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Facemasks for the prevention of infection in healthcare and community settings

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ABSTRACT

Facemasks are recommended for diseases transmitted through droplets and respirators for respiratory aerosols, yet recommendations and terminology vary between guidelines. The concepts of droplet and airborne transmission that are entrenched in clinical practice have recently been shown to be more complex than previously thought. Several randomised clinical trials of facemasks have been conducted in community and healthcare settings, using widely varying interventions, including mixed interventions (such as masks and handwashing), and diverse outcomes. Of the nine trials of facemasks identified in community settings, in all but one, facemasks were used for respiratory protection of well people. They found that facemasks and facemasks plus hand hygiene may prevent infection in community settings, subject to early use and compliance. Two trials in healthcare workers favoured respirators for clinical respiratory illness. The use of reusable cloth masks is widespread globally, particularly in Asia, which is an important region for emerging infections, but there is no clinical research to inform their use and most policies offer no guidance on them. Health economic analyses of facemasks are scarce and the few published cost effectiveness models do not use clinical efficacy data. The lack of research on facemasks and respirators is reflected in varied and sometimes conflicting policies and guidelines. Further research should focus on examining the efficacy of facemasks against specific infectious threats such as influenza and tuberculosis, assessing the efficacy of cloth masks, investigating common practices such as reuse of masks, assessing compliance, filling in policy gaps, and obtaining cost effectiveness data using clinical efficacy estimates.



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Introduction

Most efforts on the prevention of respiratory infections have focused on drug based interventions. In an emerging outbreak of infectious disease, non-pharmaceutical measures including facemasks and respirators may be the only available protection.

Various devices are used in healthcare and community settings worldwide, ranging from cloth, cotton, or gauze masks (cloth masks); medical, surgical, or procedure mask (medical masks); and N95, N99, N100, P2, P3, FFP2, and FFP3 respirators (respirators). The difference between the products arises from their design and intended use. Medical masks and cloth masks (hereafter “facemasks”) were designed to prevent the spread of infection from wearers to others, but are commonly used to protect the wearer from splashes or sprays of blood or body fluids. Facemasks are not subject to regulation, do not provide a seal around the face, and vary widely in type and quality.^{1 2} A respirator is a fitted device designed to protect the wearer from respiratory infections, which provides a seal around the face and is defined and regulated by its filtration capacity.^{1 2}

No consensus exists around the choice between facemasks and respirators for respiratory protection, as is starkly illustrated by the widely discrepant guidelines for protection against the Ebola virus in the midst of the worst epidemic in history.³ Although the efficacy of hand washing against respiratory and gastrointestinal infection has long been established in randomised clinical trials (RCTs),⁴⁻⁶ evidence for facemasks has lagged behind. The threat of pandemic A/H5N1 influenza and resultant pandemic planning drove the first RCTs of facemasks in various settings.⁷⁻¹⁹ The aim of this review is to inform policy makers and stakeholders by examining and summarising the available evidence related to the efficacy of facemasks and respirators, current practice, and guidelines, as well as highlighting the gaps in evidence.

Sources and selection criteria

We searched for evidence on facemasks and respirators in community and healthcare settings related to efficacy, policies, guidelines, clinical practice (including compliance and non-standard practices), organisational matters, regulation and fit testing, and cost effectiveness.

The following databases were searched: Medline (January 1950 to 31 July 2014), Embase (1988 to 31 July 2014), the Cochrane Library, Web of Science, and Google scholar. We also searched the Australian New Zealand Clinical Trials Registry (ANZCTR) and the US National Institutes of Health Clinical trial registry.

We used the following keywords: “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”, “pandemic influenza and facemasks/mask/respirator”, “SARS and facemasks/mask/respirator” “tuberculosis and facemasks/mask/respirator”, “TB and facemasks/mask/respirator” 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.²⁰ RCTs were considered as level 1 (high) evidence, observational studies (cohort, case control, before after, time series, case series, and case reports) as level 2 (low) evidence, and any other evidence as level 3 (very low) evidence.²⁰ Only high level evidence (from RCTs) is summarised in the tables and figures. Because this article is not a systematic review, we did not further grade individual RCTs into high, moderate, low, and very low quality evidence but summarised each RCT’s specific limitations. AAC reviewed the titles of the search articles and prepared an initial list of articles to be included in the study. Both authors then independently reviewed the abstracts included in the list and selected studies to be included in the figures.

We examined infection control policies and guidelines from the World Health Organization, US Centres for Disease Prevention and Control (CDC), European Centre for Disease Prevention and Control (ECDC), and other health organisations for recommendations on the use of facemasks and respirators. We also did a Google search and searched the websites of other health related organisations. Policies and guidelines on the use of facemasks were also searched using the following keywords: “infection 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”. Only English language articles were reviewed.

Use of facemasks and respirators in healthcare settings

Studies in the late 19th century first examined cloth masks for the prevention of the spread of infection from surgeons to patients in the operating theatre.^{21–22} Cloth masks have been used for respiratory protection since the early 20th century.²³ The first study of the use of facemasks by healthcare workers in 1918 found low rates of infection in those who used a cloth mask.²⁴ Masks were also used to protect healthcare workers from scarlet fever, measles,²⁵ influenza,^{26–27} plague,²⁸ and tuberculosis.²⁹

The use of disposable medical masks became common in the mid-20th century,^{30–31} with very little research on cloth masks since, despite their continued widespread use in developing countries.²³ Respirators were later specifically designed for respiratory protection. We identified 13 RCTs on face masks and respirators, which studied a diverse range of interventions and outcomes. Of these, four were conducted in the healthcare setting and nine in various community and household settings.^{7–19} Three unpublished RCTs were identified from clinical trial registries, two of which were carried out in healthcare settings and one in the Hajj.^{32–34} We also found systematic reviews of some RCTs, and several observational studies.^{35–43}

Efficacy of facemasks and respirators in healthcare settings

Randomised controlled trials

In line with GRADE, we considered RCTs as the best available evidence. We identified only four RCTs of the clinical efficacy of facemasks or respirators in healthcare workers, which studied a diverse range of interventions and outcomes (fig 1).^{7–10} The updated 2014 WHO guidelines on personal protective equipment (PPE) cite two of these four trials,⁴⁴ but exclude the larger two.^{9–10}

The first trial, which was carried out in healthcare workers in Japan, randomised 32 workers to a medical mask group or a control arm. It found no significant difference in respiratory illnesses ($P=0.81$) but was underpowered to examine efficacy.⁷ The second trial compared targeted use of medical masks and N95 respirators in 446 nurses in Canada and reported equal efficacy in preventing influenza (23.6% with medical masks *v* 22.9% with respirators; absolute risk difference, -0.73% , 95% confidence interval -8.8% to 7.3%).⁸ However, because the study did not have a control group it technically cannot determine efficacy—both arms may have been equally ineffective, as suggested by the high rate of influenza in both groups. Similar rates of influenza of 23% have been described in unprotected healthcare workers during hospital influenza outbreaks.⁴⁶ Studies of nosocomial influenza generally describe lower attack rates than this second study, which suggests that targeted masks and respirators are equally ineffective (rather than equally efficacious).⁴⁷

The third trial, which investigated 1922 healthcare workers in China, compared continuous use of medical masks, N95 respirators (fit tested and not fit tested), and a control group.⁹ N95 respirators protected against clinical respiratory infection (odds ratio 0.38, 0.17 to 0.86 but not against polymerase chain reaction (PCR) confirmed influenza.⁹ Trends for all outcomes, including influenza, showed the highest infection rates in the control arm and the lowest in the N95 arm.

The fourth RCT, which looked at 1669 healthcare workers in China, compared continuous use of N95 respirators, targeted use of N95 respirators while doing high risk procedures, and continuous use of medical masks. The study showed efficacy of continuous N95 use against clinical respiratory infection (hazard ratio 0.39, 0.21 to 0.71) and bacterial colonisation (0.40, 0.21 to 0.73). No difference was seen between targeted N95 use and medical mask use, which suggests that a N95 respirator

Study, year of publication	Design, methods	Mask type, intervention	Outcome	Results	Comments, limitations, biases
Jacobs ⁷ 2009	<ul style="list-style-type: none"> Block RCT Tertiary care hospitals in Tokyo Japan, 2007 32 HCWs (2464 subject days) 	<ul style="list-style-type: none"> Medical masks Control group 	<ul style="list-style-type: none"> Self reported cold symptoms 	<ul style="list-style-type: none"> No difference in outcome (cold symptoms) in intervention v control arm (P=0.81) 	<ul style="list-style-type: none"> Self reported compliance 84.3% Small study Underpowered Symptoms self reported—not laboratory confirmed
Loeb et al ⁸ 2009	<ul style="list-style-type: none"> Non-inferiority randomised clinical trial, no controls 8 tertiary care hospitals in Ontario, Canada 2008-09 446 nurses 	<ul style="list-style-type: none"> Targeted use of medical masks Fit tested N95 respirators 	<ul style="list-style-type: none"> Laboratory confirmed influenza infection assessed by PCR or seroconversion during 2008-09 	<ul style="list-style-type: none"> No difference in the outcome Rate of mostly serologically defined influenza in the medical mask group 23.6% v 22.9% in the respirator group (absolute risk difference -0.73%, 95% CI -8.8% to -7.3%) 	<ul style="list-style-type: none"> No data on compliance No control arm, no information on training or fit testing Despite statement to the contrary, reported numerator and denominator data show that seropositive vaccinated subjects included in definition of "influenza" Study was stopped early owing to influenza A/H1N1-pdm09, as respirator use became mandatory Stated as "non-inferiority" but superiority of any tested intervention not previously proved in any RCT
MacIntyre ⁹ 2011	<ul style="list-style-type: none"> Cluster RCT 15 hospitals in Beijing China, 2008-09 1441 HCWs, 481 convenience controls 	<ul style="list-style-type: none"> Medical masks N95 respirators (fit tested) N95 respirators (not fit tested) Convenience control group 	<ul style="list-style-type: none"> Self reported CRI Self reported ILI Laboratory confirmed viral infection and influenza by PCR 	<ul style="list-style-type: none"> Compared with medical masks, all outcomes were consistently lower for the N95 group CRI (OR 0.38, 0.17 to 0.86) and laboratory confirmed viral infection (0.19, 0.05 to 0.67) significantly lower in N95 group 	<ul style="list-style-type: none"> Self reported compliance 68-86% Use of convenience control group N95 protective compared with medical masks (excluding controls) Lack of power for PCR confirmed influenza
MacIntyre ¹⁰ 2013	<ul style="list-style-type: none"> Cluster RCT, no controls Beijing China 2010-11 1669 HCWs in 68 wards (19 hospitals) 	<ul style="list-style-type: none"> Continuous use of N95 respirators Targeted use of N95 respirators for high risk situations Continuous use of medical masks 	<ul style="list-style-type: none"> Self reported CRI Self reported ILI Laboratory confirmed viral infection and influenza by PCR 	<ul style="list-style-type: none"> Rates of CRI (HR 0.39, 0.21 to 0.71) and bacterial colonisation (0.40, 0.21 to 0.73) significantly lower in the continuous N95 respirator use arm 	<ul style="list-style-type: none"> Self reported compliance 57-82% Lack of power for PCR confirmed influenza
MacIntyre ⁴⁵ 2014*	<ul style="list-style-type: none"> Cluster RCT 15 hospitals in Beijing China, 2008-09 1441 HCWs 	<ul style="list-style-type: none"> Medical masks N95 respirators (fit tested and not fit tested) Convenience control group 	<ul style="list-style-type: none"> Laboratory confirmed bacterial colonisation 	<ul style="list-style-type: none"> Bacterial colonisation was significantly lower among HCWs who used N95 respirators (RR 0.34, 0.21 to 0.56) Dual infections significantly lower in N95 arm 	<ul style="list-style-type: none"> Analysis of bacterial outcomes from previous RCT Bacterial testing was done on symptomatic subjects only, so cannot determine if bacterial colonisation higher in symptomatic versus asymptomatic subjects

*Same as the RCT by MacIntyre,⁹ but reports the outcome of bacterial infection.
 CI=confidence interval; CRI=clinical respiratory infection; HCW=healthcare worker; HR=hazard ratio; ILI=influenza-like illness; OR=odds ratio; PCR=polymerase chain reaction; RCT=randomised controlled trial; RR=relative risk

Fig 1 | Summary of high level evidence (GRADE guidelines) on facemasks and respirators in the healthcare setting

needs to be worn throughout the shift to be protective.¹⁰ None of the four RCTs showed that medical masks were efficacious, although efficacy might have been at a lower level than the trials were able to detect.^{9 10}

Bacterial colonisation

An analysis published in 2014 showed that laboratory confirmed bacterial colonisation (mainly *Streptococcus pneumoniae* and *Haemophilus influenzae*) is common in healthcare workers with symptoms of respiratory illness.⁴⁵ Importantly, N95 respirators significantly reduced the risk of bacterial colonisation by 62% compared with no mask and by 46% compared with medical masks, which were not efficacious. These findings may have important implications for policy and practice, but the role of respirators to help combat antibiotic resistant bacteria has not been tested in an RCT. The analysis also found that simultaneous infection of healthcare workers with two bacteria and a virus, or a bacterium and two viruses was common,⁴⁵ and that an N95 respirator significantly protected against dual infections.

Non-randomised studies

Lower levels of evidence are available from cohort,⁴⁸ case-control,⁴⁹⁻⁵⁵ cross sectional,⁵⁶⁻⁶¹ laboratory experimental,⁶²⁻⁶⁸ and observational (including time series and case series)

studies.⁶⁹⁻⁷⁸ Most were conducted during the severe acute respiratory syndrome (SARS) outbreak,^{50-55 59-61 69 72-75 79} but others examined tuberculosis,^{77 80 81} respiratory syncytial virus (RSV),⁴⁸ and pertussis.⁵⁸

With a few exceptions,^{53 60 74} evidence from SARS favoured the use of facemasks or respirators (or both) in healthcare workers. Respirators are generally recommended for tuberculosis, although most of these studies examined a combination of simultaneous infection control practices (environmental and source control measures).^{77 80 81} No study has measured the efficacy of facemasks or respirators in preventing tuberculosis (either asymptomatic infection or disease) in healthcare workers. A small study found no significant difference in the rate of RSV between hand hygiene versus mask wearing or hand hygiene versus gown wearing.⁴⁸ An observational study showed that medical masks protected against nosocomial transmission of pertussis in staff and patients.⁵⁸

In vivo studies report varying levels of filtration performance and protection for different types of barrier, with the degree of protection increasing from cloth masks, to medical masks, and finally to respirators.^{37 64 68} Conflicting advice is given by different agencies for other infections such as Middle East respiratory syndrome coronavirus (MERS-CoV) and Ebola virus disease.^{3 82}

Study, year of publication	Design, participants	Mask type, intervention	Outcome	Results	Comments, limitations, biases
Cowling ¹¹ 2008	<ul style="list-style-type: none"> Cluster RCT 198 index cases and household contacts Hong Kong 	<ul style="list-style-type: none"> Medical masks Hand hygiene Control 	<ul style="list-style-type: none"> Self reported influenza symptoms Laboratory confirmed influenza (by culture or RT-PCR) in household 	<ul style="list-style-type: none"> No significant difference in rates of laboratory confirmed influenza (OR 1.16, 95% CI 0.31 to 4.34) and ILI (0.88, 0.34 to 2.27) in the medical masks arm versus control arm 	<ul style="list-style-type: none"> Both index cases and household contacts used medical masks This pilot study was small and underpowered Compliance 45% in index cases and 21% in household contacts Compliance data showed that some index cases in the control and hand hygiene arms used medical masks
Cowling ¹² 2009	<ul style="list-style-type: none"> Cluster RCT 407 index cases and 794 household contacts Hong Kong 	<ul style="list-style-type: none"> Hand hygiene Masks + hand hygiene Control (education) 	<ul style="list-style-type: none"> Self reported influenza symptoms Laboratory confirmed influenza (by RT-PCR) in household 	<ul style="list-style-type: none"> No significant difference in rate of laboratory confirmed influenza in three arms Significant difference if masks + hand hygiene together applied within 36 hours of illness (OR 0.33, 0.13 to 0.87) Hand hygiene alone was not significant 	<ul style="list-style-type: none"> No separate medical mask arm, making it difficult to evaluate the efficacy of masks Both index cases and household contacts used masks Compliance 49% in index cases and 26% in household contacts using masks Compliance data showed that some index cases in the control and hand hygiene arms used medical masks
MacIntyre ¹³ 2009	<ul style="list-style-type: none"> Cluster RCT 145 child index cases and well adult household contacts Australia 	<ul style="list-style-type: none"> Medical masks for contacts P2 respirators (equivalent to N95) for contacts Control 	<ul style="list-style-type: none"> Self reported ILI Laboratory confirmed respiratory infection 	<ul style="list-style-type: none"> No significant difference in ILI and laboratory confirmed respiratory infections in all three arms Adherent use of P2 or medical masks significantly reduced the risk of ILI (HR 0.26, 0.09 to 0.77) 	<ul style="list-style-type: none"> Only household contacts used medical masks Low compliance: 21% of household contacts wore masks often/always
Aiello ¹⁴ 2010	<ul style="list-style-type: none"> Cluster RCT 1437 well university residents Michigan, USA 	<ul style="list-style-type: none"> Medical masks Medical masks + hand hygiene Control 	<ul style="list-style-type: none"> Self reported ILI Laboratory confirmed influenza (by culture or RT-PCR) 	<ul style="list-style-type: none"> No significant difference in ILI in three arms Significant reduction in ILI in the medical masks + hand hygiene arm over 4-6 weeks (P<0.05) 	<ul style="list-style-type: none"> Self reported ILI Not all ILI cases (n=368) were laboratory tested (n=94) No data on compliance
Larson ¹⁵ 2010	<ul style="list-style-type: none"> Block RCT 617 households Manhattan, USA 	<ul style="list-style-type: none"> HE HE + hand sanitiser HE + hand sanitiser + medical masks 	<ul style="list-style-type: none"> Self reported ILI Self reported URI Laboratory confirmed influenza through culture or PCR 	<ul style="list-style-type: none"> No significant difference in rates of URI, ILI, or laboratory confirmed influenza between the three arms Significantly lower secondary attack rates of URI/ILI/influenza in the HE + hand sanitiser + medical mask arm (OR 0.82, 0.70 to 0.97). 	<ul style="list-style-type: none"> No separate medical masks group Household contacts used medical masks Low compliance and around half of household in the masks arm used masks within 48 hours There was no index case at home
Canini ¹⁶ 2010	<ul style="list-style-type: none"> Cluster RCT 105 index cases and 306 households France 	<ul style="list-style-type: none"> Medical mask (as source control to be used by index case) Control 	<ul style="list-style-type: none"> Self reported ILI in household 	<ul style="list-style-type: none"> No significant difference in the rates of ILI between the two arms (OR 0.95, 0.44 to 2.05) 	<ul style="list-style-type: none"> Trial stopped early owing to low recruitment and influenza A/H1N1-pdm09 in subsequent year
Simmerman ¹⁷ 2011	<ul style="list-style-type: none"> Cluster RCT 465 index patients and their families Thailand 	<ul style="list-style-type: none"> Hand hygiene Hand hygiene + medical masks Control 	<ul style="list-style-type: none"> Self reported ILI Laboratory confirmed influenza by PCR and serology in family members 	<ul style="list-style-type: none"> No significant difference in secondary influenza infection rates between hand hygiene arm (OR 1.20, 0.76 to 1.88) and hand hygiene plus medial masks arm (1.16, 0.74 to 1.82) 	<ul style="list-style-type: none"> No separate medical mask group Owing to H1N1 pandemic, hand and respiratory hygiene campaigns and mask use substantially increased among the index cases (from 4% to 52%) and families (from 17.6% to 67.7%) in control arm
Aiello ¹⁸ 2012	<ul style="list-style-type: none"> Cluster RCT 1178 university residents Michigan, USA 	<ul style="list-style-type: none"> Medical masks Medical masks + hand hygiene Control 	<ul style="list-style-type: none"> Clinically diagnosed and laboratory confirmed influenza (by RT-PCR) 	<ul style="list-style-type: none"> No overall difference in ILI and laboratory confirmed influenza in three arms Significant reduction in ILI in the medical masks + hand hygiene arm over 3-6 weeks (P<0.05) 	<ul style="list-style-type: none"> Good compliance: medical mask + hand hygiene group used masks for 5.08 h/day (SD 2.23) and medical mask group used masks for 5.04 h/day (SD 2.20) Self reported ILI Effect may have been due to hand hygiene because medical masks alone not significant
Suess ¹⁹ 2012	<ul style="list-style-type: none"> Cluster RCT 84 index cases and 218 household contacts Berlin, Germany 	<ul style="list-style-type: none"> Masks Masks + hand hygiene Control 	<ul style="list-style-type: none"> Laboratory confirmed influenza infection and ILI 	<ul style="list-style-type: none"> No significant difference in rates of laboratory confirmed influenza and ILI in all arms by intention to treat analysis The risk of influenza was significantly lower if data from two intervention arms (masks and masks + hand hygiene) were pooled and intervention was applied within 36 hours of the onset of symptoms (OR 0.16, 0.03 to 0.92) 	<ul style="list-style-type: none"> Around 50% participants wore masks "mostly" or "always" Participants paid to provide respiratory samples

CI=confidence interval; CRI=clinical respiratory infection; HCW=healthcare worker; HE=health education; HR=hazard ratio; ILI=influenza-like illness; OR=odds ratio; PCR=polymerase chain reaction; RCT=randomised controlled trial; RR=relative risk. RT=reverse transcriptase; SD=standard deviation; URI=upper respiratory tract infection.

Fig 2 | Summary of high level evidence (GRADE guidelines) on facemasks in the household setting

Role of cloth masks

Cloth masks are commonly used in developing countries and many non-standard practices around cleaning and reuse have evolved. However, no RCTs of cloth masks have been published. Most studies were conducted before the development of disposable masks.²³ Data on the use of cloth masks for the prevention of diphtheria, measles, and tuberculosis are limited and outdated.^{24 25 29} The penetration through cloth is reported to be high—40–90% of particles penetrated in one study.⁶³ Without an RCT it is unclear whether cloth masks provide clinical protection. Given their widespread use in developing countries, including Asia, where the risk of emerging infectious diseases is high, research on the clinical efficacy of cloth masks is needed. Healthcare workers in the west African Ebola outbreak use cloth masks when other supplies are not available (personal communication, W Beckley, 2014). Guidelines make cautious recommendations about the use of such masks when medical masks and respirators are in high demand and supplies are exhausted.^{83 84}

Facemasks as source control

Facemasks were first used in operating theatres to maintain a sterile operating field and to prevent transmission of infection from surgeons to patients. However, studies fail to show any efficacy for this indication.^{85–87} Only one randomly controlled clinical trial reported high infection rates after gynaecological and abdominal surgery—three of five women developed infection in the “no mask” group compared with no infections in the four women operated on by a masked surgeon.⁸⁸ Guidelines have recommended medical masks for use in operating theatres to protect staff from the splash and spray of blood and body fluids.⁸⁹ A visor or protective face shield may be used, subject to adequate air circulation and ventilation,⁹⁰ but no studies have directly compared these options. Although the use of facemasks for source control has not been proved in the operating theatre setting, their use is standard across most healthcare sites.

As source control, facemasks are also used by sick people to prevent the spread of infection to others. An experimental study showed that the spread of influenza virus from a sick patient may be reduced by the patient wearing a facemask or a respirator.⁹¹ A study on volunteers with influenza-like illnesses symptoms reported a more than threefold reduction of viral particles in exhaled samples with use of medical masks.⁹² During the SARS outbreak, medical and cloth masks were used as source control and were reported to be effective.⁶¹ Evidence shows that the use of facemasks by infective patients with tuberculosis reduces the risk of tuberculosis transmission.⁹³ Despite the lack of data from human clinical trials, medical masks are highly recommended by WHO, the CDC, and the ECDC for source control in tuberculosis.^{44 94 95}

The use of facemasks in the community setting

Facemasks are used in the community in Asian countries, not only to protect people from acquiring respiratory infections but also to minimise spread of infection from the wearer. Such use often increases during outbreaks and pandemics. Cloth masks were reportedly used by the

general public during the 1918 influenza pandemic.^{26 27} During the SARS outbreaks, masks were widely used in diverse community settings.^{96 97}

Efficacy of facemasks in the community

We identified nine RCTs of facemasks in various household and community settings,^{11–19} and in all but one they were used for respiratory protection. In one household trial the use of facemasks was tested as source control to prevent the spread of infections from the wearer.¹⁶ These RCTs had diverse settings, designs, and interventions—many of which were mixed, such as hand washing and facemasks (fig 2).

An RCT in Hong Kong randomised index cases (198 laboratory confirmed influenza cases) and their households into medical masks, hand hygiene, or a control arm. Rates of laboratory confirmed influenza and influenza-like illness were not significantly different in the medical mask arm versus the control arm (influenza: odds ratio 1.16, 0.31 to 4.34; influenza-like illness: 0.88, 0.34 to 2.27).¹¹ In a second trial by the same group, medical masks plus hand hygiene and hand hygiene alone groups were compared with a control group (total 407 index cases). There was no significant difference across the three arms, although medical masks plus hand hygiene were protective when the intervention was implemented early (within 36 hours of onset of symptoms in the index case, adjusted odds ratio 0.33, 0.13 to 0.87).¹²

An Australian study randomised 145 index cases and their household members to one of three arms—medical masks, P2 respirators (equivalent to N95), or control.¹³ In contrast to the second trial above, where both index cases and household members used a mask,¹² only household contacts used a medical mask in this study. No significant difference in the risk of influenza-like illness was seen between the three arms in the per protocol analysis, but risk was significantly lower with the adherent use of P2 or medical masks (hazard ratio 0.26, 0.09 to 0.77).¹³

Two RCTs in university residence halls in the United States over two influenza seasons randomised well students into medical masks plus hand hygiene, medical masks alone, or control.^{14 18} Influenza-like illness and laboratory confirmed influenza were not significantly reduced after either intervention, although during the first four to six weeks, influenza-like illness was significantly lower in the medical masks plus hand hygiene arm in both trials ($P < 0.05$).^{14 18} This suggests that hand hygiene might have been the major contributor to protection.

An RCT in the US randomised 617 households to education, hand sanitiser alone, or hand sanitiser plus medical masks. Although the rates of upper respiratory tract infections, influenza-like illness, and laboratory confirmed influenza were low in the hand sanitiser and hand sanitiser plus medical masks groups, the difference was not significant after adjusting for other factors. However, the hand sanitiser plus medical masks group had significantly lower secondary attack rates for influenza, influenza-like illness, and upper respiratory tract infections (odds ratio 0.82, 0.70 to 0.97) compared with the education group. Results for the hand sanitiser only group were not significant (1.01, 0.85 to 1.21).¹⁵

Table 1 | Summary indications for use of masks and respirators for selected infectious diseases

Disease	Healthcare setting*		Community setting†	
	Low risk	High risk	Low risk	High risk
Seasonal influenza	First choice: medical mask‡§; Second choice: cloth mask**	First choice: respirator‡§; Second choice: medical mask**; Third choice: cloth mask**	Not recommended‡§	Not recommended‡§
Pandemic influenza	First choice: respirator‡ or medical mask§; Second choice: cloth mask**	First choice: respirator‡§; Second choice: medical mask**; Third choice: cloth mask**	Not recommended‡§	First choice: medical mask‡§; Second choice: cloth masks**
MERS-CoV	First choice: respirator‡ or medical mask§	First choice: respirator‡§	Not recommended	Not recommended
Tuberculosis	First choice: respirator‡§	First choice: respirator‡§	Not recommended‡§	Not recommended*†
Ebola virus	First choice: respirator‡ or medical mask§; Second choice: cloth mask**	First choice: respirator‡§; Second choice: medical mask**; Third choice: cloth mask**	Not recommended‡§	First choice: medical mask‡; Second choice: cloth masks**

*Low risk: routine patient care, not within 1–2 m of infective patient; High risk: high risk procedures such as aerosol generating procedures, new or drug resistance organism.

†Low risk: home, non-crowded settings; high risk: crowded settings (such as public transport), pre-existing illness, pregnancy, older age (pandemic influenza), contact with human remains or infected animals (Ebola virus).

‡Centres for Disease Control and Prevention (CDC).

§World Health Organization.

**Not stated explicitly—inference drawn from Institute of Medicine (IOM) guidelines and other policy documents prepared for low recourse settings (As efficacy data is not available, cloth masks should be used only when no other option is available).

MERS-CoV=Middle East respiratory syndrome coronavirus.

An RCT in Thailand randomised 465 index patients and their families to hand hygiene, hand hygiene plus medical masks, and a control arm. No significant difference between secondary influenza rate was seen.¹⁷

In a cluster randomised controlled trial in Germany, 84 index cases and 218 household contacts were randomised into a mask arm, masks plus hand hygiene arm, and a control arm. There was no significant difference in rates of laboratory confirmed influenza and influenza-like illness in all arms by intention to treat analysis. However, the risk of influenza was significantly lower if the data from two intervention arms were pooled and the intervention was applied within 36 hours of the onset of symptoms (odds ratio 0.16, 0.03 to 0.92).¹⁹

A household trial in France examined the role of medical masks as source control—index patients were randomised into medical mask (52 household and 148 contacts) and control groups (53 household and 158 contacts). There was no difference between the groups (0.95, 0.44 to 2.05), and the trial was finished early owing to low recruitment and subsequent H1N1-pdm09 infection.¹⁶

Community use of facemasks during outbreaks and pandemics

The routine use of facemasks is not recommended by WHO, the CDC, or the ECDC in the community setting.^{98–100} However, the use of facemasks is recommended in crowded settings (such as public transport) and for those at high risk (older people, pregnant women, and those with a medical condition) during an outbreak or pandemic.^{98 99}

A modelling study suggests that the use of facemasks in the community may help delay and contain a pandemic, although efficacy estimates were not based on

RCT data.¹⁰¹ Community masks were protective during the SARS outbreaks, and about 76% of the population used a facemask in Hong Kong.¹⁰² There is evidence that masks have efficacy in the community setting, subject to compliance¹³ and early use.^{12 18 19} It has been shown that compliance in the household setting decreases with each day of mask use, however, which makes long term use over weeks or months a challenge.¹³

The statistical power of each individual RCT may have been too low to determine efficacy by intention to treat, and larger trials may be needed. A meta-analysis of the existing community trials would be difficult because of the diverse settings, interventions, outcomes, and measurements. The study designs of all but one of the RCTs used mixed interventions, where one intervention was present in both intervention arms (such as hand hygiene alone compared with masks plus hand hygiene; fig 2), which makes it more difficult to determine the efficacy of masks alone.

Choice of facemask versus respirator

In communities where facemasks are commonly used, such as in Asia, the choice is between medical masks and cloth masks. In the healthcare setting, the choice is between respirators or medical masks in developed countries, and between respirators, medical masks, or cloth masks in developing countries (table 1). In the healthcare sector the purpose of PPE is the occupational health and safety of healthcare workers, and the choice should be made using a risk analysis framework.³ The framework should be based on expected mode of transmission, level of exposure or risk, severity of the disease in question, availability of other preventive or therapeutic agents, and uncertainty about transmission. Cost considerations, organisational factors, and individual factors (such as compliance) may affect implementation but should not drive best practice guidelines. In developing countries, the cost of N95 respirators may limit their use, and cloth masks are popular because they can be cleaned and reused.

Transmission modes

Infectious diseases can spread through droplets, respiratory aerosols, or direct and indirect contact with contaminated surfaces (table 2). Droplets are large

Table 2 | Primary modes of transmission of respiratory infections

Presumed main mode of transmission	Examples of virus	Examples of bacteria
Droplet	Influenza virus A and B*, coronavirus*	<i>Streptococcus pneumoniae</i> , <i>Haemophilus influenzae</i>
Airborne	Rhinovirus A and B	Tuberculosis, <i>Bordetella pertussis</i> *
Contact	Adenovirus, parainfluenza virus, respiratory syncytial virus, Middle East respiratory syndrome coronavirus*	

*Primary mode is by droplet transmission, but airborne transmission may occur in high risk situations.

particles ($>5 \mu\text{m}$), generally emitted while coughing or sneezing, which do not remain suspended in the air, whereas aerosols are small particles ($<5 \mu\text{m}$), which can remain suspended in the air for several hours and transmit infection over long distances.^{2 103}

A medical mask is theoretically sufficient to prevent droplet infection, whereas a respirator is needed to prevent airborne infection. In terms of facemask use, the physical barrier may also prevent contact transmission such as hand to face, mouth, or nose. A facemask or a respirator may provide protection against multiple modes of transmission, including droplet, airborne, and hand to mouth (or nose) transmission.

The relative contribution of each mode is difficult to quantify and is controversial,^{104 105} but the debate about mode of transmission is academic if an intervention is shown to prevent infection in a clinical trial. Clinical efficacy data should take precedence over theoretical debates about modes of transmission, which have long dominated the discourse on PPE.

The current paradigm of droplet and airborne transmission is based on outmoded experiments from the 1950s, done using outdated equipment, and it oversimplifies the complexity of pathogen transmission.¹⁰⁶ Enough evidence exists for us to know that pathogens are not transmitted by three mutually exclusive routes, and that the term “aerosol transmissible” is preferable to droplet or airborne.¹⁰⁶ For example, evidence exists that influenza, which has been thought of as predominantly droplet spread,¹⁰⁴ can also be spread by the airborne route.^{103 105 107} Pathogens that are spread predominantly through droplets do not need to travel long distances in air currents (as in the current definition of airborne) to be inhaled and cause infection. They can be transmitted in short range aerosols, for which a facemask does not offer sufficient protection.¹⁰⁶

It is further argued that aerosol transmission and airborne transmission are not the same. Airborne transmission can occur through inhalation of small infectious particles at long or short distances from the infectious person, even in the absence of aerosols or aerosol generating procedures owing to evaporation of larger droplets.¹⁰⁶ Diseases transmitted mainly through the airborne route, such as tuberculosis, require a properly fitted N95 or higher respirator. Aerosol transmission may also occur during high risk procedures with organisms that are normally transmitted by other routes. Similarly, evidence suggests that infective aerosols may be generated from vomitus and faecal matter in people infected with norovirus and SARS.¹⁰⁸⁻¹¹¹ Respirators have also been shown to be more effective against aerosol transmission.¹¹²

When the transmission dynamics of a newly emergent infection are unknown, a respirator should be used as a precaution.⁴⁴ For example, respirators were initially recommended for SARS and H1N1-pdm09,^{99 113} but recommendations were later changed in favour of masks.^{44 114} It is unclear what evidence underpinned this change.

High risk situations

Healthcare workers who undertake high risk aerosol generating procedures have a threefold higher risk of

acquiring nosocomial respiratory infections than those who do not.¹¹² WHO and the CDC recommend medical masks to protect from seasonal influenza; however, a respirator is recommended when high risk procedures are performed.^{44 115} Recent debate about “surgical smoke” (aerosols generated during surgery that uses lasers or diathermy) indicates that superior respiratory protection is needed for operating theatre staff.¹¹⁶

During the SARS epidemic, high risk procedures put healthcare workers at high risk of acquiring infection.¹¹⁷ In a study in Hong Kong, none of the staff who wore medical masks or respirators became infected. However, the study excluded one hospital in which cases occurred as a result of a high risk procedure (drug nebulisation), and the authors concluded that medical masks are sufficient to protect against SARS if there is no risk of aerosol transmission.⁵⁰ Inconsistent use of N95 respirators was not associated with the acquisition of infection during the SARS outbreak in the US, and this was attributed to low rates of aerosol generating procedures.⁶⁰ In the Ebola virus outbreak of 2014, the CDC and other agencies changed their guidelines from surgical masks to respirators after nurses became infected.¹¹⁸

Organisational and individual factors

Organisational and individual factors play a role in use of respiratory protection. Healthcare workers may be limited by what is available in the workplace. Availability, cost, and the ability to conduct annual fit testing are important.

Few options are available in most low resource settings, and healthcare workers may have to buy their own masks.¹¹⁹ During the H1N1-pdm09 pandemic, the supply of respirators was exhausted in many hospitals, and healthcare workers had to reuse respirators or rely on other types of facemask.^{120 121}

Current stockpiling guidelines are based on assumptions about the size and duration of a pandemic, hospital stay, number of healthcare workers, and length of shifts,¹²² but these may be inaccurate.^{123 124} It has been documented that non-standard practices occur during outbreaks, especially when there is a shortage of supplies.¹¹⁹ There is very little research on such practices, which include reuse, cleaning of facemasks, and double masking.¹²⁵

The balance between risk perception and discomfort affects individual decisions to use facemasks and respirators. When the risk of infection is thought to be high, acceptance and compliance with interventions to prevent infection are generally higher.¹²⁶ Compliance was reported to be high during the initial phase of the H1N1-pdm09 pandemic, when risk perception was high, but it later decreased when healthcare workers thought that the pandemic was less severe than initially estimated.¹²¹

In countries that have experienced epidemics such as SARS, mask wearing is more acceptable, but it is not commonplace in countries such as the UK, US, and Australia.¹²⁷ Compliance with the wearing of facemasks is lower than for other PPE,^{128 129} and it decreases with increased duration of use.⁹ Compared with medical masks, respirators are associated with more adverse effects, such as discomfort, headache, skin irritation,

and pressure on the nose.^{9 10} However, in China, despite healthcare workers reporting the same level of discomfort with respirators as in Western countries, compliance remains high.^{9 10 127} Discomfort is therefore not the sole determinant of compliance, which is also influenced by cultural factors, risk perception, and experience of serious outbreaks such as SARS.

Healthcare workers are known to be poorly compliant with other infection control interventions, such as hand hygiene and vaccination, which points to a particularly challenging organisational culture.^{130 131} A supportive organisational environment, promotion of a safety culture, regular communication, availability of respiratory protective equipment, and training programmes improve compliance.^{56 132-134} Legislation may also work—New York State recently passed legislation that compels all frontline healthcare workers to either receive influenza vaccination or use a facemask.¹³⁵

Regulations, training, and fit testing of respirators

The optimal use of respirators requires selection of certified respirators, training and fit testing, and inspection, as well as suitable maintenance and storage of the equipment.¹³⁶ Certified respirators should be used in the healthcare setting, and the certification process should be managed by a regulatory body, such as the US National Institute for Occupational Safety and Health (NIOSH).¹³⁷ In Europe, European Norm (EN) standards and in Australia, AS/NZS 1716 standards regulate the use of respirators.^{138 139}

Low resource countries may lack the resources to manage the regulation and certification process. A recent survey of 89 hospital in low to middle income countries showed that very few hospitals used certified respirators, and where used the various types of respirators were of unknown quality (unpublished data).

Training, fit checking (previously known as user seal checking), and fit testing are vital components of any respiratory protection programme, which must ensure a seal between the respirator and the face so that air does not leak out. Healthcare workers should be trained in donning (order and methods of putting on facemasks and respirators) and doffing (order and methods of removing facemasks and respirators) techniques so that they do not contaminate themselves. Fit checking is a qualitative process and not a substitute for fit testing; it should be done every time a respirator is donned to ensure that it is sealed to the face, with no gap between the face and the respirator.¹⁴⁰

Fit testing ensures that the specific type (for example, model and size) of respirator is suitable for the wearer. Fit testing can be quantitative or qualitative, with the second option being cheaper for most workplaces.¹⁴¹ Qualitative fit test is performed by releasing a bitter or sweet agent into an exposure chamber to test whether the wearer can taste the agent.¹⁴¹ This test is easy to perform but indicates lack of fit only and does not measure leakage around the respirator.

In the quantitative test, air sampling is performed from inside the respirator through a fit testing instrument and the amount of leakage is calculated.¹⁴¹ No clinical data

are available to support the use of fit testing—the recommendation to fit test is based on laboratory evidence. The efficacy of a respirator is thought to improve with fit testing,¹⁴² but the only trial to compare fit tested and non-fit tested respirators showed no difference in efficacy with fit testing.⁹ These results are specific to the respirator used in that trial and cannot be generalised to other respirators because respirators are regulated for filtration only and not for fit, which varies widely between products.

In vivo studies showed that properly fitted respirators decrease the risk of infection transmission and block most viral particles.¹⁴² Fit testing is recommended annually, because weight gain or changes in facial shape or size can change the adequacy of fit.

Current data suggest that rates of fit checking and fit testing are low among healthcare workers.^{143 144} Surveys of health professionals and home based healthcare workers in the US showed that respirators were supplied to most during the H1N1-pdm09 pandemic, but that less than a third were fit tested.^{145 146} Various types of respirators were fit tested in an Australian study and 28% of healthcare workers were unable to fit any available respirator owing to variations in face shape.¹⁴⁷

Policies and guidelines around the use of facemasks and respirators

Different health organisations and countries have diverse policies and guidelines on the use of facemasks and respirators.^{3 148} WHO and the CDC have consistent policies for the use of facemasks and respirators to protect against seasonal influenza and tuberculosis,^{44 94 115 149} but policies for pandemic influenza are inconsistent.^{44 150}

For seasonal influenza, both organisations recommend medical masks in low risk situations and N95 respirators in high risk situations, such as aerosol generating procedures. For some other infections, such as Ebola virus, MERS-CoV, and during an influenza pandemic, WHO recommends the use of medical masks in low risk situations and N95 respirators in high risk situations,^{44 151 152} whereas, the CDC now recommends respirators in both situations.^{82 118 150} Respirators are recommended by both organisations to protect healthcare workers from tuberculosis.^{94 149}

High, middle, and low income countries also have diverse policies on the use of facemasks and adopt variations on WHO or CDC guidelines depending on resources and occupational health and safety legislation.^{148 153} For Ebola virus, which is mostly spread by contact, WHO and many countries recommend a medical mask, but this recommendation has been challenged on multiple grounds.³ No RCTs have compared respirators with facemasks for Ebola, but several healthcare workers have contracted Ebola while using PPE.¹⁵⁴ Many countries look to the WHO and CDC guidelines to model their own guidelines. The CDC remains highly influential for developed countries, Australia being an example.

Different policy recommendations may reflect the paucity of evidence and varying results of the few available RCTs of facemasks in the healthcare setting. However, for end users in the hospital setting, the conflicting guidance from different sources (such as WHO and the CDC)

RESEARCH QUESTIONS

How efficacious are various types of facemasks and respirators to protect against specific infections such as influenza, tuberculosis, and Ebola virus?
 What research exists on common clinical practices such as cloth mask use, mask reuse, extended use, and double masking?
 What strategies can help improve compliance and use?
 What is the comparative cost effectiveness of respirators versus facemasks?

is not ideal. A US study showed that healthcare workers used various types of facemasks and respirators during the H1N1-pdm09 pandemic as a result of the conflicting guidance from WHO and the CDC.¹²¹

Despite widespread use in low resource settings, most guidelines do not cover or only briefly mention cloth masks.²³ In addition, most policy documents do not discuss recommendations on the extended use and reuse of facemasks and respirators.¹⁴⁸

Research gaps**Limitations of existing evidence**

Clinical trials of facemasks report a range of outcomes from self reported clinical syndromes to laboratory confirmed viruses,^{7-13 15-19} which might not be generalisable to other specific infectious diseases. Cross sectional and observational studies of masks largely draw from the SARS outbreak, and may not be applicable to other pathogens,³⁶ because SARS was less infectious than many other respiratory infections and was mostly nosocomial.¹⁵⁵

Laboratory based studies of masks are mostly simulated and so have limited clinical application because they cannot account for events such as compliance, coughing, talking, and other subtle actions by the wearer. Although masks and respirators are commonly used to protect the wearer against tuberculosis, no clinical trial data are available to prove their efficacy, and a trial of respirators versus a “no mask” group is unlikely to be conducted. Elastomeric respirators (reusable full face respirators with a changeable cartridge) and powered air purifying respirators are increasingly recommended in the healthcare setting but have not been tested in an RCT.¹⁴⁸

Another limitation of the available facemask studies is the mixing of interventions. In four trials in the community setting facemasks were combined with hand hygiene as an intervention, which makes it difficult to ascertain the efficacy of masks alone.^{12 15 17 18}

Most studies failed to control for other infection control measures (administrative and environmental controls) and the use of other types of PPE, and compliance was variably accounted for.

Many observational and cross sectional studies also examined facemasks together with other forms of PPE and hand hygiene, so the observed effect might be due to the combined effect of hand hygiene or use of other types of PPE (or both).^{48 58 70 73 75} Similarly, in some community based trials both index cases and household members used a mask,¹² whereas in others only household members used a mask.¹³ In the first case, it may be difficult to

ascertain whether efficacy is due to mask use by the index case, by a household member, or by both.

RCTs of facemasks are difficult to design and conduct owing to the complexity of follow-up and measurement of infection outcomes, the statistical power needed to examine outcomes such as influenza, and the difficulty in identifying settings where adequate compliance can be achieved to make a trial feasible. In most clinical trials, controls followed routine practice, and trials without a control arm cannot determine efficacy if no difference is found between interventions. The use of facemasks and respirators in the non-hospital healthcare setting (for example, in home based healthcare workers, nursing homes, paramedics, and ambulatory clinics) has not been studied.

New research

For influenza, further study is needed on the role of facemasks and other types of PPE in the hierarchy of other interventions such as vaccines, antivirals, and social distancing in pandemic planning. In general, a matched pandemic vaccine will not be available for three to six months after the emergence of a new pandemic influenza strain, so masks and respirators—along with other non-pharmaceutical measures and antivirals—will be particularly important in the early phase of a pandemic. The type of product used, estimated stockpiling, and role of extended use and reuse are important factors to consider. Cloth masks may be the only option for some countries, and their role in healthcare and community settings needs also to be further explored.

Studies should also be conducted on the storage of facemasks and respirators and stockpiling for pandemics. The shelf life of respirators is around three years, whereas medical masks have no specified shelf life.¹²³

Given the large cost differential between respirators and masks, health economic studies that incorporate clinical efficacy data are needed to determine cost effectiveness.

Finally, more education and research are needed on modes of transmission to supersede the blunt experiments of the 1950s, the findings of which have become entrenched in the dogma on hospital infection control.¹⁰⁶ Old paradigms around droplet, airborne, and contact spread need to be reviewed when formulating guidelines to take into account clinical data that prove multi-modal spread for many pathogens.^{103 105 107}

Conclusion

Facemasks and respirators are important but under-studied forms of PPE, which offer protection against respiratory infections. They may be the only available protection for healthcare workers when no drugs or vaccines are available and the mode of transmission is unknown.

Community RCTs suggest that facemasks provide protection against infection in various community settings, subject to compliance and early use. For healthcare workers, the evidence suggests that respirators offer superior protection to facemasks. During pandemics and outbreaks these form part of a suite of protection offered to frontline workers to ensure occupational health and

safety. Respirators are also preferable when the disease is severe, with a high case fatality rate, and no drug treatment or vaccine is available.³

In developed countries, the choice for healthcare workers is between disposable masks and respirators, whereas in developing countries reusable cloth masks are also widely used in hospitals. RCTs on cloth masks are lacking, and policy guidance on their use is sparse.

Compliance is a determinant of protection, and it decreases with increasing duration of continuous mask use. Policies and guidelines on mask use worldwide are inconsistent, perhaps reflecting the relatively small number of RCTs available to inform them.

Ultimately the greatest priority is to provide evidence based choices for healthcare workers, whose occupational health and safety must be protected to ensure integrity and an effective response during an epidemic.

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