



Evidence-based Practice Center Living Rapid Review Protocol

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

(Amended July 2, 2020)

Condition or Domain Being Studied

The use of masks by healthcare workers to prevent the transmission of COVID-19 from infected patients is recommended by the World Health Organization and the Centers for Disease Control and Prevention. The Centers for Disease Control and Prevention has also encouraged the use of masks in the community to prevent transmission of COVID-19.¹ Although single-use N95 and other similar respirators are currently considered the first choice of mask protection for healthcare workers,² there have been reports of shortages in the United States and worldwide.³ Reuse of N95 and similar respirators has been tested in laboratory settings,⁴ but there is a lack of evidence on the clinical effectiveness and safety of mask reuse.^{4,5} Other more readily available types of facemasks may have the potential to confer protection from viral respiratory infection transmission.^{6,7} This review will seek to address the comparative effectiveness of various types of facemasks in healthcare workers and in the community and to address the effectiveness and safety of mask reuse.

Key Questions

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. Community setting
 - b. Healthcare setting
 - i. In high-risk settings (e.g., intensive care unit, emergency room)
 - ii. In 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?

Inclusion and Exclusion Criteria

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, surgical/medical masks, and cloth masks
- Exclude: Powered air-purifying respirators (PAPR), 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 re-use
- 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 outcomes:

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

Types of studies to be included:

- Randomized controlled trials of one mask type versus another for prevention of COVID-19, SARS-1, MERS, influenza-like 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, influenza-like illness, and laboratory-confirmed viral respiratory illness
- Cohort and case-control studies on effects of mask use and risk for prevention of COVID-19, SARS-1, and MERS

- 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

Literature Searches

We will search for systematic reviews and primary studies that address the research questions. Systematic reviews will be used to identify relevant primary studies.

- Databases: PubMed®, Embase®, WHO COVID-19 Database; medRxiv Preprint Server
- Searches will be updated at least monthly.

Data Extraction (Selection and Coding)

Title and abstract review will be performed by one reviewer. A second reviewer will verify exclusion decisions. Disagreements will be resolved through discussion. In the event that agreement cannot be reached on inclusion decisions, a third reviewer will be consulted.

Data will be extracted into Excel® spreadsheets. Data extracted will include author, year, country, study design, study dates, sample size, intervention or exposure characteristics, duration of intervention, population characteristics, and outcomes.

Quality Assessment

For randomized controlled trials, quality will be assessed using criteria adapted from the U.S. Preventive Services Task Force (USPSTF).⁸ Limitations of observational studies will be assessed and summarized using criteria adapted from the USPSTF.

Strategy for Data Synthesis

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

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

After each update search, the report will be updated with a surveillance notice (if there is no change in evidence) or an updated report. For this living review, evidence tables will be housed on a publicly available website (SRDR.ahrq.gov) and updated after each search (if there is a change in evidence).

External Peer Review

We will have at least one content expert review the draft report.

Definition of Terms

COVID-19: Coronavirus Disease 2019; the disease caused by the novel coronavirus SARS-CoV-2

MERS: Middle East Respiratory Syndrome

MERS-CoV: The virus causing MERS

SARS-CoV-1: The virus causing SARS-1

SARS-CoV-2: The virus causing COVID-19

SARS-1: Severe Acute Respiratory Syndrome-1; the disease caused by the coronavirus SARS-CoV-1

Table 1. Summary of Protocol Amendments

Date	Section	Original Protocol	Revised Protocol	Rationale
July 2, 2020	Inclusion/Exclusion Criteria - Types of studies to be included	Did not specify inclusion or exclusion based on peer reviewed status	Only peer reviewed studies will be included.	Few peer-reviewed studies were available on mask use and SARS-CoV-2 infection initially, so non-peer-reviewed studies were in the original review. There is now peer-reviewed evidence available, so in keeping with AHRQ methods, only peer-reviewed studies will be included in future surveillance.
July 2, 2020	Literature Searches	Databases: PubMed®, Embase®, WHO COVID-19 Database; medRxiv Preprint Server	Databases: PubMed®, Embase®	As non-peer-reviewed studies will not be included in future surveillance, there is no need to search the preprint server.

References

- 1 U.S. Centers for Disease Control and Prevention. Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission. 2020. <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover.html>. Accessed April 15 2020.
- 2 U.S. Centers for Disease Control and Prevention. Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-

- 19) in Healthcare Settings. 2020. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html>. Accessed April 15 2020.
- 3 World Health Organization. Shortage of personal protective equipment endangering health workers worldwide. 2020. <https://www.who.int/news-room/detail/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide>. Accessed April 15 2020.
- 4 ECRI. Clinical Evidence Assessment: Safety of Extended Use and Reuse of N95 Respirators. 2020. <https://assets.ecri.org/PDF/COVID-19-Resource-Center/COVID-19-Clinical-Care/COVID-ECRI-N95-Respirators-updated.pdf>. Accessed April 10 2020.
- 5 U.S. Centers for Disease Control and Prevention. Decontamination and Reuse of Filtering Facepiece Respirators. 2020. <https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html>. Accessed April 15 2020.
- 6 Bartoszko JJ, Farooqi MAM, Alhazzani W, et al. Medical Masks vs N95 Respirators for Preventing COVID-19 in Health Care Workers A Systematic Review and Meta-Analysis of Randomized Trials. *Influenza Other Respir Viruses*. 2020 Apr 4. doi: 10.1111/irv.12745. PMID: 32246890.
- 7 Long Y, Hu T, Liu L, et al. Effectiveness of N95 respirators versus surgical masks against influenza: A systematic review and meta-analysis [published online ahead of print, 2020 Mar 13]. *J Evid Based Med*. 2020;10.1111/jebm.12381. doi:10.1111/jebm.12381. PMID: 32167245.
- 8 U.S. Preventive Services Task Force. Criteria for Assessing Internal Validity of Individual Studies. 2017. <https://www.uspreventiveservicestaskforce.org/uspstf/appendix-vi-criteria-assessing-internal-validity-individual-studies>. Accessed April 15 2020.