

# Facemasks and similar barriers to prevent respiratory illness such as COVID-19: A rapid systematic review

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## ABSTRACT

The current pandemic of COVID-19 has led to conflicting opinions on whether wearing facemasks outside of health care facilities protects against the infection. To better understand the value of wearing facemasks we undertook a rapid systematic review of existing scientific evidence about development of respiratory illness, linked to use of facemasks in community settings.

**Methods:** We included all study designs. There were 31 eligible studies (including 12 RCTs). Narrative synthesis and random-effects meta-analysis of attack rates for primary and secondary prevention in 28 studies were performed. Results were reported by design, setting and type of face barrier in primary prevention, and by who wore the facemask (index patient or well contacts) in secondary prevention trials. The preferred outcome was influenza-like illness (ILI) but similar outcomes were pooled with ILI when ILI was unavailable. GRADE quality assessment was based on RCTs with support from observational studies.

**Results:** Where specific information was available, most studies reported about use of medical grade (surgical paper masks). In 3 RCTs, wearing a facemask may very slightly reduce the odds of developing ILI/respiratory symptoms, by around 6% (OR 0.94, 95% CI 0.75 to 1.19,  $I^2$  29%, low-certainty evidence). Greater effectiveness was suggested by observational studies. When both house-mates and an infected household member wore facemasks the odds of further household members becoming ill may be modestly reduced by around 19% (OR 0.81, 95%CI 0.48 to 1.37,  $I^2$  45%, 5 RCTs, low certainty evidence). The protective effect was very small if only the well person (OR 0.93, 95% CI 0.68 to 1.28,  $I^2$  11%, 2 RCTs, low uncertainty evidence) or the infected person wore the facemask (very low certainty evidence).

**Discussion:** Based on the RCTs we would conclude that wearing facemasks can be very slightly protective against primary infection from casual community contact, and modestly protective against household infections when both infected and uninfected members wear facemasks. However, the RCTs often suffered from poor compliance and controls using facemasks. Across observational studies the evidence in favour of wearing facemasks was stronger. We expect RCTs to under-estimate the protective effect and observational studies to exaggerate it. The evidence is not sufficiently strong to support widespread use of facemasks as a protective measure against COVID-19. However, there is enough evidence to support the use of facemasks for short periods of time by particularly vulnerable individuals when in transient higher risk situations. Further high quality trials are needed to assess when wearing a facemask in the community is most likely to be protective.

**Keywords:** Coronavirus, facemask, influenza-like-illness, Hajj, respiratory infection

## INTRODUCTION

On 30 January 2020 the World Health Organisation (WHO) declared a Public Health Emergency of International Concern (PHEIC) in response to the emergence of a novel coronavirus in Wuhan, China (World Health Organization, 2020a). In the declaration, the WHO stated there had been 170 deaths so far linked to the viral disease, later formally designated COVID-19. At the time of writing, more than 4600 deaths have been linked to COVID-19 (John Hopkins University Coronavirus Resource Centre, 2020) (accessed 12<sup>th</sup> March 2020, 9:46am). On the 11<sup>th</sup> March 2020 the WHO started referring to the COVID-19 epidemic as a pandemic (World Health Organization, 2020b). It is not clear when this outbreak will abate.

Amongst other advice widely sought by the public in response to this outbreak, was whether wearing face coverings, especially medical-grade coverings (e.g. masks, goggles or similar) might reduce the risk of catching or transmitting disease (Gajanan, 2020), particularly in domestic and public places. Despite no support by WHO encouraging wearing facemasks in the community, sales of inexpensive facemask products soared following the PHEIC declaration, leading to potential shortages for health care workers (Asgari and Wells, 2020; Carter, 2020; O'Connor, 2020; Taylor, 2020; Wu *et al.*, 2020; US Surgeon General, 2020). Most previous similar systematic reviews investigating the effect of facemask use either focused solely on facemask use in health care settings or restricted study design to randomized controlled trials (RCTs), many of which were of low quality (MacIntyre and Chughtai, 2015).

We responded to this information demand by undertaking a rapid systematic review of the existing scientific evidence with regard to transmission of either respiratory disease or development of respiratory symptoms, especially influenza-like illness (ILI), linked to use of face barriers by non-health professionals and non-inpatients.

## METHODS

### Review question

Can wearing a face barrier (mask, goggles, shield, veil) in community settings prevent transmission of respiratory illness, such as from coronaviruses, rhinoviruses, influenza viruses or tuberculosis? We use the word 'facemask' as an umbrella term for diverse facial coverings that may cover any combination of mouth, nose and/or eyes.

### Search Strategy

Two recent literature reviews (MacIntyre and Chughtai, 2015; Jefferson *et al.*, 2008) were consulted, to find eleven exemplar studies (Aiello *et al.*, 2010; Aiello *et al.*, 2012; Canini *et al.*, 2010; Cowling *et al.*, 2009; Cowling *et al.*, 2008; Larson *et al.*, 2010; Lau *et al.*, 2004a; Lau *et al.*, 2004b; MacIntyre *et al.*, 2009; Simmerman *et al.*, 2011; Suess *et al.*, 2012) that met our eligibility criteria. We designed search strategies that were sensitive enough to find these exemplar studies and similar research, yet specific enough to exclude most irrelevant records. The bibliographic databases Scopus, Embase and Medline were searched with the phrases in Box 1 on 31 Jan 2020. We also recent systematic reviews (Barasheed *et al.*, 2016; Benkouiten *et al.*, 2014; Cowling *et al.*, 2010; MacIntyre and Chughtai, 2015; bin-Reza *et al.*, 2012; Saunders-Hastings *et al.*, 2017; Jefferson *et al.*, 2008) on similar non-pharmaceutical practices for any missing primary studies.

### Assessment of inclusion

Two authors (JB and NJ) independently screened the retrieved titles and abstracts. Disagreements were resolved by discussion with other authors. The inclusion criteria were:

- Original research (not a review, guidelines, discussion, regulations, debate or commentary) published in English since January 1980
- The research needed to describe facemask use that might prevent disease transmission or symptom development among people in the community (rather than prevent transmission to or from clinically trained persons)
- The study described an observed relationship between facemask use and respiratory symptoms or infection by respiratory pathogens: (e.g. influenza, coronavirus, TB).
- There was a comparator or control group (non-barrier users, other barrier users or non-cases)
- Any study design in any country

The full text of each article that passed screening was retrieved and eligibility verified as part of data extraction.

### **BOX 1 Bibliographic database search phrases**

#### **SCOPUS**

TITLE-ABS-KEY (  
(facemask? OR "facemasks?" OR mask? OR goggle? OR faceshield? OR respirator OR respirators)  
AND  
(influenza OR flu OR sars OR tuberculosis OR mers OR coronav\* OR "cov" OR respiratory-  
syndrome OR wuhan OR "ncov")  
)  
AND  
( LIMIT-TO ( SUBJAREA , "MEDI" ) OR LIMIT-TO ( SUBJAREA , "NURS" ) OR LIMIT-TO ( SUBJAREA , "IMMU" ) )

#### **EMBASE & Medline via the OVID portal**

((facemask? or "face-masks?" or mask? or goggle? or face-shield? or respirator or respirators).ti.  
or (facemask? or "face-masks?" or mask? or goggle? or face-shield? or respirator or respirators).ab.  
or (facemask? or "face-masks?" or mask? or goggle? or face-shield? or respirator or respirators).kw.)  
and  
((influenza or flu or sars or tuberculosis or mers or coronav\* or "cov" or respiratory-syndrome or "ncov" or  
wuhan).kw.  
or  
(influenza or flu or sars or tuberculosis or mers or coronav\* or "cov" or respiratory-syndrome or "ncov" or  
wuhan).ti.  
or  
(influenza or flu or sars or tuberculosis or mers or coronav\* or "cov" or respiratory-syndrome or "ncov" or  
wuhan).ab.)

### **Data Extraction & risk of bias assessment**

Qualitative data and numbers of participants who developed respiratory outcomes in relevant study arms were extracted. The preferred specific outcome was ILI, defined as fever  $\geq 38\text{ C}^\circ$  with cough and onset  $\leq 10$  days previous (World Health Organization, 2014). Where a WHO-definition was unavailable, we accepted other similar case definitions (e.g. cold symptoms, acute respiratory infections, clinical cases of influenza or SARS). Where studies reported three arms we extracted data for arms where the only difference was whether a facemask was worn (e.g. hand hygiene vs. hand hygiene + facemasks). Risk of bias in included RCTs was assessed (by LH) using the Cochrane risk of

bias tool (Atkins *et al.*, 2004), and biases and limitations identified by primary study authors of observational studies were noted. We assessed the quality of evidence using the GRADE framework, based on the RCT data and supported or contradicted by observational data (Atkins *et al.*, 2004).

### Synthesis

All characteristics of included studies were tabulated. Numbers of infections and numbers of people at risk in each study arm were input to Review Manager 5.3 (The Cochrane Collaboration, 2014) for meta-analysis by JB, verified by NJ or LH. We calculated pooled odds ratios using Mantel-Haenszel random effects meta-analysis (due to expected high heterogeneity) separately for primary prevention (when no cases were yet been identified) and prevention of secondary cases (when an individual was diagnosed with an infection and the aim was to prevent contacts from getting disease). We subgrouped by study design (RCT, pre/post, cohort, case-control or cross-sectional), and presented these subgroups in forest plots without global pooling to understand consistency of evidence across study designs. We also showed the trend of evidence within settings (subgrouping by setting). For secondary transmission (in RCTs) we subgrouped by who wore the facemask: index case, well contacts of the index case, or both. Outcomes after wearing faceveils were also presented where evidence was available.

A prospective patient (a mature adult living with many chronic health conditions including reduced lung function) commented on the draft manuscript and how the results could be made meaningful to laypeople.

## RESULTS

Altogether, 979 titles and abstracts were retrieved from Scopus, and 1443 from Embase and Medline combined. Our search located all 11 exemplar articles. Combining and deduplicating left 1725 articles. Of these 233 were not written in English and 81 were published before 1980, so were removed. This left 1458 titles and abstracts to screen, of which 46 were selected to be collected in full text. Full text review identified 26 eligible studies. Checking previous systematic reviews on protective effects of facemask use in the community identified a further five studies (all in the Hajj setting). Of the 31 included studies, 12 were cluster-RCTs, three were cohort studies, five were case-control and ten were cross-sectional, of which 28 reported data suitable for meta-analysis. Settings included schools, university residences, visits to health care providers, family households, the Hajj mass gathering, and non-specific community settings. Most studies reported on influenza-like illness (ILI) as an outcome ( $n=19$ ), but fever with respiratory symptoms, upper respiratory tract infection, lab-confirmed or clinical influenza, toxic pneumonitis, common colds and other respiratory symptoms were used when ILI was unavailable. All mass gathering studies were associated with the Hajj pilgrimage. Table S1 lists the characteristics of the included studies.

### Prevention of primary infection

GRADE assessment suggested that wearing a facemask may very slightly reduce the odds of developing ILI/respiratory symptoms, by around 6% (OR 0.94, 95% CI 0.75 to 1.19,  $I^2$  29%, low-certainty evidence, downgraded once each for risk of bias and imprecision). Figure 1 shows grouping of results by study design. Pooled data are presented to calculate a single odds ratio to compare and contrast study designs. Risk of biases for RCTs are also presented.

### Prevention of primary infection, subgrouping by study design

The three RCTs which measured the prevention of primary infection, indicated a slight, non-significant, reduction in the odds of primary infection with ILI (OR 0.94, 95%CI 0.75-1.19) (Figure 1, Comparison 1.1; Table 1). Heterogeneity was low ( $I^2$  29%). Protection appeared greater in observational studies. Pre/post facemask wearing by visitors to hospital (Sung *et al* 2012) suggested

a strong, significant reduction in infections among inpatient stem cell recipients (OR 0.30, 95%CI 0.17-0.52) (Figure 1, Comparison 1.2), but this finding is interpreted with caution because of likely changes in hygiene practices in the pre/post periods.

Evidence from the six cohort studies suggested facemasks provided some protection (OR 0.71, 95%CI 0.24-2.05), although, these findings were not significant (Figure 1, Comparison 1.3). Heterogeneity was very high ( $I^2 = 96\%$ ) and the men-only cohort from Choudhry *et al.* (2006) was a noticeable outlier. This set of studies included observational data based on actual facemask wearing habits from one RCT (Alfelali *et al.* (2019)).

Among case-control (OR 0.39, 95%CI 0.18-0.84,  $I^2 77\%$ ) (Figure 1, Comparison 1.4) and cross-sectional studies (OR 0.61, 95%CI 0.45-0.85,  $I^2 95\%$ ) (Figure 1, Comparison 1.5), pooled data suggested that facemask wearing was protective, but effects were highly heterogeneous. Of the cross-sectional studies, Tahir *et al.* (2019) and Zein (2002) were noticeable outliers. Removal of these outliers still indicates facemask wearing as protective, although no longer significant, and heterogeneity falls slightly (OR 0.89, 95%CI 0.78-1.01,  $I^2 = 64\%$ ) (data not shown).

Two further studies did not provide suitable data for pooling but reported that they had done analysis supporting their conclusions to comment narratively that facemasks were not protective (Hashim *et al.*, 2016; Gautret *et al.*, 2011). A third study without estimable data, Hashim *et al.* 2016 concluded that respirators were not effective protection against ILI.

#### **Prevention of primary infection by exposure setting**

Figure 2 groups results by exposure setting. Pooling of data from different study designs is not appropriate to calculate a single odds ratio statistic. Most results favoured facemask wearing.

Facemask wearing was consistently protective (the point-estimates of all included studies favoured facemask wearing) in the general community (2 cohort and 1 case-control; 1 significant protective finding) (Figure 2, Comparison 2.1), schools and universities (2 cluster-randomised RCTs and 2 cross-sectional; 1 significant protective finding) (Figure 2, Comparison 2.2), and for visits to health care clinics (1 pre/post and 2 case-control; 3 significant protective findings) (Figure 2, Comparison 2.3).

The results were less consistent (the point-estimates showed both protective and non-protective relationships) for animal contact (2 cross-sectional studies; 1 significant protective finding) (Figure 2, Comparison 2.4) and mass gatherings (all Hajj pilgrims; 1 cluster-randomised RCT, 2 cohort, 1 case-control and 3 cross-sectional; 3 significant protective findings) (Figure 2, Comparison 2.5).

One case-control study on air travel suggested a protective but non-significant relationship (Figure 2, Comparison 2.6).

#### **Prevention of primary infection among face veil wearers**

Figure 3 shows data from two studies (cross-sectional and cohort) examining case incidence among women who wore face veils often/always while on Hajj pilgrimage. Both studies indicate a protective but non-significant relationship.

#### **Secondary transmission**

GRADE assessment suggested that when both house-mates and an infected household member wore facemasks the odds of further household members becoming ill may be modestly reduced by around 19% (OR 0.81, 95%CI 0.48 to 1.37,  $I^2 45\%$ , 5 RCTs, low certainty evidence, downgraded twice overall for risk of bias, imprecision and inconsistency). The protective effect was very small if only the well people wore facemasks (OR 0.93, 95% CI 0.68 to 1.28,  $I^2 11\%$ , 2 RCTs, low uncertainty

evidence, downgraded twice overall for risk of bias, imprecision and inconsistency) and unclear due to very low certainty evidence when only the infected person wore a facemask (downgraded once for risk of bias, twice for imprecision).

Figure 4 shows results for secondary transmission subdivided by study design and who wore the facemask (index patient, well contacts or both). Presented are pooled data to calculate a single odds ratio and risk of biases for RCTs. Findings from the two RCTs when only infected persons wore a facemask, suggested a very small, non-significant protective effect (OR 0.95, 95%CI 0.53 to 1.72,  $I^2$  0%) (Figure 4, Comparison 4.1; Table 1). The evidence of a very small protective effect was stronger in the 2 RCTs where only well people wore facemasks (OR 0.93, 95%CI 0.68 to 1.28,  $I^2$  11%) (Figure 4, Comparison 4.2; Table 1).

Pooled data from five RCTs where both infected and non-infected household members wore facemasks showed the odds of infection fell modestly and not significantly (OR 0.81, 95%CI 0.48 to 1.37,  $I^2$  45%) (Figure 4, Comparison 4.3, Table 1). Findings from the one case-control study where both infected and non-infected household members wore facemasks indicated a similar relationship (OR 0.45, 95%CI 0.18 to 1.10) (Figure 4, Comparison 4.4).

### **Secondary transmission and commencement of facemask wearing**

Figure 5 shows results for the four secondary transmission RCT studies providing data for attack rates when facemask wearing started < 36 hours after index patient became symptomatic. A single odds ratio statistic and risk of biases for RCTs are presented.

Facemask wearing was not protective in this subgroup analysis (OR 1.36, 0.66-2.79,  $I^2$  0%). Some of the original investigators in these studies undertook logistic regression to adjust their findings for other confounders and found evidence that early facemask wearing (< 36 hours after symptom onset) could be protective, but acknowledged that their models were underpowered.

## **DISCUSSION**

In this study we have undertaken a rapid review to examine whether the use of facemasks impacts on the transmission of respiratory symptoms. Evidence based on RCTs suggests that wearing a facemask may very slightly reduce the odds of primary infection with ILI by around 6% (low-certainty evidence). Observational studies suggested greater effectiveness. In households where infected people were grouped with uninfected people, if both house-mates and the infected household member wore facemasks the odds of further household members becoming ill were reduced by around 19% (low certainty evidence). Where only the uninfected people wore facemasks the effect was very small (reducing the odds of infection by 7%, low certainty evidence). The evidence is similar where only the infected household members wore facemasks (reducing the odds of infection by 5%, very low certainty evidence). However, due to controls wearing facemasks when they shouldn't and poor compliance (intervention participants not wearing facemasks when they should) we expect that RCT evidence under-estimated efficacy. In contrast, we expect observational studies, especially those based on self-reported symptoms, have over-estimated how protective facemask wearing can be because of confounding. Therefore, specific accurate estimates of the degree of protectiveness of facemasks are not feasible from the currently available evidence base.

Facemasks appear to be most effective when worn to prevent primary respiratory illness in relatively low risk situations: community settings where contact may be casual and relatively brief, such as on public transport, in shops, in workplaces and perhaps in university residences or schools with limited shared public spaces. Facemask wearing is probably not protective during mass gatherings, but evidence on use during mass gatherings is inconsistent. All studies focussed on Hajj pilgrimage

which may not be a typical mass gathering event (especially large and prolonged). Facemask wearing within households where infection was already present was modestly effective in the included studies, and this evidence was fairly consistent (low-medium heterogeneity,  $I^2$  from 0% to 45%). Limited effectiveness of primary prevention at Hajj or secondary prevention within households may be because of the multiplicity of transmission pathways within these settings and high level of recurring contact. It may also be due to the late use of facemasks, usually > 24 hours after a household or group member became symptomatic which could be 48 hours after they became infectious (Centers for Disease Control, 2018).

That facemasks might protect wearers has been cast in doubt during the COVID-19 outbreak (eg., Abramson, 2020; Geggel, 2020; Harris, 2020), often supported by the observation that surgical facemasks were designed (originally) to protect patients from the wearers, and that facemasks soon become very moist with condensation from wearer's breath (facilitating microbial ingress and growth). Nevertheless, worn correctly for brief periods, wearing surgical masks have been shown to provide an average 6-fold reduction in exposure to aerosolized influenza virus (Booth *et al.*, 2013), so it is unsurprising that facemask wearing was linked to fewer cases in our synthesis, especially primary observational studies in community settings. With regard to secondary attack rates, whether the ill or the initially well people in a household wore facemasks (or both, or neither wore facemasks) did not seem to matter: attack rates were similar in household-setting RCTs. These details suggest that other factors (not who wore the facemask, but rather duration and type of contact) also matter greatly to disease transmission. Many barriers exist that can make it difficult for individuals to wear facemasks correctly for hours over a multi-day period, including perceived breathing impairment and other discomforts (Sim *et al.*, 2014; Suess *et al.*, 2011). Facemasks are perceived to or genuinely do interfere with ordinary physical activities such as heavy exertion, sleep, oral hygiene and eating. Facemasks can be uncomfortable, hot, cause skin rashes or simply feel anti-social (Al Badri, 2017; Donovan *et al.*, 2007).

Previous systematic literature reviews on the efficacy of using facemasks in community settings are often combined with other personal protection measures (Saunders-Hastings *et al.*, 2017; Jefferson *et al.*, 2008; Wong *et al.*, 2014) or mixed health care workers with non-health care workers (Jefferson *et al.*, 2008; bin-Reza *et al.*, 2012; Wang *et al.*, 2015). Those that have looked specifically at community use have focused only on RCTs (Cowling *et al.*, 2010; MacIntyre and Chughtai, 2015). Overall, the reviews had mixed conclusions about community settings: that facemasks were highly effective (Jefferson *et al.*, 2008), definitely effective (Barasheed *et al.*, 2016; bin-Reza *et al.*, 2012), may be effective for protection (Benkouiten *et al.*, 2014; Cowling *et al.*, 2010; MacIntyre and Chughtai, 2015) or had a not statistically significant protective effect (Saunders-Hastings *et al.*, 2017). There was near consensus that the evidence base was inadequate (Cowling *et al.*, 2010; bin-Reza *et al.*, 2012; Barasheed *et al.*, 2016; MacIntyre and Chughtai, 2015; Saunders-Hastings *et al.*, 2017; Benkouiten *et al.*, 2014).

RCTs may not be the best quality evidence to evaluate a population behaviour like facemask use that is likely to be imperfectly implemented. Many of the included RCTs reported that participants did not follow instructions (Alfelali *et al.*, 2019; Barasheed *et al.*, 2016; Cowling *et al.*, 2009; Cowling *et al.*, 2008; MacIntyre *et al.*, 2009; MacIntyre *et al.*, 2016). In these RCTs, large proportions of controls wore facemasks during the monitoring period (Simmerman *et al.*, 2011; MacIntyre *et al.*, 2016; Cowling *et al.*, 2008), while intervention participants did not wear facemasks the majority of the time (MacIntyre *et al.*, 2009; MacIntyre *et al.*, 2016; Larson *et al.*, 2010; Cowling *et al.*, 2009; Cowling *et al.*, 2008). Compared to RCTs, observational data (cohort and case-control studies) may give superior quality evidence for efficacy of facemask wearing to avoid ILI, given they are trying to relate actual behaviour to outcomes. Of course, observational data are subject to recall bias and other confounding factors that RCTs may obviate. For expediency, we have not undertaken formal quality



assessment on the diverse observational studies included in this review: we expect that the observational evidence would be found to have many potential sources of bias that RCT designs are intended to avoid. We found original study authors gave many informative comments on their own study limitations (Supplemental Table 1). We argue that there is merit in combining study types to generate a full view of existing evidence.

A difficulty with previous reviews and also in our own review, is the mix of facial barrier used. All of the RCTs included in our review provided specific facemasks (usually surgical grade, rarely P2 or equivalent grade respirator) with instructions how to wear the facemask, as well as told users the frequency facemasks should be changed and how to hygienically dispose of used facemasks. Information was not reported about the types of facemasks that (contrary to protocol) some controls in RCTs used. Only a few of the observational studies collected specific information about what type of face covering was used.

We assume that where not explicitly stated, most facemasks worn were surgical grade in the included observational studies. This view concurs with survey of facemasks visible in recent street scene photography of Hong Kong, Korean, Chinese and Japanese cities where facemask wearing is common: most of the evident facemasks resemble surgical styles and is somewhat supported by surveys and discussions of habitual facemask users, usually in Far East countries (Wada *et al.*, 2012; Shirai, 2019; Hung, 2018; Burgess and Horii, 2012).

Future investigations should collect information about what facemasks people had, how the facemasks were worn, whether they were reused and how they were prepared for reuse, as well as duration of facemask wear. The impact of the timing of intervention is worth analysing further especially if studies can be fully powered to produce more definitive results, or if evidence should emerge about facemask use within homes before symptom onset or within a very short period (perhaps 4-12 hours) after symptom onset.

### **Limitations**

The search strategy tried to include all 'respiratory' illnesses. However, actual transmission risks vary with the type of pathogen: adequate protection for one germ may be unsafe against others. All of the articles we found related to viruses, most typically influenza but also SARS coronavirus. The lack of tuberculosis studies included in this review may relate to the date cut off we imposed (we omitted studies published before 1980 for expediency). If the evidence base were larger then we could meaningfully subset the studies by the types of pathogen studied: e.g. coronaviruses vs. influenza. Similarly, although we preferred clinical case definitions of ILI or respiratory illness (based on symptoms), where only lab-confirmed case definitions were available, we grouped these with clinical cases. The case definitions were also based mostly on self-report. These pathogens, outcomes and reporting origins could be meaningfully separated with a larger evidence base.

Due to the rapidity of this review we did not consider other article archives or databases such as Google Scholar, CINAHL and MedRxiv. We did not undertake quality assessment of observational studies, although we have provided the authors own assessments of their study limitations which highlight many potential issues. We did not classify outcomes by severity of symptoms or other clinical outcomes (Paulo *et al.*, 2010). It is possible that facemask wearing reduced duration or severity of symptoms experienced due to reducing infectious dose received, although not actual disease. Severity or duration of symptoms and other specific clinical outcomes are important to patients and this is an area which requires further research. We also didn't separate results by duration that facemasks were worn; some studies did subgroup analysis that found this influenced attack rates.

The only mass-gathering setting where facemask wearing evidence has been gathered and published is the Hajj. This event may not be comparable to many smaller mass-gatherings and the Hajj is exceptional for high contact levels (Zein, 2002; Deris *et al.*, 2010; Shirah *et al.*, 2017; Hashim *et al.*, 2016; Gautret *et al.*, 2011).

We have not undertaken a full cost-benefit analysis. The sudden emergence of COVID-19 led to high community demand for face barriers and raised valid concerns that insufficient supplies of facemasks were available for health care workers (Wu *et al.*, 2020; US Surgeon General, 2020). The environmental and economic costs of regularly using facemasks are notable, and only partly abated by reuse. Wearing facemasks consistently and correctly for long periods may not be easy for many people. There is a need to calculate where the balance of benefits and costs lie in facemask wearing for disease prevention (Baracco *et al.*, 2015; Rivera *et al.*, 1997; McGain *et al.*, 2017; Coulter, 2017).

We make no comment on the relative utility of other proposed protective measures compared to facemask wearing, such as self-isolation or frequent handwashing: we have not undertaken research on those measures for comparison. We did not formally assess likelihood of publication bias in the primary research evidence base, due to this being a rapid review.

## CONCLUSIONS

Our study was a rapid review of the literature on the impact of the use of facemasks on the transmission of respiratory symptoms. Based on randomized trial data, wearing a facemask may very slightly reduce the odds of primary infection with influenza-like illness (ILI). However, included trials generally had very low compliance and comparisons undermined by some controls also wearing facemasks. Considering both experimental and observational studies, we consider that the balance of evidence is that facemasks may offer some protection against primary respiratory virus infection when used in community settings outside the home. We surmise that this relates to relatively short exposure windows, brief duration of wear and casual contact, while noting that existing evidence is prone to recall bias and lack of information about what kind of facemasks were worn or if they were worn correctly. Facemasks appear to be slightly effective for preventing secondary infection within household settings, but the certainty of this evidence is low. Facemasks used in the Hajj-related multi-day mass gatherings (which typically involve 2-6 weeks of inter-related activities) have not consistently prevented respiratory symptoms from developing. We do not consider that the balance of evidence across all available studies supports routine and widespread use of facemasks in the community. However, using a mask for short periods of time by particularly vulnerable individuals during transient exposure events may be justified.

**SUPPLEMENTAL** See Table S1 for full list of included studies.

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**Figure 1. Mask wearing to prevent primary infection, by study design**

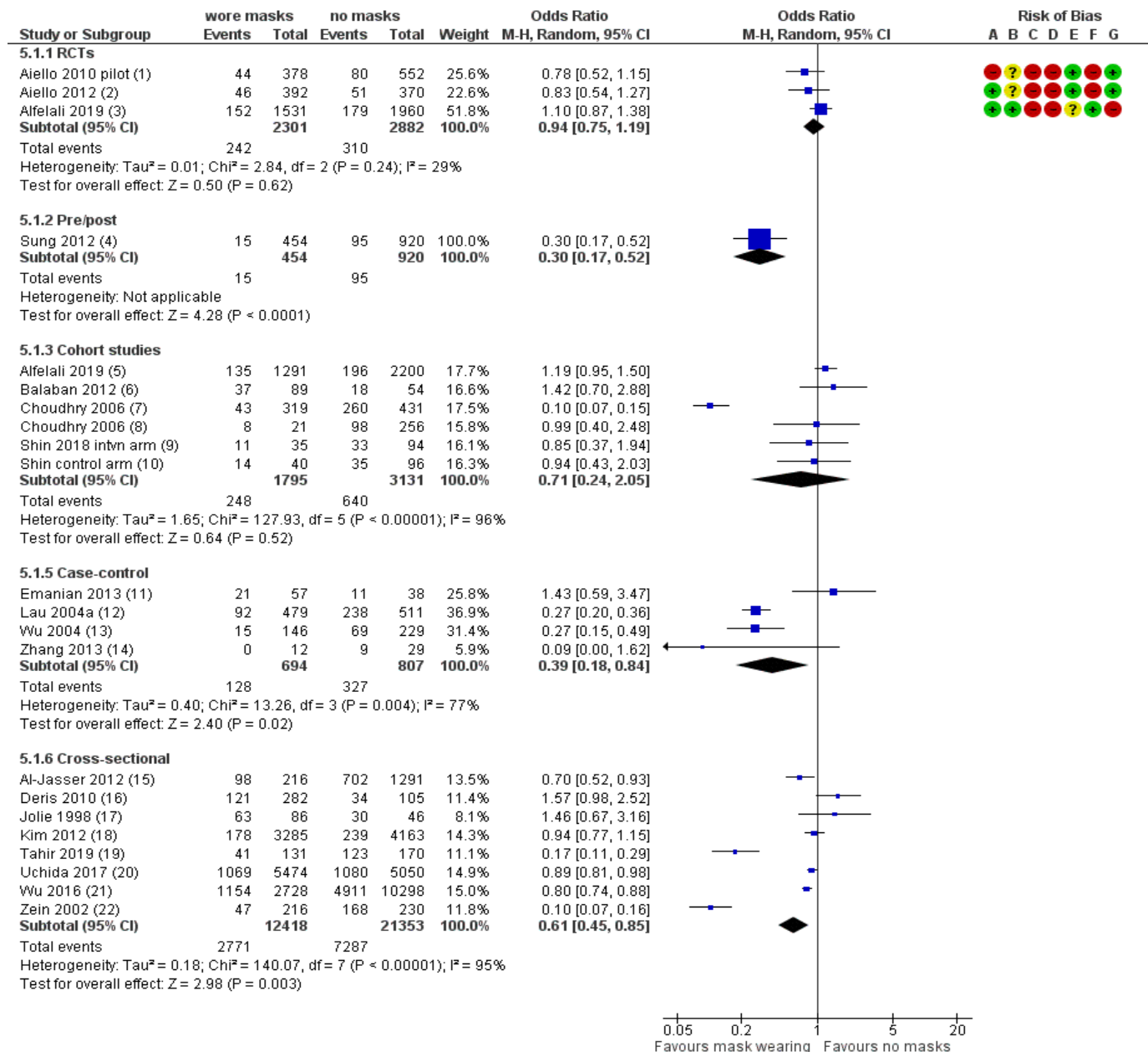
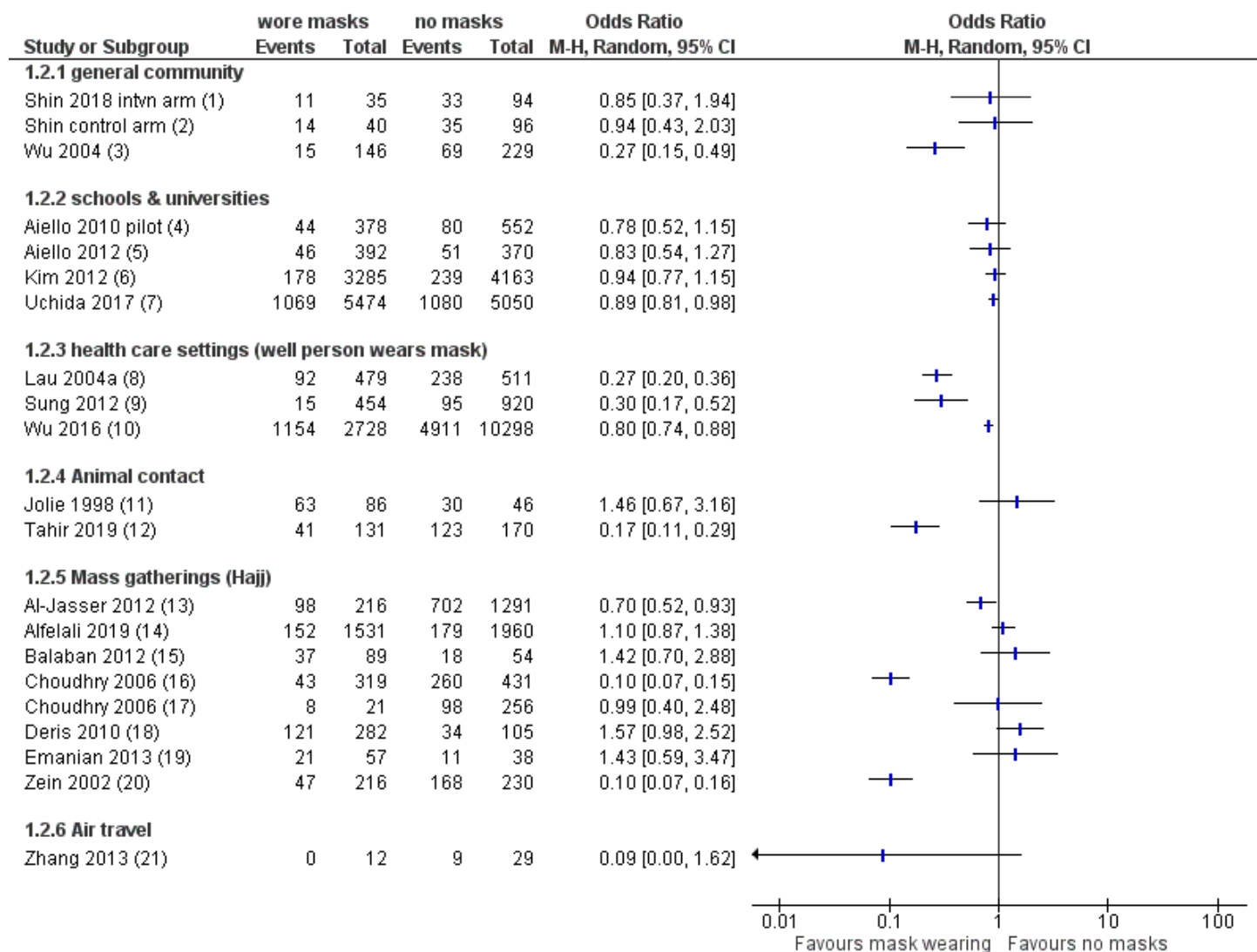


Figure 2. Mask wearing to prevent primary infection, by exposure setting

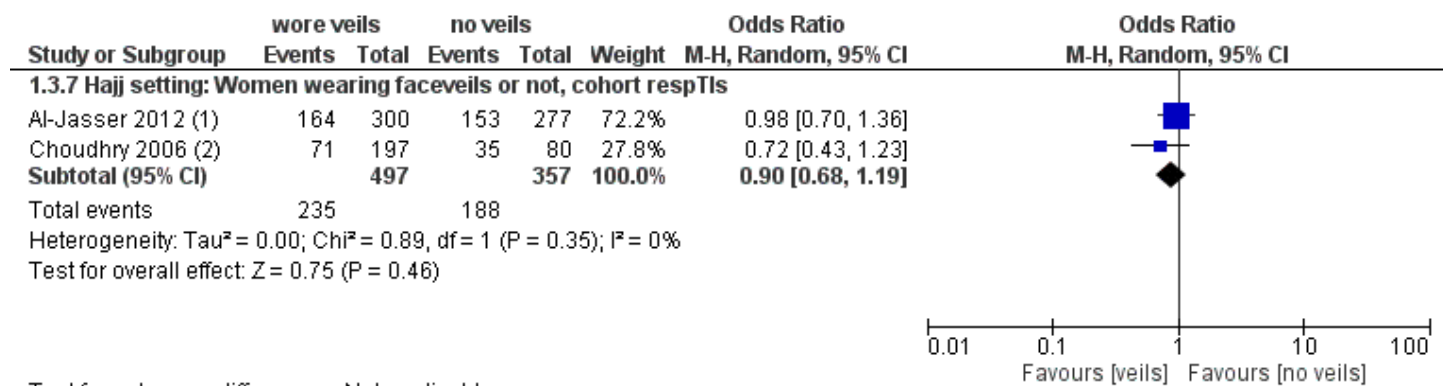


**Footnotes**

- (1) Setting community, Design cohort, Outcome common cold symptoms
- (2) Setting community, Design cohort, Outcome common cold symptoms
- (3) Setting community, Design case control, Outcome SARS (WHO definition)
- (4) Setting University residences, Design cluster RCT, Outcome 'fever' symptoms
- (5) Setting University residences, Design cluster RCT, Outcome ILI symptoms
- (6) Setting schools, Design cross-sectional, Outcome rt-PCR tested, Continuous or irregular' vs. non-users; school pupils,
- (7) Setting schools, Design cross-sectional, Outcome rapid diagnostic kit, Issues denominators add up to > total respondents
- (8) Setting visiting index patients, Design case control, Outcome SARS (WHO definition), Comparison 'frequently vs. seldom/no
- (9) Setting stem-cell recipients in hospital, Design pre-post design, Outcome respiratory infections (various), lab-confirmed
- (10) Setting hospital visitors, Design case control, Outcome ILI
- (11) Setting students on pig farm, Design cross-sectional, Outcome respiratory symptoms
- (12) Setting poultry workers, Design cross-sectional, Outcome serological tests for A(H9N2) influenza, Comparison Always vs....
- (13) Setting Hajj pilgrims, Design cross sectional, Outcome respiratory illness, Details Most of the time vs. sometimes/never
- (14) Setting Hajj pilgrims, Design cluster RCT, Outcome respiratory illness
- (15) Setting Hajj pilgrims, Design retrospective cohort, Outcome respiratory illness
- (16) Setting male Hajj pilgrims, Design prospective cohort, Outcome respiratory illness, Details most of time vs. sometimes/never
- (17) Setting female Hajj pilgrims, Design prospective cohort, Outcome respiratory illness, Details most of time vs. sometimes/never
- (18) Setting Hajj pilgrims, Design cross-sectional, Outcome ILI
- (19) Setting Hajj pilgrims, Design nested case control, Outcome respiratory illness (not colds)
- (20) Setting Hajj pilgrims (masks supplied), Design cross-sectional, Outcome URTI symptoms
- (21) Setting long-haul flights, Design case-control, Outcome ILI linked to H1N1 (WHO definition)



**Figure 3. Faceveil wearing to prevent primary infection**



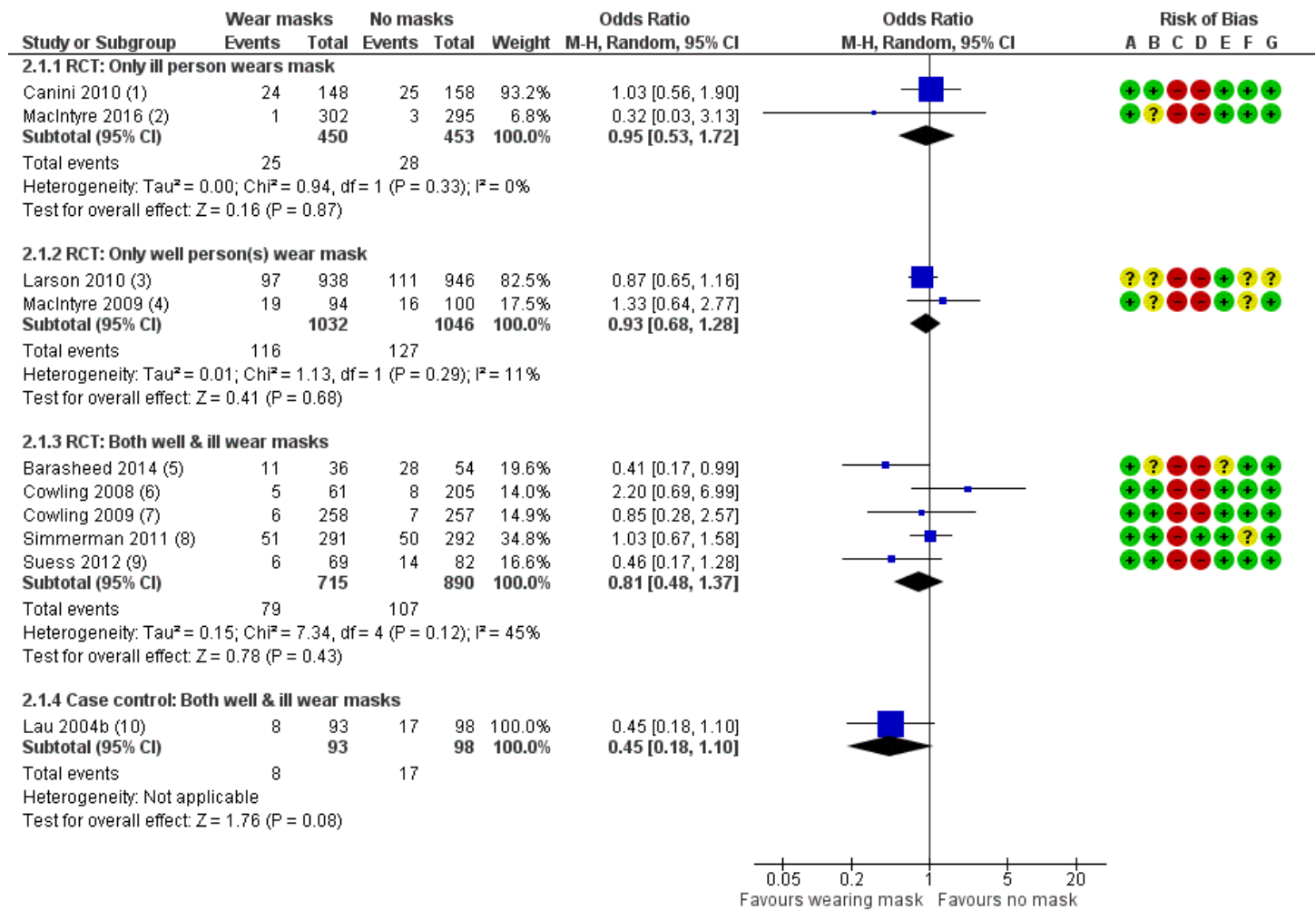
Test for subgroup differences: Not applicable

Footnotes

(1) Setting Hajj pilgrims, Design cross sectional, Outcome respiratory illness, Most of the time vs. sometimes/never Table 5

(2) Setting female Hajj pilgrims, Design prospective cohort, Outcome respiratory illness, Most of the time vs. sometimes/never, Table 3

Figure 4. Mask wearing to prevent secondary infection, households



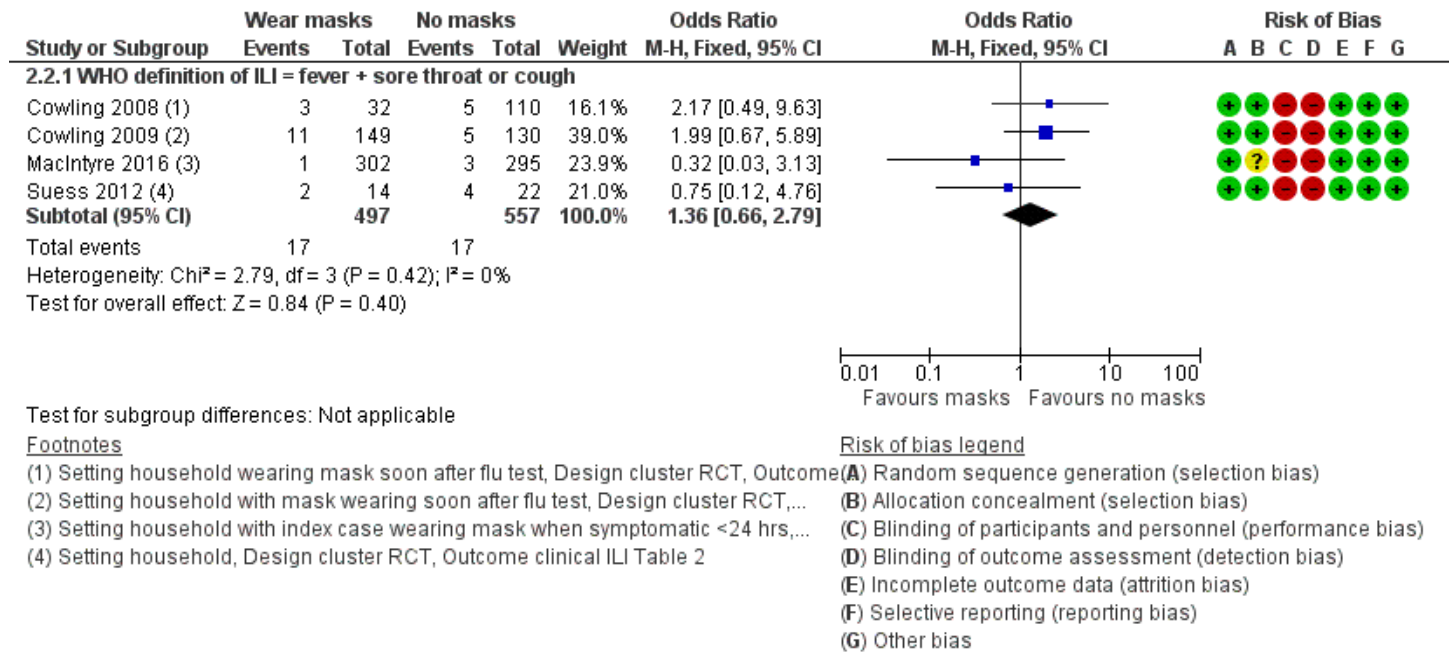
Footnotes

- (1) Setting household with index case wearing mask when symptomatic <48 hrs, Design...
- (2) Setting household with index case wearing mask when symptomatic <24 hrs, Design...
- (3) Setting carers, Design cluster RCT, Outcome ILI
- (4) Setting household - adults wear mask caring for sick child, Design cluster RCT,...
- (5) Setting Hajj pilgrims sleeping near index cases, Design cluster RCT, Outcome...
- (6) Setting household wearing mask <36 hours after flu test, Design cluster RCT, Outcome...
- (7) Setting household with mask wearing soon after flu test, Design cluster RCT, Outcome...
- (8) Setting household, Design cluster RCT, Outcome ILI
- (9) Setting household wearing masks when index case symptomatic <48 hrs, Design...
- (10) Setting visitors to index cases (SARS), Design case control, Outcome ILI, mask worn...

Risk of bias legend

- (A) Random sequence generation (selection bias)
- (B) Allocation concealment (selection bias)
- (C) Blinding of participants and personnel (performance bias)
- (D) Blinding of outcome assessment (detection bias)
- (E) Incomplete outcome data (attrition bias)
- (F) Selective reporting (reporting bias)
- (G) Other bias

**Figure 5. Mask wearing to prevent secondary infection starting <36 hours after onset in index patient, households**



**Table 1 Summary of GRADE findings**

**Masks compared to no masks for influenza-like-illness (ILI)**

**Patient or population:** people without ILI, either in contact with a person with ILI (secondary transmission) or not (primary prevention)

**Setting:** Any

**Intervention:** Advice to wear a mask and/or provision of masks

**Comparison:** No advice to wear a mask

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk without masks	Risk with masks				
Primary prevention, well wear masks - RCT data - outcome ILI	108 per 1,000	<b>102 per 1,000</b> (83 to 125)	<b>OR 0.94</b> (0.75 to 1.19)	5183 (3 RCTs)	⊕⊕○○ LOW <sup>a,b,c,d,e</sup>	Wearing a mask may very slightly reduce the odds of primary infection with influenza-like illness (ILI) by around 6%. Low-certainty evidence, downgraded once each for risk of bias and imprecision.
Secondary transmission, use of masks in homes, only ill person wears mask – RCT data – outcome ILI	68 per 1,000	<b>65 per 1,000</b> (38 to 108)	<b>OR 0.95</b> (0.53 to 1.72)	903 (2 RCTs)	⊕○○○ VERY LOW <sup>f,g</sup>	When one household member becomes ill with an ILI the effect of their wearing a mask on the odds of house-mates developing ILI is unclear, as the evidence is of very low certainty (downgraded once for risk of bias, twice for imprecision).
Secondary transmission, use of masks in homes, only well person(s) wears mask – RCT data – outcome ILI	121 per 1,000	<b>114 per 1,000</b> (86 to 150)	<b>OR 0.93</b> (0.68 to 1.28)	2078 (2 RCTs)	⊕⊕○○ LOW <sup>fh</sup>	Both house-mates and the infected household member wearing masks once one household member has contracted an infectious disease may modestly reduce the odds of further household members becoming ill by around 19%. Low certainty evidence (downgraded twice overall for risk of bias, imprecision and inconsistency).
Secondary transmission, use of masks in homes, both well and ill person(s) wear mask – RCT data – outcome ILI	192 per 1,000	<b>173 per 1,000</b> (121 to 242)	<b>OR 0.81</b> (0.48 to 1.37)	1605 (5 RCTs)	⊕⊕○○ LOW <sup>h,i,j</sup>	Both house-mates and the infected household member wearing masks once one household member has contracted an infectious disease may modestly reduce the odds of further household members becoming ill by around 19%. Low certainty evidence (downgraded twice overall for risk of bias, imprecision and inconsistency).

\***The risk in the intervention group** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **OR:** Odds ratio

**GRADE Working Group grades of evidence**

**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect

**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

**Explanations**

- a. Risk of bias: Outcome assessors were not blinded for ILI (as outcomes are self-reported and participants could not be blinded), but were for lab-based diagnoses (not shown). Allocation concealment often unclear. Downgraded once.
- b. Inconsistency: I2 was 19%. Evidence from other study designs were roughly confirmatory of a small beneficial effect. Not downgraded.
- c. Indirectness: measured exactly what we wanted to know re primary prevention. Not downgraded.

- d. Imprecision: the 95% CIs included both benefits and harms. Downgraded once.
- e. Publication bias: no suggestion of publication bias, not downgraded.
- f. Risk of bias: In most trials outcome assessors were not blinded (as outcomes are self-reported and participants could not be blinded), and allocation concealment was often unclear. Downgraded once.
- g. Imprecision: the 95% CIs included both big benefits and big harms. Downgraded twice.
- h. Imprecision: the 95% CIs included both benefits and harms. Downgraded once.
- i. Risk of bias: In most trials outcome assessors were not blinded (as outcomes were self-reported and participants could not be blinded). Downgraded once in conjunction with inconsistency.
- j. Inconsistency: I2 was 53%. Downgraded in conjunction with Risk of Bias (downgraded once between both factors).



**Table S1 Study Characteristics**

Study name and design	Who wore masks (or not)	Setting	When potentially exposed; Duration of monitoring	Outcomes reported	Type of face barrier	Author conclusions	Limitations or possible biases stated by study authors
<b>Community settings not households or mass gatherings</b>							
Aiello et al 2010 <sup>1</sup> Cluster RCT	Well university students	University of Michigan halls of residence	2006-2007 flu season: 26 Jan-16 March 2007  6 weeks	ILI AND influenza	Medical masks with ear loops (TECNOL procedure masks; Kimberly-Clark)	Mask-wearing led to reduction in ILI in weeks 4-6	Trial interrupted by spring break, in weeks 4-5 of monitoring. Mask-only group wore masks 3.92 (sd 3.31) hrs/day.
Aiello et al. 2012 <sup>2,3</sup> Cluster RCT	Well university students	University of Michigan halls of residence	2007-2008 flu season  6 weeks	ILI AND influenza	Medical masks with ear loops (TECNOL procedure masks; Kimberly-Clark)	Mask-wearing led to reduction in ILI in weeks 3-6	Adherence to wearing masks was variable; students only wore masks within halls, average 5.04 (sd 2.2) hrs/day. Transmission was quite possible outside halls; reliance on self-reported data. Average 11.86% of observation shifts that any mask was seen worn correctly.
Jolie et al 1998 <sup>4</sup> X-sectional	Veterinary students	USA WI (south central) pig farm	exposed Oct 1993/Oct 1994  single surveys post farm visit (unclear how long after)	Toxic pneumonitis	Preformed cone style facemask (Deseret Filtermask cat. no. 375201)	The presence of respiratory and/or general symptoms was not significantly different between mask users and non-users.	Not as rigorous as an RCT, single strap mask design may have had an impact.
Kim et al 2012 <sup>5</sup> X-sectional	Children age 7-18 yrs	South Korea school pupils	18 Nov-8 Dec 2009 monitoring	H1N1 flu	"facemask"	Continuous use of facemasks exhibited a significant negative relationship with H1N1 infection (OR 0.51, 95% CI 0.3-0.88)	This study was testing an hypothesis that obesity would affect influenza risk, was not designed to assess masks as protective/risk factors. Reliant on self-reporting by children.
Lau, et al 2004a <sup>6</sup> Case-control	Community dwellers	Within and outside of Hong Kong HHs	spring 2003	ILI = likely SARS	"facemask"	Masks were protective 0.36 (0.25-0.52)	Respondents may have interpreted questions incorrectly and inconsistently, including what wearing a mask "frequently" vs. "occasionally" meant.

Study name and design	Who wore masks (or not)	Setting	When potentially exposed; Duration of monitoring	Outcomes reported	Type of face barrier	Author conclusions	Limitations or possible biases stated by study authors
Lau et al 2004b <sup>7</sup>  Case-control	index pt &/or contracts of known pts (has these as separate RFs); visit at home or in hospital	Hong Kong	spring 2003	ILI = likely SARS	"facemask"	Wearing masks to visit index patients in hospital/patient's separate home reduced transmission (Sec Attk rates): n=2195 (table 6) OR 3.12 (1.65 to 5.91) both without mask table 6 and OR 4.16 (2.37 to 7.30) both without mask, table 1	Known patient may not be source of infection in others; other nosocomial infection possible; case definition was nonspecific; interviewee sometimes was not a case but someone else in same HH, recall bias. Unclear if masks were worn for full duration of visit.
Shin et al 2018 <sup>8</sup>  Observational data collected during an RCT	healthy adult volunteers age 20-65	Community dwelling near Kyushu University, Japan	Jan-March 2015  8 weeks	Common cold	"facemasks"	Habit of wearing facemasks made no difference	Not commented upon with respect to masks; trial was designed to test supplements that might reduce or prevent common cold. Facemask 'habit' was not defined.
Sung et al 2012 <sup>9</sup>  Pre-post period comparisons	Community visitors to vulnerable people (stem cell recipients) in hospital/clinic	probably USA NC	10 Jan 2010 to 9 Jan 2012  Duration of hospital stay, implies typically about 30 days	Specific respiratory viral infections, especially parainfluenza	"surgical masks"	The incidence of any RVI was 10.3% in the pre-mask period and 3.3% in the mask period (P < .0001). Surgical mask usage had the most pronounced effect on reducing the incidence of PIV3 (8.1% to 2.1%, P < .0001), which was the most common virus (74% and 60% of infections), followed by RSV (16% and 13%).	No comments on limitations; this was a short conference abstract.
Tahir et al 2019 <sup>10</sup>  X-sectional	People in jobs with contact with poultry (wide range of jobs)	Rawalpindi, Pakistan	Surveyed and sampled December 2016-May 2017	Seroprevalence for antibodies against H9 influenza	"facemasks"	Persons who used facemasks had significantly lower (P < 0.002) seroprevalence (29.6%) than those who never used them (90.6%) Facemask used: sometimes/never/always positive serological result: 64%/91%/31%; p=0.001	Insufficient distinction for type of contact/poultry farming; x-sectional design meant they missed seasonal trends. Reliant on self-report; always/sometimes/never durations not clearly defined.
Uchida et al 2017 <sup>11, 12</sup>  X-sectional	Healthy primary school children (age 7-12yrs)	Matsumoto City, Nagano, Japan.	2014/2015 flu season surveyed end Feb 2015 about most recent winter period	Influenza	"facemask"	The overall effectiveness of ... mask wearing was ... 8.6%... wearing masks (0.859, 0.778-0.949) had significant protective association	Expected they had missed sub-clinical and asymptomatic cases; Limited age sample; x-sectional rather than RCT design. Mask wearing was simple yes/no, self-report by children's guardians. No indication of frequency of use.



Study name and design	Who wore masks (or not)	Setting	When potentially exposed; Duration of monitoring	Outcomes reported	Type of face barrier	Author conclusions	Limitations or possible biases stated by study authors
Wu et al 2004 <sup>13</sup> matched case-control	Cases and matched controls (in community, lacked known contact)	Beijing PRC	28 April to 16 Jun 2003	ILI = likely SARS (clinical illness definition)	"facemask" when going out	Wearing masks outside the home was strongly protective; more protection the more they reported wearing the masks. wore a mask never =ref, sometimes OR 0.5 (0.2 to 0.9) p=0.02 always OR 0.3 (0.2 to 0.6) p= <0.001	Self-report, self-selection in those who answered; uncertainty if SARS; some refusal of blood tests; likely over diagnosis.
Wu et al 2016 <sup>14</sup> X-sectional	Community dwelling people going to hospitals for any purpose	Beijing PRC	January 2011 survey About illness in previous year	ILI	"facemask"	Habit of facemask use when going to hospitals (OR 0.87; 95% CI 0.80–0.95) was protective.	Recall bias; ILI symptoms from non-pathogen cause(s); no pandemic at time led to case number.
Zhang et al 2013 <sup>15</sup> case-control	Airplane passengers	Flights between to Hong Kong, Vancouver and New York NY	Three long haul flights, May 2009	Influenza A(H1N1)pdm09; ILI	Unknown, authors stated "presumably, individually acquired masks represented a mixture of N95 and other less efficient masks"	None of the 9 case-passengers, compared with 47% (15/32) of control passengers, wore a facemask for the entire flight (odds ratio 0, 95% CI 0–0.71).	Unclear what type of mask people used, lack of seating information, severity of illness information, missing case passengers, lost many to follow-up (limited sampling frame), recommended an RCT. Not clear if passengers wore mask entire or how much of flight duration.
<b>Household (cluster) RCTs to prevent secondary attacks</b>							
Canini et al 2010 <sup>16</sup> Cluster RCT	Sick person who tested + for flu < 48hrs after symptom onset, in HH with others	Within French HHs	2008-2009 flu season Surveyed 7 days after recruitment	Influenza, ILI	Surgery masks with earloops, 3 plys, anti fog (AEROKYNH, LCH medical products)	Mask wearing was not protective	Too underpowered to make conclusions, no laboratory confirmation, discomfort reported with mask use. Average count of masks used was about 60% of expected use over period.
Cowling et al 2008 <sup>17</sup> Cluster RCT	HHs where someone tested + for flu, started wearing < 36 hrs after +test	Hong Kong HHs	Feb-Sept 2007 exposure period 9 days after start wearing masks	Influenza; ILI	TecnoL – The Lite One, Kimberly Clark, Roswell, GA)	Neither masks nor handwashing intervention were protective in general, but subgroup for those who put on masks when index patient < 36 hours symptomatic suggested masks were protective	Attrition, bias in recruitment. Compliance not high and contamination noted: eg., >25% of contacts did not wear a mask at all, 30% of index cases in the control group wore masks at home; underpowered

Study name and design	Who wore masks (or not)	Setting	When potentially exposed; Duration of monitoring	Outcomes reported	Type of face barrier	Author conclusions	Limitations or possible biases stated by study authors
Cowling et al 2009 <sup>18</sup>  Cluster RCT	HHS where someone tested + for flu, starting soon after +test	Hong Kong HHS	2 Jan - 30 Sept 2008  7 days after start wearing masks	Influenza; ILI	Tecnol – The Lite One, Kimberly Clark, Roswell, GA)	Hand hygiene and facemasks can reduce influenza virus transmission if implemented early after symptom onset in an index patient; else intervention wasn't effective	Delay in donning masks after symptom onset may be too large; recruitment bias. 5% of contacts wore masks, 31% of index patients wore masks, 26% of intervention contacts wore masks often/always; 49% of intervention index patients wore masks as directed.
Larson et al. 2010 <sup>19</sup>  Cluster RCT	Mostly care givers in close proximity, also ill patients	Manhattan HHS	2007-2009  Monitoring over 19 months	ILI	Procedure Facemasks for adults and children, Kimberly-Clark	[Although] compliance with mask wearing was poor, mask wearing [was] associated with significantly lower secondary transmission rates (p = 0.02).	Compliance was described as low, both for mask-wearing and symptom reporting.
MacIntyre et al 2009 <sup>20</sup>  Cluster RCT	all (min2) adults caring for index child = 0-15 yrs; at all times around child	Within Sydney Australia HHS	Aug-Oct 2006 & Jun-Oct 2007  7 days after masks issued	Respirat'y illness = ILI = fever &/or other symptoms	3M surgical mask, cat. no. 1820; and 3M flat-fold P2 mask, cat. no. 9320	Neither mask was effective	No fit-testing for P2 masks. Possible some patients were incubating when recruited; prospective study would be better. Between 31% and 38% of intervention group wore masks (of whole group supposed to wear masks).
MacIntyre et al 2016 <sup>21</sup>  Cluster RCT	Only index cases (unwell people)	Beijing PRC, within HHS	18 Nov-20 Jan recruited people who had symptoms < 24 hrs and been to hospital; no other ILI history in HH in previous 14 d  7 days after recruited	ILI: clinical respirat'y illness (list of symptoms stated); also lab Test detected virus infections	3M 1817 surgical mask	Rates of clinical respiratory illness (relative risk (RR) 0.61, 95% CI 0.18 to 2.13), ILI (RR 0.32, 95% CI 0.03 to 3.13) and laboratory-confirmed viral infections (RR 0.97, 95% CI 0.06 to 15.54) were consistently lower in the mask arm compared with control, although not statistically significant. A post hoc comparison between the mask versus no-mask groups showed a protective effect against clinical respiratory illness HazRat = 0.22 (0.06 to 0.86), but not against ILI and lab-confirmed viral respiratory infections.	Underpowered; participants removed masks to eat together. There was contamination = average 1.4 hrs/day mask use in controls compared to average wearing = 4.4 hrs/day in intervention. 35% of control index patients wore masks. 7/123 index patients in intervention arm didn't wear mask at all.

Study name and design	Who wore masks (or not)	Setting	When potentially exposed; Duration of monitoring	Outcomes reported	Type of face barrier	Author conclusions	Limitations or possible biases stated by study authors
Simmerman et al 2011 <sup>22</sup>  Cluster RCT	index ill child & all healthy HH members	near Bangkok, Thailand; index pts = kids age 1m-15yrs	Recruited 9 Apr-13 Aug 2009  3 weeks after start mask	Influenza; ILI	50 standard paper surgical facemasks and 20 pediatric facemasks (Med-con co. Thailand #14IN-20AMB-30IN)	Influenza transmission [ & ILI] was not reduced by interventions to promote hand washing and facemask use.	Study was complicated by arrival of 2009 H1N1 influenza pandemic and subsequent national hygiene campaign that may have changed behaviour in control group (possible contamination). 23% of control index patients wore masks, 90% of them after June 2009.
Suess et al 2012 <sup>23, 24</sup>  Cluster RCT	both index patient & HH contacts of index pt, starting <2d after symptom onset	Berlin, Germany households	2009-2011  8 days after start wearing masks	Influenza; ILI	Child's Facemask, Kimberly-Clark, USA, or adults: Aérokyn Masques, LCH Medical Products, France	When analysing only households where intervention was implemented within 36 h after symptom onset of the index case, secondary infection in the pooled M and MH groups was significantly lower compared to the control group (adjusted odds ratio 0.16, 95% CI, 0.03-0.92). In a per-protocol analysis OR were significantly reduced among participants of the M group (adjusted odds ratio, 0.30, 95% CI, 0.10-0.94). Also reported lower sec-atk-rate the less they were at home.	Cannot say who wearing the mask reduced transmission (patient or contacts); There was limited testing for same influenza subtype that index patient had; variable implementation protocols. There was mask-wearing in 2/30 control households, while 55% of intervention households reported wearing masks often/always.
<b>Hajj pilgrims (mass gatherings)</b>							
Alfelali et al 2019 <sup>25</sup>  Cluster RCT but we also treated data as observation in meta-analysis due to contamination	Well pilgrims age 18+	Hajj pilgrimage events	2013-2015 (late Sept-mid Oct)  5 days during Hajj	Viral respirat'y infection	3MTM Standard Tie-On surgical mask, Cat No: 1816	Facemask did not prevent clinical or laboratory-confirmed viral respiratory infections among most Hajj pilgrims, although some subgroup differences were found, and clinical respiratory infections were lower in the intervention arm (13% versus 10%, p=0.03)	Short duration (4-5 days) of follow-up. Only 25% of intervention participants used facemasks daily, while 14% of control participants used masks daily. Controls were allowed to wear masks if they wanted
Al-Jasser et al. 2012 <sup>26</sup>  X-sectional survey	Pilgrims	Hajj pilgrimage events	Nov-Dec 2009  slightly variable, within two weeks of finish	Upper respirat'y tract infections	"facemasks"	Increased protection with increased habit of wearing masks. Unadj. model results: Most of time worn = referent, Sometimes worn had RR 1.17 (1.0-1.38) & Never had RR 1.21 (1.06-1.43) p = 0.14, but no effect in adjusted models.	Self reported outcome, self-selected participants, recall bias, lack of demographic data on respondents

Study name and design	Who wore masks (or not)	Setting	When potentially exposed; Duration of monitoring	Outcomes reported	Type of face barrier	Author conclusions	Limitations or possible biases stated by study authors
Balaban et al 2012 <sup>27</sup>  pre-post travel surveys	Pilgrims	Hajj pilgrimage events	2009 Hajj (Nov-Dec)  Implies most were on Hajj for 2-4 weeks	Respirat'y illness; ILI	"facemasks"	Not possible to determine the effectiveness of facemasks from these data, although wearing masks was associated with greater likelihood of illness (not statistically significant)	Problems with generalisability, no evaluation of pre-Hajj health information, likely under-ascertainment, self reported adherence without independent collaboration
Barasheed et al 2014 <sup>28</sup>  Cluster RCT	Pilgrims age 15+ in tents with a person ill ≤ 3d, both ill & any well who slept in adjacent bed to wear masks	Hajj pilgrims Mina Valley, Mecca, Saudi	early November 2011  5 days during Hajj, after recruitment	ILI; respirat'y symptoms	Surgical facemasks = (3M™ Standard Tie-On Surgical Mask, Cat No: 1816	More symptoms in the no-mask group, but laboratory test for pathogens found no difference between groups	Small number of participants. 56/75 (76% of intervention group were deemed compliant); 12% of controls (11/89) wore masks.
Choudhry et al 2006 <sup>29</sup>  Prospective cohort	Unsymptomatic Saudi Pilgrims from Riyadh at recruitment ; separated results for males and females	Hajj activities	2002 Hajj (core dates 20-25 Feb)  Surveyed about 2 weeks after recruitment	Acute respirat'y symptoms	mostly masks, also veils	Strongly increased risk of having ARI the less they used the mask (men)	Using the facecover as a proxy for a facemask in women may be leading to misclassification of exposure status.  Men, however, were using the facemask as a personal hygiene measure, independent of the place where they were, so suggested separate data by sex
Deris et al 2010 <sup>30</sup>  X-sectional survey	Malaysian pilgrims	Hajj pilgrimage events	2007 Hajj (17-22 Dec 2007)  Questions covered entire Hajj pilgrimage period	Respirat'y symptoms ; ILI	Unclear type of facemask, but implies not respirators	Wearing facemasks was associated with more symptoms, but not statistically significant, and no real controls	Very few unaffected persons: only 3.6% did not have at least one respiratory symptom
Emamian et al 2013 <sup>31</sup>  Prospective Nested case-control study	Iranian pilgrims	Hajj pilgrimage events	November 2010  Monitoring was simultaneous	Respirat'y tract infections that were not colds	"facemasks"	Masks not even effective in univariate	Small sample size

Study name and design	Who wore masks (or not)	Setting	When potentially exposed; Duration of monitoring	Outcomes reported	Type of face barrier	Author conclusions	Limitations or possible biases stated by study authors
Gautret et al 2011 <sup>32</sup> X-sectional survey	French pilgrims	Hajj pilgrimage events	November 2009 core dates, asked about entire visit, usually 4 weeks	Acute respirat'y symptoms	Surgical facemasks	Influenza vaccine and facemask use did not significantly reduce respiratory symptoms.	Low incidence may have been due to under reporting
Hashim et al 2016 <sup>33</sup> X-sectional survey	Malaysian pilgrims	Hajj pilgrimage events	2013 Hajj (12-17 October are core dates); most had 2-4 week stay	Respirat'y illness; ILI	Distinguished: N95, surgical, wet or dry towel and veil	Facemask wearing not signif in unadjusted or adj model; 78% had ILI & 93.4% had respy symptoms, even though about 84% said they used masks	Inadequate sample size, poor response rate, loss to followup from # originally recruited. (no data suitable for pooling)
Zein 2002 <sup>34</sup> x-sectional; masks were known to have been given by non-researchers to all respondents	pilgrims	Hajj pilgrimage events	2002, 20-25 Feb are core dates  Unclear if symptoms collected from daily diaries or in single survey afterwards	Acute upper respirat'y tract infections	Maybe nose+mouth masks, normally cotton, by Indonesian Hajj committee	Masks were very protective No-mask user OR = 3.10 (Confidence limit : 2.65 < MHRR < 3.82 ; p < 0.000).	Other covariates such as humidity or dust level not adjusted for

Note to Table 1: HH = Household(s)

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