

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	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
<b>AUTHORS</b>	MacIntyre, C Raina; Dung, Tham; Chughtai, Abrar; Seale, Holly; Rahman, Bayzidur

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Trisha Greenhalgh University of Oxford, UK
<b>REVIEW RETURNED</b>	08-Jul-2020

<b>GENERAL COMMENTS</b>	<p>This is a reanalysis of data collected some years ago. That's fine, but because the topic is so important and politically contentious, this MUST be made clear in the abstract. The study was nothing to do with COVID-19 despite the mention of COVID-19 in the abstract! It's an interesting side-study of what happened nearly 10 years ago in Vietnam when different contextual factors were at play. At the time, HCWs were issued with cloth masks. This was rather parochial I think - I have never seen this in any hospital or clinic in any country I've worked. Also since the RCT showed they were ineffective, I suspect even fewer healthcare organisations even in LMICs use them now.</p> <p>Results need to be expressed as absolute not relative risks. I can't work out the most basic data for this study (maybe its me - I'm tired - but readers will be tired too!). What % of masks were contaminated and what were they contaminated with?</p> <p>I have no idea for example whether these HCWs had washing machines at home! "Self washing" is not a clear intervention. Unless we know HOW they were "self washed" we can conclude precisely nothing about the efficacy of washing outside the hospital.</p> <p>I'm REALLY worried that this study will be misinterpreted as evidence that "cloth masks are dangerous in the prevention of COVID-19 unless professionally laundered". The study did not test anything remotely like this hypothesis!</p> <p>The other issue of course is the question of source control. It's a GOOD thing that if someone has a cold, their cloth face covering is full of rhinovirus. It means less rhinovirus was sneezed over the rest of us.</p> <p>In sum, I'm keen on more mask research but I fear this novel take on an old study will generate more heat than light in an already confused field.</p>
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<b>REVIEWER</b>	Ji-Ming Chen College of Veterinary Medicine, Qingdao Agricultural University, China
<b>REVIEW RETURNED</b>	09-Jul-2020

<b>GENERAL COMMENTS</b>	<p>Because masks are of worldwide concern this year for the COVID-19 pandemic, this study is of significance for publication. However, some critical issues pertaining to use and decontamination of masks should be clarified in the manuscript.</p> <ol style="list-style-type: none"> <li>1. it should be clarified that the poor performance of cloth masks is due to the fact the materials of cloth and cotton are not suitable for blocking viruses, rather than structure design. Wearing the 12-layer cloth masks is not realistic.</li> <li>2. it should be clarified that previous studies showed that wearing cloth masks is useless for providing protection against viruses, and even increases the infection risk, and this study showed incorrect cleaning/decontamination of masks can further increases the risk or is one of the risk sources.</li> <li>3. it should be clarified that for most types of masks, cloth or medical, washing is not a good method for decontamination, steaming on hot water is a much more simple and effective approach for mask decontamination (<a href="https://doi.org/10.1002/jmv.25921">https://doi.org/10.1002/jmv.25921</a>).</li> <li>4. The authors should revise this manuscript, particularly the abstract, introduction, conclusions, and discussion, as per the comments given above.</li> <li>5. If possible, the authors should add more newly published original researches on the effect and decontamination of masks for COVID-19 as the references.</li> <li>6. the title may be better to be revised as "Relationship of cloth mask washing and respiratory infection risk in health workers."</li> </ol>
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<b>REVIEWER</b>	harry Peled St Jude Medical Center Fullrton/Providence USA
<b>REVIEW RETURNED</b>	12-Jul-2020

<b>GENERAL COMMENTS</b>	<p>I think this is a very important manuscript that needs to be published as soon as possible. Many have distorted the initial article into a claim that masks provide no benefit. It is important for the record to be corrected. I would consider making the following small modifications and add some references:</p> <p>page 7 line 26 I believe should be "disinfect" rather than sterilize".</p> <p>page 11 line 48 perhaps better define "hospital laundry" and how it may differ from home. Recommendation per WHO is " Machine washing with warm water at 60–90°C and laundry detergent is recommended" <a href="https://www.who.int/publications/i/item/water-sanitation-hygiene-and-waste-management-for-covid-19">https://www.who.int/publications/i/item/water-sanitation-hygiene-and-waste-management-for-covid-19</a>.. Most use minimum 60 and often 70, which may be more than home and certainly more than hand wash.</p> <p>page 14 line 10 perhaps reference for ties better than loops</p>
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## VERSION 1 – AUTHOR RESPONSE

### Reviewer 1

Results need to be expressed as absolute not relative risks. I can't work out the most basic data for this study (maybe its me - I'm tired - but readers will be tired too!). What % of masks were contaminated and what were they contaminated with?

**Response:** *The contamination data were presented in the results under the subheading "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...". We have also added the rates of infection in each group: "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)."*

I have never seen this (cloth masks) in any hospital or clinic in any country I've worked. Also since the RCT showed they were ineffective, I suspect even fewer healthcare organisations even in LMICs use them now.

**Response:** *Author Dung from the Vietnam Ministry of Health confirms that cloth masks are used widely by health workers in Vietnamese hospitals currently. However, the design is improved (3 layers) and they are used mainly in smaller, provincial hospitals.*

I have no idea for example whether these HCWs had washing machines at home! "Self washing" is not a clear intervention. Unless we know HOW they were "self washed" we can conclude precisely nothing about the efficacy of washing outside the hospital.

**Response:** *The washing method was self-reported by the HCW. They hand-washed the masks themselves in the hospital with soap and water, and hung them to dry, as is the usual practice in Vietnam. Some had access to the hospital laundry and had the masks washed in an automatic washing machine. Hand washing is the usual means of washing of masks in hospitals in Vietnam. This has been clarified in the methods – see page 5, paragraph 1 of the methods. "They could hand-wash the masks themselves in the hospital with soap and water and hang them out to dry, or they could get the masks laundered in the hospital laundry in an automatic washing machine, if available in their hospital. They were provided written instructions on washing the mask themselves and self-reported their washing practices daily." We have also added a photograph of washed masks hanging to dry.*

### Reviewer 2

1. it should be clarified that the poor performance of cloth masks is due to the fact the materials of cloth and cotton are not suitable for blocking viruses, rather than structure design. Wearing the 12-layer cloth masks is not realistic.

**Response:** The analysis suggests poor washing is the main factor which explains the poor performance of cloth masks. However, we agree that material and design are also important. We have revised the discussion (page 13, para 2) to discuss the unsuitability of cotton for the outer layer of a mask. "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.<sup>7</sup>”

2. it should be clarified that previous studies showed that wearing cloth masks is useless for providing protection against viruses, and even increases the infection risk, and this study showed incorrect cleaning/decontamination of masks can further increase the risk or is one of the risk sources.

**Response:** *There are no previous RCTs on cloth masks. As far as we are aware, this is the only one. We have added a reference to a review of the evidence around cloth masks (reference 6,7).*

3. it should be clarified that for most types of masks, cloth or medical, washing is not a good method for decontamination, steaming on hot water is a much more simple and effective approach for mask decontamination (<https://doi.org/10.1002/jmv.25921>).

**Response:** *Disposable masks such as medical masks or respirators are made of polypropylene, and the structure will degrade with washing. Therefore other methods such as steam and H2O2 vapour have been used for disinfection. However, these methods may not get rid of particulate matter caught in the facepiece. Cloth masks can withstand washing, and proper washing in hot water and soap will remove particulate matter and is preferable. However, if washing is not possible or only hand-washing is available, we agree steam would be a good idea. We have revised the paper as follows (page 12, last paragraph) “If laundry facilities are not available, using steam sterilisation may be a safer alternative to hand washing.<sup>5</sup>”*

4. The authors should revise this manuscript, particularly the abstract, introduction, conclusions, and discussion, as per the comments given above.

**Response:** *the manuscript has been revised throughout.*

5. If possible, the authors should add more newly published original researches on the effect and decontamination of masks for COVID-19 as the references.

**Response:** *we have cited the suggested paper on steam sterilisation, as well as a new review on use of cloth masks (references 5 and 7).*

6. the title may be better to be revised as "Relationship of cloth mask washing and respiratory infection risk in health workers."

**Response:** *We have changed the title*

Reviewer 3

I would consider making the following small modifications and add some references: page 7 line 26 I believe should be "disinfect" rather than sterilize".

**Response:** *This has been changed*

page 11 line 48 perhaps better define "hospital laundry" and how it may differ from home. Recommendation per WHO is "Machine washing with warm water at 60–90°C and laundry detergent is recommended" <https://www.who.int/publications/i/item/water-sanitation-hygiene-and-waste-management-for-covid-19>. Most use minimum 60 and often 70, which may be more than home and certainly more than hand wash.

page 14 line 10 perhaps reference for ties better than loops

**Response:** *more detail on the washing methods has been added to the methods (page 5, para 1) The WHO washing recommendations have been added to the revised discussion (page 12, para 2), and a reference for ear loops added.*

**VERSION 2 – REVIEW**

<b>REVIEWER</b>	Trish Greenhalgh University of Oxford, UK
<b>REVIEW RETURNED</b>	21-Jul-2020

<b>GENERAL COMMENTS</b>	<p>The authors have extensively revised this paper in response to comments from editors and three reviewers (who had different views). It now comes across as a much more parochial study. If we weren't in the midst of the COVID-19 pandemic I'd be reasonably happy, but I am EXTREMELY worried that this study will be misinterpreted by the large number of people who already hold the view that "cloth masks don't work". I know that this isn't what the paper says, but masks are one of the most emotive issues in science right now! As an example, an Oxford professor of evidence-based medicine tweeted the link to the original RCT from MacIntyre et al the other day to support his [implicit] claim that "cloth masks don't work". He seemed to have no understanding of source control or the different contexts of healthcare and community. I have been sent that same RCT five times (unsolicited) by anti-mask activists. So one old RCT in Vietnam is already doing a huge amount of ideological heavy lifting.</p> <p>I'm not saying we should suppress science, but equally, it would be irresponsible not to consider the terrible unintended consequences which could ensue if this paper comes out right now. I predict that the press will bill it as a "new BMJ paper shows that cloth masks don't work".</p> <p>What to do about this? FIRST, the finding that cloth masks were as good as medical masks IF WASHED IN THE LAUNDRY must be included in the abstract and reflected in the title. ("There was no significant difference in infection rate between cloth masks washed in the hospital laundry and medical masks (p=0.5)."). This isn't a finding about cloth masks, it's a finding about badly-laundered cloth masks. SECOND, the parochial nature of the study (it relates to a time past in a single country where particularly flaky-looking cloth masks were provided to workers who washed them under the tap) must be emphasised. THIRD, the abstract must include explicit statement that the findings have no direct bearing on the current policies in many countries to recommend or mandate cloth masks IN THE COMMUNITY for the prevention of a different disease.</p> <p>I would also suggest that the paper be published (if at all) with an accompanying commentary which draws out the NON-APPLICABILITY of the findings to the current crisis. I remain troubled that the COVID-19 crisis has prompted a secondary analysis of old data, yet the study actually has almost no bearing on this crisis (because in most countries this kind of cloth mask isn't used in hospitals as PPE; it's directly against WHO guidance on PPE; and cloth masks as source control is a completely different question).</p> <p>However, I'm not saying the study is worthless. MacIntyre and her team have done some leading work on masks and infection control, and I don't want to come across as disrespecting that work. I'm just worried - more worried than I've ever been in 30 years of reviewing - that deaths could result from publishing this paper in the current context (because it will be will be seized upon, misinterpreted and used to support positions which the authors themselves would</p>
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	challenge).
<b>REVIEWER</b>	Ji-Ming Chen Qingdao Agricultural Univeristy, China
<b>REVIEW RETURNED</b>	26-Jul-2020
<b>GENERAL COMMENTS</b>	I am satisfied with this revision.

## VERSION 2 – AUTHOR RESPONSE

### Response

“What to do about this? FIRST, the finding that cloth masks were as good as medical masks IF WASHED IN THE LAUNDRY must be included in the abstract and reflected in the title. (“There was no significant difference in infection rate between cloth masks washed in the hospital laundry and medical masks ( $p=0.5$ ).”). This isn't a finding about cloth masks, it's a finding about badly-laundered cloth masks.

**Response:** *The result “There was no significant difference in infection rate between cloth masks washed in the hospital laundry and medical masks ( $p=0.5$ ).” was already in the abstract but did not have the  $p$  value – we have added the  $p$  value. We also revised the conclusion of the abstract to specify that the results pertain to seasonal respiratory viruses and added the closing statement of “A well washed cloth mask can be as protective as a medical mask.”*

*We have also changed the title to “**Adequacy of washing of cloth masks determines the level of protection in health workers**”*

SECOND, the parochial nature of the study (it relates to a time past in a single country where particularly flaky-looking cloth masks were provided to workers who washed them under the tap) must be emphasised.

**Response:** *We note that many health workers in low income countries wear masks like the ones in the study and do not have access to washing facilities. Many health facilities in rural and remote areas of low-income countries do not have laundry facilities, and some which we have visited do not even have running water. We do not believe the fact that study was done in 2011 makes it irrelevant. The transmission of most respiratory viruses is similar, and at a time when no guideline in the world (including WHO) even mentioned cloth masks, we were the only researchers to believe this was an important research question. We reported the findings of the original RCT honestly, and have been*

*equally distressed about it being used to imply all cloth masks are ineffective. This was the reason for doing this post-hoc analysis of washing.*

*The previous revision added an explanation about washing under the tap in the methods, and a statement in the discussion “ 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.<sup>4</sup> “ We have revised it again to further emphasise the inadequacy of this method. See discussion, para 2.*

THIRD, the abstract must include explicit statement that the findings have no direct bearing on the current policies in many countries to recommend or mandate cloth masks IN THE COMMUNITY for the prevention of a different disease.

I would also suggest that the paper be published (if at all) with an accompanying commentary which draws out the NON-APPLICABILITY of the findings to the current crisis. I remain troubled that the COVID-19 crisis has prompted a secondary analysis of old data, yet the study actually has almost no bearing on this crisis (because in most countries this kind of cloth mask isn't used in hospitals as PPE; it's directly against WHO guidance on PPE; and cloth masks as source control is a completely different question).

**Response:** *The secondary analysis was done to provide further understanding of why cloth masks performed poorly in the original trial, which we, as advocates for well-designed cloth masks, felt was critical. We hypothesised that inadequate washing may explain the results, and set out to test that hypothesis. The findings actually provide reassurance about cloth mask use, and highlight the importance of adequate washing. We believe the revised paper makes this clearer.*

*Whilst SARS-COV-2 is a new virus, it is a respiratory virus and is transmitted in a similar way to the respiratory viruses studied. The issue of inadequate washing applies to cloth masks universally, as washing is a method of disinfection against any microbial contamination (viral or bacterial), and disinfection is a key, universal concept in infection control. However, please note that we do not make any statements about the results being directly applicable to the pandemic.*

*We changed the opening of the discussion to emphasise that a well-washed cloth mask is as protective as a surgical mask: “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.” (opening line of discussion)*

*We also added a line to the concluding paragraph: “This study shows that a well-washed cloth mask is as protective as a medical mask,” to ensure there is no misinterpretation of the results.*

*We believe the change in title and revision of the paper ensure that the main message of the study, that a well washed cloth mask is as good as a surgical mask, is conveyed. We believe this will be able to counteract arguments against cloth masks which cite the 2015 RCT.*