Evidence summary for universal face mask use by healthcare workers in the context of COVID-19

13 August 2020

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Key points

- Prior to COVID-19, continuous face mask use by healthcare workers (HCWs) has not been routine practice in the Irish healthcare setting. This evidence summary reviewed the impact of continuous face mask use by HCWs at all times in the healthcare setting in reducing the transmission of respiratory viruses. In total, two systematic reviews and three primary studies were identified.
- Of the three primary studies, two were randomised controlled trials (RCTs) comparing continuous face mask use with non-routine face mask use in reducing the transmission of respiratory viruses in healthcare settings. The third study included two randomised arms, comparing respirators with medical masks, and a non-randomised control group.
- The outcomes reported across the studies included clinical respiratory illness, influenza-like illness, and laboratory-confirmed viral respiratory infections.
- All three primary studies focused on the risk of acquisition of respiratory viruses by the healthcare workers; no studies were identified that examined transmission from HCWs to patients.
- HCWs included doctors and nurses in two studies, and doctors, nurses and co-medical personnel (not defined) in one study.
- From the limited available evidence, continuous face mask use appears to confer some protection against self-reported respiratory illness, and limited evidence indicates some protection against laboratory-confirmed viral infections.
- Cloth masks were associated with a higher risk of influenza-like illness suggesting they are not suitable for healthcare workers.
- Self-reported compliance with face mask use ranged from 56% to 84.3%.
- All of the included primary studies were conducted in Asia, where face mask wearing in the control groups was common, and may have limited applicability to the Irish healthcare setting.
- It is reported that SARS CoV-2 is more infectious than a number of other pathogens causing respiratory diseases; it can be transmitted before symptom onset, and laboratory-confirmed cases can remain asymptomatic, but infectious.

Key points continued

- None of the studies in this review included patients with COVID-19. Although plausible, caution should be exercised in extrapolating evidence on whether continuous face mask wearing can prevent the acquisition and or transmission of SARS CoV-2.
- Current policy in Ireland (as of April 21) is that surgical masks should be worn by all HCWs when they are providing care to people and are within two metres of a person, regardless of the COVID-19 status of the person. Surgical masks should also be worn by all healthcare workers for all encounters, of 15 minutes or more, with other healthcare workers in the workplace where a distance of two metres cannot be maintained.

Introduction

The Health Information and Quality Authority (HIQA) has developed a series of 'Evidence Summaries' to assist the Clinical Expert Advisory Group (EAG) in supporting the National Public Health Emergency Team (NPHET) as well as those developing infection prevention and control guidance in their response to COVID-19. These summaries are based on specific research questions.

Prior to COVID-19, continuous face mask use by healthcare workers (HCWs) has not been routine practice in the Irish healthcare setting. This evidence summary was developed to address the following research question:

What is the evidence that universal face mask use by healthcare workers at all times in the healthcare setting is of value in reducing the transmission of respiratory viruses?

The processes as outlined in HIQA's protocol, available on www.hiqa.ie, were followed. Below is the summary of all relevant evidence from 01 January 2000 until 09 April 2020.

Results

Two systematic reviews were identified, examining the effectiveness of face mask and respirators against respiratory infections in healthcare workers (HCWs) generally.[1, 2] For the comparison of interest for this evidence review, only three primary studies were included in both reviews. Both systematic reviews included the same two[3, 4] randomised controlled trials (RCTs), comparing continuous face mask use with no face mask use in reducing the transmission of respiratory viruses in healthcare settings. Both reviews also identified a third study that included two randomised arms, comparing respirators with medical masks and a non-randomised control group. Offeddu et al.,[1] included all three arms;[5] however, only the RCT data from this study were included in Jefferson (2020).[2] The systematic reviews and the included primary studies are described in more detail below and in Table 1.

Of the three primary studies, one was conducted in Vietnam in 14 hospitals,[4] one in China in emergency or respiratory wards in 15 hospitals,[5] and one was conducted in Japan in a tertiary care hospital.[3] Healthcare workers (HCWs) included doctors and nurses in two studies,[4, 5] and doctors, nurses and co-medical personnel (not defined) in one.[3] Sample sizes ranged from 32 to 1,607. All three studies focused on the risk of acquisition of respiratory viruses by the HCWs; no studies were identified that examined transmission from HCWs to patients.

Reduction of transmission of respiratory viruses

MacIntyre et al. (2015),[4] in a three-arm cluster RCT conducted in Vietnam, compared continuous cloth mask and medical mask wearing with routine care, which

may or may not include mask (cloth or medical) use (n=1,607) in selected high-risk wards (emergency, infectious or respiratory disease, intensive care and paediatrics). The medical mask group was supplied with two masks daily for each eight-hour shift, while participants in the cloth mask arm were provided with five masks (two layer, made of cotton) in total for the study duration, which they were asked to wash and rotate over the study period. The outcomes reported across groups included clinical respiratory illness, influenza-like illness, and laboratory-confirmed (RT-PCR) viral respiratory infection. The authors reported that most participants in the routine care control arm also used a mask (both types of mask) during the trial period. The cloth mask arm was associated with the highest rates in healthcare workers for all infection outcomes. Viral infections (laboratory-confirmed RT-PCR) were 5.4% in the cloth mask group compared with 3.3% in the medical mask group and 4% in the control. Cloth masks also had higher rates of influenza-like illness compared with the control arm (RR = 3.49, 95% CI 1.00 to 12.17). There was no significant difference in rates of influenza-like illness for control compared with medical masks (RR = 2.80, 95% CI 0.40 - 36.40).

In a Chinese three-arm non-RCT, MacIntyre et al. (2014)[5] compared continuous face mask wearing on every shift (excluding toilet breaks and lunch breaks) in emergency or respiratory wards, to convenience-selected controls who did not routinely wear face masks (n=1,441). Participants in the intervention were randomly assigned to either a medical mask (supplied with three daily) or N95 respirators (two daily) group. They were asked to store the mask in a paper bag every time they removed it (for toilet breaks, tea and lunch breaks and at the end of every shift) and place the bagged medical mask or respirator in their locker. For the outcome of viral infections, fewer viral infections were detected in the medical mask group compared with the control group (RR = 0.84, not presented in paper).

In a small (n=32) Japanese RCT, Jacobs et al.[3] compared medical mask wearing while on hospital property serving in their role as a healthcare worker, to controls who refrained from wearing a face mask while on hospital property unless required to do so as part of job duties. They reported that medical mask use in healthcare workers did not demonstrate benefit in terms of cold symptoms or getting colds.[3] One participant in each group reported a cold during the study (RR = 0.9).

In the systematic review by Offeddu et al.,[1] both MacIntyre studies (one an RCT and the other a non-RCT) were included in a meta-analysis,[4, 5] while Jacobs et al.[3] was excluded as it was deemed to have a high risk of bias. The conclusion of the meta-analysis was that wearing a medical mask or N95 respirator throughout the work shift conferred protection against self-reported clinical respiratory illness (RR = 0.59; 95% CI: 0.46–0.77) and influenza-like illness (RR = 0.34; 95% CI: 0.14–0.82). It also suggested a protective, but non-statistically significant, effect against laboratory-confirmed viral infections (RR = 0.70; 95% CI: 0.47–1.03).

Jefferson et al.[2] included both RCTs — Jacobs et al.[3] and MacIntyre et al. (2015)[4] — in a meta-analysis, and reported no statistically significant difference between the face mask and no face mask groups for rates for influenza-like illness (RR = 0.37, 95% CI 0.05 to 2.50).

Compliance

Compliance was self-reported, and definitions of compliance varied across the two studies reporting this outcome. MacIntyre et al. (2015)[4] defined it as wearing the face mask more than 70% of working hours (self-reported diary) while Jacobs et al.[3] defined it as self-reported full compliance. Self-reported compliance with face mask use ranged from 56% to 84.3%.[3]

Quality of studies

Neither included systematic review[1, 2] fulfilled all items of AMSTAR-2.[6] The overall confidence in the results was graded as low for both systematic reviews. While the review by Jefferson et al.[2] is an update of a previous Cochrane review, it is currently published as a non-peer-reviewed article.[2] The RCTs and non-RCT were assessed using the Cochrane risk of bias tool, and overall, studies were found to be of low quality (Figure 1).[7] Reporting of sequence generation was low risk in only one study,[4] and allocation concealment was unclear in all three. All studies were unblinded due to the nature of the face mask and only one study adequately reported on blinding of outcome assessment.[5] Two studies were low risk for attrition,[4, 5] and all studies had a high or unclear risk of selective outcome reporting.

Discussion and conclusion

There is limited evidence that universal wearing of a face mask confers protection on healthcare workers against the acquisition of respiratory viruses. However, the level of evidence overall is low as the existing evidence identified in this review is sparse, limited to three primary studies of poor quality, with low event rates, which are included across two systematic reviews.

From the limited available evidence, continuous face mask use compared to non-routine face mask wearing appears to confer some protection against self-reported respiratory illness, and limited evidence indicates some protection against laboratory-confirmed viral infections, although this was not statistically significant. Cloth masks were associated with a higher risk of influenza-like illness suggesting they are not suitable for healthcare workers. All of the included primary studies were conducted in Asia, where face mask wearing in the control groups was common, and may have limited applicability to the Irish healthcare setting. No primary studies were identified that included overall transmission in the healthcare setting. Further research in this area is necessary, as most current research is focused on the

effectiveness of face mask use by HCWs when treating patients with confirmed or suspected respiratory viruses, and in head-to-head comparisons between different face mask types.[1, 2, 8, 9]

HIQA's previous evidence summaries[10] have identified that COVID-19 can be transmitted before symptom onset and that there is evidence that laboratory-confirmed cases of COVID-19 can remain asymptomatic, but infectious. In addition, it is reported that SARS CoV-2 may be more infectious than a number of other pathogens causing respiratory diseases,[11] including SARS CoV-1 (estimated reproduction number (R) 1.77),[12] pandemic 2009 H1N1 (estimated R 1.46), 1918 pandemic H1N1 (estimated R 1.8), seasonal influenza (estimated R 1.27),[13] and MERS-CoV (estimated R <1) viruses.[14]

None of the studies in this review included patients with SARS CoV-2 as they predated the first identification of this new coronavirus in humans. Although plausible, caution on extrapolating the evidence on the extent to which continuous mask wearing can prevent acquisition and or transmission of SARS-CoV-2 should be exercised.

Prior to COVID-19, continuous face mask use by HCWs has not been routine practice in the Irish healthcare setting. Current policy in Ireland (as of April 21) is that surgical masks should be worn by all HCWs when they are providing care to people and are within two metres of a person, regardless of the COVID-19 status of the person. Surgical masks should also be worn by all healthcare workers for all encounters, of 15 minutes or more, with other healthcare workers in the workplace where a distance of two metres cannot be maintained.

Table 1: Summary of identified studies

| Author Study design Setting	Population Review search parameters	Intervention and controls Primary outcome definition	Primary outcome results
Offeddu (2017)[1] **Systematic review** **Setting:** all healthcare settings **DOI:** https://10.1093/cid/cix681	**Population:** Healthcare workers **Included studies:** 6 RCTs and 23 observational studies **Review search parameters** *Electronic searches*: Pubmed, Web of Science, and EMBASE, up to 3 November 2015 *Inclusion criteria:* RCTs and observational studies of effectiveness of respiratory personal protective equipment in reducing the risk of clinical or laboratory-confirmed respiratory outcomes in healthcare workers.	**Intervention:** respiratory personal protective equipment (rPPE) **Control:** Other rPPE and no rPPE *Studies with relevant comparison*: 3, 2 studies included in the meta-analysis	**Reduction of transmission of respiratory viruses** Self-reported clinical respiratory illness: RR = 0.59; 95% CI: 0.46–0.77 Influenza-like illness: RR = 0.34; 95% CI: 0.14–0.82 Laboratory-confirmed viral infections: RR = 0.70; 95% CI: 0.47–1.03 **Compliance with universal face mask use** Not presented
Jefferson (2020)[2] **Systematic review (update)** **Setting:** all healthcare settings **DOI:** https://doi.org/10.1101/2020.03.30.20047217	**Population:** All people, all ages. **Included studies:** 15 RCTs **Review search parameters** *Electronic searches*: PubMed, the Cochrane Central Register of Controlled Trials, Embase, CINAHL from October 2010 to 9 March 2020 *Inclusion criteria:* RCTs that tested the use of face masks, eye protection, or person distancing against control.	**Intervention:** Physical interventions (face masks, eye protection, or person distancing) **Control:** Standard practice, or a similar physical barrier, or compared any of these interventions *Studies with relevant comparison*: 3, 2 studies included in the meta-analysis **Primary outcome definition** Acute respiratory illness – such as influenza-like illness, influenza, or respiratory infections	**Reduction of transmission of respiratory viruses** Influenza-like illness: RR 0.37 (95% CI 0.05 to 2.50). **Compliance with universal face mask use** Not presented

Author Study design Setting	Population Review search parameters	Intervention and controls Primary outcome definition	Primary outcome results
MacIntyre C (2015)[4] **Setting:** 14 hospitals, Vietnam **3-arm cluster RCT** **DOI:** https://10.1136/bmjopen-2014-006577	**Participants:** 1,607 HCWs (nurses or doctors) aged ≥18 years working full-time in selected high-risk wards (emergency, infectious/respiratory disease, intensive care and paediatrics). *Mean age (range)* Intervention 1: 36 (35.6 - 37.3) Intervention 2: 35 (34.6 – 36.3) Control: 36 (35.1 – 37.0) *Gender (M)* Intervention 1: 122/580 (21%) Intervention 2: 133/569 (23.4%) Control: 122/458 (26.6%) **Duration of study/intervention time:** 4-week follow-up plus 1 week without masks for symptom development.	**Intervention 1 (n=580)** Medical masks at all times on work shift, supplied with 2 masks daily for each 8 hour shift. **Intervention 2 (n=569)** Cloth masks (2 layer, made of cotton) at all times on shift, provided with five masks in total for the study duration, which they were asked to wash and rotate over the study period. Continuous mask use: wearing masks all the time during a work shift, except while in the toilet or during tea or lunch breaks. **Control (n= 458)** Standard practice, which may or may not include mask use **Primary outcome definition** 1) Clinical respiratory illness (CRI), defined as 2 or more respiratory symptoms or one respiratory symptom and a systemic symptom (2) influenza-like illness (ILI), defined as fever ≥38°C plus one respiratory symptom (3) laboratory-confirmed (RT-PCR) viral respiratory infection. Swabs of both tonsils and the posterior pharyngeal wall were collected from symptomatic participants (day symptoms reported).	**Reduction of transmission of respiratory viruses** *Primary outcomes per group* CRI Medical masks: 28/580 (4.8%) Cloth masks: 43/569 (7.6%) Control: 32/458 (7.0%) ILI Medical masks: 1/580 (0.2%) Cloth masks: 13/569 (2.3%) Control: 3/458 (0.7%) Confirmed viral infection Medical masks: 19/580 (3.3%) Cloth masks: 31/569 (5.4%) Control: 18/458 (4.0%) Cloth masks compared to control ILI: RR=3.49 (95% CI 1.00 to 12.17) CRI: not reported Confirmed viral infections: not reported Control compared to medical mask CRI: RR=1.45 (95% CI 0.88 - 2.37); ILI: RR=2.80 (95% CI 0.40 - 36.40); Confirmed viral infections: RR=1.20 (95% CI 0.64-2.26) **Compliance with universal face mask use** Wearing more than 70% of working hours (self-reported diary) Medical masks: 56.6% Cloth masks: 56.8% Control: 23.6% Compliance significantly higher in the cloth mask arm (RR=2.41, 95% CI 2.01 to 2.88) and medical masks arm (RR=2.40, 95% CI 2.00 to 2.87), compared with the control arm. Note: almost all participants in the control arm used a mask.

Author Study design Setting	Population Review search parameters	Intervention and controls Primary outcome definition	Primary outcome results
MacIntyre 2014[5] **Cluster RCT** **Setting:** EDs or respiratory wards in 15 hospitals, China **DOI:** https://10.1016/j.ypmed.2014.01.015	**Participants:** 1441 HCWs (nurses or doctors) who worked full-time *Mean age (SD):* Not reported *Gender (M):* Not reported **Duration of study/intervention time:** 4 weeks	**Intervention 1 (n=492)** Medical masks (3M) on every shift (8–12 h), supplied daily with 3 masks **Intervention 2 (n=949)** Fit-tested or non fit-tested N95 respirator on every shift (8–12 h), supplied daily with 2 respirators Participants asked to store the mask in a paper bag every time they removed it (for toilet breaks, tea /lunch breaks and at the end of every shift) and place the bagged mask or respirator in their locker. **Control (n=481)** Convenience sample who did not routinely wear face masks **Primary outcome definition** Infection: laboratory-confirmed bacterial colonisation of the respiratory tract; laboratory-confirmed viral infection (PCR), 2 pharyngeal swabs collected from subjects with respiratory symptoms both tonsil areas and the posterior pharyngeal wall.	**Reduction of transmission of respiratory viruses** Virus detected: Medical mask: 13/492 (2.6%) N95: 13/949 (1.4%) Control: 15/481 (3.1%) RR mask versus control (not presented in paper): 0.84 Bacteria detected: Medical mask: 26/492 (5.3%) N95: 27/949 (2.8%) Control: 38/481 (7.5%) Efficacy of N95 Vs control for detection of infection (bacterial): 62% (38.0-77.0) RR N95 V control (not presented in paper): 0.37 Infection (combined viral and bacterial): Medical mask: 32/492 (6.3%) N95: 31/949 (3.3%) Control: 39/481 (8.1%) Efficacy of medical mask versus control for detection of infection (combined viral and bacterial): 29% (0.0-59.2) RR medical mask versus control (not presented in paper): 0.80

Author Study design Setting	Population Review search parameters	Intervention and controls Primary outcome definition	Primary outcome results
Jacobs (2009)[3] **RCT** **Setting:** tertiary care hospital, Japan **DOI:** https://10.1016/j.ajic.2008.11.002	Participants: 32 HCWs Doctor: 7 Nurses: 12 Co-medical personnel (not defined): 11 **Mean age (SD)** Intervention: 35 (14) Control: 36 (9.6) **Gender (M)** Intervention 5/17 Control 4/15 Duration of study/intervention time: 77-day	**Intervention (n= 17)** Medical masks (hospital-standard disposable, MA-3) while on hospital property, serving in their role as a healthcare worker. **Control (n=15)** Refrained from wearing mask while on hospital property unless required to do so as part of job duties.	**Reduction of transmission of respiratory viruses** Self-reported upper respiratory infection (URI; or cold): Intervention: 1/17 Control: 1/15 RR (not presented in paper): 0.9 **Compliance with universal face mask use** Self-reporting full compliance with mask use and non-use: 84.3% The remainder were compliant 79.2%-98.7% of the time.

Figure 1 Risk of bias summary
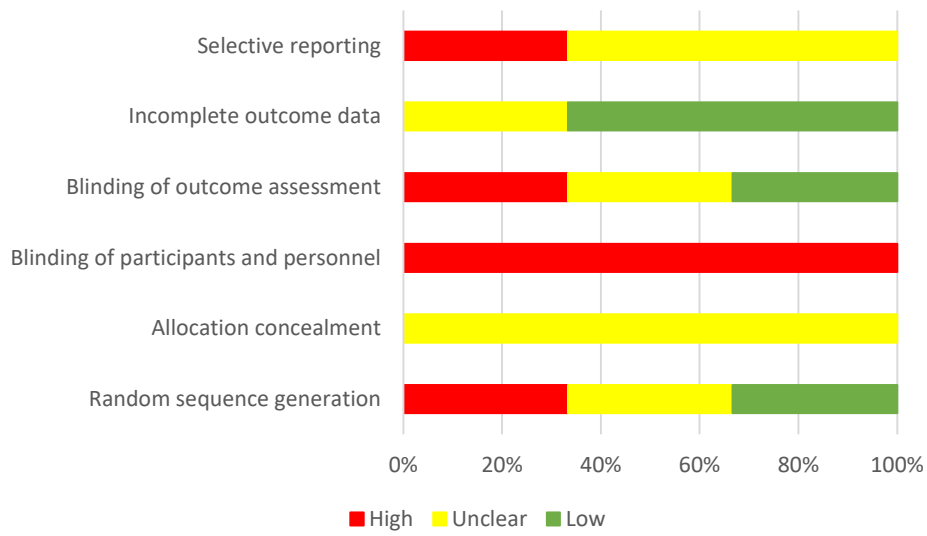
References

1. Offeddu V, Yung CF, Low MSF, Tam CC. *Effectiveness of Masks and Respirators Against Respiratory Infections in Healthcare Workers: A Systematic Review and Meta-Analysis.* Clin Infect Dis. 2017;65(11):1934-42.

2. Jefferson T, Jones M, Al Ansari LA, Bawazeer G, Beller E, Clark J, et al. *Physical interventions to interrupt or reduce the spread of respiratory viruses. Part 1 - Face masks, eye protection and person distancing: systematic review and meta-analysis.* medRxiv. 2020:2020.03.30.20047217.

3. Jacobs JL, Ohde S, Takahashi O, Tokuda Y, Omata F, Fukui T. *Use of surgical face masks to reduce the incidence of the common cold among health care workers in Japan: a randomized controlled trial.* American journal of infection control. 2009;37(5):417-9.

4. MacIntyre CR, Seale H, Dung TC, Hien NT, Nga PT, Chughtai AA, et al. *A cluster randomised trial of cloth masks compared with medical masks in healthcare workers.* BMJ open. 2015;5(4):e006577.

5. MacIntyre CR, Wang Q, Rahman B, Seale H, Ridda I, Gao Z, et al. *Efficacy of face masks and respirators in preventing upper respiratory tract bacterial colonization and co-infection in hospital healthcare workers.* Preventive medicine. 2014;62:1-7.

6. Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, et al. *Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews.* BMC medical research methodology. 2007;7(1):10.

7. Higgins JP, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, et al. *The Cochrane Collaboration's tool for assessing risk of bias in randomised trials.* BMJ (Clinical research ed). 2011;343:d5928.

8. Bin-Reza F, Lopez Chavarrias V, Nicoll A, Chamberland ME. *The use of masks and respirators to prevent transmission of influenza: a systematic review of the scientific evidence.* Influenza and other respiratory viruses. 2012;6(4):257-67.

9. Cowling BJ, Zhou Y, Ip DK, Leung GM, Aiello AE. *Face masks to prevent transmission of influenza virus: a systematic review.* Epidemiology and infection. 2010;138(4):449-56.

10. The Health Information and Quality Authority. *Evidence summary for asymptomatic transmission of COVID-19.* Dublin HIQA, 2020

11.   Park M, Cook AR, Lim JT, Sun Y, Dickens BL. *A Systematic Review of COVID-19 Epidemiology Based on Current Evidence.* Journal of Clinical Medicine. 2020;9(4):967.

12.   Liu Y, Gayle AA, Wilder-Smith A, Rocklöv J. *The reproductive number of COVID-19 is higher compared to SARS coronavirus.* Journal of Travel Medicine. 2020;27(2).

13.   Biggerstaff M, Cauchemez S, Reed C, Gambhir M, Finelli L. *Estimates of the reproduction number for seasonal, pandemic, and zoonotic influenza: a systematic review of the literature.* BMC infectious diseases. 2014;14(1):480.

14.   World Health Organization. *WHO MERS-CoV Global Summary and risk assessment.* 2016 WHO/MERS/RA/16.1.