Question: "Does the use of face marks in the general population make a difference to spread of infection?"

Answer

- Based on the evidence from three recent systematic reviews and meta-analyses [including our re-analysis focusing on community trials] <u>wearing face masks in the community was not significantly associated with a reduction in episodes of influenza-like illness</u> [ILI]; the overall assessment of the quality was classified as low.
  - o Jefferson 2020 [re-analysed]: 7 RCTs in the general population with ILI outcome [OR (95% CI) 0.92 (0.87, 1.07)]
  - o Xiao 2020: 10 RCTs in non-healthcare settings with pandemic influenza outcomes [OR (95% CI) 0.97 (0.79, 1.18]
  - o Brainard 2020: various study designs with respiratory illness outcome; OR (95% CI): 0.94 (0.75, 1.19)
- <u>SARS-CoV-2 is transmissible by contact and droplets</u> [aerodynamic diameter >5μm]. SARS-CoV-2 can be detectable and viable in aerosols [aerodynamic diameter ≤5μm], suggesting possible transmission routes by aerosols. However, <u>there is little current evidence demonstrating actual aerosol transmission episodes by SARS-CoV-2</u>.
- <u>The quality of the evidence on face mask effectiveness is moderate to low.</u> See table 1. Many of the cohort and cross-sectional studies rely on self-reported symptoms not confirmed clinically or using lab tests. There is very little information on duration or frequency of use or correct usage of masks.
- Whilst some of the RCTs specify the type of mask used, <u>many of the studies do not define the type of mask or the materials masks are made from</u>. This makes it difficult to evaluate the evidence.
- Mask-wearing alone, in the absence of other preventive measures, is unlikely to be effective, yet most studies do not take this into account. <u>Many studies did not gather information on general hygiene and other relevant health behaviours</u> (e.g. hand sanitiser, hand-washing). Many of the studies do not make a distinction between indoor and outdoor settings.
- Much of the evidence is not generalizable to a UK community setting. For example, 8 of the 24 studies focus on face mask use during the annual hajj pilgrimage in Saudi Arabia – a very specific context in very different climatic conditions. <u>The influence of cultural and socio-behavioural factors (e.g. fear, stigma, altruism) on levels of compliance during a pandemic may differ meaningfully from other circumstances</u>.
- There is little evidence on the behavioural aspects of facemask use. The most-studied aspect relates to frequency / consistency of use, with more consistent use linked to a greater reported protective effect (although this must be taken in the context of our overall findings which failed to find a clear protective effect of facemasks). One study found that facemasks contribute to an increased sense of isolation.
- Public health awareness campaigns [Aiello-2010], specific education [Barasheed-2016] and provision of free facemasks [Alabdeen-2005] all appeared to incentivise greater uptake of facemasks. There were little data on how long people can be expected to comply with requirements to wear a facemask. One review reported that

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"in one study, rates of self-reported adherence were found to decline over a 5-day period" [PHE-2014].

Conclusion

- **This review found mixed and low quality evidence on the use of face masks to prevent community transmission of respiratory illness, with much of the evidence generated in very different contexts from the UK. Key issues are the need for better quality research in community settings, which focuses not only on evaluating different types of mask but also on evaluating adherence (duration and frequency of mask use, correct procedure for putting on and removing masks) and the use of masks in conjunction with hand hygiene.**

Please note: This review was conducted very quickly, and as such has the following weaknesses: full text screening, extracted data and quality assessment were not checked by a second reviewer, thus introducing a risk of bias. We will continue to update and refine this review going forward.

Note in parenthesis: Reviewers note that the WHO Expert Panel reported yesterday on 6/4/2020 that "the wide use of masks by healthy people in the community setting is not supported by current evidence and carries uncertainties and critical risks". This report was read by the reviewers after our review was completed and did not influence our findings.

Contact details of lead reviewer (including mobile number)

Date of review: 7 April 2020

Extended abstract

Background: Current UK advice advises that "respiratory etiquette when coughing or sneezing " and social distancing of at least 2m apart should give sufficient protection against transmission from viruses carried in droplets which evaporate or fall to the ground within that distance. However, recent data has suggested that exhalation, coughing and sneezing can carry liquid droplets / aerosols over larger distances and has led to renewed interest in the role of facemasks to limit transmission risk. If there were a general recommendation to wear face masks indoor when symptomatic, or outdoors in public is there evidence to suggest that this may help slow the spread of coronavirus? Could wearing a mask be as effective as social distancing? The WHO Expert Panel on this topic reported on 6/4/2020 that "the wide use of masks by healthy people in the community setting is not supported by current evidence and carries uncertainties and critical risks". This is in contrast to US CDC who recommended the US public wear cloth coverings in pharmacies, groceries and other public places where social distancing is hard to maintain.

Background policy relevance

- Can the use of masks prevent transmission of SARS-COV-2?
- Do masks reduce the virus shedding in respiratory droplets and/ or aerosols?
- Is there a difference between different types of masks (eg surgical or home-made masks)?
- Are there behavioural aspects of face mask wearing by the general population that relate to compliance or risk taking behaviour that are relevant?

Methods:

We adapted rapid review methods outlined by the Cochrane Collaboration. To address these broad and complex questions rapidly, we broke the review into four main inter-connected research questions:

- sub-review 1: what is the effectiveness of face masks in preventing respiratory transmission in the community?
- sub-review 2: what is the relative effectiveness of medical masks versus non-medical masks or equivalent barriers?
- sub-review 3: what important behavioural aspects of wearing masks in terms of compliance with advice and impact on risk taking behaviour can be identified?
- sub-review 4: what is known about the nature and spread of respiratory airway particles?

Literature Search:

Preliminary groundwork: We were aware of work to produce reviews and evidence summaries on COVID-19 -related topics. Since there is currently no register of existing reviews we have been compiling a database of reviews from websites of partners taking part in the WHO Evidence Collaborative and have so far identified ~170 COVID-19 evidence reviews, including some on use of face masks. To support this rapid review, and avoid

duplication of effort, we contacted experts in the field and searched for prior reviews or evidence summaries on facemasks to prevent transmission of infection. We identified 14 prior reviews/summaries, appraised them for scope and quality, and for this update rapid review selected the three most recent, on-topic, and robust quality [Jefferson 2020, Brainard 2020, Xiao 2020] for updating and re-analysis.

The methods described here apply to sub-reviews 1 and 2.
We re-ran the searches reported in the three selected reviews, limited to publications from the date onward that each of the systematic review had stopped their search. We searched the databases used in the prior reviews (PubMed, Medline, Embase, Scopus, CENTRAL, CINAHL) and augmented the methods by including a search for pre-prints on medRxiv. The searches were carried out by one reviewer (MD).
From the updated search results set, we excluded publications published before 2020, from nosocomial settings, modelling data, animal models, providing commentary but no data. All component studies of the three systematic reviews were included in this update. There were no language limitations as part of the search, but due to time and resource constraints, non-English publications were not included in analysis

Sub-review 1: What is the effectiveness of face masks in preventing respiratory transmission in the community?

Background
Community face mask use was part of successful control policies in China, South Korea and Vietnam, but it is not possible to disentangle their separate contribution to reducing transmission. This rapid review was carried out to establish whether there is evidence for the use of face masks in the general population to reduce the spread of infection with SARS-COV-2.

Methods
For a description of the underlying literature search, please see Literature search methods section above.

From the updated search results set, we excluded publications from nosocomial settings, modelling data, animal models, providing commentary but no data, and, due to time constraints studies published before 2020. All component studies of the three systematic reviews [Jefferson 2020, Brainard 2020, Xiao 2020] were included in this update.

Screening was shared between three reviewers (MG, XL, WX). Each new title, abstract and full text was screened by one reviewer (MG). References of previous systematic reviews were searched by two reviewers (XL, WX). No new studies meeting the inclusion criteria were identified.

Results

4

- A total of 766 new results was found from the database searching, reduced to 81 after removal of duplicates and pre-2020 publications. We excluded 72 records by screening titles and abstracts and a further 9 at the full text screen/quality assessment phase, leaving 0 new articles for inclusion in the final review. The key findings from this rapid review were:

- Of the three high quality recent reviews we scrutinised in detail, two included only RCTs [Jefferson 2020, Xiao 2020], whereas Brainard 2020 included population studies too. We ran updated literature searches for these reviews to identify new studies. No new studies meeting inclusion criteria were identified.

- All component studies of the three systematic reviews were included for analysis in this update.

- Jefferson 2020 included 9 RCTs (7 in the general population and 2 in health care workers) and reported that there was no reduction of Influenza-like illness (ILI) for masks compared to no masks [Random effects OR (95% CI): 0.93 (0.83, 1.05)].

- We re-ran a random effects meta-analysis restricting to the 7 RCTs conducted in the general population from Jefferson 2020 and also found no significant reduction of ILI [OR (95% CI): 0.92 (0.87, 1.07)]. Risk of bias analysis using the Cochrane tool done by Jefferson et al indicated that there was high or unknown risk of bias in relation to performance, detection and reporting bias.

- Xiao 2020 evaluated environmental and personal protective measures for pandemic influenza in non-healthcare settings. They run a fixed effect meta-analysis of 10 RCTs of community use of face masks (with or without hand hygiene measures) and they reported a no significant reduction of ILI [Fixed effect OR (95% CI): 0.92 (0.75, 1.12)]. We repeated the analysis using random effects meta-analysis and the result was similar [Random effects OR (95%CI): 0.97 (0.79, 1.18)]. The study quality of the included studies was evaluated using GRADE by Xiao et al and the overall assessment of the quality was classified as low.

- Brainard 2020 included all study designs on facemasks and similar barriers to prevent respiratory illness. Based on random effects meta-analyses on RCTs, they concluded that wearing face masks can be very slightly protective against primary infection from casual community contact, but this was not significant, and the evidence was classified as low certainty-evidence using the Cochrane risk assessment [Random effects OR (95% CI): 0.94 (0.75, 1.19)]. Similar were the findings for the prevention of household infections when both infected and uninfected members wear face masks.

Conclusion

- Based on the evidence from three recent systematic reviews and meta-analyses wearing face masks in the community is not significantly associated with a reduction in ILI and the overall assessment of the quality was classified as low.

Key References – see separate file
Lead reviewers [with contact details of lead]

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Sub-review 2: What is the relative effectiveness of medical masks versus non-medical masks or equivalent barriers?

Background

This review evaluates the evidence on the effectiveness of face masks for preventing respiratory infection in community settings.

Methods

- For a description of the underlying literature search, please see Literature search methods section above.
- We sought published or pre-published observational or intervention studies, investigating face masks or respirators to prevent the transmission of respiratory viruses in community settings. Face masks could be surgical, medical, N95 respirators, homemade, improvised or repurposed (e.g. DIY masks) made of any material. Included studies had to report a measure of respiratory virus infection and/or its consequences (e.g. days off work, complications, hospital admission, deaths). We excluded case series, case reports, review articles, guidelines, discussions, regulations, debates, and commentaries. We also excluded publications which investigated the prevention of transmission to/from clinically trained persons in clinical settings, studies based on mathematical modelling, and studies investigating transmission from non-humans. Due to time constraints, studies published before 2020. All component studies of the three systematic reviews [Jefferson 2020, Brainard 2020, Xiao 2020] were included in this update.
- Title and abstract screening was conducted by three people, each person screening a third of the studies. A second person checked all rejected studies. Where the second reviewer disagreed with the decision of the first reviewer, the paper was retained for full text screening. Full text screening was again split between the three reviewers. Data extraction and quality appraisal were conducted by a different reviewer from the reviewer who conducted the screening. We used the following quality assessment checklists: CASP checklist for randomised controlled trials, cohort and case-control studies and Joanna Briggs checklists for case series and cross-sectional studies.

Results

- We identified a total of 182 studies (107 were primary studies from the 3 key systematic reviews and 78 were studies identified in our update search). We rejected 125 through screening titles and abstracts and a further 32 when reviewing full texts. Reasons for rejection at full text screen were: not meeting inclusion and exclusion criteria (n=18), not primary studies (n=6), full text not available (n=8). We retained 25 studies for detailed analysis and quality appraisal. Key findings were that:
- The quality of the evidence on face mask effectiveness is moderate to low. See table 1.

6

- Many of the cohort and cross-sectional studies rely on self-reported symptoms not confirmed clinically or using lab tests.
- There is very little information on duration or frequency of use or correct usage of masks.
- Whilst some of the RCTs specify the type of mask used, many of the studies do not define the type of mask or the materials masks are made from. This makes it difficult to evaluate the evidence.
- Mask-wearing alone, in the absence of other preventive measures, is unlikely to be effective, yet most studies do not take this into account. Many studies did not gather information on general hygiene and other relevant health behaviours (e.g. hand sanitiser, hand-washing)
- Many of the studies do not make a distinction between indoor and outdoor settings.
- Much of the evidence is not generalizable to a UK community setting. For example, 8 of the 24 studies focus on face mask use during the annual hajj pilgrimage in Saudia Arabia – a very specific context in very different climatic conditions. Only one lack of transferability between different populations.
- Of the seven studies of moderate quality (table 3) – i.e. the strongest evidence found – three reported no evidence of effectiveness of face masks, whilst 4 reported some evidence of effectiveness. However, a key consideration is the difference between evidence of effectiveness in a controlled study and the evidence of effectiveness in real life situations, where compliance may not be optimum.

Conclusions

- This review found mixed and low-quality evidence on the use of face masks to prevent community transmission of respiratory illness, with much of the evidence generated in very different contexts from the UK. A key issue is the need for better quality research in community settings, which focuses not only on evaluating different types of mask but also on evaluating adherence (duration and frequency of mask use, correct procedure for putting on and removing masks). This review was conducted very quickly, and as such has the following weaknesses: full text screening, extracted data and quality assessment were not checked by a second reviewer, thus introducing a risk of bias. We will continue to update and refine this review going forward.

Key References – see separate file

Lead reviewers [with contact details of lead]

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7

Sub-review 3: What evidence is there for the role of behavioural factors on the effectiveness of face mask use in the community?

Background

We looked at behavioural factors that are linked directly to facemask use: Is the facemask put on and taken off correctly? How often do people wear facemasks? Does this change over time? Do the population comply with advice on their use?

Methods

- For this sub-review, we focused on the 14 prior reviews and summaries found during the preliminary ground-work described in the literature search methods above.
- These reviews were screened by three reviewers (EMS, MP, AN) for relevance to our sub-question (behavioural aspects of facemask use) and 11 were identified that met our inclusion criteria. The primary studies within these reviews were then taken forward for title & abstract, and subsequent full-text, screening.

Screening Criteria: We included studies that considered:

- How masks are used (e.g. whether people are putting them on or taking them off safely) and whether this alters their effectiveness;
- How mask use affects other relevant protective or risk-taking behaviours;
- Whether mask use changes in the long term; and
- What behavioural interventions (e.g. training, communications) may affect mask use.

We excluded studies that considered:

- Mask use among healthcare workers or in care settings only.

Screening and Data Extraction

- 84 primary studies were identified from the reference lists of the relevant reviews. 8 studies were excluded because full-text was unavailable, and 2 because they were not in English, by the team who retrieved the studies (RMQ, LG and YB).
- 74 studies remained to be screened. Of these, 9 were prioritised by MP for data extraction, based on our full-text screening of the existing reviews. Data extraction was carried out by two reviewers (MP and AN).
- Title and abstract screening was carried out by one reviewer (EMS) for the other 65 studies, based on our inclusion criteria. 30 studies were included at this stage. Exclusions were checked by a second reviewer (MP), and one further study was included for data extraction.
- Data extraction on these 31 studies was carried out by three reviewers (EMS, AN and MP). 9 further studies were excluded as a result of full-text screening, principally because they did not include any investigation of the behavioural aspects of mask use.

Quality assessment

- We carried out a quality assessment of the remaining 22 reviews based on templates adapted from the CASP checklists for critical appraisal.

8

Results

The key findings from this rapid review were:

- Behavioural aspects of mask use have not been a primary focus of any study on the effectiveness of facemasks. A small number of studies compare the effectiveness of occasional vs regular facemask use, but these terms are not clearly defined and the studies depend on self-reporting of compliance.
- The limited evidence base suggests that regular/consistent use of masks may be more protective than irregular use (but within the context of a wider literature which is inconclusive about the general protective effect of masks). However, the difference between 'consistent' and 'irregular' use is not clearly defined in existing studies, and is therefore of limited use in developing guidance.
- One review found that adherence to facemask use tended to drop off after five days. Another found that adherence depended on health beliefs and perception of risk.
- Reported concerns that people may wear masks 'incorrectly', and therefore ineffectively, in the community are a feature of the literature, but there do not appear to be any studies which assess the extent to which this actually happens, nor how it impacts on effectiveness.
- One study found that people who wore facemasks appeared to have increased compliance with hand hygiene practices. Of concern, however, the same study found an increased rate of respiratory infection among non-vaccinated people who wore facemasks. The evidence is not strong enough to allow us to conclude that facemask use encourages either protective or risk-taking behaviours, but these findings certainly suggest that a degree of caution should be applied.
- A small number of studies found that behavioural incentives – including specific training, public health awareness campaigns, and provision of free face masks – encouraged uptake of masks.
- One study addressed the barriers to use of facemasks, and found that masks contributed to a sense of isolation from others (as well as discomfort and difficulty breathing). This study was not carried out in the context of a pandemic, with mass distancing and 'lockdown', but the possible mental health implications of this finding may require some consideration in this context.
- Most of the studies looking at the use of masks in community settings relate to very specific contexts: schools, university halls of residence, and, most frequently, the Hajj. The Hajj in particular is a unique, time-limited event. Care should be taken when generalising from these studies to the community in general.

Conclusions

- There is little evidence on the behavioural aspects of facemask use, and most studies relate to unique, defined contexts (predominantly the Hajj). The aspect most frequently studied relates to frequency / consistency of use, and it is suggested that more consistent use is linked with a more protective effect (although this must be taken in the context of overall findings about the [limited] protective effect of facemasks).

9

- One study found that facemasks contribute to an increased sense of isolation, while another found higher rates of respiratory infection among some participants who wore a facemask, which may hint at a link between facemask use and risk-taking behaviours. Neither of these findings is supported by substantial or robust evidence, but both might merit further research in order to inform a full appraisal of the costs vs benefits of facemask use in community settings.

Key References – see separate file

Lead reviewers [with contact details of lead]

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Sub-review 4: What is the mode of transmission of SARS-CoV-2 and other common respiratory pathogens?

Background

- This rapid review was conducted to address the question of whether an understanding of SARS-CoV-2 transmission routes can help inform decisions regarding community use of face masks.

Methods

Two working strands were conducted in parallel to address the question.

- Strand 1 searched for original studies and reviews that reported the mode of transmission of coronaviruses, including SARS-CoV-2, MERS-CoV, SARS-CoV-1, and seasonal coronaviruses (i.e. NL63, 229E, OC43 and HKU1).
- Strand 2 searched for existing reviews that reported the mode of transmission of common human respiratory pathogens.

Selection criteria are in the Appendix. As studies applied different approaches to infer mode of transmission, we grouped the approaches into three levels based on the strength of the evidence:

- Level 1. Pathogen being detectable (in aerosols, droplets or surfaces);
- Level 2. Pathogen being detectable and viable;
- Level 3. Actual transmission events being confirmed. All studies were extracted to an extraction template attached in Appendix.2.

Results

A total of 25 studies were included and their findings were summarised in Table 1. Key findings include:

- All respiratory pathogens included in the review can be transmitted by direct/indirect contact and droplets.
- Measles, influenza virus and adenovirus are known to be transmissible by aerosols.

10

- SARS-CoV-2 can be detected and is viable in aerosols but with no direct evidence of transmission via aerosols.

Conclusions
- SARS-CoV-2 is transmissible by contact and droplets.
- SARS-CoV-2 can be detectable and viable in aerosols, suggesting possible transmission routes by aerosols. However, little evidence is available so far demonstrating actual aerosol transmission episode by SARS-CoV-2.

Key References – see separate file

Lead reviewers [with contact details of lead]
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Table 2. Summary of findings on mode of transmission of common human respiratory pathogens [see separate file]

11