

The role of masks and respirators in preventing respiratory infections in healthcare and community settings

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Series explanation: State of the Art Reviews are commissioned on the basis of their relevance to academics and specialists in the US and internationally. For this reason they are written predominantly by US authors.

ABSTRACT

The covid-19 pandemic saw frequent changes and conflicts in mask policies and politicization of masks. On reviewing the evidence, including studies published after the pandemic, the data suggest respirators are more effective than masks in healthcare, but must be continuously worn to be protective. Healthcare and aged care settings amplify outbreaks, so protection of patients and staff is paramount. Most guidelines assume risk is only present during close contact or aerosol generating procedures, but studies show intermittent use of respirators is not protective. New research in aerosol science confirms the risk of infection is widespread in health facilities. In community settings, any mask use is protective during epidemics, especially if used early, when combined with hand hygiene, and if wearers are compliant. Community use of N95 respirators is more protective than surgical masks, which are more protective than cloth masks, but even cloth masks provide some protection. Mask guidelines should be adaptable to the specific context and should account for rising epidemic activity, and whether a pathogen has asymptomatic transmission. The main rationale for universal masking during pandemics is asymptomatic transmission, which means risk of transmission cannot be self-identified. The precautionary principle should be applied during serious emerging infections or pandemics when transmission mode is not fully understood, or vaccines and drugs are not available. If respirators are not available, medical or cloth masks could be used as a last resort. Data exist to support extended use and reuse of masks and respirators during short supply. In summary, extensive evidence generated during the covid-19 pandemic confirms the superiority of respirators and supports the use of masks and respirators in the community during periods of high epidemic activity. Some gaps in research remain, including economic analyses, research in special population groups for whom masking is challenging, and research on countering disinformation.

Introduction

The covid-19 pandemic put masks in the spotlight, with guidelines that were conflicting and rapidly changing. In early 2020, the World Health Organization initially recommended that masks be used only by people who had respiratory symptoms, but actively discouraged their use by healthy people.¹ Advice from WHO, the United States Centers for Disease Control and Prevention (CDC), and other agencies changed several times during the pandemic, and at times swung between discouraging masks to suggesting N95 masks could be used in the community (fig 1).²⁵ There was widespread

disinformation and politicization of masks, with masks becoming a symbol of government control and oppression.^{26 27} Yet early in a pandemic, when drugs and vaccines are unavailable, masks are among the few available protective measures, especially for frontline workers.²⁸⁻³³

Masks and respirators reduce transmission of respiratory infections³⁴ by protecting the uninfected wearer and by blocking exhaled infectious particles from infected wearers (source control). Masks designed for healthcare use (medical or surgical masks) are water resistant, fit loosely around the face allowing unfiltered air to pass through the

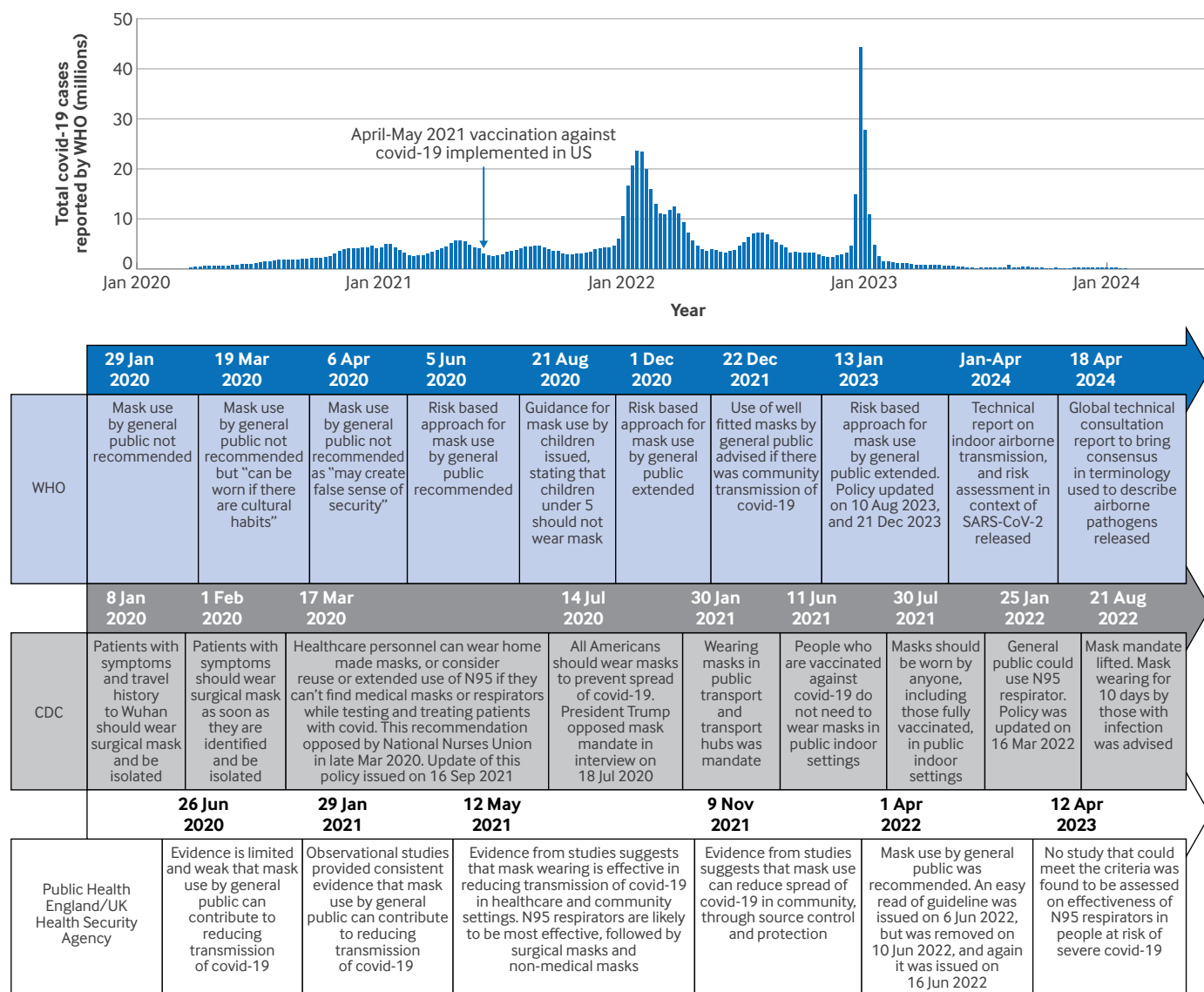


Fig 1 | Changes in guidelines on use of facemasks and respirators throughout covid-19 pandemic. Guidance from: World Health Organization (WHO),²⁻¹¹ United States Centers for Disease Control and Prevention (CDC),¹²⁻²¹ and Public Health England—changed to UK Health Security Agency (HSA) in April 2021²²⁻²⁴

gaps around the edges, and their filtration efficacy might be variable.³⁵ Cloth masks are widely used in low income countries and during shortages of medical masks, such as during the early months of the covid-19 pandemic, yet were not mentioned in any WHO policy document at the start of the covid-19 pandemic.³⁶ Respirators are designed for occupational protection and provide superior protection through high grade filtration and a tight seal around the face.³⁴⁻³⁷ Respirators, including disposable filtering facepiece respirators and reusable forms (elastomeric or powered air purifying respirators),³⁸⁻³⁹ are mainly used in healthcare settings and require fit testing.⁴⁰⁻⁴⁴ Some types of powered air purifying respirators do not require fit testing because they have a hood over the entire face and head instead of a face piece. These respirators are the most suitable for long, continuous use in high risk settings.

In our previous *BMJ* review,³⁴ we examined evidence from randomized controlled trials (RCTs) of masks. Since then, three further RCTs in healthcare,⁴⁵⁻⁴⁷ two in community settings,⁴⁸⁻⁴⁹ and three as source control⁵⁰⁻⁵² have been published. A 2023 Cochrane review was interpreted by some to have shown that masks "do not work,"²⁸ forcing Cochrane to issue an apology and clarification.⁵³ The aim of this review is to summarize the current evidence around the protection provided by masks and respirators in healthcare and community settings, and how this evidence aligns with current policy.

Methods

We conducted a state of the art review examining the evidence on the effectiveness of masks and respirators in healthcare, community, and special settings. Articles were identified from PubMed (from January 1950 to 31 December 2023), Embase (from

Table 1 | Summary of high level evidence by GRADE guidelines—clinical trials on facemasks or respirators in healthcare setting (adapted and summarized from Greenhalgh et al³² under Creative Commons license)

Study, year of publication	Design, methods	Mask type, intervention	Outcomes	Results	Comments, limitations, biases
Jacobs, ⁸³ 2009	Block randomized controlled trial, tertiary care hospitals in Tokyo Japan, 32 healthcare workers randomized to medical masks and control arm (2464 subject days), 2008	Medical masks, control group	Self-reported cold symptoms	No difference in outcome (cold symptoms) in intervention and control arm (P=0.81)	Self-reporting compliance 84.3%. Small study, underpowered. Self-reporting symptoms and no laboratory confirmation
Loeb, ⁸² 2009	Non-inferiority RCT, no control, 446 nurses from 8 tertiary care hospitals, Ontario, Canada, 2008-09	Targeted use of medical masks, fit tested N95 respirators	Laboratory confirmed influenza infection by PCR or seroconversion during 2008-09	No difference in outcome, rate of influenza in medical masks group was 23.6% compared with 22.9% in respirator group (absolute risk difference -0.73%, 95% CI -8.8% to 7.3%)	Compliance was not a trial endpoint and was not measured throughout entire trial. Despite statement to the contrary, reported numerator and denominator data show that seropositive vaccinated people included in definition of "influenza." Serology comprised majority of outcomes. Study stopped early because of influenza A (H1N1) pandemic in 2009 as respirator use became mandatory. Stated as "non-inferiority," but superiority of any tested intervention not previously proven in any RCT
MacIntyre, ⁸⁰ 2011	Cluster randomized controlled clinical trial, 1441 healthcare workers in 15 hospitals randomized, 481 convenience controls, Beijing, China, 2008-09	Medical masks, N95 respirators (fit tested), N95 respirators (non-fit tested), convenience control group	Self-reported clinical respiratory illness, self-reported influenza-like illness, laboratory confirmed viral infection and influenza by PCR	Compared with medical masks, all outcomes were consistently lower for N95 group: clinical respiratory illness (OR 0.38, 95% CI 0.17 to 0.86) and laboratory confirmed viral infection (0.19, 0.05 to 0.67) significantly lower in N95 group	Self-reporting compliance 68-76%, use of convenience control group. However, N95 is protective compared with medical masks (excluding controls). Lack of power for PCR confirmed influenza
MacIntyre, ³³ 2013	Cluster randomized clinical trial, no controls, 1669 healthcare workers in 68 wards (19 hospitals) in Beijing, China, 2009-10	Continuous use of N95 respirators, targeted use of N95 respirators for high risk situations, continuous use of medical masks	Self-reported clinical respiratory illness, self-reported influenza-like illness, laboratory confirmed viral infection and influenza by PCR	Rates of clinical respiratory illness (HR 0.39, 95% CI 0.21 to 0.71) and bacterial colonization (0.40, 0.21 to 0.73) significantly lower in arm that used N95 respirators continuously	Self-reporting compliance 57-82%. Lack of power for PCR confirmed influenza
MacIntyre, ⁴⁵ 2015	Cluster RCT conducted in 14 secondary level or tertiary level hospitals, Hanoi, Vietnam	Participants randomized to medical mask, cloth mask, and control arms	Clinical respiratory illness, influenza-like illness, and laboratory confirmed viral respiratory infection	In intention-to-treat analysis, rate of influenza-like illness was significantly higher in cloth mask arm (RR 13.00, 95% CI 1.69 to 100.07) than medical mask arm. Post hoc analysis (by actual mask use) showed significantly higher rates of influenza-like illness (6.64, 1.45 to 28.65) and laboratory confirmed virus (1.72, 1.01 to 2.94) in cloth mask arm compared with medical mask arm	Mask use was high in control group; post hoc analysis was done comparing all those using only medical mask (from control and medical mask arms) with all those using only cloth mask (from control and cloth arms). Self-reported compliance with mask use and hand hygiene was reported. A lack of influenza circulation was found during study period. Subsequent study analyzed data on washing cloth masks from this RCT, suggesting inadequate washing explains findings. Cloth masks washed in washing machine perform as well as medical masks
Radonovich, ⁸¹ 2019	Cluster randomized trial, no controls, conducted at 137 outpatient study sites at 7 US medical centers, 2011-15	Participants randomized to targeted medical mask and targeted N95 arms	Laboratory confirmed influenza (PCR or serology), acute respiratory illness, laboratory detected respiratory infection, and influenza-like illness	No significant difference in any outcome between medical mask and targeted N95 arms	Trial was only in outpatient setting, without control arm. Intervention comprised wearing mask or respirator when participants were positioned within 6 ft (1.83 m) of patients with suspected or confirmed respiratory illness. In respirator group, 89.4% reported "always" or "sometimes" wearing assigned devices v 90.2% in mask group
Loeb, ⁴⁷ 2022	Randomized non-inferiority trial, no controls, conducted in 29 healthcare facilities in Canada, Israel, Pakistan, and Egypt	Participants randomized to medical mask and fit tested N95 respirator arms	covid-19 on reverse transcriptase PCR, acute respiratory illness, lower respiratory infection or pneumonia, and work related absenteeism	In intention-to-treat analysis, no difference in reverse transcriptase PCR confirmed covid-19 in medical mask arm compared with N95 respirator arm (HR 1.14, 95% CI 0.77 to 1.69). Other outcomes also non-significant	Non-inferiority defined as HR of 2 or a 100% relative increase in risk of medical mask compared with N95. Underpowered to find differences less than twofold increase in risk. Fourfold increase in sample size needed to identify a 50% increase in relative hazard. ⁸⁴ Most of outcomes from Egypt, a site that was not registered in original trial registration. Self-reported adherence was lower in N95 arm, however randomly conducted audited adherence was similar in both groups

CI=confidence interval; GRADE=Grading of Recommendations Assessment, Development and Evaluation; HR=hazard ratio; OR=odds ratio; PCR=polymerase chain reaction; RCT=randomized controlled trial; RR=relative risk.

1988 to 31 December 2023), Cochrane Library, Web of Science, and Google Scholar. The Australian New Zealand Clinical Trials Registry (ANZCTR) and the US National Institutes of Health clinical trial registry were also searched. Only English language publications were included. We used the following keywords for the search: “facemask,” “mask,” “surgical mask,” “medical mask,” “cotton/cloth mask,” “respirator,” “N95/N97, N99 respirator,” “FFP2/FFP3 respirator,” “P2/P3 respirator,” “respiratory protection,” “respiratory protective device,” “infection control,” “respiratory infections and facemasks/mask/respirator,” “influenza and facemasks/mask/respirator,” “flu and facemasks/mask/respirator,” “SARS-CoV2”/“covid-19”/“coronavirus disease,” “pandemic influenza and facemasks/mask/respirator,” “SARS and facemasks/mask/respirator,” “tuberculosis and facemasks/mask/respirator,” “TB and facemasks/mask/respirator,” “Ebola”/“Ebola virus Diseases,” and “emerging infections and facemasks/mask/respirator.” The GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach was used to examine the type of evidence.⁵⁴ RCTs were considered level 1 (high) evidence, observational studies (cohort, case-control, before-after, time series, case series, and case reports) were considered level 2 (low), and any other evidence was considered level 3 (very low) evidence.⁵⁴ AAC reviewed the titles of publications identified by our searches and prepared an initial list of articles to be included in the study. Then CRM and AAC independently reviewed the abstracts of these articles and selected those suitable for inclusion. A separate search of the same databases was conducted by MK to identify meta-analyses of masks. A total of 29 studies were reviewed by all the authors and are summarized in supplementary table S1.^{28-32 54-78} Only studies classed as high level (RCTs) have been included, and we give specific limitations for each RCT.

We also searched infection control policies and guidelines from WHO, the US CDC, the UK Health Security Agency, and other health organizations to identify recommendations on the use of masks and respirators, with a focus on changing policies over the course of the pandemic. Additionally, we searched health organization websites and Google for policies and guidelines on the use of masks and respirators. Only English language literature was reviewed. Key terms used in our search were “Infection control guideline/policy/plan,” “COVID-19 guideline/policy/plan,” “Ebola control guideline/policy/plan,” “Pandemic influenza guideline/policy/plan,” “Personal protective equipment use/guideline,” “Personal protective equipment use/guideline for infection control,” “Masks use/guideline for infection control,” “Respirator use/guideline for infection control.”

Previous meta-analyses on masks and respirator use

Meta-analyses of masks have reported conflicting results (online supplementary table S1). Some

of these meta-analyses included only RCTs,⁵⁵⁻⁵⁷ while others included RCTs and observational studies.⁵⁸⁻⁶¹ Some meta-analyses found mask use to be protective^{59 62 63} and others did not,^{58 61} reflecting varied methods and data selection procedures. The most definitive study to date found substantial heterogeneity in the settings, interventions, and measurement of outcomes of RCTs, and identified important flaws in some meta-analyses.³² These flaws included combining dissimilar outcomes (such as differing clinical case definitions or laboratory diagnostics—eg, polymerase chain reaction (PCR) and serological testing) and dissimilar settings (such as healthcare and community).⁷⁹ A positive PCR test is a rarer but more reliable outcome⁸⁰ than a positive serological test, yet serological testing accounted for most primary outcome measures in some trials.^{47 81 82} One meta-analysis corrected for this by combining only similar outcomes.³²

Use of masks and respirators in healthcare settings RCTs in healthcare settings

We identified seven RCTs comparing the efficacy of masks with that of respirators in healthcare settings. Six were conducted before the covid-19 pandemic and one during the pandemic.^{33 45 47 80-83} These trials used different interventions and some of them measured different outcomes. Table 1 presents details of study design, interventions, results, and risk of biases.

A key design issue was whether healthcare workers in the respirator arm of the trial wore their device continuously throughout a shift or whether they wore it only when undertaking what was assumed to be a high risk procedure (so-called targeted or intermittent use of respirators). A recent meta-analysis that separately analyzed continuous and targeted use of respirators found that respirators were considerably more effective than masks if worn continuously.³² Intermittent use of respirators or medical masks only when performing high risk procedures was not protective. Three North American trials found no difference in efficacy between masks and respirators when used intermittently for aerosol generating procedures or treatment of patients with known infection.^{47 81 82} These findings are consistent with those of a trial in China that compared medical masks, intermittent use of N95 respirators, and continuous use of N95 respirators; this study showed no difference in efficacy between intermittent N95 respirators and medical masks, but considerably greater protection from continuous N95 use.^{33 80}

The superiority of N95 respirators over medical masks has also been shown against a range of viral and bacterial respiratory infections.⁸⁵ These findings suggest that these infections are likely transmitted through inhalation of contaminated air⁸⁶ because medical masks (designed to stop splash or spray of liquid) were not sufficiently protective. Airborne transmission of common respiratory infections means that the risk of transmission is likely to be widespread throughout health facilities owing to

Table 2 | Summary of high level evidence by GRADE guidelines—clinical trials on facemasks in household setting (adapted and summarized from Greenhalgh et al³² under Creative Commons license)

Study, year of publication	Design, participants	Mask type, intervention	Outcome	Results	Comments, limitations, biases
Cowling 1, ¹³⁴ 2008	Cluster RCT, 198 index cases and household contacts, Hong Kong	Medical masks, hand hygiene, control	Self-reported influenza symptoms, laboratory confirmed influenza (by culture or reverse transcriptase PCR) in household	Rates of laboratory confirmed influenza (OR 1.16, 95% CI 0.31 to 4.34) and influenza-like illness (0.88, 0.34 to 2.27) were not significantly different in medical mask arm compared with control arm	Index cases and household contacts used masks. This was a small pilot study and underpowered. Compliance 45% in index cases and 21% in household contacts. Compliance data showed some index cases in control and hand hygiene arms used medical masks
Cowling 2, ¹³⁹ 2009	Cluster RCT, 407 index cases and 794 household contacts, Hong Kong	Hand hygiene, masks plus hand hygiene, control (education)	Self-reported influenza symptoms, laboratory confirmed influenza (by reverse transcriptase PCR) in household	No significant difference in rate of laboratory confirmed influenza in three arms. Significant difference if masks plus hand hygiene together applied within 36 hours of illness (OR 0.33, 95% CI 0.13 to 0.87). Hand hygiene alone was not significant	Index cases and household contacts used masks. No separate medical mask arm, making it difficult to evaluate efficacy of masks alone. Compliance 49% in index cases and 26% in household contacts. Compliance data showed some index cases in control and hand hygiene arms used medical masks
MacIntyre, ¹³⁶ 2009	Cluster RCT, 145 child index cases and well adult household contacts, Australia	Medical masks for contacts, P2 respirators (equivalent to N95) for contacts, control	Self-reported influenza-like illness, laboratory confirmed respiratory infection by multiplex respiratory PCR	No significant difference in influenza-like illness and laboratory confirmed respiratory infections in three arms. Adherent use of P2 or medical masks significantly reduces risk of influenza-like illness (HR 0.26, 95% CI 0.09 to 0.77)	Only household contacts used medical masks. Low compliance: 21% of household contacts wore masks often or always
Aiello 1, ¹³² 2010	Cluster RCT, 1437 well university residents, Michigan, US	Medical masks, medical masks plus hand hygiene, control	Self-reported influenza-like illness, laboratory confirmed influenza (by culture or reverse transcriptase PCR)	No significant difference in influenza-like illness in three arms. Significant reduction in influenza-like illness in medical masks plus hand hygiene arm during weeks 4-6 (P<0.05)	Self-reported influenza-like illness—not all (n=368) were laboratory tested (n=94). No data on compliance. Week 4-6 data reflect a period of higher influenza circulation
Larson, ¹³⁵ 2010	Block RCT, 617 households, Manhattan, US	Health education, health education plus hand sanitizer, health education plus hand sanitizer plus medical masks	Self-reported influenza-like illness, self-reported upper respiratory infection, laboratory confirmed influenza through culture or PCR. Secondary attack rate of upper respiratory infection, influenza-like illness, or influenza	No significant difference in rates of upper respiratory infection, influenza-like illness, or laboratory confirmed influenza between three arms. Significantly lower secondary attack rates of influenza-like illness or influenza in the health education plus hand sanitizer plus medical mask arm (OR 0.82, 95% CI 0.70 to 0.97)	Only household contacts used medical masks. No separate medical masks group. Low compliance and around half of household in masks arm used masks within 48 hours. No index case at home
Simmerman, ¹³⁷ 2011	Cluster randomized controlled clinical trial, 465 index patients and their families, Thailand	Hand hygiene, hand hygiene plus medical masks, control	Self-reporting influenza-like illness, laboratory confirmed influenza by PCR and serology in family members	No significant difference in secondary influenza infection rates in hand hygiene arm (OR 1.20, 95% CI 0.76 to 1.88) and hand hygiene plus medical masks arm (1.16, 0.74 to 1.82)	No separate medical mask group. Due to influenza A (H1N1) pandemic, hand and respiratory hygiene campaigns and mask use substantially increased among index cases (from 4% to 52%) and families (from 17.6% to 67.7%) in control arm
Aiello 2, ¹³³ 2012	Cluster RCT, 1178 university residents, Michigan, US	Medical masks, medical masks plus hand hygiene, control	Influenza-like illness and laboratory confirmed influenza (reverse transcriptase PCR)	No overall difference in influenza-like illness and laboratory confirmed influenza in three arms. Significant reduction in influenza-like illness in the medical mask plus hand hygiene arm during 3-6 weeks (P<0.05)	Good compliance—medical mask plus hand hygiene group used mask for 5.08 hours/day (SD 2.23) and medical mask group used mask for 5.04 hours/day (SD 2.20). Self-reporting influenza-like illness. Effect might have been owing to hand hygiene, as medical masks alone not significant
Suess, ¹⁴⁰ 2012	Cluster RCT, 84 index cases and 218 household contacts, Berlin, Germany	Masks, masks plus hand hygiene, control	Laboratory confirmed influenza infection and influenza-like illness	No significant difference in rates of laboratory confirmed influenza and influenza-like illness in all arms by intention-to-treat analysis. Risk of influenza was significantly lower if data from two intervention arms (masks and masks plus hand hygiene) pooled and intervention applied within 36 hours of symptom onset (OR 0.16, 95% CI 0.03 to 0.92)	Around 50% of participants wore masks “mostly” or “always.” Monetary benefits provided. Only household contacts used mask
Alfelali, ⁴⁸ 2020	Cluster RCT conducted over three consecutive Hajj seasons (2013, 2014, 2015) among pilgrims' tents in Makkah, Saudi Arabia	Participants at Hajj were randomized by tent to masks to be worn over 4 days or no masks	Laboratory confirmed viral respiratory infections, and clinical respiratory infection	In intention-to-treat analysis and per protocol analysis, facemasks were not effective against laboratory confirmed viral respiratory infections or clinical respiratory infections	Poor protocol adherence noted by authors. Short duration of intervention (4 days). Compliance low in both arms—overall 24.7% of participants used masks daily, while 47.7% used masks intermittently. In control arms a few participants also used masks daily (14.3%) or intermittently (34.9%)

(Continued)

Table 2 | Continued

Study, year of publication	Design, participants	Mask type, intervention	Outcome	Results	Comments, limitations, biases
Bundgaard, ¹³⁸ 2021	RCT conducted in Denmark, from April and May 2020. Participants were community dwelling adults who reported being outside home among others for at least 3 hours/day	Participants randomized to recommendation to wear masks outside home, or no recommendation	SARS-CoV-2 infection by antibody testing, PCR, or hospital diagnosis. PCR positivity for other respiratory viruses	No difference in any outcome between two arms	Mask wearing recommended outside home, but highest risk of transmission is within households. Low incidence of covid-19 at the time. Compliance not measured. Loss to follow-up was 19%. Sample size powered to detect 50% reduction of infection, so study underpowered to detect smaller differences
Abaluck, ⁴⁹ 2022	Cluster randomized trial in rural Bangladesh from November 2020 to April 2021	Participants randomized to medical mask, cloth mask and control arms. Asked to wear masks whenever outside their house and around other people	Symptomatic SARS-CoV-2 seroprevalence and symptoms consistent with covid-19 illness	Mask use was effective in reducing covid symptoms and symptomatic seroprevalence of SARS-CoV-2	Mask wearing increased from 13% to 43% in intervention villages, but results reflect protective effects with low compliance. Social distancing also measured and unchanged by interventions. Only people with symptoms tested, so infection rate underestimated and might have biased results towards the null
Solberg, ¹⁴¹ 2024	Pragmatic randomized superiority trial in Norway between 10 February 2023 and 27 April 2023	Intervention arm (wear surgical face mask in public spaces, eg, shopping centers, streets, public transport), no mask control arm	Primary outcome: self-reported respiratory symptoms. Secondary outcomes: self-reported and registered covid-19 infection	Respiratory symptoms reported in 163 (8.9%) participants in intervention arm and 239 (12.2%) in control arm (OR 0.71, 95% CI 0.58 to 0.87; P=0.001). Rates of self-reported and registered covid-19 infection were not significantly different in two arms	Participants were individually randomized. Study conducted only for 2 weeks. Some participants exposed to infection during study period might have become symptomatic later. Among intervention arm, only a quarter wore masks continuously in public places. No data on mask wearing at home

CI=confidence interval; GRADE=Grading of Recommendations Assessment, Development and Evaluation; HR=hazard ratio; OR=odds ratio; PCR=polymerase chain reaction; RCT=randomized controlled trial; SD=standard deviation.

ventilation systems mixing and dispersing air,³² and calls into question many guidelines suggesting risk is only present during close contact or aerosol generating procedures.⁸⁷

Healthcare facilities and many buildings use heating, ventilation, and air conditioning systems, which can draw in fresh air and might filter the air, are designed primarily for climate control. These systems use ducts to disperse air throughout a building, so human respiratory aerosols generated in one part of a building might be dispersed to another. In reality, infectious airborne particles accumulate and disperse widely in an indoor setting,⁸⁸ posing a risk to people distant from the source of infection.⁸⁹

When the covid-19 pandemic began, one RCT had been published comparing cloth masks with single use medical masks in a healthcare setting in Vietnam.⁴⁵ The incidence of the primary outcome (influenza-like illness) was significantly higher in participants in the cloth mask arm (relative risk 13.00, 95% confidence interval 1.69 to 100.07), but there was no significant difference between arms for laboratory confirmed infection. The study was conducted in a setting where many participants washed their cloth masks by hand in cold water. A further post hoc analysis conducted in 2020 of data from that 2011 trial (after widespread concern about the safety of cloth masks) showed that if cloth masks were washed in a washing machine, their performance was similar to medical masks.⁹⁰ WHO has since issued a recommendation for washing cloth masks after use at 60°C.⁹¹

Observational, case-control, cohort, and experimental studies in healthcare settings

A range of evidence exists from cohort,⁹² case-control,⁹³⁻⁹⁹ cross sectional,¹⁰⁰⁻¹⁰⁵ laboratory experimental,¹⁰⁶⁻¹¹² and other epidemiological (including time series, modeling, and case series) studies.¹¹³⁻¹²² Some of these studies were conducted during the SARS outbreak,⁹⁴⁻⁹⁹ 103-105 113 116-119 123 others examined transmission of tuberculosis,¹²¹⁻¹²⁵ respiratory syncytial virus,⁹² and pertussis.¹⁰² A systematic review and meta-analysis performed in early 2020 using observational data from SARS, Middle East respiratory syndrome (MERS), and early data on SARS-CoV-2 showed 85% protection from medical masks or respirators (analyzed together) in all settings combined, with greater protection in the healthcare setting, attributed to increased N95 use.⁶⁹ In a subanalysis, respirators were 96% effective compared with masks, which were 67% effective.⁶⁹

Respirators are recommended as source control for people with tuberculosis,^{121 124 125} but no studies could be found that measured their clinical efficacy in preventing tuberculosis.¹²⁶ One study in South Africa found that use of masks as source control by patients with multidrug resistant tuberculosis greatly reduced airborne transmission to guinea pigs exposed to ward air.¹²⁷ Additionally, an observational study found medical masks protect against nosocomial transmission of pertussis.¹⁰² In vivo studies have also reported increasing levels of filtration performance and protection factors (in ascending order) for cloth masks, medical masks, and respirators.^{108 112 128}

There is a large body of experimental evidence supporting the effectiveness of masks and the superiority of respirators, summarized in a review.³² Laboratory based studies have shown low filtration efficiency of surgical masks compared with N95 respirators.^{32 129} Additionally, aerosol studies have reported that the blocking of exhaled aerosols improves with the number of layers of a mask, and is better with a surgical mask than a cloth mask.³⁵ The overall protection factor of N95 respirators was 8-12 times greater than that of surgical masks.¹³⁰ Protection improves when two or more surgical masks are worn, but is still lower than protection from respirators.¹³¹

Use of masks in community for primary prevention RCTs in community settings

We identified 12 heterogeneous RCTs of facemasks in community settings used for primary prevention in wearers without infection.^{48 49 132-141} Of the primary prevention trials, some showed a protective effect of masks, while others did not. Table 2 summarizes the heterogeneity in settings, interventions, outcomes, and results of these trials. In general, there were low rates of compliance or low incidence of infection. The largest trial, a well designed community RCT in Bangladesh, showed statistically significant protection against symptomatic SARS-CoV-2 infection.⁴⁹ The data suggest masks are protective in high transmission community settings, especially if used early during epidemics, if combined with hand hygiene, and if wearers are compliant.³² A recently published meta-analysis showed that community mask use compared with no mask use protected against influenza-like or covid-like illness, and against PCR confirmed influenza when masks were combined with hand hygiene.³² The most recent community RCT in Norway showed surgical masks were 29% protective against self-reported respiratory symptoms compared with no mask.¹⁴¹

Observational, case-control, cohort, and laboratory studies in community settings

Observational studies might be affected by confounding and bias and should be interpreted cautiously. However, there are several reasons why these biases would all tend to skew results towards the null.³² Cloth masks were used by the general public during the 1918 influenza pandemic^{142 143} and found to be effective. During SARS in 2002-03, masks were reported to be effective in China, Hong Kong, and Canada where compliance was high.¹⁴⁴⁻¹⁴⁶ Several observational and natural experiments have shown masks to be protective in high risk settings.^{142-145 147} Other than aged care and long term care facilities, the highest risk community setting is households because close, prolonged exposure occurs when an infected family member is present. A household study early in the covid-19 pandemic showed that use of masks in the household reduced the risk of infection by 79% when they were worn before the

index case became symptomatic, confirming the role of presymptomatic transmission in outbreaks.¹⁴⁸

Mask use was mandatory in many countries during the peak of the covid-19 pandemic and various types of product were used.¹⁴⁹ A large, well designed case-control study conducted in California, US during the covid-19 pandemic showed consistent use of any mask in indoor public settings reduced risk of infection, with the highest protection provided by a N95 respirator (83%), followed by a surgical mask (66%), and a cloth mask (56%).¹⁵⁰ A range of modeling studies have also shown reduced population transmission.^{149 151-154} Studies that have used epidemiological approaches to analyzing the effect of mask use during universal masking also suggest protection.¹⁵⁵⁻¹⁵⁷

Children

No RCTs of mask use in children were identified, but there is no scientific reason why masks, if worn correctly, would be less effective in this age group. Mask use was protective against influenza in a study in all elementary school children in Matsumoto City, Japan during the 2014-15 influenza season, particularly in children in the higher grade group (9-12 years, grades 4-6).¹⁵⁸ One study found that masks reduced a range of respiratory pathogens in school children.¹⁵⁹ Another showed that cessation of school mask mandates resulted in a surge of SARS-CoV-2 infection rates.¹⁶⁰ In Arizona, US, the odds of covid-19 outbreaks in schools without a mask requirement were 3.5 times higher than those in schools with an early mask requirement (odds ratio 3.5, 95% confidence interval 1.8 to 6.9).¹⁶¹

Other studies during covid-19 generated mixed results.¹⁶² Mask acceptance and compliance in children could be low owing to social and physiological factors, including parental and teacher concerns about the impact on speech, language and learning, parental anxiety, and the availability of small size masks.¹⁶²⁻¹⁶⁴

In August 2020, WHO and Unicef issued guidance on mask use by children and recommended masks only for children aged 5-18 years,¹⁶⁵ and that cloth masks should be worn if physical distance of at least 1 m could not be maintained. However, the same policy stated that the age cutoff for wearing a mask should be adapted to social or school settings according to national standards. During the covid-19 pandemic, the US CDC also recommended universal mask use for all students and staff from kindergarten to grade 12.¹⁶⁶ During one covid-19 school outbreak when masking for teachers and students was mandatory, one teacher with covid-19 infection removed their mask to read to the class, resulting in a large outbreak, despite spacing of 6 ft (1.83 m) between desks.¹⁶⁷

Mask use as source control

Source control is mask use by a person with an infection to protect others. People with acute infection, whether symptomatic or not, might exhale

Table 3 | Randomized controlled trials on mask use as source control

Study, year of publication	Design, participants	Mask type, intervention	Outcome	Results	Comments, limitations, biases
Canini, ¹⁷⁰ 2010	Cluster RCT, 105 index cases and 306 households, France	Index patients randomized to medical mask (52 index cases and 148 household contacts) and control groups (53 index cases and 158 household contacts)	Self-reported influenza-like illness in household	No significant difference in rates of influenza-like illness between two arms (OR 0.95, 95% CI 0.44 to 2.05)	Trial stopped early because of low recruitment and influenza A (H1N1) pandemic in 2009
Barasheed, ⁵⁰ 2014	Pilot study in Hajj setting in Saudi Arabia, 75 pilgrims with influenza-like illness in mask and 89 in control group	Pilgrims with influenza-like illness symptoms for <3 days were recruited as cases and those who slept within 2 m of them as contacts. Mask and control: 22 tents randomized to supervised mask use (n=12) or control (n=10)	Outcomes measured in contacts of influenza-like illness cases. Outcome measures were influenza-like illness, laboratory confirmed viruses using real time, multiplex reverse transcription PCR assay targeting human coronaviruses (OC43, 229E, and NL63), influenza A and B viruses, respiratory syncytial virus, parainfluenza viruses 1-3, human metapneumovirus, rhinovirus, enterovirus, and adenovirus	Less influenza-like illness among the contacts of mask users compared with control tents (31% v 53%, P=0.04). Laboratory results did not show any difference between groups	Some people in control group also used masks. Mask use compliance was 76% in mask group and 12% in control group
MacIntyre, ⁵¹ 2016	Cluster RCT, 245 index cases and 597 household contacts in 6 major hospitals in 2 districts of Beijing, China	Medical mask worn by index case, control (no mask) household contacts followed for infection	Clinical respiratory illness, influenza-like illness, and laboratory confirmed viral respiratory infection (multiplex PCR) for adenoviruses, human metapneumovirus, coronaviruses 229E/NL63 and OC43/HKU1, parainfluenza viruses 1-3, influenza viruses A and B, respiratory syncytial virus A and B, or rhinovirus A or B	In intention-to-treat analysis no difference in rates of clinical respiratory illness (RR 0.61, 95% CI 0.18 to 2.13), influenza-like illness (0.32, 0.03 to 3.13) and laboratory confirmed viral infections (0.97, 0.06 to 15.54). When analysed by actual mask use, rate of clinical respiratory illness lower in contacts of masks group (0.23, 0.06 to 0.88)	Compliance was suboptimal in mask group and some controls wore masks. Sample size of study was small and study underpowered to detect statistically significant difference in outcome in intention-to-treat analysis
Leung, ⁵² 2020	Experimental study, 246 participants with respiratory infections confirmed by reverse transcriptase PCR in 123 of 246 (50%) participants with influenza-like illness. 111/123 (90%) were infected by human (seasonal) coronavirus (n=17), influenza virus (n=43), or rhinovirus (n=54)	Adults and children with confirmed viral respiratory infection were randomized to surgical mask and no mask	Virus generation rate in tidal breathing of infected participants was measured	Masks significantly reduced exhaled (seasonal) coronavirus and influenza. More virus was found in fine aerosols than large droplets, supporting viral origin in lower respiratory tract	Laboratory based study and real life efficacy is known

CI=confidence interval; OR=odds ratio; PCR=polymerase chain reaction; RCT=randomized controlled trial; RR=relative risk.

large amounts of highly infectious particles that could be inhaled by others.⁵² Long range airborne transmission of SARS-CoV-2, for example, has been documented at church events, during choir practice, and on aircraft.^{168 169} Patients with tuberculosis historically have worn masks as source control.

Randomized controlled trials

Four RCTs examined mask use as source control^{50-52 170} (table 3). In the first RCT in France, there was no difference between the two arms (medical masks v no masks; odds ratio 0.95, 95% confidence interval 0.44 to 2.05), but the trial finished early because of low recruitment and the subsequent influenza A (H1N1) pandemic in 2009.¹⁷⁰ The second RCT was conducted among Hajj pilgrims. Lower rates of symptomatic illness (influenza-like

illness) were reported among contacts of pilgrims who used masks (31%) compared with those who did not use masks (53%; P=0.04). However, compliance was low, and laboratory confirmed viral infection was not statistically significantly different between the two groups. The third RCT randomized 245 patients with influenza-like illness presenting to a fever clinic to mask or control arms and observed infection rates in their household contacts.¹⁷¹ No difference between the two groups was found in intention-to-treat analysis, however analysis by actual mask use showed low rates of infection in household contacts of patients who wore masks.¹⁷¹ A fourth RCT quantified the amount of influenza virus and seasonal coronavirus in the exhaled breath of participants with a range of respiratory infections, with and without masks. There was a significant

Table 4 | Current guidelines on use of masks or respirators to protect from selected infectious diseases. Guidance from: World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), European Centre for Disease Prevention and Control (ECDC), and National Health Service (NHS) England, UK Health Security Agency (HSA)

Disease	Healthcare setting		Community setting	
	Low risk*	High risk†	Low risk‡	High risk§
Seasonal influenza	Medical masks (WHO, ²²⁶ CDC, ²²⁷ ECDC, ²²⁸ NHS ²²⁹)	Medical masks (WHO ²²⁶) Respirators (CDC, ²²⁷ ECDC, ²²⁸ NHS ²²⁹)	Not recommended (WHO, ²²⁶ CDC, ²²⁷ ECDC, ²²⁸ NHS ²²⁹)	Choose the most protective type (ECDC ²²⁸) Not recommended (WHO, ²²⁶ CDC, ²²⁷ NHS ²²⁹)
Pandemic influenza	Medical masks (WHO, ²²⁶ 230 231 NHS) ²²⁹ 232 Respirators (CDC, ²³³ ECDC ²²⁸)	Medical masks (WHO) ²²⁶ 230 231 Respirators (CDC, ²³³ ECDC, ²²⁸ NHS ²²⁹ 232)	Medical masks (WHO, ²²⁶ 230 231 CDC ²³³) Not recommended (ECDC, ²²⁸ NHS ²²⁹ 232)	Medical masks (WHO, ²²⁶ 230 231 CDC, ²³³ NHS ²²⁹ 232) Choose the most protective type (ECDC) ²²⁸
covid-19	Medical masks (WHO, ²³⁴ 235 NHS ²²⁹) Respirators (CDC, ²³⁶ 237 ECDC ²²⁸ 238)	Respirators (WHO, ²³⁴ 235 CDC, ²³⁶ 237 ECDC, ²²⁸ 238 NHS ²²⁹)	Not recommended (WHO, ²³⁴ 235 CDC, ²³⁶ 237 ECDC, ²²⁸ 238 NHS ²²⁹)	Medical masks (WHO, ²³⁴ 235 NHS ²²⁹) Choose the most protective type (CDC, ²³⁶ 237 ECDC ²²⁸ 238)
Middle East respiratory syndrome coronavirus	Medical masks (WHO, ²³⁹ ECDC ²⁴⁰) Respirators (CDC, ²⁴¹ NHS ²⁴²)	Respirators (WHO, ²³⁹ CDC, ²⁴¹ ECDC, ²⁴⁰ NHS ²⁴²)	Not recommended (WHO, ²³⁹ CDC, ²⁴¹ ECDC, ²⁴⁰ NHS ²⁴²)	Not recommended (WHO, ²³⁹ CDC, ²⁴¹ ECDC, ²⁴⁰ NHS ²⁴²)
Ebola virus	Medical masks (WHO, ²⁴³ ECDC, ²⁴⁴ NHS ²⁴⁵) Respirators (CDC ²⁴⁶)	Medical masks (NHS) ²⁴⁵ Respirators (WHO, ²⁴³ CDC, ²⁴⁶ ECDC ²⁴⁴)	Not recommended (WHO, ²⁴³ CDC, ²⁴⁶ ECDC, ²⁴⁴ NHS ²⁴⁵)	Not recommended (WHO, ²⁴³ CDC, ²⁴⁶ ECDC, ²⁴⁴ NHS ²⁴⁵)
Tuberculosis	Medical masks (WHO ²⁴⁷) Respirators (CDC, ²⁴⁸ ECDC, ²⁴⁹ 250 NHS ²²⁹)	Respirators (WHO, ²⁴⁷ CDC, ²⁴⁸ ECDC, ²⁴⁹ 250 NHS ²²⁹)	Not recommended (WHO, ²⁴⁷ CDC, ²⁴⁸ ECDC, ²⁴⁹ 250 NHS ²²⁹)	Not recommended (WHO, ²⁴⁷ CDC, ²⁴⁸ ECDC, ²⁴⁹ 250 NHS ²²⁹)

"Not recommended" for respiratory protection in community settings, but might be recommended for people who are unwell to prevent spread of infection (source control) or for people caring for those who are unwell in certain situations.

*Routine patient care.

†High risk situations, eg, high risk aerosol generating new or drug resistant organism, poor ventilation, or increased community transmission.

‡Home, non-crowded settings.

§Crowded settings (eg, public transport), contact with people who are unwell, pre-existing illness, pregnancy, old age (influenza pandemic), people touching human remains or in contact with infected animals (Ebola).

reduction in influenza and coronavirus RNA in exhaled aerosols in the mask group.⁵² Both these viruses were especially found in small aerosols rather than large droplets, but viral load was low.⁵² Table 3 presents further details of the trials.

Other source control studies

An experimental study showed that the spread of influenza virus from an infected patient, measured by coughing onto a Petri dish, might be reduced when the patient wears a facemask or a respirator.¹⁷² In this study, nine patients with influenza participated, and each one repeated the experiment with an N95 respirator, a medical mask, and no mask. No virus was detected when an N95 or medical mask was worn for any patient, while seven samples were positive when patients were unmasked. A study on volunteers with influenza reported an almost threefold reduction of viral particles in exhaled breath with the use of medical masks.¹⁷³ This study also found an almost ninefold higher viral load in fine aerosols compared with larger exhaled particles, supporting evidence that influenza is an airborne virus. During the SARS outbreak, medical and cloth masks were used as source control and reported to be effective.¹⁰⁵ A recent study showed that all types of face covering (cloth masks, surgical masks, and respirators) reduce SARS-CoV viral load in exhaled breath of volunteers with covid-19. However, N95 respirators were superior to other face coverings, even when used without training and fit testing.¹⁷⁴ There is also evidence that use of facemasks reduces

the risk of tuberculosis transmission in people with the disease.¹⁷⁵ Despite the lack of human clinical trial data, medical masks are recommended by WHO, the CDC and the European Centre for Disease Prevention and Control to use as source control for patients with tuberculosis.¹⁷⁶⁻¹⁷⁸

Selection of masks or respirators

Occupational health and safety factors

The occupational health and safety hierarchy of controls rates removal of the worker from the hazard or substitution of the hazard as more important than personal protective equipment (PPE).¹⁷⁹ However, unlike construction workers and other workers where the hazard (such as a faulty ladder) is incidental to the job, for a health worker, the hazard is the job itself; they must treat patients with deadly infectious diseases, and removal of these patients or substitution of them is clearly not an option. This context and the importance of respirators for health workers has never been explicitly recognized. Infection prevention and control guidelines traditionally consider only assumed mode of transmission, but a risk based approach is recommended that considers the pathogen, the setting, the occupational health and safety requirements, availability of treatment or vaccines, and uncertainty.¹⁸⁰ Figure 2 presents a model for considering host, pathogen, and organization.¹⁸¹ Availability of masks and respirators is one of the most important organizational factors, particularly in low resource settings or during global PPE shortages, so organizations should ensure

Pathogen related factors	Host factors	Organizational factors
<ul style="list-style-type: none"> • Transmission mode • Asymptomatic and presymptomatic transmission • Risk of nosocomial infection • New pathogen with unusual outbreak pattern • Community level of transmission – low v high transmission period • Severity of infection and case fatality rate 	<ul style="list-style-type: none"> • Staff willingness to wear mask • Risk perception • Presence of adverse events owing to mask use • Immune status and pre-existing illness 	<ul style="list-style-type: none"> • Occupational health and safety obligations • Cost of products • Training and fit testing for respirators • Availability of products • Stockpiling and having reusable respirators for emergencies • Availability of vaccines, drugs, and alternative control measures

Fig 2 | Multifactorial approach to selection of masks and respirators in healthcare settings

adequate supplies of respirators for frontline staff.¹⁸² The precautionary principle should be used if a disease has high morbidity and mortality, or for a newly emerging infection with unknown impact or high risk of nosocomial infection.¹⁸³ Risk perception, cultural background, discomfort, immune status, and pre-existing illness of the wearer might also influence use of masks and respirators.¹⁸⁴ When risk perception is high, compliance will be higher, so studies of masks conducted during low risk periods might not reflect actual compliance during a pandemic.¹⁸⁵

Fit testing of respirators

Fit testing is important for respirators, which can be done using qualitative or quantitative methods.¹⁸⁶ For maximum protection, a respirator should fit the face and there should be no gap between the face and the respirator. Facial fit depends on face shape, shape of respirators (dome shape v duckbill shape), and type of straps (head straps v ear loops). Ear loops have poorer fit than head straps. Fit factors for respirators with ear loops (KN95) are lower compared with respirators with head straps.¹⁸⁷ However, respirators might interfere with breathing owing to a build up of carbon dioxide inside the facepiece, particularly in people with pre-existing lung conditions such as asthma and chronic obstructive pulmonary disease.^{188 189} Therefore, medical evaluation is a part of a respiratory protection programme and is highly recommended before the use of respirators for people with chronic obstructive pulmonary disease or other relevant medical conditions.¹⁹⁰ A physician or other licensed healthcare professional should perform a medical evaluation of employees and keep records for follow-up.

Mask mandates, universal masking, and situational considerations

Mask policies might vary over time during the same epidemic, or situationally. Guidelines might recommend masks only for people who are sick, or for healthy people (universal masking, such as during mask mandates), or for specific settings or specific times. One of the key determinants of the value of community masking during pandemics or serious epidemics is asymptomatic or presymptomatic

transmission. Asymptomatic transmission of influenza has long been recognized, but SARS-CoV-2 has a much higher degree of asymptomatic transmission.¹⁹¹ It is estimated that 30-50% of SARS-CoV-2 transmission is asymptomatic.^{191 192} In one study, around 44% (95% confidence interval 30% to 57%) of secondary infections occurred during the presymptomatic stage¹⁹¹; this means that, in a high risk setting, people who are sick or healthy cannot self-identify risk of exposure in a crowded public setting unless testing is done.¹⁹³⁻¹⁹⁵ This is one of the strongest justifications for mass masking during epidemic waves of SARS-CoV-2. Special consideration is needed for high risk settings such as hospitals and aged care facilities. Nosocomial covid-19 is a major, ongoing problem, with a high mortality rate.¹⁹⁶ Masking of staff in clinical areas can reduce this risk. One study showed that during the covid-19 pandemic, facilities that started universal staff masking had smaller epidemics than those that did not.⁷⁸ Nosocomial influenza risk was also reduced by 50% with mask mandates.¹⁹⁷ The covid-19 pandemic also highlighted the importance of asymptomatic, presymptomatic, and early symptomatic transmission, which is a rationale for universal masking in high risk settings or during periods of high community transmission.

Non-standardized practices around mask use during epidemics or pandemics

PPE shortages might occur during pandemics, as seen during the H1N1 pandemic in 2009 and the covid-19 pandemic. Non-standardized practices, such as extended use and reuse of masks and respirators, double masking, and use of cloth masks in healthcare, were seen during the covid-19 pandemic.¹⁹⁸⁻²⁰⁰ Knotting of the ear loops around the ear and tucking around the face, and double masking, might also improve fit and filtration effectiveness.²⁰¹ Double masking can be done in various combinations, such as cloth covering the medical mask,²⁰¹ cloth or medical mask over a N95 respirator, or using two medical masks. The aim of using an additional mask is to protect the underlying mask or improve filtration and fit, however this could reduce breathability, resulting in greater discomfort. A simulation study reported more than 85%

reduction in the spread of particles emitted during a cough when a three ply cloth mask was used over a three ply medical procedure mask.²⁰¹

Extended use and reuse of masks and respirators

In situations of shortages, or where cost is a limitation, or to reduce waste, extended use and reuse could be considered. The US CDC provides guidance on extended use and reuse, as well as conventional, contingency, and crisis capacity strategies.²⁰² However, there is no standard definition of extended use and reuse of masks and respirators.^{203 204} Disposable masks are worn for up to eight hours, or during a shift, unless soiled, wet, or damaged. Extended use of a respirator refers to wearing the same N95 respirator or mask longer than the recommended usage time, without removing it between patient encounters.²⁰³ Reuse is defined as using the same N95 respirator or mask for several patient encounters with removal and reapplication after encounters.²⁰³

There is limited evidence around the safety of these practices and guidelines are inconsistent.²⁰⁵ Pathogens might be present at the outer or inner mask surfaces²⁰⁶ and this could increase the risk of self-contamination. Moreover, extended use could lead to reduction in humid air filtration efficiency.²⁰⁷ Frequent hand washing is recommended for extended use and reuse, and products should be adequately stored for reuse. Finally, facial fit might be lost after prolonged use of respirators, especially trifold shape respirators compared with dome and duckbill shaped. A study in the US showed high rates of fit testing failure after reuse of N95 respirators by healthcare workers, increasing from 38.7% after the first shift of wear to 92.8% after five shifts.²⁰⁸ Various cleaning and disinfection methods for reusing disposable products have been studied, including soap and water, bleach, autoclave, isopropyl alcohol, vaporized hydrogen peroxide, ultraviolet germicidal radiation, ethylene oxide, microwave oven irradiation, steam, and dry heat.²⁰⁹⁻²¹² However, most of these methods could degrade disposable masks. A systematic review found vaporized hydrogen peroxide and ultraviolet germicidal irradiation were the most effective decontamination methods.²⁰⁵

Use of cloth masks

Owing to shortages of disposable masks during the covid-19 pandemic, extensive research on improving the performance of cloth masks was conducted.^{90 213-217} Cloth masks are commonly used, particularly in low resource countries, and until the covid-19 pandemic were ignored in policy documents, which all assumed adequate supplies of disposable masks.¹⁸² A range of options were used in early 2020, including single or double layer masks, neck gaiters, and bandanas. During covid-19, cloth masks, homemade face coverings, or a scarf or bandana were also recommended and widely used.³⁶ Some observational studies showed they are effective, albeit less than medical masks and respirators.²¹⁸

A large body of research was conducted in 2020 on last resort strategies for masking, including optimal design of cloth masks. One published RCT of cloth masks showed that they performed poorly.⁴⁵ Cloth masks might be harmful if not washed daily in hot water owing to moisture retention and contamination accumulation. Analysis of data on washing from a cloth mask trial showed that if washed in a washing machine at high temperature, the cloth masks performed as well as surgical masks, but that poorly washed cloth masks are ineffective.⁹⁰ Washing can also improve filtration of cloth masks by shrinking pore size.^{213 219}

In vivo studies show low filtration efficacy and high particle penetration for cloth masks, ranging from 40% to 90%.^{107 220} A comprehensive study of fit, layers, fabric, washing, and water resistance showed that a high performing cloth mask could be designed.^{213 219} However, cloth masks should not be used in healthcare settings; they could be used in community settings during shortages.

Emerging areas in mask design

The protection function of masks or respirators is related to design, material, and proper use, and more research is needed in all these areas. The design of masks should be improved for proper fit to the face, as well as for easy donning and doffing. A loosely fitted respirator could provide the same protection as a medical mask, while a tightly sealed medical mask or respirator will significantly improve the protection.²²¹ Doffing is a high risk procedure with a risk of self-contamination during doffing, and mask design should enable safer doffing.²²² New fabrics should be tested to improve comfort and to minimize adverse events associated with mask or respirator use. Many new designs and fabrics of masks were tested during the covid-19 pandemic to improve comfort, reduce contact transmission, and ease breathing.²²³⁻²²⁵ However, data are limited on the effectiveness of these methods.

Guidelines

Table 4 shows current guidelines on mask use in healthcare and community settings for selected infections. In healthcare settings, masks and respirators are generally chosen based on assumed transmission mode of pathogens because most guidelines on the use of masks and respirators in respiratory diseases were written wholly or predominantly from the infection prevention and control model of infections being classified as droplet or airborne. This policy assumes most transmission is by large droplets, with hazard being present only in close proximity (1-2 m) or during aerosol generating procedures. This belief might be based on experiments from the 1950s, which suggest that droplets are large in size (10-100 µm) and do not travel more than 1-2 m.²⁵¹ In fact, droplets with a diameter of more than 10 µm can be suspended in the air²⁵² and large droplets can travel further than 2 m, in some cases up to 8 m.²⁵³ Large and small

respiratory particles are a continuum and both occur at short and long range.²⁵⁴ Therefore, an aerosolized pathogen can be inhaled at a shorter or longer distance and might cause infection, and a facemask would not offer sufficient protection from inhalation risk.²⁵¹ According to most infection control guidelines, influenza is assumed to be transmitted through large droplets, but there is ample evidence of airborne transmission of influenza.²⁵⁵ SARS-CoV-2 was initially thought to be transmitted through droplets, but is now accepted to be airborne.²⁵⁶ Moreover, most pathogens transmit through more than one route and the relative contribution of each mode is difficult to quantify.²⁵¹ In 2024, WHO also moved away from classifying transmission as droplet or airborne, and acknowledged a continuum of respiratory particles in air of various sizes at close and long range. Respirators are designed to protect against inhaled pathogens spread by the airborne route and should be recommended in closed indoor settings where transmission risk is high.

Summary of evidence and recommendations

Conflict and controversy about masks and respirators is not new—before covid-19, it occurred during the 2003 SARS epidemic, the 2009 influenza pandemic, and the 2014 Ebola epidemic.^{180 181 257} The sum of evidence shows that masks and respirators offer protection against respiratory infections. The covid-19 pandemic resulted in intensive research on masks and respirators, which added further evidence to the existing body of RCTs, observational and experimental evidence.³² The evidence shows that respirators offer better protection than masks, but that any protection is better than none during a pandemic or serious emerging respiratory infection. There was also new research during the covid-19 pandemic that highlighted the false dichotomy of droplet versus airborne transmission, and provided new insights into aerosol transmission of viruses and the resulting inhalation risk in indoor environments.³² Evidence from community and experimental studies shows that protection increases from cloth masks to surgical masks to N95 respirators.¹⁵⁰ The effectiveness is subject to compliance and if used early in an epidemic.

Hand hygiene should be used for donning and doffing of a mask, with one study showing protection of masks only when combined with hand hygiene.¹³⁹

RCTs that showed low or no community efficacy of masks by intention-to-treat analysis generally had low compliance with mask wearing. Compliance is a function of risk perception, which might increase during serious epidemics—meaning that RCTs conducted during low risk periods and with low compliance might not reflect actual protection during a pandemic when compliance would be higher.

Current community guidelines for SARS-CoV-2 have a disproportionate focus on the use of masks as source control only for people with symptoms. This is inadequate for infections with significant asymptomatic or presymptomatic transmission, such as SARS-CoV-2 and influenza. For this reason, in high risk, high transmission settings, such as aged care facilities or hospitals, universal masking is more effective.⁷⁸ For infections like SARS-CoV-2 with substantial transmission in the asymptomatic or presymptomatic period, universal masking can have a major impact on flattening the curve, while masks for source control would have less impact.²⁵⁸ The dramatic decline in other respiratory viral infections such as influenza as a result of covid mitigations such as masks in 2020 is a real world demonstration of effectiveness.²⁵⁹

Mask policies are commonly static and fail to consider changing epidemiology and risk. We suggest a multifactorial approach to policies around mask use, which consider specific characteristics of the pathogen, degree of asymptomatic transmission, host and organization, as well as context and disease epidemiology. Epidemic and pandemic infections are dynamic in nature, and use of masks and respirators should be tailored to the situational epidemiology. For example, SARS-CoV-2 has had several epidemic waves since it emerged, with periods of lower incidence between waves. A rising wave of a serious epidemic or pandemic can be a trigger for community masking. A stepwise plan for community masking could also be devised for serious epidemics, which might include earlier and ongoing masking for high risk settings such as hospitals and aged care; masking on public transport and in crowded public spaces; and reserving community wide mandates as a last resort. Figure 3 provides a schema for a stepwise plan, and shows that for healthcare and aged care, as well as other long term care facilities, masking should start earlier and continue for longer.

The highest priority is around healthcare workers, whose occupational health must be protected to ensure their safety, as well as integrity and effectiveness of health system capacity during an epidemic. High risk environments like healthcare and aged care should have agile policies that consider the pathogen, asymptomatic transmission, the level of community transmission, and the occupational safety of workers. Prevention of nosocomial outbreaks should be a goal, and a lower threshold for use of universal masking for staff and visitors should exist for aged care and healthcare during periods of high community transmission of infections like SARS-CoV-2. Research to develop new hierarchies of

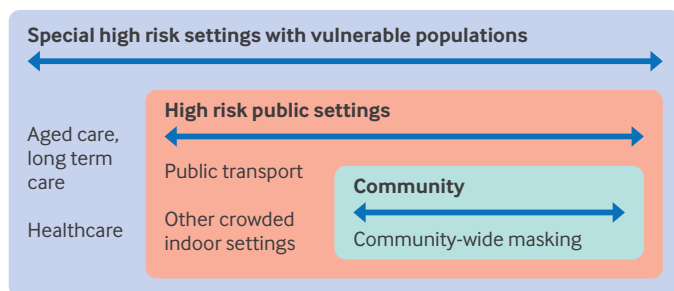


Fig 3 | Stepwise plan for mask use

control in occupational medicine for staff who treat patients with infection is also needed, as the current version was developed around physical injuries, and assumes hazards in the workplace are incidental to the job and can be removed or modified. They fail to account for healthcare workers, for whom the infectious patient is the hazard.

Respirators should be used for healthcare workers when the disease is severe with high case fatality rate, when healthcare worker absenteeism would affect health system functioning, or when no drug or vaccine is available.¹⁸¹ During emerging pandemics, healthcare workers face the hazard of a new infection as a non-negotiable part of their job, which differs from a construction worker, who might face hazards (such as faulty equipment) that can be removed or replaced. Additionally, during a pandemic, organizational changes might not occur fast enough for other protections, such as changes to ventilation systems. As such, PPE might be the only available protection for healthcare workers. The precautionary principle should be used during serious epidemics, a key lesson articulated in the aftermath of SARS in Canada, where a large, fatal outbreak occurred in Toronto, with healthcare workers refused N95 respirators.²⁶⁰ By contrast, Vancouver, where healthcare workers were provided N95s, did not have an outbreak, despite Toronto and Vancouver having their first SARS case at the same time. Unfortunately, that lesson was not learnt during the SARS-CoV-2 pandemic 17 years later, where the same disagreements about masks and respirators occurred and many healthcare workers died.²⁶¹ The evidence from healthcare supports N95 use, but continuously rather than occasionally in self-identified situations of risk.³² This will require a major paradigm shift because guidelines to date recommend targeted

use of respirators in very select situations. Targeted N95 use might be a cost saving measure, rather than evidence based policy, but all health systems must adequately cost occupational safety measures for their staff. In fact, studies suggest using cheaper, less effective masks, which might end up being costlier in the long run for hospitals.²⁶² Figure 4 shows a decision tree for selecting mask or respirator use in various settings based on available evidence, which might assist organizations or health providers.

Research gaps and the way forward

More research is needed to address research gaps (box 1). Research on sustainable and reusable products will help overcome acute shortages during emergencies, as will research and clear guidelines on contingency and crisis strategies such as reuse, extended use, and disinfection of disposable products. Effectiveness of non-standardized practices should also be studied, including the use of cloth masks, mask reuse, extended use, and double masking. Gaps remain in research on cost effectiveness to inform stockpiling of PPE for pandemics, as shortages occur during every pandemic. Stockpiling for pandemics has been inadequate during SARS-CoV-2 and the 2009 influenza pandemic, with global shortages of PPE early in each pandemic. Modeling and health economic studies might assist governments to stockpile effectively. A study during covid-19 reported the cost effectiveness of N95 respirators in terms of reducing hospital acquired infections and deaths, and a reduction in patient bed days and staff replacement needs.²⁶³ Another study showed that N95 respirators in healthcare can be cost effective, but more studies would assist with choices in the healthcare sector, and for pandemic planning and stockpiling.^{264 265} Finally, strategies

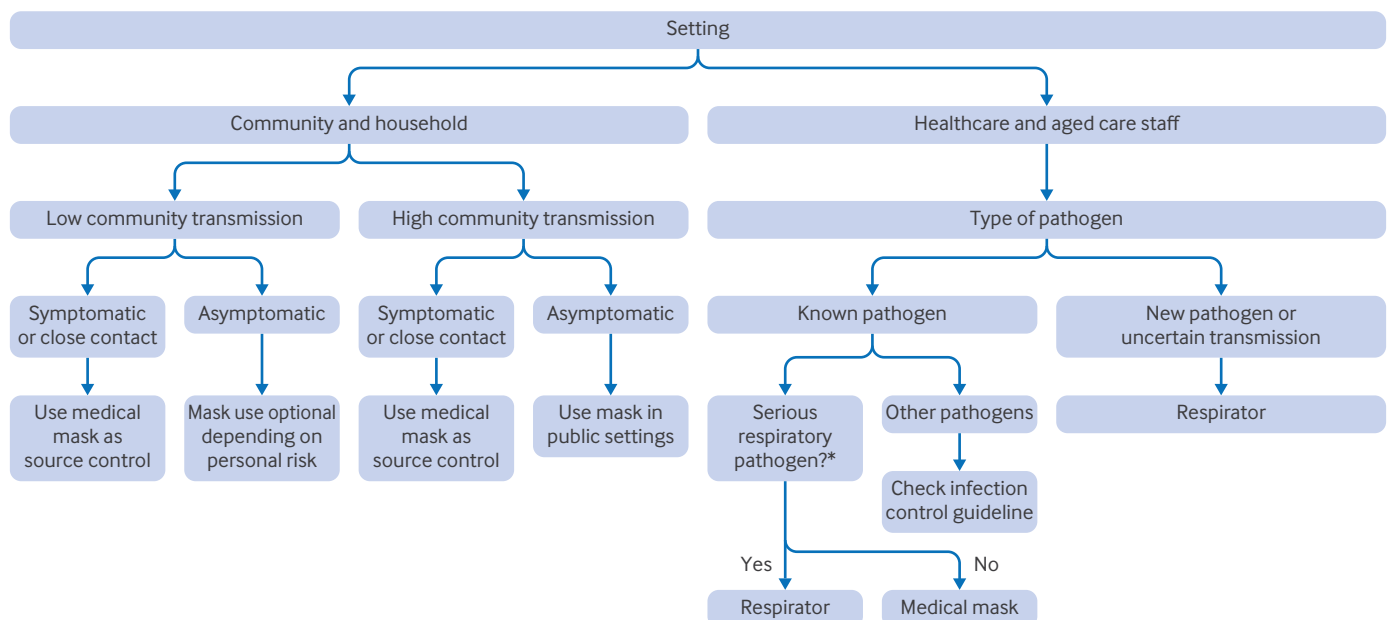


Fig 4 | Decision tree for selecting mask or respirator use in various settings to protect from respiratory infections. *Pathogens with high epidemic activity or high consequence pathogen

Box 1: Suggested directions for further research

1. Research on effective health communication, health promotion, and countering disinformation
2. Effectiveness of non-standardized practices, including cloth mask use, mask reuse, extended use, and double masking, and methods to clean and disinfect masks and respirators for reuse
3. Research to develop new materials and designs for sustainable and reusable masks and respirators for community and healthcare use
4. Research and develop new hierarchies of control in occupational medicine in the context of health workers and serious infections where avoidance and substitution are not possible for a clinician treating patients with infection
5. Research on masks for population groups with special needs, such as children, people with hearing impairment, people with respiratory, neurocognitive or psychiatric illness, and other groups
6. Modeling studies to inform better stockpiling by governments and hospitals
7. Comprehensive economic evaluation analyses of facemasks incorporating clinical efficacy estimates applied to different settings such as healthcare, aged care, and community

should be developed to improve compliance with the use of masks in healthcare and community settings. Most of the observational studies on mask use were conducted during epidemics and pandemics when compliance is generally high because of mask mandates or high risk perception. Compliance might be lower in routine occupational settings such as hospitals or aged care facilities, but proactive, early mask use in such settings is shown to reduce outbreaks.

Community engagement, especially around healthcare, aged care, and groups that have difficulty with masking such as children, those with hearing impairments, or people with chronic obstructive pulmonary disease is also key to developing mask policy. Countering disinformation and politicization of masks will also assist in preparedness for future pandemics. The discrepant and rapidly changing mask policies seen during covid-19 are concerning because the available evidence was adequate at the start of the pandemic. This suggests that ideology, lack of understanding of the available evidence, short supply and cost, rather than evidence, drove this inconsistency. In fact, contradictory mask policies during covid-19 (such as not recommending masks at the beginning of the pandemic and then recommending N95s for community settings by the US CDC) might have contributed to loss of public trust.²⁵ If health leaders are seen to hesitate, or lack knowledge or confidence, then confidence in the pandemic response might be eroded. There has been a backlash against public health measures in general, including masks and vaccines after the covid-19 pandemic.^{266 267} Widespread disinformation has polarized communities about masks, which have become a stigmatizing political symbol rather than a simple public health measure.²⁶⁸ More research is needed on effective health communication and countering disinformation.

Some population groups might have difficulty using masks, including children, people with

hearing impairment, cognitive impairment, chronic respiratory impairment, or mental illness. These groups should be considered for exemptions or other solutions and protective strategies. For example, clear masks or masks with clear panels might aid communication for people with hearing impairment.

Limitations of review

There are limitations of this review. RCTs on mask use are difficult to conduct for many reasons, such as unpredictable incidence of infection in the community, low compliance with masks, measurement of outcomes, complexity of follow-up, the statistical power needed to study relatively rare outcomes, and the lack of control groups for ethical reasons.³⁴ The available RCTs are heterogeneous in settings (eg, household v healthcare), design (eg, individual v cluster randomization), interventions (eg, continuous v intermittent use), and outcome measures (eg, serology v PCR testing). Therefore, meta-analysis of these RCTs can be misleading if they combine data from trials with heterogeneous interventions and outcomes. To address this issue, recently we performed meta-analyses of RCTs in healthcare and community settings, including studies with similar settings, interventions, and outcome measures, showing that respirators perform the best.³² Another limitation of this review is including only English language publications. During covid-19, many studies were conducted globally on masks and respirators, which might not be included in this review. Finally, one author (CRM) has conducted a large body of RCTs on mask use in healthcare and community settings, so our own work is cited in this paper. However, all other published RCTs to 2024 are included in this review (table 1, table 2, table 3).

Conclusion

In conclusion, there is ample evidence on the effectiveness of masks and respirators in community and healthcare settings to inform consistent policy.³² Respirators are superior and should be the first choice in a serious emerging epidemic or pandemic in healthcare and aged care settings. Community mask use is effective when risk is high or during periods of increased community transmission of pathogens, especially among those who are asymptomatic. The pathogen, host, and organizational context should all influence policy, which should be flexible to changing disease epidemiology. Strong leadership is required to overcome politicization and polarization around masks. The unprecedented global spread of avian influenza A (H5N1 clade 2.3.4.4b) since 2021 and the increasing risk of a human pandemic make it imperative that governments take steps to stockpile, prepare and develop sound guidelines, provide health leadership, and address disinformation.

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to manuscript writing; TG: worked on RCT and non-RCT evidence, contributed to manuscript writing.

Competing interests: We have read and understood the BMJ policy on declaration of interests and declare the following interests: CRM has in the past received funding for investigator driven research on facemasks from 3M in the form of an Australian Research Council Industry Linkage grant in 2010 (where 3M was the industry partner) and supply of masks for clinical research. She has been on an advisory board for mask manufacturer, Ascend and conducted clinical research study with them. She has also received funding or in-kind support from Detmold, Sanofi, GSK, Merck, BioCSL, and Pfizer for investigator driven research on infectious diseases. TG is a member of Independent SAGE. She has previously received funding from Wellcome Trust and UK National Institute for Health Research on pandemic related research (including rapid reviews of masks). In the past three years, TG has received grants from the UK National Institute for Health Research, Balvi, the Medical Research Council, Health Data Research UK, and Research Council of Norway. She is a governing body fellow of Green Templeton College, Oxford; and a Visitor at the Pitt Rivers Museum, Oxford; and was previously a Trustee and advisor to the Hilda Martindale Charitable Trust. TG is also a member of Independent SAGE. The other authors declared no conflict of interest.

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Web appendix: Supplementary table S1