CADTH

CADTH RAPID RESPONSE REPORT:
SUMMARY WITH CRITICAL APPRAISAL

The Use of N95 Respirators for Protection against Droplet Borne Illness: A Review of the Clinical Effectiveness and Guidelines

Service Line:	Rapid Response Service
Version:	1.0
Publication Date:	June 6, 2017
Report Length:	13 Pages

CADTH

Authors: Yi-Sheng Chao, Carolyn Spry

Cite As: The use of N95 respirators for protection against droplet borne illness: a review of the clinical effectiveness and guidelines. Ottawa: CADTH; 2017 June. (CADTH Rapid response report: summary with critical appraisal).

Acknowledgments:

ISSN: 1922-8147 (online)

About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

Context and Policy Issues

Pathogens can be transmitted through droplets produced while coughing or sneezing and can cause disease, especially respiratory tract infections.[1] These pathogens are associated with a large disease burden.[2] In addition, health care workers (HCWs), who are exposed to patients with respiratory tract infections, are considered at increased risk for being infected.[2,3] Also, HCWs are instrumental in curbing transmission to patients and decrease the risk of hospital-acquired infection.[1]

There are new and emerging diseases that may lead to outbreaks or pandemics, such as the Middle East respiratory syndrome and H1N1 influenza.[3-5] Preparedness for emerging infectious diseases, especially those that can be transmitted via droplets or air, has become necessary for HCWs.[1,3]

The reduction of airborne or droplet transmission often requires systematic efforts to achieve because the transmission of respiratory disease can be influenced by many factors, such as types of pathogens, ventilation, air filtration, sterilization, and personal protection equipment (PPE).[4,5] Two types of PPE are widely used, such as medical masks and respirators.[6,7] Both aim to reduce transfer of respiratory disease. However, "masks are recommended for disease transmitted through droplets and respirators for respiratory aerosols."[7] Respirators can either filter the airborne particles or supply clean air to the respirator wearer, air-purifying, or atmosphere-supplying respirators.[2,8] Air-purifying respirators are further classified according to the efficiency at which they remove particles (i.e., 95%, 99% or 100%) and the resistance to oil. N, R, and P-Series respirators are respectively not resistant to oil, resistant to oil and oil-proof. [2,8]

According to a 2014 CADTH rapid response report, the evidence suggested that N95 respirators were more effective in preventing viral and bacterial infections in HCWs compared with surgical masks.[9] Moreover, several clinical guidelines recommended the use of N95 respirators for managing patients with tuberculosis or highly contagious diseases, such as SARS and high-risk pandemic influenza.[9] The results, however, must be interpreted with caution due to several limitations described in the report.[9]

To update the previous CADTH review, this report aims to summarize the clinical evidence and clinical guidelines regarding the effectiveness of N95 respirators.

Research Question

1. What is the clinical effectiveness regarding the use of N95 respirators for protection against droplet borne illness?
2. What are the evidence-based guidelines regarding the use of N95 respirators for protection against droplet borne illness?

Key Findings

One systematic review did not identify any evidence on the effectiveness of N95 respirators regarding protection against methicillin-resistant *Staphylococcus aureus* (MRSA)

transmission. Evidence-based guidelines published since 2014 on the effectiveness of N95 respirators were not identified.

Methods

Literature Search Methods

A limited literature search was conducted on key resources including PubMed, The Cochrane Library, University of York Centre for Reviews and Dissemination (CRD) databases, ECRI (Health Devices Gold), Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between July 1, 2014 and May 9, 2017.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Population	Healthcare providers caring for patients with a respiratory illness
Intervention	Q1-2: N95 respiratory mask
Comparator	Q1: Other surgical/procedural masks or respiratory protection Q2: N/A
Outcomes	Clinical effectiveness, guidelines
Study Designs	Health technology assessments, SRs/meta-analyses, randomized controlled trials, non-randomized studies, evidence-based guidelines

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1, they were duplicate publications, or were published prior to 2014.

Critical Appraisal of Individual Studies

The included SRs were critically appraised using the AMSTAR tool.[10] Summary scores were not calculated for the included studies; rather, a review of the strengths and limitations assessed in each included study were described.

Summary of Evidence

Quantity of Research Available

A total of 140 citations were identified in the literature search. Following screening of titles and abstracts, 113 citations were excluded and 27 potentially relevant reports from the

electronic search were retrieved for full-text review. No potentially relevant publication was retrieved from the grey literature search. Of these potentially relevant articles, 26 publications were excluded for various reasons, while one publication met the inclusion criteria and was included in this report. Appendix 1 describes the PRISMA flowchart of the study selection.

Additional references of potential interest are provided in Appendix 5.

Summary of Study Characteristics

Additional details describing the characteristics of the included studies are reported in Appendix 2.

Study Design

One SR was identified for inclusion this report.[5]

Country of origin

The SR was conducted in Spain.[5]

Study population

Lopez-Alcalde et al. considered any person a hospital setting susceptible to methicillin-resistant *Staphylococcus aureus* (MRSA) infection as the population of interest.[5]

Interventions and Comparators

Lopez-Alcalde et al. aimed to study the clinical effectiveness of gloves, gowns, and masks in preventing the transmission of MRSA. Any comparator relevant to demonstrate the effectiveness of the interventions was eligible.[5]

Clinical outcomes

The outcomes studied by Lopez-Alcalde et al. were the effects on MRSA transmission. Outcomes regarding N95 respirators were also considered.[5]

Summary of Critical Appraisal

Additional details describing the critical appraisal of the included studies are reported in Appendix 3.

The SR in this report explicitly described the objectives of the review and the databases that were searched to find relevant literature.[5] Lopez-Alcalde et al. searched ten electronic databases, including MEDLINE, EMBASE, Web of Science and CINAHL.[5] Potential studies in all languages were considered.[5] Independent duplicate study inclusion assessment and data extraction were performed.[5] The same review had planned to assess the quality of included studies and to consider their quality to help draw conclusions from the results.[5] As well, the SR had planned to assess the publication bias.[5] Excluded studies were not listed.[5]

Summary of Findings

1. *What is the clinical effectiveness regarding the use of N95 respirators for protection against droplet borne illness?*

Facemask wearing by health-care workers

Lopes-Alcalde et al. did not find any relevant studies related to MRSA transmission.[5]

2. *What are the evidence-based guidelines regarding the use of N95 respirators for protection against droplet borne illness?*

Evidence-based guidelines regarding the use of N95 respirators for protection against droplet borne illness were not identified for this review.

Limitations

The main limitation of this report is a persistent lack of high-quality evidence informing the use of N95 respirators in HCWs. The review by Lopez-Alcalde et al. did not find any eligible studies on the effectiveness of N95 respirators on MRSA transmission.[5] The effectiveness of N95 respirators in HCWs to prevent droplet borne infection remains to be studied.

Conclusions and Implications for Decision or Policy Making

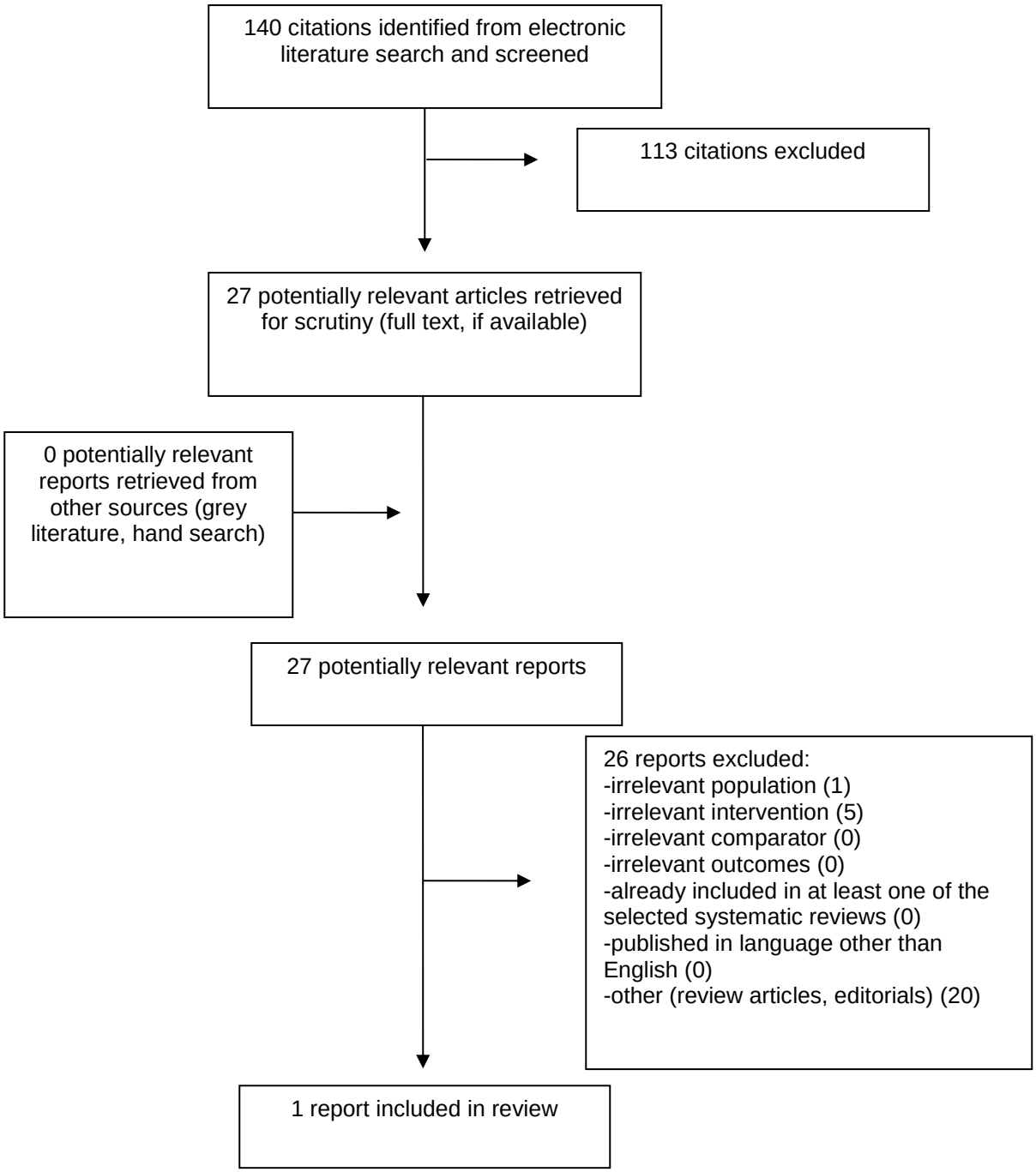
The 2014 Rapid Response report found that N95 respirators were more effective at preventing viral infection and bacterial colonization in HCWs compared with medical masks.[9] The same report, however, indicated that the included studies were of poor quality.[9]

The current report attempted to retrieve the evidence on the effectiveness of N95 respirators for protection against droplet borne illness. The SR identified did not find any eligible primary studies for inclusion.[5] Further, relevant evidence-based guidelines published since 2014 were not found.

References

1. MacIntyre CR, Chughtai AA, Seale H, Richards GA, Davidson PM. Respiratory protection for healthcare workers treating Ebola virus disease (EVD): are facemasks sufficient to meet occupational health and safety obligations? Int J Nurs Stud [Internet]. 2014 Nov [cited 2017 May 12];51(11):1421-6. Available from: http://www.sciencedirect.com/science/article/pii/S002074891400234X
2. Thomas RE. Do we have enough evidence how seasonal influenza is transmitted and can be prevented in hospitals to implement a comprehensive policy? Vaccine. 2016 Jun 8;34(27):3014-21.
3. Verbeek JH, Ijaz S, Mischke C, Ruotsalainen JH, Mäkelä E, Neuvonen K, et al. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. Cochrane Database Syst Rev. 2016 Apr 19;4:CD011621.
4. Wei J, Li Y. Airborne spread of infectious agents in the indoor environment. Am J Infect Control. 2016 Sep 2;44(9 Suppl):S102-S108.
5. López-Alcalde J, Mateos-Mazón M, Guevara M, Conterno LO, Solà I, Cabir NS, et al. Gloves, gowns and masks for reducing the transmission of meticillin-resistant Staphylococcus aureus (MRSA) in the hospital setting. Cochrane Database Syst Rev. 2015 Jul 16;(7):CD007087.
6. Seto WH. Airborne transmission and precautions: facts and myths. J Hosp Infect. 2015 Apr;89(4):225-8.
7. MacIntyre CR, Chughtai AA. Facemasks for the prevention of infection in healthcare and community settings. BMJ. 2015 Apr 9;350:h694.
8. National Academies of Sciences, Engineering, and Medicine, Health and Medicine Division, Board on Health Sciences Policy. Integration of FDA and NIOSH processes used to evaluate respiratory protective devices for health care workers: proceedings of a workshop. Washington (DC): National Academies Press (US); 2017 Feb 1.
9. Respiratory precautions for protection from bioaerosols or infectious agents: a review of the clinical effectiveness and guidelines [Internet]. Ottawa: CADTH; 2014 Aug 19. [cited 2017 May 12]. (CADTH rapid response report: summary with critical appraisal). Available from: https://www.cadth.ca/sites/default/files/pdf/htis/dec-2014/RC0576%20Respirator%20Effectiveness%20final.pdf
10. Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. BMC Med Res Methodol [Internet]. 2007 [cited 2017 May 12];7:10. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1810543/pdf/1471-2288-7-10.pdf

Appendix 1: Selection of Included Studies



Appendix 2: Characteristics of Included Publications

Table A1: Characteristics of Included Systematic Reviews

First Author, Publication Year, Country	Types and Numbers of Primary Studies Included	Population Characteristics	Intervention(s)	Comparator(s)	Clinical Outcomes, Length of Follow-up
Lopez-Alcalde et al. 2015,[5] Spain	No studies assessing the effects on MRSA transmission of wearing gloves, gowns or masks for contact with MRSA hospitalized patients, or with their immediate environment (n=0)	Any person in the hospital setting when contact is anticipated with a hospitalized patient colonized or infected with MRSA, or with the patient's immediate environment	Gloves, gowns and masks.	Gloves, gowns and masks including any comparators allowing the assessment of the effects of the interventions (p. 7)	Effects on the transmission of MRSA to patients, hospital staff, patients' caregivers or visitors.

MRSA = methicillin-resistant Staphylococcus aureus

Appendix 3: Critical Appraisal of Included Publications

Table A2: Strengths and Limitations of Systematic Reviews and Meta-Analyses using AMSTAR[10]

Strengths	Limitations
Lopez-Alcalde et al., 2015[5]	
• Protocol established *a priori* • Study selection described • Rationale for exclusion of studies described • Comprehensive search • Potential studies in all languages screened • Critical appraisal planned • Included studies described • Publication bias planned • Potential studies in all languages screened	• Assessment of conflict of interest not proposed • List of potentially relevant sources not included in the review

Appendix 4: Main Study Findings and Author's Conclusions

Table A3: Summary of Findings of Included Studies

Main Study Findings	Author's Conclusions
Lopez-Alcalde et al., 2015[5]	
No studies assessing the effects of wearing gloves, gowns or masks for contact with MRSA hospitalized patients, or with their immediate environment, on the transmission of MRSA to patients, hospital staff, patients' caregivers or visitors.	• This absence of evidence should not be interpreted as evidence of no effect for these interventions. • The effects of gloves, gowns and masks in these circumstances have yet to be determined by rigorous experimental studies, such as cluster-randomized trials involving multiple wards or hospitals, or interrupted time series studies.

MRSA = methicillin-resistant *Staphylococcus aureus*

Appendix 5: Additional References of Potential Interest

N95 respirators as a composite intervention

Verbeek JH, Ijaz S, Mischke C, Ruotsalainen JH, Mäkelä E, Neuvonen K, et al. Personal protective equipment for preventing highly infectious diseases due to exposure to contaminated body fluids in healthcare staff. Cochrane Database Syst Rev. 2016 Apr 19;4:CD011621.

Potentially relevant non-systematic review

Lee JY. Tuberculosis infection control in health-care facilities: environmental control and personal protection. Tuberc Respir Dis (Seoul) [Internet]. 2016 Oct [cited 2017 May 12];79(4):234-40. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5077726

Wei J, Li Y. Airborne spread of infectious agents in the indoor environment. Am J Infect Control. 2016 Sep 2;44(9 Suppl):S102-S108.

Thomas RE. Do we have enough evidence how seasonal influenza is transmitted and can be prevented in hospitals to implement a comprehensive policy? Vaccine. 2016 Jun 8;34(27):3014-21.

Johnson AT. Respirator masks protect health but impact performance: a review. J Biol Eng [Internet]. 2016 [cited 2017 May 12];10:4. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4748517

Hanoa RO, Moen BE. Ebola care and lack of consensus on personal protective respiratory equipment. Workplace Health Saf. 2016 Feb;64(2):48-50.

Seto WH. Airborne transmission and precautions: facts and myths. J Hosp Infect. 2015 Apr;89(4):225-8.

MacIntyre CR, Chughtai AA. Facemasks for the prevention of infection in healthcare and community settings. BMJ. 2015 Apr 9;350:h694.

Roberts V. To PAPR or not to PAPR? Can J Respir Ther [Internet]. 2014 [cited 2017 May 12];50(3):87-90. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4456839

Board on Health Sciences Policy, Institute of Medicine. The use and effectiveness of powered air purifying respirators in health care: workshop summary. Washington (DC): National Academies Press (US); 2015 May 7. (The National Academies Collection: reports funded by National Institutes of Health).

Cuta K. Powered air purifying respirators: versatility beyond respiratory protection. Occup Health Saf. 2014 Nov;83(11):20, 22.

Branch-Elliman W, Savor Price C, McGeer A, Perl TM. Protecting the frontline: designing an infection prevention platform for preventing emerging respiratory viral illnesses in healthcare personnel. Infect Control Hosp Epidemiol. 2015 Mar;36(3):336-45.

Kumar A. Priortising airborne infection control in HIV/AIDS care settings in India. Indian J Tuberc. 2014 Oct;61(4):294-7.

Wear compliance and donning/doffing of respiratory protection for bioaerosols or infectious agents: a review of the effectiveness, safety, and guidelines [Internet]. Ottawa: CADTH; 2014 Aug 19. [cited 2017 May 12]. (Rapid response report: summary with critical appraisal). Available from: https://www.cadth.ca/sites/default/files/pdf/htis/dec-2014/RC0575%20Respirator%20Compliance%20final.pdf

Katz LM, Tobian AA. Ebola virus disease, transmission risk to laboratory personnel, and pretransfusion testing. Transfusion. 2014 Dec;54(12):3247-51.