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Review

P2/N95 respirators & surgical masks to prevent SARS-CoV-2 infection: Effectiveness & adverse effects

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Cross infection

Abstract *Background:* Millions of people have acquired and died from SARS-CoV-2 infection during the COVID-19 pandemic. Healthcare workers (HCWs) are required to wear personal protective equipment (PPE), including surgical masks and P2/N95 respirators, to prevent infection while treating patients. However, the comparative effectiveness of respirators and masks in preventing SARS-CoV-2 infection and the likelihood of experiencing adverse events (AEs) with wear are unclear.
Methods: Searches were carried out in PubMed, Europe PMC and the Cochrane COVID-19 Study Register to 14 June 2021. A systematic review of comparative epidemiological studies examining SARS-CoV-2 infection or AE incidence in HCWs wearing P2/N95 (or equivalent) respirators and surgical masks was performed. Article screening, risk of bias assessment and data extraction were duplicated. Meta-analysis of extracted data was carried out in RevMan.
Results: Twenty-one studies were included, with most having high risk of bias. There was no statistically significant difference in respirator or surgical mask effectiveness in preventing SARS-CoV-2 infection (OR 0.85, [95%CI 0.72, 1.01]). Healthcare workers experienced significantly more headaches (OR 2.62, [95%CI 1.18, 5.81]), respiratory distress (OR 4.21, [95%CI 1.46, 12.13]), facial irritation (OR 1.80, [95%CI 1.03, 3.14]) and pressure-related injuries (OR 4.39, [95%CI 2.37, 8.15]) when wearing respirators compared to surgical masks.
Conclusion: The existing epidemiological evidence does not enable definitive assessment of the effectiveness of respirators compared to surgical masks in preventing infection. Healthcare

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workers wearing respirators may be more likely to experience AEs. Effective mitigation strategies are important to ensure the uptake and correct use of respirators by HCWs.

Highlights

- Respirators and surgical masks are worn by HCWs to prevent SARS-CoV-2 infection.
- Observational epidemiological studies with high bias risk have compared their effects.
- Respirator use might lead to HCWs experiencing more AEs than surgical mask use.
- The difference in infection risk between surgical mask and respirator use is unclear.
- Our findings should not be used to justify decisions for or against respirator use.

Introduction

Coronavirus disease (COVID-19) is a serious acute respiratory syndrome caused by the coronavirus SARS-CoV-2, which was declared a worldwide pandemic in March 2020 [1]. The virus can be transmitted from an infected person's mouth or nose in the form of respiratory particles which can then infect others through contamination of their eyes, nose or mouth [2,3].

In healthcare settings, personal protective equipment (PPE) respiratory protection usually includes a surgical mask or P2/N95 respirator. PPE is considered only one method of preventing SARS-CoV-2 transmission and it is recommended that it be used within a suite of control measures [4,5]. Prevention of virus transmission needs to be based on the hierarchy of controls, such as isolation, effective ventilation, and administrative controls such as physical distancing, surveillance testing, hand hygiene, vaccination and the use of PPE [5]. Application of PPE also needs to be balanced with patient care and interaction risk assessment to match appropriate application of PPE [6].

A surgical mask is made of disposable material that ties around the back of the head and is designed for use in procedures that do not require respiratory protection from the airborne transmission pathway [7]. Particulate respirators, such as P2/N95 or equivalent (e.g. FFP2, KN95 and KF94 respirators) herein referred to as "respirators", are designed to protect the wearer from the inhalation of respiratory particles. Unlike surgical masks, respirators are required to meet a standard to reduce exposure of the wearer by at least 95% of particles in the wearer's breathing zone. It has been reported that respirators protect the wearer from 96% of coronavirus transmission, compared to surgical masks that offer 67% protection [8]. Respirators have historically been preferred in the healthcare setting when the risk of pathogen transmission via respiratory particles (e.g. respiratory viruses) is considered likely [9].

To date, insufficient high-quality epidemiological evidence exists to support healthcare workers (HCWs) using P2/N95 respirators instead of surgical masks to prevent SARS-CoV-2 infection [10]. A previous meta-analysis examining the effectiveness of respirators compared to surgical masks in preventing infection of HCWs by respiratory viruses (e.g. influenza, adenovirus, echoviruses and coronaviruses) found no significant difference between surgical masks and respirators [11], with these findings further supported by a recent network meta-analysis [12]. Inconsistencies related to the understanding of the effectiveness of surgical masks and respirators for preventing SARS-CoV-2 infection among HCWs in different clinical contexts (e.g. when performing perceived high risk procedures compared to not) have contributed to the production of respiratory protection guidelines over the course of the COVID-19 pandemic that have different recommendations [13].

HCWs are at the forefront of SARS-CoV-2 infection management. They are exposed to symptomatic and asymptomatic people who might be infected with SARS-CoV-2, making them susceptible to infection themselves [14]. Due to the uncertainty surrounding the infection status of individual people, HCWs have been required in guidelines, health and safety legislation and by workplace management to wear PPE, such as surgical masks and respirators, as one means to prevent infection [15]. However, mandating mask and respirator use might not lead to use, suggesting that barriers to use are important considerations when mandating specific PPE [16]. During the pandemic, HCWs have needed to wear PPE for several hours and days in a row, rendering them susceptible to adverse events (AEs) associated with prolonged contact between mask material and the skin [17—19], such as injury and absenteeism [20], prompting measures to be taken to protect the skin of HCWs wearing PPE [21].

The aim of this systematic review and meta-analysis was to examine the differences in likelihood of SARS-CoV-2 infection and AEs between HCWs using respirators and surgical masks. The findings of this review were referenced in the development of practice recommendations guiding PPE choice by Australian HCWs [6].

Methods

Protocol

The selection criteria were determined a priori and approved by the Infection Prevention and Control (IPC) Panel of the National COVID-19 Clinical Evidence Taskforce.

Eligibility criteria

A Population, Intervention, Comparator and Outcome (PICO) framework was used to frame the following inclusion criteria:

- Population: HCWs (e.g. doctors, nurses, allied health professionals and support workers) working in settings involving contact with individuals diagnosed or potentially infected with SARS-CoV-2, such as primary care, tertiary care, residential care, patient transport and managed quarantine
- Intervention: FFP2, N95, KN95, KF94, P2 or equivalent respirators
- Comparator: surgical masks
- Outcomes: SARS-CoV-2 infection or AEs (e.g. signs and symptoms of skin conditions)
- Study design: all pre-print or peer-reviewed comparative epidemiological studies.

No date limits were applied. Only studies published in English that directly compared infection and AE outcomes of respirator or surgical mask were included.

Search methods

The rapid living systematic review on the effectiveness of PPE in preventing SARS-CoV-2 infection in HCWs by Chou, Dana [10] was used to identify relevant effectiveness studies published before December 2020. PubMed and the Cochrane COVID-19 Study Register (to ensure planned studies were identified and monitored for published results) were frequently searched to identify emerging data on infection incidence from December 2020 to 14 June 2021 using a search strategy adapted from Chou et al., 2020. These databases, and Europe PMC (restricted to preprints), were also searched on 14 June 2021, but without date restrictions, using terms specific to AEs (Supplementary material). During the same period, Research Square and medRxiv were screened daily for preprints, and the New South Wales Health COVID-19 Critical Intelligence Unit Daily Evidence Digest was scanned daily for additional sources of information (such as guidance documents).

Screening

Potentially eligible citations were imported into Covidence, an online systematic review tool, for screening. Full-text screening was performed in duplicate, with reasons for exclusion documented. Conflicts were resolved by consensus or third reviewer.

Data extraction and synthesis

Data were extracted in duplicate with conflicts resolved by consensus or third reviewer. Review Manager (RevMan 5.4) was used to pool results using the Mantel-Haenszel method and random effects model to calculate odds ratios and 95% confidence intervals (95%CI). Data on AEs and infection were extracted as event counts where possible, allowing the calculation of odds ratios. Erythema data were pooled to form standardised mean differences (SMD) and standard deviations (SD) using a random effects model.

Risk of bias assessment

Two researchers independently assessed the risk of bias using either the ROBINS-I tool for non-randomised studies or the RoB-2 tool for randomised studies [22,23]. Differences were resolved by consensus.

Results

Study selection

After removing duplicates, 2646 records were screened. The full texts of 268 were screened for eligibility, from which 21 studies met the inclusion criteria (Fig. 1).

Study characteristics

Most studies were observational, with only one being an RCT, and included adults with a mean age between 29 and 46 years. Most had a majority female representation (ranging from 39% in Niikura, Fujishiro [24] to 90% in Han, Shin [25]). Most studies compared HCWs wearing surgical masks or N95 respirators (n = 16), and the remaining studies compared HCWs wearing surgical masks compared to KF94 or KF95 (n = 1), FFP2 (n = 3) or various respirator types (n = 1). Studies were conducted in several different countries (although the USA was the most represented [n = 8]) and ranged widely in participant number (e.g. 20 participants in Han, Shin [25] compared to 20,614 in Sims, Maine [26]) (Table 1).

Risk of bias within and across studies

The majority of the studies were at high risk of bias (n = 18/21) [16,24,26—41] primarily due to the potential for recall bias (e.g. use of self-report surveys), participation bias (e.g. potential for only those with specific interest to participate) and small participant numbers. Further, adjustment for several confounding variables that might impact the likelihood of acquiring SARS-CoV-2 or AEs was lacking. Descriptions of SARS-CoV-2 activity in the community and the predominant variant (where greater activity in the community suggests greater infection risk [29]), vaccination status of HCWs, clinical tasks performed by HCWs, use of respirator fit-testing and checking, type and use of additional PPE, comorbidities expected to exacerbate potential AEs (e.g. smoking and allergies [34]), duration of wear and mitigation strategies used to reduce AE incidence or severity were inconsistently reported. Furthermore, the use of PPE outside of the healthcare setting was rarely discussed, potentially leading to inaccuracies in infection and AE counts assumed to result from exposure to SARS-CoV-2 in the healthcare setting alone. The infection and AE count, and consequently our summarised findings, might be influenced positively or negatively by any or all of these variables.

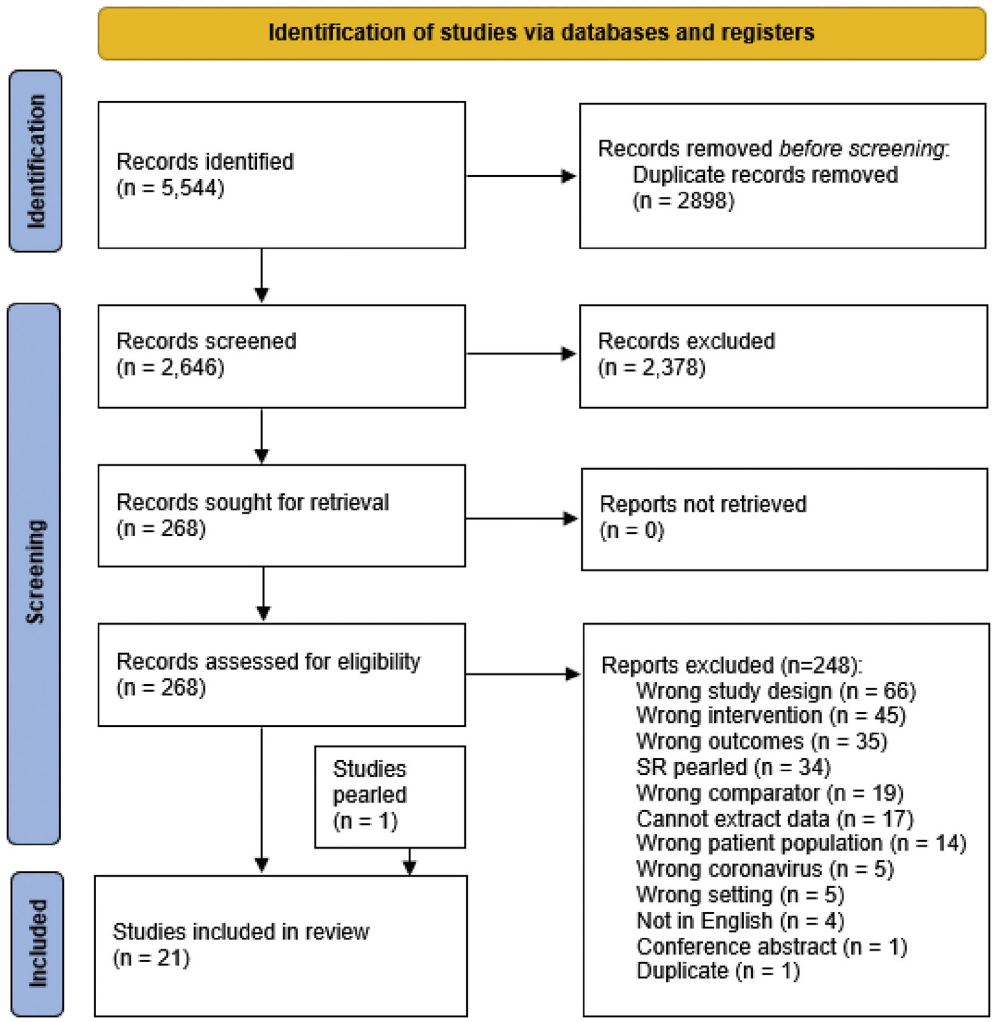

Figure 1 PRISMA flow chart. Template adapted from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021; 372:n71. https://doi.org/10.1136/bmj.n71.

Results synthesis

Twelve studies reported the rate of SARS-CoV-2 infection in HCWs who wore surgical masks compared to those who wore respirators [16,24,26–29,31,33,35,37,38,40]. Overall, a similar percentage of HCWs wearing respirators (1398/15,598 = 8.96%) and surgical masks (1698/17,947 = 9.46%) acquired SARS-CoV-2 infection (Fig. 2). The likelihood of HCWs becoming infected with SARS-CoV-2 did not significantly differ between HCWs wearing respirators compared to those wearing surgical masks (OR 0.85, [95%CI 0.72, 1.01], I^2 = 60%) (Fig. 2).

Eight studies contributed data to the meta-analyses of AEs [25,30,32,34,36,39,41,42], with findings from Zuo, Hua [43] unable to be statistically combined. Healthcare workers wearing respirators reported more AEs than those wearing surgical masks, specifically:

- De novo headaches (respirator = 99/159 [62.3%], surgical mask = 156/314 [49.7%]);
- Respiratory distress or shortness of breath (respirator = 83/148 [56.1%], surgical mask = 52/217 [24.0%]);
- Facial itching or irritation (respirator = 66/256 [25.8%], surgical mask = 51/256 [19.9%]);
- Sweating (respirator = 1263/1485 [85.1%], surgical mask = 93/494 [18.8%]);
- Pressure-related injuries (respirator = 878/1523 [57.6%], surgical mask = 94/532 [17.7%]); and
- Attention deficit or disorders (respirator = 33/76 [43.4%], surgical mask = 40/145 [27.6%]).

Healthcare workers wearing respirators were significantly more likely to experience de novo headache (OR 2.62, [95%CI 1.18, 5.81], I^2 = 67%) [30,32,39], respiratory distress or shortness of breath (OR 4.21, [95%CI 1.46, 12.13], I^2 = 78%) [30,32,34], facial itching or irritation (OR 1.80, [95%CI 1.03, 3.14], I^2 = 0%) [30,32,41] and pressure-related injuries (OR 4.39, [95%CI 2.37, 8.15], I^2 = 52%) [30,41,42] compared to HCWs wearing surgical masks (Fig. 3).

Table 1 Characteristics of the 21 studies examining the comparative efficacy of respirators and surgical masks in preventing SARS-CoV-2 infection (n = 12) in HCWs and adverse events (n = 9) reported after wear.

Author Study design Risk of bias (RoB)	Study aim	Population characteristics	Results summary and additional considerations (e.g. mask wear time)
Included studies measuring AEs reported after wearing respirators and surgical masks			
Garra et al., 2021 Retrospective cohort High RoB	Identify the adverse effects of using extended-use N95 respirators compared to surgical masks.	N = 144 (*Respirator n = 72, Surgical mask n = 72*) Mean age: 35 years Female: n = 85 (59%) Country: USA Study period: September, 2020 Setting: Hospital	Significantly more facial bruising was reported from respirators compared to surgical masks ($p < 0.01$). Otherwise, no difference in the reporting of other symptoms was detected between the groups. Participants were required to wear a mask for ≥2 h to be eligible for the study. Mean wear time was >5 h for all participants, with no statistically significant differences between groups (surgical mask = 6.8 h, respirator = 5.7 h).
Han et al., 2021 RCT Low RoB	Evaluate the effects of surgical masks and KF94 (FFP2 equivalent) respirators on the skin barrier.	N = 20 (*Respirator n = 10, Surgical mask n = 10*) Mean age: Respirator = 38 years, Surgical mask = 35 years Female: n = 18 (90%) Country: South Korea Study period: NR Setting: Hospital	More erythema was experienced in skin areas covered by respirators compared to surgical masks, albeit not statistically significant. Furthermore, there were no significant differences in skin hydration, sebum secretion, and pH between surgical mask and respirator groups. 70% of surgical mask users wore them for >8 h, compared to 60% of respirator users. There was no statistically significant difference in mask wear time between the groups.
Ipek et al., 2021 Controlled interrupted time series High RoB	Identify adverse events associated with N95 respirator use compared to surgical mask use (after maximum wear time of 4 h).	N = 34 (*Respirator n = 34, Surgical mask n = 34*) Mean age = 31 years Female: n = 19 (56%) Country: Turkey Study period: NR Setting: Hospital	The use of N95s was significantly associated with greater reporting of headache, respiratory distress, drowsiness, facial sweating, drowning sense, concentration difficulties and fatigue compared to surgical masks. No significant difference between groups was seen for dizziness, facial itching, coughing, sneezing and dying sense between the groups.
Jiang et al., 2021 Cross-sectional Low RoB	Explore the associations between use of protective masks and goggles with skin injuries.	N = 1611 (*Respirator n = 1301, Surgical mask n = 310*) Mean age: 33 years Female: n = 1340 (83%) Country: China Study period: February, 2020 Setting: Hospital	The use of N95 respirators and goggles was associated with significantly more skin injuries (device-related pressure injuries, moisture-associated skin damage and skin tears) than surgical masks and goggles (89.5% vs 37.4%, $P < 0.001$). The majority of HCWs wearing respirators and goggles (1,157, 88.9%), and surgical masks and goggles (271, 87.4%), wore them for >4hr, with no statistically significant difference in wear time between groups. The average daily wear time for all respondents was 6.9 h.
Maniaci et al., 2021 Cross-sectional	Evaluate the impact of surgical mask and	N = 277 (*FFP2 Respirator n = 42,*	The occurrence of nasal symptoms ($p = 0.001$) and pulmonary disorders

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Table 1 (*continued*)

Author Study design Risk of bias (RoB)	Study aim	Population characteristics	Results summary and additional considerations (e.g. mask wear time)
High RoB	respirator use on health issues and working performance of HCWs	*Surgical mask n = 111*) Mean age: 43 years Female: n = 121 (44%) Country: Italy Study period: April 1 – June 31, 2020 Setting: Hospital	(p = 0.002) were more likely for HCWs wearing respirators compared to surgical masks, with the occurrence of any adverse event considered more likely in those wearing FFP2 respirators compared to surgical masks (p = 0.003). The majority (68.9%) of respondents wore masks/respirators for >6 h.
Montero-Vilchez et al., 2021 Cross-sectional High RoB	Evaluate the impact of using masks on the skin barrier and its function	N = 34 (*Respirator n = 16, Surgical mask n = 18*) Mean age: 45 years Female: n = 21 (62%) Country: Spain Study period: April–May, 2020 Setting: Hospital	Erythema was significantly greater in areas covered by either mask type. More erythema was present for those wearing surgical masks compared to FFP2 respirators but this finding was not significant (p = 0.640). Transepidermal water loss was significantly greater in areas covered by a surgical mask compared to a respirator (p = 0.034). Daily mask wear time was not stated but each respondent needed to wear a mask for >2hr to be included in the study.
Ramirez-Moreno et al., 2020 Cross-sectional High RoB	Identify any associations between mask use and de novo headache incidence.	N = 306 (*FFP2/N95/KN95 Respirator n = 53, Surgical mask n = 208*) Mean age: 43 years Female: n = 244 (80%) Country: Spain Study period: May 2020 Setting: Hospital	Occurrence of a de novo headache is more likely when using a respirator compared to a surgical mask (OR = 2.14 [95%CI 1.07, 4.32]) when controlling for profession and asthma. Headache intensity was significantly greater in those using respirators (VAS 5.7 [SD 1.5] vs 6.5 [SD 1.2], p = 0.004). Mean surgical mask wearing time was greater (7.0 h) than mean respirator wearing time (6.7 h). However, this was not statistically significant.
Zaib et al., 2020 Retrospective cohort High RoB	Identify the incidence of skin conditions associated with surgical mask and N95 respirator use. Establish responsiveness of symptoms to application of topical methylprednisolone.	N = 300 (*Respirator n = 150, Surgical mask n = 150*) Mean age: Not reported Female: n = 126 (42%) Country: Pakistan Study period: April 2020 Setting: Hospital	Most participants using surgical masks (66%) and respirators (51%) reported no skin complaints. Use of respirators was associated with greater reporting of sweating, folliculitis, erythema, contact dermatitis and frictional hyperpigmentation when compared to surgical mask use. 67% of those with contact dermatitis had improvement in symptoms with use of topical methylprednisolone. Daily mask wear time was not stated.
Zuo et al., 2020 Cross-sectional Unclear RoB	Characterize adverse reactions related to N95 respirator and surgical masks among HCWs in China.	N = 404 (*Respirator n = 38, Surgical mask n = 366*) Mean age: Not reported Female: n = 304 (75%) Country: China Study period: February, 2020	Use of respirators were associated with a higher incidence of facial skin symptoms compared to using surgical masks (OR = 2.63 [95%CI 1.3, 5.4]) when adjusted for sex, allergies, underlying inflammatory facial dermatosis, frequency and duration of use mask use.

Table 1 (*continued*)

Author Study design Risk of bias (RoB)	Study aim	Population characteristics	Results summary and additional considerations (e.g. mask wear time)
		Setting: Hospital	The majority (56.9%) of respondents wore either a surgical mask or respirator for >4 h.
Included studies measuring SARS-CoV-2 infection			
Akinbami et al., 2020 Cross-sectional study High RoB	Identify the prevalence of SARS-CoV-2 antibodies in HCWs wearing different mask types.	N = 16,397 (*Respirator n = 7,316, Surgical mask n = 9452*) Mean age: 42 years Female: n = 11,251 (69%) Country: USA Study period: May—June, 2020 Setting: Hospital	A similar proportion of HCWs who wore a surgical mask (6.6% [95%CI 6.1—7.1]) or a N95 respirator (6.9% [95% CI 6.3—7.5]) all the time tested positive for SARS-CoV-2. Consistently using either a respirator (aOR 0.83 [95%CI 1.002—1.35]) or surgical mask (aOR 0.86 [95%CI 0.75—0.98]) decreased the likelihood of testing positive for SARS-CoV-2.
Bryan et al., 2021 Cross-sectional study High RoB	Estimate the seroprevalence of SARS-CoV-2 antibodies among HCWs. Identify demographic and occupational factors associated with SARS-CoV-2 antibodies in HCWs.	N = 1290 (*Respirator n = 430, Surgical mask n = 681*) Mean age: 46 years Female: n = 543 (42%) Country: USA Study period: April 30 — June 30, 2020 Setting: Community and hospital	HCWs who always or most of the time wore a surgical mask had a slightly higher rate of SARS-CoV-2 infection (29.2%) than HCWs who always or most of the time wore a N95 or equivalent respirator (26.3%). Mean mask wearing time not reported.
Fletcher et al., 2021 Prospective cohort study. Parallel group. High RoB.	Compare the risk of asymptomatic COVID-19 disease between HCW with and without high-risk exposure outside the healthcare system across two time periods.	<u>Study period 1 (Aug 17-Sep 4 2020)</u> N = 1385 (*N95 Respirator n = 453, Surgical mask n = 792*) Mean age: 36 years in seropositive respondents, 40 years in seronegative respondents Female: n = 1104 (80%) Country: USA Setting: Community and hospital <u>Study period 2 (Dec 2-23 2020)</u> N = 1445 (*N95 Respirator n = 695, Surgical mask n = 635*) Mean age: 39 years in seropositive respondents, 40 years in seronegative respondents Female: n = 1156 (80%) Country: USA Setting: Community and hospital	<u>Period 1</u> A greater percentage of HCWs who tested positive for SARS-CoV-2 infection wore surgical masks (53.9%) compared to HCWs wearing respirators (38.5%). <u>Period 2</u> A lesser percentage of HCWs who tested positive for SARS-CoV-2 infection wore surgical masks (40.4%) compared to HCWs wearing respirators (51%). Mean mask wearing time not reported. Mask choice was determined by clinical role where surgical masks were the default choice for those in roles where enhanced respiratory protection was not considered applicable. HCWs who used enhanced respiratory protection (surgical mask or respirators) during exposure to SARS-CoV-2 in the healthcare setting had more asymptomatic disease than those who acquired the disease in the community, where they experienced more symptomatic disease.
Haller et al., 2021 Prospective cohort study High RoB	Identify the difference in SARS-CoV-2 infection between HCWs using	N = 3259 (*Respirator n = 716, Surgical mask n = 2543*)	A greater percentage of HCWs wearing surgical masks tested positive for SARS-CoV-2 compared to

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Table 1 (*continued*)

Author Study design Risk of bias (RoB)	Study aim	Population characteristics	Results summary and additional considerations (e.g. mask wear time)
	FFP2 respirators compared to surgical masks	Mean age: 39 years Female: n = 2645 (81%) Country: Switzerland Study period: June —August, 2020 Setting: Hospital	those who wore respirators. 14% of surgical mask users reported a positive SARS-CoV-2 swab, compared to 11% of respirator users. 19% of surgical mask users had documented seroconversion, compared to 13% of respirator users. There was no statistically significant difference in the number of HCWs using respirators or surgical masks testing positive for SARS-CoV-2. HCWs frequently exposed to COVID-19 were less likely to test positive for SARS-CoV-2 when using respirators compared to surgical masks (aOR 0.06, p = 0.035). Universal use of respirators when AGPs showed no statistically significant reduction in likelihood of testing positive for SARS-CoV-2. HCWs wearing respirators more often reported wearing masks outside of work (35% v 26%), being involved in AGPs (64% v 29%), working in ICU (26% v 4%) and having contact with >20 patients with COVID-19 (58% v 32%). Mean mask wearing time not reported.
Klompas et al., 2021 Case-control study High RoB	Identify the frequency of SARS-CoV-2 infection in HCWs and determine effective mitigation strategies.	N = 160 (*N95 Respirator all the time n = 3, Surgical mask all the time n = 71*) Mean age: not reported Female: not reported Country: USA Study period: September, 2020 Setting: Hospital	A greater percentage of HCWs who reported wearing surgical masks all the time tested positive for SARS-CoV-2 (23/71, 32%) compared to HCWs who wore respirators all the time (0/3, 0%). Respondents who tested positive for SARS-CoV-2 were less likely than those who did not to wear eye protection (30% vs 67%) Mean mask wearing time not reported.
Kumar et al., 2020 Retrospective cohort study High RoB	Identify risk factors of SARS-CoV-2 infection for HCWs	N = 40 (*Respirator n = 29, Surgical mask n = 11*) Mean age: 29 years Female: n = 28 (70%) Country: India Study period: April—May, 2020 Setting: Quarantine	One HCW (1/29) wearing a N95 respirator and no HCWs (0/11) wearing surgical masks tested SARS-CoV-2 positive. 96% of the quarantined HCWs had a definite history of contact with confirmed cases. Mean mask wearing time not reported.
Martischang et al., 2021 Prospective cohort study High RoB	Measure the number of HCWs who SARS-CoV-2 seroconverted and the risk factors for infection.	N = 3421 (*N95 Respirator n = 629, Surgical mask n = 1984*) Mean age: 42 years Female: n = 2654 (78%) Country: Switzerland Study period: March 30 —	A greater percentage of HCWs who reported wearing a surgical mask (9.9%) compared to a respirator (5.7%) seroconverted. HCWs who reported wearing a respirator were at lower risk of seroconversion (prevalence ratio 0.73 [95%CI 0.55,

Table 1 (*continued*)

Author Study design Risk of bias (RoB)	Study aim	Population characteristics	Results summary and additional considerations (e.g. mask wear time)
		June 12, 2020 Setting: Hospital	0.96]) A greater percentage of HCWs working in COVID-19 wards (32%) seroconverted compared to HCWs working in non-COVID-19 wards (12%). Mean mask wearing time not reported.
Ng et al., 2020 Retrospective cohort study Parallel group High RoB	Identify SARS-CoV-2 infection frequency in HCWs treating a patient who tested positive for SARS-CoV-2	N = 41 (*Respirator n = 6, Surgical mask n = 35*) Mean age: not reported Female: not reported Country: Singapore Study period: February, 2020 Setting: Hospital	No HCWs contracted tested positive for SARS-CoV-2 during the study. 85% of HCWs used a surgical mask and 15% used an N95 respirator during AGPs. HCWs were exposed to AGPs for at least 10min and within 2 m from the patient. Mean mask wearing time not reported.
Niikura et al., 2021 Retrospective cohort study High RoB	Evaluate the SARS-CoV-2 infection rate of HCWs performing endoscopic procedures	N = 384 (*Respirator n = 74, Surgical mask n = 310*) Mean age: 42 years Female: n = 151 (39%) Country: International Study period: April 15 — August 8, 2020 Setting: Endoscopy suite	None of the HCWs wearing N95 respirators or surgical masks became infected with SARS-CoV-2. Mean mask wearing time not reported.
Periyasamy et al., 2020 Retrospective cohort study High RoB	Evaluate the SARS-CoV-2 infection rate of HCWs performing AGPs on a SARS-CoV-2 positive patient admitted to ICU	N = 25 (*Respirator n = 6, Surgical mask n = 19*) Mean age: not reported Female: not reported Country: Malaysia Study period: NR Setting: Hospital	None of the HCWs wearing N95 respirators or surgical masks became infected with SARS-CoV-2. HCWs performing AGPs were exposed to the patient for approximately 34min (mean). Mean mask wearing time not reported.
Sims et al., 2020 Prospective cohort study High RoB	To assess COVID-19 exposure and infection risk associated with different job functions at a major hospital.	N = 20,614 (*Respirator n = 5,165, Surgical mask n = 1305*) Mean age: 43 years Female: n = 15,728 (76%) Country: USA Study period: April 13 — May 28, 2020 Setting: Hospital	HCWs with direct exposure to patients who had tested positive for SARS-CoV-2 tested seropositive significantly less often when wearing a N95 respirator (532/5,165, 10.2%) compared to surgical masks (171/1,305, 13.1%). Mean mask wearing time not reported.
Venugopal et al., 2021 Cross sectional study High RoB	Identify seropositivity for SARS-CoV-2 in HCWs in a New York City public hospital	N = 500 (*N95 Respirator n = 76, Surgical mask n = 109*) Mean age: 43 years Female: n = 329 (66%) Country: USA Study period: May, 2020 Setting: Hospital	137/500 (27%) of HCWs tested positive for SARS-CoV-2. 39/109 (36%) wearing surgical masks tested positive for SARS-CoV-2 in comparison to 19/76 (25%) using N95 respirators. Community exposure was 34% among those who had positive antibodies. Mean mask wearing time not reported.

Key: AE = Adverse events; AGP = aerosol generating procedure; aOR = Adjusted odds ratio; HCWs = healthcare workers; ICU = intensive care unit; IgG = immunoglobulin; NR = Not reported; OR = odds ratio; RCT = randomised controlled trial; RoB = risk of bias, determined by the ROBINS-I for observational studies, or RoB-2 for randomised trials; SARS-CoV-2 = Severe acute respiratory syndrome coronavirus 2; SD = Standard deviation; USA = United States of America.

Study or Subgroup	Respirator Events	Respirator Total	Surgical mask Events	Surgical mask Total	Weight	Odds Ratio M-H, Random, 95% CI
Akinbami 2020	505	7316	624	9452	20.2%	1.05 [0.93, 1.18]
Bryan 2021	113	430	199	681	14.3%	0.86 [0.66, 1.13]
Fletcher 2021a	10	453	14	792	3.6%	1.25 [0.55, 2.85]
Fletcher 2021b	101	695	80	635	12.6%	1.18 [0.86, 1.62]
Haller 2021	81	716	352	2543	14.8%	0.79 [0.61, 1.03]
Klompas 2021	0	3	23	71	0.3%	0.29 [0.01, 5.94]
Kumar 2020	1	29	0	11	0.3%	1.21 [0.05, 31.95]
Martischang 2021	36	629	196	1984	10.9%	0.55 [0.38, 0.80]
Ng 2020	0	6	0	35		Not estimable
Niikura 2021	0	74	0	310		Not estimable
Periyasamy 2020	0	6	0	19		Not estimable
Sims 2020	532	5165	171	1305	17.8%	0.76 [0.63, 0.92]
Venogopal 2021	19	76	39	109	5.2%	0.60 [0.31, 1.15]
Total (95% CI)		**15598**		**17947**	**100.0%**	**0.85 [0.72, 1.01]**
Total events	1398		1698			

Heterogeneity: Tau² = 0.03; Chi² = 22.46, df = 9 (P = 0.008); I² = 60%
Test for overall effect: Z = 1.85 (P = 0.06)

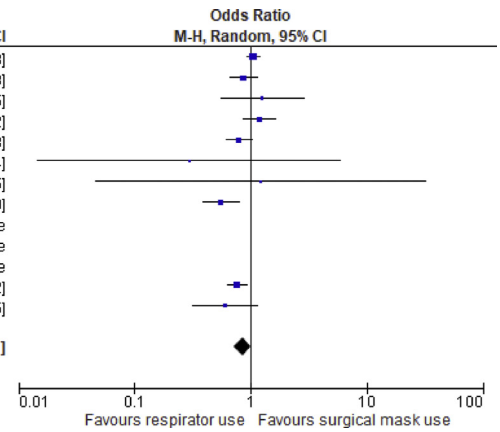

Figure 2 The odds of SARS-CoV-2 infection in healthcare workers who wore surgical masks compared to those who wore respirators in the clinical setting. Note: Fletcher et al., 2021, collected infection data at two time points (Fletcher 2021a: Aug 17-Sep 4 2020, Fletcher 2021b: Dec 2—23 2020). Those who tested positive at the first time point were excluded from analysis at the second time point.

The odds of experiencing sweating (OR 6.80, [95%CI 0.55, 84.68], $I^2 = 98\%$)) [32,41,42], and attention deficit or disorders (OR 2.59, [95%CI 0.62, 10.87], $I^2 = 77\%$)) [32,34] did not differ significantly between the groups (Fig. 3). Likewise, degree of erythema did not significantly differ between groups (SMD -0.29, [95%CI -0.82, 0.25], $I^2 = 0\%$) [25,36].

Discussion

This systematic review and meta-analysis of epidemiological studies aimed to compare the likelihood of HCWs acquiring SARS-CoV-2 infection and experiencing AEs when wearing surgical masks or respirators at work. Twenty-one studies contributed to the overall analysis, the majority of which had a high risk of bias, limiting our ability to provide definitive results. Results of meta-analyses did not find a statistically significant difference in the likelihood of HCWs wearing surgical masks or respirators becoming infected with SARS-CoV-2. However, HCWs wearing respirators had a higher likelihood of experiencing de novo headache, respiratory distress or shortness of breath, facial itching or irritation, and pressure-related injuries compared to those wearing surgical masks.

It should not be assumed that respirators do not provide superior protection from infection based on these results. Although the likelihood of infection was not significantly different between HCWs wearing surgical masks compared to respirators, the direction of effect favoured the use of respirators and the risk of bias of included studies was high, with many important confounders not adjusted for. For example, HCWs might be more likely to wear respirators when they work in high infection-risk situations, such as in intensive care units (ICU), or when performing aerosol-generating procedures. The use of various respirators during aerosol-generating procedures has been shown to reduce infection risk [44]. Thus, clinical context could influence infection risk and not adjusting for this could potentially bias infection outcomes towards the null. Therefore, the inability of this review to demonstrate a statistically significant difference in the effect of respirators and surgical masks in protecting against infection might suggest that current risk-stratification approaches, where those working in higher risk settings wear respirators, may effectively reduce SARS-CoV-2 transmission.

Without randomised trials with large participant numbers that control for relevant confounding factors (e.g. use of additional infection control measures), the conclusions regarding the comparison between respirators and surgical masks remain tentative, and guidelines specific to PPE use might remain inconsistent [13]. The ethics of deliberately exposing HCWs to SARS-CoV-2 in settings where safety may be compromised (e.g. ICU) remain questionable. Thus, studies that control for potential confounding variables are unlikely to be conducted. Consequently, it remains important to use existing infection prevention and control guidelines to guide the appropriate clinical use of respirators and surgical masks [5].

HCWs wearing respirators instead of surgical masks experience more AEs, potentially reducing their willingness to use them, or use them correctly (i.e. avoiding touching them). For example, itching can encourage the wearer to adjust a respirator, potentially putting them at a greater risk for infection by compromising the seal [43]. It has been suggested that the humidity from exhaled breath and sweat accumulation underneath a respirator, as well as the prevention of dry air entering the sealed space, could create pressure and moisture-related discomfort and skin damage [30,42,45]. In addition, a relationship might exist between hypercapnia and wearing of respirators, possibly contributing to headaches and shortness of breath in wearers [46]. Thus, seeing greater odds of HCWs wearing respirators experiencing pressure sores, facial itching or irritation, headaches and shortness of breath or respiratory distress is unsurprising. These effects might also be exacerbated the longer the mask is worn for [19,47]. Although these findings are supported by similar recently published literature [48], the small number of studies, wide confidence intervals, small sample sizes and the substantial potential for confounding (i.e. lack of controlling for stress and air ventilation [34,39]) suggests that caution should be taken when using these findings to inform decision making

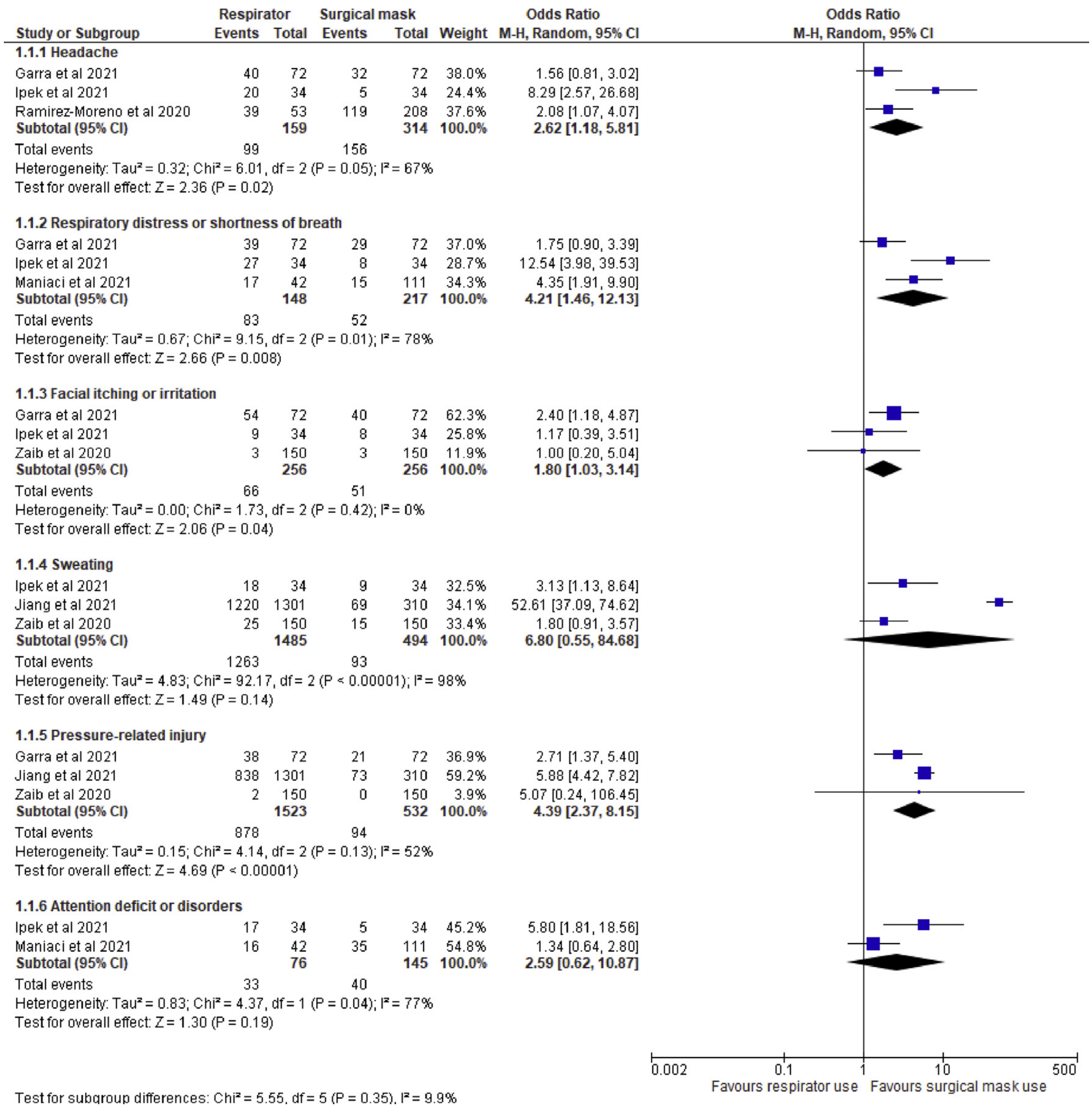

Figure 3 The odds of healthcare workers experiencing adverse events from wearing surgical masks compared to respirators in the clinical setting.

regarding PPE choice. The presence of AEs should not encourage HCWs to avoid respirator use, but instead encourage them to use appropriate mitigation strategies to ensure comfort and safety.

The Australian guidelines for SARS-CoV-2 infection prevention and control of COVID-19 in HCWs recommend that Australian HCWs have access to and use fit-tested and, at time of use, fit-checked respirators when there is a high risk of SARS-CoV-2 transmission to the HCW [6]. It is important to mitigate any AEs HCWs might experience when choosing to use a respirator to support effective use. Mitigation strategies used by HCWs include medical assessments to identify pre-existing skin or respiratory problems, early medical assessment should any AEs develop, fit-testing by a person competent in identifying the best-fitting respirator for the HCW, use of well-designed respirators (e.g. those that fit the face well, preventing the need to excessively tighten straps), taking breaks from respirator wearing or interchanging between mask types as appropriate (i.e., avoiding universal use), working shorter shifts, and using topical creams and washes to prevent and treat skin complaints [32,34,39,41,42,47,49—51]. The use of hydrogel patches and similar dressings can also reduce the prevalence and subjective experience of skin injuries [52]. However, it is important to ensure respirators still pass fit-testing once mitigation strategies have been implemented to ensure ongoing effectiveness. Organisations should consider how to most effectively manage and mitigate AEs from respirator and surgical mask use in the context of a wider respiratory protection program.

It is difficult to draw definitive conclusions on infection and AE likelihood from the epidemiological studies included in this review given the high risk of bias. Most studies included in this review had small sample sizes and could be potentially impacted by important confounders, such as whether respirators were fit-tested and fit-checked prior to use. This is important because the effectiveness of respirators depends on appropriate fit [4]. Future research should be designed to control or adjust for variables, such as the use of fit-checked and fit-tested respirators, SARS-CoV-2 prevalence and variant in the community, and the presence of relevant contextual factors that might impact infection and AE risk (e.g. levels of ventilation, mask-wearing duration or closer/longer duration contact with infected patients). This review should be updated once more high quality, peer-reviewed epidemiological studies are published.

This review has some limitations worthy of consideration. Although our search covered PubMed and the Cochrane COVID-19 Study Register (including relevant studies from Embase, medRxiv and ClinicalTrials.gov), we did not search CINAHL and so cannot rule out the possibility that some studies may have been overlooked. Some of the included studies were published as preprints and have not been peer-reviewed prior to inclusion. However, all studies were subject to risk of bias assessment. The studies exploring infection rate used different outcome measures (i.e. polymerase chain reaction test vs. serology). It is unclear how the use of different tests might have affected infection counts. Importantly, given the lack of controlled studies in this area, the findings of this review cannot imply causation but rather suggest the presence of a relationship between the use of surgical masks or respirators and infection rate and AEs, the nature of which requires further exploration.

This review has several strengths. This review reports findings specific to infection rates in HCWs wearing surgical masks and respirators, but also the likelihood of HCWs experiencing AEs from such devices. Thus, the findings of this review, and practical suggestions for mitigating AEs, have useful clinical applications. The methods underpinning this review have been extensively applied in various research and policy settings [53], ensuring rigorous evidence identification and synthesis to inform the development of clinically relevant and informed recommendations for practice. The formulation of the research question and discussion around applicability to practice and practical suggestions to support uptake of respirator use was made possible by collaboration with a multidisciplinary group with wide-ranging expertise in clinical care, occupational hygiene, medicine and engineering.

Conclusion

HCWs treating patients infected with SARS-CoV-2 are required to wear appropriate PPE, in addition to other control measures, to minimise infection risk. The existing epidemiological evidence is at high risk of bias and does not enable a definitive assessment of the effectiveness of respirators compared to surgical masks in preventing infection. Healthcare workers wearing respirators may be more likely to experience de novo headaches, shortness of breath or respiratory distress, facial itching or irritation, and pressure sores compared to those wearing surgical masks. These AEs require effective mitigation strategies to facilitate the uptake and correct use of respirators by HCWs who are required to use them. Our findings should not be used to justify decisions for or against respirator use.

Authorship statement

TT, SN, HH and BK (as internal team members of The National COVID-19 Clinical Evidence Taskforce) collaborated with and the remaining authors (the IPC Panel members) to conceive the review and draft the guiding research questions. A search specialist, SM, conducted all database searches. SN, HH and BK screened search yields, extracted data from included studies and performed statistical analyses. All authors contributed to interpretation of the analysis. BK, SN, TT and HH wrote the manuscript. All authors provided critical review and approved the final manuscript.

Conflict of interest

TT, SN, SM and HH have no conflicts to declare. BK has been involved in data collection on COVID-19 behaviours funded by the Victorian Department of Premier and Cabinet. The 15 members of the IPC Panel, including Phillipa Hore and John Ferguson, who significantly contributed to the development of the living guideline that the findings of this manuscript are based on have declared conflicts of interests on page 1 of this document (https://covid19evidence.net.au/wp-content/uploads/NC19CET_COISummary_IPC210429.pdf). BM is a member of the IPC Panel and the editor-in-chief of IDH. JF is on the IDH editorial board. Neither BM or JF were involved in the handling of this paper or any editorial decisions related to it. AJS is supported by an Australian National Health and Medical Research Council Early Career Fellowship (GNT1141398). The authors have no other conflicts to declare.

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In January, 2021, the National COVID-19 Clinical Evidence Taskforce, in partnership with the Infection Control Expert Group which advises the Australian Health Protection Principal Committee, was commissioned to develop recommendations in a living guideline to inform decision-making in the prevention of SARS-COV-2 infection in HCWs.

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Provenance and peer review

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Ethics

Ethics approval and informed consent was not required as this was a systematic review of previously published data.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.idh.2022.01.001.

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