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Washing of cloth masks and the relationship to respiratory infection risk in health workers

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Strengths and limitations of this study

- The use of cloth masks is widespread around the world during the COVID-19 pandemic, in healthcare and community settings due to shortages of medical masks.
- We previously published the only prospective randomised clinical trial (RCT) of cloth masks in 2015, which has been highly cited during the COVID-19 pandemic for the evidence it presents on poor performance and increased infection risk of cloth masks.
- This study provides analysis of unpublished data on washing of the cloth masks to examine whether the poor performance of cloth masks can be explained by washing practices.
- We show that self-washing of cloth masks are associated with double the risk of infection, and washing in the hospital laundry is protective. The design of the cloth mask, with 2 layers and cotton fabric, is also not ideal.
- Placing the burden of washing a cloth mask on health workers may result in forgetting to wash or inadequate washing. Hospitals should provide health workers with clean medical masks daily and not expect them to work in cloth masks or do their own washing.
- The data do not preclude better protection from a well designed cloth mask which is washed daily.

Abstract

Background: In a previous randomised controlled trial in hospital health care workers (HCWs), cloth masks resulted in a higher risk of respiratory infections compared to medical masks. This was the only published RCT of cloth masks at the time of the COVID-19 pandemic.

Objective: to understand the association of washing to risk of respiratory infection from a two-layered cotton cloth mask in health care workers.

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

Participants: A subgroup of 607 HCWs aged ≥18 years working full-time in selected high-risk wards, who used a two-layered cloth mask and were part of a randomised controlled clinical trial comparing medical masks and cloth masks.

Intervention: washing method for cloth masks (self-washing or hospital laundry). A sub-study of contamination of a sample of 15 cloth and medical masks was also conducted.

Outcome measure: infection rate over four weeks of follow up; and viral contamination of masks tested by multiplex PCR.

Results: Most (77%) HCW self-washed their masks. The risk of infection was more than double among HCW self-washing their masks compared to the hospital laundry (hazards ratio 2.04 (95% CI: 1.03-4.00); p=0.04). Viral contamination with rhinovirus was identified on both used medical and cloth masks.

Conclusions: The poor performance of cloth masks may reflect inadequate self-washing, incorrect reporting of washing, as well as poor design with only two layers and lacking a water-resistant outer

layer. The burden of washing a mask should not be placed on busy HCWs, and hospitals should provide clean masks daily. Until a better designed cloth mask can be proven to be as efficacious as a medical mask, these should not be used in healthcare. Daily washing of cloth masks in whatever setting they are used, including the community, is essential for safety.

Introduction

Global shortages of masks and respirators have resulted in agencies such as the US Centers for Disease Control (CDC) recommending cloth masks for health care workers (HCW) when disposable masks or respirators are not available. [1] We conducted the only randomised controlled clinical trial (RCT) of face masks available at the time of the COVID-19 pandemic, published in 2015. [2] This RCT showed that cloth masks resulted in a higher risk of infection than medical masks and also higher than the control arm. The rate of infection in the cloth mask arm was 1.67 times higher for laboratory confirmed viral illness and 13 times higher for clinical influenza-like illness. [2] In testing for water resistance, we also showed almost complete pentration of the cloth masks by sodium chloride droplets, more than double the penetration of medical masks. During the COVID-19 pandemic, where no medical grade mask was available, this RCT has raised concern about the safety of cloth masks as an alternative for HCWs.

In the RCT, over 90% of participants reported washing their masks daily. [2] On average, HCWs worked most days during the four-week trial period and reported washing their cloth masks on 92% of all days. They reported self-washing (80%), combined self-washing and hospital laundry (16%), and only hospital laundry (4%) as their method of washing.

We postulated that the poor performance of cloth masks may be due the design of the mask, which was a two-layered cotton mask manufactured in Vietnam, and possibly due to inadequate washing. [2] It was also possible that different distribution of cloth masks versus medical masks by ward type may have caused an apparently higher rate of infection in cloth mask users. Given the urgency around the safety of cloth masks and the controversy caused by the results of our RCT, we analysed unpublished data on cleaning of the cloth masks and ward allocation from the 2015 trial, as well as unpublished data from a sub-study on viral contamination of cloth and medical masks.

Aims: To determine the relationship of washing of masks to infection risk in cloth mask users. The secondary aim was to determine contamination with viral pathogens on the surface of cloth and medical masks.

Methods:

We selected all subjects who wore a cloth mask from the published RCT of cloth masks versus medical masks[2] (trial registration number in the Australian New Zealand Clinical Trials Registry was ACTRN12610000887077), which included subjects allocated to the cloth mask arm (n=569) as well as anyone in the control arm wearing only a cloth mask (38/458). This provided 607 subjects for further analysis of infection risk by washing and cleaning of cloth masks. The cloth mask used in the study was manufactured locally in Vietnam, and widely used in the secondary hospitals and also in tertiary hospitals (see Figure 1 below). The cloth mask studied was made of cotton and cotton blend fabric with 2 layers (inner and outer layer), without a filter layer, and with four strings in four corners of the mask as pictured in Figure 1. HCWs were provided five masks and asked to wash their mask daily and use a clean one each day. They were provided written instructions on washing the mask and self-reported the washing practices daily. They re-used the masks after self-washing or using the hospital laundry system for sterilization. The study was an epidemiologic analysis of unpublished data on contamination and washing of cloth masks, collected during the original RCT. We also looked at the distribution of HCW by ward type to see if there was any difference between the cloth and medical mask groups which could explain the higher rate of infection in the cloth mask group.

(Figure 1 here)

Figure 1: Cloth mask used in the study

The outcome of interest was infection, using a composite outcome variable measured in the study (clinical respiratory illness, influenza like illness and laboratory confirmation of one or multiple respiratory viruses). [2] In the study, 85% (58/68 positive RT-PCR tests) were for Rhinovirus. [2]

The data on the method of washing (self-washing or hospital laundry) as well as daily diary data on frequency of washing were analysed. Self-reported daily cleaning data from daily diary cards were analysed, as participants may have varied the cleaning frequency and type by day over the four-week follow up period. Person-days of mask washing were used as denominator data for analysis. Data on ward type (Intensive Care, Infectious Diseases, Paediatrics, Cancer and Haematology, Emergency and other) cleaning method and frequency of cleaning were analysed against infection risk

Statistical analysis:

To determine the association, we adopted a survival analysis technique with time varying covariates. The data was arranged in "counting process format" [3], where for each participant there were same number of records as the number of days of follow up. The outcome and study factor (mask cleaning) were assessed daily as binary variables. We generated Kaplan - Meier survival plots to compare the survival experience by mask cleaning practices and fitted the Cox proportional hazards model to estimate the hazards ratios. We also examined infection rate by type of ward using a Pearson's chi-squared test.

Sub-study of contamination of masks: A total of 117 masks samples were collected – 102 from subjects with clinical respiratory illness in participating hospitals; and 15 from a sub-study as described below. All participants at this time also had a swab of their nose and throat collected for lab testing.

For the sub-study of mask contamination, 15 mask samples were collected from two purposively selected wards in Thanh Nhan General Hospital (a city hospital in Hanoi) between 28 March -8 April 2011. Intervention arms were cluster randomized by ward, so staff on each ward used the same type of mask. Nine participants were randomly selected from the cloth mask group (Intensive Care Unit), and six were randomly selected from medical masks group (Pediatric ward). In the cloth mask group, three participants were given five clean cloth mask per person, along with daily washing instructions, and masks were collected after one month. Three participants were requested to provide their cloth masks for testing after use. The remaining three participants were asked to provide their cloth masks which they used for previous four weeks.

In the medical mask group, three randomly selected participants were given one new medical mask per person in morning by the study team and the masks were collected the same day after one hour of use. The remaining three participants were given one new medical mask per person in morning and by the survey team and the masks were collected after four hours of use.

Mask testing

The mask testing method is shown in Figure 2. Mask samples were folded in double vertically. They were cut at the central part of the mask into 3 x 5 cm rectangles and separated into different layers - three layers for medical masks and two with cloth masks. Masks were cut and placed in a tube (as described in figure 2) and sent to the lab for testing as described in the original study. [2] Each layer was put into different VTM tube and labelled, using a sterilized bamboo stick to push the layer deep into the media. Testing was performed using both normal and concentrated samples. A multiplex respiratory viral RT-PCR test was done for SVA/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), as described in the original trial. [2]

Figure 2: Mask testing

(Figure 2 here)

Ethics approval for the study was granted by National Institute for Hygiene and Epidemiology (NIHE), Vietnam (approval number 05 IRB) and the Human Research Ethics Committee of the University of New South Wales (UNSW), Australia, (HREC approval number 10306).

Patient and Public Involvement

There was no patient or public involvement.

Results

There were 607 subjects with 9253 person-days of follow up who wore a cloth mask during the study. The highest rates of infection among cloth mask users was in the emergency (12%) and Intensive Care Units (10%). There was a similar distribution of participants between the ward types, in the medical mask and cloth mask arms with 138 medical mask users and 180 cloth mask users in ICU; and 163 medical mask users and 143 cloth mask users in the Emergency Department.

We also compared the infection rate of ICU and ED combined with other wards (paediatrics, infectious diseases, internal medicine, other). In the ICU and ED wards there were 36 (11.2%) infections among 323 cloth mask users and in all other wards there were 16 (5.6%) infections among 284 subjects. This difference was statistically significant (P=0.015). There was no significant difference in infection rate between any ward types for medical masks, which was 5.33% overall (range 3.8-6.9%). In ICU, medical masks had 8/138 infections (5.8%) and in emergency 7/163 (4.2%).

The most common method of cleaning was self-washing (77%,) followed by hospital laundry (13%). Over 90% (8396/9253 person-day observations) reported washing their mask daily. Only 15 subjects reported cleaning their mask <50% of the time over the four weeks of follow up. There were 7091/9253 person-days of self-washing reported, and 1177/9253 person-days of hospital laundry washing. Figure 3 shows that hospital laundry was superior to self-washing in the survival analysis.

Figure 3. Survival analysis of infection by mask washing location (hospital laundry vs self-washing)

(Figure 3 here)

The risk of infection just over double for HCW who self-washing their cloth masks compared to using the hospital laundry. The hazards ratio of infection for self-washing was 2.04 (95% CI: 1.03-4.00); p=0.04.

Mask testing results:

In standard testing, 2% (2/117) of masks samples were positive for virus. Rhinoviruses were isolated from the internal layer and external layers respectively of one medical mask sample each.

In concentrated testing, around 4% (4/117 mask samples were positive, two medical masks and two cloth masks. Rhinoviruses were isolated from internal and external layers of two medical masks and only the internal layer of two cloth mask samples. Paired nose and throat swabs of these same subjects were also positive for Rhinoviruses.

Discussion

While the majority of participants reported washing their mask daily, self-washing more than doubled the risk of infection. We do not have data on the quality of self-washing, but it is possible that those who reported self-washing either did not actually wash the masks daily (but reported that they did) or washed them insufficiently. Participants who were busy and did not have time for washing may have felt uncomfortable reporting that they failed to wash the masks. Given self-washing was by far the commonest methods reported (77%), if a proportion who reported daily washing did not actually do so, this could explain the poor performance of cloth masks in the original RCT, and reiterates the importance of daily washing of these products. [2] Unlike medical masks, which are regulated on water resistance, cotton masks are not water resistant, and will become damp more readily than medical masks. Given the outer layer of the cloth mask was absorbent cotton rather than water-resistant, this could pose a risk of contamination if masks are not washed daily.

The difference in clinical outcomes in the trial may be explained by the fact the medical mask users received a new mask daily, whereas cloth mask users received 5 masks to wash and reuse. The principle of a re-usable cloth mask is that a user has at least two masks so they can be washed daily to ensure a clean mask each day. However, for medical mask users the simple fact of being provided a clean mask daily may be a key factor in reducing risk of infection, whereas busy health workers may forget to wash a cloth mask daily, as it is an added burden on their workload. We do not recommend cloth masks for health workers, but if used, health facilities should provide clean masks daily to health workers, and also launder them in the hospital laundry. Placing the burden of cleaning on a HCW may increase the risk of unsafe use and infection.

The majority of participants in the trial who had a confirmed viral infection had rhinovirus, and this was the only virus identified on mask samples, on both the inner and outer layers in medical masks and on the inner layer of cloth masks. Whilst both mask types can become contaminated, there was no difference in contamination between medical and cloth masks - however, the sample size was very small. More research is needed to quantify longitudinal contamination of unwashed cloth masks over time and by usage frequency.

A meta-analysis of mask use for SARS, SARS-CoV-2 and MERS CoV showed that masks were 85% protective, and that a 12-layered cloth mask is as protective as a medical mask. [4] There are no data on other combinations of layers, except that single layered masks are not protective. [4] Our original

RCT suggests that even a two-layered cotton and cotton blend mask is not protective. [5] However, this does not preclude more protective cloth mask designs for community use.

The principles of a safer cloth mask would include at least three layers, water-resistant fabric for the outer layer, fine weave, high thread count, fit around the face and ties instead of ear loops, the latter which have been reported to reduce fit. They should also be washed daily in soap and water, and the design should allow frequent washing without compromising the design features. The WHO changed it's recommendation on community mask use in June 2020 and provided guidance on optimal design of a cloth mask. [6]

The distribution of trial participants between ward types was similar, so this did not explain the poor performance of cloth masks. Further, infection rates were not significantly different by ward type for medical masks – only for cloth masks, which had a significantly higher infection risk for ICU and emergency wards. ICU and Emergency wards are recognised as high-risk, high transmission settings, with documented aerosolised viruses such as influenza and COVID-19,[7,8,9] so a cloth mask may not be adequate in these wards. Health workers in ICU or emergency should not be asked to wear a cloth mask.

We conclude that two-layered cotton masks as used in the original RCT are not a safe option for health workers, especially in ICU or Emergency wards. A respirator provides 96% protection for health workers, compared to 67% with a medical mask, [4] and should be the standard for health workers treating COVID-19 patients. [10] Countries should take responsibility for scaling up manufacturing of medical masks and respirators for health workers, instead of forcing them to work in sub-optimal personal protective equipment.[11]

In summary, the poor performance of cloth masks in our RCT may reflect inadequate washing as well as poor design with only two layers and lacking a water-resistant outer layer. Daily washing of cloth masks in whatever setting they are used, including the community, is essential for safety. Reports of self-washing may have over-estimated frequency of washing and there may have been variability in the quality of washing. The additional burden of being responsible for cleaning of a mask for busy HCWs in the midst of a pandemic may compromise safety, if workers forget to wash the mask. Removing this responsibility from HCWs and minimising the burden on them for their own protection, by providing daily clean masks is recommended in hospitals. If cloth masks are used, cleaning in the hospital laundry and daily provision of clean masks is safer than self-washing. The data from our RCT are specific to a two-layered cotton mask and cannot be generalised to all cloth

masks. More research is needed on optimal design of cloth masks to improve protection, and until such a design can be proven to be as effective as medical masks, they should not be used for HCWs.

Author contributions: CR MacIntyre conceived, designed study, developed data analysis plan, wrote the manuscript. B Rahman and AA Chughtai analysed the data and wrote and reviewed the manuscript. TC Dung reviewed original data and reviewed and wrote the manuscript. H Seale reviewed the analysis and wrote the manuscript.

Competing interests: TC Dung works for the Vietnam Ministry of Health. There are no other competing interests.

Data sharing: The data are not available for sharing under the conditions of ethics approval from Vietnam.

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https://blogs.bmj.com/bmj/2020/04/09/covid-19-should-cloth-masks-be-used-by-healthcare-workers-as-a-last-resort/

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Figure 1: Cloth mask used in the study

Figure 2: Mask testing

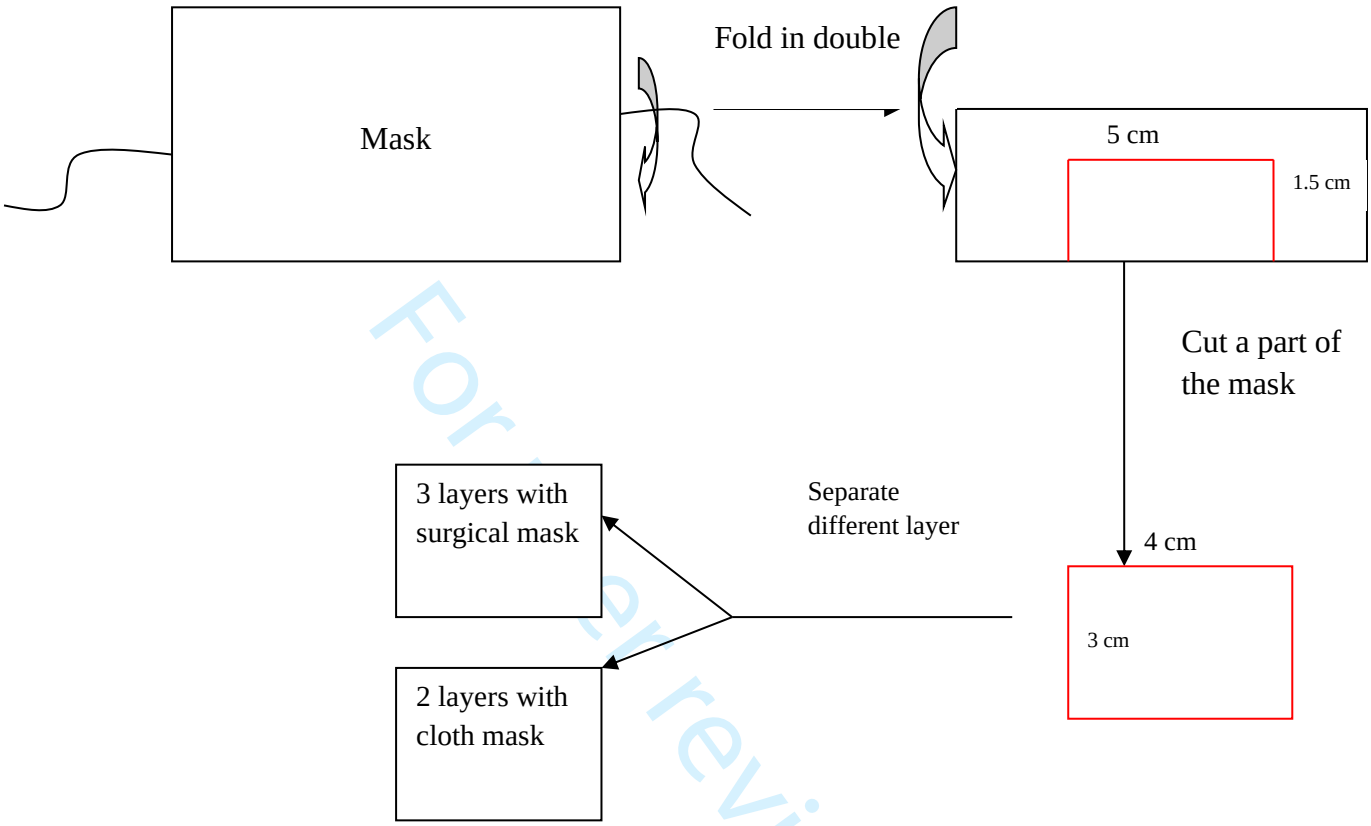

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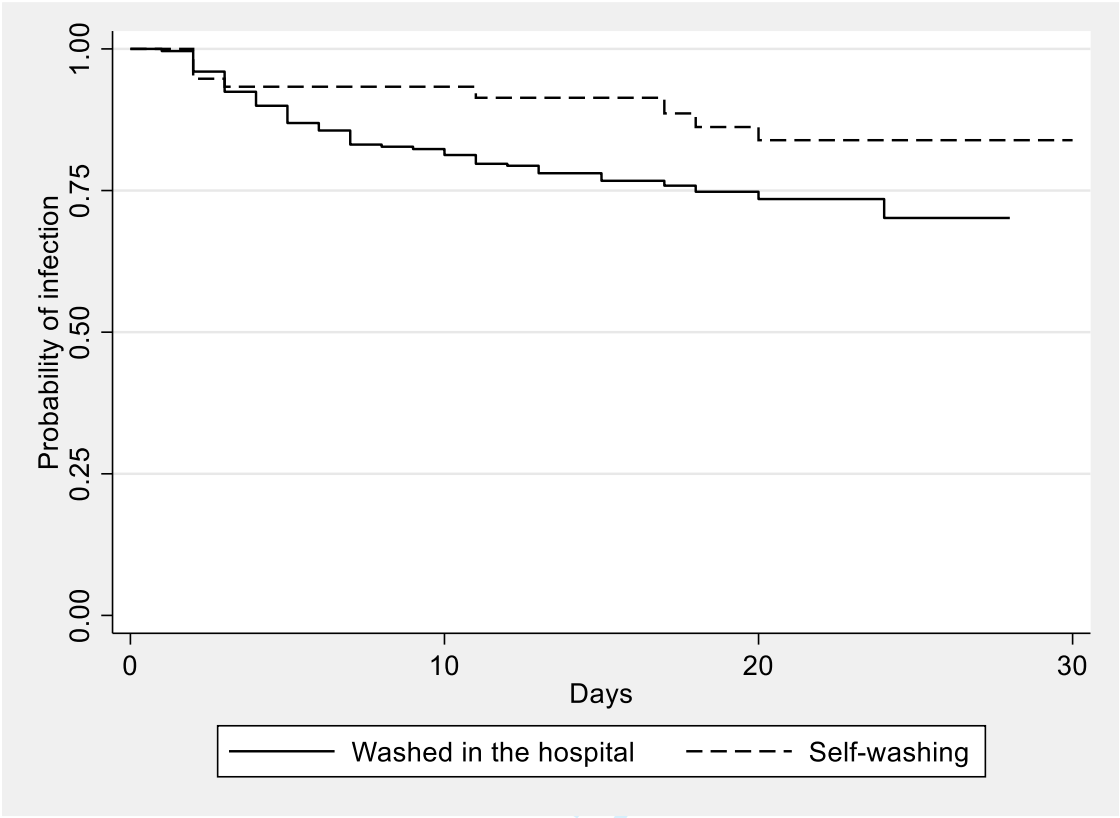
Figure 3. Survival analysis of infection by mask washing location (hospital laundry vs self-washing)



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Abstract

Background: In a previous randomised controlled trial in hospital health care workers (HCWs), cloth masks resulted in a higher risk of respiratory infections compared to medical masks. This was the only published RCT of cloth masks at the time of the COVID-19 pandemic.

Objective: to do a post-hoc analysis of unpublished data on mask washing and mask contamination from the original RCT to further understand poor performance of the two-layered cotton cloth mask used by health care workers in that RCT.

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

Participants: A subgroup of 607 HCWs aged ≥18 years working full-time in selected high-risk wards, who used a two-layered cloth mask and were part of a randomised controlled clinical trial comparing medical masks and cloth masks.

Intervention: washing method for cloth masks (self-washing or hospital laundry). A sub-study of contamination of a sample of 15 cloth and medical masks was also conducted.

Outcome measure: infection rate over four weeks of follow up; and viral contamination of masks tested by multiplex PCR.

Results: Viral contamination with rhinovirus was identified on both used medical and cloth masks. Most HCW (77%) self-washed their masks by hand. The risk of infection was more than double among HCW self-washing their masks compared to the hospital laundry (hazards ratio 2.04 (95% CI: 1.03-4.00); p=0.04). There was no significant difference in infection

between HCW who wore cloth masks washed in the hospital laundry compared to medical masks.

Conclusions: Using self-reported method of washing, we showed double the risk of infection risk if masks were self-washed by hand by HCW. The majority of HCWs in the study reported hand-washing their mask themselves. This could explain the poor performance of two layered cloth masks, if the self-washing was inadequate or not done as frequently as reported. Both cloth and medical masks were contaminated, but only cloth masks were re-used in the study, reiterating the importance of daily washing of re-usable cloth masks using proper method.

Trial registration number in the Australian New Zealand Clinical Trials Registry was ACTRN12610000887077

Strengths and limitations of this study

- Unpublished data on washing and contamination of the cloth masks was available for post-hoc analysis of an original published RCT, which allowed further understand of reasons for the poor performance of cloth masks in the RCT.
- The method and frequency of washing of cloth masks was self-reported by health workers, which could be subject to recall bias or misreporting.
- The contamination study showed contamination of both medical and cloth masks but had a small sample.
- The data are specific for the 2-layered cloth mask used in the study and do not preclude better protection from a well-designed cloth mask which is washed daily.

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Introduction

Global shortages of masks and respirators have resulted in agencies such as the US Centers for Disease Control (CDC) recommending cloth masks for health care workers (HCW) when disposable masks or respirators are not available. [1] We conducted the only randomised controlled clinical trial (RCT) of face masks available at the time of the COVID-19 pandemic, published in 2015. [2] This RCT showed that cloth masks resulted in a higher risk of infection than medical masks and also higher than the control arm. The rate of infection in the cloth mask arm was 1.67 times higher for laboratory confirmed viral illness and 13 times higher for clinical influenza-like illness. [2] In testing for water resistance, we also showed almost complete pentration of the cloth masks by sodium chloride droplets, more than double the penetration of medical masks. During the COVID-19 pandemic, where no medical grade mask was available, this RCT has raised concern about the safety of cloth masks as an alternative for HCWs.

In the RCT, over 90% of participants reported washing their masks daily. [2] On average, HCWs worked most days during the four-week trial period and reported washing their cloth masks on 92% of all days. They reported self-washing (80%), combined self-washing and hospital laundry (16%), and only hospital laundry (4%) as their method of washing.

We postulated that the poor performance of cloth masks may be due the design of the mask, which was a two-layered cotton mask manufactured in Vietnam, and possibly due to inadequate washing. [2] It was also possible that different distribution of cloth masks versus medical masks by ward type may have caused an apparently higher rate of infection in cloth mask users. Given the urgency around the safety of cloth masks and the controversy caused by the results of our RCT, we analysed unpublished data on cleaning of the cloth masks and ward allocation from the 2015 trial, as well as unpublished data from a sub-study on viral contamination of cloth and medical masks.

Aims: To determine the relationship of washing of masks to infection risk in cloth mask users. The secondary aim was to determine contamination with viral pathogens on the surface of cloth and medical masks.

Methods:

We selected all subjects who wore a cloth mask from the published RCT of cloth masks versus medical masks[2] (trial registration number in the Australian New Zealand Clinical Trials Registry was ACTRN12610000887077), which included subjects allocated to the cloth mask arm (n=569) as well as anyone in the control arm wearing only a cloth mask (38/458). This provided 607 subjects for further analysis of infection risk by washing and cleaning of cloth masks. The cloth mask used in the study was manufactured locally in Vietnam, and widely used in the secondary hospitals and also in tertiary hospitals (see Figure 1 below). The cloth mask studied was made of cotton and cotton blend fabric with 2 layers (inner and outer layer), without a filter layer, and with four strings in four corners of the mask as pictured in Figure 1. HCWs were provided five masks and asked to wash their mask daily and use a clean one each day. They could hand-wash the masks themselves in the hospital with soap and tap water and hang them out to dry in a space provided for HCW (Figure 1), or they could get the masks laundered in the hospital laundry in an automatic washing machine with detergent and hot water, if available in their hospital. They were provided written instructions on washing the mask themselves and self-reported their washing practices daily. They re-used the masks after self-washing or using the hospital laundry system. The study was an epidemiologic analysis of unpublished data on contamination and washing of cloth masks, collected during the original RCT. We also looked at the distribution of HCW by ward type to see if there was any difference between the cloth and medical mask groups which could explain the higher rate of infection in the cloth mask group.

(Figure 1 here)

Figure 1: Cloth mask used in the study

The outcome of interest was infection, using a composite outcome variable measured in the study (clinical respiratory illness, influenza like illness and laboratory confirmation of one or multiple respiratory viruses). [2] In the study, 85% (58/68 positive RT-PCR tests) were for Rhinovirus. [2]

The data on the method of washing (self-washing or hospital laundry) as well as daily diary data on frequency of washing were analysed. Self-reported daily cleaning data from daily diary cards were analysed, as participants may have varied the cleaning frequency and type by day over the four-week follow up period. Person-days of mask washing were used as

denominator data for analysis. Follow up data were censored when infection occurred. We compared cloth masks which were self-washed by hand, with cloth masks that were washed in the hospital laundry and medical masks. Data on ward type (Intensive Care, Infectious Diseases, Paediatrics, Cancer and Haematology, Emergency and other) cleaning method and frequency of cleaning were analysed against infection risk

Statistical analysis:

To determine the association, we adopted a survival analysis technique with time varying covariates. The data was arranged in "counting process format" [3], where for each participant there were same number of records as the number of days of follow up. The outcome and study factor (mask cleaning) were assessed daily as binary variables. We generated Kaplan - Meier survival plots to compare the survival experience by mask cleaning practices and fitted the Cox proportional hazards model to estimate the hazards ratios. We also examined infection rate by type of ward using a Pearson's chi-squared test.

Sub-study of contamination of masks: A total of 117 masks samples were collected – 102 from subjects with clinical respiratory illness in participating hospitals; and 15 from a sub-study as described below. All participants at this time also had a swab of their nose and throat collected for lab testing.

For the sub-study of mask contamination, 15 mask samples were collected from two purposively selected wards in Thanh Nhan General Hospital (a city hospital in Hanoi) between 28 March -8 April 2011. Intervention arms were cluster randomized by ward, so staff on each ward used the same type of mask. Nine participants were randomly selected from the cloth mask group (Intensive Care Unit), and six were randomly selected from medical masks group (Pediatric ward). In the cloth mask group, three participants were given five clean cloth mask per person, along with daily washing instructions, and masks were collected after one month. Three participants were requested to provide their cloth masks for testing after use. The remaining three participants were asked to provide their cloth masks which they used for previous four weeks.

In the medical mask group, three randomly selected participants were given one new medical mask per person in morning by the study team and the masks were collected the

same day after one hour of use. The remaining three participants were given one new medical mask per person in morning and by the survey team and the masks were collected after four hours of use.

Mask testing

The mask testing method is shown in Figure 2. Mask samples were collected after use by HCWs. They were folded in double vertically. They were cut at the central part of the mask into 3 x 5 cm rectangles and separated into different layers - three layers for medical masks and two with cloth masks. Masks were cut and placed in a tube (as described in figure 2) and sent to the lab for testing as described in the original study. [2] Each layer was put into different VTM tube and labelled, using a sterilized bamboo stick to push the layer deep into the media. Testing was performed using both normal and concentrated samples. A multiplex respiratory viral RT-PCR test was done for SVA/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), as described in the original trial. [2]

Figure 2: Mask testing

(Figure 2 here)

Ethics approval for the study was granted by National Institute for Hygiene and Epidemiology (NIHE), Vietnam (approval number 05 IRB) and the Human Research Ethics Committee of the University of New South Wales (UNSW), Australia, (HREC approval number 10306).

Patient and Public Involvement

There was no patient or public involvement.

Results

There were 607 subjects with 9253 person-days of follow up who wore a cloth mask during the study. The highest rates of infection among cloth mask users was in the emergency (12%) and Intensive Care Units (10%). There was a similar distribution of participants between the ward types, in the medical mask and cloth mask arms with 138 medical mask users and 180 cloth mask users in ICU; and 163 medical mask users and 143 cloth mask users in the Emergency Department.

We also compared the infection rate of ICU and ED combined with other wards (paediatrics, infectious diseases, internal medicine, other). In the ICU and ED wards there were 36 (11.2%) infections among 323 cloth mask users and in all other wards there were 16 (5.6%) infections among 284 subjects. This difference was statistically significant (P=0.015). There was no significant difference in infection rate between any ward types for medical masks, which was 5.33% overall (range 3.8-6.9%). In ICU, medical masks had 8/138 infections (5.8%) and in emergency 7/163 (4.2%).

The most common method of cleaning was self-washing by hand (77%,) followed by hospital laundry (13%). Some HCW used both methods at different times. Over 90% (8396/9253 person-day observations) reported washing their mask daily. Only 15 subjects reported cleaning their mask <50% of the time over the four weeks of follow up. There were 7091/9253 person-days of self-washing reported, and 1177/9253 person-days of hospital laundry washing. Rates of infection among HCW who self-washed their cloth masks by hand and who used the hospital laundry were 2/100 person days (110/5417 person days) and 0.85 per 100 person days (9/1052 person days) respectively. The rate of infection among HCW who wore a medical mask was 0.85 per 100 person days (139/16,284 person days). The risk of infection just over double for HCW who self-washed their cloth masks by hand compared to using the hospital laundry. The hazards ratio of infection for self-washing was 2.04 (95% CI: 1.03-4.00); p=0.04.

There was no significant difference in infection rate between cloth masks washed in the hospital laundry and medical masks (p=0.5). Figure 3 shows that hospital laundry was superior to self-washing in the survival analysis.

Figure 3. Survival analysis of infection by mask washing location (hospital laundry vs self-washing)

(Figure 3 here)

Mask testing results:

In standard testing, 2% (2/117) of masks samples were positive for virus. Rhinoviruses were isolated from the internal layer and external layers respectively of one medical mask sample each.

In concentrated testing, around 4% (4/117 mask samples were positive, two medical masks and two cloth masks. Rhinoviruses were isolated from internal and external layers of two medical masks and only the internal layer of two cloth mask samples. Paired nose and throat swabs of these same subjects were also positive for Rhinoviruses.

Discussion

HCW who self-washed their masks in the hospital by hand had double the risk of infection than those who used the hospital laundry. Self-washing was by far the commonest method of washing (77% of cloth mask users), which could explain the poor performance of cloth masks in the intention to treat analysis in the original RCT, and reiterates the importance of daily washing of these products. [2] HCW whose cloth masks were laundered in the hospital laundry were protected at the same level as those who wore disposable medical masks.

While the majority of participants reported washing their mask daily, it appears that the hand washing was not adequate or that a proportion who reported daily washing did not actually do so every day. Hand washing in the hospital is usually done in the available wash basins, some of which do not have hot water, which may reduce the effectiveness of washing. The WHO recommends machine washing with warm water at 60–90°C and laundry detergent.[4]

We showed that both cloth and medical mask can become contaminated. There was no difference in contamination between medical and cloth masks - however, the sample size was very small. The majority of participants in the trial who had a confirmed viral infection had rhinovirus, and this was the only virus identified on mask samples, on both the inner and outer layers in medical masks and on the inner layer of cloth masks. More research is needed to quantify longitudinal contamination of unwashed cloth masks over time and by usage frequency.

On a practical level, the difference in clinical outcomes in the trial may be explained by the fact the medical mask users received a new mask daily, whereas cloth mask users received 5 masks to wash and reuse. The principle of a re-usable cloth mask is that a user has at least two masks so they can be washed daily to ensure a clean mask each day. However, for medical mask users the simple fact of being provided a clean mask daily may be a key factor in reducing risk of infection, whereas busy health workers may forget to wash a cloth mask daily or wash them inadequately, as it is an added burden on their workload. We do not recommend cloth masks for health workers, but if used as a last resort where no other options are available, health facilities should provide clean masks daily to health workers, and also launder them in the hospital laundry. Placing the burden of cleaning on a HCW may increase the risk of unsafe use and infection. If laundry facilities are not available, using steam sterilisation may be a safer alternative to hand washing.[5]

A meta-analysis of mask use for SARS, SARS-CoV-2 and MERS CoV showed that masks were 85% protective, and that a 12-layered cloth mask is as protective as a medical mask. [6] There are no data on other combinations of layers, except that single layered masks are not protective. [6] Our original RCT suggests that even a two-layered cotton and cotton blend mask is not protective. [2] However, this

does not preclude more protective cloth mask designs, especially if washing is done daily according to WHO recommendations. [4]

Cotton is not a suitable fabric for the outer layer of a mask, as it is absorbent, can become damp and pose a risk of contamination not washed daily or if washed inadequately.[7] The principles of a safer cloth mask would include at least three layers, water-resistant fabric for the outer layer, fine weave, high thread count, fit around the face and ties instead of ear loops, the latter which have been reported to reduce fit. [8] They should also be washed daily in soap and water, and the design should allow frequent washing without compromising the design features. The WHO changed it's recommendation on community mask use in June 2020 and provided guidance on optimal design of a cloth mask. [9]

The distribution of trial participants between ward types was similar, so this did not contribute to the poor performance of cloth masks. Further, infection rates were not significantly different by ward type for medical masks – only for cloth masks, which had a significantly higher infection risk for ICU and emergency wards. ICU and Emergency wards are recognised as high-risk, high transmission settings, with documented aerosolised viruses such as influenza and COVID-19,[10,11,12] so a cloth mask may not be adequate in these wards.

We conclude that two-layered cotton masks as used in the original RCT are not a safe option for HCW if they are held responsible for their own washing, especially in ICU or Emergency wards. A respirator provides 96% protection for health workers, compared to 67% with a medical mask, [6] and should be the standard for health workers treating COVID-19 patients. [13] This does not preclude the use of well-designed cloth masks in the community, as there has been unprecedented efforts in development and research into novel re-usable cloth masks during the pandemic. [6] However, countries should take responsibility for scaling up manufacturing of medical masks and respirators for health workers, instead of forcing them to work in sub-optimal personal protective equipment.[14]

In summary, the poor performance of cloth masks in our RCT may reflect inadequate washing. Daily washing of cloth masks at the recommended temperature of 60-90°C in whatever setting they are used, including the community, is essential for safety. Reports of self-washing may have over-estimated the frequency of washing and there may have been variability in the quality of washing. The additional burden of being responsible for cleaning of a mask for busy HCWs in the midst of a pandemic may compromise safety, if workers forget to wash the mask. Removing this responsibility from HCWs and minimising the burden on them for their own protection, by providing daily clean masks is the safest option in hospitals. If cloth masks are used, cleaning in the hospital laundry and daily provision of clean masks is safer than self-washing. The data from our RCT are specific to a two-layered cotton mask and cannot be generalised to all cloth masks. The trial was conducted in 2011, at a time when cloth masks were not well researched and not even mentioned in PPE guidelines

despite being used widely in Asia. As a result of the COVID-19 pandemic, unprecedented research on cloth mask design is being conducted, which will result in better designs. Well-designed cloth masks may provide protection in the community, [5,8] but design is only one aspect of the safety and effectiveness of a cloth mask. Daily washing as recommended by the WHO is also necessary.

Author contributions: CR MacIntyre conceived, designed study, developed data analysis plan, wrote the manuscript. B Rahman and AA Chughtai analysed the data and wrote and reviewed the manuscript. TC Dung reviewed original data and reviewed and wrote the manuscript. H Seale reviewed the analysis and wrote the manuscript.

Competing interests: TC Dung works for the Vietnam Ministry of Health. There are no other competing interests.

Data sharing: The data are not available for sharing under the conditions of ethics approval from Vietnam.

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Figure 1: Cloth mask used in the study and hanging of washed cloth masks to dry.

Figure 2: Mask testing

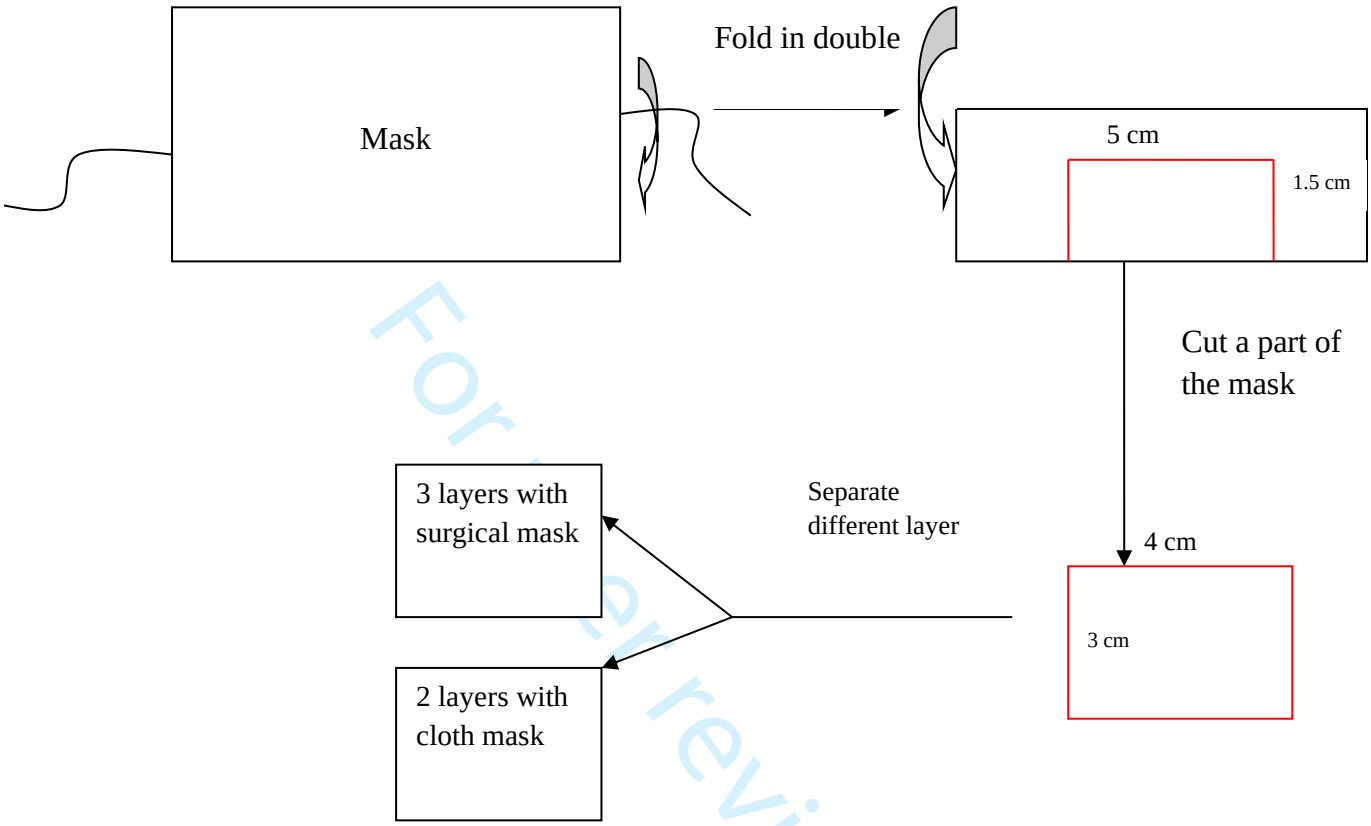

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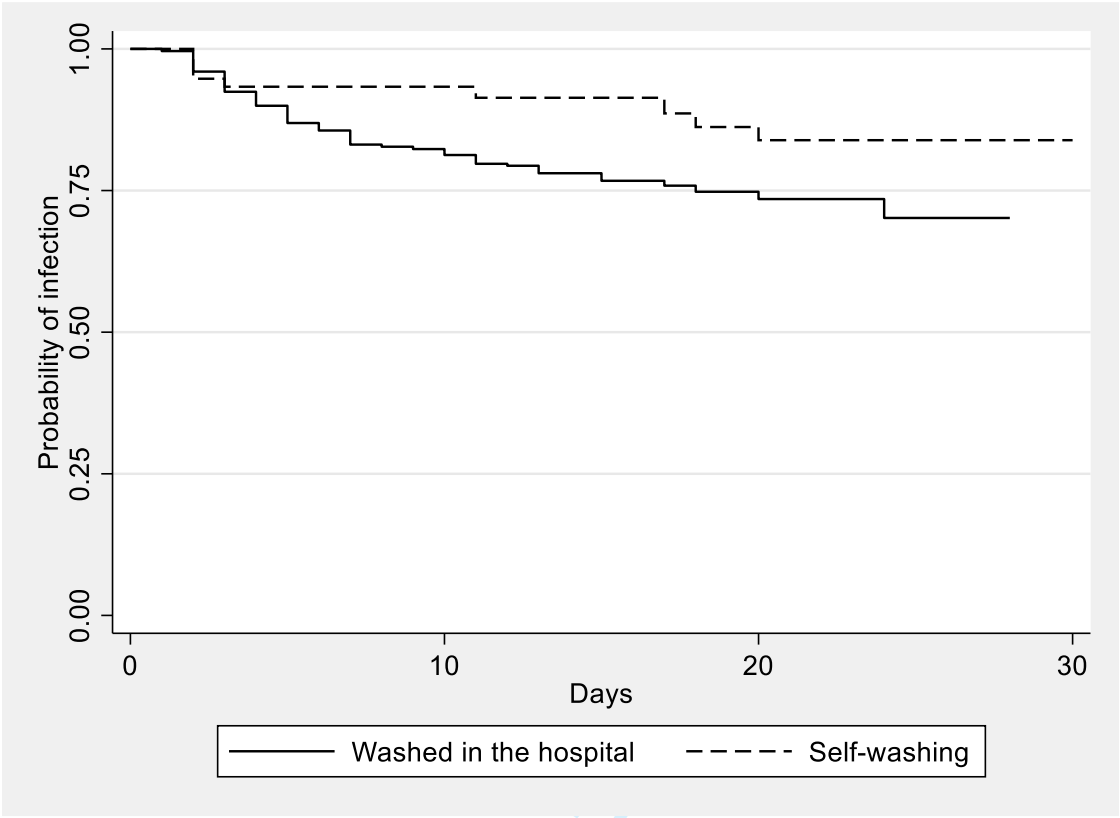
Figure 3. Survival analysis of infection by mask washing location (hospital laundry vs self-washing)



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Contamination and washing of cloth masks and risk of infection among hospital health workers in Vietnam – a post-hoc analysis of a randomized controlled trial

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Abstract

Background: In a previous randomised controlled trial in hospital health care workers (HCWs), cloth masks resulted in a higher risk of respiratory infections compared to medical masks. This was the only published RCT of cloth masks at the time of the COVID-19 pandemic.

Objective: to do a post-hoc analysis of unpublished data on mask washing and mask contamination from the original RCT to further understand poor performance of the two-layered cotton cloth mask used by health care workers in that RCT.

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

Participants: A subgroup of 607 HCWs aged ≥18 years working full-time in selected high-risk wards, who used a two-layered cloth mask and were part of a randomised controlled clinical trial comparing medical masks and cloth masks.

Intervention: washing method for cloth masks (self-washing or hospital laundry). A sub-study of contamination of a sample of 15 cloth and medical masks was also conducted.

Outcome measure: infection rate over four weeks of follow up; and viral contamination of masks tested by multiplex PCR.

Results: Viral contamination with rhinovirus was identified on both used medical and cloth masks. Most HCW (77%) self-washed their masks by hand. The risk of infection was more than double among HCW self-washing their masks compared to the hospital laundry (hazards ratio 2.04 (95% CI: 1.03-4.00); p=0.04). There was no significant difference in infection

between HCW who wore cloth masks washed in the hospital laundry compared to medical masks (p=0.5).

Conclusions: Using self-reported method of washing, we showed double the risk of infection with seasonal respiratory viruses if masks were self-washed by hand by HCW. The majority of HCWs in the study reported hand-washing their mask themselves. This could explain the poor performance of two layered cloth masks, if the self-washing was inadequate. Cloth masks washed in the hospital laundry were as protective as medical masks. Both cloth and medical masks were contaminated, but only cloth masks were re-used in the study, reiterating the importance of daily washing of re-usable cloth masks using proper method. A well washed cloth mask can be as protective as a medical mask.

Trial registration number in the Australian New Zealand Clinical Trials Registry was ACTRN12610000887077

Strengths and limitations of this study

- Unpublished data on washing and contamination of the cloth masks was available for post-hoc analysis of an original published RCT, which allowed further understand of reasons for the poor performance of cloth masks in the RCT.
- The method and frequency of washing of cloth masks was self-reported by health workers, which could be subject to recall bias or misreporting.
- The contamination study showed contamination of both medical and cloth masks but had a small sample.
- The data are specific for the 2-layered cloth mask used in the study and do not preclude better protection from a well-designed cloth mask which is washed daily.

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Introduction

Global shortages of masks and respirators have resulted in agencies such as the US Centers for Disease Control (CDC) recommending cloth masks for health care workers (HCW) when disposable masks or respirators are not available. [1] We conducted the only randomised controlled clinical trial (RCT) of face masks available at the time of the COVID-19 pandemic, published in 2015. [2] This RCT showed that cloth masks resulted in a higher risk of infection than medical masks and also higher than the control arm. The rate of infection in the cloth mask arm was 1.67 times higher for laboratory confirmed viral illness and 13 times higher for clinical influenza-like illness. [2] In testing for water resistance, we also showed almost complete pentration of the cloth masks by sodium chloride droplets, more than double the penetration of medical masks. During the COVID-19 pandemic, where no medical grade mask was available, this RCT has raised concern about the safety of cloth masks as an alternative for HCWs.

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The outcome of interest was infection, using a composite outcome variable measured in the study (clinical respiratory illness, influenza like illness and laboratory confirmation of one or multiple respiratory viruses). [2] In the study, 85% (58/68 positive RT-PCR tests) were for Rhinovirus. [2]

The data on the method of washing (self-washing or hospital laundry) as well as daily diary data on frequency of washing were analysed. Self-reported daily cleaning data from daily diary cards were analysed, as participants may have varied the cleaning frequency and type by day over the four-week follow up period. Person-days of mask washing were used as

denominator data for analysis. Follow up data were censored when infection occurred. We compared cloth masks which were self-washed by hand, with cloth masks that were washed in the hospital laundry and medical masks. Data on ward type (Intensive Care, Infectious Diseases, Paediatrics, Cancer and Haematology, Emergency and other) cleaning method and frequency of cleaning were analysed against infection risk

Statistical analysis:

To determine the association, we adopted a survival analysis technique with time varying covariates. The data was arranged in "counting process format" [3], where for each participant there were same number of records as the number of days of follow up. The outcome and study factor (mask cleaning) were assessed daily as binary variables. We generated Kaplan - Meier survival plots to compare the survival experience by mask cleaning practices and fitted the Cox proportional hazards model to estimate the hazards ratios. We also examined infection rate by type of ward using a Pearson's chi-squared test.

Sub-study of contamination of masks: A total of 117 masks samples were collected – 102 from subjects with clinical respiratory illness in participating hospitals; and 15 from a sub-study as described below. All participants at this time also had a swab of their nose and throat collected for lab testing.

For the sub-study of mask contamination, 15 mask samples were collected from two purposively selected wards in Thanh Nhan General Hospital (a city hospital in Hanoi) between 28 March -8 April 2011. Intervention arms were cluster randomized by ward, so staff on each ward used the same type of mask. Nine participants were randomly selected from the cloth mask group (Intensive Care Unit), and six were randomly selected from medical masks group (Pediatric ward). In the cloth mask group, three participants were given five clean cloth mask per person, along with daily washing instructions, and masks were collected after one month. Three participants were requested to provide their cloth masks for testing after use. The remaining three participants were asked to provide their cloth masks which they used for previous four weeks.

In the medical mask group, three randomly selected participants were given one new medical mask per person in morning by the study team and the masks were collected the

same day after one hour of use. The remaining three participants were given one new medical mask per person in morning and by the survey team and the masks were collected after four hours of use.

Mask testing

The mask testing method is shown in Figure 2. Mask samples were collected after use by HCWs. They were folded in double vertically. They were cut at the central part of the mask into 3 x 5 cm rectangles and separated into different layers - three layers for medical masks and two with cloth masks. Masks were cut and placed in a tube (as described in figure 2) and sent to the lab for testing as described in the original study. [2] Each layer was put into different VTM tube and labelled, using a sterilized bamboo stick to push the layer deep into the media. Testing was performed using both normal and concentrated samples. A multiplex respiratory viral RT-PCR test was done for SVA/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), as described in the original trial. [2]

Figure 2: Mask testing

(Figure 2 here)

Ethics approval for the study was granted by National Institute for Hygiene and Epidemiology (NIHE), Vietnam (approval number 05 IRB) and the Human Research Ethics Committee of the University of New South Wales (UNSW), Australia, (HREC approval number 10306).

Patient and Public Involvement

There was no patient or public involvement.

Results

There were 607 subjects with 9253 person-days of follow up who wore a cloth mask during the study. The highest rates of infection among cloth mask users was in the emergency (12%) and Intensive Care Units (10%). There was a similar distribution of participants between the ward types, in the medical mask and cloth mask arms with 138 medical mask users and 180 cloth mask users in ICU; and 163 medical mask users and 143 cloth mask users in the Emergency Department.

We also compared the infection rate of ICU and ED combined with other wards (paediatrics, infectious diseases, internal medicine, other). In the ICU and ED wards there were 36 (11.2%) infections among 323 cloth mask users and in all other wards there were 16 (5.6%) infections among 284 subjects. This difference was statistically significant (P=0.015). There was no significant difference in infection rate between any ward types for medical masks, which was 5.33% overall (range 3.8-6.9%). In ICU, medical masks had 8/138 infections (5.8%) and in emergency 7/163 (4.2%).

The most common method of cleaning was self-washing by hand (77%,) followed by hospital laundry (13%). Some HCW used both methods at different times. Over 90% (8396/9253 person-day observations) reported washing their mask daily. Only 15 subjects reported cleaning their mask <50% of the time over the four weeks of follow up. There were 7091/9253 person-days of self-washing reported, and 1177/9253 person-days of hospital laundry washing. Rates of infection among HCW who self-washed their cloth masks by hand and who used the hospital laundry were 2/100 person days (110/5417 person days) and 0.85 per 100 person days (9/1052 person days) respectively. The rate of infection among HCW who wore a medical mask was 0.85 per 100 person days (139/16,284 person days). The risk of infection just over double for HCW who self-washed their cloth masks by hand compared to using the hospital laundry. The hazards ratio of infection for self-washing was 2.04 (95% CI: 1.03-4.00); p=0.04.

There was no significant difference in infection rate between cloth masks washed in the hospital laundry and medical masks (p=0.5). Figure 3 shows that hospital laundry was superior to self-washing in the survival analysis.

Figure 3. Survival analysis of infection by mask washing location (hospital laundry vs self-washing)

(Figure 3 here)

Mask testing results:

In standard testing, 2% (2/117) of masks samples were positive for virus. Rhinoviruses were isolated from the internal layer and external layers respectively of one medical mask sample each.

In concentrated testing, around 4% (4/117 mask samples were positive, two medical masks and two cloth masks. Rhinoviruses were isolated from internal and external layers of two medical masks and only the internal layer of two cloth mask samples. Paired nose and throat swabs of these same subjects were also positive for Rhinoviruses.

Discussion

HCW whose cloth masks were laundered in the hospital laundry were protected as well as those who wore disposable medical masks, highlighting that a cloth mask can be protective if well washed. However, HCW who self-washed their masks in the hospital by hand had double the risk of infection than those who used the hospital laundry. Self-washing was by far the commonest method of washing (77% of cloth mask users), which could explain the poor performance of cloth masks in the intention to treat analysis in the original RCT, and reiterates the importance of daily washing of these products. [2]

While the majority of participants reported washing their mask daily, it appears that the hand washing was not adequate or that a proportion who reported daily washing did not actually do so every day. Hand washing in the hospital is usually done in the available wash basins, some of which do not have hot water, which may reduce the effectiveness of washing. This may have been an important factor in the poor performance of cloth masks in those who self-washed. The WHO recommends machine washing with warm water at 60−90°C and laundry detergent.[4]

We showed that both cloth and medical mask can become contaminated. There was no difference in contamination between medical and cloth masks - however, the sample size was very small. The majority of participants in the trial who had a confirmed viral infection had rhinovirus, and this was the only virus identified on mask samples, on both the inner and outer layers in medical masks and on the inner layer of cloth masks. More research is needed to quantify longitudinal contamination of unwashed cloth masks over time and by usage frequency.

On a practical level, the difference in clinical outcomes in the trial may be explained by the fact the medical mask users received a new mask daily, whereas cloth mask users received 5 masks to wash and reuse. The principle of a re-usable cloth mask is that a user has at least two masks so they can be washed daily to ensure a clean mask each day. However, for medical mask users the simple fact of being provided a clean mask daily may be a key factor in reducing risk of infection, whereas busy health workers may forget to wash a cloth mask daily or wash them inadequately, as it is an added burden on their workload. We do not recommend cloth masks for health workers, but if used as a last resort where no other options are available, health facilities should provide clean masks daily to health workers, and also launder them in the hospital laundry. Placing the burden of cleaning on a HCW may increase the risk of unsafe use and infection. If laundry facilities are not available, using steam sterilisation may be a safer alternative to hand washing.[5]

A meta-analysis of mask use for SARS, SARS-CoV-2 and MERS CoV showed that masks were 85% protective, and that a 12-layered cloth mask is as protective as a medical mask. [6] There are no data on other combinations of layers, except that single layered masks are not protective. [6] Our original

RCT suggests that even a two-layered cotton and cotton blend mask is not protective. [2] However, this does not preclude more protective cloth mask designs, especially if washing is done daily according to WHO recommendations. [4]

Cotton is not a suitable fabric for the outer layer of a mask, as it is absorbent, can become damp and pose a risk of contamination not washed daily or if washed inadequately.[7] The principles of a safer cloth mask would include at least three layers, water-resistant fabric for the outer layer, fine weave, high thread count, fit around the face and ties instead of ear loops, the latter which have been reported to reduce fit. [8] They should also be washed daily in soap and water, and the design should allow frequent washing without compromising the design features. The WHO changed it's recommendation on community mask use in June 2020 and provided guidance on optimal design of a cloth mask. [9]

The distribution of trial participants between ward types was similar, so this did not contribute to the poor performance of cloth masks. Further, infection rates were not significantly different by ward type for medical masks – only for cloth masks, which had a significantly higher infection risk for ICU and emergency wards. ICU and Emergency wards are recognised as high-risk, high transmission settings, with documented aerosolised viruses such as influenza and COVID-19,[10,11,12] so a cloth mask may not be adequate in these wards.

We conclude that two-layered cotton masks as used in the original RCT are not a safe option for HCW if they are held responsible for their own washing, especially in ICU or Emergency wards. A respirator provides 96% protection for health workers, compared to 67% with a medical mask, [6] and should be the standard for health workers treating COVID-19 patients. [13] This does not preclude the use of well-designed cloth masks in the community, as there has been unprecedented efforts in development and research into novel re-usable cloth masks during the pandemic. [6] However, countries should take responsibility for scaling up manufacturing of medical masks and respirators for health workers, instead of forcing them to work in sub-optimal personal protective equipment.[14]

In summary, the poor performance of cloth masks in our RCT may reflect inadequate washing. Daily washing of cloth masks at the recommended temperature of 60-90°C in whatever setting they are used, including the community, is essential for safety. Reports of self-washing may have over-estimated the frequency of washing and there may have been variability in the quality of washing. The additional burden of being responsible for cleaning of a mask for busy HCWs in the midst of a pandemic may compromise safety, if workers forget to wash the mask. Removing this responsibility from HCWs and minimising the burden on them for their own protection, by providing daily clean masks is the safest option in hospitals. If cloth masks are used, cleaning in the hospital laundry and daily provision of clean masks is safer than self-washing. The data from our RCT are specific to a two-layered cotton mask and cannot be generalised to all cloth masks. The trial was conducted in 2011,

at a time when cloth masks were not well researched and not even mentioned in PPE guidelines despite being used widely in Asia. As a result of the COVID-19 pandemic, unprecedented research on cloth mask design is being conducted, which will result in better designs. Well-designed cloth masks may provide protection in the community, [5,8] but design is only one aspect of the safety and effectiveness of a cloth mask. Daily washing as recommended by the WHO is also necessary. This study shows that a well-washed cloth mask is as protective as a medical mask.

Author contributions: CR MacIntyre conceived, designed study, developed data analysis plan, wrote the manuscript. B Rahman and AA Chughtai analysed the data and wrote and reviewed the manuscript. TC Dung reviewed original data and reviewed and wrote the manuscript. H Seale reviewed the analysis and wrote the manuscript.

Competing interests: TC Dung works for the Vietnam Ministry of Health. There are no other competing interests.

Data sharing: The data are not available for sharing under the conditions of ethics approval from Vietnam.

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Figure 1: Cloth mask used in the study and hanging of washed cloth masks to dry.

Figure 2: Mask testing

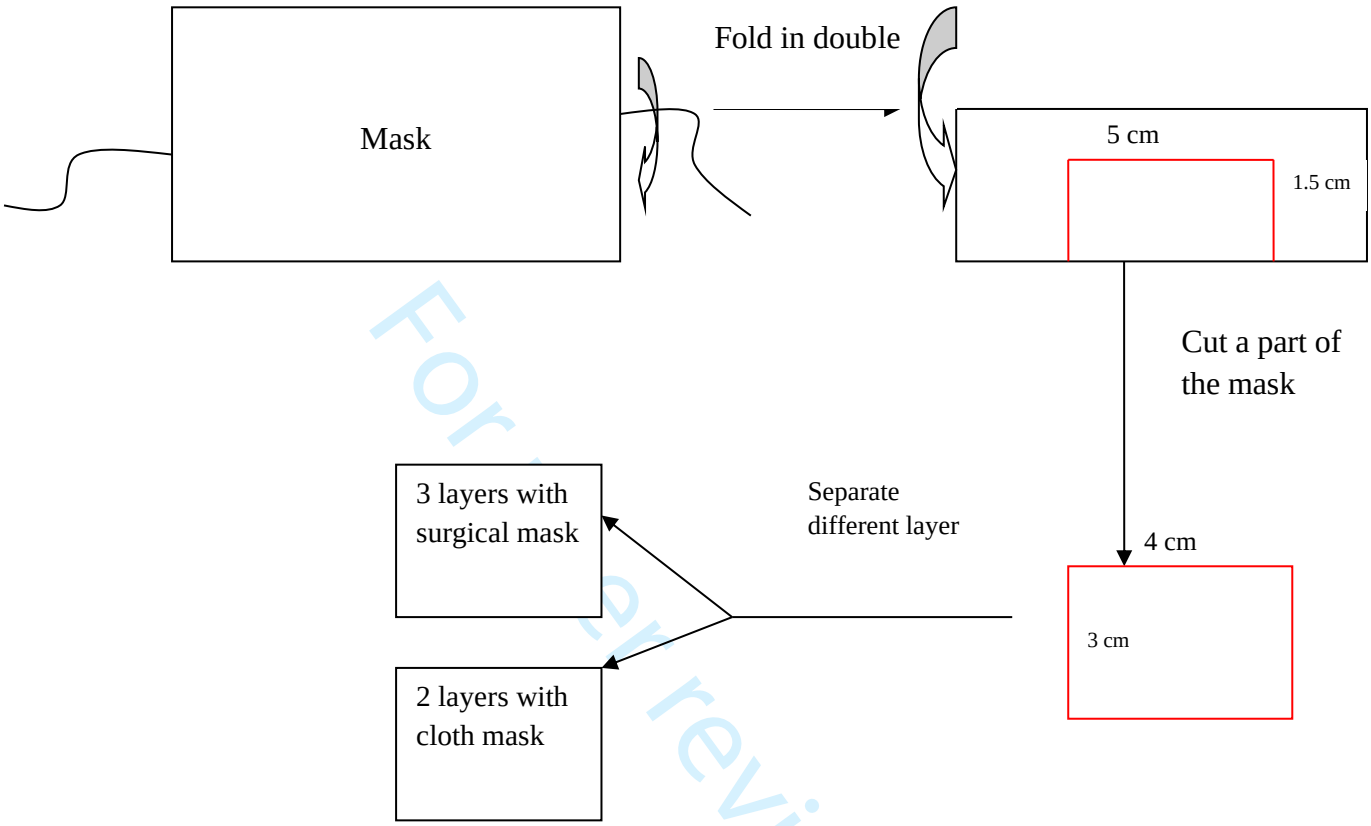

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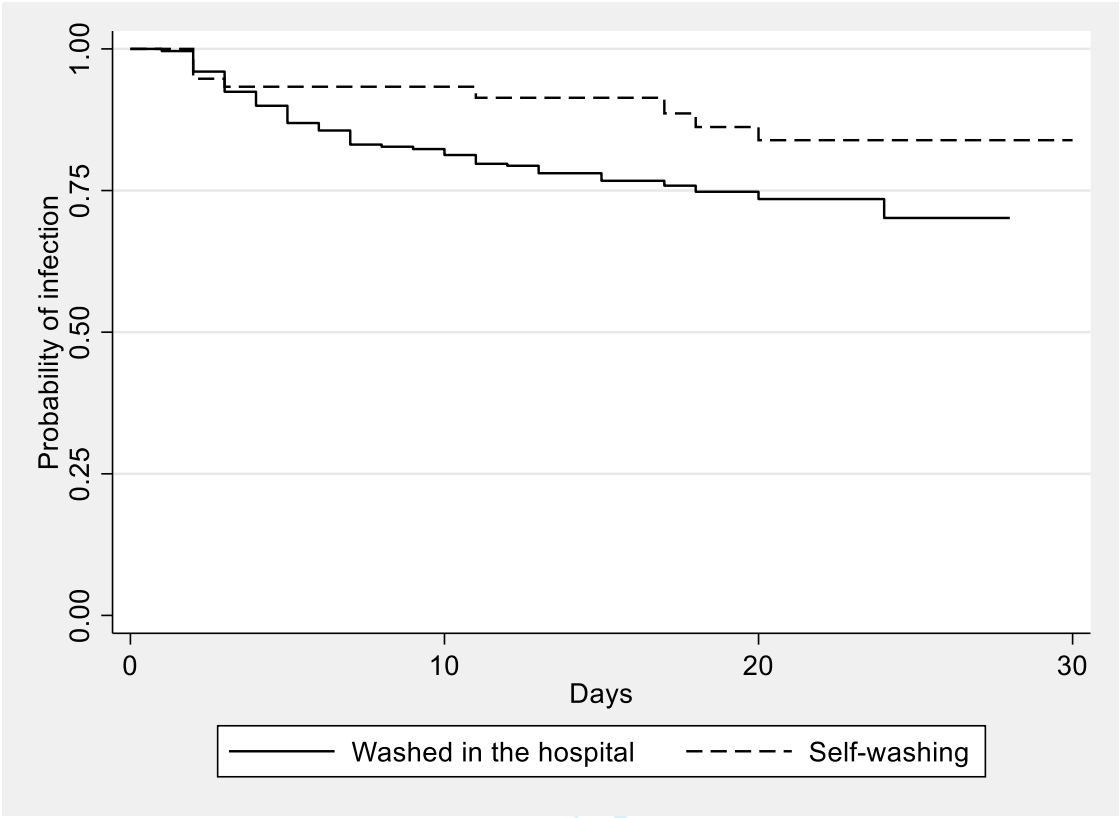
Figure 3. Survival analysis of infection by mask washing location (hospital laundry vs self-washing)



Research checklist

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