COVID-19 Living Evidence Synthesis 14.1: Effectiveness of masks for reducing transmission of COVID-19 and other respiratory infections in non-health care community-based settings

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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?

Executive summary

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.
- Masks, respirators, and other facial coverings such as face shields have been common PHSMs during the pandemic. The aim of the first version of this LES is to summarize randomized controlled trials (RCTs) and quasi-experimental 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. Other study designs (e.g., observational studies) were excluded from this deliverable but will be included in the next report.

Key points

- RCTs about the effectiveness of masks in reducing transmission of COVID-19 in the community are limited. Only three RCTs in community-based settings have been published. All three RCTs were assessed to have high risk of bias.
- The body of RCT evidence included in this review related to the effectiveness of masks in reducing transmission of COVID-19 is sparse and inconclusive. While one 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 wore nothing, another RCT (Bundgaard et al., 2021) found no statistically significant difference in reduction of SARS-CoV-2 transmission between the intervention group (masking recommendation) and control group.
- Two RCTs compared different types of masks. In one (Abaluck et al., 2022), surgical masks outperformed cloth masks when compared with the control group without masks. In another (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.
- High-quality evidence relating to mask mandates for reducing transmission of COVID-19 in community settings is also lacking. Two quasi-experimental studies have been published. In one, a comparative interrupted time series study of the State of New York (Li et al., 2021), the decrease in the average daily numbers of confirmed cases and deaths after implementation of a statewide mask mandate was significantly greater than in Massachusetts, where a mandate was implemented three weeks later. In another (Islam et al., 2022), small United States counties with mask mandates had a lower average of COVID-19 cases than counties without mask mandates.
- Only one study (Bundgaard et al., 2021) included the reduction of transmission of other respiratory infections as a secondary outcome. Nine participants (0.5%) in the mask group tested positive for 1 or more of the 11 respiratory viruses of interest (other than COVID-19) versus 11 participants (0.6%) in the control group.
- 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 varied across included studies.

Patient-identified key messages

- **Patients and families, particularly those with compromised health, worry about how the level of evidence 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 high-quality evidence about effectiveness. The body of observational evidence examining masks in relation to the transmission of COVID-19 will be included in future versions of this report.
- Modelling and mechanical studies were the most common type of study 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.

- Standardized strategies for recording and reporting adherence to masking are needed.

Findings

- Five studies (3 RCTs, 2 quasi-experimental studies) are included in this LES. Two RCTs report on the effectiveness of masks in reducing transmission, two RCTs report on different types of masks, and two quasi-experimental studies report on the effectiveness of mask mandates.
- Risk of bias was assessed as high for all three RCTs, and both quasi-experimental studies were assessed to have serious risk of bias
- A PRISMA 2020 flow diagram of the screening process is shown in Figure 1.

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

2 studies were included that report on masks for reducing transmission of COVID-19. The characteristics, findings and assessment of risk of bias for each study is presented in Table 1.

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, the intervention

Box 1: 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 were identified up to ten days before the version release date. 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 1-4**. A list of systematic relating to negative outcomes is provided in **Table 5.**

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 2**.

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 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. Additional ROB tools will be added as needed to fit with other study designs. 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 3**.

Summaries: We summarized the evidence by presenting narrative evidence profiles across studies by outcome measure. Future versions may include statistical pooling of results if deemed appropriate.

We will update this document every six weeks up to the end of March 2023.

increased proper mask wearing 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=3030) and control (n=2994) 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 to 0.4); p=0.38 (OR, 0.82 [95%CI, 0.54 to 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.

Both studies were assessed to have high risk of bias.

Summary of findings about primary outcome: Types of masks for reducing transmission of COVID-19

2 studies 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 2.

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% to 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 to 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 to 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.

Both studies examining types of masks were assessed to have high risk of bias.

Summary of findings about primary outcome and secondary outcome 1: Mask mandates for reducing transmission of COVID-19 and COVID-19 related deaths

2 studies conducted in the USA 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 is presented in Table 3.

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 (2686, 95%CI, 412 to 4961) and the trend change (223, 95%CI, 80 to 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.

Both studies were assessed to have serious risk of bias using the ROBINS-I tool.

Summary of findings about secondary outcome 2: Masks to reduce transmission of other respiratory infections

1 study 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 4.

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 to 0.4); p=0.87, OR, 0.84 (95%CI, 0.35 to 2.04); p=0.71.

Summary of findings about negative outcomes associated with masks

Although not included as a secondary outcome in this version of the LES, the search identified 4 systematic reviews of negative outcomes associated with masks. The characteristics, findings, and quality assessment for each systematic review is presented in Table 5. Negative outcomes assessed are: prevalence of PPE-related headaches; pressure injuries; exercise performance and physiological variables; and cutaneous adverse events. *NB: This list of systematic reviews is not exhaustive, as the search was not oriented to this sub-question.*

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 1: Summary of studies reporting on effectiveness 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
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 specified	• 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 ROB

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 **VOCs assessed:** None specified	• 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 to 0.4 percentage point; 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 ROB

Table 2: 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 (closed face shields and surgical masks) / 156 active control group (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 specified	• 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 ROB

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.](https://doi.org/10.1126/science.abi9069) 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 specified	• 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 general results not relating to types of masks, see Table 1	High ROB

Table 3: 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
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 ROB
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 specified	• 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 ROB

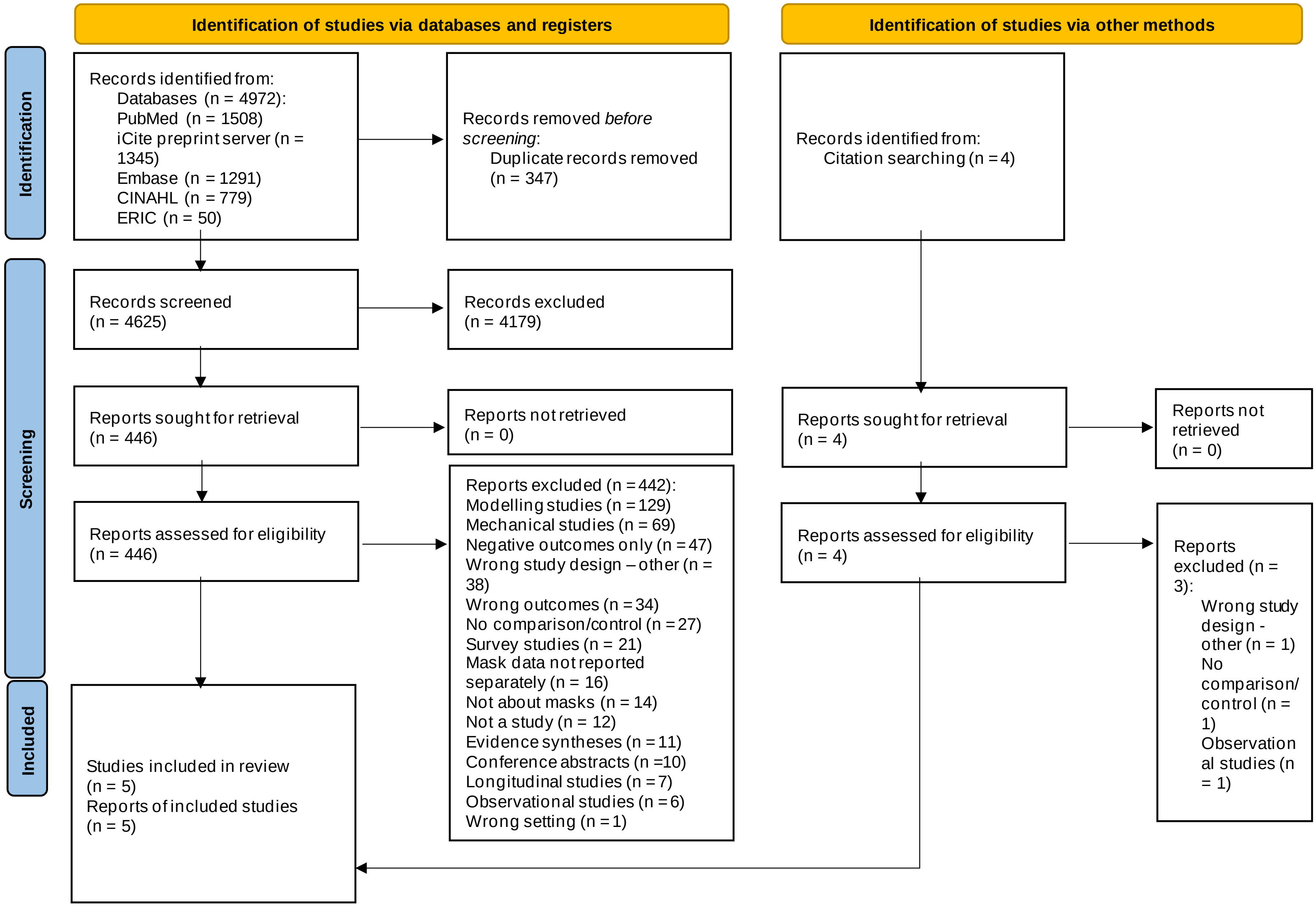
Table 4: Summary of studies reporting on effectiveness of masks in reducing other respiratory infections

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 to 0.4 percentage point]; P= 0.87) (OR, 0.84 [CI, 0.35 to 2.04]; P= 0.71).	High ROB

Table 5: Summary of systematic reviews reporting on negative outcomes associated with masks

Reference	Date released	Objective	Summary of key findings	Quality Rating
Sahebi, A., Hasheminejad, N., Shohani, M., Yousefi, A., Tahernejad, S., & Tahernejad, A. (2022). Personal protective equipment-associated headaches in health care workers during COVID-19: A systematic review and meta-analysis. Frontiers in public health, 10, 942046. https://doi.org/10.3389/fpubh.2022.942046	12 October 2022	To investigate the prevalence of PPE-associated headaches in HCWs during COVID-19 pandemic	According to the results of meta-analysis, the prevalence of headache after and before the use of PPE was 48.27% (95% CI: 40.20–56.34, I2 = 99.3%, p = 0 < 001) and 30.47% (95% CI: 20.47–40.47, I2 = 97.3%, p = 0 < 001), respectively.	Low
Yu, J. N., Wu, B. B., Feng, L. P., & Chen, H. L. (2021). COVID-19 related pressure injuries in patients and personnel: A systematic review. Journal of tissue viability, 30(3), 283–290. https://doi.org/10.1016/j.jtv.2021.04.002	August 2021	To summarize the pressure injuries caused by COVID-19 and the corresponding preventive measures and treatments	There are two main types of pressure injuries caused by the COVID-19: 1) Pressure injuries that caused by protective equipment (masks, goggles and face shield, etc.) in the prevention process; 2) pressure injuries caused by prolonged prone position in the therapy process.	Low
Shaw, K. A., Zello, G. A., Butcher, S. J., Ko, J. B., Bertrand, L., & Chilibeck, P. D. (2021). The impact of face masks on performance and physiological outcomes during exercise: a systematic review and meta-analysis. Applied physiology, nutrition, and metabolism = Physiologie appliquee, nutrition et metabolisme, 46(7), 693–703. https://doi.org/10.1139/apnm-2021-0143	July 2021	To investigate the impact of wearing a mask during exercise on performance and physiological variables	Surgical, or N95 masks did not impact exercise performance (SMD −0.05 [−0.16, 0.07] and −0.16 [−0.54, 0.22], respectively) but increased ratings of perceived exertion (SMD 0.33 [0.09, 0.58] and 0.61 [0.23, 0.99]) and dyspnea (SMD 0.6 [0.3, 0.9] for all masks). End-tidal CO2 (MD 3.3 [1.0, 5.6] and 3.7 [3.0, 4.4] mm Hg), and heart rate (MD 2 [0,4] beats/min with N95 masks) slightly increased. Face masks can be worn during exercise with no influences on performance and minimal impacts on physiological variables.	High
Montero-Vilchez, T., Cuenca-Barrales, C., Martinez-Lopez, A., Molina-Leyva, A., & Arias-Santiago, S. (2021). Skin adverse events related to personal protective equipment: a systematic review and meta-analysis. Journal of the European Academy of Dermatology and Venereology : JEADV, 35(10), 1994–2006. https://doi.org/10.1111/jdv.17436	02 June 2021	To summarize the prevalence, type and risk factors for cutaneous adverse events related to PPE and prevention measures to avoid them	The media of skin side events related to PPE was 75.13%. The rate of cutaneous adverse events related to mask was 57.71%, and those associated with gloves and hand hygiene products was 49.16%. Most common skin adverse events were contact dermatitis, acne and itching. The most damaged anatomical regions were the nasal bridge, the cheeks and the hands. The duration of PPE wearing was the most common risk factor. Frequent handwashing, gloves and masks were the agents most frequently related to skin reactions. N95 respirators were the most harmful mask type for the skin. Hydrocolloid use prevented from developing skin adverse events related to masks.	Low

Figure 1: PRISMA 2020 Flow Diagram



Appendices

Appendix 1: Detailed search strategy

PubMed Search:

#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: Data extraction form

Metadata:

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

Masks for reducing transmission:

- 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)
- Length of intervention (i.e., when/how long were masks worn?)
- Was mask use mandated?
- How was mask mandate or use promoted or communicated?
- Type(s) of mask(s) studied
- Outcomes of interest
- Outcome measure(s)
- Results – reduction in transmission
- Results – reduction in deaths
- Results – other outcomes
- Reduction in hospitalizations measured? (Y/N)

Types of masks:

- 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)
- Length of intervention (i.e., when/how long were masks worn?)
- Was mask use mandated?

- How was mask mandate or use promoted or communicated?
- Type(s) of mask(s) studied
- Outcomes of interest
- Outcome measure(s)
- Results – reduction in transmission related to types of masks
- Results – reduction in deaths
- Results – other outcomes
- Reduction in hospitalizations measured? (Y/N)

Mask mandates:

- 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)
- Description of mask mandate
- Duration of mask mandate
- How mandate was communicated
- Duration of mask mandate relative to length of study (e.g., entire study period; portion of study period)
- How mandate was communicated
- Comparator (if applicable) (e.g., recommendation to mask; no mandate)
- Mandated population(s)
- Outcomes of interest
- Outcome measure(s)
- Results – reduction in transmission
- Results – reduction in deaths
- Results – other outcomes
- Reduction in hospitalizations measured? (Y/N)

Appendix 3: Approach to critical appraisal

ROB-2 was used to assessed RCTs. ROBIN-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.

AMSTAR 2 was used to assess systematic reviews of negative outcomes associated with masking. Numerical scores were derived by assigning 1 point for "Yes", 0.5 point for "Partial Yes", and 0 points for "No". Score denominators were determined by the number of checklist items that applied to each review. Quality rankings were assigned according to score percentages: ≥70% = high-quality, 36-69% = medium-quality, and ≤35 = low-quality.