outcome	Risk of Bias
Varela, A. R., Gurruchaga, A. P., Restrepo, S. R., Martin, J. D., Landazabal, Y. D. C., Tamayo-Cabeza, G., Contreras-Arrieta, S., Caballero-Díaz, Y., Florez, L. J. H., González, J. M., Santos-Barbosa, J. C., Pinzón, J. D., Yepes-Nuñez, J. J., Laajaj, R., Buitrago Gutierrez, G., Florez, M. V., Fuentes Castillo, J., Quinche Vargas, G., Casas, A., Medina, A., … CoVIDA Working Group (2022). Effectiveness and adherence to closed face shields in the prevention of COVID-19 transmission: a non-inferiority randomized controlled trial in a middle-income setting (COVPROSHIELD). Trials, 23(1), 698. https://doi.org/10.1186/s13063-022-06606-0	20 August 2022	Bogota, Colombia Jan 12 – Mar 13, 2021	**Design:** Open-label, non-inferiority randomized controlled trial **Intervention:** Closed face shields and surgical masks vs. surgical masks alone **Sample:** 316 participants: 160 intervention group (IG: closed face shields and surgical masks) / 156 active control group (ACG: surgical masks only) **Key outcomes:** Primary: difference in cumulative incidence of COVID-19 between the two groups; Secondary: difference in PPE use and adherence between the two groups **VOCs assessed:** None	• Primary outcome was identified in 1 participant in the IG vs. 3 in the ACG; in intention-to-treat analysis, absolute risk difference was − 1.40% (95%CI: − 4.14%–1.33%); in per-protocol analysis, aRD was − 1.40% (95%CI: − 4.20%–1.40%); this indicates non-inferiority of the closed face shield with surgical face mask • Secondary outcomes: # of days of assigned PPE use and face mask use were higher in ACG; higher adherence was reported in the ACG vs. the IG (88.6% reported high or medium-high adherence in the ACG vs. only 27.4% in the IG)	**High**
Andrejko, K. L., Pry, J. M., Myers, J. F., Fukui, N., DeGuzman, J. L., Openshaw, J., Watt, J. P., Lewnard, J. A., Jain, S., & California COVID-19 Case-Control Study Team (2022). Effectiveness of Face Mask or Respirator Use in Indoor Public Settings for Prevention of SARS-CoV-2 Infection - California, February-December 2021. MMWR. Morbidity and mortality weekly report, 71(6), 212–216. https://doi.org/10.15585/mmwr.mm7106e1	11-Feb-2022	California, USA Feb 18 – Dec 1, 2021	**Design**: Test-negative design case-control study **Intervention**: Mask use and type of mask **Sample**: n=1,828 California residents (cases: n=652; controls: n=1,176) **Key outcomes**: COVID-19 positive test result **VOCs assessed**: None	Analysis of mask type identified wearing a N95/KN95 respirator (aOR = 0.17; 95%CI: 0.05–0.64) or surgical mask (aOR = 0.34; 95%CI: 0.13–0.90) were associated with lower positive test rates compared to no mask wearing. Cloth masks also had a lower positive rate when compared to non-masking, however it was not significant (aOR:0.44; 95%CI: 0.17-1.17). For results related to all mask types, see Table 1	**Critical in at least one domain**

Abaluck, J., Kwong, L. H., Styczynski, A., Haque, A., Kabir, M. A., Bates-Jefferys, E., Crawford, E., Benjamin-Chung, J., Raihan, S., Rahman, S., Benhachmi, S., Bintee, N. Z., Winch, P. J., Hossain, M., Reza, H. M., Jaber, A. A., Momen, S. G., Rahman, A., Banti, F. L., Huq, T. S., … Mobarak, A. M. (2022). Impact of community masking on COVID-19: A cluster-randomized trial in Bangladesh. Science (New York, N.Y.), 375(6577), eabi9069. https://doi.org/10.1126/science.abi9069	14 January 2022	Bangladesh Nov 2020 – Apr 2021	**Design**: Cluster-randomized controlled trial **Intervention**: Intervention group cross-randomized to receive free surgical masks or free cloth masks **Sample**: 342,183 adults (at baseline) from 572 villages: 178,322 in intervention group (100 villages assigned to cloth mask group and 200 villages assigned to surgical mask group) vs. 163,861 in control group; 336,010 provided symptom data; 10,790 consented to blood collection **Key outcomes**: Symptomatic seroprevalence of SARS-CoV-2 in participants wearing surgical masks vs. cloth masks **VOCs assessed**: None	Surgical masks found to be more effective than cloth; surgical masks led to relative reduction in symptomatic seroprevalence of 11.1% (adjusted prevalence ratio = 0.89 [0.78, 1.00]); confidence limits for cloth masks include include both an effect size similar to surgical masks and no effect (adjusted prevalence ratio = 0.94 [0.78, 1.10]) For results related to all mask types, see Table 1	**High**

Doung-Ngern, P., Suphanchaimat, R., Panjangampatthana, A., Janekrongtham, C., Ruampoom, D., Daochaeng, N., Eungkanit, N., Pisitpayat, N., Srisong, N., Yasopa, O., Plernprom, P., Promduangsi, P., Kumphon, P., Suangtho, P., Watakulsin, P., Chaiya, S., Kripattanapong, S., Chantian, T., Bloss, E., Namwat, C., … Limmathurotsakul, D. (2020). Case-Control Study of Use of Personal Protective Measures and Risk for SARS-CoV 2 Infection, Thailand. Emerging infectious diseases, 26(11), 2607–2616. https://doi.org/10.3201/eid2611.203003	15-Sep-2020	Thailand Apr 30 – May 27, 2020	**Design:** Retrospective case-control study **Intervention:** Personal protective measures including types of mask (none - referent; nonmedical masks only; nonmedical and medical; medical mask only) and compliance with mask-wearing (not wearing a mask - referent; wearing a mask; wearing a mask sometimes; always wearing a mask) **Sample:** COVID-19 case group = 211 persons who tested positive for SAR-CoV-2 by 2020 Apr 21; Control group = 839 person who were negtaive for COVID-19 as of 2020 Apr 21 **Key outcomes:** SARS-CoV-2 infection: Cases were defined as asymptomatic contacts of COVID-19 patients who later tested positive for SARS-CoV-2; controls were asymptomatic contacts who never tested positive **VOCs assessed:** None	Type of masks was not significantly associated with infection risk. For results related to all mask types, see Table 1	**Critical in at least one domain**

Table 4: Summary of studies reporting on effectiveness of mask mandates in reducing transmission of COVID-19

Reference	Date released	Setting and time covered	Study characteristics	Summary of key findings in relation to the outcome	Risk of Bias
DeJonge, P. M., Pray, I. W., Gangnon, R., McCoy, K., Tomasallo, C., & Meiman, J. (2022). School District Prevention Policies and Risk of COVID-19 Among In-Person K-12 Educators, Wisconsin, 2021. American journal of public health, 112(12), 1791–1799. https://doi.org/10.2105/AJPH.2022.307095	16-Nov-2022	Wisconsin, USA Sep 2 – Nov 24, 2021	**Design**: Cohort study **Intervention**: Various COVID-19 preventive policies (including masking policies): Compared districts with and without robust masking policies **Sample**: 51,997 educators from 307 districts; Linked to COVID-19 cases—2,838 educators from 300 districts; N=298 districts for masking policy (73 had a robust masking policy; 202 absent a robust masking policy) **Key outcomes**: COVID-19 cases **VOCs assessed**: None	2,828 (5.5%) educators were infected with COVID-19 during September 2 to November 24, 2021. Seventy-three school districts reported having a robust masking policy that required masking in both educators and students. In comparison to school districts without a robust masking policy, those who worked in districts with such requirements had a 19% reduced COVID-19 hazard during the study period (HR=0.81; 95%CI: 0.71–0.92), which remain statistically significant when stratified by grade levels (i.e., elementary, middle, high school).	**Critical in at least one domain**
Moek, F., Rohde, A., Schöll, M., Seidel, J., Baum, J. H. J., & der Heiden, M. A. (2022). Attack Rate for Wild-Type SARS-CoV-2 during Air Travel: Results from 46 Flights Traced by German Health Authorities, January-March and June-August 2020. The Canadian journal of infectious diseases & medical microbiology = Journal canadien des maladies infectieuses et de la microbiologie medicale, 2022, 8364666. https://doi.org/10.1155/2022/8364666	22-Oct-2022	Berlin, Germany Jan 23 - Aug 10, 2020	**Design:** Retrospective cross-sectional study **Intervention:** Mandatory masking vs. no mandatory masking **Sample:** 95 persons from 46 flights **Key outcomes:** Prevalence of acute wild-type SARS-CoV2 infection among close in-flight contact persons **VOCs assessed:** None	4 instances of probable in-flight transmission occurred - 2 before the implementation of mandatory masking, and 2 after. This would suggest that the mask mandate did not affect in-flight transmission. However, the researchers were unable to report data about actual mask usage in these cases, and assumed that passengers generally did not wear masks before the mask mandate was enforced.	**Critical in at least one domain**

Islam, H., Islam, A., Brook, A., & Rudrappa, M. (2022). Evaluating the effectiveness of countywide mask mandates at reducing SARS-CoV-2 infection in the United States. Journal of osteopathic medicine, 122(4), 211–215. https://doi.org/10.1515/jom-2021-0214	27 January 2022	Missouri, Iowa, Tennessee, and Florida, USA Jul – Oct 2020	**Design:** Comparison controlled prospective study **Intervention:** Mask mandates at the county level **Sample:** 1,355,000 in test counties (masks mandated) vs. 1,371,000 in control counties (masks not mandated) **Key outcomes:** COVID-19 infection rate **VOCs assessed:** Delta	After each county was followed for 30 days after mask mandates came into effect, the test counties had an average of 19.63 new COVID-19 infections per day, and the control counties had an average of 23.34 new COVID-19 infections per day. T-test analysis revealed a p value of 0.009. Difference-in-difference analysis revealed that test counties had a similar average COVID-19 case rate 10 days before the mask mandate was passed compared to the controls (16.05 average cases and 14.01 average cases). After 30 days of the mask mandate, the test counties had a lower average of COVID-19 cases than the controls. The average treatment effect reduced COVID-19 cases by 4.22 cases per day, or 16.9% when utilizing the difference-in-difference analysis.	**Serious**
Sombetzki, M., Lücker, P., Ehmke, M., Bock, S., Littmann, M., Reisinger, E. C., Hoffmann, W., & Kästner, A. (2021). Impact of Changes in Infection Control Measures on the Dynamics of COVID-19 Infections in Schools and Pre-schools. Frontiers in public health, 9, 780039. https://doi-org.ezproxy.library.dal.ca/10.3389/fpubh.2021.780039	20-Dec-2021	Mecklenburg-Western Pomerania, Germany Calendar week (CW) 32 in 2020 to CW 19 in 2021	**Design**: Prospective observational study **Intervention**: Infection control measures (including face mask obligation: yes vs no) **Sample**: Of the included n = 913 infections, n = 475 occurred in schools and n = 438 in pre- schools **Key outcomes**: SARS-CoV-2 positivity **VOCs assessed**: None	Using multivariate regression model analyses, mask mandates for children and adults within school and pre-school settings were reported to significantly decrease the likelihood of secondary SARS-CoV-2 infections.	**Critical in at least one domain**

Boutzoukas, A. E., Zimmerman, K. O., Benjamin, D. K., Jr, & ABC Science Collaborative (2021). School Safety, Masking, and the Delta Variant. Pediatrics, e2021054396. Advance online publication. https://doi.org/10.1542/peds.2021-054396	7-Dec-2021	North Carolina, USA Jun 14 - Aug 13, 2021	**Design**: Retrospective observational study **Intervention**: Universal mask mandate for students and staff **Sample**: 59,561 students and 11,854 staff at 783 schools across 20 districts **Key outcomes**: COVID-19 spread within schools vs. the community in the context of the Delta variant **VOCs assessed**: Delta	The ratio of community-acquired to school-acquired infections was about 12.4 (808:64), and the estimated secondary attack rate was 2.6%, suggesting that the in-school mask mandate was associated with a low rate of secondary infection.	**Critical in at least one domain**
Ulyte, A., Radtke, T., Abela, I. A., Haile, S. R., Ammann, P., Berger, C., Trkola, A., Fehr, J., Puhan, M. A., & Kriemler, S. (2021). Evolution of SARS-CoV-2 seroprevalence and clusters in school children from June 2020 to April 2021: prospective cohort study Ciao Corona. Swiss medical weekly, 151, w30092. https://doi-org.ezproxy.library.dal.ca/10.4414/smw.2021.w30092	25-Oct-2021	Canton of Zurich, Switzerland Jun 16 – Jul 9, 2020 Oct 26 - Nov 19, 2020 Mar 15 - Apr 16, 2021	**Design**: Prospective cohort **Intervention**: Mask mandate in schools **Sample**: 2,487 children from 275 classes in 55 schools **Key outcomes**: Clusters of seropositive children **VOCs assessed**: None	Using Bayesian logistic regression to estimate the proportion of seropositive children, and a difference-in-differences model, it was found that there was evidence to support the preventative effects of masking on seropositivity rates.	**Critical in at least one domain**

Jehn, M., McCullough, J. M., Dale, A. P., Gue, M., Eller, B., Cullen, T., & Scott, S. E. (2021). Association Between K-12 School Mask Policies and School-Associated COVID-19 Outbreaks - Maricopa and Pima Counties, Arizona, July-August 2021. MMWR. Morbidity and mortality weekly report, 70(39), 1372–1373. https://doi.org/10.15585/mmwr.mm7039e1	1-Oct-2021	Arizona, USA July - August 2021	**Design**: Epidemiological analysis **Intervention**: Masking policies **Sample**: 1,020 of 1,041 (98.0%) K–12 public non-charter schools in Maricopa and Pima counties **Key outcomes**: Association between school mask policies and school-associated COVID-19 outbreaks in K–12 public non-charter schools open for in-person learning **VOCs assessed**: None	Using crude analysis of school-associated outbreak data gathered from Arizona's Medical Electronic Disease Surveillance Intelligence System, the odds of a school-associated outbreak in schools with no mask requirement was 3.7 times higher than those in schools with an early mask requirement.	**Critical in at least one domain**
Doyle, T., Kendrick, K., Troelstrup, T., Gumke, M., Edwards, J., Chapman, S., Propper, R., Rivkees, S. A., & Blackmore, C. (2021). COVID-19 in Primary and Secondary School Settings During the First Semester of School Reopening - Florida, August-December 2020. MMWR. Morbidity and mortality weekly report, 70(12), 437–441. https://doi.org/10.15585/mmwr.mm7012e2	26-Mar-2021	Florida, USA Aug 10 - Dec 21, 2020	**Design**: Epidemiological analysis **Intervention**: Districts with vs districts without mandatory mask use policies **Sample**: 63,654 cases of COVID-19 among persons aged 5–17 years reported to FDOH (34,959 school-related COVID-19 cases, including 25,094 (72%) among students and 9,630 (28%) among staff) **Key outcomes**: COVID-19 cases **VOCs assessed**: None	Overall, higher student incidences of COVID-19 were reported in school districts without mask mandates than those with mask mandates.	**Critical in at least one domain**

Herstein, J. J., Degarege, A., Stover, D., Austin, C., Schwedhelm, M. M., Lawler, J. V., Lowe, J. J., Ramos, A. K., & Donahue, M. (2021). Characteristics of SARS-CoV-2 Transmission among Meat Processing Workers in Nebraska, USA, and Effectiveness of Risk Mitigation Measures. Emerging infectious diseases, 27(4), 1032–1038. https://doi.org/10.3201/eid2704.204800	16-Feb-2021	Nebraska, USA Apr 1 - Jul 31, 2020	**Design**: Epidemiological analysis **Intervention**: Masking policies **Sample**: ≈26,000 meat processing workers **Key outcomes**: SARS-CoV-2 rates **VOCs assessed**: None	Using confirmed case data, incidence of SARS-CoV-2 infection before and after the date the last intervention was initiated (e.g., physical barriers were installed if universal mask policy began first) was reported. Ten days after the last intervention was initiated, 8 facilities (62%) showed a statistically significant decrease in incidence and 3 showed a non-significant decrease, while 1 facility showed a statistically significant increase in incidence and 1 showed a non-significant increase in incidence.	**Critical in at least one domain**
Li, L., Liu, B., Liu, S. H., Ji, J., & Li, Y. (2021). Evaluating the Impact of New York's Executive Order on Face Mask Use on COVID-19 Cases and Mortality: a Comparative Interrupted Times Series Study. Journal of general internal medicine, 36(4), 985–989. https://doi.org/10.1007/s11606-020-06476-9	26 January 2021	States of New York (NY) and Massachusetts (MA), USA Mar 25 – May 6, 2020	**Design**: Comparative interrupted time series **Intervention**: Statewide mask mandate in NY, then 3 weeks later in MA **Sample**: Not specified **Key outcomes**: Daily numbers of confirmed cases and deaths from March 25, 2020, to May 6, 2020 **VOCs assessed:** None	The average daily number of confirmed cases in NY decreased from 8549 to 5085 after the Executive Order took effect, with a trend change of 341 (95%CI: 187–496) cases per day. The average daily number of deaths decreased from 521 to 384 during the same two time periods, with a trend change of 52 (95%CI: 44–60) deaths per day. Compared to MA, the decreasing trend in NY was significantly greater for both daily numbers of confirmed cases ($P = 0.003$) and deaths ($P < 0.001$).	**Serious**

Table 5: Summary of studies reporting on effectiveness of masks in reducing other respiratory infections

Reference	Date released	Setting and time covered	Study characteristics	Summary of key findings in relation to the outcome	Risk of Bias
Bundgaard, H., Bundgaard, J. S., Raaschou-Pedersen, D. E. T., von Buchwald, C., Todsen, T., Norsk, J. B., Pries-Heje, M. M., Vissing, C. R., Nielsen, P. B., Winsløw, U. C., Fogh, K., Hasselbalch, R., Kristensen, J. H., Ringgaard, A., Porsborg Andersen, M., Goecke, N. B., Trebbien, R., Skovgaard, K., Benfield, T., Ullum, H., … Iversen, K. (2021). Effectiveness of Adding a Mask Recommendation to Other Public Health Measures to Prevent SARS-CoV-2 Infection in Danish Mask Wearers : A Randomized Controlled Trial. Annals of internal medicine, 174(3), 335–343. https://doi.org/10.7326/M20-6817	18 November 2020	Denmark Apr – Jun 2020	**Design:** Randomized controlled trial **Intervention:** Instruction to wear a mask when outside the home; 50 surgical masks were provided to intervention group participants; written instructions and instructional videos guided proper use of masks; help line was available to participants **Sample:** 3030 participants in intervention group vs. 2994 in control group; 4862 completed the study **Key outcomes:** Primary: SARS-CoV-2 infection; Secondary: infection with other respiratory viruses **Other respiratory infections assessed:** Para-influenza-virus type 1, Para-influenza-virus type 2, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1, Respiratory Syncytial-Virus A, Respiratory Syncytial-Virus B, Influenza A virus or Influenza B virus	In the mask group, 9 participants (0.5%) were positive for 1 or more of the 11 respiratory viruses other than SARS-CoV-2, compared with 11 participants (0.6%) in the control group (between-group difference, 0.1 percentage point [CI: 0.6–0.4 percentage point]; p= 0.87) (OR, 0.84 [CI: 0.35–2.04]; p= 0.71).	**High**

Acknowledgements

To help Canadian decision-makers as they respond to unprecedented challenges related to the COVID-19 pandemic, COVID-END in Canada is preparing evidence syntheses like this one. This living evidence synthesis was commissioned by the Office of the Chief Science Officer, Public Health Agency of Canada. The development and continued updating of this living evidence synthesis has been funded by the Canadian Institutes of Health Research (CIHR) and the Public Health Agency of Canada. The opinions, results, and conclusions are those of the team that prepared the evidence synthesis, and independent of the Government of Canada, CIHR, and the Public Health Agency of Canada. No endorsement by the Government of Canada, Public Health Agency of Canada or CIHR is intended or should be inferred.

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Appendices

Appendix 1: PubMed search strategy

#1 ("COVID 19"[MeSH] OR "COVID 19"[All Fields] OR "sars cov 2"[All Fields] OR "sars cov 2"[MeSH] OR "severe acute respiratory syndrome coronavirus 2"[All Fields] OR ncov[All Fields] OR "2019 ncov"[All Fields] OR "coronavirus infections"[MeSH] OR coronavirus[MeSH] OR coronavirus[All Fields] OR coronaviruses[All Fields] OR betacoronavirus[MeSH] OR betacoronavirus[All Fields] OR betacoronaviruses[All Fields] OR "wuhan coronavirus"[All Fields] OR 2019nCoV[All Fields] OR Betacoronavirus*[All Fields] OR "Corona Virus*"[All Fields] OR Coronavirus*[All Fields] OR Coronovirus*[All Fields] OR CoV[All Fields] OR CoV2[All Fields] OR COVID[All Fields] OR COVID19[All Fields] OR COVID-19[All Fields] OR HCoV-19[All Fields] OR nCoV[All Fields] OR "SARS CoV 2"[All Fields] OR SARS2[All Fields] OR SARSCoV[All Fields] OR SARS-CoV[All Fields] OR SARS-CoV2[All Fields]) AND English[la])

#2 (Masks[Mesh:NoExp] OR "Respiratory Protective Devices"[Mesh] OR mask[TIAB] OR masks[TIAB] OR masking[TIAB] OR face-mask[TIAB] OR facemask[TIAB] OR face-masks[TIAB] OR facemasks[TIAB] OR "face covering"[TIAB] OR "facial covering"[TIAB] OR "mouth covering"[TIAB] OR "face piece"[TIAB] OR "face protect*"[TIAB] OR "face protection"[TIAB] OR "face shield"[TIAB] OR respirator[TIAB] OR respirators[TIAB] OR "respiratory protection"[TIAB] OR "respiratory equipment"[TIAB] OR "respiratory device"[TIAB] OR "respiratory devices"[TIAB] OR n95[TIAB] OR "n 95"[TIAB] OR kn95[TIAB] OR kf94[TIAB] OR ffp[TIAB] OR ffp1[TIAB] OR ffp2[TIAB] OR ffp3[TIAB] OR n97[TIAB] OR n99[TIAB] OR p2[TIAB] OR airborne[TIAB] OR droplet[TIAB] OR droplets[TIAB]) AND (protection[TIAB] OR precaution[TIAB] OR prevention and control[MeSH Subheading] OR prevention[TIAB]) AND (transmi*[TIAB] OR spread*[TIAB]) NOT (mechanical[TIAB])

#1 and #2

#4 search*[Title/Abstract] OR meta-analysis[Publication Type] OR meta analysis[Title/Abstract] OR meta analysis[MeSH Terms] OR review[Publication Type] OR diagnosis[MeSH Subheading] OR associated[Title/Abstract]

#5(clinical[TIAB] AND trial[TIAB]) OR clinical trials as topic[MeSH] OR clinical trial[Publication Type] OR random*[TIAB] OR random allocation[MeSH] OR therapeutic use[MeSH Subheading]

#6 comparative study[pt] OR Controlled Clinical Trial[pt] OR quasiexperiment[TIAB] OR "quasi experiment"[TIAB] OR quasiexperimental[TIAB] OR "quasi experimental"[TIAB] OR quasi-randomized[TIAB] OR "natural experiment"[TIAB] OR "natural control"[TIAB] OR "Matched control"[TIAB] OR (unobserved[TI] AND heterogeneity[TI]) OR "interrupted time series"[TIAB] OR "difference studies"[TIAB] OR "two stage residual inclusion"[TIAB] OR "regression discontinuity"[TIAB] OR non-randomized[TIAB] OR pretest-posttest[TIAB]

#7 cohort studies[mesh:noexp] OR longitudinal studies[mesh:noexp] OR follow-up studies[mesh:noexp] OR prospective studies[mesh:noexp] OR retrospective studies[mesh:noexp] OR cohort[TIAB] OR longitudinal[TIAB] OR prospective[TIAB] OR retrospective[TIAB]

#8 Case-Control Studies[Mesh:noexp] OR retrospective studies[mesh:noexp] OR Control Groups[Mesh:noexp] OR (case[TIAB] AND control[TIAB]) OR (cases[TIAB] AND controls[TIAB]) OR (cases[TIAB] AND controlled[TIAB]) OR (case[TIAB] AND comparison*[TIAB]) OR (cases[TIAB] AND comparison*[TIAB]) OR "control group"[TIAB] OR "control groups"[TIAB]

#9 #3 and #4 (will retrieve Reviews)

#10 #3 and #5 (will retrieve RCTs)

#11 #3 and #6 (will retrieve Quasi-experimental studies)

#12 #3 and #7 (will retrieve Cohort studies)

#13 #3 and #8

#14 #9 or #10 or #11 or #12 or #13

#15 #14 NOT (Animals[Mesh] NOT (Animals[Mesh] AND Humans[Mesh]))

Appendix 2: Studies excluded at full text screening, with reasons for exclusion

See accompanying Excel spreadsheet

Appendix 3: Data extraction form

Metadata:
- PMID
- Open access URL
- Reference (APA format)
- Date of publication
- Preprint or published
- Variant(s) of concern of focus
- Other public health measures studied
- Relevance to other LESs within the suite

Study data:
- Study design
- Location (city/region, country; or "global")
- Setting (e.g., schools, restaurants, community)
- Date range of data collection
- Population
- Sample size (include size of each group)
- Intervention and comparison (if applicable)
- Was there a comparator? (Y/N)
- Length of intervention (i.e., when/how long were masks worn?)
- Was the intervention intended to prevent or control transmission?
- Was mask use mandated?

- Mandated population(s) (if applicable)
- Description and duration of mandate (if applicable)
- How was mask mandate or use promoted or communicated?
- Type(s) of mask(s) studied
- Outcomes of interest
- Outcome measure(s)
- Follow-up / how results were gathered
- Results – reduction in transmission
- Results – reduction in deaths
- Results – other outcomes
- Reduction in hospitalizations measured? (Y/N)
- Caveats or other notes

Appendix 4: Approach to critical appraisal

ROB-2 was used to assessed RCTs. A modified version of ROBINS-I was used to assess observational studies. Once a study met one criterion that made it "critical" risk of bias, it was dropped from further risk of bias assessment. The original modified version of ROBINS-I is located here; the below is further modified for the mask intervention.

Modified ROBINS-I instrument

Critical Appraisal Process for Assessment of Public Health Measures for COVID-19 in Cohort Studies

1. **Bias due to confounding**

Did the study adjust for other COVID protective interventions (including vaccination, prior community infection history, concurrent public health measures, mobility)? (Mobility especially relevant to mask mandate studies - i.e., was everyone staying in their homes?)**
(critical = multiple co-interventions with no controlling or adjustment; serious = one co-intervention not controlled for; moderate = all known important interventions controlled for)

Did the study adjust for calendar time (implications for circulating variant, season), demographics, and other relevant factors?**
(critical = no adjustment; serious = at least one known important domain not measured or controlled for; moderate = all known important confounding domains measured)

Were participants free of confirmed COVID infection at the start of the study?**
(critical = unclear or high likelihood pts had COVID at start of study; serious = COVID status of intervention group known but unclear for control group OR COVID status of both groups known by self-report only; low = negative COVID status of both groups known at study start (lab confirmed))

2. **Bias in selection of participants**

Was it a single-arm cohort study?
(serious = yes; low = no)

Were both study groups recruited from the same population during the same time period?
(critical = same or diff country/province/state measured at a diff time prior to pandemic)
(serious = same or diff country/province/state measured at a diff time during pandemic *or* diff country/province/state with dissimilar cultural/political landscapes measured at same time)
(moderate = same country/province/state measured at same time)

Were the COVID protective interventions implemented prior to period of data collection? (prevalent users)
(critical = not addressed and highly likelihood of prevalent users; moderate = prevalent users likely but appropriately controlled for; low = start of data collection at same time as implementation with no prevalent users)

Were the study groups balanced with respect to participant adherence (based on internal and external factors unrelated to COVID)?
(For example, people who are less likely to adhere to PHSMs anyway may be more likely to be exposed to COVID and require quarantine & isolation but then are less likely to adhere. Similar for e.g. people who work are essential workers without paid time off.)
(critical = not addressed and highly likelihood of difference in adherence; moderate = difference in adherence likely but appropriately controlled for; low = adherence confirmed to be same in both groups at start of study)

3. **Bias in classification of interventions**

Were the authors able to definitively relate outcomes to only masking?
(critical = masking was reported separately but in reality it would be **impossible** to separate it from other interventions; serious = masking was reported separately but in reality it would be **difficult** to separate it from other interventions; moderate = other interventions were implemented but there was an attempt to tie transmission directly to mask usage (e.g., identifying specific mask-related exposure events); low = masking was implemented in a controlled environment

Was the method for confirming the intervention clearly defined and applied consistently across study samples (e.g., districts within a country)?
(critical = not addressed; serious = intervention status not well defined or applied inconsistently; moderate = well defined but some aspects of assignment of intervention status determined retrospectively; low = well defined and solely based on information collected at time of intervention)

In periods of co-occurring interventions, do the authors clearly classify each individual intervention?
(critical = not addressed and co-interventions present; serious = co-intervention classification not well defined or applied inconsistently; moderate = co-intervention classification well defined but some aspects of assignment of status determined retrospectively; low = all co-interventions well defined and solely based on information collected at time of intervention)

Does classification into intervention/control group depend on self-report in a way that might introduce bias?
(For example, where negative consequences of providing truthful responses may lead to negative consequences e.g. self-reporting COVID symptoms would trigger 14 day quarantine and loss of income)
(critical = not addressed and reliant on self-report; moderate = reliant on self-report but appropriately controlled for/analyzed separately; low = not reliant on self-report)

For household transmission studies, was it clear that exposure to the index case was the most likely the only exposure to COVID for household or close contacts?
(critical = not addressed; serious = high risk occupational and social exposures likely and not accounted for; moderate = all participants isolated to same house or hospital from time of index case identification; low = all participants isolated to same house or hospital prior to index case identification)

4. Bias due to deviations from intended intervention?

Did the authors assess adherence to the protective behaviours/interventions after intervention implementation?**
(critical = not addressed; serious = reliant on self-report of adherence without verification or adjustment; moderate = adherence verified in at least a subset of each study group or appropriately adjusted for; low = adherence verified in all study participants)

5. **Risk of bias due to missing data**

Was outcome data at the end of the study period available for all or nearly all participants?
(critical = critical differences in missing data between groups; moderate: missing data did not differ between groups or was accounted for by appropriate statistical methods; low = no missing data)

Were participants excluded due to missing data?
(critical = participants excluded based on data missing unevenly across groups; moderate = participants excluded due to missing data, but rationale was appropriate and applied the same across all groups; low = no exclusions due to missing data)

6. **Risk of bias in measurement of outcomes**

Was the outcome of COVID confirmed by laboratory testing?**
(critical = not reported; serious = only sample or subset of population had PCR; moderate = most participants had PCR; low = all participants had PCR)

If the outcomes were derived from databases, were the databases constructed specifically for the collection of COVID data?**
(critical = no or unclear; serious = database for non-COVID purpose without individual level data; moderate = database for non-COVID purpose with individual level data (e.g. health records, employee records); low = national/state/province level surveillance database or specifically for COVID)

Were appropriate tools/methods with validated/justified cut-points used to determine outcomes of interest (other than COVID infection/transmission which is covered under laboratory testing)? **
(critical = not reported; serious = outcomes solely dependent on self-report without a validated measure; moderate = objective measure applied but validation uncertain; low = objective validated measure used consistently across all groups)

If the intervention was self-reported, did the authors attempt to control for social desirability?**
(critical = not reported and outcome likely to be influenced by social desirability; moderate = attempt made to control for social desirability; low = outcome not influenced by social desirability)

Was the frequency of testing for the outcome different between the study groups?
(critical = routinely done more frequently in one group more than the other; moderate = some differences but rationale appropriate; low = no difference in frequency of testing between groups)

If outcome was observed, was there more than one assessor and if so, was interrater agreement reported?
(critical = not reported; serious = reported with low agreement; moderate = reported with moderate agreement; low = reported with excellent agreement)

**relevant to single arm cohort studies