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April 21, 2020

Dr. Christopher Farnitano, MD, Health Officer
Office of the Director
Health Services, Contra Costa County
1220 Morello, Suite 200
Martinez, California 94553

Re: Order of the Health Officer of the County of Contra Costa , No. HO-COVID19-08; Generally Requiring Members of the Public and Workers to Wear Face Coverings (Public Health Emergency Order dated April 17, 2020)

Dear Dr. Farnitano:

I am writing to you regarding the abovementioned Emergency Order (Order), and respectfully ask you to consider the contents of this letter and its attachments, and to thoughtfully consider a rescinding of said order before it goes into effect on April 22nd.

I come to you as an experienced professional with over 39 years of experience consulting to primarily the healthcare industry, and consulting specifically relative to infection control and prevention as it relates to bioaerosols, such as those in question, for over 20 of those years. I have taught many classes to a variety of professionals over the years, including public health nurses, relative to the use of both PPE and masks of various types and their inherent limitations. I am of the studied opinion—an opinion shared by a number of professionals across the country—that the advice to members of the general public and workers to wear face coverings is ill-advised, is not based on sound science, and is actually *counter-productive* to the end-goal of slowing/limiting the spread of a very contagious virus. Certainly a mandatory order citing this advice will produce the same counter-productive results to even a greater measure.

SUPPORT FOR THESE ASSERTIONS

While the CDC recommendation indicates that a wide-spread wearing of cloth masks will limit the spread of the SARS-CoV-2 virus, it appears that the science does not support this recommendation, as you will see in Attachment 1—a commentary (*Commentary: Masks-for-all for COVID-19 Not Based on Sound Data*) published at the University of Illinois at Chicago (UIC), School of Public Health, dated April 2, 2020 and endorsed by the Center for Infectious Disease Research and Policy (CIDCAP). Not only are such masks demonstrably ineffective at preventing (or even substantially limiting) bioaerosol droplet release, their use by a largely untrained populace actually increases instinctive human behaviors that are more likely to result in the spreading of potential pathogens through fomites, and a lateral release of bioaerols through the facepiece-face interchange.

Some studies, for example a randomized trial of cloth masks published in the BMJ Open in April 2015[1] (Attachment 2) suggest that the use of cloth masks may increase the rate of ineffectiveness in controlling bioaerosols. The contributors to the trial report released an update[2] on March 30, 2020 demonstrating that CDC's initial recommendation for masks, including cloth masks was for the purposes of personal protection of the person wearing the mask, and the inherent ineffectiveness of such masks were so great that medical personnel treating COVID-19 patients using a cloth mask (due to shortages of surgical masks and N-95 respirators) would be better off wearing no mask than wearing a cloth mask. In addition to the data indicated in the UIC document in Attachment 1, and the referenced publications above, some general observations worth considering are as follows:

1. While the Order indicates a desire that the public use cloth masks so as to not limit supply of surgical masks and N-95's for the healthcare industry, and that the aim of the mask use is to protect others, and not themselves—this message simply does not reach the general public. The public's view is an uneducated/misinformed view (from word-of mouth and misinformation by media) that the masks are to protect themselves from others, and that they are effective. It also is clear, simply from standing in line at any store, that many people are figuring a way to buy surgical masks and N-95's, and are putting them on themselves and on small children. This behavior will continue if masks are generally advised or mandated, leaving the medical community in short supply. A speedy rescinding of the order would make people take notice if a brief and reasoned explanation were given.

2. The general public is largely not trained in the use of masks or PPE. We see:

    a. people putting masks on in ways that greatly limit their potential effectiveness, as there is little attention placed on attempting any face-to-facepiece seal of any kind (and most masks have little to no sealing mechanism);
    b. constant handling of the masks by gloved and non-gloved hands after touching a variety of fomites in a way that is sure to introduce potential biocontaminants to the inside of the masks;
    c. a false sense of security when wearing masks (thought to be PPE), thus making people tend to ignore social distancing behavior (this has been objectively demonstrated);

3. The inherent nature of a purchased or home-made face-covering of the types outlined by CDC prohibits their effectiveness (as shown in the UIC document). When a person exhales into a mask, they create a momentary positive-pressure differential inside the mask compared to the static air-pressure outside the mask. Exhaled air, and the bioaerosols within that exhalation, flow (air is a fluid—it flows) in the path of least resistance. This path will not be through the torturous-path filter (cloth or paper) so much as through the face-to-facepiece interchange which is not sealed. In a sneeze or cough, this positive-pressure differential (compared to air

[1] MacIntyre CR, Seale H, Dung TC, et al, A cluster randomised trial of cloth masks compared with medical masks in healthcare workers. BMJ Open 2015;5:e006577. doi: 10.1136/bmjopen-2014-006577
[2] https://bmjopen.bmj.com/content/5/4/e006577.responses#covid-19-shortages-of-masks-and-the-use-of-cloth-masks-as-a-last-resort, Accessed April 20, 2020.

pressure outside the mask) is *dramatically* increased—as is the flowrate and velocity. Thus a greater volume of bioaerosols are ejected *laterally* from the sides of the facepiece—and with greater velocity than if the mask were not present (fluids that flow through a narrowed space increase velocity - see Bernoulli's principle), thus projecting bioaerosols further from the person who sneezed/coughed than would have occurred without the mask.

4. Without a mask, people are more inclined to cover their sneeze/cough with a sleeve, tissue or handkerchief more effectively than the masks; and people are generally more accustomed to such procedures.

5. While aerosol droplets are emitted through normal breathing, their velocity and volume is much lower, and not at all likely to be distributed past a reasonable social distancing measure of six feet (even less) especially when taking into account viral loading.

6. There are a number of people who need to access or provide essential services who have some measure of claustrophobia that makes them either very uneasy about, or incapable of, wearing a face covering for any length of time.

An article appearing March 20, 2020 in The Lancet, titled, *Rational use of face masks in the COVID-19 pandemic*[3], states the following,

> *"the US Surgeon General advised against buying masks for use by healthy people. One important reason to discourage widespread use of face masks is to preserve limited supplies for professional use in health-care settings. Universal face mask use in the community has also been discouraged with the argument that face masks provide no effective protection against coronavirus infection."*

This appears to be sound advice. The article is mentions recommendations from a large panel of authorities across the globe, including the World Health Organization (WHO) whose stance was, *"If you are healthy, you only need to wear a mask if you are taking care of a person with suspected SARS-CoV-2 infection."*

The article generally offers the opinion that *"Notably, improper use of face masks, such as not changing disposable masks, could jeopardise* (sic) *the protective effect and even increase the risk of infection.*

CONCLUDING REMARKS

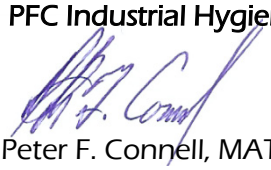
While we appreciate the desire to protect the public at large from a very contagious virus that has potential, in particular, for impacting the vulnerable segment of our communities, such as the elderly and neutropenic individuals, the available data seems to indicate that the requiring of masks by the general public and essential workers in their workplaces is counterproductive to the goal in view for the reasons stated above, and in the attachments.

[3] https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30134-X/fulltext; Accessed April 20, 2020

Were Contra Costa County Health Services to take the bold move to rescind the April 17th Order with a clear and brief outline of the reasons (something that could be printed in two pages and included, *in toto*, in news media), this could really garner the attention of the community, and help get our county residents to focus rather on getting surgical masks and N-95's to healthcare providers; on using social distancing more effectively; on clearing up the misunderstanding that such masks are for personal protection. It would induce a social consciousness of the more effective procedures of covering sneezes/coughs; appropriate social distancing; appropriate hand-washing; avoidance of, and routine cleaning, of fomites; and of keeping unwashed hands away from eyes, nose and mouth.

Since other Bay Area counties are also instituting like wording, which gives the clear impression of a collaborative effort between the Health Officers for these counties, I am sending a similar letter to these county health officials as well. If you have any questions regarding any of the contents of this letter, please do not hesitate to contact me at (707) 235-0475 or email me at pfcihconsulting@gmail.com.

Yours very truly,
PFC Industrial Hygiene Consulting



Peter F. Connell, MAT, CAC, CDPH I/A, PM
Principal Scientist

Cc: Anna M. Roth, Health Services Director, Contra Costa County

Attachments:

Attachment 1 – Commentary: Masks-for-all for COVID-19 Not Based on Sound Data
Attachment 2 – A Cluster Randomised Trial of Cloth Masks Compared with Medical Masks in Healthcare Workers. BMJ Open 2015

Attachment 1

Commentary: Masks-for-all for COVID-19 Not Based on Sound Data

COMMENTARY: Masks-for-all for COVID-19 not based on sound data

cidrap.umn.edu/news-perspective/2020/04/commentary-masks-all-covid-19-not-based-sound-data

Lisa M Brosseau, ScD, and Margaret Sietsema, PhD | Apr 01, 2020

Dr. Brosseau is a national expert on respiratory protection and infectious diseases and professor (retired), University of Illinois at Chicago.
Dr. Sietsema is also an expert on respiratory protection and an assistant professor at the University of Illinois at Chicago.

In response to the stream of misinformation and misunderstanding about the nature and role of masks and respirators as source control or personal protective equipment (PPE), we critically review the topic to inform ongoing COVID-19 decision-making that relies on science-based data and professional expertise.

As noted in a previous commentary, the limited data we have for COVID-19 strongly support the possibility that SARS-CoV-2—the virus that causes COVID-19—is transmitted by inhalation of both droplets and aerosols near the source. It is also likely that people who are pre-symptomatic or asymptomatic throughout the duration of their infection are spreading the disease in this way.

Data lacking to recommend broad mask use

We do not recommend requiring the general public who do not have symptoms of COVID-19-like illness to routinely wear cloth or surgical masks because:

- There is no scientific evidence they are effective in reducing the risk of SARS-CoV-2 transmission
- Their use may result in those wearing the masks to relax other distancing efforts because they have a sense of protection
- We need to preserve the supply of surgical masks for at-risk healthcare workers.

Sweeping mask recommendations—as many have proposed—will not reduce SARS-CoV-2 transmission, as evidenced by the widespread practice of wearing such masks in Hubei province, China, before and during its mass COVID-19 transmission experience earlier this year. Our review of relevant studies indicates that cloth masks will be ineffective at preventing SARS-CoV-2 transmission, whether worn as source control or as PPE.

Surgical masks likely have some utility as source control (meaning the wearer limits virus dispersal to another person) from a symptomatic patient in a healthcare setting to stop the spread of large cough particles and limit the lateral dispersion of cough particles. They may also have very limited utility as source control or PPE in households.

Respirators, though, are the only option that can ensure protection for frontline workers dealing with COVID-19 cases, once all of the strategies for optimizing respirator supply have been implemented.

We do not know whether respirators are an effective intervention as source control for the public. A non-fit-tested respirator may not offer any better protection than a surgical mask. Respirators work as PPE only when they are the right size and have been fit-tested to demonstrate they achieve an adequate protection factor. In a time when respirator supplies are limited, we should be saving them for frontline workers to prevent infection and remain in their jobs.

These recommendations are based on a review of available literature and informed by professional expertise and consultation. We outline our review criteria, summarize the literature that best addresses these criteria, and describe some activities the public can do to help "flatten the curve" and to protect frontline workers and the general public.

We realize that the public yearns to help protect medical professionals by contributing homemade masks, but there are better ways to help.

Filter efficiency and fit are key for masks, respirators

The best evidence of mask and respirator performance starts with testing filter efficiency and then evaluating fit (facepiece leakage). Filter efficiency must be measured first. If the filter is inefficient, then fit will be a measure of filter efficiency only and not what is being leaked around the facepiece.

Filter efficiency

Masks and respirators work by collecting particles through several physical mechanisms, including diffusion (small particles) and interception and impaction (large particles).[1] N95 filtering facepiece respirators (FFRs) are constructed from electret filter material, with electrostatic attraction for additional collection of all particle sizes.[2]

Every filter has a particle size range that it collects inefficiently. *Above and below this range, particles will be collected with greater efficiency*. For fibrous non-electret filters, this size is about 0.3 micrometers (μm); for electret filters, it ranges from 0.06 to 0.1 μm. When testing, we care most about

the point of inefficiency. As flow increases, particles in this range will be collected less efficiently.

The best filter tests use worst-case conditions: high flow rates (80 to 90 liters per minute [L/min]) with particle sizes in the least efficiency range. This guarantees that filter efficiency will be high at typical, lower flow rates for all particle sizes. Respirator filter certification tests use 84 L/min, well above the typical 10 to 30 L/min breathing rates. The N95 designation means the filter exhibits at least 95% efficiency in the least efficient particle size range.

Studies should also use well-characterized inert particles (not biological, anthropogenic, or naturogenic ones) and instruments that quantify concentrations in narrow size categories, and they should include an N95 FFR or similar respirator as a positive control.

Fit

Fit should be a measure of how well the mask or respirator prevents leakage around the facepiece, as noted earlier. Panels of representative human subjects reveal more about fit than tests on a few individuals or mannequins.

Quantitative fit tests that measure concentrations inside and outside of the facepiece are more discriminating than qualitative ones that rely on taste or odor.

Mask, N95 respirator filtering performance

Following a recommendation that cloth masks be explored for use in healthcare settings during the next influenza pandemic,[3] The National Institute for Occupational Safety and Health (NIOSH) conducted a study of the filter performance on clothing materials and articles, including commercial cloth masks marketed for air pollution and allergens, sweatshirts, t-shirts, and scarfs.[4]

Filter efficiency was measured across a wide range of small particle sizes (0.02 to 1 μm) at 33 and 99 L/min. N95 respirators had efficiencies greater than 95% (as expected). For the entire range of particles tested, t-shirts had 10% efficiency, scarves 10% to 20%, cloth masks 10% to 30%, sweatshirts 20% to 40%, and towels 40%. All of the cloth masks and materials had near zero efficiency at 0.3 μm, a particle size that easily penetrates into the lungs.[4]

Another study evaluated 44 masks, respirators, and other materials with similar methods and small aerosols (0.08 and 0.22 μm).[5] N95 FFR filter efficiency was greater than 95%. Medical masks exhibited 55% efficiency, general masks 38% and handkerchiefs 2% (one layer) to 13% (four layers).

These studies demonstrate that cloth or homemade masks will have very low filter efficiency (2% to 38%). Medical masks are made from a wide range of materials, and studies have found a wide range of filter efficiency (2% to 98%), with most exhibiting 30% to 50% efficiency.[6-12]

We reviewed other filter efficiency studies of makeshift cloth masks made with various materials. Limitations included challenge aerosols that were poorly characterized[13] or too large[14-16] or flow

rates that were too low.[17]

Mask and respirator fit

Regulators have not developed guidelines for cloth or surgical mask fit. N95 FFRs must achieve a fit factor (outside divided by inside concentration) of at least 100, which means that the facepiece must lower the outside concentration by 99%, according to the OSHA respiratory protection standard. When fit is measured on a mask with inefficient filters, it is really a measure of the collection of particles by the filter plus how well the mask prevents particles from leaking around the facepiece.

Several studies have measured the fit of masks made of cloth and other homemade materials.[13,18,19] We have not used their results to evaluate mask performance, because none measured filter efficiency or included respirators as positive controls.

One study of surgical masks showing relatively high efficiencies of 70% to 95% using NIOSH test methods measured total mask efficiencies (filter plus facepiece) of 67% to 90%.[7] These results illustrate that surgical masks, even with relatively efficient filters, do not fit well against the face.

In sum, cloth masks exhibit very low filter efficiency. Thus, even masks that fit well against the face will not prevent inhalation of small particles by the wearer or emission of small particles from the wearer.

One study of surgical mask fit described above suggests that poor fit can be somewhat offset by good filter collection, but will not approach the level of protection offered by a respirator. The problem is, however, that many surgical masks have very poor filter performance. Surgical masks are not evaluated using worst-case filter tests, so there is no way to know which ones offer better filter efficiency.

Studies of performance in real-world settings

Before recommending them, it's important to understand how masks and respirators perform in households, healthcare, and other settings.

Cloth masks as source control

A historical overview of cloth masks notes their use in US healthcare settings starting in the late 1800s, first as source control on patients and nurses and later as PPE by nurses.[20]

Kellogg,[21] seeking a reason for the failure of cloth masks required for the public in stopping the 1918 influenza pandemic, found that the number of cloth layers needed to achieve acceptable efficiency made them difficult to breathe through and caused leakage around the mask. We found no well-designed studies of cloth masks as source control in household or healthcare settings.

In sum, given the paucity of information about their performance as source control in real-world

settings, along with the extremely low efficiency of cloth masks as filters and their poor fit, there is no evidence to support their use by the public or healthcare workers to control the emission of particles from the wearer.

Surgical masks as source control

Household studies find very limited effectiveness of surgical masks at reducing respiratory illness in other household members.[22-25]

Clinical trials in the surgery theater have found no difference in wound infection rates with and without surgical masks.[26-29] Despite these findings, it has been difficult for surgeons to give up a long-standing practice.[30]

There is evidence from laboratory studies with coughing infectious subjects that surgical masks are effective at preventing emission of large particles[31-34] and minimizing lateral dispersion of cough particles, but with simultaneous displacement of aerosol emission upward and downward from the mask.[35]

There is some evidence that surgical masks can be effective at reducing overall particle emission from patients who have multidrug-resistant tuberculosis,[36] cystic fibrosis,[34] and influenza.[33] The latter found surgical masks decreased emission of large particles (larger than 5 μm) by 25-fold and small particles by threefold from flu-infected patients.[33] Sung[37] found a 43% reduction in respiratory viral infections in stem-cell patients when everyone, including patients, visitors, and healthcare workers, wore surgical masks.

In sum, wearing surgical masks in households appears to have very little impact on transmission of respiratory disease. One possible reason may be that masks are not likely worn continuously in households. These data suggest that surgical masks worn by the public will have no or very low impact on disease transmission during a pandemic.

There is no evidence that surgical masks worn by healthcare workers are effective at limiting the emission of small particles or in preventing contamination of wounds during surgery.

There is moderate evidence that surgical masks worn by patients in healthcare settings can lower the emission of large particles generated during coughing and limited evidence that small particle emission may also be reduced.

N95 FFRs as source control

Respirator use by the public was reviewed by NIOSH: (1) untrained users will not wear respirators correctly, (2) non-fit tested respirators are not likely to fit, and (3) improvised cloth masks do not provide the level of protection of a fit-tested respirator.

There are few studies examining the effectiveness of respirators on patients. An N95 FFR on

coughing human subjects showed greater effectiveness at limiting lateral particle dispersion than surgical masks (15 cm and 30 cm dispersion, respectively) in comparison to no mask (68 cm). [35] Cystic fibrosis patients reported that surgical masks were tolerable for short periods, but N95 FFRs were not.[34]

In summary, N95 FFRs on patients will not be effective and may not be appropriate, particularly if they have respiratory illness or other underlying health conditions. Given the current extreme shortages of respirators needed in healthcare, we do not recommend the use of N95 FFRs in public or household settings.

Cloth masks as PPE

A randomized trial comparing the effect of medical and cloth masks on healthcare worker illness found that those wearing cloth masks were 13 times more likely to experience influenza-like illness than those wearing medical masks.[38]

In sum, very poor filter and fit performance of cloth masks described earlier and very low effectiveness for cloth masks in healthcare settings lead us conclude that cloth masks offer no protection for healthcare workers inhaling infectious particles near an infected or confirmed patient.

Surgical masks as PPE

Several randomized trials have not found any statistical difference in the efficacy of surgical masks versus N95 FFRs at lowering infectious respiratory disease outcomes for healthcare workers.[39-43]

Most reviews have failed to find any advantage of one intervention over the other.[23,44-48] Recent meta-analyses found that N95 FFRs offered higher protection against clinical respiratory illness[49,50] and lab-confirmed bacterial infections,[49] but not viral infections or influenza-like illness.[49]

A recent pooled analysis of two earlier trials comparing medical masks and N95 filtering facepiece respirators **with controls** (no protection) found that healthcare workers continuously wearing N95 FFRs were 54% less likely to experience respiratory viral infections than controls ($P = 0.03$), while those wearing medical masks were only 12% less likely than controls ($P = 0.48$; result is not significantly different from zero).[51]

While the data supporting the use of surgical masks as PPE in real-world settings are limited, the two meta-analyses and the most recent randomized controlled study[51] combined with evidence of moderate filter efficiency and complete lack of facepiece fit lead us to conclude that surgical masks offer very low levels of protection for the wearer from aerosol inhalation. There may be some protection from droplets and liquids propelled directly onto the mask, but a faceshield would be a better choice if this is a concern.

N95 FFRs as PPE

A retrospective cohort study found that nurses' risk of SARS (severe acute respiratory syndrome, also caused by a coronavirus) was lower with consistent use of N95 FFRs than with consistent use of a surgical mask.[52]

In sum, this study, the meta-analyses, randomized controlled trial described above,[49,51] and laboratory data showing high filter efficiency and high achievable fit factors lead us to conclude that N95 FFRs offer superior protection from inhalable infectious aerosols likely to be encountered when caring for suspected or confirmed COVID-19 patients.

The precautionary principle supports higher levels of respiratory protection, such as powered air-purifying respirators, for aerosol-generating procedures such as intubation, bronchoscopy, and acquiring respiratory specimens.

Conclusions

While this is not an exhaustive review of masks and respirators as source control and PPE, we made our best effort to locate and review the most relevant studies of laboratory and real-world performance to inform our recommendations. Results from laboratory studies of filter and fit performance inform and support the findings in real-world settings.

Cloth masks are ineffective as source control and PPE, surgical masks have some role to play in preventing emissions from infected patients, and respirators are the best choice for protecting healthcare and other frontline workers, but not recommended for source control. These recommendations apply to pandemic and non-pandemic situations.

Leaving aside the fact that they are ineffective, telling the public to wear cloth or surgical masks could be interpreted by some to mean that people are safe to stop isolating at home. It's too late now for anything but stopping as much person-to-person interaction as possible.

Masks may confuse that message and give people a false sense of security. If masks had been the solution in Asia, shouldn't they have stopped the pandemic before it spread elsewhere?

Ways to best protect health workers

We recommend that healthcare organizations follow US Centers for Disease Control and Prevention (CDC) guidance by moving first through conventional, then contingency, and finally crisis scenarios to optimize the supply of respirators. We recommend using the CDC's burn rate calculator to help identify areas to reduce N95 consumption and working down the CDC checklist for a strategic approach to extend N95 supply.

For readers who are disappointed in our recommendations to stop making cloth masks for themselves or healthcare workers, we recommend instead pitching in to locate N95 FFRs and other types of respirators for healthcare organizations. Encourage your local or state government to organize and reach out to industries to locate respirators not currently being used in the non-

healthcare sector and coordinate donation efforts to frontline health workers.

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Attachment 2

A Cluster Randomised Trial of
Cloth Masks Compared with Medical Masks in Healthcare Workers.
BMJ Open 2015

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A cluster randomised trial of cloth masks compared with medical masks in healthcare workers

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ABSTRACT

Objective: The aim of this study was to compare the efficacy of cloth masks to medical masks in hospital healthcare workers (HCWs). The null hypothesis is that there is no difference between medical masks and cloth masks.

Setting: 14 secondary-level/tertiary-level hospitals in Hanoi, Vietnam.

Participants: 1607 hospital HCWs aged ≥18 years working full-time in selected high-risk wards.

Intervention: Hospital wards were randomised to: medical masks, cloth masks or a control group (usual practice, which included mask wearing). Participants used the mask on every shift for 4 consecutive weeks.

Main outcome measure: Clinical respiratory illness (CRI), influenza-like illness (ILI) and laboratory-confirmed respiratory virus infection.

Results: The rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI statistically significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% CI 1.69 to 100.07) compared with the medical mask arm. Cloth masks also had significantly higher rates of ILI compared with the control arm. An analysis by mask use showed ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) were significantly higher in the cloth masks group compared with the medical masks group. Penetration of cloth masks by particles was almost 97% and medical masks 44%.

Conclusions: This study is the first RCT of cloth masks, and the results caution against the use of cloth masks. This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection. Further research is needed to inform the widespread use of cloth masks globally. However, as a precautionary measure, cloth masks should not be recommended for HCWs, particularly in high-risk situations, and guidelines need to be updated.

Trial registration number: Australian New Zealand Clinical Trials Registry: ACTRN12610000887077.

Strengths and limitations of this study

- The use of cloth masks is widespread around the world, particularly in countries at high-risk for emerging infections, but there have been no efficacy studies to underpin their use.
- This study is large, a prospective randomised clinical trial (RCT) and the first RCT ever conducted of cloth masks.
- The use of cloth masks are not addressed in most guidelines for health care workers—this study provides data to update guidelines.
- The control arm was 'standard practice', which comprised mask use in a high proportion of participants. As such (without a no-mask control), the finding of a much higher rate of infection in the cloth mask arm could be interpreted as harm caused by cloth masks, efficacy of medical masks, or most likely a combination of both.

INTRODUCTION

The use of facemasks and respirators for the protection of healthcare workers (HCWs) has received renewed interest following the 2009 influenza pandemic,[1] and emerging infectious diseases such as avian influenza,[2] Middle East respiratory syndrome coronavirus (MERS-coronavirus)[3 4] and Ebola virus.[5] Historically, various types of cloth/cotton masks (referred to here after as 'cloth masks') have been used to protect HCWs.[6] Disposable medical/surgical masks (referred to here after as 'medical masks') were introduced into healthcare in the mid 19th century, followed later by respirators.[7] Compared with other parts of the world, the use of face masks is more prevalent in Asian countries, such as China and Vietnam.[8–11]

In high resource settings, disposable medical masks and respirators have long since replaced the use of cloth masks in hospitals. Yet cloth masks remain widely used

globally, including in Asian countries, which have historically been affected by emerging infectious diseases, as well as in West Africa, in the context of shortages of personal protective equipment (PPE).[12 13] It has been shown that medical research disproportionately favours diseases of wealthy countries, and there is a lack of research on the health needs of poorer countries.[14] Further, there is a lack of high-quality studies around the use of facemasks and respirators in the healthcare setting, with only four randomised clinical trials (RCTs) to date.[15] Despite widespread use, cloth masks are rarely mentioned in policy documents,[16] and have never been tested for efficacy in a RCT. Very few studies have been conducted around the clinical effectiveness of cloth masks, and most available studies are observational or in vitro.[6] Emerging infectious diseases are not constrained within geographical borders, so it is important for global disease control that use of cloth masks be underpinned by evidence. The aim of this study was to determine the efficacy of cloth masks compared with medical masks in HCWs working in high-risk hospital wards, against the prevention of respiratory infections.

METHODS

A cluster-randomised trial of medical and cloth mask use for HCWs was conducted in 14 hospitals in Hanoi, Vietnam. The trial started on the 3 March 2011, with rolling recruitment undertaken between 3 March 2011 and 10 March 2011. Participants were followed during the same calendar time for 4 weeks of facemasks use and then one additional week for appearance of symptoms. An invitation letter was sent to 32 hospitals in Hanoi, of which 16 agreed to participate. One hospital did not meet the eligibility criteria; therefore, 74 wards in 15 hospitals were randomised. Following the randomisation process, one hospital withdrew from the study because of a nosocomial outbreak of rubella.

Participants provided written informed consent prior to initiation of the trial.

Randomisation

Seventy-four wards (emergency, infectious/respiratory disease, intensive care and paediatrics) were selected as high-risk settings for occupational exposure to respiratory infections. Cluster randomisation was used because the outcome of interest was respiratory infectious diseases, where prevention of one infection in an individual can prevent a chain of subsequent transmission in closed settings.[8 9] Epi info V.6 was used to generate a randomisation allocation and 74 wards were randomly allocated to the interventions.

From the eligible wards 1868 HCWs were approached to participate. After providing informed consent, 1607 participants were randomised by ward to three arms: (1) medical masks at all times on their work shift; (2) cloth masks at all times on shift or (3) control arm (standard practice, which may or may not include mask use). Standard practice was used as control because the IRB deemed it unethical to ask participants to not wear a mask. We studied continuous mask use (defined as wearing masks all the time during a work shift, except while in the toilet or during tea or lunch breaks) because this reflects current practice in high-risk settings in Asia.[8]

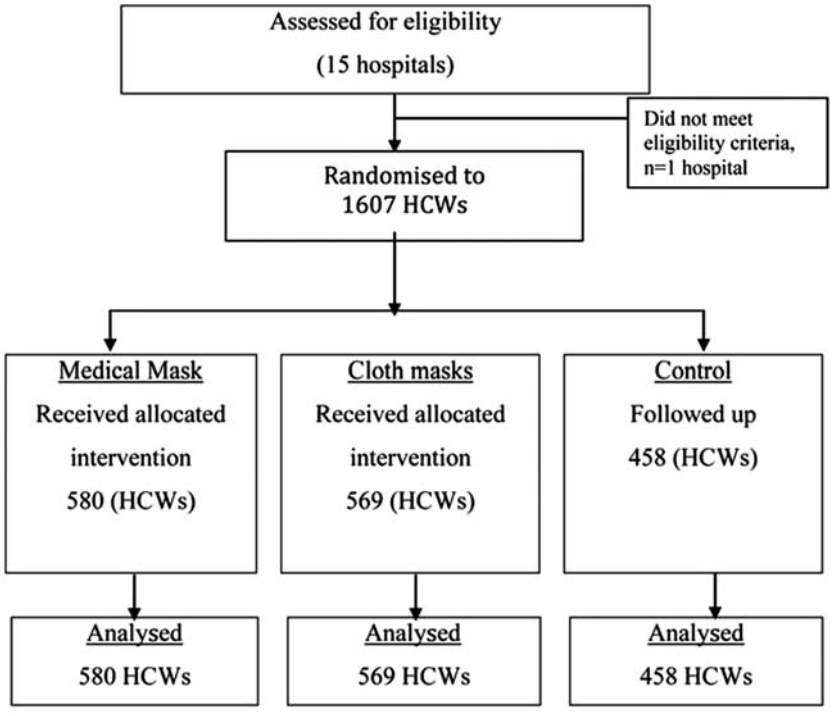

Figure 1 Consort diagram of recruitment and follow-up (HCWs, healthcare workers).

The laboratory results were blinded and laboratory testing was conducted in a blinded fashion. As facemask use is a visible intervention, clinical end points could not be blinded. Figure 1 outlines the recruitment and randomisation process.

Primary end points

There were three primary end points for this study, used in our previous mask RCTs:[8 9] (1) Clinical respiratory illness (CRI), defined as two or more respiratory symptoms or one respiratory symptom and a systemic symptom;[17] (2) influenza-like illness (ILI), defined as fever ≥38°C plus one respiratory symptom and (3) laboratory-confirmed viral respiratory infection. Laboratory confirmation was by nucleic acid detection using multiplex reverse transcriptase PCR (RT-PCR) for 17 respiratory viruses: respiratory syncytial virus (RSV) A and B, human metapneumovirus (hMPV), influenza A (H3N2), (H1N1)pdm09, influenza B, parainfluenza viruses 1–4, influenza C, rhinoviruses, severe acute respiratory syndrome (SARS) associated coronavirus (SARS-CoV), coronaviruses 229E, NL63, OC43 and HKU1, adenoviruses and human bocavirus (hBoV).[18–23] Additional end points included compliance with mask use, defined as using the mask during the shift for 70% or more of work shift hours.[9] HCWs were categorised as 'compliant' if the average use was equal or more than 70% of the working time. HCW were categorised as 'non-compliant' if the average mask use was less than 70% of the working time.

Eligibility

Nurses or doctors aged ≥18 years working full-time were eligible. Exclusion criteria were: (1) Unable or refused to consent; (2) Beards, long moustaches or long facial hair stubble; (3) Current respiratory illness, rhinitis and/or allergy.

Intervention

Participants wore the mask on every shift for four consecutive weeks. Participants in the medical mask arm were supplied with two masks daily for each 8 h shift, while participants in the cloth mask arm were provided with five masks in total for the study duration, which they were asked to wash and rotate over the study period. They were asked to wash cloth masks with soap and water every day after finishing the shifts. Participants were supplied with written instructions on how to clean their cloth masks. Masks used in the study were locally manufactured medical (three layer, made of non-woven material) or cloth masks (two layer, made of cotton) commonly used in Vietnamese hospitals. The control group was asked to continue with their normal practices, which may or may not have included mask wearing. Mask wearing was measured and documented for all participants, including the control arm.

Data collection and follow-up

Data on sociodemographic, clinical and other potential confounding factors were collected at baseline. Participants were followed up daily for 4 weeks (active intervention period), and for an extra week of standard practice, in order to document incident infection after incubation. Participants received a thermometer (traditional glass and mercury) to measure their temperature daily and at symptom onset. Daily diary cards were provided to record number of hours worked and mask use, estimated number of patient contacts (with/without ILI) and number/type of aerosol-generating procedures (AGPs) conducted, such as suctioning of airways, sputum induction, endotracheal intubation and bronchoscopy. Participants in the cloth mask and control group (if they used cloth masks) were also asked to document the process used to clean their mask after use.

We also monitored compliance with mask use by a previously validated self-reporting mechanism.[8] Participants were contacted daily to identify incident cases of respiratory infection. If participants were symptomatic, swabs of both tonsils and the posterior pharyngeal wall were collected on the day of reporting.

Sample collection and laboratory testing

Trained collectors used double rayon-tipped, plastic-shafted swabs to scratch tonsillar areas as well as the posterior pharyngeal wall of symptomatic participants. Testing was conducted using RT-PCR applying published methods.[19–23] Viral RNA was extracted from each respiratory specimen using the Viral RNA Mini kit (Qiagen, Germany), following the manufacturer's instructions. The RNA extraction step was controlled by amplification of a RNA house-keeping gene (amplify pGEM) using real-time RT-PCR. Only extracted samples with the house keeping gene detected by real-time RT-PCR were submitted for multiplex RT-PCR for viruses.

The reverse transcription and PCRs were performed in OneStep (Qiagen, Germany) to amplify viral target genes, and then in five multiplex RT-PCR: RSVA/B, influenza A/H3N2, A(H1N1) and B viruses, hMPV (reaction mix 1); parainfluenza viruses 1–4 (reaction mix 2); rhinoviruses, influenza C virus, SARS-CoV (reaction mix 3); coronaviruses OC43, 229E, NL63 and HKU1 (reaction mix 4); and adenoviruses and hBoV (reaction mix 5), using a method published by others.[18] All samples with viruses detected by multiplex RT-PCR were confirmed by virus-specific mono nested or hemi-nested PCR. Positive controls were prepared by in vitro transcription to control amplification efficacy and monitor for false negatives, and included in all runs (except for NL63 and HKU1). Each run always included two negatives to monitor amplification quality. Specimen processing, RNA extraction, PCR amplification and PCR product analyses were conducted in different rooms to avoid cross-contamination.[19 20]

Filtration testing

The filtration performance of the cloth and medical masks was tested according to the respiratory standard AS/NZS1716.[24] The equipment used was a TSI 8110 Filter tester. To test the filtration performance, the filter is challenged by a known concentration of sodium chloride particles of a specified size range and at a defined flow rate. The particle concentration is measured before and after adding the filter material and the relative filtration efficiency is calculated. We examined the performance of cloth masks compared with the performance levels—P1, P2 (=N95) and P3, as used for assessment of all particulate filters for respiratory protection. The 3M 9320 N95 and 3M Vflex 9105 N95 were used to compare against the cloth and medical masks.

Sample size calculation

To obtain 80% power at two-sided 5% significance level for detecting a significant difference of attack rate between medical masks and cloth masks, and for a rate of infection of 13% for cloth mask wearers compared with 6% in medical mask wearers, we would need eight clusters per arm and 530 participants in each arm, and intracluster correlation coefficient (ICC) 0.027, obtained from our previous study.[8] The design effect (deff) for this cluster randomisation trial was 1.65 (deff=1+(m −1)×ICC=1+(25−1)×0.027=1.65). As such, we aimed to recruit a sample size of 1600 participants from up to 15 hospitals.

Analysis

Descriptive statistics were compared among intervention and control arms. Primary end points were analysed by intention to treat. We compared the event rates for the primary outcomes across study arms and calculated p values from cluster-adjusted χ^2 tests[25] and ICC.[25 26] We also estimated relative risk (RR) after adjusting for clustering using a log-binomial model under generalised estimating equation (GEE) framework.[27] We checked for variables which were unequally distributed across arms, and conducted an adjusted analysis accordingly. We fitted a multivariable log-binomial model, using GEE to account for clustering by ward, to estimate RR after adjusting for potential confounders. In the initial model, we included all the variables that had p value less than 0.25 in the univariable analysis, along with the main exposure variable (randomisation arm). A backward elimination method was used to remove the variables that did not have any confounding effect.

As most participants in the control arm used a mask during the trial period, we carried out a post-hoc analysis comparing all participants who used only a medical mask (from the control arm and the medical mask arm) with all participants who used only a cloth mask (from the control arm and the cloth arm). For this analysis, controls who used both types of mask (n=245) or used N95 respirators (n=3) or did not use any masks (n=2) were excluded. We fitted a multivariable log-binomial model, to estimate RR after adjusting for potential confounders. As we pooled data of participants from all three arms and analysed by mask type, not trial arm, we did not adjust for clustering here. All statistical analyses were conducted using STATA V.12.[28]

Owing to a very high level of mask use in the control arm, we were unable to determine whether the differences between the medical and cloth mask arms were due to a protective effect of medical masks or a detrimental effect of cloth masks. To assist in interpreting the data, we compared rates of infection in the medical mask arm with rates observed in medical mask arms from two previous RCTs,[8 9] in which no efficacy of medical masks could be demonstrated when compared with control or N95 respirators, recognising that seasonal and geographic variation in virus activity affects the rates of exposure (and hence rates of infection outcomes) among HCWs. This analysis was possible because the trial designs were similar and the same outcomes were measured in all three trials. The analysis was carried out to determine if the observed results were explained by a detrimental effect of cloth masks or a protective effect of medical masks.

RESULTS

A total of 1607 HCWs were recruited into the study. The participation rate was 86% (1607/1868). The average number of participants per ward was 23 and the mean age was 36 years. On average, HCWs were in contact with 36 patients per day during the trial period (range 0–661 patients per day, median 20 patients per day). The distribution of demographic variables was generally similar between arms (table 1). Figure 2 shows the primary outcomes for each of the trial arms. The rates of CRI, ILI and laboratory-confirmed virus infections were lowest in the medical mask arm, followed by the control arm, and highest in the cloth mask arm.

Table 2 shows the intention-to-treat analysis. The rate of CRI was highest in the cloth mask arm, followed by the control arm, and lowest in the medical mask arm. The same trend was seen for ILI and laboratory tests confirmed viral infections. In intention-to-treat analysis, ILI was significantly higher among HCWs in the cloth masks group (RR=13.25 and 95% CI 1.74 to 100.97), compared with the medical masks group. The rate of ILI was also significantly higher in the cloth masks arm (RR=3.49 and 95% CI 1.00 to 12.17), compared with the control arm. Other outcomes were not statistically significant between the three arms.

Among the 68 laboratory-confirmed cases, 58 (85%) were due to rhinoviruses. Other viruses detected were hMPV (7 cases), influenza B (1 case), hMPV/rhinovirus co-infection (1 case) and influenza B/rhinovirus co-infection (1 case) (table 3). No influenza A or RSV infections were detected.

Compliance was significantly higher in the cloth mask arm (RR=2.41, 95% CI 2.01 to 2.88) and medical masks

Table 1 Demographic and other characteristics by arm of randomisation

Variable	Medical mask (% and 95% CI) (n=580)	Cloth mask (% and 95% CI) (n=569)	Control (% and 95% CI) (n=458)
Gender (male)	112/580	133/569	112/458
	19.3 (16.2 to 22.8)	23.4 (20.0 to 27.1)	24.5 (20.6 to 28.7)
Age (mean)	36 (35.6 to 37.3)	35 (34.6 to 36.3)	36 (35.1 to 37.0)
Education (postgraduate)	114/580	99/569	78/458
	19.7 (16.5 to 23.1)	17.4 (14.3 to 20.8)	17.0 (13.7 to 20.8)
Smoker (current/ex)	78/580	79/569	66/458
	13.4 (10.8 to 16.5)	13.9 (11.1 to 17.0)	14.4 (11.3 to 18.0)
Pre-existing illness*	66/580	70/569	47/458
	11.4 (9.0 to 14.2)	12.3 (9.8 to 15.3)	10.3 (7.8 to 13.4)
Influenza vaccination (yes)	21/580	21/569	15/458
	3.6 (2.4 to 5.4)	3.7 (2.4 to 5.6)	3.3 (2.0 to 5.3)
Staff (doctors)	176/580	165/569	134/458
	30.3 (26.6 to 34.3)	29.0 (25.3 to 32.9)	29.3 (25.1 to 33.7)
Number of hand washings per day (geometric mean)†	14 (13.8 to 15.4)	11 (10.9 to 11.9)	12 (11.5 to 12.7)
Number of patients had contact with (median and range)‡	21 (0 to 540)	21 (0 to 661)	18 (3 to 199)

*Includes asthma, immunocompromised and others.
†'Hand wash' variable was created by taking average of the number of hand washes performed by a healthcare worker (HCW) over the trial period. The variable was log transformed for the multivariate analysis.
‡'Number of patients had contact with' variable was created by taking average of the number of patients in contact with a HCW over the trial period. Median and range is presented in the table.

arm (RR=2.40, 95% CI 2.00 to 2.87), compared with the control arm. Figure 3 shows the percentage of participants who were compliant in the three arms. A post-hoc analysis adjusted for compliance and other potential confounders showed that the rate of ILI was significantly higher in the cloth mask arm (RR=13.00, 95% CI 1.69 to 100.07), compared with the medical masks arm (table 4). There was no significant difference between the medical mask and control arms. Hand washing was significantly protective against laboratory-confirmed viral infection (RR=0.66, 95% CI 0.44 to 0.97).

In the control arm, 170/458 (37%) used medical masks, 38/458 (8%) used cloth masks, and 245/458 (53%) used a combination of both medical and cloth masks during the study period. The remaining 1% either reported using a N95 respirator (n=3) or did not use any masks (n=2).

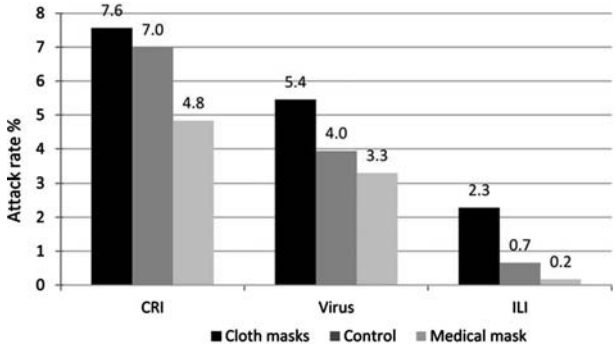

Figure 2 Outcomes in trial arms (CRI, clinical respiratory illness; ILI, influenza-like illness; Virus, laboratory-confirmed viruses).

Table 5 shows an additional analysis comparing all participants who used only a medical mask (from the control arm and the medical mask arm) with all participants who used only a cloth mask (from the control arm and the cloth arm). In the univariate analysis, all outcomes were significantly higher in the cloth mask group, compared with the medical masks group. After adjusting for other factors, ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) remained significantly higher in the cloth masks group compared with the medical masks group.

Table 6 compares the outcomes in the medical mask arm with two previously published trials.[8 9] This shows that while the rates of CRI were significantly higher in one of the previously published trials, the rates of laboratory-confirmed viruses were not significantly different between the three trials for medical mask use.

On average, HCWs worked for 25 days during the trial period and washed their cloth masks for 23/25 (92%) days. The most common approach to washing cloth masks was self-washing (456/569, 80%), followed by combined self-washing and hospital laundry (91/569, 16%), and only hospital laundry (22/569, 4%). Adverse events associated with facemask use were reported in 40.4% (227/562) of HCWs in the medical mask arm and 42.6% (242/568) in the cloth mask arm (p value 0.450). General discomfort (35.1%, 397/1130) and breathing problems (18.3%, 207/1130) were the most frequently reported adverse events.

Table 2 Intention-to-treat analysis

	CRI N (%)	RR (95% CI)	ILI N (%)	RR (95% CI)	Laboratory-confirmed viruses N (%)	RR (95% CI)
Medical mask*	28/580 (4.83)	Ref	1/580 (0.17)	Ref	19/580 (3.28)	Ref
Cloth masks†	43/569 (7.56)	1.57 (0.99 to 2.48)	13/569 (2.28)	**13.25 (1.74 to 100.97)**	31/569 (5.45)	1.66 (0.95 to 2.91)
Control‡	32/458 (6.99)	1.45 (0.88 to 2.37)	3/458 (0.66)	3.80 (0.40 to 36.40)	18/458 (3.94)	1.20 (0.64 to 2.26)

Bold typeface indicates statistically significant.
*p Value from cluster adjusted χ^2 tests is 0.510 and intracluster correlation coefficients is 0.065.
†p Value from cluster adjusted χ^2 tests is 0.028 and intracluster correlation coefficients is 0.029.
‡p Value from cluster adjusted χ^2 tests is 0.561 and intracluster correlation coefficients is 0.068.
CRI, clinical respiratory illness; ILI, influenza-like illness; RR, relative risk.

Laboratory tests showed the penetration of particles through the cloth masks to be very high (97%) compared with medical masks (44%) (used in trial) and 3M 9320 N95 (<0.01%), 3M Vflex 9105 N95 (0.1%).

DISCUSSION

We have provided the first clinical efficacy data of cloth masks, which suggest HCWs should not use cloth masks as protection against respiratory infection. Cloth masks resulted in significantly higher rates of infection than medical masks, and also performed worse than the control arm. The controls were HCWs who observed standard practice, which involved mask use in the majority, albeit with lower compliance than in the intervention arms. The control HCWs also used medical masks more often than cloth masks. When we analysed all mask-wearers including controls, the higher risk of cloth masks was seen for laboratory-confirmed respiratory viral infection.

The trend for all outcomes showed the lowest rates of infection in the medical mask group and the highest rates in the cloth mask arm. The study design does not allow us to determine whether medical masks had efficacy or whether cloth masks were detrimental to HCWs by causing an increase in infection risk. Either possibility, or a combination of both effects, could explain our results. It is also unknown whether the rates of infection observed in the cloth mask arm are the same or higher than in HCWs who do not wear a mask, as almost all participants in the control arm used a mask. The physical properties of a cloth mask, reuse, the frequency and effectiveness of cleaning, and increased moisture retention, may potentially increase the infection risk for HCWs. The virus may survive on the surface of the facemasks,[29] and modelling studies have quantified the contamination levels of masks.[30] Self-contamination through repeated use and improper doffing is possible. For example, a contaminated cloth mask may transfer pathogen from the mask to the bare hands of the wearer. We also showed that filtration was extremely poor (almost 0%) for the cloth masks. Observations during SARS suggested double-masking and other practices increased the risk of infection because of moisture, liquid diffusion and pathogen retention.[31] These effects may be associated with cloth masks.

We have previously shown that N95 respirators provide superior efficacy to medical masks,[8 9] but need to be worn continuously in high-risk settings to protect HCWs.[9] Although efficacy for medical masks was not shown, efficacy of a magnitude that was too small to be detected is possible.[8 9] The magnitude of difference between cloth masks and medical masks in the current study, if explained by efficacy of medical masks alone, translates to an efficacy of 92% against ILI, which is possible, but not consistent with the lack of efficacy in the two previous RCTs.[8 9] Further, we found no significant difference in rates of virus isolation in medical mask users between the three trials, suggesting that the results of this study could be interpreted as partly being explained by a detrimental effect of cloth masks. This is further supported by the fact that the rate of virus isolation in the no-mask control group in the first Chinese RCT was 3.1%, which was not significantly different to the rates of virus isolation in the medical mask arms in any of the three trials including this one. Unlike the previous RCTs, circulating influenza and RSV were almost completely absent during this study,

Table 3 Type of virus isolated

Study arm	hMPV	Rhino	Influenza B virus	hMPV & rhino	Influenza B virus & rhino	Total
Medical masks arm	1	16	1	1	0	19
Cloth mask arm	4	26	0	0	1	31
Control arm	2	16	0	0	0	18
Total	7	58	1	1	1	68

hMPV, human metapneumovirus; Rhino, rhinoviruses.

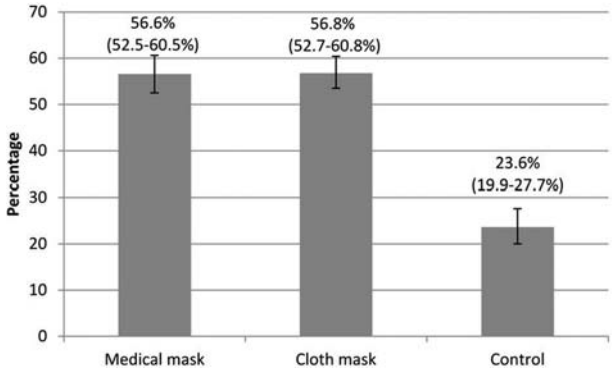

Figure 3 Compliance with the mask wearing—mask wearing more than 70% of working hours.

with rhinoviruses comprising 85% of isolated pathogens, which means the measured efficacy is against a different range of circulating respiratory pathogens. Influenza and RSV predominantly transmit through droplet and contact routes, while Rhinovirus transmits through multiple routes, including airborne and droplet routes.[32 33] The data also show that the clinical case definition of ILI is non-specific, and captures a range of pathogens other than influenza. The study suggests medical masks may be protective, but the magnitude of difference raises the possibility that cloth masks cause an increase in infection risk in HCWs. Further, the filtration of the medical mask used in this trial was poor, making extremely high efficacy of medical masks unlikely, particularly given the predominant pathogen was rhinovirus, which spreads by the airborne route. Given the obligations to HCW occupational health and safety, it is important to consider the potential risk of using cloth masks.

In many parts of the world, cloth masks and medical masks may be the only options available for HCWs. Cloth masks have been used in West Africa during the Ebola outbreak in 2014, due to shortages of PPE, (personal communication, M Jalloh). The use of cloth masks is recommended by some health organisations, with caveats.[34–36] In light of our study, and the obligation to ensure occupational health and safety of HCWs, cloth masks should not be recommended for HCWs, particularly during AGPs and in high-risk settings such as emergency, infectious/respiratory disease and intensive care wards. Infection control guidelines need to acknowledge the widespread real-world practice of cloth masks and should comprehensively address their use. In addition, other important infection control measure such as hand hygiene should not be compromised. We confirmed the protective effects of hand hygiene against laboratory-confirmed viral infection in this study, but mask type was an independent predictor of clinical illness, even adjusted for hand hygiene.

A limitation of this study is that we did not measure compliance with hand hygiene, and the results reflect self-reported compliance, which may be subject to recall or other types of bias. Another limitation of this study is the lack of a no-mask control group and the high use of masks in the controls, which makes interpretation of the results more difficult. In addition, the quality of paper and cloth masks varies widely around the world, so the results may not be generalisable to all settings. The lack of influenza and RSV (or asymptomatic infections) during the study is also a limitation, although the predominance of rhinovirus is informative about pathogens transmitted by the droplet and airborne routes in this setting. As in previous studies, exposure to infection outside the workplace could not be estimated, but we would assume it to be equally distributed between trial arms. The major strength of the randomised trial study design is in ensuring equal distribution of confounders and effect modifiers (such as exposure outside the workplace) between trial arms.

Cloth masks are used in resource-poor settings because of the reduced cost of a reusable option. Various types of cloth masks (made of cotton, gauze and other fibres) have been tested in vitro in the past and show lower filtration capacity compared with disposable masks.[7] The protection afforded by gauze masks increases with the fineness of the cloth and the number of layers,[37] indicating potential to develop a more effective cloth mask, for example, with finer weave, more layers and a better fit.

Cloth masks are generally retained long term and reused multiple times, with a variety of cleaning methods and widely different intervals of cleaning.[34] Further studies are required to determine if variations in frequency and type of cleaning affect the efficacy of cloth masks.

Table 4 Multivariable cluster-adjusted log-binomial model to calculate RR for study outcomes

	CRI RR (95% CI)	ILI RR (95% CI)	Laboratory-confirmed viruses RR (95% CI)
Medical masks arm	Ref	Ref	Ref
Cloth mask arm	1.56 (0.97 to 2.48)	**13.00 (1.69 to 100.07)**	1.54 (0.88 to 2.70)
Control arm	1.51 (0.90 to 2.52)	4.64 (0.47 to 45.97)	1.09 (0.57 to 2.09)
Male	0.67 (0.41 to 1.12)	1.03 (0.34 to 3.13)	0.65 (0.34 to 1.22)
Vaccination	0.83 (0.27 to 2.52)	1.74 (0.24 to 12.56)	1.27 (0.41 to 3.92)
Hand washing	0.91 (0.66 to 1.26)	0.94 (0.40 to 2.20)	**0.66 (0.44 to 0.97)**
Compliance	1.14 (0.77 to 1.69)	1.86 (0.67 to 5.21)	0.86 (0.53 to 1.40)

Bold typeface indicates statistically significant.
CRI, clinical respiratory illness; ILI, influenza-like illness; RR, relative risk.

Table 5 Univariate and adjusted analysis comparing participants who used medical masks and cloth masks*

	Univariate RR (95% CI)	Adjusted RR (95% CI)
CRI		
Medical mask (35/750, 4.67%)	Ref	Ref
Cloth mask (46/607, 7.58%)	**1.62 (1.06 to 2.49)**	1.51 (0.97 to 2.32)
Male	0.60 (0.32 to 1.12)	0.58 (0.31 to 1.08)
Vaccination	0.66 (0.17 to 2.62)	0.68 (0.17 to 2.67)
Hand washing	0.81 (0.58 to 1.15)	0.84 (0.59 to 1.20)
Compliance	1.01 (1.00 to 1.03)	1.01 (1.00 to 1.02)
ILI		
Medical mask (2/750, 0.27%)	Ref	Ref
Cloth mask (13/607, 2.14%)	**8.03 (1.82 to 35.45)**	**6.64 (1.45 to 28.65)**
Male	0.95 (0.27 to 3.35)	0.92 (0.26 to 3.22)
Vaccination	1.87 (0.25 to 13.92)	1.97 (0.27 to 14.45)
Hand washing	0.56 (0.24 to 1.27)	0.61 (0.23 to 1.57)
Compliance	1.04 (1.01 to 1.08)	1.04 (1.00 to 1.08)
Laboratory-confirmed viruses		
Medical mask (22/750, 2.93%)	Ref	Ref
Cloth mask (34/607, 5.60%)	**1.91 (1.13 to 3.23)**	**1.72 (1.01 to 2.94)**
Male	0.64 (0.30 to 1.33)	0.61 (0.29 to 1.27)
Vaccination	0.97 (0.24 to 3.86)	1.03 (0.26 to 4.08)
Hand washing	0.61 (0.41 to 0.93)	0.65 (0.42 to 1.00)
Compliance	1.00 (0.99 to 1.02)	1.0 (0.99 to 1.02)

Bold typeface indicates statistically significant.
*The majority (456/458) of HCWs in the control arm used a mask. Controls who exclusively used a medical mask were categorised and analysed with the medical mask arm participants; and controls who exclusively wore a cloth mask were categorised and analysed with the cloth mask arm.
CRI, clinical respiratory illness; HCWs, healthcare workers; ILI, influenza-like illness; RR, relative risk.

Table 6 A comparison of outcome data for the medical mask arm with medical mask outcomes in previously published RCTs

	CRI N (%)	RR (95% CI)	ILI N (%)	RR (95% CI)	Laboratory-confirmed viruses N (%)	RR (95% CI)
Vietnam trial	28/580 (4.83)	Ref	1/580 (0.17)	Ref	19/580 (3.28)	Ref
Published RCT China 1[8]	33/492 (6.70)	1.40 (0.85 to 2.26)	3/492 (0.61)	3.53 (0.37 to 33.89)	13/492 (2.64)	0.80 (0.40 to 1.62)
Published RCT China 2[9]	98/572 (17.13)	**3.54 (2.37 to 5.31)**	4/572 (0.70)	4.06 (0.45 to 36.18)	19/572 (3.32)	1.01 (0.54 to 1.89)

Bold typeface indicates statistically significant.
CRI, Clinical respiratory illness; ILI, influenza-like illness; RCT, randomised clinical trial; RR, relative risk.

Pandemics and emerging infections are more likely to arise in low-income or middle-income settings than in wealthy countries. In the interests of global public health, adequate attention should be paid to cloth mask use in such settings. The data from this study provide some reassurance about medical masks, and are the first data to show potential clinical efficacy of medical masks. Medical masks are used to provide protection against droplet spread, splash and spray of blood and body fluids. Medical masks or respirators are recommended by different organisations to prevent transmission of Ebola virus, yet shortages of PPE may result in HCWs being forced to use cloth masks.[38–40] In the interest of providing safe, low-cost options in low income countries, there is scope for research into more effectively designed cloth masks, but until such research is carried out, cloth masks should not be recommended. We also recommend that infection control guidelines be updated about cloth mask use to protect the occupational health and safety of HCWs.

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Contributors CRM was the lead investigator, and responsible for the conception and design of the trial, obtaining the grant funding, overseeing the whole study, analysing the data and writing of the report. HS contributed to overseeing the study, staff training, form/database development and drafting of the manuscript. TCD was responsible for overseeing the study, database management, recruitment, training and revision of the manuscript. NTH was responsible for the implementation of research and revision of the manuscript. PTN was responsible for the laboratory testing in Vietnam. AAC contributed to the statistical analysis and drafting of the manuscript. BR was responsible for the statistical analysis and revision of the manuscript. DED contributed to the laboratory technical assistance and revision of the manuscript. QW assisted in comparing the rates of infection from two previous RCTs conducted in China and revision of the manuscript.

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