

Masks for Prevention of Respiratory Virus Infections, Including SARS-CoV-2, in Health Care and Community Settings

A Living Rapid Review

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Background: Recommendations on masks for preventing coronavirus disease 2019 (COVID-19) vary.

Purpose: To examine the effectiveness of N95, surgical, and cloth masks in community and health care settings for preventing respiratory virus infections, and effects of reuse or extended use of N95 masks.

Data Sources: Multiple electronic databases, including the World Health Organization COVID-19 database and medRxiv preprint server (2003 through 14 April 2020; surveillance through 2 June 2020), and reference lists.

Study Selection: Randomized trials of masks and risk for respiratory virus infection, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and observational studies of mask use and coronavirus infection risk were included. New evidence will be incorporated by using living review methods.

Data Extraction: One reviewer abstracted data and assessed methodological limitations; a second reviewer provided verification.

Data Synthesis: 39 studies (18 randomized controlled trials and 21 observational studies; 33 867 participants) were included. No study evaluated reuse or extended use of N95 masks. Evidence on SARS-CoV-2 was limited to 2 observational studies with serious limitations. Community mask use was possibly associated with decreased risk for SARS-CoV-1 infection in observational studies. In high- or moderate-risk health care settings, observational studies found that risk for infection with SARS-CoV-1 and Middle East respiratory syndrome coronavirus probably decreased with mask use versus nonuse and possibly decreased

with N95 versus surgical mask use. Randomized trials in community settings found possibly no difference between N95 versus surgical masks and probably no difference between surgical versus no mask in risk for influenza or influenza-like illness, but compliance was low. In health care settings, N95 and surgical masks were probably associated with similar risks for influenza-like illness and laboratory-confirmed viral infection; clinical respiratory illness had inconsistency. Bothersome symptoms were common.

Limitations: There were few SARS-CoV-2 studies, observational studies have methodological limitations, and the review was done by using streamlined methods.

Conclusion: Evidence on mask effectiveness for respiratory infection prevention is stronger in health care than community settings. N95 respirators might reduce SARS-CoV-1 risk versus surgical masks in health care settings, but applicability to SARS-CoV-2 is uncertain.

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Update Alerts: The authors have specified in the Methods section the interval and stop date for updates to this Living Review. As Annals receives updates, they will appear in the Comments section of the article on Annals.org. Reader inquiries about updates that are not available at approximately the specified intervals should be submitted as Comments to the article.

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Clinicians and policymakers recommend preventive measures, including use of respiratory protective devices, to reduce the risk for coronavirus disease 2019 (COVID-19), the disease caused by infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It is thought that SARS-CoV-2 is spread primarily through contact and large respiratory droplets, but evidence also indicates potential transmission by fine respiratory aerosols (1). Several types of respiratory protective devices (collectively referred to as “face masks”) are available (2). Disposable N95 and equivalent respirators are fitted devices that have been tested to achieve very efficient filtration of small airborne particles, including aerosols. Surgical or medical masks (hereafter referred to as “surgical masks”) are loose-fitting, create a physical barrier, block larger particles, and are fluid-resistant. Cloth masks are nonmedical face coverings that vary with regard to filtration and fluid resistance depending on the material used, the number of layers, and fit. Single-use N95 and equivalent

respirators provide higher respiratory protection than surgical masks (3), but shortages have been reported (4). Extended use and reuse of N95 respirators have been tested in laboratory settings (5), but clinical effectiveness and safety are uncertain (5, 6).

This living rapid review addresses the comparative effectiveness of face masks in community and health care settings for prevention of SARS-CoV-2 infection and associated COVID-19 disease, and the effectiveness and safety of mask reuse. This report will be used by the American College of Physicians (ACP) to develop evidence-based practice points on mask use in different settings. Because evidence is limited on SARS-

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CoV-2, this review also includes evidence on SARS-CoV-1 (causing SARS-1) and Middle East respiratory syndrome coronavirus (MERS-CoV) (causing MERS) and other viral respiratory illness (including influenza and influenza-like illness).

METHODS

Detailed methods are available in the full report (7). The key questions were developed with input from staff at ACP and the Agency for Healthcare Research and Quality (AHRQ), with input from the review authors.

Key Question 1a. What is the effectiveness and comparative effectiveness of respirators (N95 or equivalent), face masks (surgical), and cloth masks in addition to standard precautions in community and health care (high- or non-high-risk) settings for prevention of SARS-CoV-2 infection?

Key Question 1b. For SARS-CoV-1 or MERS-CoV infection?

Key Question 1c. For influenza, influenza-like illness, and other viral respiratory infection?

Key Question 2. What is the evidence for extended or reuse of N95 respirators for prevention of SARS-CoV-2, SARS-CoV-1, or MERS-CoV infection?

Owing to the urgent and ongoing nature of the COVID-19 pandemic, a rapid, living review approach was used (8). Rapid reviews utilize streamlined systematic review processes. For this review, modified methods included 1) a gray literature search limited to 1 website; 2) dual review of excluded abstracts only; 3) critical appraisal of observational studies not conducted by using a formal instrument; and 4) critical appraisal and data abstraction by a single reviewer, with verification by a second reviewer. Living reviews use methods for continually updating, as new evidence becomes available (9).

Data Sources and Searches

A medical librarian searched PubMed, MEDLINE, and Elsevier Embase (from 2003 through 14 April 2020). Search strategies are shown in **Supplement Table 1** (available at [Annals.org](#)). We also searched the World Health Organization (WHO) COVID-19 database (10) and the medRxiv preprint server (11) and reviewed reference lists of relevant articles, including a living review on risk factors (including mask use) for coronavirus infections in health care workers (HCWs) (12). Daily MEDLINE surveillance and weekly surveillance on EMBASE, the WHO database, and the medRxiv server is ongoing; this article includes surveillance through 2 June 2020.

Study Selection

Studies were selected by using predefined criteria (**Supplement Table 2**, available at [Annals.org](#)). The population was HCWs and persons in the community. Interventions were disposable N95 filtering facepiece respirators, surgical masks, and cloth masks. For key question 1, we included randomized controlled trials (RCTs) of one mask type versus another that reported effects on risk for infection with SARS-CoV-2 (including

infections meeting criteria for COVID-19), SARS-CoV-1 (including SARS-1), or MERS-CoV (including MERS); influenza-like illness; laboratory-confirmed viral respiratory illness; and harms. To inform indirect comparisons, we also included RCTs of masks versus no masks. We included cohort and case-control studies on the association between mask use and risk for COVID-19, SARS-1, and MERS, owing to the lack of randomized trials for these outcomes. Studies on noncoronavirus infections were restricted to randomized trials, because such studies are available. We also included studies on reuse or extended use of masks versus standard use and risk for SARS-CoV-2, SARS-CoV-1, or MERS-CoV infection.

One investigator reviewed each citation for potential full-text review and reviewed each full-text article for inclusion. A second investigator verified exclusion decisions at both the citation and full-text level; disagreements were resolved through consensus. We included non-peer-reviewed articles for SARS-CoV-2 because peer-reviewed literature was sparse. Chinese-language articles were translated by a native speaker.

Data Extraction

One investigator extracted study data into standardized tables, and a second verified data: study author, year; setting (country, health care setting, dates), population characteristics (sample size, age, sex, HCW role or position, number of cases, exposures, personal protective equipment use), mask interventions (randomized trials, including adherence) or mask use (observational studies), and results. If necessary, we calculated relative risks (randomized trials) and odds ratios (observational studies) from available data. For observational studies on HCWs and coronavirus, we categorized risk settings as high (coronavirus infection exposures in intensive care units, frequent aerosol-generating procedures [such as tracheal intubation or bronchoscopy], or with inadequate infection control [for example, unrecognized patient infections]), moderate (exposure to coronavirus infections, not meeting criteria for high risk), or low (no care of patients with coronavirus infections) (13). We categorized randomized trials on HCWs and risk for influenza or influenza-like illness as higher risk (inpatient) or lower risk (outpatient).

Quality Assessment

Randomized trials were assessed by using criteria adapted from the U.S. Preventive Services Task Force (14). For observational studies, we noted key limitations of each study, such as potential recall, selection, or participation bias; issues regarding outcome evaluation and analytic methods; and confounding (15, 16).

Data Synthesis and Analysis

Results were synthesized narratively. For cluster randomized trials, risk estimates adjusted for cluster effects were presented when available (17). For observational studies, unadjusted and adjusted risk estimates were presented. Quantitative synthesis was not done owing to methodological limitations; study design variability; and heterogeneity in populations, comparisons,

and analytical methods. We created an evidence map showing the strength of evidence and effect direction by setting and infection type. The strength of evidence was classified as high, moderate, low, or insufficient, on the basis of the study design, risk for bias, inconsistency, indirectness, and imprecision (18).

Living Review

This review is being maintained as a living review focusing on key questions 1a and 2 (SARS-CoV-2 and COVID-19), with a planned end date 1 year from initial searches. Surveillance is ongoing, using the same searches as the original review, except dropping searches of preprint servers. Study selection and quality assessment will follow the same processes described, except that observational study quality will be formally assessed by using published criteria (14). New evidence that does not substantively change review conclusions will be briefly summarized on a monthly basis; a major update will be performed when new evidence changes the nature or strength of the conclusions.

Role of the Funding Source

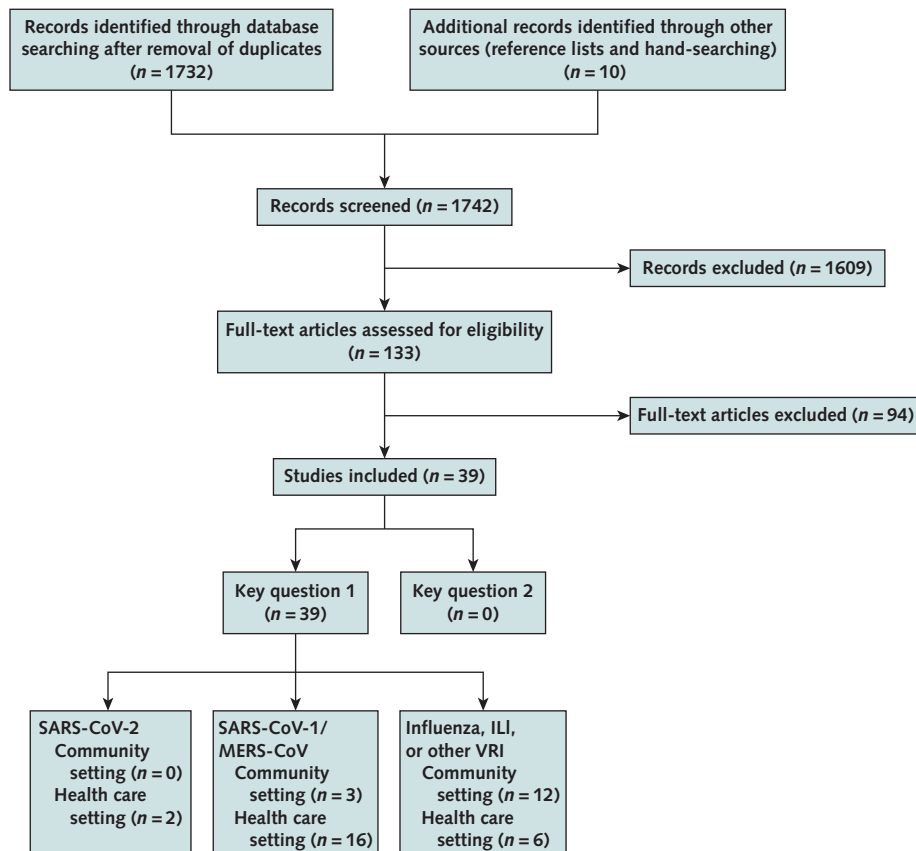
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RESULTS

Thirty-nine studies (33 867 participants), all addressing key question 1, met the inclusion criteria (19–50–51–57). **Figure 1** summarizes the study selection process and number of included studies, by setting (community or health care) and study type. Twelve RCTs (19–21, 23, 24, 28–30, 37, 41, 48, 49) and 3 observational studies (31, 51, 54) were conducted in the community, and 6 RCTs (27, 34, 38–40, 46) and 18 observational studies (22, 25, 26, 32, 33, 35, 36, 42–45, 47, 50, 52, 53, 55–57) were conducted in HCWs (**Supplement Tables 3 and 4**, available at [Annals.org](https://www.annals.org)). There were no RCTs on risk for coronavirus infections. For SARS-CoV-2, there were 2 cohort studies (52, 56). Eighteen observational studies addressed SARS-CoV-1 (25,

Figure 1. Literature search and selection.



ILI = influenza-like illness; VRI = viral respiratory illness; MERS-CoV = Middle East respiratory syndrome coronavirus; SARS-CoV = severe acute respiratory syndrome coronavirus.

26, 31–33, 35, 36, 42–45, 47, 50, 51, 53–55, 57), and 1 cohort study addressed MERS-CoV (22). No death was recorded in any study. The RCTs were usually conducted during influenza season and evaluated the risk for nonspecific clinical respiratory illness, influenza-like illness, and laboratory-confirmed viral respiratory illness. Two Chinese-language studies were translated into English by a native Chinese speaker on the review team (36, 55).

Two RCTs (27, 34) were randomized by individual participant; the remaining trials were randomized by clusters (households, university residence halls, tents during Hajj, hospitals, hospital wards, or outpatient settings). The number of participants ranged from 164 to 7687. The RCTs were conducted during influenza season, except for 2 RCTs of Hajj pilgrims staying in tents (21, 23). Two RCTs (34, 37) reported the incidence of laboratory-confirmed nonpandemic coronavirus infections, but 1 trial only reported 1 case (37). Four trials were conducted in the United States, 1 in Canada, 1 in Australia, 2 in Europe, 2 in Saudi Arabia, and 8 in Asia. Eleven RCTs were rated good-quality, and 7 were rated fair-quality (Supplement Table 5, available at Annals.org). Limitations of the fair-quality trials included baseline between-group differences and high attrition; one cluster RCT (23) did not adjust for cluster correlation. Blinding of participants to the mask and other interventions (for example, hand hygiene) was not possible.

The observational studies had important limitations (Supplement Table 4). All were retrospective and potentially susceptible to recall bias for determining mask use and other exposures. The studies were limited in their ability to measure and control for the amount and intensity of exposures. Six studies did not control for potential confounders. Of the 15 studies that did control for confounders, only 1 (33) evaluated correlations between masks and other infection control measures (such as gloves, gowns, goggles, or handwashing) to inform variable selection for model building. In the other studies that reported results from multivariate models, correlations between infection control measures and potential collinearity were not addressed.

Effectiveness of Masks

Key Question 1a: SARS-CoV-2

Community settings. No study evaluated masks for preventions of SARS-CoV-2 infections in community settings.

Health care settings. Two cohort studies evaluated mask use and risk for SARS-CoV-2 infection, but had important limitations (52, 56). One study (493 participants) of HCWs in higher- and lower-risk hospital units found N95 respirators to be associated with decreased infection risk versus no mask, but mask use was based on whether the HCW worked in a department in which masks were used, not on assessment of individual use (52). In addition, departments with N95 respirator use differed from departments that did not use N95 respirators in other infection control measures (such as handwashing and use of protective clothing) and exposure to patients with COVID-19. There were also few

HCW cases and serious imprecision. The other study was small (37 participants) and evaluated HCWs with inadequate personal protective equipment during exposure to a patient with unrecognized SARS-CoV-2 infection (56). It reported 3 cases of SARS-CoV-2 infection in HCWs, resulting in very imprecise estimates.

Key Question 1b: SARS-CoV-1 and MERS-CoV

Community settings. Three observational studies (2857 participants) evaluated masks and SARS-1 risk in community settings (Supplement Table 4) (31, 51, 54). The studies did not compare mask types or provide details regarding mask type. Wearing a mask was associated with decreased risk for infection in persons without known SARS-1 contacts in 1 study (54) and in household contacts of patients with SARS-1 in 2 studies (Supplement Table 6, available at Annals.org) (31, 51).

Health care settings. Fifteen observational studies (3994 participants) evaluated the association between mask use by HCWs and risk for SARS-CoV-1 infection (25, 26, 32, 33, 35, 36, 42–45, 47, 50, 53, 55, 57), and 1 study (283 participants) (22) evaluated the association between mask use and MERS-CoV infection (Supplement Table 4). Five studies were conducted in high-risk settings, and the remainder in moderate-risk settings (Supplement Table 7, available at Annals.org); no study was low risk. The proportion of HCWs with close or direct contact with SARS-CoV-1 or MERS-CoV cases was high in studies that reported this information; use of personal protective equipment varied (Supplement Table 7).

Five observational studies (1208 participants) consistently found N95 respirators to be associated with decreased risk for SARS-CoV-1 infection versus surgical masks (sometimes described as “disposable” masks) in HCWs (Supplement Table 8, available at Annals.org) (25, 33, 35, 45, 57); all but 1 study (33) were conducted in high-risk settings. Results of 3 comparisons (1207 participants) involving an N95 respirator or surgical versus cloth mask and risk for SARS-CoV-1 in moderate-risk settings were somewhat inconsistent (33, 36, 55). The cloth mask material was cotton or not reported, and cloth masks were described as 12- or 16-layer masks, potentially reducing generalizability to the United States and other countries where cloth masks typically have far fewer layers.

Twelve observational studies (2998 participants) consistently found mask use associated with decreased risk for SARS-CoV-1 infection versus no use (Supplement Table 8) (33, 35, 36, 42–45, 47, 50, 53, 55, 57); of these, 8 specifically evaluated N95 respirators or surgical masks (33, 35, 36, 45, 47, 50, 55, 57). Results were consistent when studies were stratified by high- or moderate-risk setting (34, 45, 53, 57). Masks were associated with decreased risk for SARS-CoV-1 infection in multivariate models in 5 studies (33, 43, 47, 50, 55).

Four studies (626 participants) found more consistent mask use by HCWs to be associated with decreased risk for SARS-CoV-1 or MERS-CoV infection versus less consistent use (Supplement Table 8) (22,

Table 1. Randomized Controlled Trials of Masks for Prevention of Viral Respiratory Infection in Community Settings

Study, Year (Reference)	Interventions*	Clinical Respiratory Illness	Influenza-like Illness	Laboratory-Confirmed Infection
Aiello et al, 2010 (19)	A: Surgical mask + hand sanitizer (<i>n</i> = 367) B: Surgical mask (<i>n</i> = 378) C: No mask or hand sanitizer (<i>n</i> = 552)	–	A: 25.1% (92/367) B: 26.2% (99/378) C: 32.1% (177/552) Unadjusted IRR, 0.88 (95% CI, 0.75 to 1.03) for A vs. C, 0.92 (95% CI, 0.79 to 1.06) for B vs. C Adjusted IRR, 0.87 (95% CI, 0.73 to 1.02) for A vs. C, 0.90 (95% CI, 0.77 to 1.05) for B vs. C	Influenza A: 0.5% (2/367) B: 1.3% (5/378) C: 0.5% (3/552)
Aiello et al, 2012 (20)	A: Surgical mask + hand sanitizer (<i>n</i> = 349) B: Surgical mask (<i>n</i> = 392) C: No mask or hand sanitizer (<i>n</i> = 370)	–	A: 8.9% (31/349) B: 11.7% (46/392) C: 13.8% (51/370) Unadjusted IRR, 0.78 (CI, 0.59 to 1.05) for A vs. C, 1.08 (CI, 0.86 to 1.34) for B vs. C Adjusted IRR, 0.78 (CI, 0.57 to 1.08) for A vs. C, 1.10 (CI, 0.88 to 1.38) for B vs. C	Influenza A or B viruses A: 1.7% (6/349) B: 3.1% (12/392) C: 4.3% (16/370) Unadjusted HR, 0.57 (CI, 0.26 to 1.24) for A vs. C, 0.93 (CI, 0.60 to 1.42) for B vs. C Adjusted HR, 0.57 (CI, 0.26 to 1.24) for A vs. C, 0.92 (CI, 0.59 to 1.42)
Alfelali et al, 2019 (21)	A: Surgical mask (<i>n</i> = 3199) B: No mask (<i>n</i> = 3139)	A: 11% (354/3199) B: 10% (322/3139) OR, 1.10 (CI, 0.88 to 1.39)	–	Viral respiratory illness A: 44% (96/218) B: 37% (60/161) OR, 1.35 (CI, 0.88 to 2.07)
Barasheed et al, 2014 (23)	A: Surgical mask (<i>n</i> = 75) B: No mask (<i>n</i> = 89)	–	A: 31% (11/36) B: 53% (28/53) <i>P</i> = 0.04	Viral respiratory illness A: 10.3% (4/39) B: 5.7% (2/35)
Canini et al, 2010 (24)	A: Surgical mask (<i>n</i> = 52 index cases, 148 household contacts) B: No mask (<i>n</i> = 53 index cases, 158 household contacts)	–	A: 16.2% (24/148) B: 15.8% (25/158) Absolute risk difference: 0.40% (CI, –10% to 11%) Adjusted OR, 0.95 (CI, 0.44 to 2.05)	–
Cowling et al, 2008 (29)	A: Surgical mask + lifestyle intervention (<i>n</i> = 22 index cases, 65 contacts) B: Hand hygiene + lifestyle intervention (<i>n</i> = 32 index cases, 92 contacts) C: Lifestyle intervention (<i>n</i> = 74 index cases, 213 contacts)	–	Definition 1: A: 8% (5/61) B: 4% (3/84) C: 4% (8/205) OR, 2.00 (CI, 0.57 to 7.02) for A vs. C, 0.80 (CI, 0.22 to 2.89) for B vs. C Definition 2: A: 18% (11/61) B: 18% (15/84) C: 18% (37/205) OR, 0.88 (CI, 0.34 to 2.27) for A vs. C, 0.86 (CI, 0.39 to 1.91) for B vs. C Definition 3: A: 10% (6/61) B: 11% (9/64) C: 11% (23/205) OR, 0.87 (CI, 0.30 to 2.51) for A vs. C, 0.88 (CI, 0.36 to 2.14) for B vs. C	Influenza A: 7% (4/61) B: 6% (5/84) C: 6% (12/205) OR, 1.16 (CI, 0.31 to 4.34) for A vs. C, 1.07 (CI, 0.29 to 4.00) for B vs. C

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Table 1—Continued

Study, Year (Reference)	Interventions*	Clinical Respiratory Illness	Influenza-like Illness	Laboratory-Confirmed Infection
Cowling et al, 2009 (28)	A: Surgical mask (n = 83 index cases, 258 contacts) B: Hand hygiene (n = 85 index cases, 257 contacts) C: Lifestyle education (n = 91 index cases, 279 contacts)	—	Definition 1: A: 7.0% (18/258) B: 3.5% (9/257) C: 5.0% (14/279) P = 0.52 Adjusted OR, 1.68 (CI, 0.68 to 4.15) for A vs. C, 0.81 (CI, 0.33 to 2.00) for B vs. C; when restricted to contacts of index cases receiving intervention within 36 h of symptom onset: 1.45 (CI, 0.49 to 4.24) for A vs. C, 0.64 (CI, 0.20 to 2.02) for B vs. C Definition 2: A: 21.3% (55/258) B: 16.3% (42/257) C: 19.0% (53/279) Adjusted OR, 1.25 (CI, 0.79 to 1.98) for A vs. C, 0.92 (CI, 0.57 to 1.48) for B vs. C Adjusted OR, 0.86 (CI, 0.48 to 1.53) for A vs. C, 0.46 (CI, 0.22 to 0.96) for B vs. C when restricted to contacts of index cases receiving intervention within 36 h of symptom onset	Influenza A: 7.0% (18/258) B: 5.4% (14/257) C: 10.0% (28/279) Adjusted OR, 0.77 (CI, 0.38 to 1.55) for A vs. C, 0.57 (CI, 0.26 to 1.22) for B vs. C; when restricted to contacts of index cases receiving intervention within 36 h of symptom onset: 0.33 (CI, 0.13 to 0.87) for A vs. C, 0.46 (CI, 0.15 to 1.43) for B vs. C
Larson et al, 2010 (30)	A: Surgical mask + hand sanitizer (n = 938 [166 households]) B: Hand sanitizer (n = 946 [169 households]) C: Education (n = 904 [174 households])	Primary illness, unadjusted rate per 1000 person-weeks A: 38.91 (1972/50, 676) B: 29.06 (1416/48, 731) C: 35.38 (1646/46, 526) From adjusted model, p = 0.19 for A vs. C, p = 0.14 for B vs. C Secondary illness (secondary attack rate = number of secondary cases divided by the number of household members minus 1) A: 0.12 (SD, 0.22) B: 0.14 (SD, 0.23) C: 0.14 (SD, 0.22) Adjusted OR, 0.82 (CI, 0.70 to 0.97) for A vs. C, 1.01 (CI, 0.85 to 1.21) for B vs. C	Primary illness: unadjusted rate per 1000 person-weeks A: 1.56 (79/50, 676) B: 1.93 (94/48, 731) C: 2.26 (105/46, 526) From adjusted model, p = 0.16 to A vs. C, p = 0.46 for B vs. C Secondary illness (secondary attack rate = number of secondary cases divided by the number of household members minus 1) A: 0.18 (SD 0.08) B: 0.02 (SD 0.07) C: 0.02 (SD 0.08)	Influenza: unadjusted rate per 1000 person-weeks A: 0.49 (29/50, 676) B: 0.60 (25/48, 731) C: 0.52 (24/46, 526) From adjusted model, p = 0.89 for A vs. C, p = 0.20 for B vs. C
MacIntyre et al, 2009 (37)	A: P2 mask (n = 92 [46 households]) B: Surgical mask (n = 94 [47 households]) C: Control (n = 100 [50 households])	—	A: 15% (14/92) B: 20% (19/94) C: 16% (16/100) Unadjusted RR, 0.75 (CI, 0.40 to 1.41) for A vs. B† Adjusted RR, 0.95 (CI, 0.49 to 1.84) for A vs. C and 1.29 (CI, 0.69 to 2.31) for B vs. C Adherence to P2 or surgical mask associated with decreased risk for ILI; HR, 0.26 (CI, 0.09 to 0.77) for 1-day incubation and 0.32 (CI, 0.11 to 0.98) for 2-day incubation	Viral respiratory illness A: 9% (8/92) B: 6% (6/94) C: 3% (3/100) Unadjusted RR, 1.36 (CI, 0.49 to 3.77) for A vs. B† Adjusted RR, 2.90 (CI, 0.79 to 10.6) for A vs. C and 2.13 (CI, 0.55 to 8.26) for B vs. C

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Table 1—Continued

Study, Year (Reference)	Interventions*	Clinical Respiratory Illness	Influenza-like Illness	Laboratory-Confirmed Infection
MacIntyre et al, 2016 (41)	A: Surgical mask (<i>n</i> = 123) B: No mask (<i>n</i> = 122)	Number of household contacts with outcome per person-days A: 4/2098 (1.91/1000) B: 6/2036 (2.95/1000) RR, 0.65 (CI, 0.18 to 2.29) Adjusted for age: RR, 0.61 (CI, 0.18 to 2.13) Post hoc analysis of mask wearers (<i>n</i> = 159) vs. non-mask wearers (<i>n</i> = 86) irrespective of randomization group Mask: 3/2694 (1.11/1000) No mask: 7/1440 (4.86/1000) RR, 0.23 (CI, 0.06 to 0.88)	Number of household contacts with outcome per person-days A: 1/2098 (0.48/1000) B: 3/2036 (1.47/1000) RR, 0.32 (CI, 0.03 to 3.11) Post hoc analysis of mask wearers (<i>n</i> = 159) vs. non-mask wearers (<i>n</i> = 86) irrespective of randomization group Mask: 1/2694 (0.37/1000) No mask: 3/1440 (2.08/1000) RR, 0.18 (CI, 0.02 to 1.71)	Viral respiratory illness Number of household contacts with outcome per person-days A: 1/2098 (0.48/1000) B: 1/2036 (0.59/1000) RR, 0.97 (CI, 0.06 to 15.5) Post hoc analysis of mask wearers (<i>n</i> = 159) vs. non-mask wearers (<i>n</i> = 86) irrespective of randomization group Mask: 0/2694 (0/1000) No mask: 2/1440 (0.70/1000) HR, 0.11 (CI, 0.01 to 4.40)
Simmerman et al, 2011 (48)	A. Paper (surgical) face mask + hand washing training (<i>n</i> = 395 [145 households]) B. Handwashing training (<i>n</i> = 367 [147 households]) C. Control (<i>n</i> = 385 [150 households])	—	A. 18% (51/291) B. 17% (50/292) C. 9% (26/302) Adjusted OR, 2.15 (CI, 1.27 to 3.62) for A vs. C, 2.01 (CI, 1.25 to 3.50) for B vs. C OR, 2.16 (CI, 1.14 to 4.07) for A vs. C, 2.38 (CI, 1.32 to 4.29) for B vs. C, in household members who received intervention within 48 h of index case symptom onset	Influenza A. 23% (66/291) B. 23% (66/292) C. 19% (58/302) Adjusted OR, 1.16 (CI, 0.74 to 1.82) for A vs. C, 1.20 (CI, 0.76 to 1.88) for B vs. C; limited to household members who received intervention within 48 h of index case symptom onset: 1.15 (CI, 0.68 to 1.93) for A vs. C, 1.06 (CI, 0.62 to 1.82)
Suess et al, 2012 (49)	A. Surgical mask + hand sanitizer (<i>n</i> = 82 [30 households]) B. Surgical mask (<i>n</i> = 69 [26 households]) C. Control (<i>n</i> = 67 [28 households])	—	A. 9% (6/67) B. 9% (6/69) C. 17% (14/82) Unadjusted OR, 0.47 (CI, 0.15 to 1.49) for A vs. C and 0.56 (CI, 0.18 to 1.68) for B vs. C Adjusted OR, 0.49 (CI, 0.20 to 1.6) for A vs. C and 0.50 (CI, 0.20 to 1.60) for B vs. C (including adjustment for cluster correlation) Adjusted OR, 0.17 (CI, 0.01 to 2.03) for A vs. C and 0.63 (CI, 0.08 to 4.92) for B vs. C, restricted to implementation of intervention within 36 h after symptom onset	Influenza A. 15% (10/67) B. 9% (6/69) C. 23% (19/82) Unadjusted OR, 0.61 (CI, 0.23 to 1.66) for A vs. C and 0.39 (CI, 0.13 to 1.19) for B vs. C Adjusted OR, 0.59 (CI, 0.20 to 1.5) for A vs. C and 0.30 (CI, 0.10 to 0.94) for B vs. C (including adjustment for cluster correlation) Adjusted OR, 0.13 (CI, 0.01 to 1.28) for A vs. C and 0.21 (CI, 0.02 to 2.02) for B vs. C, restricted to implementation of intervention within 36 h after symptom onset

HR = hazard ratio; IRR = incidence rate ratio; OR = odds ratio; RR = relative risk.

* Descriptions of interventions appear in Supplement Table 3 (available at [Annals.org](https://annals.org)).

† Calculated and not adjusted for cluster correlation.

32, 35, 43); of these, 3 specifically evaluated N95 or surgical masks (22, 32, 35) and 1 was in a high-risk setting (32). In 1 of the studies, consistent use of N95 respirators or surgical masks was associated with decreased infection risk in HCWs who had direct contact with SARS-1 patients, direct contact with non-SARS-1 patients, and no direct patient contact (32).

Key Question 1c: Influenza, Influenza-like Illness, and Other Viral Respiratory Illness

Community settings. Twelve RCTs (16 836 participants) evaluated masks in community settings (Table 1 and Supplement Table 3) (19–21, 23, 24, 28–30, 37, 41, 48, 49). The settings were households, university residence halls, and tents used by Hajj pilgrims. Masks

were used by infected index cases (“source control”), household contacts of index cases, cases and contacts, or persons without specific contact with cases. All participants generally received education on preventing respiratory infection and hand hygiene. All of the trials compared a mask versus no mask; 1 trial also compared a mask versus a mask plus handwashing training (48).

Only 1 RCT (290 participants) directly compared different mask types (37). It evaluated a P2 mask (Australian equivalent to an N95 respirator) versus a surgical mask in adult household contacts of children with influenza-like illness. There were no differences between either mask type versus no mask in infection outcomes, though estimates were imprecise. The RCT did

Table 2. Randomized Controlled Trials of Masks for Prevention of Viral Respiratory Infection in Health Care Settings

Study, Year (Reference)	Interventions*	Clinical Respiratory Illness	Influenza-like Illness	Laboratory-Confirmed Infection
Loeb et al, 2009 (34)	A: N95 respirators (n = 210) B: Surgical mask (n = 212)	A: 6.2% (13/210) B: 6.1% (13/212) RR, 1.01 (95% CI, 0.48 to 2.13)	A: 1.0% (2/210) B: 4.2% (9/212) RR, 0.22 (CI, 0.05 to 1.03)	Viral respiratory illness A: 33.3% (70/210) B: 33.0% (70/212) RR, 1.01 (CI, 0.77 to 1.32) Influenza A: 22.9% (48/210) B: 23.6% (50/212) RR, 0.97 (CI, 0.68 to 1.37) Coronavirus A: 5.7% (12/210) B: 4.3% (9/212) RR, 1.35 (CI, 0.58 to 3.13)
MacIntyre et al, 2011 (39)	A. N95 mask, fit tested (n = 461) B. N95 mask, not fit tested (n = 488) C. Surgical mask (n = 492)	A: 4.6% (21/461) B: 3.3% (16/488) A or B: 3.9% (37/949) C: 6.7% (33/492) OR, 0.38 (CI, 0.17 to 0.86) for A or B vs. C, adjusted for hospital, high-risk procedures, flu vaccine in 2008, and handwashing	A: 0.2% (1/461) B: 0.4% (2/488) C: 0.6% (3/492) OR, 0.58 (95% 0.10 to 3.47) for A or B vs. C, adjusted for hospital, high-risk procedures, flu vaccine in 2008, and handwashing	Viral respiratory illness A: 1.7% (8/461) B: 1.0% (5/488) C: 2.6% (13/492) OR, 0.19 (CI, 0.05 to 0.67) for A or B vs. C, adjusted for hospital, high-risk procedures, flu vaccine in 2008, and handwashing Influenza A: 0.7% (3/461) B: 0.5% (0/488) C: 1.0% (5/492) OR, 0.27 (CI, 0.06 to 1.17) for A or B vs. C, adjusted for hospital, high-risk procedures, flu vaccine in 2008, and handwashing
MacIntyre et al, 2013 (40)	A. N95 mask (n = 581) B. N95 mask (n = 516) C. Surgical mask (n = 572)	A: 7.2% (42/581) B: 11.8% (61/516) A or B: 9.4% (103/1097) C: 17.1% (98/572) HR, 0.39 (0.21 to 0.71) for A vs. C, 0.70 (CI, 0.39 to 1.24) for B vs. C, adjusted for age, vaccination, handwashing, and being a doctor	A: 1.0% (6/581) B: 0.4% (2/516) C: 0.7% (4/572) P = 0.54 for A vs. C, 0.49 for B vs. C	Viral respiratory illness A: 2.2% (13/581) B: 3.3% (17/516) C: 3.3% (19/572) P = 0.44 for A vs. C, 0.99 for B vs. C Influenza A: 0.5% (3/581) B: 0.4% (2/516) C: 0.2% (1/572) P = 0.35 for A vs. C, 0.52 for B vs. C

Continued on following page

Table 2—Continued

Study, Year (Reference)	Interventions*	Clinical Respiratory Illness	Influenza-like Illness	Laboratory-Confirmed Infection
MacIntyre et al, 2015 (38)	A: Surgical mask (<i>n</i> = 580) B: Cloth mask (<i>n</i> = 569) C: Standard practice (<i>n</i> = 458)	A: 4.83% (28/580) B: 7.56% (43/569) C: 6.99% (32/458) RR, 1.57 (CI, 0.99 to 2.48) for B vs. A RR, 1.56 (CI, 0.97 to 2.48) adjusted for sex, vaccination, handwashing, and compliance RR, 1.45 (CI, 0.88 to 2.37) for C vs. A RR, 1.51 (CI, 0.90 to 2.52) adjusted as above Post hoc analysis of HCWs who exclusively used a cloth (<i>n</i> = 607) or surgical mask (<i>n</i> = 705) irrespective of randomization group: Surgical mask: 4.67% (35/750) Cloth mask: 7.58% (46/607) RR, 1.51 (CI, 0.97 to 2.32) for cloth versus surgical mask adjusted for sex, vaccination, hand washing, and compliance	A: 0.17% (1/580) B: 2.28% (13/569) C: 0.66% (3/458) RR, 13.25 (CI, 1.74 to 100.97) for B vs. A RR, 13.00 (CI, 1.69 to 100.07) adjusted for sex, vaccination, handwashing, and compliance RR, 3.80 (CI, 0.40 to 36.40) for C vs. A RR, 4.64 (CI, 0.47 to 45.97) adjusted as above Post hoc analysis of HCWs who exclusively used a cloth (<i>n</i> = 607) or surgical mask (<i>n</i> = 705) irrespective of randomization group: Surgical mask: 0.27% (2/750) Cloth mask: 2.14% (13/607) RR, 6.64 (1.45 to 28.65) for cloth versus surgical mask adjusted for sex, vaccination, hand washing, and compliance	Viral respiratory illness A: 3.28% (19/580) B: 5.45% (31/569) C: 3.94% (18/458) RR, 1.66 (CI, 0.95 to 2.91) for B vs. A RR, 1.54 (CI, 0.88 to 2.70) adjusted for sex, vaccination, handwashing, and compliance RR, 1.20 (CI, 0.64 to 2.26) for C vs. A RR, 1.09 (CI, 0.57 to 2.09) adjusted as above Post hoc analysis of HCWs who exclusively used a cloth (<i>n</i> = 607) or surgical mask (<i>n</i> = 705) irrespective of randomization group: Surgical mask: 2.93% (22/750) Cloth mask: 5.60% (34/607) RR, 1.51 (CI, 0.97 to 2.32) for cloth vs. surgical mask adjusted for sex, vaccination, hand washing, and compliance
Radonovich et al, 2019 (46)	A: N95 respirator (<i>n</i> = 2512 HCW seasons) B: Surgical mask (<i>n</i> = 2668 HCW seasons)	Events per HCW seasons A: 1556/2512 (619.4/1000) B: 1711/2668 (641.3/1000) Adjusted IRR, 0.99 (CI, 0.92 to 1.06); per protocol analysis IRR, 1.00 (CI, 0.93 to 1.08)	Events per HCW seasons A: 128/2512 (51.0/1000) B: 166/2668 (62.2/1000) Adjusted IRR, 0.86 (CI, 0.68 to 1.10); per protocol analysis IRR, 0.83 (CI, 0.64 to 1.06)	Events per HCW seasons Laboratory-detected respiratory infection A: 679/2512 (270.3/1000) B: 745/2668 (279.2/1000) Adjusted IRR, 0.99 (CI, 0.89 to 1.09) Respiratory illness A: 371/2512 (147.7/1000) B: 417/2668 (156.3/1000) Adjusted IRR, 0.96 (CI, 0.83 to 1.11) Influenza A: 207/2512 (82.4/1000) B: 193/2668 (72.3/1000) Adjusted IRR, 1.18 (CI, 0.95 to 1.45) Adjusted IRR, per protocol analysis, 1.20 (CI, 0.97 to 1.48)

HCW = health care worker; HR = hazard ratio; IRR = incidence rate ratio; OR, = odds ratio; RR = relative risk.

* Descriptions of interventions appear in Supplement Table 3 (available at [Annals.org](https://annals.org)).

not report cluster-adjusted risk estimate for the P2 versus the surgical mask, but the calculated (crude) unadjusted estimate was not statistically significant. Adherence to mask use was low, potentially reducing effectiveness (Supplement Table 9, available at [Annals.org](https://annals.org)). In a multivariate analysis, adherence to either mask was associated with decreased risk for influenza-like illness (hazard ratio, 0.26 to 0.32).

Eight trials (6510 participants), including the trial described above, evaluated use of surgical masks

within households with an influenza or influenza-like illness index case (child or adult) (24, 28–30, 37, 41, 48, 49). Compared with no masks, surgical masks were not associated with decreased risk for clinical respiratory illness, influenza-like illness, or laboratory-confirmed viral illness in household contacts when masks were worn by household contacts (30, 37, 48), index cases (24, 41), or both (28, 29, 49). However, some estimates were imprecise, mask-wearing adherence was limited (Supplement Table 9/e), and some crossover oc-

curred. Two trials found no differences between surgical masks plus handwashing versus handwashing alone in risk for infections in household contacts of index cases (30, 48).

Two trials (2475 participants) of students living in university residence halls without specific contacts with cases also found no significant differences between a surgical mask versus no mask and risk for influenza-like illness (19, 20). Two trials (7851 participants) found that surgical masks, compared with no masks, were not associated with decreased risk for infections in Hajj pilgrims with or without an infected index case within the same tent (21, 23).

Health care settings. Six RCTs (9411 participants) evaluated mask use among HCWs in health care settings (Table 2 and Supplement Table 3) (27, 34, 38–40, 46). One was a pilot trial that reported adherence and harms but not effects on risk for infections (27). Of the other 5 trials, 4 compared an N95 respirator versus surgical mask (38–40, 46) and 1 (38) compared a surgical versus cloth mask (Table 2). Masks were generally used in addition to handwashing, though details on use of personal protective equipment (for example, eye protection, gowns, and gloves) were limited.

Three RCTs (3532 participants) compared N95 respirators versus surgical masks in higher-risk settings (such as emergency departments, respiratory wards, pediatric wards, and intensive care units) (34, 39, 40). One trial (422 participants) found both N95 respirators and surgical mask to be associated with a very similar likelihood of a physician visit for acute respiratory illness (6.2% vs. 6.1%) (34). Two trials (3110 participants) found an N95 respirator to be associated with decreased risk for clinical respiratory illness, with absolute differences that ranged from -2.8% to -7.7% (39, 40).

In all 3 trials, there were few cases of influenza-like illness, resulting in imprecise estimates (34, 39, 40). For laboratory-confirmed viral respiratory infections, 1 trial (34) that did not require HCWs to have symptoms found no difference between an N95 respirator and a surgical mask in infection risk. In the other 2 trials, only symptomatic laboratory-confirmed viral respiratory infections were diagnosed; the number of cases was small, and estimates were imprecise. One trial reported no difference in the subgroup of laboratory-confirmed (not necessarily symptomatic) viral infections by nonpandemic coronaviruses but was underpowered for this outcome, with a total of 21 cases (34). The other 2 trials did not report nonpandemic coronavirus infections.

Two trials described above included 2 N95 respirator arms (39, 40). One trial found that the effects of an N95 respirator versus surgical mask on clinical respiratory illness were similar for fit-tested and non-fit-tested N95 respirators (4.6% vs. 3.3%) (39). The other trial found continuous use (at all times while working) of an N95 respirator to be associated with a small decrease in clinical respiratory illness risk versus intermittent use (only during high-risk procedures or barrier situations) of an N95 respirator (7.2% vs. 11.8%) (40).

One trial (1868 participants) of HCWs in higher-risk settings found a surgical mask to be associated with

decreased risk for clinical respiratory illness, influenza-like illness, and laboratory-confirmed viral infections versus cloth masks, but estimates were imprecise and not statistically significant (38).

One trial of HCWs (2862 participants) in lower-risk outpatient settings found no differences between an N95 respirator and a surgical mask in risk for clinical respiratory illness, influenza-like illness, laboratory-confirmed viral illness, or laboratory-confirmed influenza (46).

Harms

Reporting of harms in the RCTs was suboptimal but did not indicate serious harms with mask use (Supplement Table 9). When reported, the most common adverse events were discomfort, breathing difficulties, and skin events. One trial found use of an N95 respirator to be associated with increased risk for headache and breathing difficulty compared with a surgical mask in HCWs (39), but 1 trial found no difference between a P2 mask (N95 respirator equivalent) versus surgical mask in adverse events in persons in the community (37). One trial reported no differences in harms between a surgical versus cloth mask in HCWs (38).

DISCUSSION

This rapid, living review summarizes the evidence on the comparative effectiveness and effectiveness for preventing coronavirus and other respiratory infections. Figure 2 is an evidence map summarizing the strength of evidence for key comparisons by setting and infection type (Supplement Table 10, available at Annals.org). The map shows that direct evidence on the comparative effectiveness of masks for preventing COVID-19 due to SARS-CoV-2 infection is lacking. Therefore, it was necessary to also consider evidence for other respiratory infections, though the applicability to COVID-19 is uncertain. In addition, the strength of evidence varied from moderate to insufficient; no comparison was graded high strength of evidence.

In community settings, one RCT found no difference between N95 or equivalent respirators versus surgical masks in risk for noncoronavirus respiratory illness (37). The RCTs in community settings, typically conducted during influenza seasons, also did not indicate effectiveness of mask use versus no mask use for reducing viral respiratory infection risk, though mask compliance was suboptimal. Observational data on mask use effectiveness in community settings for preventing infections associated with epidemic coronaviruses were limited but suggest possible reduced risk for SARS-1. The difference in findings could be related to higher mask compliance in pandemic outbreak settings, greater effectiveness of masks for SARS-1, or residual confounding.

In HCWs, observational studies suggest that N95 masks might be associated with decreased risk for SARS-CoV-1 infection compared with surgical masks, and mask use in general appears to be associated with decreased risk for SARS-CoV-1 infection. All studies were conducted in high- or moderate-risk settings, with

uncertain applicability to low-risk settings (those without direct care of infected patients). Review of RCTs indicates that N95 respirators and surgical masks are probably associated with similar risk for influenza-like illness and laboratory-confirmed viral infections in high- and low-risk settings. However, there was some inconsistency in effects of N95 respirators versus surgical masks on clinical respiratory infections in high-risk settings, with 1 trial (34) showing no difference in physician visits for respiratory illness and 2 trials (39, 40) showing N95 respirators to be associated with a small decrease in risk. The only trial comparing N95 respirators versus surgical masks in a low-risk (primary care) setting found no difference in risk for clinical respiratory illness (46). There was no evidence to address effects of extended or reuse of N95 respirators on infection risk; evidence on nonclinical outcomes (for example, measures of filtration, contamination, and mask failure) is summarized elsewhere (5).

Our findings are generally consistent with those of recent systematic reviews on mask use in community and health care settings that found N95 respirators and surgical masks to be associated with similar risk for in-

fluenza and influenza-like illness (58–62). It differs from prior reviews by considering both randomized trials and observational studies, evaluating mask use in community and health care settings, considering harms, comparing effects of consistent versus less consistent mask use, and including a more comprehensive set of relevant studies. We also implemented living review processes in order to incorporate new evidence on an ongoing basis. There was some overlap between this review and our living review on risk factors (including various types of personal protective equipment) for coronavirus infections in HCWs (12). This review differed from our prior review by including studies conducted in community settings, focusing on mask use, and including effects on noncoronavirus viral respiratory infections.

The evidence base has important limitations. As noted, the evidence on mask use and risk for SARS-CoV-2 infection is very sparse. In randomized trials, adherence to mask use was suboptimal, potentially reducing estimates of effectiveness compared with use during pandemic outbreaks, when adherence may be higher. Observational studies were retrospective, sus-

Figure 2. Masks for prevention of respiratory virus infection: evidence map.

Comparison (Intervention A vs. Intervention B)	SARS-CoV-2 Infection*	SARS-CoV-1 or MERS-CoV Infection*	Influenza, ILI, and Other VRI (Excluding Pandemic Coronaviruses)†
Community setting			
Mask (type not specified) vs. no mask (k = 3 observational studies) (31, 51, 54)	-	◆	-
N95‡ vs. surgical mask in household contacts (k = 1 RCT) (37)	-	-	◆
N95‡ vs. no mask in household contacts (k = 1 RCT) (37)	-	-	◆
Surgical mask vs. no mask in households with an index case and other community settings (k = 12 RCTs) (19–21, 23, 24, 28–30, 37, 41, 48, 49)	-	-	●
Health care setting—moderate or higher risk (inpatient)			
Any mask vs. no mask (k = 12 observational studies) (33, 35, 36, 42–45, 47, 50, 53, 55, 57)	-	●	-
N95 vs. no mask (k = 5 observational studies) (33, 45, 47, 50, 52)	■	◆	-
Surgical mask vs. no mask (k = 6 observational studies) (33, 35, 42, 45, 47, 55)	-	■	-
N95 or surgical mask vs. no mask (k = 1 observational study)	-	■	-
Mask (type not specified) vs. no mask (k = 5 observational studies) (36, 43, 47, 53, 55)	-	◆	-
Cloth mask vs. no mask (k = 3 observational studies) (33, 44, 55)	-	■	-
Consistent/always mask use vs. inconsistent mask use (k = 5 observational studies) (22, 32, 35, 43, 56)	■	◆	-
N95 vs. surgical mask (k = 3 RCTs and 5 observational studies) (25, 33–35, 39, 40, 45, 57)	-	◆	●
N95 or surgical mask vs. cloth mask (k = 3 observational studies) (33, 36, 55)	-	■	-
Surgical mask vs. cloth mask (k = 1 RCT) (38)	-	-	◆
Health care setting—lower risk (outpatient)			
N95 vs. surgical mask (k = 1 RCT) (46)	-	-	●

Strength of Evidence
 ● Moderate
 ◆ Low
 ■ Insufficient
 - No evidence

Direction of Effect
 ■ Favors intervention A
 ◆ Effects similar or no difference
 □ No evidence or unable to determine

ILI = influenza-like illness; RCT = randomized controlled trial; VRI = viral respiratory illness; MERS-CoV = Middle East respiratory syndrome coronavirus; SARS-CoV = severe acute respiratory syndrome coronavirus.

* Only observational evidence was included for these infections.

† Only RCT evidence was included for these infections.

‡ N95 respirator or equivalent (for example, P2 mask).

ceptible to recall bias and confounding, and did not address correlations between mask use and other infection prevention and control measures. Applicability of evidence on masks and risk for SARS-CoV-1, MERS-CoV, and other viral respiratory illness to SARS-CoV-2 is uncertain. The applicability of evidence on influenza and influenza-like illnesses to SARS-CoV-2 could be reduced owing to differential transmission dynamics, lower mask adherence, or limited use of other personal protective equipment (63).

The review process had limitations. In particular, we used streamlined rapid review methods for searching and selecting studies. We did not perform critical appraisal of observational studies by using a formal instrument, though key methodological limitations were highlighted. We included 1 non-peer-reviewed study (21), which could reduce data quality. Meta-analysis was not attempted owing to study limitations and heterogeneity in study designs, comparisons, and analyses.

Research is urgently needed to clarify the comparative effectiveness of masks for transmission of COVID-19 in community and health care settings; randomized trials are in progress (64, 65). Observational studies that prospectively measure mask use, other infection prevention and control measures (accounting for potential correlations), and exposures could supplement randomized trials. Given limitations in the supply of N95 respirators, understanding the effects of reuse or extended use of N95 respirators is a priority (66).

In conclusion, evidence on the effectiveness of masks for prevention of respiratory infection is stronger in health care than community settings. Use of N95 respirators might reduce SARS-CoV-1 risk versus surgical masks in health care settings, but applicability to SARS-CoV-2 is uncertain.

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