

Protecting healthcare workers from pandemic influenza: N95 or surgical masks?

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Objective: The successful management of an influenza pandemic will be reliant on the expertise of healthcare workers at high risk for occupationally acquired influenza. Recommended infection control measures for healthcare workers include surgical masks to protect against droplet-spread respiratory transmissible infections and N95 masks to protect against aerosol-spread infections. A literature review was undertaken for evidence of superior protective value of N95 masks or surgical masks for healthcare workers against influenza and extraneous factors influencing conferred protection.

Methods: Four scientific search engines using 12 search sequences identified 21 mask studies in healthcare settings for the prevention of transmission of respiratory syncytial virus, Bordetella pertussis, and severe acute respiratory syndrome. Each was critically assessed in accordance with Australian National Health Medical Research Council guidelines. An additional 25 laboratory-based publications were also reviewed.

Results: All studies reviewed used medium or lower level evidence study design. In the majority of studies, important confounders included the unrecognized impact of concurrent bun-

dling of other infection control measures, mask compliance, contamination from improper doffing of masks, and ocular inoculation. Only three studies directly compared the protective value of surgical masks with N95 masks. The majority of laboratory studies identified both mask types as having a range of filtration efficiency, yet N95 masks afford superior protection against particles of a similar size to influenza.

Conclusions: World Health Organization guidelines recommend surgical masks for all patient care with the exception of N95 masks for aerosol generating procedures. Because of the paucity of high-quality studies in the healthcare setting, the advocacy of mask types is not entirely evidence-based. Evidence from laboratory studies of potential airborne spread of influenza from shedding patients indicate that guidelines related to the current 1-meter respiratory zone may need to be extended to a larger respiratory zone and include protection from ocular inoculation. (Crit Care Med 2010; 38:657–667)

KEY WORDS: pandemic; influenza; masks; occupational safety; intubation

In healthcare settings, face masks, whether N95 filtering face piece respirators (N95 masks) or surgical masks, are used either to protect patients from healthcare-associated infections or to protect healthcare workers (HCW) from occupationally acquired infections through droplet or airborne spread. It will be crucial for the successful management of a pandemic to keep susceptible HCW safe from hospitalized patients shedding droplet and airborne influenza particles. Consequently, in most national pandemic plans, specific attention has been on ensuring the

health of front-line clinicians. Infection control measures for HCW, such as N95 mask use, along with vaccination, social distancing, and pharmaceutical prophylaxis, are documented policies in most national pandemic plans (1–10). However, these plans are often based on historical evidence because of the paucity of high-quality current evidence.

Masks

There are two main types of masks used in health care: surgical and N95 masks. Despite conflicting evidence suggesting effectiveness in the healthcare setting (11–16), surgical masks have traditionally been used by HCW during surgery to prevent contamination of the surgical site, whereas N95 masks were used to protect HCW from inhaling *Mycobacterium tuberculosis* particles (17) from infected patients. The two masks are structurally different (Table 1). The name “N95” refers to the mask being certified to exclude 95% of non-oil-based sodium chloride particles, sized at 0.3 μm in diameter, as pre-specifications set by the

National Institute of Occupational Safety and Health (18). Henceforth, in this article the term “masks” will refer to both N95 masks and surgical masks.

Our review of the evidence of masks was commissioned by the Australian Commonwealth Department of Health and Aging to aid in developing an evidence-based algorithm for the protection of HCW in the event of pandemic influenza. The literature review also aimed to determine whether there is an evidential basis for advocating the superior protective value of either surgical or N95 mask types for the protection of HCW against communicable respiratory diseases such as influenza.

MATERIALS AND METHODS

Publications were located using four scientific search engines: Web of Science, MEDLINE, EMBASE, and Cochrane Database of Systematic Reviews. Potentially relevant publications were identified using 12 search sequences:

Infection Control + severe acute respiratory syndrome (SARS)

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Table 1. Mask structures

Properties	Surgical Mask	N95 Masks
Shape	Pleated face	Raised dome or duckbill
Layers	2–3	4–5
Filtering material	All polypropylene layers	Outer polypropylene layers, central layers of electret (charged polypropylene)
Method of filtration	Mechanical impaction	Mechanical impaction electrostatic capture (95–97)
Sealing	Elasticized ties at crown and bottom of head	Elasticized ties at crown and bottom of head, pliable metal nose bridge

Influenza + Healthcare + Personal + Protection
 SARS + Healthcare
 Influenza + Healthcare + Pandemic + Planning
 Influenza + Healthcare + Masks
 Pandemic + Masks
 Influenza + Masks
 SARS + Masks
 N95 + Gowns + Gloves
 Masks + Gowns + Gloves
 Face* + Influenza
 Goggles + Influenza

The Search strategy used an open date limit to 2008, an English language restriction, and allowed for abstracts.

Both authors independently reviewed publications for relevance and conferred when a review differed. To be included in this review, studies had to provide information about the actual use of masks by individuals and present data in such a way that an evaluation of the protective value of masks could be attempted by the review authors. Publications that reported mask use only in general terms were excluded from the review. The authors excluded studies that did not involve HCW. Systematic reviews, reviews, editorials, and overviews were initially excluded because these publications were considered to be interpretative and may potentially bias the present review. Once the review of the original publications was completed, systematic reviews and overviews were also reviewed.

Publications were critically assessed for the quality of evidence determined by the Designations of Levels of Evidence set by the National Health and Medical Research Council (19). Lower study designs not classified (19) but commonly used in health service research, such as cross-sectional and case report study designs, were included in the review. Publications were critically assessed for the impact of study bias, internal and external biases, and confounding on study outcomes and generalizability. The majority of studies did not provide 95% confidence intervals (95% CI) around proportions and measures of effects. The purpose of our exact 95% CI calculations was to identify potential issues of under power of a study as we reviewed authors' conclusions

for factuality (20, 21). Our univariate analysis could not provide accurate measures of effect for the influence of interaction terms nor did we attempt to measure the effect of confounding. However, wide 95% CI were used to assist in establishing whether the study was potentially under-powered and therefore whether statistically significant measures of effect were over-interpreted. Recalculations of the measures of effect using EpiInfo (version 6.04b; CDC, Atlanta, GA) were performed using only the epidemiologic data published in the result sections.

RESULTS

Twenty-one human studies in the healthcare setting were identified and reviewed (22–42) (Table 2), as well as 25 laboratory studies (43–67) (Table 3) that assessed mask filtering efficiency. Six studies (22–27) provided sufficient epidemiologic data to enable a univariate re-analysis of the measures of effect and 95% CI.

Articles on the Use of Surgical Masks by Healthcare Workers

Six studies attempted to evaluate the protective value of surgical masks for HCW. Three lower-level studies reported surgical masks protect HCW from occupational acquisition of respiratory infections when bundled with hand hygiene, glove use, and gown use (24, 28–29) (Table 2). When all HCW and visitors were required to wear surgical masks before entering the isolation area, while other concurrent infection control measures were in place, the use of surgical masks was concluded to be effective (28). Surgical masks were reported to have reduced the risk of occupational acquisition of severe acute respiratory syndrome (SARS) during the early onset of the outbreak, during the latter stage of the SARS outbreak when hospital-acquired spread was suspected, and when used in combination with gowning and gloving and

hand hygiene measures (24). Re-analysis of surgical masks found there was no protective effect against SARS in the early onset of the outbreak but concurred with original findings that masks were protective in the latter stages. The bundling of surgical mask use, gowning, gloving, and hand hygiene significantly reduced the incidence of healthcare-associated respiratory syncytial virus (RSV) pediatric patients from 17.4% before mask use to 3.6% at 2 yrs after intervention (29). However, this reduction may have been confounded by a reduced number of cases presentations during the study period and the predominance of droplet spread transmission, making gowning and gloving more important than mask use. All three studies did not attempt to control for the impact of inconsistent mask use, poor hand hygiene, and poor donning/doffing practices on the effectiveness of surgical mask use.

Conversely, surgical mask use was reported to have conveyed no protective value in two studies and an equivocal outcome in another study. A time series analysis of surveillance data of susceptible HCW for RSV concluded that gowning and masking did not provide increased protection with a reported rate of acquisition of 33% in the pre-intervention period and 42% in the post-intervention period (30). A small cohort study of the protectiveness of surgical mask use combined with hand washing and gowning from RSV in HCW on a pediatric ward found no significant protection compared with hand washing alone (31). Reanalysis identified that no conclusion could be drawn as the study was under powered (relative rate [RR], 0.96; 95% CI, 0.6–1.4; $p = .84$). Only scant details were given for a case series of 16 HCW who acquired SARS infections during an outbreak in a Taiwanese hospital where three HCW reportedly wore surgical masks and gloves during an intubation procedure on a SARS patient; no details were reported for the remaining 13 infected HCW (32). The equivocal results were likely attributable to small sample size and an inadequate study design for determining causal association.

Articles on the Use of N95 Masks by Healthcare Workers

N95 masks were reported to confer protection in three studies, but inconclusive findings were reported by a further six studies. A case-control study during

Table 2. Masks studies in healthcare workers

Author, Date, Reference	Study Design Mask Type and Exposure Type	Reported Findings	Bias and Confounding
Teleman et al (22)	Case-control (cases = 36; controls = 50) N95 masks	Masks were protective (OR, 0.1; 95% CI, 0.03–0.4; $p = .001$) Reanalysis: masks were protective (OR, 0.1; 95% CI, 0.02–0.4; $p = .0004$)	Recall bias Small sample size
Wilder-Smith et al (23)	Cross-sectional (n = 80) N95 masks SARS contacts	Masks were protective for severity of SARS: 8% nil mask acquired pneumonic SARS vs. 50% who nil mask acquired asymptomatic SARS ($p = .025$); 8% (pneumonic) vs. 50% (asymptomatic) vs. 40% (nil SARS) (for difference between any two proportions $p = .002$) Reanalysis: masks were protective (OR, 0.25; 95% CI, 0.08–0.75; $p = .005$)	Small sample size Compliance and correct use Recall bias Exclusion of subclinical cases from study group Compliance and correct use Concurrent IC measures Comparability of exposure levels in the ward
Nishiura et al (24)	Case-control (cases = 29; controls = 98) Surgical SARS contacts	Stage 1: mask was protective (OR, 0.3; 95% CI, 0.1–0.7; $p = .011$) Stage 2: mask was protective (OR, <0.1; 95% CI, <0.0–0.3; $p = .001$) Stage 1: masks with hygiene, gowns, masks and gloves was protective (OR, 0.2; 95% CI, 0.0–1.0; $p = .059$) Stage 2: masks with hygiene, gowns, masks and gloves was protective (OR, <0.1; 95% CI, 0.0–0.3; $p = .001$) Reanalysis: stage 1: mask was not protective (OR, 0.6; 95% CI, 0.2–1.7; $p = .3$) Reanalysis: stage 2: mask was protective (OR, 0.01; 95% CI, 0.0–0.4; $p = .004$)	Recall bias Small sample size Duration of exposure
Lau et al (25)	Case-control (cases = 72; controls = 144) N95 and surgical masks SARS contacts	Masks were not protective if used inconsistently (OR, 2.0; 95% CI, 0.5–∞; $p = .67$) N95 masks were not protective (OR, 2.9; 95% CI, 0.7–13.7; $p = .1683$) Reanalysis: Mask were not protective (OR, 4.1; 95% CI, 0.2–214.0; $p = .26$)	Recall bias Compliance and correct use Concurrent IC measures
Loeb et al (26)	Case-control (cases = 8; controls = 35) N95 and surgical masks SARS contacts	Masks were protective (RR, 0.23; 95% CI, 0.07–0.78; $p = .02$) N95 masks were protective (RR, 0.22; 95% CI, 0.05–0.93; $p = .06$) Reanalysis: masks were not protective (OR, 0.43; 95% CI, 0.02–33.6; $p = .51$) Reanalysis: N95 masks were not protective (OR, 0.11; 95% CI, 0.01–1.1, $p = .058$)	Information bias Selection bias: small nested sample Compliance and correct use Effect of hand hygiene
Seto et al (27)	Case-control (Cases = 13; controls = 241) N95 and surgical masks SARS contacts	Any mask use protective (OR, 13; 95% CI, 3–60; $p = .0001$) Surgical mask use was protective ($p = .007$), N95 use was protective ($p = .0004$) Reanalysis: any mask type was protective 100.0% (95% CI, 75.0–100.0%); infected HCW nil N95/surgical mask use vs. 40.0% (95.0% CI, 34.0–47.0%); uninfected HCW nil N95/surgical mask use ($p = .00003$)	Recall bias Small sample size Compliance and correct use Potentially variable exposure levels to patients

Table 2. —continued

Author, Date, Reference	Study Design Mask Type and Exposure Type	Reported Findings	Bias and Confounding
Christie et al (28)	Cross-sectional (n = 206) Surgical masks	Masks with other IC measures was protective	Other IC measures
Simon et al (29)	<i>Bordatella pertussis</i> Time Series (n = 2200, 2298, 1959 admissions) Surgical masks RSV contacts	Masks with other IC measures were protective ($p = 0.0392$)	Prevalence of vaccination in community and in HCW Effect of antibiotics Hawthorne effect Inherent immunosuppression in hospitalized patients Duration of PPE use Concurrent IC measures Effect of any antiviral treatment or prophylaxis Number of HCW not provided Concomitant illness or medication Effectiveness of hand washing Correct use and compliance Maternal antibody effect Concurrent IC measures Recall bias
Hall and Douglas (30)	Time series control (n = 30) Surgical masks RSV contacts	Masks with gowns was NOT protective ($p = 0.489$)	No masks only arm Hawthorne effect Concurrent IC measures Compliance and correct use Unknown number of exposed and unmasked HCW Small sample size Influence of the procedures undertaken on extent of exposure Effect of hand hygiene No control set of exposed but not infected Compliance of use Effect of hand hygiene Cases may have been already incubating virus before symptom onset and before increased IC implementation
Murphy et al (31)	Cohort-control (n = 58) Surgical masks RSV contacts	Masks with gowns were not protective ($p = 0.94$)	Recall bias Cohort bias (variability of exposure in cohort) Compliance and correct use Recall bias Interview structure Compliance of use Effect of hand hygiene Cases may have been already incubating virus before symptom onset and before increased IC implementation
Liu et al (32)	Case series (n = 255) Surgical masks SARS contacts	Mask efficacy was not established	Compliance and correct use Recall bias Interview structure Compliance of use Effect of hand hygiene Cases may have been already incubating virus before symptom onset and before increased IC implementation Cohort bias: little information on 5 HCW non-cases that were also present at intubation
Chen et al (33)	Case series (n = 60) N95 masks SARS contacts	Mask with other IC measures was protective	Compliance and correct use Recall bias Interview structure Compliance of use Effect of hand hygiene Cases may have been already incubating virus before symptom onset and before increased IC implementation
CDC (34)	Case series (n = 11) N95 mask	Mask efficacy was not established	Compliance and correct use Recall bias Interview structure Compliance of use Effect of hand hygiene Cases may have been already incubating virus before symptom onset and before increased IC implementation
Dwosh et al (35)	SARS contacts Case series (n = 6) N95 masks SARS contacts	Mask efficacy was not established	Compliance and correct use Recall bias Interview structure Compliance of use Effect of hand hygiene Cases may have been already incubating virus before symptom onset and before increased IC implementation
Twu et al (36)	Case report (n = 1) Surgical masks SARS contacts	Mask efficacy was not established	Compliance and correct use Effect of hand hygiene Incomplete use of PPE Excluded six infected cases Potentially variable levels of exposure to patients Concurrent IC measures Effect of super-spreaders not explored
Tambyah et al (37)	Case report (n = 1) N95 masks SARS contacts	Mask efficacy was not established	Compliance and correct use Effect of hand hygiene Incomplete use of PPE Excluded six infected cases Potentially variable levels of exposure to patients Concurrent IC measures Effect of super-spreaders not explored

Table 2. —continued

Author, Date, Reference	Study Design Mask Type and Exposure Type	Reported Findings	Bias and Confounding
Park et al (38)	Cross-sectional (n = 110) N95 masks SARS contacts	Mask efficacy was not established because of lack of high-risk cases	Lack of high-risk cases Recall bias Influence of the procedures undertaken on extent of exposure Antiviral prophylaxis and treatment Concurrent IC measures Compliance and correct use
Ofner-Agnostini et al (39)	Case series (n = 17) Surgical masks SARS contacts	Mask efficacy was not established	Recall bias Open-ended questions in interview No comparison with non-cases for breaches in IC Selection bias Compliance and correct use Lack of consistent use of other IC
Chen et al (40)	Cross-sectional (n = 223) N95 mask SARS contacts	Surgical mask use by patient was protective for unmasked and N95-masked HCW	Recall bias Selection bias: data sets for HCW exposed to patients who were masked and patient that were unmasked was not provided Cohort bias: data set for post-IC implementation was not provided Compliance and correct use Effect of hand hygiene
Leung et al (41)	Case report (n = 26) N95 and surgical masks SARS contacts	Masks with other IC measures is protective	Correct use
WHO (42)	Case series(n = 3) N95 and surgical masks SARS contact	Mask efficacy was not established	Recall bias Cohort bias: no information for other exposed HCW Lack of consistent use of other IC Compliance and correct use

IC, infection control; HCW, healthcare workers; OR, odds ratio; CI, confidence interval; PPE, personal protective equipment; RR, relative risk; RSV, respiratory syncytial virus; SARS, severe acute respiratory syndrome; CDC, Centers for Disease Control and Prevention; WHO, World Health Organization.

the SARS outbreak in Singapore reported HCW who wore a N95 mask had a significantly reduced risk of SARS compared with HCW who did not (22). A cross-sectional survey of HCW with direct SARS patient care in Singapore found HCW who wore N95 masks were four-times more likely to have asymptomatic illness rather than pneumonic SARS compared with those who did not use N95 masks (23). A case series of 60 occupationally acquired SARS in a Singapore hospital found 81.6% of infections occurred before the implementation of infection control measures, which included N95 mask use compared with 18.3% of infections occurring after implementation (33). Although the number of sus-

ceptible HCW was not provided to establish the protective effect of mask use, the reduced cumulative incidence of HCW after implementation suggested a protective effect when masks were bundled with gowning, glove use, and patient isolation HCW.

N95 mask effectiveness could not be determined from six lower-level studies that were severely underpowered (34–39). A case series of 11 Canadian HCW exposed to SARS patients found that even though all wore N95 masks, nine acquired SARS (34). In another case series, six HCW who acquired SARS had unprotected exposure with two SARS patients in a Canadian hospital despite other areas of the hospital implementing N95 mask

use and other infection control measures (35). A single case report of occupational-acquisition SARS by a physician described his personal protective equipment (PPE) use that included N95 mask, double-gloves, and double-gowns while performing a chest ultrasound and supervising the intubation of a SARS patient in a Taiwanese hospital (36). Five other HCW who were present during the intubation did not acquire SARS, but no description was provided of their PPE use. Another case report detailed the occupational-acquisition of SARS by a HCW who wore a N95 mask, gowns, and gloves while performing a bronchoscopy on SARS patients in non-SARS-designated Singapore hospital (37). There was no

Table 3. Laboratory studies assessing filtering efficacy of masks

Author, Date, Reference	Type of Mask	Challenge Particle, Size	Laboratory Findings	Limitations for Generalizability of Laboratory Findings
Lee et al (43)	N95 Surgical	NaCl (0.04–1.3 μm)	N95 masks provided more protection than surgical masks	Limited by use of inert particles
Gawn et al (44)	N95 Surgical	Inert particles (0.03–0.06 μm), influenza	N95 masks confer better filtering efficiency than surgical masks for inert particles	Limited by comparative testing only with inert particles, not influenza
Johnson and Grayson (45)	N95 Surgical	Influenza	Use of either mask prevented detection of virus on Petri dishes in all cases	Small sample size, reliance on droplet transmission only
Balazy et al (46)	N95 Surgical	MS2 bacteriophage (20–80 nm)	Efficiency of N95 mask against MS2 bacteriophage: >95%	—
Li et al (47)	N95 Surgical	Fluorescein-KCl particles	Efficiency of surgical mask against MS2 bacteriophage: 20%–98%	Limited by use of inert particles
Qian et al (48)	N95 Surgical	NaCl (<0.7 μm) Polystyrene latex particles (PSL) (0.60–5.10 μm) <i>Bacillus subtilis</i> (0.7–0.8 μm) <i>Bacillus megaterium</i> (1.2–1.5 μm)	N95 masks confer better filtering efficiency than surgical masks for fluorescein-KCl particles Efficiency of N95 masks against PSL: 96%–98.8% Efficiency of surgical masks against PSL: 71% Efficiency of N95 masks against salt: 95%–96% Efficiency of N95 masks against bacterial challenge: >99.5%	Limited by use of inert particles and bio-aerosols larger than influenza
Balazy et al (49)	N95	NaCl (0.01–0.6 μm)	Efficiency of N95 mask against bio-aerosol (10–600 nm) particles: >95%	Limited by use of inert particles
Chen et al (50)	Surgical	Corn oil particles (2.3 μm)	Efficiency of surgical mask against inert particles (0.1–1.0 μm): 20–80%	Limited by use of inert particles
Chen et al (51)	Surgical	<i>Mycobacterium chelonae</i> (0.6–0.9 μm) Polystyrene latex particles (0.8 μm)	Efficiency of surgical mask against bio-aerosols: >96% Efficiency of surgical mask against inert particles: >95%	Limited by use of inert particles and bio-aerosols larger than influenza
CDC (52)	N95	—	Efficiency increases when N95 masks are fit tested	—
Eninger et al (53)	N95	NaCl (0.1–0.5 μm) MS2 bacteriophage (28 nm) T4 bacteriophage (225 nm) SP01 (237 nm)	Efficiency of N95 mask against inert particles: >96% Efficiency of N95 mask against bio-aerosol particles: >96%	—
Johnson et al (54)	Surgical	<i>Bacillus subtilis</i> (0.7–0.8 μm × 1.5–1.8 μm)	Efficiency of N95 mask against bio-aerosol particles: 66%	Limited by bio-aerosol larger than influenza
Lee et al (55)	N95	<i>Aspergillus</i> sp. <i>Penicillium</i> sp. <i>Cladosporium</i> sp. <i>Epicoccum</i> sp. <i>Alternaria</i> sp.	68% N95 masks exceeded NIOSH assigned protection factor (0.7–1.0 μm in size) 50% N95 masks exceeded NIOSH assigned protection factor (2.0–10.0 μm in size)	Limited by bio-aerosols larger than influenza
McCullough et al (56)	Surgical	Polystyrene latex particle (0.55 μm) <i>Mycobacterium abscessus</i> (1–4 μm) <i>Bacillus subtilis</i> (0.5–1.5 μm) <i>Staphylococcus epidermidis</i> (2–3 μm)	Surgical masks filtered better bio-aerosols compared with dust, mist and fume respirators	Limited by bio-aerosols larger than influenza Limited by use of inert particles larger than influenza
Madsen and Madsen (57)	Surgical	<i>Bacillus stearothermophilus</i>	Efficiency of mask: 98%	Limited by bio-aerosols larger than influenza
Oberg and Brosseau (58)	Surgical	Latex spheres (0.8–3.1 μm) NaCl (0.3 μm)	Efficiency of mask for inert particles (0.8–3.1 μm): 11–99%	Limited by use of inert particles larger than influenza
Pippin et al (59)	Surgical	<i>Lycopodium clavatum</i> spores (22 μm)	Surgical masks provided the same amount of protection as to not wearing a mask	Limited by bio-aerosols larger than influenza

Table 3. —continued

Author, Date, Reference	Type of Mask	Challenge Particle, Size	Laboratory Findings	Limitations for Generalizability of Laboratory Findings
Rengasamy et al (60)	N95	Ag particles (0.0046 μm -0.0151 μm) NaCl (0.02 μm -0.4 μm)	Efficiency of N95 mask against bio-aerosol particles (4.6–400 nm): >99%	Limited by use of inert particles
van der Sande et al (61)	N95 Surgical	Ambient particles (0.02–1.0 μm)	N95 masks provide adults 25 \times more protection than surgical masks Children 6 \times more protection than surgical masks Children were significantly less protected than adults for all masks types ($p < 0.001$)	—
Wake et al (62)	Surgical	<i>Pseudomonas alcaligenes</i> (2.0 μm)	Efficiency of surgical mask against bio-aerosol (0.7–2.0 μm): 17–99%	Limited by use of particles larger than influenza
Redmayne et al (63)		<i>Bacillus subtilis</i> (0.7–0.8 μm) <i>Micrococcus luteus</i> (0.9–1.8 μm) NaCl test system (1.5–9.0 μm)	Efficiency of surgical masks against inert particle (1.5–9.0 μm): 1.5–99%	
Weber et al (64)	Surgical	Corn oil particles (0.1–4.0 μm)	Efficiency of surgical masks against inert particle: 0%–80%	Limited by use of inert particles
Willeke et al (65)	Surgical	—	Efficiency of surgical masks: 0%–80%	—
Willeke et al (66)	Surgical	<i>Pseudomonas fluorescens</i> (0.7–0.8 μm) Corn oil particles	Efficiency of surgical mask against bioaerosol (0.7–1.0 μm): 80%–88%	Limited by use of particles larger than influenza
Willeke et al (67)	N95	NaCl (0.2 μm) <i>Bacillus subtilis</i> (0.8 μm)	Efficiency of surgical masks against inert particle (1.4–0.5 μm): 68% Efficiency of N95 mask against NaCl: 96.2%–96.8% Efficiency of N95 mask against bio-aerosol: >99.5%	Limited by use of particles larger than influenza

Ag, silver; KCl, potassium chloride; NaCl, sodium chloride; CDC, Centers for Disease Control and Prevention; NIOSH, National Institute for Occupational Safety and Health; PSL, polystyrene latex particle.

disclosure, however, as to whether any other HCW were present and, if so, to what extent was their exposure to SARS patients and whether masks were used. Of the 110 exposed HCW during SARS across eight American hospitals, 52% were reported to have worn N95 masks whereas 48% did not use any mask; 44% of the HCW exposed were within a 1-meter respiratory zone of a SARS case without a mask and 40% who were exposed to a coughing patient did so while not wearing a mask (38). None of the 44% of exposed HCW acquired SARS despite the lack of protection. Yet, the lack of SARS transmission in HCW may have been attributable to an absence of high risk or shedding cases. In a case series of 17 Canadian HCW with occupationally acquired SARS, 93% wore an N95 mask in the patient's room and 87% also wore a N95 mask within the SARS designated ward. However, these 17 infected HCW were documented to have inconsistently or incorrectly used N95 masks while utilizing other

infection control measures such as gowning, gloving, and hand hygiene (39). No details of compliance of use of these additional precautions were provided.

Articles on the Use of Both N95 and Surgical Masks

A case-control study of SARS in HCW in five Hong Kong hospitals examined the effect of surgical mask use and N95 mask use in 13 HCW who acquired SARS. All 13 HCW who acquired SARS did not wear either a surgical or a N95 mask. Reanalysis concurred that more HCW infected with SARS did not wear either a N95 or a surgical mask compared with mask users ($p = .00003$) (27). Consistent use of N95 masks in a Canadian intensive care unit with SARS patients significantly reduced the risk of contracting SARS by 78% (RR, 0.22; 95% CI, 0.05–0.93; $p = .06$) compared with inconsistent mask use (26). In fact, consistent use of either type of mask significantly reduced the risk of SARS

infecting HCW by 77% (RR, 0.23; 95% CI, 0.07–0.78; $p = .02$) when compared with inconsistent use of either mask. Reanalysis identified equivocal levels of protection that may have been attributable to inadequate sample size for consistent N95 mask use compared with inconsistent N95 mask use (OR, 0.11; exact 95% CI, 0.01–1.1; $p = .058$) as well as for consistent use with N95 mask compared with consistent use of a surgical mask (OR, 0.43; exact 95% CI, 0.02–33.6; $p = .51$).

The protective effects of N95 mask use by HCW when combined with symptomatic patients wearing a surgical mask has been examined in two studies (40, 41). A cross-sectional survey of 223 HCW exposed to five SARS patients in a Taiwanese hospital assessed the effect of infection control measures before and after mask implementation (40). Before the mask intervention, 73 HCWS were in the same room as a SARS patient, 46 HCW had direct contact with a SARS patient,

and 37 HCW had direct exposure to respiratory secretions from infected patients. Despite only 51%, 65%, and 54% of HCW, respectively, wearing masks in these situations, no HCW was found to be serologically positive for SARS. After an intervention, which included HCW wearing N95 masks, 155 HCW had been in the same room as a SARS patient. Of these 155 HCW, 132 had direct contact with a SARS patient and 92 were exposed to the respiratory secretions of SARS-infected patients. After the implementation of N95 mask use, compliance with mask use improved significantly ($p < .001$) in the reported three scenarios and only one HCW was infected. A case series using HCW caring for all suspected and probable SARS pediatric patients admitted to an ultra-high-risk isolation ward were examined for the protective value of patients wearing surgical masks while HCW wore N95 masks (41). None of the 26 HCW cohorts who nursed ultra-high-risk patients acquired SARS. The findings supports the use of surgical masks by the SARS patient together with compliance of other personal protective equipment and infection control measures because these may act synergistically to confer protection.

Only one study could not find a protective effect of either N95 or surgical masks for the HCW (25). In a case-control study of HCW in a Hong Kong hospital, inconsistent use of either mask type did not alter the risk of SARS acquisition for HCW who had direct SARS patient contact (OR, 2.0; 95% CI, 0.5– ∞ ; $p = .67$) (25). Furthermore, regardless of consistency of use, N95 masks could not be shown to reduce the risk of SARS acquisition for HCW who had direct SARS patient contact (OR, 2.9; 95% CI, 0.7–13.7; $p = .1683$). These findings were possibly attributable to the study being under-powered and were mirrored in our reanalysis. We found that HCW who used a N95 or surgical mask during direct contact with patients were neither significantly protected nor significantly at risk for SARS compared with HCW who did not wear a mask (OR, 4.1; exact 95% CI, 0.2–241.0; $p = .26$).

Articles on the Use of Multiple Masking

The World Health Organization reported a case series of three HCW who acquired SARS, one of whom wore a surgical mask beneath an N95 mask, from

two SARS-infected patients in a Philippines hospital (42). All three cases reported varying compliance with infection control measures and it was not possible to evaluate the effectiveness of either mask type.

Laboratory Studies Investigating the Filtering Efficiency of Mask Use

Twenty-five publications describing filtering efficiency of either N95 masks or surgical masks were found (Table 2). Six laboratory studies (43–48) tested both N95 and surgical masks for the ability to limit penetration of inert and bio-aerosol challenges and found that N95 masks afford more protection to the wearer than surgical masks. Five studies reported N95 masks excluded at least 95% of particles within the most penetrating particle size range of 0.1 to 0.3 μm (48, 49, 53, 60, 67). However, variability of the filtering efficiency between and within models of N95 and surgical masks did exist (43, 44, 50, 58, 62, 65). Models of surgical masks achieved filtering efficiencies from 0% to 99%, with a median of 40%, whereas variability within the N95 model ranged from 95% to 99.5%.

DISCUSSION

This review has found an absence of high-level study designs with conclusive evidence describing the effectiveness of both surgical and N95 mask use in HCW. The highest level of evidence emerged from five case-control studies (22, 24–27) and one cohort study (31). Four of these studies reported mask use alone conferred protective benefit and after reanalysis these claims were upheld for three of these studies (22, 24, 27). Additionally, four cross-sectional studies (23, 28, 38, 40), two time series (29, 30), three case reports (36, 37, 41), and six case studies (32–35, 39, 42) investigated mask protectiveness; six studies (28, 29, 33, 41) reported masks being protective, of which four (28, 29, 33, 41) used masks concurrently with other infection control measures, eight studies (32, 34–39, 42) could not conclusively determine the protective value, and one study concluded masks did not confer protection (30). Of the 25 laboratory studies, two used influenza virus, (44, 45) and only one tested both mask types (45).

Lack of compliance is a common issue and is one of the most important confounders that was not controlled for in most of the studies reviewed. In a cross-sectional study of mask compliance among nurses working with communicable respiratory diseases (68), 42% of nurses were compliant with mask precautions. This study, performed outside of any specific epidemic, highlights contributing factors for compliance such as contamination from incorrect donning and doffing order, availability of masks, organizational support, and long and difficult procedures. As a case in point, during SARS, lack of masks and difficult procedures, such as intubation, were identified as risk factors for occupational acquisition of infection (26, 39). Lack of education about correct donning and doffing of masks may also reduce the protective effect. Correct mask use is not intuitive, with up to 65% of HCW not donning masks correctly (69–71), which is only marginally better than 78% of the general public who cannot use masks correctly (72). Education and training may improve compliance rates; however, infrequent use of masks undermine the effects of education (71). Compliance may be further compromised by discomfort of surgical masks (73), local irritation associated with N95 mask such as acne (74), heat and humidity stress (75), and tolerability of CO₂ build-up associated with air-purifying full-face-piece respirator mask (76–77). The N95 mask structure consists of four to five layers of polypropylene sandwiching one to two layers of electret that may account for CO₂ accumulation, inducing reports of headaches (78) and high heart rates in N95 masks users (75). However, it has been suggested that such side effects may be more likely to be related to poor fitting than the mask structure itself (78–79).

Fit-testing of N95 masks came to prominence during SARS and is a method to assess whether mask seal has been achieved to minimize mask leakage. A sealed mask still has to be established as principally preventing entry of particles of 0.3 μm in size into the nasopharynx or increasing the comfort for the wearer, which in turn may reduce the need to touch the mask with contaminated hands. Case studies (32, 34–37, 39, 42) and studies examining both mask types (25–27, 41) that did not establish a superior protective value

of N95 masks may have been the result of ill-fitting masks or simply a lack of under-powered sample. Inconsistent filtering efficiency together with compliance and correct issues might partially explain the occupational acquisition of SARS by HCW (32–34, 36, 39, 40, 42) despite HCW using mask use. The generalizability of the *in vitro* laboratory studies is limited by the use of particles that are inert or larger than influenza and that travel at constant air flow rates, which is atypical of respiratory events such as coughing and sneezing. The use of inert particles traveling at constant speed of constant size are a potentially serious effect modifier (which can either fallaciously increase or decrease filtering efficacy).

It is accepted that droplet-transmitted diseases, such as tuberculosis, varicella, and measles, are spread by evaporated droplets containing infectious particles being disseminated into the air and traveling small distances (<1-meter) because of their large size (>5 μm). It is therefore not surprising that two reviewed studies of RSV acquisition (30, 31) found that surgical masks did not provide HCW with significant protective benefit. In these circumstances, gowning and gloving may play a far more important role in controlling transmission than surgical masks. Meanwhile, the mode of transmission of influenza remains contentious (80–82). Viable influenza virions have been observed to be transmitted beyond 1-meter and remain suspended in the air for up to 24 hrs (83). During a human sneeze, approximately 40,000 particles of 0.5 μm to 12 μm in size are released at 100 meters per second (84, 85). Sneezed particles containing *Streptococci*, of 0.5 μm to 1.0 μm in size, have traveled as far as 2.9 meters and remain suspended at 0.9 meters above the ground (86). Sneezed particles of shedding influenza patients will most likely contain influenza virions and, for the purpose of protecting HCW, it would be rational to assume an influenza particle, only 0.1 μm in size, may also travel up to 2.9 meters. Animal models determining the communicability of influenza over distances found infection in susceptible ferrets when placed 1.6 meters away and >1 meter above infected ferrets and guinea pigs (87, 88). Transmission of influenza also occurred between infected and uninfected ferrets separated by a U-bend and

S-bend tube of 2.5 meters in length and connected only by an airstream comparable to that of human breathing (87). These transmission models and theoretical examples are highly suggestive that aerosol transmission of influenza is plausible. Historically, a 1-meter respiratory zone for masking against droplet spread has been deemed effective (89, 90) based on experimental studies with smallpox. More recently the 1-meter zone has been disputed, albeit by retrospective studies examining transmission of SARS outbreaks (91). The Healthcare Infection Control Practices Advisory Committee in the United States (92) has also recently advised that a 6-foot to 10-foot (2–3 meters) zone is prudent for masking purposes and that distance should not be the only criterion for deciding when a mask should be donned. Because eye protection has been found to reduce the incidence of a droplet-spread infection (93) and because of the potential for influenza to be airborne-spread (87, 88), it may now be necessary to rethink policy and couple mask use with goggles or a face shield.

The protective effect of masks may only be apparent when mask use is bundled with other infection-control measures (25). Rather, a synergistic combination of mask use with, for example, the decontamination of hands before doffing masks or a comfortable mask that does not induce the need to adjust it, may better-protect HCW from infection than mask use alone. In the event of a pandemic, mask use will not be used as a single protective measure for HCW. Rather, mask use will be bundled with prophylaxis, vaccination, and other PPE, (33, 28, 30, 41, 31, 24, 29), including face shields or goggles, plus a heightened compliance with PPE donning/doffing technique and hand hygiene. However, the bundling effect will always limit the ability to establish the individual protective value of either mask.

CONCLUSIONS

World Health Organization guidelines recommend surgical masks for all patient care with the exception of N95 masks for aerosol-generating procedures (94). Because of the paucity of high-quality studies in the healthcare setting, the current guidelines for the advocacy of certain mask types cannot be supported or nullified

given the current evidence. Guidelines should reconsider the current 1-meter respiratory zone in view of the laboratory evidence of airborne-spread influenza. A larger respiratory zone and possible airborne spread of influenza also has implications for the protection of HCW from ocular inoculation.

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