

Masks for Prevention of COVID-19 in Community and Healthcare Settings



Background and Purpose

Currently, no proven treatments are available for coronavirus disease 2019 (COVID-19), the disease caused by infection with the novel (new) coronavirus SARS-CoV-2. Therefore, clinicians and policymakers advise preventive measures. This rapid review addresses the comparative effectiveness of various types of facemasks in the community and in healthcare workers (HCWs) for prevention of infection with SARS-CoV-2 and the effectiveness and safety of mask reuse. Given this rapidly emerging field and the urgent need for answers, the AHRQ Evidence-based Practice Center (EPC) Program will update this report as new evidence becomes available. Comments and any unpublished data should be sent to epc@ahrq.hhs.gov and appropriate changes will be made in the next version.

Several types of respirators and facemasks (collectively referred to in this report as facemasks) are available for potentially preventing infection with SARS-CoV-2. Disposable N95 filtering facepiece (and equivalent) respirators are devices designed to achieve a very close facial fit and very efficient filtration of airborne particles (blocking at least 95% of very small [0.3 micron] particles). Surgical/medical masks (referred to in this report as surgical masks) are loose-fitting, disposable devices designed to create a physical barrier between the wearer's mouth and nose and the immediate environment, blocking larger particles and splashes or spatters. Cloth masks are non-medical, unstandardized face coverings that vary in the cloth material used, the number of layers, and the tightness of fit. They are generally meant to be washable and reusable. Other respiratory protective devices, such as reusable N95 elastomeric respirators and powered air-purifying respirators are not addressed in this report (the term N95 respirator in this report refers to disposable N95 filtering facepiece respirators).



Recommendations from the World Health Organization and the Centers for Disease Control and Prevention (CDC) on use of facemasks by HCWs have differed with regard to when an N95 respirator or equivalent should be used. The CDC has encouraged the use of cloth masks in the community to prevent asymptomatic spread of COVID-19.¹ Although single-use N95 and similar respirators are considered to provide superior respiratory protection for HCWs compared with surgical masks,² shortages have been reported in the United States and elsewhere.³ Reuse of N95 and equivalent respirators has been tested in laboratory settings,⁴ but clinical effectiveness and safety of mask reuse in practice is unknown.^{4,5}

Key Questions

The Key Questions used to guide this rapid review were developed with input from staff at the American College of Physicians and the Agency for Healthcare Research and Quality.

1. What is the effectiveness of respirators (e.g., N95) versus facemasks (surgical) versus cloth masks for prevention of COVID-19 in addition to standard precautions (gowns + gloves + handwashing)?
 - a. In community settings
 - b. In healthcare settings
 1. In high-risk healthcare settings (e.g., intensive care unit, emergency room)
 2. In healthcare settings with close contact but unknown risk (e.g., primary care, other settings)
2. What is the evidence for extended or reuse of N95 respirators for prevention of COVID-19?



Evidence Summary

Benefits

Community settings

- Possibly no difference between an N95 respirator or equivalent versus surgical mask in risk of non-coronavirus respiratory infections, but estimates were imprecise and compliance with mask use was low.
- Probably no difference between surgical mask versus no mask in risk of non-coronavirus respiratory infections, but compliance with mask use was low.
- Mask use (type not specified) is possibly associated with decreased risk of SARS-CoV-1 infection versus no use.

Healthcare settings

- N95 respirators and surgical masks are probably associated with similar risk of influenzalike illness and laboratory-confirmed viral infections in higher- or lower-risk settings, though there was some inconsistency in effects on clinical respiratory illness.
- N95 respirators are possibly associated with decreased risk of SARS-CoV-1 infection versus surgical masks.
- Mask use is probably associated with decreased risk of SARS-CoV-1 and MERS-CoV infection versus no use.
- More consistent mask use is possibly associated with decreased risk of SARS-CoV-1 and MERS-CoV infection versus less consistent use.

Extended or reuse of N95 respirators

- No evidence.

Harms

- No serious harms reported with N95 respirators and surgical masks in randomized controlled trials.
- Discomfort, breathing difficulty, and skin issues common with N95 respirators and masks.
- Limited evidence of no difference in harms by mask type.

Ongoing Research and Future Research Needs

- Randomized trials on the comparative effectiveness of masks for preventing COVID-19 in community and healthcare settings are needed.
- Studies on the effects of extended or reuse of N95 respirators are needed.
- Prospective observational studies on mask use and risk of COVID-19 in healthcare and community settings, including studies that compare risks associated with different mask types, would complement information from randomized trials.
- Ongoing studies include a randomized controlled trial of N95 respirators versus surgical masks in healthcare workers (estimated completion December 2020), a prospective longitudinal study on healthcare workers and risk of COVID-19 (estimated completion September 2020), and a randomized trial on surgical masks versus no mask in the community and risk of COVID-19 (estimated completion July 2020).

Methods

Detailed methods are available in **Appendix A**.

A medical librarian searched PubMed MEDLINE[®] and Elsevier Embase[®] (from 2003 through April 14, 2020) (Appendix A). Surveillance for new studies was conducted through May 6, 2020. The World Health Organization Global Literature on Coronavirus Disease database,⁶ and the medRxiv preprint server⁷ also were searched. Reference lists of systematic reviews and included studies were reviewed for additional studies.

Because evidence on facemasks and SARS-CoV-2 infection is currently limited, this report also includes evidence about the use of facemasks and effects on risk of other respiratory infections, including other coronaviruses involved in epidemic respiratory illness outbreaks (SARS-CoV-1, the cause of severe acute respiratory syndrome-1 [SARS-1] and MERS-CoV, the cause of Middle East Respiratory Syndrome [MERS]), influenza and influenzalike illness, and other viral respiratory illness.

Evidence Base

Searches identified 1,286 citations and 10 additional citations were identified through other sources; of the total screened (1,296), 38 studies were relevant.⁸⁻⁴⁵ For Key Question (KQ) 1, there were 18 randomized controlled trials (RCTs) (Appendix Table B-1) and 20 observational studies (Appendix tables B-2 and B-3). Twelve RCTs^{8-10,12,13,17,18,20,27,31,38,39} and three observational studies^{21,41,44} were conducted in the community, and six RCTs^{16,24,28-30,36} and 17 observational studies^{11,14,15,19,22,23,25,26,32-35,37,40,42,43,45} were conducted in HCWs. None of the RCTs addressed effects of masks on risk of infection with SARS-CoV-2, SARS-CoV-1, or MERS-CoV. Rather, the RCTs usually were conducted during influenza season and evaluated the risk of nonspecific clinical respiratory illness, influenzalike illness, and laboratory-confirmed viral respiratory illness. Of the observational studies, two cohort studies addressed SARS-CoV-2,^{19,42} 17 studies addressed SARS-CoV-1 (5 cohort studies^{14,25,33,35,43} and 12 case-control studies^{15,21-23,26,32,34,37,40,41,44,45}), and one cohort study addressed MERS-CoV.¹¹ Two Chinese-language studies were translated into English by a native Chinese speaker at the EPC.^{26,45} Figure 1 summarizes the study selection process. A list of included studies is provided in Appendix C.

Two RCTs^{16,24} 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 7,687. The RCTs were conducted during influenza season, with the exception of two RCTs conducted among pilgrims staying in tents during Hajj.^{10,12} Two RCTs^{24,27} reported the incidence of laboratory-confirmed nonpandemic coronavirus infections, but there was only one case in one trial.²⁷ Four trials were conducted in the United States, one in Canada, one in Australia, two in Europe, two in Saudi Arabia and eight in Asia. Eleven RCTs were rated good quality and seven were rated fair quality (Appendix D). Limitations in the fair quality trials included baseline differences between groups and high attrition; one cluster RCT¹² did not adjust for cluster

correlation. Blinding of participants to the mask and other interventions (e.g., hand hygiene) was not possible.

The observational studies had important limitations (Appendix tables B-2 and B-3). All were retrospective and potentially susceptible to recall bias for determining mask use and other exposures. The studies were generally limited in their ability to measure and control for the amount and intensity of exposures. Six studies did not attempt to control for potential confounders. Of the 14 studies that did control for confounders, only one²³ evaluated correlations between masks and other infection control measures (e.g., gloves, gowns, goggles, or handwashing) to inform selection of variables for model building. In the other studies that reported results from multivariate models, correlations between infection control measures and potential collinearity were not addressed.

KQ 1. What is the effectiveness of respirators (e.g., N95) versus facemasks (surgical) versus cloth masks for prevention of COVID-19 in addition to standard precautions (gowns + gloves + handwashing)?

Community Settings

Twelve RCTs evaluated masks in community settings (Appendix Table B-1).^{8-10,12,13,17,18,20,27,31,38,39} The settings were households, university residence halls, and tents used by pilgrims during Hajj. Masks were used by index cases, household contacts of index cases, cases and contacts, or people without specific contact with cases. Participants in the trials generally received education on preventing respiratory infection and hand hygiene regardless of whether they were randomized to masks or another intervention. All of the trials compared a mask versus no mask. One trial also compared a mask versus a mask plus handwashing training.³⁸ In addition, three trials compared a mask versus hand hygiene^{17,18,20} and two trials compared a mask plus hand sanitizer versus hand sanitizer alone;^{8,9,39} these comparisons were beyond the scope of this report and are not discussed further, though data are shown in Appendix Table B-1.

Only one RCT directly compared different mask types.²⁷ It evaluated a P2 mask (Australian equivalent to an N95) versus a surgical mask in adult household contacts of children with influenzalike illness. There were no differences between either mask type versus a no-mask control in infection outcomes, though estimates were imprecise. The RCT did not report a cluster-adjusted risk estimate for the P2 versus the surgical mask, but the calculated (crude) unadjusted estimate was not statistically significant. Adherence to masks was poor in the trial, which could have reduced effectiveness. In a multivariate analysis, adherence to either mask was associated with decreased risk of influenzalike illness (hazard ratio 0.26 to 0.32).

Seven other trials, in addition to the trial described above, evaluated use of surgical masks within households with an influenza or influenzalike illness index case (child or adult).^{13,17,18,20,31,38,39} Compared with no masks, surgical masks were not associated with decreased risk of clinical respiratory illness, influenzalike illness, or laboratory-confirmed viral illness in household contacts when masks were worn by household contacts,^{20,27,38} index cases,^{13,31} or both.^{17,18,39} However, some estimates were imprecise, adherence to mask-wearing was limited, and some crossover occurred. Two trials found no differences between surgical

masks plus handwashing versus handwashing alone in risk of infections in household contacts of index cases.^{20,38}

Two trials 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 of influenzalike illness.^{8,9} Surgical masks, compared with no masks, were not associated with decreased risk of infections in Hajj pilgrims with or without an infected index case within the same tent.^{10,12}

Three observational studies evaluated effects of masks on risk of SARS-1 in community settings (Appendix Table B-2).^{21,41,44} None of the studies compared one mask type to another. In addition, the studies did not provide details regarding mask type. Wearing a mask was associated with decreased risk of infection in persons without known contacts with SARS-1 patients in one study⁴⁴ and in household contacts of persons with SARS-1 in two studies.^{21,41}

Healthcare Settings

Six RCTs evaluated masks in HCWs in healthcare settings (Appendix Table B-1).^{16,24,28-30,36} One was a pilot trial that reported adherence and harms but not effects on risk of HCW infections.¹⁶ Of the other five trials, four compared an N95 versus surgical mask and one²⁸ compared a surgical versus cloth mask. In the trials, masks were generally used in addition to other personal protective equipment (PPE) items and handwashing, though details regarding other infection control measures were limited.

Three RCTs compared N95 respirators versus surgical mask in higher-risk settings (e.g., emergency department, respiratory wards, pediatric wards, intensive care units).^{24,29,30} One trial found an N95 and surgical mask were both associated with very similar likelihood of a physician visit for acute respiratory illness (6.2% vs. 6.1%).²⁴ Two trials found an N95 associated with decreased risk of clinical respiratory illness, with absolute differences that ranged from -2.8% to -7.7%.^{29,30}

In all three trials, there were few cases of influenzalike illness, resulting in imprecise estimates. For laboratory-confirmed viral respiratory infections, one trial²⁴ that did not require HCWs to have symptoms found no difference between an N95 versus surgical mask in risk of infections. In the other two trials, laboratory-confirmed viral respiratory illness was only diagnosed in symptomatic patients; 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, based on a total of 21 cases.²⁴ The other two trials did not report nonpandemic coronavirus infections.

Two of the trials described above included two N95 respirator arms. One of the trials found that effects of an N95 versus surgical mask on clinical respiratory illness were similar for fit-tested and non-fit-tested N95s (4.6% vs. 3.3%).²⁹ The other trial found that continuous N95 use (at all times while working) was associated with a small decrease in risk of clinical respiratory illness versus intermittent (only during high-risk procedures or barrier situations) N95 use (7.2% vs. 11.8%).³⁰

One other trial of HCWs in higher-risk settings found a surgical mask associated with decreased risk of clinical respiratory illness, influenzalike illness, and laboratory-confirmed viral infections when compared with cloth masks, but estimates were imprecise and not statistically significant.²⁸

One trial of HCWs in lower-risk outpatient settings found no differences between an N95 versus surgical mask in risk of clinical respiratory illness, influenzalike illness, laboratory-confirmed viral illness, or laboratory-confirmed influenza.³⁶

Seventeen observational studies evaluated the association between mask use by HCWs or directness of contact and risk of infection with SARS-CoV-2, SARS-CoV-1, or MERS-CoV.^{11,14,15,19,22,23,25,26,32-35,37,40,42,43,45} Two studies evaluated effects of masks on risk of infection with SARS-CoV-2, 14 studies evaluated effects of masks on risk of infection with SARS-CoV-1, and one study evaluated masks' effects on risk of infections with MERS-CoV (Appendix Table B-3).

Two cohort studies evaluated the association between mask use and risk of SARS-CoV-2 infections but had important limitations. One study found N95 respirators associated with decreased risk of infection versus no mask,⁴² but mask use was based on the department that the HCW worked in, not on individual use of masks.⁴² In addition, confounding was likely because departments in which N95s were used also differed from the non-N95 departments in use of handwashing and other infection control measures. There were also few cases and serious imprecision. The other study was small (n=37) and only reported three cases of SARS-CoV-2 infection in HCWs, resulting in very imprecise estimates regarding the association with mask use.¹⁹

Four observational studies consistently found an N95 respirator associated with decreased risk of SARS-CoV-1 infection versus a surgical mask (sometimes described as a “disposable” mask) in HCWs.^{14,23,25,35} Results of three comparisons involving an N95 or surgical versus cloth mask and risk of SARS-CoV-1 infection were somewhat inconsistent.^{23,26,45} In addition, the applicability of the cloth masks evaluated in these studies to other settings may be limited, as they were described as 12- or 16-layer masks, or many more layers than typically found in cloth masks in the United States and other countries.

Eleven observational studies consistently found mask use associated with decreased risk of SARS-CoV-1 infection versus no use,^{23,25,26,32-35,37,40,43,45} of these, six specifically evaluated N95 or surgical masks.^{23,25,35,37,40,45} Masks were usually associated with decreased risk of SARS-CoV-1 infection in multivariate models, but in some cases masks were not included as variables in the models. However, correlations between mask use and other infection control measures could have impacted variable selection for model building, but were not described.

Four studies found more consistent use of masks associated with decreased risk of SARS-CoV-1 or MERS-CoV infection versus less consistent use;^{11,22,25,33} of these, three specifically evaluated N95 or surgical masks. In one of the studies, consistent use of N95 or surgical masks was associated with decreased risk of infections in HCWs with direct contact with SARS-1 patients or direct patient contact in general, as well as in HCWs without direct patient contact.²²

Harms

Reporting of harms in the RCTs was suboptimal, but did not indicate serious harms associated with use of masks (Appendix Table B-1). When reported, the most common adverse events were discomfort, breathing difficulties, and skin events. One trial found an N95 respirator associated with increased risk of headache and breathing difficulty compared with a surgical mask in HCWs,²⁹ but one trial found no difference between a P2 (N95 equivalent) respirator versus surgical mask in adverse events in persons in the community.²⁷ One trial reported no differences in harms between a surgical versus cloth mask in HCWs.²⁸

Key Question 2. What is the evidence for extended or reuse of N95 respirators for prevention of COVID-19?

No study evaluated effects of extended or reuse of N95 respirators and risk of COVID-19.



Conclusions and Future Research

Direct evidence on the effectiveness and comparative effectiveness of masks for preventing COVID-19 due to SARS-CoV-2 infection is lacking. Therefore, it was necessary to also consider evidence on masks and risk of other respiratory infections. However, the applicability of such evidence to COVID-19 is uncertain.

In community settings, one RCT found no difference between N95 or equivalent respirators versus surgical masks for prevention of noncoronavirus respiratory illness. Evidence from RCTs in community settings typically conducted during influenza seasons did not indicate effectiveness of masks in general for reducing risk of viral respiratory infections in community settings, though mask compliance was suboptimal. Observational data on effectiveness of masks for preventing infections associated with epidemic coronaviruses were limited, but suggest masks in general might be associated with reduced risk of SARS-1. This could be related to higher mask compliance in the setting of pandemic outbreaks, greater effectiveness of masks for SARS-1, or residual confounding.

In HCWs, RCTs indicate that N95 and surgical masks are probably associated with similar risk of influenzalike illness and laboratory-confirmed viral infections in high- and low-risk settings. However, there was some inconsistency in effects of N95 versus surgical masks on clinical respiratory infections in high-risk settings, with one good quality trial showing no difference in physician visits for respiratory illness and two fair quality, cluster-randomized trials showing N95 masks associated with a small decrease in risk. The only trial comparing N95 versus surgical masks in a low-risk (primary care) setting found no difference in risk of clinical respiratory illness. Observational studies suggest that N95 masks might be associated with decreased risk of SARS-CoV-1 infections compared with surgical masks, and mask use in general is probably associated with decreased risk of SARS-CoV-1 infection. There was no evidence to address effects of extended or re-use of N95 respirators on risk of infection, though evidence on effects of extended or re-use for non-clinical outcomes (e.g., measures of filtration, contamination, and mask failure) has been summarized elsewhere.⁴ Table 1 summarizes the strength of evidence for key comparisons and outcomes.

Research is urgently needed to understand the effectiveness and comparative effectiveness of masks for preventing COVID-19 in community and healthcare settings and to understand the effects of extended use and reuse of N95 respirators. Ongoing studies (Appendix E) include an RCT comparing disposable N95 respirators versus surgical masks in HCWs (estimated completion December 2020),⁴⁶ a longitudinal study on risk factors for COVID-19 in HCWs (estimated completion September 2020),⁴⁷ and a randomized trial on surgical masks versus no mask in the community and risk of COVID-19 (estimated completion July 2020).⁴⁸ The World Health Organization also has published a protocol for a prospective study on risk factors for COVID-19 in HCWs.⁴⁹

Figure 1. Literature flow diagram

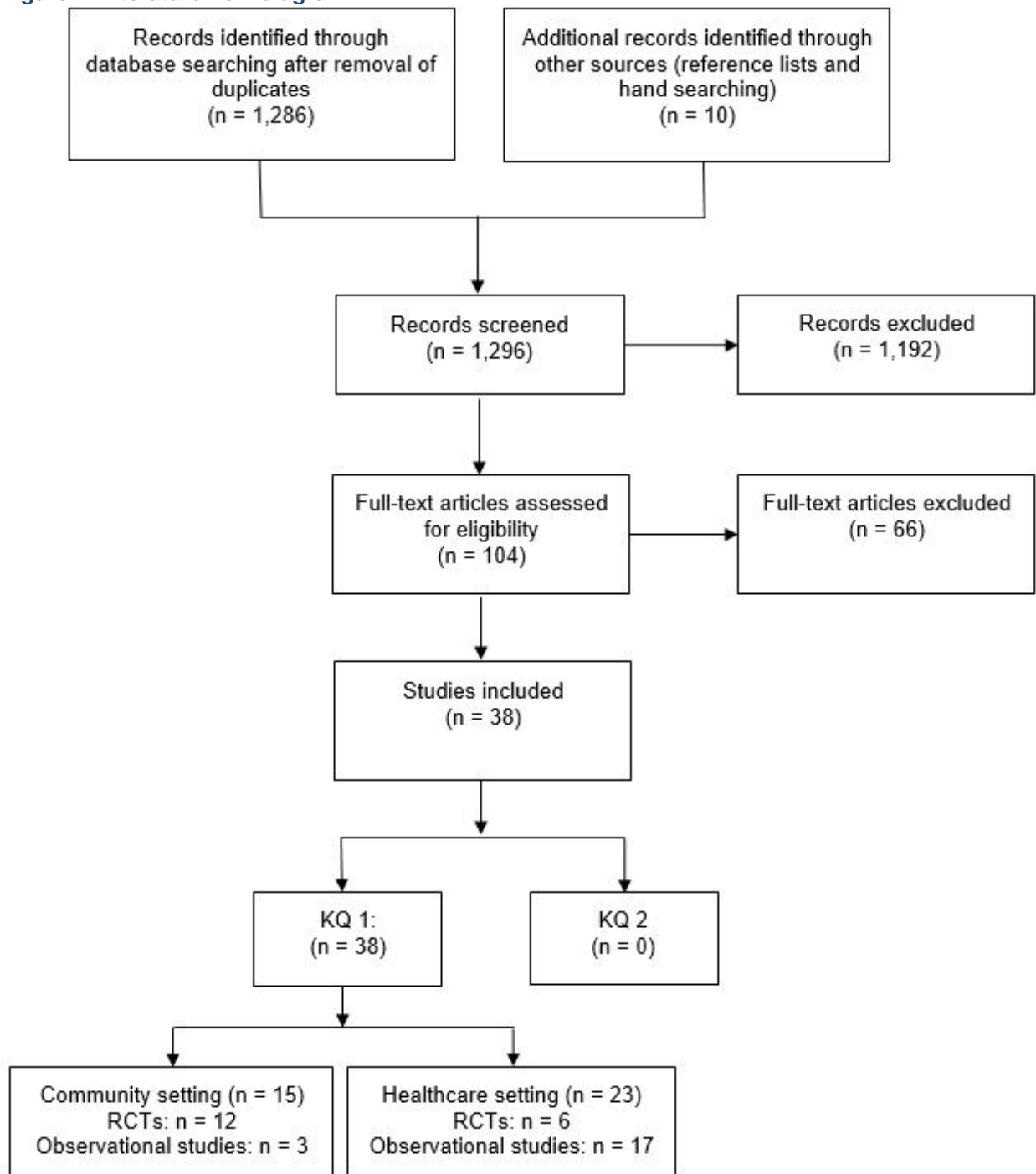


Table 1. Summary of evidence

Setting	Comparison	Outcome	Number and Type of Studies	Number of Subjects	Directness	Precision	Study Limitations	Consistency	Findings	Strength of Evidence
Community	N95 equivalent versus surgical mask	Influenzalike illness, laboratory-confirmed viral respiratory illness	1 RCT ²⁷	n=290	Direct	Imprecise	Low	Unable to assess	No difference	Low
Community	Surgical mask versus no mask	Clinical respiratory illness, influenzalike illness, laboratory-confirmed viral respiratory illness, or laboratory-confirmed influenza	12 RCTs ^{8-10,12,13,17,18,20,27,31,38,39}	n=16,836	Direct	Precise	Moderate	Inconsistent	No differences overall	Moderate
Community	Mask versus no mask	SARS-1 infection	3 observational studies (1 cohort ⁴¹ and 2 case-control ^{21,44})	Cohort: n=212 Case-control: n=225 cases, 2,420 controls	Direct	Precise	Moderate	Consistent	Masks associated with decreased risk of SARS-1	Low

Setting	Comparison	Outcome	Number and Type of Studies	Number of Subjects	Directness	Precision	Study Limitations	Consistency	Findings	Strength of Evidence
Healthcare	N95 versus surgical mask, higher risk settings	Clinical respiratory illness, influenzalike illness, laboratory-confirmed viral respiratory illness, or laboratory-confirmed influenza	3 RCTs ^{24,29,30}	n=3,532	Direct	Imprecise (for influenzalike illness, laboratory-confirmed viral respiratory illness, or laboratory-confirmed influenza)	Low	Inconsistent (for clinical respiratory illness)	No differences in risk for influenzalike illness, laboratory-confirmed viral respiratory illness, or laboratory-confirmed influenza; inconsistent results for clinical respiratory illness	Moderate
Healthcare	N95 versus surgical mask, lower risk settings	Clinical respiratory illness, influenzalike illness, laboratory-confirmed viral respiratory illness, or laboratory-confirmed influenza	1 RCT ³⁶	n=2,862	Direct	Precise	Low	Unable to assess	No difference in risk	Moderate
Healthcare	N95 versus surgical mask	SARS-CoV-1 infection	4 observational studies (3 cohort ^{14,25,35} and 1 case-control ²³)	Cohort: n=700 Case-control: n=51 cases, 426 controls	Direct	Precise	Moderate	Consistent	N95 associated with decreased risk	Low

Glossary

COVID-19: Coronavirus Disease 2019; the disease caused by the novel coronavirus SARS-CoV-2. In this report, the term COVID-19 is used when referring to patients with SARS-CoV-2 infection meeting the COVID-19 case definition.

MERS-CoV: The virus causing MERS. In this report, “MERS-CoV infection” is used when referring to infection with MERS-CoV that does not necessarily meet the case definition for MERS (e.g., laboratory diagnosis of MERS-CoV 1 infection but asymptomatic, mildly symptomatic, or symptom status not reported).

MERS: Middle East Respiratory Syndrome; the disease caused by the coronavirus MERS-CoV. In this report, the term MERS-CoV is used when referring to patients with MERS-CoV infection meeting the MERS case definition.

SARS-CoV-1: The virus causing SARS-1. In this report, “SARS-CoV-1 infection” is used when referring to infection with SARS-CoV-1 that does not necessarily meet the case definition for SARS-1 (e.g., laboratory diagnosis of SARS-CoV-1 infection but asymptomatic, mildly symptomatic, or symptom status not reported).

SARS-CoV-2: The virus causing COVID-19. In this report, “SARS-CoV-2 infection” is used when referring to infection with SARS-CoV-2 that does not necessarily meet the case definition for COVID-19 (e.g., laboratory diagnosis of SARS-CoV-2 infection but asymptomatic, mildly symptomatic, or symptom status not reported).

SARS-1: Severe Acute Respiratory Syndrome-1; the disease caused by the coronavirus SARS-CoV-1. In this report, the term SARS-1 is used when referring to patients with SARS-CoV-1 infection meeting the SARS-1 case definition.

Authors

Roger Chou, M.D., FACP
Tracy Dana, M.L.S.
Rebecca Jungbauer, Dr.P.H.
Chandler Weeks, M.P.H.
Marian S. McDonagh, Pharm.D.

Disclaimers

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The information in this report is intended to help health care decision makers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Afterword

Recognized for excellence in conducting comprehensive systematic reviews, the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center (EPC) program is developing a range of rapid evidence products to assist end-users in making specific decisions in a limited timeframe.

The AHRQ EPC Program recognizes that people are struggling with urgent questions on how to control the COVID-19 pandemic. To shorten timelines, reviewers make strategic choices about which review processes to abridge. However, the adaptations made for expediency may limit the certainty and generalizability of the findings from the review, particularly in areas with a large literature base. Transparent reporting of the methods used and the resulting limitations of the evidence synthesis are extremely important.

Given the rapidly evolving field, the AHRQ EPC Program will update these reviews on a regular basis to keep the medical community and public up to date as more studies are published through the summer of 2020. If you have comments or have unpublished data to share related to this report, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov and will be considered in the next version of the report.

Gopal Khanna, M.B.A.
Director
Agency for Healthcare Research and Quality

Arlene S. Bierman, M.D., M.S.
Director
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Stephanie Chang, M.D., M.P.H.
Director
Evidence-based Practice Center Program
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Jill S. Huppert, M.D., M.P.H.
Task Order Officer
Evidence-based Practice Center Program
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Christine S. Chang, M.D., M.P.H.
Associate Director
Evidence-based Practice Center Program
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality

Appendix A. Methods

Searches

We searched for systematic reviews and primary studies that address the research questions. Systematic reviews were used to identify relevant primary studies.

Search Strategies

Key Question 1

Randomized Controlled Trials

PubMed MEDLINE

((("Respiratory Protective Devices"[Mesh]) OR ("Masks"[Mesh])) OR (((("N95"[Title/Abstract] OR "N 95"[Title/Abstract] OR mask[Title/Abstract] OR masks[Title/Abstract]) OR ("N95"[Other Term] OR "N 95"[Other Term] OR mask[Other Term] OR masks[Other Term])) OR (facemask OR facemasks OR FFP)) OR (((airborne OR droplet* OR respirator OR respirators) AND (protect OR protection OR protective OR precaution)) NOT (mechanical[Title/Abstract]))) AND (prevent OR prevents OR prevention OR transmit OR transmission OR infect OR infection OR infected) Filters: Randomized Controlled Trial

Elsevier Embase

('respiratory protection'/exp OR 'air-purifying respirator'/exp OR 'face mask'/exp OR n95:ti,ab,kw OR mask:ti,ab,kw OR masks:ti,ab,kw OR facemask:ti,ab,kw OR facemasks:ti,ab,kw OR ffp:ti,ab,kw) AND (prevent OR prevents OR prevention OR transmit OR transmission OR infect OR infection OR infected) AND 'randomized controlled trial'/de AND [embase]/lim NOT ([embase]/lim AND [medline]/lim)

Observational Studies

((("Respiratory Protective Devices"[Mesh]) OR ("Masks"[Mesh])) OR (((("N95"[Title/Abstract] OR "N 95"[Title/Abstract] OR mask[Title/Abstract] OR masks[Title/Abstract]) OR ("N95"[Other Term] OR "N 95"[Other Term] OR mask[Other Term] OR masks[Other Term])) OR (facemask OR facemasks OR FFP)) OR (((airborne OR droplet* OR respirator OR respirators) AND (protect OR protection OR protective OR precaution)) NOT (mechanical[Title/Abstract]))) AND (prevent OR prevents OR prevention OR transmit OR transmission OR infect OR infection OR infected) AND (((("COVID-19" [Supplementary Concept]) OR ("SARS Virus"[Mesh]) OR ("Severe Acute Respiratory Syndrome"[Mesh]) OR ("Middle East Respiratory Syndrome Coronavirus"[Mesh]) OR ((coronavirus[Title/Abstract] OR COVID[Title/Abstract] OR "severe acute respiratory syndrome*" [Title/Abstract] OR SARS[Title/Abstract] OR "middle eastern respiratory syndrome" [Title/Abstract] OR MERS[Title/Abstract]) OR (coronavirus[Other Term] OR COVID[Other Term] OR "severe acute respiratory syndrome*" [Other Term] OR SARS[Other Term] OR "middle eastern respiratory syndrome" [Other Term] OR MERS[Other Term])))

Elsevier Embase

('respiratory protection'/exp OR 'air-purifying respirator'/exp OR 'face mask'/exp OR n95:ti,ab,kw OR mask:ti,ab,kw OR masks:ti,ab,kw OR facemask:ti,ab,kw OR facemasks:ti,ab,kw OR ffp:ti,ab,kw) AND (prevent OR prevents OR prevention OR transmit OR transmission OR infect OR infection OR infected) AND ('severe acute respiratory syndrome' OR 'sars-related coronavirus' OR 'middle east respiratory syndrome' OR 'sars' OR 'mers' OR 'covid') AND ('case control study'/de OR 'cohort analysis'/de OR 'comparative study'/de OR 'controlled study'/de OR 'cross sectional study'/de OR 'crossover procedure'/de OR 'observational study'/de OR 'prospective study'/de OR 'retrospective study'/de) AND [embase]/lim NOT ([embase]/lim AND [medline]/lim)

Key Question 2

PubMed MEDLINE

((("Respiratory Protective Devices"[Mesh]) OR ("Masks"[Mesh])) OR (((("N95"[Title/Abstract] OR "N 95"[Title/Abstract] OR mask[Title/Abstract] OR masks[Title/Abstract]) OR ("N95"[Other Term] OR "N 95"[Other Term] OR mask[Other Term] OR masks[Other Term])) OR (facemask OR facemasks OR FFP)) OR (((airborne OR droplet* OR respirator OR respirators) AND (protect OR protection OR protective OR precaution)) NOT (mechanical[Title/Abstract]))) AND (reuse OR "re use" OR "extended use" OR "multiuse" OR "multi use" OR "multiple use"))

Elsevier Embase

('respiratory protection'/exp OR 'air-purifying respirator'/exp OR 'face mask'/exp OR n95:ti,ab,kw OR mask:ti,ab,kw OR masks:ti,ab,kw OR facemask:ti,ab,kw OR facemasks:ti,ab,kw OR ffp:ti,ab,kw) AND (prevent OR prevents OR prevention OR transmit OR transmission OR infect OR infection OR infected) AND ('reuse' OR 're use' OR 'extended use' OR 'multiuse' OR 'multi use' OR 'multiple use') AND [embase]/lim NOT ([embase]/lim AND [medline]/lim)

Types of Studies Included

- Randomized controlled trials of one mask type versus another for prevention of COVID-19 (the disease caused by SARS-CoV-2 infection), SARS-1 (the disease caused by SARS-CoV-1 infection), and MERS (the disease caused by MERS-CoV infection). influenzalike illness, and laboratory-confirmed viral respiratory illness.
- Randomized controlled trials of masks versus no masks (to inform indirect comparisons) for prevention of COVID-19, SARS-1, MERS, influenzalike illness, and laboratory-confirmed viral respiratory illness.
- Cohort and case-control studies on effects of mask use and risk for prevention of COVID-19 (the disease caused by SARS-CoV-2 infection), SARS-1 (the disease caused by SARS-CoV-1 infection), and MERS (the disease caused by MERS-CoV infection).
- Randomized controlled trials, cohort studies, and case-control studies on re-use or extended use of masks versus standard use for prevention of COVID-19, SARS-1, or MERS.

PICOTS

Participants/population

- Include: Healthcare workers or community members at risk of contracting COVID-19 or other viral respiratory illnesses due to workplace or community-based exposure
- Exclude: Bacterial or other nonviral infection; nonrespiratory infection

Intervention/exposure

- Include: N95 respirators or equivalent, surgical/medical masks, and cloth masks.
- Exclude: Powered air-purifying respirators, reusable N95 elastomeric respirators, other types of personal protective equipment (PPE).

Comparator/control

- Include: One type of mask versus another type of mask; mask use versus nonuse; mask single use versus reuse
- Exclude: Other personal protective equipment

Context

- Include: Community or healthcare settings; mask use by healthcare workers (HCWs) or non-HCWs; all geographic areas; findings considered within social distancing and PPE/handwashing context
- Exclude: Masks for prevention of other epidemic viruses (e.g., Ebola) and bacterial infections (e.g., tuberculosis)

Primary outcome(s)

- Infection with SARS-CoV-2, SARS-CoV-1, or MERS-CoV
- Influenzalike illness, lab-confirmed viral infection, lab-confirmed influenza, and clinical respiratory illness
- Harms of mask usage

Data Extraction (Selection and Coding)

Title and abstract review was performed by one reviewer. A second reviewer verified exclusion decisions. Disagreements were resolved through discussion.

Data was extracted into Excel[®] spreadsheets. Data extracted includes author, year, country, study design, study dates, sample size, intervention or exposure characteristics, duration of intervention, population characteristics, and outcomes. Chinese-language studies that met inclusion criteria were translated by a Chinese-language speaker.

We calculated risk estimates if they were not reported and data were available. We reversed the direction of the comparisons if necessary for consistency across studies (e.g., so that all studies reported risk estimates as mask use versus nonuse, instead of some reporting as mask nonuse vs. use).

Quality Assessment

For randomized controlled trials, quality was assessed using criteria adapted from the U.S. Preventive Services Task Force (USPSTF).⁵⁰ Limitations of observational studies was assessed and summarized using criteria adapted from the USPSTF.

Strategy for Data Synthesis

Data were compiled into evidence tables and synthesized qualitatively. We did not conduct meta-analysis. The strength of evidence was graded for key comparisons and outcomes.

Analysis of Subgroups or Subsets

No formal subgroup analyses were performed. Studies were stratified according to setting (healthcare versus community). For studies conducted in the community, we stratified studies according to whether the mask is worn by someone with infection, someone uninfected, or both.

External Peer Review

One content expert reviewed the draft report.

Appendix B. Evidence Tables

See associated Excel[®] files:

- Table B-1: Randomized controlled trials of mask use
- Table B-2: Observational studies of mask use in community settings
- Table B-3: Observational studies of mask use in healthcare settings

Appendix C. Included Studies

Aiello AE, Murray GF, Perez V, et al. Mask use, hand hygiene, and seasonal influenza-like illness among young adults: a randomized intervention trial. *J Infect Dis.* 2010 Feb 15;201(4):491-8. doi: 10.1086/650396. PMID: 20088690.

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Appendix D. Risk of Bias Assessments

Author, Year	Randomization	Allocation Concealment	Baseline Groups Comparable	Blinding of Study Participants	Blinding of Outcomes Assessment	Attrition and Missing Data Reported	Attrition and Missing Data	Intention -To-Treat Analysis	Analysis for Adherence	Cluster Trials: Adjustment for Clustering	Overall Quality Rating
Aiello A, 2010 ⁸	Yes	Yes	Yes	No	Unclear	Yes	7.6% (99/1,297) loss to followup	Yes	Yes	Yes	Good
Aiello A, 2012 ⁹	Yes	Yes	Yes	No	Yes	Yes	6.1% loss to followup	Yes	Yes	Yes	Good
Alfelali M, 2019 ¹⁰	Yes	Unclear	Yes	No	Yes for laboratory outcomes	Yes	5.8% did not return their health diaries	Yes	Yes	Yes	Good
Barasheed O, 2014 ¹²	Yes	Unclear	No	No	No	Yes	None reported	Yes	Yes	No	Fair
Canini L, 2010 ¹³	Yes	Yes	Yes	No	Yes for laboratory outcomes	Yes	Two households were loss to followup	Yes	Yes	Yes	Good
Chughtai A, 2016 ¹⁶	Yes	Unclear	Unclear	No	No	Yes	For adverse event outcomes, 19 missing data	No	Yes	Yes	Fair
Cowling BJ, 2008 ¹⁸	Yes	Yes	No	No	Yes for laboratory outcomes	Yes	35% (70/198) withdrew or could not be contacted	Yes	Yes	Yes	Fair

Author, Year	Randomization	Allocation Concealment	Baseline Groups Comparable	Blinding of Study Participants	Blinding of Outcomes Assessment	Attrition and Missing Data Reported	Attrition and Missing Data	Intention -To-Treat Analysis	Analysis for Adherence	Cluster Trials: Adjustment for Clustering	Overall Quality Rating
Cowling BJ, 2009 ¹⁷	Yes	Yes	No	No	Yes for laboratory outcomes	Yes	21% (85/407) households withdrew or could not be contacted	Yes	Yes	Yes	Fair
Larson EL, 2010 ²⁰	Yes	Unclear	No	No	Unclear	Yes	18% (108/617) withdrew consent or were lost to followup; 13% (66/509) dropped out	Unclear	Yes	NA	Fair
Loeb M, 2009 ²⁴	Yes	No	Yes	No	Yes for laboratory outcomes	Yes	5% (24/446) withdrew prior to followup	Yes	Yes	NA	Good
MacIntyre C, 2009 ²⁷	Yes	No	Yes	No	Yes for laboratory outcomes	Yes	1% (2/145) lost to f/u	Yes	Yes	Yes	Good
MacIntyre C, 2011 ²⁹	Yes	Unclear	No	No	Unclear	Yes	None reported	Yes	Yes	Yes	Fair
MacIntyre C, 2013 ³⁰	Unclear	Unclear	No	No	Unclear	Yes	None reported	Yes	Yes	Yes	Fair
MacIntyre C, 2015 ²⁸	Yes	Unclear	Yes	No	Yes for laboratory outcomes	Yes	None reported	Yes	Yes	Yes	Good
MacIntyre C, 2016 ³¹	Yes	Unclear	Yes	No	Yes for laboratory outcomes	Yes	None reported	Yes	Yes	Yes	Good
Radonovich L, 2019 ³⁶	Yes	Yes	Yes	No	Yes	Yes	17% (491/2862) withdrew or excluded	Yes	Yes	Yes	Good

Author, Year	Randomization	Allocation Concealment	Baseline Groups Comparable	Blinding of Study Participants	Blinding of Outcomes Assessment	Attrition and Missing Data Reported	Attrition and Missing Data	Intention -To-Treat Analysis	Analysis for Adherence	Cluster Trials: Adjustment for Clustering	Overall Quality Rating
Simmerman J, 2011 ³⁸	Yes	Unclear	Yes	No	Unclear	Yes	4.9% (23/465) excluded from analysis	No	Yes	Yes	Good
Suess T, 2012 ³⁹	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Good

Appendix E. Ongoing Studies

NCT Number	Title	Population, Interventions, Condition, Outcomes (PICOs)	Anticipated Primary Completion Date
NCT04337541	Reduction in COVID-19 Infection Using Surgical Facial Masks Outside the Healthcare System	<p><u>Population</u> People working outside of their home, who have not previously been infected with COVID-19 and who do not wear facial masks (e.g., healthcare personnel) when working.</p> <p><u>Interventions</u> Surgical facial mask No mask</p> <p><u>Condition</u> COVID-19</p> <p><u>Outcomes</u> Reduction in COVID-19 infection frequency</p>	July 2020
NCT04336215	Cohort Study of SARS-CoV-2 Incidence, Transmission, and Disease Severity in Healthcare Workers	<p><u>Population</u> HCW from two hospitals in New Brunswick and Newark, NJ Non-healthcare workers from Rutgers faculty, staff, and hospital employees without patient contact Household members of participants who contract SARS-CoV-2 during the study period</p> <p><u>Interventions</u> Not applicable</p> <p><u>Condition</u> SARS-CoV-2 infection</p> <p><u>Outcomes</u> Prevalence and incidence of infection</p>	September 2020

NCT Number	Title	Population, Interventions, Condition, Outcomes (PICOs)	Anticipated Primary Completion Date
NCT04362267	Incidence of SARS-Cov2 Infection Among HCW in Lille University Hospital	<p><u>Population</u> Healthcare workers with COVID-19 high exposure during care activities</p> <p><u>Interventions</u> Self-administered questionnaire</p> <p><u>Condition</u> COVID-19</p> <p><u>Outcomes</u> Incidence of SARS- Cov2 infection healthcare worker diagnosed by the positivity of SARS-Cov2 RT-PCT and serological testing Risk of infection based on occupational and environmental exposures</p>	September 2020
NCT04296643	Medical Masks Versus N95 Respirators to Prevent 2019 Novel Coronavirus Disease (COVID-19) in Healthcare Workers: A Randomized Trial	<p><u>Population</u> Nurses who work > 37 hours per week in medical, emergency, pediatric units</p> <p><u>Interventions</u> N95 respirator Medical mask</p> <p><u>Condition</u> COVID-19</p> <p><u>Outcomes</u> Number of participants with RT-PCR confirmed COVID-19 infection</p>	December 2020
NCT04342884	A Multicenter, Prospective Study of COVID-19 Using Real-Time Syndromic Surveillance, Scheduled At-home Serologic Testing, and Electronic Health Records	<p><u>Population</u> Clients of Wake Forest Baptist Health (WFBH) Health care workers of Wake Forest Baptist Health (WFBH)</p> <p><u>Interventions</u> Not reported</p> <p><u>Condition</u> SARS-CoV-2 infection and COVID-19</p> <p><u>Outcomes (selected)</u> Seroprevalence of SARS-CoV-2 infection among healthcare workers of North Carolina Stratified incidence of SARS-CoV-2 infection by use of personal protective equipment (PPE) by health workers Relative risk of SARS-CoV-2 infection by use of PPE by health workers</p>	December 2021

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